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德勤

2024全球生命科学行业展望

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目录

前言

随着曾席卷全球的新冠疫情成为过去，当下生命科学公司纷纷着眼于探究宏观和微观经济的主要驱动因素，以指导其未来发展。尽管具有全球广泛影响的趋势不胜枚举，但在2024年，生命科学公司更为关注颠覆性趋势，包括定价压力上行、美国监管变化、生成式人工智能 (GenAI) 的加速应用和影响、地缘政治环境，以及一如既往的突破性科学和成果。各大公司正探索生成式AI的发展能够如何影响其运营，并明确优先事项以及如何产生差异化价值。生命科学公司正致力探究先进技术的潜力并积极开展相关合作，以改善患者疗效并优化研发决策。

各大公司正在探索生成式AI在降低成本和提高收入方面的更大价值潜力。生成式AI和其他AI技术与数字化转型工具相结合，有望提高生命科学价值链许多领域的整体效率并推动流程创新。一家年均收入为650-750亿美元的十强生物制药公司，如果在5年内持续扩大AI部署，最高可增创50-70亿美元的价值。[1] 由于大型公司纷纷希望获取技术能力、保留行业人才并提升竞争优势，预计2024年下半年将有更多AI和生成式AI合作项目落地。

未来一年，制药公司将调整战略，通过战略并购提升营收，随着通胀有望放缓、利率或将企稳，预计并购和资本市场环境将趋于谨慎但仍具活力。活跃的并购市场也有望抵消生命科学公司因独家专利到期而造成的逾2,000亿美元的收入损失。[2] 不过，在并购方面，企业仍将期待有关部门对反垄断问题的监管。

围绕AI和生成式AI达成的合作也带来了加速实现研发活动价值的新趋势。随着监管形势的不断变化、定价压力的日趋上升以及2024年独家专利的到期，企业将需利用创新力量，[3] 发挥AI和生成式AI的潜力以攻克复杂疾病生物学难题，加速药物发现过程，缩短研究周期，提升临床试验体验，并提高监管审批通过率。领先的生物制药公司已在整个价值链中采纳新的AI/生成式AI技术及其他数据创新技术，同时寻求建立新的合作伙伴关系，与监管机构尽早开展合作，并利用外包策略来节省成本和时间。

医药贸易自2023年第三季度开始回暖，[4] 预计2024年全球医药市场销量将达到近1.2万亿美元。[5] 新冠疫情期间，贸易和供应链对于医疗用品和疫苗的提产和分销起到至关重要的作用，[6] 但在过去两年里，全球贸易集中化日趋明显，地缘政治也更加封闭。这意味着主要市场的对外贸易依存度不断降低，[7] 并试图保护和建设正在崛起的本地市场。因此，跨国企业正在游说政府官员寻找方法，以减轻出口管制所带来的打击。[8]

跨国企业还与各国政府合作，共同解决药品定价和价格问题，随着全球药品定价压力逐渐显现，这些问题仍旧受到各界密切关注。[9] 尽管欠发达国家几十年来一直在表达对药品价格难以负担的担忧，但当下发达国家出现的相同担忧正将药品“难负担”问题推至全球医疗卫生议程的首位。[10] 2024年下半年，各国政府实施的药品定价监管和调控措施预计将对部分药品的可负担性和可及性产生更多积极影响。[11]

上述示例揭示了生命科学公司的首要关注事项：改善患者疗效。生命科学公司始终致力于直接或间接地提升患者体验，最终改善患者健康。数据证明了这一点。接受德勤美国调研的生命科学公司高管认为，其所在组织在2024年需要采取的主要行动是"提升患者体验、参与度和信任感"。[12] 随着个性化护理和治疗支持提升患者体验，生物制药和医疗科技公司正在探寻更多机会，以改善整个患者旅程中的触点。[13] 这包括前瞻性地预测患者需求。[14] 随着就医流程日益数字化和个性化，其也将提供更加"直接"和无缝的诊疗体验。一切正朝着有益于患者及其未来愿景的方向发展。

本报告将深入探讨多个颠覆性趋势，如生成式AI的影响、肥胖症市场的增长和GLP-1类药物的普及、《通胀削减法案》（IRA）的首个年度影响，以及其他更具演变性质的趋势——如在不确定的地缘政治环境中驾驭全球化的持续复杂性，或推进打造更加个性化的患者体验。由于地缘政治、经济和监管环境仍存在不确定性，生命科学行业或仍需凭借创新合作、提升敏捷性，以践行致力改善患者生活的坚定承诺。

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价值创造：借助并购、建立合作伙伴关系、达成协作、寻找新的资本来源和调整投资组合等策略实现价值创造

2024年行业展望审慎乐观

2024年，企业决策可能会继续受经济形势和地缘政治格局的影响。

在过去一年里，生命科学和医疗技术领域企业一直积极应对通货膨胀、利率攀升（或将限制资本获取）和经济增长放缓等问题。然而，展望2024年，通胀压力似乎正在缓解，利率走势趋于稳定，如果不进一步下降，经济有望适度增长——从而将营造一个谨慎但仍然充满活力的并购和资本市场环境。

2023年，生物制药、平台技术、医疗技术和诊断领域的并购活动总体表现比预期更为乐观——共达成254笔并购交易，交易总金额为2,098亿美元，超过了2022年的1,435亿美元。[1] 生命科学行业的并购活动表现优于全行业并购市场的表现，2023年，美国地区和全球范围内的全行业并购交易总金额与2022年相比分别下降了11%和18%。[2]

在过去一年里，生命科学行业各公司在其发展周期的多数阶段均实现了估值增长。步入2024年，制药企业将精细调整其战略，通过战略收购实现公司营收增长，并同步规划资产剥离和成本削减等长期净利润提升措施。

尽管胰高血糖素样肽1（GLP-1）肥胖症药物为制药企业带来了显著收益，但这类药物的日益普及，连同宏观经济环境的挑战，却对医疗技术行业的公司估值带来了不确定性。2023年，医疗技术行业估值因此下降了3亿美元。然而，行业基本面依然强劲，随着供应链状况的逐步改善，医疗技术行业领导者对2024年的增长前景持乐观态度。

并购：并购激发增长动力

制药行业的巨额并购交易展示出制药企业的雄厚购买力

2023年，并购市场强劲增长的主要动力来自那些拥有大量未部署资本的大型或超大型制药企业（见图1）。[3] 这些企业对于具有高商业潜力的资产不惜支付高额溢价，尤其是在投资吸引力最为强劲的肿瘤学领域。[4] 在2023年完成的十大巨额交易中，每笔交易的价值均超过40亿美元，其中辉瑞与Seagen之间的交易额最高，达430亿美元，其次是百时美施贵宝与Karuna Therapeutics之间的交易，金额达140亿美元。[5] 一些主要的收购交易涉及即将获得监管批准或正处于后期试验阶段的药物。[6]

2024年，制药公司应继续预期其各种投资活动将面临监管机构的严格审查。为了促成辉瑞与Seagen之间的交易并应对反垄断监管机构的顾虑，辉瑞承诺将其销售癌症药物Bavencio所产生的特许权使用费权益捐赠给美国癌症研究协会。[7] 此外，2023年底，美国联邦贸易委员会（FTC）亦就安进与Horizon Therapeutics的并购案达成和解。[8]

> “在并购领域，具有巨大市场潜力的产品机会最受关注，预计这一趋势在2024年将持续。随着市场上最优质的后期阶段资产被各大企业争相收购，预计在年底之前，针对早期阶段资产的合作伙伴关系和并购活动将会增多，原因在于市场对于开拓新产品增长机会表现出极大的热情。”
>
> —**Acumen首席执行官Daniel O’ Connell**

图1：2023年生命科学领域按买家群体划分的并购交易特点分析

资料来源：德勤分析

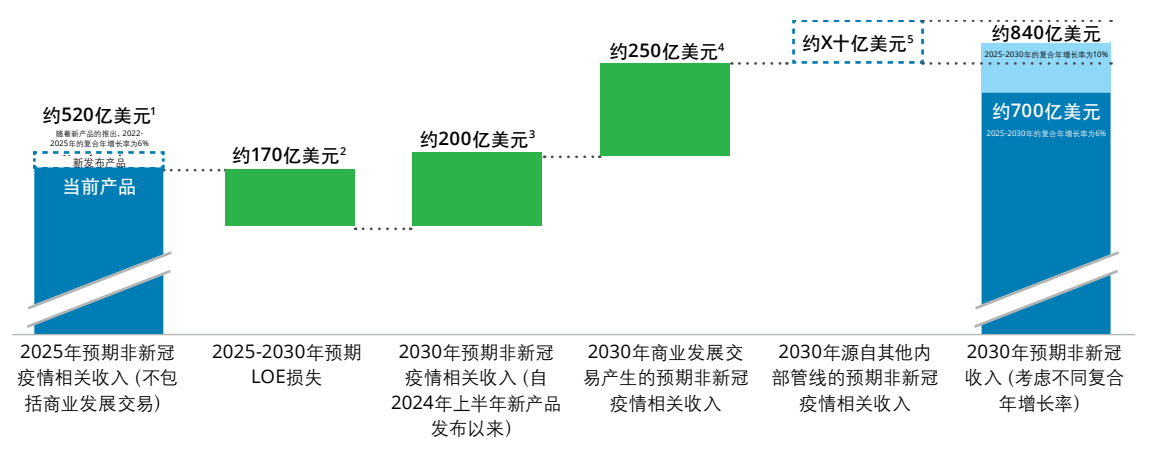
在未来一年里，一些大型制药公司将持续利用并购策略，弥合因各治疗领域专利独占权丧失（LoE）所导致的投资组合缺口。具体而言，未来几年，那些处于晚期研发阶段或早期商业化阶段的资产，预计将为制药公司的营收增长带来显著影响，因而有望成为极具吸引力的收购目标。[9]

制药行业并购策略亮点：实施新的并购策略以补偿专利独占权丧失 (LOE) 所带来的损失

大型制药公司可借助成功的并购交易来补偿专利独占权丧失所带来的损失。预计在2022年至2030年间，制药公司将因即将到来的重大专利悬崖而遭受超过2,000亿美元的营收损失。[10]

考虑到2025年至2030年间可能遭受高达170亿美元的LOE损失，以及其新冠肺炎产品组合所带来的大量未部署现金，2023年，辉瑞完成了一项行业规模最大的并购交易。辉瑞以430亿美元的价格收购了Seagen公司，后者是抗体药物偶联技术市场的领先企业，此举加强了辉瑞在肿瘤学领域的市场地位。[11] 辉瑞预计，这笔交易将在2024年为公司带来31亿美元的营收增长，从长期来看还将改善公司的盈利能力（见图2）。[12]

图2：辉瑞收购Seagen公司后加强营收增长的长期计划（示意图）



来源：辉瑞，《辉瑞投入430亿美元对抗癌症》（Pfizer Invests $43 Billion to Battle Cancer），2023年3月13日

制药行业近期的资产剥离或成本削减措施

随着多家制药巨头宣布了资产剥离和成本削减措施[13]（包括部分裁员），短期内市场前景似乎更加黯淡。[14] 一些管线资产可能会被出售给其他大型制药公司，而其他资产则可能出售给小型公司，同时原公司将保留少数股份。考虑到一些突出的成功案例，制药公司剥离资产和削减成本的趋势在2024年可能会持续。[15]

因此，释放出的资本可能会被重新投入到增值交易中。[16] 尽管对2024年的行业前景持谨慎乐观态度，[17] 但许多专家预计，在未来一年内，交易量和价值将有所回升。[18]

继2023年进行资产剥离之后，医疗技术行业重回增长轨道

2023年，制药行业的并购活动表现良好，而医疗技术和诊断行业的并购活动却相对疲软。在过去的一年里，并购或风险投资活动均呈下降趋势，但这一趋势并不意外，原因在于医疗技术公司主要致力于投资组合的合理化、资产剥离和成本转型。[19] 根据德勤美国的研究，通过资产剥离来减少债务、改善资本结构，从而打造更为强健的资产负债表，已成为行业的一种普遍做法。[20]

尽管总交易价值同比大幅下降了近45%至135亿美元，但交易量实际上有所增加。一些利益相关者对2024年的交易量持乐观态度，[21] 许多公司的目标是2亿至8亿美元之间的较小规模交易。[22]

此外，监管机构也密切关注医疗技术行业的交易。在与监管机构的长期博弈中，Illumina最终在2023年底剥离了其在Grail的权益。[23] 同时，美敦力也取消了一项价值7.38亿美元的收购交易，该交易原本旨在收购韩国胰岛素贴片泵制造商EOFlow。[24]

步入2024年，随着战略投资者和私募股权公司重新进入收购领域，并购活动有望迎来积极的拐点，实现活动复苏。医疗技术行业巨头在并购活动中可能瞄准那些具有高增长潜力的中小型公司，以及那些拥有可能颠覆现有业务的新颖技术的新兴公司。[25] 此外，数字疗法和家庭诊断技术的兴起，生物识别诊断技术的广泛应用，以及产品的快速上市，均在不断提振行业的乐观情绪。[26]

私募股权：巨额交易涌现与筹资环境日益严峻

私有化浪潮兴起

预计2024年，更多由私募股权公司资助的企业可能会选择私有化，而不是在低于首次公开募股（IPO）价格的低迷股价中继续挣扎。[27] 2021年，私募股权（PE）在生命科学领域的投资活动达到顶峰，共完成了695宗交易，总投资额高达1,275亿美元。[28] 这一领域涵盖了生物技术公司、医疗设备制造商，以及提供相关工具和服务的合同研究组织（CRO）等。[29]

生命科学供应商的私募股权交易量激增

私募股权（PE）持续对生命科学供应商展现出浓厚兴趣，已向合同开发和制造组织（CDMO）投入逾100亿美元的资金。在该行业中，涉及合同研究组织、合同开发和制造组织以及供应商的并购交易价值同比激增近85%，达到283亿美元，同时交易量也实现了50%的增长。随着对高度专业化生产设施的需求持续增加，预计在2024年及未来数年，合同开发和制造组织将越来越受到私募股权投资者的青睐。[30]

筹资环境愈发严峻

2023年私募股权领域值得注意的巨额交易包括：私募股权公司以71亿美元的价格将生物制药CRO公司Syneos Health私有化，以及瑞典私募股权公司EQT公司以约61亿美元的价格收购了英国兽药制造商Dechra Pharmaceuticals，这是2023年英国私募股权领域的一笔重大交易。[31] 然而，在筹资环境愈发严峻的情况之下，EQT公司近年来在筹资方面很成功，他们正着手寻求私人财富基金等新的资本渠道。[32]

风险投资：在生物技术行业面临挑战的情况下筹资数十亿

自2021年创下历史新高以来，生命科学领域初创企业的交易活动有所放缓，但仍然高于疫情前水平。与许多其他领域相比，生物技术行业的风险投资 (VC) 依旧保持活跃并具有韧性。[33] 2023年下半年，有六只风险投资基金完成了募集过程，这些基金目前拥有超过60亿美元的资金，可用于2024年的新投资。[34] 2024年初，初创企业投资的一个显著发展动态是，生物技术公司Arch成功筹集了30亿美元的资金——这是该公司筹集类似金额资金大约两年后所达成的又一笔巨额交易。[35]

2023年，生物技术公司首次公开募股 (IPO) 的步伐放缓，仅有19家制药公司为新股首次销售定价。[36] 尽管如此，许多专家对2024年前景持谨慎乐观态度，一些人预计这一年将充满波动。[37] 然而，2024年伊始，包括基因编辑初创公司Metagenomi在内的六家公司启动了IPO，Metagenomi的融资金额达9,380万美元。值得注意的是，Metagenomi的IPO交易，是近期少数几家在没有药物已进入临床试验阶段的情况下，便成功实现公开上市的生物技术公司之一。[38]

此外，2023年，生物技术行业经历了10年来的破产高峰，共有18家公司申请了破产保护，这一数字远远超过了其他年份，2022年有8家公司申请破产保护，2014年有7家。[39] 2024年初，已有三家公司提交了破产申请，分别是Humanigen、Athersys [40] 以及Invitae，其中Invitae目前正处于资产出售的准备阶段。[41]

建立合作伙伴关系和协作：在技术和研发方面扩展能力

集成人工智能或机器学习

人们越来越关注精准医疗和个性化治疗，这些治疗方式融合了人工智能 (AI) 和机器学习 (ML) 等尖端技术，这一趋势表明行业正在经历一场更广泛的转型。[42] 随着大型公司寻求获取新技术能力、吸引行业人才以及增强竞争力，预计到2024年，人工智能的巨大潜力将促成更多新的合作关系。

在2023年的第三季度和第四季度，行业签署了几项基于人工智能的药物开发合作协议。[43] 其中，Verge Genomics与Alexion (阿斯利康旗下罕见病业务子公司) 达成一项合作协议，Verge Genomics将获得包括费用、股权和近期付款在内高达4,200万美元的资金，还有可能获得高达8.4亿美元的里程碑付款，以及下游特许权使用费。[44] 此次合作将利用Verge的人工智能药物发现平台CONVERGE®，识别针对罕见神经退行性疾病和神经肌肉疾病的新型药物靶点。[45]

此外，艾伯维与人工智能/机器学习制药企业BigHat Biosciences签署合作协议，旨在合作研发用于肿瘤学和神经科学领域的抗体。BigHat Biosciences将获得3,000万美元的预付款，此外还有可能获得里程碑付款和特许权使用费。[46]

医疗技术公司持续在整个医疗生态系统内探索战略合作，以利用人工智能技术。举例而言，GE医疗 (GE HealthCare) 最近与生物医学高级研究与发展管理局 (BARDA) 签署了一份价值4,400万美元的合同，旨在合作开发人工智能辅助超声波技术。此外，GE医疗还与梅奥诊所 (Mayo Clinic) 达成一项战略合作，旨在医学成像和诊疗一体化方面进行创新，通过多模态数据、人工智能和数字健康解决方案，提高诊断的精确性和改善患者治疗体验。

美敦力与英伟达 (NVIDIA) 和Cosmo Pharmaceuticals达成合作，拟将英伟达 (NVIDIA) 的人工智能技术集成到美敦力GI Genius™智能内窥镜模块中。同时，还与IBM Watson Health达成合作，旨在开发用于心脏病诊疗的人工智能工具。

研发势头增强，一项数十亿美元的交易即将达成

专利独占权丧失促使市场领导者达成各类合作伙伴关系。2023年，在根据交易价值由高至低排列的前20项许可协议、合作合同和伙伴关系项目中，每笔交易的价值均不低于10亿美元——到2023年第三季度，此等交易的总额已达约750亿美元——其中最大的一笔交易的潜在价值高达220亿美元。[47]

在2023年交易额排名前20的交易中，有一半涉及肿瘤学资产和技术平台，其次是心脏病学和神经退行性疾病领域。在飞速发展的抗体-药物偶联物领域，默克公司 (Merck and Co.) 与第一三共株式会社 (Daiichi Sankyo) 达成了一项总额达55亿美元的合作协议，预计其整个生命周期的潜在价值将高达220亿美元。[48] 这笔交易创下了十年来的最高纪录，其特殊性在于交易的现金预付款高达40亿美元。第一三共株式会社将保留其在日本市场开发销售相关药物的权利，同时，这两家行业巨头将在全球范围内携手合作，共同开发全球其他市场的候选药物。[49]

2024年，拥有强大后期阶段管线的生物技术公司已成为收购的理想目标，或通过其他方式实现资本退出。[50] 然而，许多中小型生物技术公司正面临现金流紧张的困境，从而也试图通过被收购的方式获得资金支持，与此同时，申请破产保护的公司数量创下新高。[51] 建立合作伙伴关系正逐渐成为一种趋势，并可能成为2024年除并购以外的另一种提升企业价值的途径。

寻找新的资本来源：将建立合作伙伴关系和战略联盟视为生物技术公司并购的替代路径

2023年，对于中小型生物技术公司来说，资本市场变得更加紧张，这迫使许多公司寻求替代融资方式，包括削减成本和吸引私人投资。首次公开募股 (IPO) 和公开市场的热情有所减退，风险投资额低于2022年的水平，但仍然高于疫情前的水平。在2023年末举行的生物技术展览暨会议（BIO Europe) 上，制药公司明确表示，将投入大量资金用于早期阶段投资。然而，生物技术公司对于资金的易获取性仍然持谨慎和不确定的态度。[52]

以创新和智慧应对挑战

生物技术公司越来越多地考虑将合作伙伴关系和其他创新性协作方式视为并购的替代方案或先导策略。获取监管许可所需的时间可能尤其具有挑战性，而步入2024年，许多中小型生物技术公司的现金储备期限较以往更短。此外，在并购之前，可通过建立联盟和合资企业来证明商业计划的可行性，让监管机构对并购交易更加放心。[53]

利用合作伙伴关系和战略协作的优势

通过携手合作，可以获得以下实质性好处：

- 获得新资产，如创新科学、平台和技术专利
- 获得新的能力和资源，如专门知识、生产制造、大规模适应症的商业化、全球范围内建立的基础设施以及人工智能等先进技术
- 开拓新市场，接触新患者群体
- 通过公私合作伙伴关系实现整个生态系统的协同效应和弥合资金缺口
- 建立信任关系，为未来的并购活动奠定基础

为了寻找互惠共生的合作伙伴，企业首先需要批判性地评估双方的契合度、互补技能/资源以及各方带来的价值/优势。然而，即使确定了契合度，并且交易已经完成了详细的条款制定和协商过程，真正的挑战才刚刚开始。

> “中小型生物技术公司可能会低估合作所需的资源和努力。如果从一开始资源就有限，就没有很多部门可以分担这些任务。此外，公司还应该充分认识到建立信任所需付出的努力，并应始终坚守最初合作的基本原则。”
>
> **—Calliditas Therapeutics首席执行官 Renee Aguiar-Lucander**

开拓新市场和接触新患者群体

2019年，在其首次合作伙伴关系中，Calliditas Therapeutics将目光投向了全球第二大医药市场——中国。为了满足庞大的患者需求，Calliditas与云顶新耀签订了许可协议，旨在大中华区和新加坡开发用于治疗IgA肾病的治疗方法并将其商业化。[54] 在中国及其他亚洲国家，慢性免疫介导性肾脏疾病是肾脏衰竭的主要原因，尽管在美国和欧洲它被视为一种罕见病。

Calliditas在该合作伙伴关系中须保持敏捷——由于其临床试验计划受到疫情的中断——并需在斯堪的纳维亚文化与中国文化之间存在的差异上开展工作。例如，首席执行官Renee Aguiar-Lucander指出，她的瑞典同事在无法完成任务时，往往避免直接说“不”。在许多文化中，直接拒绝可能被视为挑战或不礼貌的行为。[55]

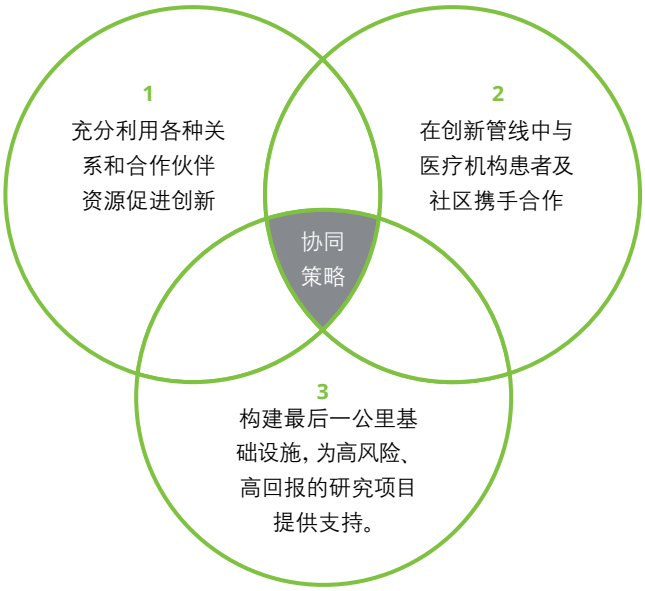
寻找新的资本来源：建立公私合作伙伴关系，支持生物医学创新

在私营部门资金吃紧的情况下，一些公司发现可借助政府资金填补资金缺口。在新冠疫情期间，政府与各种合作伙伴建立公私合作伙伴关系，为推进各类疾病治疗和护理提供了典范，同时，与普遍看法相反，政府和非政府机构在生物医学领域的投资并不会减少私营部门在研发上的支出。[56]

除了应对疫情之外，政府可能会通过以下措施，继续推动那些能够引起整个生物医学行业生态系统发生根本性变革的创新解决方案：

- 在创新管线中优先考虑患者和社区的需求；
- 充分利用各种关系和合作伙伴资源；
- 为“最后一公里”创新提供资金和合作支持。[57]

图3：政府与其合作伙伴可采取的三种协同策略



资料来源：德勤分析

政府为未竟医疗需求 (unmet need) 领域研发提供资金支持的机制，有助于推动研究进入“最后一公里”(last-mile) 管线 (见图3)。[58] 一些政府在过去采用了两种机制，这些机制可能是降低高风险研究领域风险的关键：

- **推力激励 (Push incentives)**，包括提供财务补贴、税收优惠和技术支持激励等，以降低研发成本，不论市场是否预期失败
- **拉力激励 (Pull incentives)**，涉及对市场上已经显示出潜力且科学上可行的研发成果提供奖励，旨在确保开发者的财务可持续性，即使在市场效率低下的情况下，也能持续推动这些成果的发展和应用 [59]

政府提供适当的基础设施和激励措施，可以极大地提高实现重大突破性生物医学创新的可能性。[60]

寻找新的资本来源：医疗技术风险投资公司发起新基金

在经历了一段市场低迷期之后，2023年年中，风险投资公司对医疗技术领域再次表现出兴趣。埃隆·马斯克创立的脑机接口初创公司Neuralink（通过植入式芯片实现“人脑与机器交互”），以及Beta Bionics（致力于为糖尿病患者提供几乎无需人工干预的自动胰岛素输注系统）达成上亿美元的投资交易，引领了行业的复苏趋势。[61]

投资更趋慎重

风险投资者正在寻找有远见的医疗技术创始人，以期在2024年进行更为慎重的投资。数字健康市场可为真正的行业创新者提供前景看好的机会。[62] 医疗技术风险投资最活跃的领域是心血管手术设备。在2020年至2023年第三季度期间，启明创投是领先的医疗技术风险投资机构，而美敦力则是最活跃的收购方（见图4）。[63]

图4：2020年至2023年9月30日医疗技术领域最主要的收购方与风险投资机构

投资者名称	交易数量	投资者类型
Medtronic	5	企业
Boston Scientific	4	企业
Thermo Fisher Scientific	3	企业
Laborie Medical Technologies	3	私募股权背景
Philips	3	企业
Ottobock	3	私募股权背景

投资者名称	交易数量	种子前/种子轮	早期阶段风投	晚期阶段风投	风投成长阶段	投资者类型
启明创投	49	0	25	22	2	风险投资
红杉资本	39	0	16	17	4	风险投资
Enterprise Ireland	34	3	7	14	10	风险投资
元生创投	33	0	18	13	2	风险投资
European Innovation Council Fund	33	1	6	21	3	风险投资
Khosla Ventures	30	3	3	18	3	风险投资
Lilly Aisa Ventures	27	2	17	7	1	企业风险投资
SOSV	27	6	2	18	1	风险投资
上湾资本	26	3	14	7	2	风险投资
强生创新投资-JJDC	24	0	7	13	4	企业风险投资

来源：Pitchbook；地域范围：全球

专家估计，自2019年初以来，大型医疗技术公司的平均现金储备增加了15亿美元，在2023年底达到约50亿美元。[64] 潜在的并购兴趣领域包括机械循环支持、经导管二尖瓣和三尖瓣修复与置换、脉冲场消融、外周血管解决方案、治疗静脉血栓栓塞的介入设备以及糖尿病技术。[65] 左心耳（LAA）封堵术作为一项旨在降低中风风险的医疗技术，其市场规模已达14亿美元。同时，强生和美敦力这两家公司分别通过达成独立交易对这一领域表现出兴趣。预计到2030年，LAA市场的规模将达到60亿美元。[66]

利用医疗技术巨头的风险投资部门

有远见的初创公司创始人可通过波士顿科学公司和强生公司等医疗技术巨头的风险投资部门寻找合作机会。[67] 举例而言，强生公司旗下的风险投资机构强生创新投资（JJDC）在全球各地（包括上海、波士顿、旧金山和伦敦）设有创新团队，专门为处于早期阶段的初创公司提供支持，[68] 其最引人注目的退出案例包括23andMe、Nevro和Grail。[69]

2023年底，直觉外科公司（Intuitive Surgical）的风险投资部门增设了1.5亿美元的基金，由此其管理的总资产在2024年将达到2.5亿美元，涉及三个投资领域：[70] 改善医疗服务的可及性与协调性、精准诊断与干预，以及安全且丰富的数字医疗生态系统。[71]

除了关注医疗服务的可及性和可负担性之外，专注于早期检测和预防性保健的新商业模式也在吸引投资。[72] 同时，专注于通过诊断技术来改善患者预后的数字健康公司也显示出巨大的发展潜力。[73]

寻找新的资本来源：借助政府举措，为医疗技术领域提供资金支持

数字健康和医疗技术创新发展路径得到了多种不同经济举措的支持，而这些举措愈发注重降低医疗服务和设备的成本，并提高相关服务和设备的可及性。

近期全球各地政府出台的生物医学或医疗技术举措包括：

美国—美国政府近期拟在全国范围内设立31个区域科技中心，其中13个致力于生物医学或医疗技术创新，如大费城地区精准医疗技术中心（The Greater Philadelphia Region Precision Medicine Tech Hub）和科罗拉多州的Elevate Quantum Colorado。[74] 量子计算有望更高效地训练医学诊断方面的人工智能。[75]

加拿大—加拿大政府通过加拿大草原经济发展部（PrairiesCan）拨款逾210万加元，助力阿尔伯塔省健康与医疗技术行业加快其人类移动能力和家庭健康领域创新的商业化进程。[76]

苏格兰—苏格兰工商委员会（Scottish Enterprise）向医学设备制造中心（MDMC）额外拨款335万英镑，用以推动医学设备创新并提升行业的可持续性。[77]

英国—英国政府宣布向其国民医疗服务体系（NHS）的64个信托基金拨款2,100万英镑，用于部署新的人工智能工具，以提高诊疗服务的效率。[78]

澳大利亚—为了支持生物医学技术孵化器项目，澳大利亚政府设立了5,000万澳元的基金，与Brandon BioCatalyst和ANDHealth共同投入总计1.15亿澳元的资金。[79]

调整投资组合：在重磅药物新纪元实现价值创造

一些公司正加大对肿瘤学和特殊疾病领域的投入，而另一些公司则专注于更普遍的慢性疾病领域。在肿瘤学领域，辉瑞与Seagen之间的交易激起了行业对抗体药物偶联物（ADC）的极大兴趣，触发了一场抢购ADC相关资产和技术的交易热潮。[80]

默克、第一三共、百时美施贵宝和艾伯维等制药巨头在2023年底之前均已开始采取行动，以获取进军ADC领域的机会和/或扩大各自在该领域的地位。日本第一三共还计划投资10.8亿美元，拟于2030年之前在德国建立一个“国际创新中心”，并将该中心打造成未来ADC的研发和生产基地。[81] ADC的投资规模反映出这类药物的价值和重要性在不断提升，一些支持者希望这类药物最终能取代某些形式的标准化疗。[82]

随着利用抗体的特异性实现强效细胞毒性药物靶向递送的方法日趋成熟，预计ADC领域的发展势头将会持续。[83] 2024年，强生与Ambryx之间的交易，以及罗氏与MediLink Therapeutics之间的交易拉开了这一年的序幕，此外还完成了一系列规模较小的收购和许可交易。[84] 制药和生物技术行业对ADC领域的高度关注，也吸引风险投资资金流向ADC初创公司。[85]

与此同时，市场对于那些专注于常见疾病领域的公司给予了积极反馈，GLP-1肥胖药物在市场上所受的关注及该市场的扩张也是近年来罕见的。那些未参与GLP-1药物或其他常见疾病领域开发的公司，现在需要向利益相关者解释其产品组合和科研战略的合理性。

在2024年1月举行的J.P. Morgan医疗健康大会，诺华公司阐明了其决定加大对放射性配体疗法（RLT）投入的考量。该公司相信，其能够在RLT这一领域保持并延续其已有的领先地位。与抗体-药物偶联物（ADC）类似，RLT就像“制导导弹”一样，可通过配体引导精确地靶向癌细胞，并利用治疗性放射性同位素杀死癌细胞。[86]

诺华公司认为，相比抗体-药物偶联物，RLT不仅能够提供更好的疗效，还能减少治疗过程产生的不良反应。[87]

随着GLP-1减肥药物的兴起，其市场估值和市场预测也备受关注

原本为治疗Ⅱ型糖尿病而开发的药物，目前正被配制成流行的减肥药物。就此而言，礼来公司推出了用于治疗糖尿病的Mounjaro（2022年获批）及其新近获批的减重版Zepbound。[88]诺和诺德也是减肥药市场的领头羊，其推出了Wegovy（2021年获批）和Ozempic（2022年获批）两款产品。[89]

在生物制药行业的领军企业中，诺和诺德和礼来公司在代谢疾病（包括糖尿病和肥胖症等最常见疾病）领域拥有长期增长预期，并在该领域处于市场领先地位，因此，这两家公司的市场估值位居前列。截至2024年第一季度末，诺和诺德的市值已攀升至5,729.2亿美元的历史新高，较2016年11月底的885.3亿美元显著上升。礼来公司的市值也达到了7,403.0亿美元的峰值，较2016年11月的741亿美元大幅增长。[90]

市场对GLP-1类药物的巨大潜力持有积极态度，这推动礼来公司和诺和诺德的市值与一些顶尖科技成长股（如特斯拉）相当甚至更高，并且显著超越了标普500医药指数的表现（见图5）。分析师预测这种上升势头将会持续。

图5：2021年第二季度至2024年第一季度，礼来公司和诺和诺德的股票表现与标普500及标普500医药指数的对比图

来源：德勤分析

专家指出，肥胖治疗正逐渐被纳入主流初级医疗保健服务，其增长趋势与20世纪90年代高血压药物市场的迅速扩张相似，当时该市场规模迅速膨胀至300亿美元。[91] 随着生活方式相关疾病发病率的不断上升，预计这将进一步推动GLP-1激动剂药物市场的整体增长预期。预计到2030年，该市场的潜在价值将达到370亿美元至1,000亿美元以上。[92] 尽管确切的市场规模尚不可知，[93] 但这一市场的增长势头主要是由肥胖症和糖尿病治疗需求所推动，预计到2020年代末，仅在美国就有望触及3,000万人的潜在市场。[94]

此外，由于GLP-1激动剂的潜在新用途不断显现，这类药物登顶了《科学》杂志所公布的“2023年度十大科学突破”。[95] GLP-1类药物在心血管疾病治疗方面展现出巨大潜力，同时针对药物成瘾、阿尔茨海默病和帕金森病治疗的研究也在进行。随着这些新用途的探索，预计未来保险公司的保障范围可能会进一步扩大。[96]

高质量集中收入来源不断增长

礼来公司通过增加高质量集中收入来源实现增长，在过去的四到六个季度中展示了一条非常成功且值得效仿的价值创造路径。礼来公司在肥胖药物市场做出了长期投资承诺，旗下多款肥胖药物候选药物已进入中后期临床试验阶段。2023年底，该公司还宣布与初创公司Fauna Bio达成长期合作协议，共同致力于利用动物基因组进行肥胖研究，这进一步表明了该公司对肥胖药物市场的十年长期承诺。[97] 凭借这一战略布局，礼来公司实现了12%的销售额增长和20%的净利润增长，一跃成为全球市值最高的制药公司。

解决医疗费用报销不足问题

在2024年及之后年份，除了应对肥胖药物需求不断上升的问题之外，还有两大问题有待解决：一是肥胖药物的可获得性不足，二是肥胖药物的保险覆盖范围不够广泛。在美国，由于政府医疗保险计划不予报销肥胖治疗相关费用，这导致患者基本上无法负担这些治疗费用。[98] 尽管某些地区专为美国低收入人群设计的医疗保险计划确实覆盖了这些药物费用，但这些药物的获取途径并不统一。[99]

美国数百万依赖Medicare提供医疗服务的老年人无法获得这些药物，原因在于肥胖药物曾在2003年被归类为美容产品；美国立法机构计划于2024年推动政策改革，以改变这一现状。[100] 如果美国Medicare保险覆盖的肥胖症患者中有10%开始使用GLP-1类药物，那么预计Medicare每年的总费用将介于136亿美元至268亿美元之间。然而，美国肥胖成年人的年均医疗开支比健康体重人群高出1,861美元。[101]

公共和私人医疗保险提供商可以借鉴挪威、荷兰、波兰和意大利等欧盟国家的保险报销指南。[102] 这些国家实施的报销政策可为美国提供一种实现负担得起保险覆盖范围的途径——也有助于减缓疾病的恶化。举例而言，欧洲的一些医疗保险模式为体重指数 (BMI) 较低、未达到“肥胖”标准但仍可从治疗中获益的患者提供有效且成本较低的药物。[103]

减肥市场竞争加剧，数字健康支持服务增长

新兴竞争者以及成本更低、潜在副作用更少的药物配方正逐步进入市场。新产品须具备明显优势以在市场上脱颖而出，制药公司正着手就以下方面开展研究：

- 开发具有替代给药途径的新型分子靶点
- 延长治疗间隔
- 研发新型的双重激动剂和三重激动剂机制[104]

随着辉瑞和安进公司预计在2024年公布新的研究成果，减肥药物市场的竞争日渐加剧，[105]一些在研药物可能成为收购焦点。2023年12月底，罗氏以27亿美元的先期价格收购了未上市的肥胖药物开发商Carmot Therapeutics。[106]

一些小型制药公司正在开发具有新颖作用机制 (MOAs) 的药物，其中包括瑞士的Aphaia制药公司和日本的Shionogi公司。[107]这一趋势预计将对药物成分和支持服务产生影响。随着消费者对健康管理的兴趣高涨，风险投资公司正在寻找通过远程医疗和教练指导来投资体重管理和减肥领域的机会 (见图6) 。[108]

图6：全球风险投资在减肥初创公司方面的重大交易

公司名称	交易完成时间	交易额（美元）	交易标的估值	交易类型	交易地点
Lark	10/13/2021	$100	$800.0	后期阶段	加利福尼亚州山景城
Calibrate	11/08/2022	$37.5	$365.0	早期阶段	纽约
Zoe	11/01/2022	$34.8	$264.3	后期阶段	伦敦
Nutrisense	06/28/2022	$25.0	$95.0	早期阶段	芝加哥
Form Health	01/13/2023	$22.9	$6209	早期阶段	波士顿
BooHee	11/21/2021	$15.6	$310.0	后期阶段	上海
January AI	08/15/2022	$13.0	$28.8	后期阶段	加利福尼亚州门洛帕克
Nourish	01/20/2023	$9.3	$40.3	种子阶段	奥斯汀
Intelliheath	02/15/2022	$8.5	$58.7	种子阶段	旧金山
Veri	06/01/2022	$7.9	$12.5	早期阶段	赫尔辛基

来源：Pitchbook

借助GLP-1类药物强化投资组合

GLP-1类药物的兴起为肥胖及其相关领域带来了大量机会。同时，一些市场领军企业也致力于借助GLP-1类药物来强化自身投资组合，纷纷涌入罕见病、神经病学和肿瘤学等“GLP-1耐药”治疗领域。此外，医疗技术公司可能会探索那些不受GLP-1类药物影响的资产，或者是那些寿命延长意味着利用率提高的资产。[109]

探索生成式AI和新兴技术的价值

探索可能的应用领域

生成式人工智能 (GenAI) 一经问世，便以其语音用户界面和强大的全新大型语言模型 (LLM) 迅速火爆全球。[1] LLM是一种基础模型，更具体而言，是基于海量数据集进行预先训练的机器学习 (ML) 模型，可用于解决一系列问题，也为构建应用程序或其他基础模型提供了新方法。[2]

尽管最初的热潮来自于消费者的体验分享，但生成式AI很快就在商界崭露头角，其可为企业工作流程增加情境感知并作出类人决策。[3] 在这个充满创造力的生成式AI时代，企业领导人面临着巨大压力，因其在利用这项技术的能力和潜力的同时，也须应对多重现实挑战。[4] 如何在维护好企业信誉和地位的同时，探索生成式AI的价值并管理其风险，是许多领导人未来一年的战略要务。[5]

亚马逊首席执行官Andy Jassy表示，生成式AI可能是近几十年来最具颠覆性的技术变革之一，[6] 而世界经济论坛 (WEF) 主席Børge Brende则提醒各方领导人，潜在的生产力显著提升凸显了负责任的AI治理的必要性。[7]

《财富》/德勤2024年冬季首席执行官调查显示，全球领军企业首席执行官对生成式AI的采用明显增加。[8] 大多数首席执行官 (57%) 拟将这一新技术整合至业务模式以获取增长机会，逾半数首席执行官 (56%) 已经在利用生成式AI来提高效率。[9]

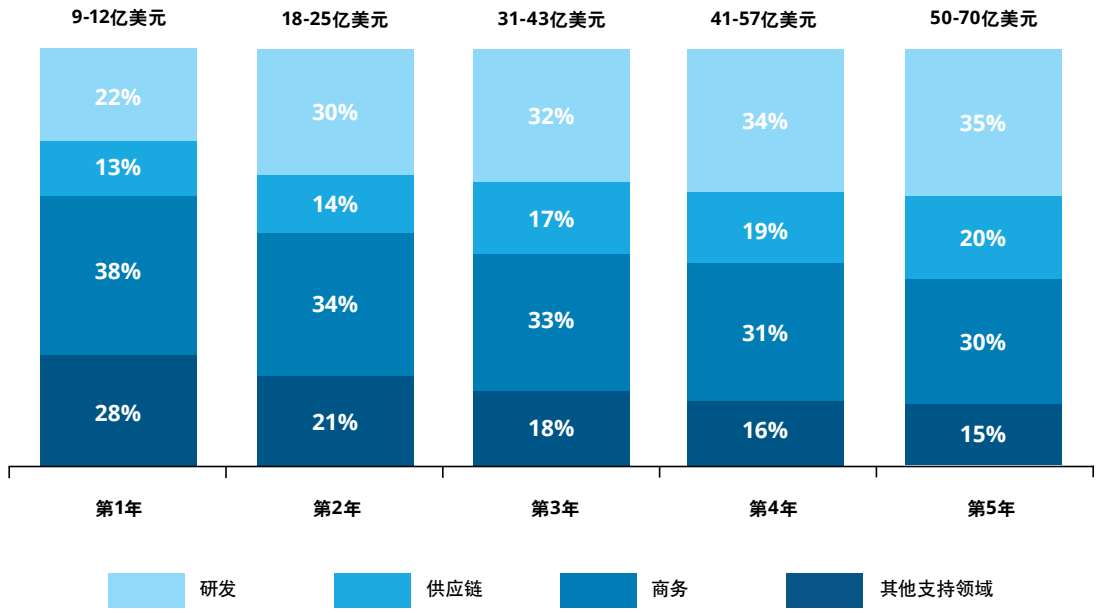
打造竞争优势

降本增效

据德勤调查，逾九成生物制药和医疗科技公司预计，生成式AI将在未来一年对其组织产生一定影响。[10] 生成式AI和其他AI技术与数字化转型工具相结合，有望提高生命科学价值链许多领域的整体效率并推动流程创新（图1）。[11]

一家年均收入为650-750亿美元的十强生物制药公司，如果在5年内持续扩大AI部署，最高可增创50-70亿美元的价值。具体取决于企业的规模。[12]

图1：AI部署的5年平均价值增创预测（已实现峰值的百分比）



上述数据基于以下假设得出：

01. 基础数据和基础设施已就位，可支持变革性用例开发
02. 各职能均采用了一整套的变革性AI 用例（例如，AI临床试验、AI制造、AI营销）

资料来源：德勤“Realizing Transformative Value from AI and Generative AI in Life Sciences”，2024年。

在整个价值链中创造价值

企业当下就生成式AI做出的选择能否创造价值和优势？虽然目前下结论还为时尚早，但与其他方法相比，一些基于生成式AI的方法有助于加速价值实现。[13] 在生命科学领域，近90%的AI应用价值或来自三个职能领域：研发、制造与供应链以及商务化（图2）。[14]

研发是提供价值机会的主要领域，可创造30%~45%的价值。将AI应用于新药鉴定和加速药物开发，既能节约成本，又能提高收入。在商务化方面，AI可通过优化营销成本、提高脚本利用率等活动，创造25%~35%的价值。在制造、供应链和其他支持领域（包括信息技术、人力资源和财务），AI主要通过提高效率和降低供应商成本提供成本转型机会。

企业如何将这些影响转化为竞争优势？速度和效率的提升可以将资本重新分配至其他价值创造领域。与其他影响因素相比，效率的提升可以帮助企业推动科学发展，提升客户和患者参与度，并最终改善患者的治疗效果。

图2：按职能划分的价值创造细分

资料来源：德勤 “Realizing Transformative Value from AI and Generative AI in Life Sciences”， 2024年。

探寻协同效应：大型制药公司和大型科技公司与生成式AI合作

2024 年，许多生物制药公司欲探寻将丰富的科学数据集与最新的生成式AI技术相结合的新方法。[15] 另外，拥有先进AI能力的科技巨头也希望抓住生命科学与医疗行业带来的巨大机遇。[16] 据估计，到2025年，全球36%的数据将来自于生命科学与医疗行业。[17] 透过生成式AI，大型制药公司和大型科技公司可能会意识到，这两大行业的合作比竞争更有利。[18]

生成式AI能否助力打造万亿美元级制药公司？

在2024年初举行的摩根大通医疗健康产业大会上，科技巨头纷纷出席足以证明其兴趣所在。[19] 各大科技公司高管都希望与生物制药公司就生成式AI/AI技术建立合作，其中包括英伟达，该公司首席执行官也出席了此次会议。[20] 英伟达于2023年市值突破万亿美元大关，[21] 并相信这类生成技术也将助力打造下一个万亿美元级制药公司。[22]

制药公司与科技巨头联手开发生成式AI

科技巨头正在与生命科学公司合作，在许多不断发展的领域开发更先进的生成式AI，具体包括：

英伟达：为生物制药公司提供生成式AI药物发现云服务BioNeMo，这些制药公司希望创建或定制专属的生成式模型，然后通过云API以软件即服务 (SaaS) 模式向其他公司提供这些模型。[23] 与英伟达合作的制药公司包括安进、阿斯利康、葛兰素史克和罗氏的子公司基因泰克 (Genentech)。[24, 25]

微软：通过微软服务 (包括Copilot、Microsoft 365应用程序、Microsoft Azure 和必应搜索引擎提供生成式AI。[26] 微软正在与制药公司诺和诺德 [27] 和诺华合作进行人工智能药物研发。[28] 医疗领域的一些生成式AI合作伙伴包括Epic、[29] 西门子[30] 以及医疗系统制造商，如Mercy和Duke Health。[31]

Alphabet：通过谷歌服务 (包括Gemini和谷歌云) 提供生成式AI。 其推出的AI工具Target and Lead Identification Suite旨在加速药物发现，而Multiomics Suite则用于共享海量基因组数据以推进精准医疗。[32] 谷歌云正与生物安全和工程生物学公司Ginko Bioworks [33]以及Insmed建立生成式AI项目合作，以变革药物开发和商业化流程。[34] Insmed利用谷歌推出的AI搜索工具Vertex AI Search为其内部记录搭建了基于生成式AI的搜索功能，该功能还允许分类访问外部医学文章。[35]

亚马逊云科技 (AWS)：其推出的GenAI on AWS Cloud可与许多领先的基础模型 (包括Amazon、AI21 Labs、Anthropic、Cohere、Meta和Stability AI) 集成，用于生成新的候选疗法、更好地为患者匹配合适的临床试验、鼓励患者参与试验以及加强生产监督。[36] AWS正携手诺和诺德进行大规模蛋白质结构预测；与安进合作推进药物发现和生产；[37] 并与Eversana合作，将AI “药学化” 以应用于整个生命科学行业，初步计划推出用于医疗和监管内容审批的生成式AI应用程序。[38] AWS还与辉瑞合作，为该公司开发专有的生成式AI平台VOX，以便员工访问LLM。[39] 辉瑞利用生成式AI创建专利申请、医疗和科学内容的初稿，再由人工审核和定稿，生产率大大提高。[40]

利用生成式AI模型实现表型组学领域 10 亿美元投资的民主化

Recursion Pharmaceuticals成立于2013年，是当今“科技生物”领域一家领先的人工智能生物科技公司，致力于推进数据驱动药物发现领域的临床阶段管线。[41] Recursion使用自有操作系统Recursion OS，将药物发现转化为“搜索”问题——生成、分析海量生物和化学数据集，并从中获得洞察。[42] 其表型组学平台集成像技术和AI于一体，可快速验证和推进肿瘤治疗新靶点的研究。[43]

为实现表型组学领域10亿美元投资的民主化，Recursion正对外公开其多年的专有研究成果，希望它能“推动全人类加速前进”。[44] 该公司正在开发的生成式AI系列基础模型中的第一个模型——Phenom-Beta——现托管于英伟达的BioNeMo平台上。[45] 2023年7月，Recursion还获得了来自多年AI技术合作伙伴英伟达5,000万美元的投资。[46] 此次投资旨在利用生成式AI/AI技术，使Recursion内部产品线及其合作伙伴的产品线受益，其中包括拜耳 (Bayer) 的纤维化疾病产品线和罗氏/基因泰克的肿瘤学和神经科学产品线。[47]

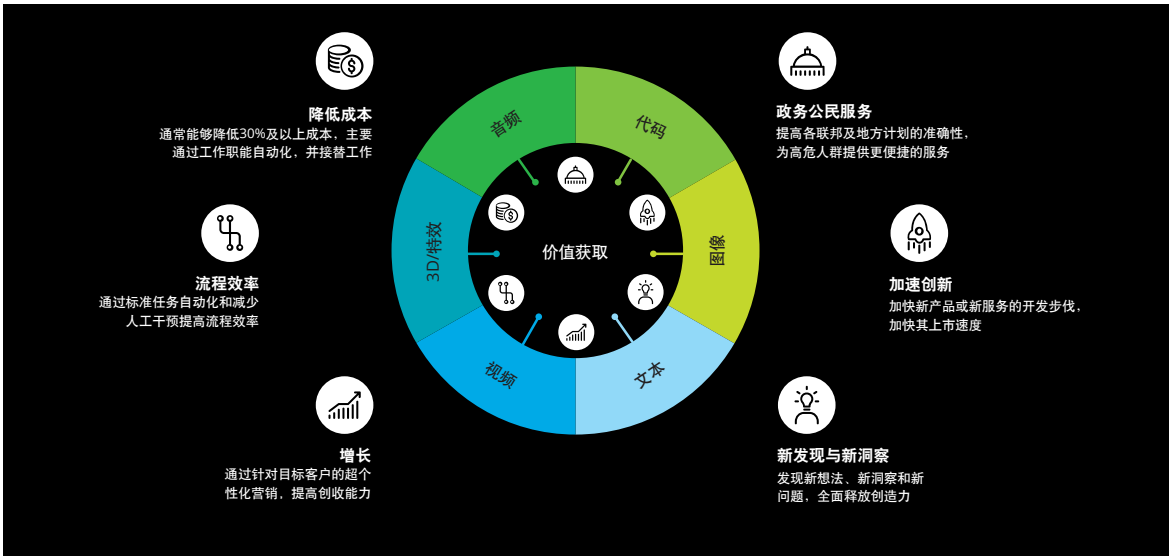
了解技术，挖掘价值

多模态LLM——通用人工智能 (AGI) 的基石

目前，多模态LLM在模拟人类智能方面又向前迈进一步。[48] 集音频、代码、图像、文本、视频生成和模拟能力于一体的生成式AI已经在改变内容生成和交付的方式，并有望重塑多种类型的消费、商业和医疗体验 (图3) 。[49, 50]

据德勤美国健康解决方案中心调查显示，半数消费者表示在某种程度上使用过生成式AI，逾半数消费者认为生成式AI可以改善医疗服务的获取；46%的消费者认为生成式AI能够提高医疗服务的经济可负担性。[51]

图3：生成式AI可提供的各类价值



资料来源：德勤“Realizing Transformative Value from AI and Generative AI in Life Sciences”， 2024年。

生成式AI的简单应用，如生成创意和设计图稿，已足以值得企业在启动生成式AI计划时“无悔下注”，其可降低投资风险并加快流程。[52]更高阶的用例则开始融入更多模态和技术。[53]每种模态（如文本或视频）都是用例的一个潜在价值驱动因素；扩展模态可提升用例的潜在效益。[54]

例如，在药物发现中寻找治疗方法的生成式AI用例则是通过模拟和图像提供价值驱动因素（图4）。该用例的潜在优势在于，生成式AI能够从海量数据（包括图像）中分析和学习，从而提供更具针对性、更有效的治疗方法。利用生成式AI进行模拟以选择最佳潜在候选药物的能力，可最大限度地减少在现实世界中进行迭代的需要。[55]

由于多模态AI系统可以同时解读多种类型的数据，如文本和图像数据，因此其开发和验证需要多个学科的通力合作。[56]各领导人应召集一支由具备领域知识的人员组成的跨学科团队，创造性地思考潜在用例。[57]（欲了解更多用例，请参阅德勤人工智能研究院发布的Generative AI Dossier）。

从单个用例转向“珍珠链”战略

LLM和其他基础模型正开始解锁一系列高价值应用。约三分之二的受访生命科学公司表示正在构建生成式AI用例，36%的公司表示生成式AI将影响其未来一年的战略。[58]

由于对专有数据的依赖，生命科学特定垂直领域的用例或需要更多投资。将专有内容嵌入生成式模型可以通过微调现有的LLM或从头开始训练LLM来实现。[59] 2024年，专有数据和合成数据的获取或将催生出新经济。[60]

尽管每个单独的生成式AI用例都可能带来一些改进，但将多个用例与机器学习、物联网（IoT）等其他数字工具相串联或将改变整个流程，而这正是释放价值之处。从研究到临床开发，再到客户参与和患者体验，都可以采用这种“珍珠链”战略。每个用例都会连接到另一个用例，再连接到另一个用例，以此类推。[61]

图4：生成式AI可在药物发现中识别候选新药

探寻治疗方法
（新药发现/生成）

生成式AI可模拟蛋白质和生物大分子的结构和功能，从而加速分子的识别和验证，并创造新的候选药物。

问题/机会

尽管医疗技术不断进步，但由于药物发现和验证过程复杂、成本高昂且耗时较长，许多疾病仍然缺乏有效的治疗方案。药物开发的挑战不仅在于发现潜在疗法，还在于对其有效性进行严格验证，这一过程既耗资又耗时。临床试验的独特复杂性使上述问题变得更加复杂，原因在于临床试验需要考虑到不同的人群、与其他疗法的相互作用以及潜在的副作用。此外，由于某些疾病的罕见性，导致患者数据有限，这也为临床试验带来了更多障碍，使研发工作更具挑战性。

生成式AI如何提供帮助

降低成本
在临床开发过程中使用生成式AI验证药物，可大大降低成本。这是因为它能够进行模拟，选择最佳的潜在候选药物或进行进一步测试，从而最大限度地减少在现实世界中进行大量迭代的需要。

改善公共医疗卫生
生成式AI可加速发现更优的疾病疗法，从而极大地改善公共医疗卫生。其分析和学习海量数据的能力可带来更具针对性、更有效的疗法，直接造福于患者，进而造福于整个社会。

促进合作
生成式AI可以促进研究小组间的交流和知识共享。其可以处理和理解不同来源的数据，打破数据孤岛，为实验中的合作与创新提供新契机。

资料来源：德勤“The Generative AI Dossier”，2024年。

生成式AI之“珍珠链”战略在科研中的应用

根据工作流程、职能领域和更大的计划任务来思考用例，有助于企业确定用例组合。每颗“珍珠”都应做出重大贡献，推进达成主要目标，从而增强整体力量。[62]

实施“珍珠链”战略以扩大科研生产力、推动全球合作

生成式AI如何提供帮助？

1. 作为拥有奇思妙想的科研伙伴，提供强大的跨知识库（包括专有数据）搜索能力
2. 为荟萃分析总结科学文献[63]
3. 处理和理解不同来源的数据
4. 打破数据孤岛，促进跨研究小组和跨地域的交流和知识共享
5. 协助撰写研究论文、审批文件、文献综述和非技术性数据摘要
6. 创建多模态演示文稿
7. 翻译作品，使其可以跨地域共享（图5）[64]

图5：生成式AI可拓展科研合作

大规模语言翻译
（内容本地化）

生成式AI可将文本和音频翻译和转换为本地语言，快速、轻松地实现跨地区内容扩展。

问题/机会

大规模创建和翻译内容的能力可成为跨国企业的竞争优势，但这也需要大量的时间和资源，按需快速翻译或难以实现。

生成式AI如何提供帮助

自定义本地化和质量保证工具
生成式AI可助力组织和管理复杂的文件类型，在翻译前分析内容以实现本地化优化，以及将词汇表、术语库和语言工具集成至工作流程。

跨行业的内容个性化
AI赋能的内容个性化可以提高参与度、建立品牌忠诚度并增加转化率，从而为本地化工作增添动力。

翻译过程中的语音识别
生成式AI可启用语音用户界面（VUI）、将音视频内容转录为文本，并同时将口语内容翻译为目标语言。

资料来源：德勤“The Generative AI Dossier”，2024年。

如何扩展语言翻译用例以提供文本和音频两种以上的价值驱动因素？生成式AI不仅可将文本转换为多种语言的音频，还可以生成另一种语言的辅助视频——这即是又一大价值驱动因素，从而支持跨地域和更多平台的内容共享。

采纳进化式AI思维模式

随着企业领导者们开始探索孤立试验和单一用例之外的更多可能性，他们将生成式AI纳入企业转型的考量之中。这不仅从根本上改变了完成工作和创造价值的方式，还解决了合规、隐私、监管和信任方面的问题。[65] 为有效推动大规模的AI转型，必须在整个过程中采取进化式思维（图6）。

将生成式AI融入企业技术栈

企业决策者应制定战略，确保现行的AI战略与生成式AI和谐统一，同时还要考虑生成式AI的潜力和限制。[66] 为最大限度发挥生成式AI的潜力，需要基于整个技术栈构建企业级基础设施和平台。[67]

为构建和扩展应用程序，需要拥有安全的云基础设施、基础模型、现代化数据平台（用于管理高质量、背景丰富的数据），以及低代码/无代码平台。此外，还需建立大型语言模型运维（LLMOps）和云成本管理。

生成式AI的模型层——基础模型

生成式AI与以往AI的不同之处在于基础模型（图7）。[68] 例如，微软的Win32为开发人员提供访问基础硬件和操作系统功能的API，而模型层则将应用开发人员与最优硬件相连接，促进生成式AI的普及和民主化进程。[69] 专家们表示，基础模型将成为生成式AI在企业环境中未来发展的基石。[70]

开发人员通过封闭和开放的API访问基础模型，使用更多的训练数据进行模型微调，以增强其在特定用例和垂直领域中的背景知识、相关性和性能。[71] 在模型层，闭源模型提供商（如Cohere和谷歌）负责托管和管理构建于庞大数据库之上的模型，并向用户收取使用费。开源模型提供商（如Meta和Stability.ai）则由社区管理，并在模型微调过程中收取费用，或者作为公司的职能部门收取使用费。[72]

图6：AI转型之旅

思维	领导力	投资	文化	实施
摆脱无限循环的短期概念验证，在关键领域对AI进行长期投资和布局	企业领导者设定可衡量的AI目标和价值目标，以促进AI推广和责任落实	将AI投资视为企业业务战略的核心驱动力，而非试探性举措	将AI视作员工提升工作效率的必备技能，而非工具	改变前台与后台各自为政的方法，将其“合二为一”，确保业务与IT目标一致

资料来源：德勤“Realizing Transformative Value from AI and Generative AI in Life Sciences”，2024年。

图7：生成式AI技术栈

资料来源：德勤 “A new frontier in artificial intelligence”，2023年。

提高运行效率

模型构建完成之后，企业需具备LLMOps能力。LLMOps专门解决模型的独特需求，包括计算、迁移学习、人工反馈、成本/性能调整、新指标、提示工程和LLM管道构建。LLMOps解决了LLM开发的复杂性，提高了效率和可扩展性，同时降低了风险，并确保将应用程序扩展至生产环境。

除LLMOps外，云成本管理也是一个关键因素。它有助于企业充分利用生成式AI的潜力，同时优化云资源使用并确保投资回报最大化。

管理风险，构建适当的基础模型

部署本地和专有LLM

企业部署生成式AI模型（尤其是LLM）存在风险，部署方式如下：

- 通过服务提供商以SaaS模式部署，可避免配置或安装问题
- 在企业的私有云或专用网络上进行本地部署，可控制和管理API配置 [73]

本地部署的LLM安装在组织的基础设施之上，用户只需访问组织网络和应用程序即可使用LLM。某些本地部署的系统与互联网的开放访问隔离开来，但可以通过安全方式实现连接。

2024年，部分生命科学公司将着手构建专有LLM，以建立一个“围墙花园”，从而避免数据泄露至公共领域，同时实现成本控制。[74] 使用专有LLM训练而成的生成式AI能够在可控的环境下运行，其数据收集活动将遵循具体指导原则、质量标准和预定目标。[75] 对专注于特定目标构建解决方案的公司而言，LLM将带来最为显著的影响。[76]

利用协调型初创企业管理LLM

随着越来越多的组织开始采用生成式AI，同时也面临众多选择，预计2024年，**协调型初创企业**将发挥巨大作用。这类初创企业获得了大量风险资本的关注，[77] 它们的使命是协调整合有关LLM管理的任务：

- 简化模型选择
- 选择并微调模型
- 将多个LLM整合为单项服务
- 以较低成本部署应用程序
- 创建平台，普及LLM访问[78]

处理监管的不确定性，实施治理

弥合AI信任鸿沟

由于生成式AI能够模仿人类的思维和行为，许多人因此而受到吸引。然而，人类的思维和行为并非完美无缺，有时无法预测或不为社会所接受，AI技术亦是如此。[79] 专家们指出，对于检查和验证AI的准确性以及解决可能出现的问题，人类的参与至关重要。[80]

社会各界希望建立统一的指导原则，使人们信任AI所提供的东西。[81] 信任并非AI天然具备的属性，而是源于AI治理、风险缓解，以及企业内部人员、流程和技术的协同努力。[82]

德勤于2023年12月对全球范围内不同行业且拥有AI经验的高管进行调研，受访者对生成式AI所涉及的风险提出了各种问题，包括：

- 如何管理AI幻觉和模型偏差，
- 如何解决潜在的知识产权问题，以及
- 透明度和可解释性问题。[83]

到2026年，预计超过80%的企业将在生产环境中使用生成式AI和/或部署由生成式AI驱动的应用程序。[84] 企业用户必须理解生成式AI的本质，并始终将最终用户的利益放在首位，而非仅仅依赖AI工程师和数据科学家来应对信任工具所引发的风险和后果。[85] 监管和法律问题带来的不确定性预计将影响整个市场的发展。[86] 一项针对技术人员的调研显示，41%的技术人员对其公司使用的AI工具所涉及的道德问题表达了担忧。[87] 在另一项覆盖25个国家的消费者和买家调研中，超过半数的受访者表示不相信自己的公司会以合乎道德的方式使用AI。[88] 其中近70%的受访者认为，随着AI技术的发展，信任公司将变得更加重要。[89]

组织可通过制定具体的策略来补充创新，同时增强客户信任和品牌价值。德勤开发了“可信AI框架”，以帮助组织遵循不断演变的相关法规（图8）。[90]

图8：可信AI框架

资料来源：德勤，“Trustworthy AI”，2022年。

隐私保护：尊重隐私，用户数据不会超出预期和声明的使用或存储范围；用户可以选择是否共享他们的数据。

透明/可解释：用户理解AI技术的使用方式和决策方式；AI决策都是可理解、可审计和公开可检查的。

公平/公正：AI技术的设计和使用具有包容性，可实现公平应用、访问和输出。

负责任：AI技术的开发和使用都应对社会负责。

可追究：制定政策来确定谁对利用AI技术做出或衍生的决策负责。由于AI模型缺乏自主性或目的性，因此无法对其进行有意义的责任追究。[91]

稳健/可靠：AI技术的输出结果既一致又准确，能够经受住反复的测试，并能迅速从不可预见的干扰和误用中恢复。

使用安全：AI技术可以受到保护，以防止可能导致个人身体、情感、社区环境和/或数字损害的风险。[92]

任命首席人工智能官 (CAIO)

有远见的企业已经着手任命首席人工智能官 (CAIO) 来引领其商业愿景，并负责管理声誉、监管及法律风险。[93] 高效的AI治理框架有助于识别潜在风险和能力差距、验证性能和保障企业运营。[94]

尽管AI与IT治理存在一定的交集，但它是一门独立的学科，技术和非技术利益相关方均可从中获益。[95] 美国政府鼓励各联邦机构任命CAIO，并采纳新的治理策略，以确保AI的应用合法、安全且透明。[96]

在生命科学领域，特别需要注意的是，尽管目前存在保障措施，但LLM仍可能对通过这些系统传输的专有或敏感信息构成重大风险。此外，专家们建议，公司在利用内部数据对现有基础模型进行微调时，应格外加强数据管理，尤其是在涉及外部供应商执行微调的情况下更是如此。[97]

公司还可以考虑创建一个隔离的“沙盒”环境，让员工能够在不向开发人员共享提示或数据的情况下探索生成式AI工具的功能。为确保生成式AI的高质量输出和持续改进，开发人员和用户均需实施监控和反馈流程，同时公司还要确定最佳的透明度。[98]

预计未来监管挑战

在监管层面，有效采用“珍珠链”战略，结合多种技术和多个地区，构建统一的监管环境。[99] 虽然制定一套全球性的统一法规可能不切实际，但基于各国的监管策略建立全球性指导原则或许可以增加监管透明度，也能产生积极影响。[100] 全球性协作和清晰的监管环境有助于促进AI发展和跨地区采用。[101]

研究显示，拥有AI经验的董事和首席高管正在全球范围内寻求更广泛的监管与协作 (图9) 。[102] 监管环境迅速变化和生成式AI技术不断创新，为技术构建者和管理者营造了一个充满挑战的环境。

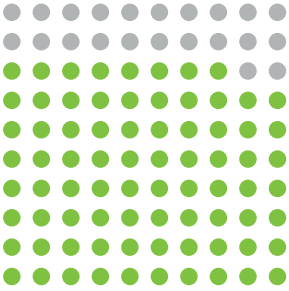
部分LLM和基础模式正在验证监管的局限性，包括欧盟的《数字服务法案》。[103] 若企业未实施保障措施来确保AI技术的有效、负责任和合法使用，则会面临风险。[104]

在《企业生成式AI应用现状》调研中，近一半的企业 (47%) 表示，已经将监管要求监控纳入其风险管理行动之中。许多人提出担忧，认为生成式AI的广泛应用可能会集中化权力，并加剧经济不平等。[105]

2023年，立法者们达成了一致愿景。2024年，这些政策将转化为具体措施，科技公司将承担起相应的责任。其中，内容标注、水印技术和透明度将成为关注的焦点。[106]

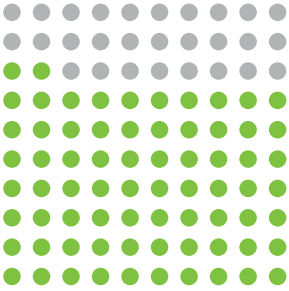
美国：美国政府于2023年10月30日发布了一项行政命令，其中包含了一套美国迄今为止最全面的AI监管规则和指导原则。[107] 该行政命令不仅涉及AI的安全性和保障措施，还包含了一项要求：如果新的AI模型技术可能对国家安全构成威胁，其开发者必须向美国政府提供安全测试结果。然而，这项行政命令并未详细阐明这些政策的执行机制。[108] 该行政命令的重点内容包括但不限于：

图9：领导者支持加强监管和全球协作



加强监管

78%的领导者赞成政府应就生成式AI工具/应用程序的普及**加强对人工智能的监管**



加强协作

72%的领导者认同**全球协作**尚不足，无法确保负责任地开发基于AI的系统

资料来源：德勤《企业生成式AI应用现状》，2024年1月。

- **标注原则**：要求美国商务部就AI生成内容标注制定指导原则，旨在通过标注文本、音频和视频内容的来源，使消费者更容易识别出哪些内容是通过在线AI工具创建的。
- **标注和水印工具**：要求AI开发者开发各联邦机构亦可采用的标注和水印工具。利益相关方指出，目前尚无完全可靠的方法来标注文本或调查内容是否由机器生成，同时也没有强制规定必须使用这些工具。[109]

2024年，新成立的美国人工智能安全研究所将负责实施上述行政命令中规定的大部分政策。类似于欧盟的《人工智能法案》，我们将看到一种按照类型、用途和风险程度对AI进行分类的体系。[110]

欧盟：欧盟《人工智能法案》堪称全球首部全面的AI法律。[111] 该法案基于风险程度为生成式AI/AI的供应商和用户设定了相应的义务。尽管许多AI系统的风险很低，但欧洲议会依旧认为需要对其进行评估。[112] 关键基础设施和其他高风险组织必须开展AI风险评估，并遵守网络安全标准。[113]

构成“不可接受风险”的AI系统被认为对人类构成威胁，将被禁止使用（执法部门将享有某些特例）。[114] 关键基础设施和其他高风险组织必须开展AI风险评估，并遵守网络安全标准。[115]

通用的生成式AI技术（如谷歌的Gemini 和ChatGPT）必须遵守以下透明度要求：

- 标注内容为AI生成
- 设计模型时应考虑防止生成非法内容
- 公开训练数据的版权信息摘要[116]

对于风险较低的AI系统，透明度要求提供充分的信息，以便用户做出知情决策。用户应能清楚意识到正与AI进行互动，并有权选择是否继续使用AI。[117]

最重要的是，欧盟《人工智能法案》确立了一套具有强制性的透明度和道德标准。[118] 对于建立开源AI模型的公司，《人工智能法案》允许它们免于大部分透明度要求的限制，但GPT-4这类计算密集型模型除外。[119] 其他国家在制定AI技术监管政策时，将参考欧盟的这部法案[120]，科技公司预计有两年的时间来落实这些规则。[121]

新加坡：新加坡2019年推出的AI治理框架也受到了全球关注。[122] 新加坡信息媒体发展管理局（IMDA）最近开发出了“AI Verify”，这是一个AI治理测试框架和软件工具包，用于评估AI系统的当前状况。[123]

随着生成式AI到来，各国政府持续努力缓解AI所带来的社会风险，企业内部的风险意识（包括AI素养和个人责任感）将在日常运营中发挥越来越重要的作用。为促进公司员工对AI的了解，首席信息官和企业领导者应提供资源支持，增加对现有员工的培训和学习课程，并培养持续学习的企业文化。[124]

（欲了解更多，请参阅德勤人工智能研究院）

未来展望

为跨过概念验证的门槛，向规模化迈进，企业需要进行技术升级，并将生成式AI融入更新的工作流程中。各组织应识别受生成式AI影响最大的领域，并逐步实现数字化，从基础的生产力用例转向更高级的结构性机遇，如新型且独特的服务或商业模式。[125] 此外，建立健全的治理模式有助于推动AI技术采纳，确保对AI技术的输出结果进行责任追究，并帮助实现价值最大化。[126]

生命科学和医疗科技领域的利益相关方所关注的生成式AI相关战略性问题

01. 我们组织的生成式AI相关策略能否体现价值创造和优势思维？
02. 我们应采取何种策略以最佳方式扩大规模，并为长期价值创造奠定基础？
03. 我们是否拥有足够多元化的生态系统合作伙伴？在面对多种多样的解决方案和能力时，我们如何平衡专注重点与促进多元化？
04. 我们的组织需遵循哪些指导原则以确保负责任地使用生成式AI，以及如何确保我们的做法与不断变化的社会期望保持一致？
05. 为确保我们的人才和组织充分准备好适应不断变化的趋势和技术，我们需要采取哪些措施？

全球药品定价压力上升，影响研发创新积极性

药品支出增加

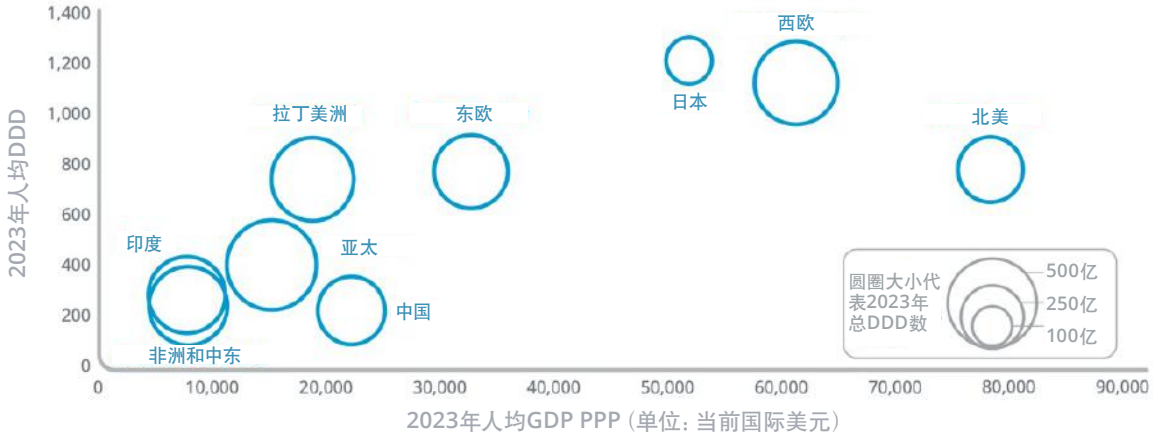
未来几年，全球药品支出和增幅将呈现上升趋势，但各国的具体情况存在差异。[1] 药品支出在很大程度上受经济发展水平的影响，因此在评估时需综合考虑国家的总体医疗支出[2]及其所占的GDP比重。[3] 高收入国家的药品使用量通常高于低收入国家（图1）。[4]

有的国家更关注药品使用量，有的国家则重视创新药的采用。[5] 到2028年，特药预计将占全球药品支出的40%以上，其中发达国家市场占总支出的一半以上。[6]

未来五年，北美、东欧、西欧、拉丁美洲、非洲和中东将出现人口带动药品使用量增长的情况，同时药品结构也将转向高成本产品。与此同时，中国的药品支出将不再以量为主，而是更注重扩大新药的可及性。日本由于药品创新与价格削减的相互抵消作用，其药品支出将保持稳定。[7]

图1：人均药品使用量

各地区的人均限定日剂量 (DDD) 与人均GDP PPP对比 (单位：当前国际美元)



资料来源：艾昆纬研究所，2023年12月；世界银行，2023年7月；国际货币基金组织，2023年10月。

全球药品定价压力

随着全球药品定价压力逐渐显现，药品定价和价格受到审查。[8] 2024年，各国政府实施药品定价监管和调控措施，将对部分药品的可负担性和可及性产生更多积极影响。[9] 由于世界各国的治理模式不同，并且需要平衡众多利益相关方的利益，因此药品定价具有复杂性。

目前，美国政府正在进行首次药品定价谈判。[10] 为解决药品定价问题，美国政府采取了各种政策措施，但《通货膨胀削减法案》(IRA) [11] 中有关医疗保健的规定使部分制药公司陷入担忧。[12]

同时，欧洲各国也存在类似的问题。例如，英国实施了一项新的价格监管协议——品牌药品定价和获取自愿计划（VPAS）——旨在控制创新药支出水平。[13] VPAS设定了英国国家医疗服务体系 (NHS) 每年的品牌药品销售总额上限。[14] 该上限额度统一以每年2%的增长率递增，但若实际药品销售额超出该上限，英国卫生与社会保障部 (DHSC) 将对超出部分征税。[15]

在亚洲地区，日本每两年降低一次药品价格。经过最新的2023财年同比审查，降价幅度约为2%至9.4%不等。[16] 中国则利用其庞大的人口基数，采取带量采购政策，大幅降低了药品价格。截至2021年底，中国通过该政策节省了约363亿美元的药品开支。[17]

发达国家对药品定价问题的关注日益增加，将药品可负担性问题推至2023年世界卫生大会 (WHA) 全球卫生议程的首要位置。[18] 几十年来，发展中国家始终担忧其卫生系统承担药品开支的能力。2024年，药品可及性基金会将加强对中低收入国家 (LMIC) 的监管协调。该基金会的最新两年期报告预计将于2024年发布，届时将评估制药公司如何监测中低收入国家可获得基本医疗保健产品的患者人数。

美国《通货膨胀削减法》的影响

德勤美国的一项调研显示，2024年，一半以上的美国生命科学公司最关注药品定价及可及性的影响。[19] 未来五年内，预计IRA将对制药行业的研发和商业决策与资源分配产生深远影响，进而影响全球药品可及性。美国占据全球制药市场近43%的份额，众多全球性制药巨头公司都将总部设于美国。[20]

由于医疗保险D部分的患者自付费用降低，谈判达成的药品价格将直接惠及患者，因此IRA对患者的负担能力具有积极作用。此外，自2025年起，医疗保险D部分的处方药自付费用上限为每年2,000美元。[21] 因此，未来几年内，商业保险架构可能发生重大变化，包括采取措施将患者的自付费用成本计入药品的净价与标价之中。

这可能对制药公司的药品标价和净价、分子药品价值（尤其是谈判资产）、价格调整、研发与业务拓展资本分配产生重大影响。

预计IRA将对美国的医疗保险计划、药品福利管理公司（PBM）、药店、雇主、医院、医疗系统和其他供应商的运营及财务产生影响。例如，价格谈判可能影响医疗服务提供者和药店采购药品的价格及其可获得的补偿和返点。对所有行业参与者而言，药品价格下降将为其商业活动带来压力。[22]

除此之外，还可能出现一些意想不到的影响。例如，小分子药与生物药之间存在区别对待，孤儿药市场也将发生变化（所有孤儿药均未纳入谈判范围）。预计在12至24个月或更短时间内，一些参与谈判的药品将面临仿制药/生物类似药的竞争。IRA规定，为避免出现经济利益驱使生物类似药进入市场受阻的情况，可延期对相关选定药品的谈判。[23]

政府深入评估选定的谈判药品

美国卫生与公众服务部（HHS）对首批选定的10种谈判药品进行了深入评估，即“医疗保险药品价格谈判项目：评估选定药品的使用及支出发展趋势”。这10种药品占医疗保险D部分药品福利支出的近20%，并且均已在七年或更早之前就获得了美国食品药品监督管理局（FDA）的批准。[24]

评估报告显示，从2018年至2022年，这10种药品的支出翻了一倍以上，从200亿美元增至460亿美元左右，增幅达134%。[25] 此外，它们的支出增长率是同期所有医疗保险D部分药品支出增长率的三倍以上。[26] 价格谈判将综合考虑保险费用和患者自付费用。[27]

价格谈判选定的首批10种药品

选定的10种药品占医疗保险D部分药品福利支出的近20%，并且均已在七年或更早之前就获得了美国食品药品监督管理局 (FDA) 的批准。[28] 2024年，美国政府将开始对医疗保险中的10种药品进行价格谈判，这些药品是老年人和残疾人群体常用的处方药。到2029年，将对另外60种药品进行谈判 (图2) 。[29] 首轮谈判所涵盖的药品主要用于治疗糖尿病、心脏衰竭、关节炎、银屑病、克罗恩氏病、溃疡性结肠炎、血液稀释和白血病。治疗罕见病的孤儿药因其所针对的患者人数少于20万，将不纳入谈判范围。

最初两年的谈判内容为可在药店购买的医疗保险D部分药品，预计2028年将医疗保险B部分药品 (医生在诊疗服务中开具的药品) 纳入谈判范围。首批10种药品的谈判价格预计将于2024年9月公布。[30]

除药品价格谈判外，IRA还规定，对于通过医疗保险销售药品的制药公司，若其药品价格上涨幅度超过消费通胀率，则需向美国政府支付相应的返点。基于此返点政策，在2024年1月1日至2024年3月31日期间，医疗保险B部分受益人共付保险的48种处方药价格将下降。[31]

政府关注成本节约

未来十年内，IRA的药品定价政策预计将节省总开支2,370亿美元，其中谈判项目将节省医疗保险开支1,000亿美元[32]。[33] 美国政府认为，即使存在返点和折扣，美国民众不应该为同样的药品支付比其他经济合作与发展组织 (OECD) 成员国家多两至三倍的价格。[34]

近期，美国参议院健康、教育、劳工和养老金委员会 (HELP) 发布的一份报告显示，美国的药品价格与其他国家相比，处于较高水平。[35] 这个问题相当复杂，需要考虑的变量较多。例如，HELP委员会的关注重点是药品的毛价，也是谈判的内容。2022年，美国品牌原研药的毛价显著高于其他国家，是其他国家的4.22倍。[36]

图2：2024年参与价格谈判的首批10种医疗保险药品

药品	类型	制药公司
Eliquis	血液稀释剂	辉瑞、百时美施贵宝
Xarelto	血液稀释剂	强生公司旗下杨森制药公司
Jardiance	糖尿病、心脏衰竭	勃林格殷格翰、礼来
Januvia	糖尿病	默克
Farxiga	糖尿病、慢性肾病	阿斯利康、百时美施贵宝
Novolog	糖尿病	诺和诺德
Enbrel	关节炎、银屑病	安进旗下子公司英姆纳克斯
Stelara	银屑病、克罗恩氏病、溃疡性结肠炎	强生公司旗下杨森制药公司
Entresto	心脏衰竭	诺华
Imbruvica	白血病	艾伯维旗下Pharmacyclics、强生公司旗下杨森制药公司

资料来源：美国卫生与公众服务部

制药公司的实际收入（即“净价”）最多可减少75%。药品标价与净价之间的差额主要在于第三方支付方收取的协商及法定返点。[37] 2023年前三个季度，品牌药净价连续第六年呈下降趋势，经通胀调整后达到了7.4%的降幅。[38]

药品毛价的对比无疑会影响公众的态度。美国有1.58亿雇员享有雇主提供的医保，但他们所缴纳的保险费用和自付费用（如处方药费用）在家庭预算中所占的比例日益增加。[39] 美国政府不仅为生物医学基础研究提供大部分资金，还出资补贴就业相关的医疗保险，这些都有利于处方药需求增长。[40]

制药行业关注药品福利管理制度改革

制药公司呼吁对药品福利管理制度进行重大改革。[42] 美国药品研究与制造企业协会（PhRMA）担忧政府的政策可能不利于建立透明度和问责机制。在美国医疗体系中，唯有处方药是将标价与净价之间的差额转化为返点，并通过中间方重新分配给支付方。[43] PhRMA主席兼首席执行官Stephen Ubl表示，改革的重点应当是确保制药公司与中间方（如PBM）之间协商的返点能够直接在药店柜台惠及患者。[44]

设立PBM的初衷是为了管理医疗计划福利，以降低医疗成本，[45] 但制药公司的标价却因为返点机制而升高。[46] PBM利用返点政策，导致供应链中多方参与者为追求经济利益而损害患者利益，并限制患者获取某些药品的途径。[47] 此外，PBM自身也经营药店，许多人认为这会引发巨大的利益冲突，破坏市场竞争并导致药品定价扭曲。[48]

毛价与净价之间的差额流向了哪里？

药品净价是指制药公司在支付返点、折扣和其他减免后获得的实际收入。[41] 品牌药品的标价与净价之间的差额在于：

- 向商业保险支付方支付的返点、折扣和费用
- 医疗保险D部分规定的返点和承保缺口折扣
- 向医疗补助项目支付的返点
- 340B药品定价计划规定的折扣
- 制药公司向渠道商支付的费用，包括向PBM支付的管理费和其他费用，以及向药店、批发商和其他购买方支付的费用和折扣
- 患者援助和共付支持基金

美国众议院在2023年发布了一份报告，发现以下情况：

- PBM经常施加繁杂的事先批准要求，可能导致处方药的审批受到长时间拖延。
- 由于长时间拖延，部分患者在等待批准期间可能会经历痛苦甚至死亡。[49]
- 即使存在更经济实惠的替代药品，有的患者一开始也不得不使用更昂贵的药品，这是因为PBM可能出于经济利益考虑倾向于推广使用价格更高的药品。[50]

2020年11月，美国卫生与公众服务部 (HHS) 颁布了有关PBM返点政策的最终规定，在医疗保险D部分和医疗补助管控型医疗保险计划中，将取消现行的返点机制，改为在销售点提供折扣。[51] 本质上，该规定旨在废除对返点政策的长期保护。[52] 然而，IRA将这项规定的执行时间延期至了2032年。[53]

制药行业利益相关方对于美国三大PBM巨头所拥有的巨大权力和影响力表示担忧，它们控制着美国80%以上处方药的使用和报销流程。[54] 2022年，这三家PBM公司将1,150多种药品从其标准商业保险药品目录中剔除。自2014年以来，被剔除的药品数量几乎增加了10倍，其中包括许多能够以较低成本为患者提供必需治疗的药品。[55]

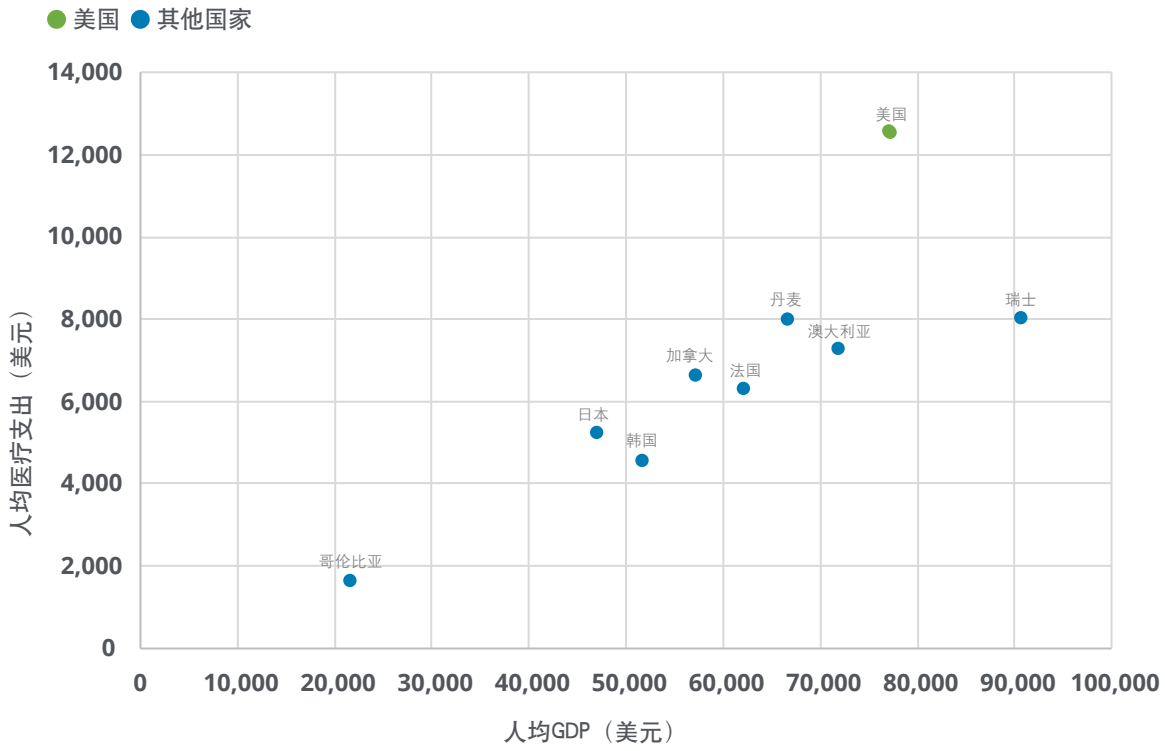
专家们指出，在美国的主要PBM公司实现两位数利润增长的同时，许多患者的自付费用也同步上升。[56] 美国联邦贸易委员会 (FTC) 等执法机构以及国会立法者们已经启动了审查程序，通过举行听证会和提出议案来探讨PBM的运营模式，因此PBM将面临持续的监督和审查。[57]

> “只有在美国市场，我们的成员公司所获取的药品销售利润不足药品标价的50%，其余利润则被供应链中的其他环节以极高的效率所吸收。
>
> **—PhRMA主席兼首席执行官Stephen Ubl [58]**

基于人均医疗支出和人均GDP的药品定价

2022年，美国的人均医疗支出为12,500美元左右，显著高于其他国家，人均GDP则大约为77,000美元 (图3) 。[59] 瑞士和德国的人均医疗支出紧随其后，约为8,000美元。瑞士的人均GDP约为90,000美元，比德国 (近67,000美元) 高。[60]

图3：2022年人均GDP和人均医疗支出（美元）（按现行价格和PPP调整后）



资料来源：Petersen KFF Health Tracker, OECD数据分析

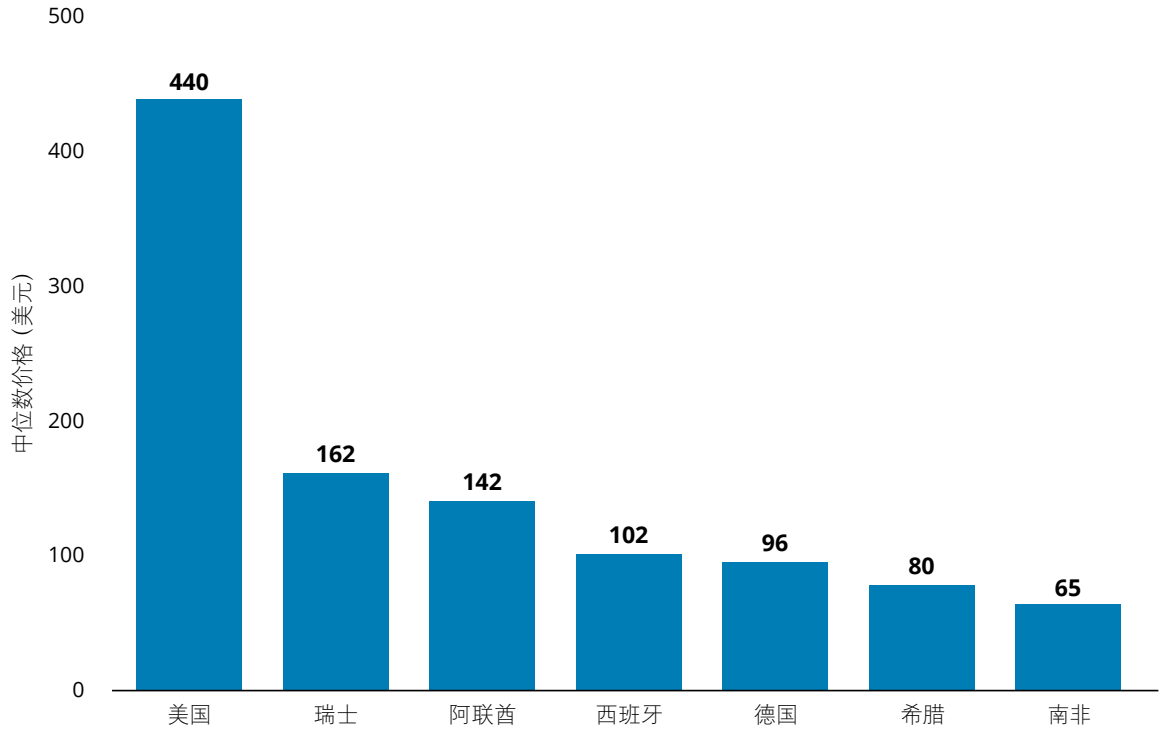
全球范围内，基本药品的价格存在显著差异。2019年，一项针对私营医疗保险公司的抽样调查显示，在美国、瑞士和德国，60片装Eliquis血液稀释药的中位数价格分别为440美元、162美元和96美元（图4）。[61] 其中，美国的价格是德国的4.5倍以上。[62]

百时美施贵宝（BMS）在其专门为客户节省开支和提供支持的网页上宣称，Eliquis已被纳入90%的商业保险和医疗保险D部分计划中，但患者需承担的共付额存在差异。该网页提供了一张价值10美元的共付额卡，符合条件的患者（即有保险但需要承担共付额的患者，或者没有保险的患者）可将其用于支付他们所需承担的任何共付额。[63]

在美国，各大药店通过GoodRX平台向消费者提供的60片装Eliquis折扣价格约为592至626美元，比零售价低9%至17%。[64] GoodRX所提供的折扣和优惠价格是基于药店（或药品采购组织）与PBM公司（负责设定价格）之间的合约协议，这些价格都是经过最优估算得出。[65] 此外，一些患者援助项目（PAP）还为收入有限的患者提供免费或低价处方药，这些药品则由生产商直接提供。[66]

正如我们在本报告的“患者”章节中所述，部分患者并不了解他们所使用药品的生产商，并且许多药品是由多家公司共同生产。如果患者无力负担必需的药品费用，则可能对其健康造成更多负面影响，因此确定药品的最合理价格和折扣不仅仅是患者需要关注的问题，也是医护人员（HCP）、药剂师、社区，乃至整个医疗系统在管理成本和财务方面所面临的挑战。[67]

图4：2019年部分国家私营医疗保险公司支付的Eliquis中位数价格



注：上图为Eliquis（阿哌沙班）片剂（规格：5毫克/60片）的价格。经过数据对比，得出了2019年11个国家的私营医疗保险公司对34种特定医疗保健服务支付的中位数价格。由于不同国家在医疗部门和收费结构上存在差异，国家之间的医疗成本对比变得复杂，且这些价格可能无法反应市场上其他保险计划所支付的价格。为尽可能减少这些局限性，该研究挑选了具有明确定义的服务项目，并确保调查问题的措辞表达与美国支付体系的基础流程保持一致。

资料来源：Statista，2022年8月12日

CMS举办医保价格谈判“患者听证会”

美国医疗保险和医疗补助服务中心 (CMS) 主持举办了关于Eliquis的患者听证会，该听证会通过网络平台向公众开放，与会者对高昂的共付额表达了担忧。[68] 该听证会以现场直播的形式进行，为患者、患者权益组织、护理工作者和公众提供了一个反馈特定药品价格的机会。[69] 在2023年第四季度，共举办了十场此类听证会，每场听证会都专注于一种正处于谈判过程的药品。[70]

每场听证会的记录稿均已在CMS官方网站发布，[71] 包括Eliquis听证会记录。[72] 其中有一名医生作为国民医生团（Doctors for America）负责可负担医疗服务的副主席，代表其组织发言，对于有固定收入的老年人而言，Eliquis的高额共付额无疑是一笔大的开销。[73]

备受公众和舆论关注

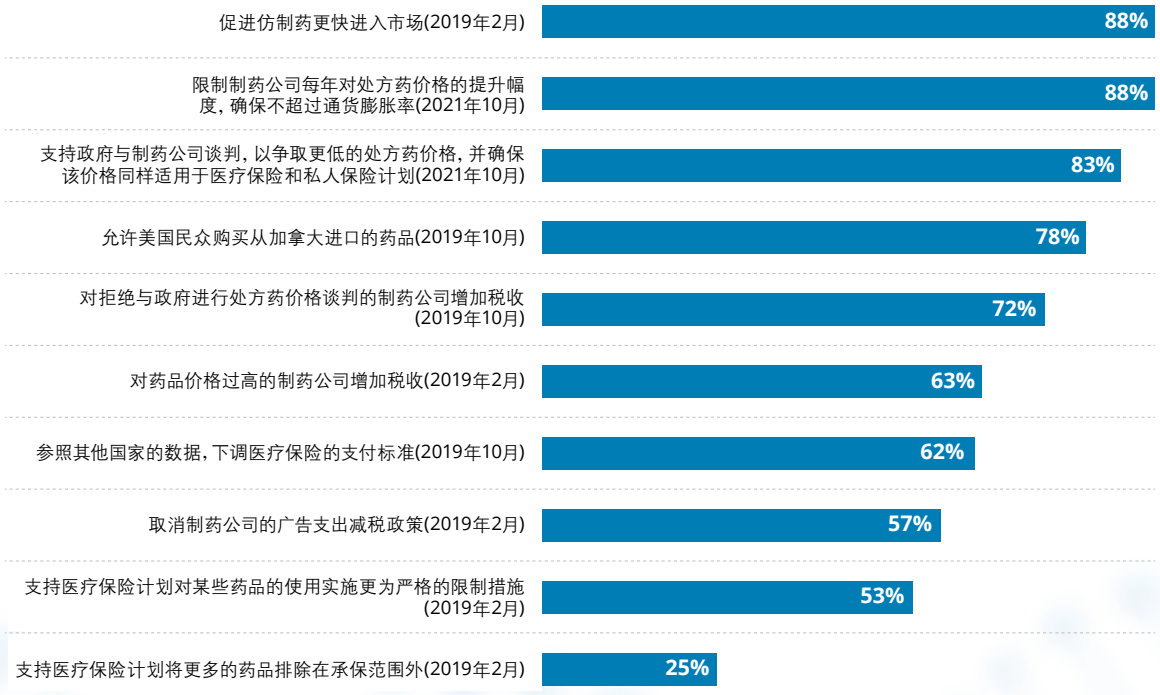
制药行业在药品定价的透明度和可负担性方面日益受到公众和媒体的监督及关注。[74] 2024年初，900多种知名药品的价格上调。[75] 但批发采购成本 (WAC) 的中位数增长率仅为4.7%，是十多年来的最低涨幅，比2023年的增长率还要低0.1%。[76]

普遍观点认为，由于处方药成本 (和总成本) 不断上升，制药行业受到不利影响。[77] 数十年来，美国的研究机构通过民意调查发现，[78] 93%的美国民众认为，即使药品价格有所下降，制药公司仍然能够获得丰厚的利润。[79]

在2023年的一项民意调查中，82%的受访者认为处方药的价格不合理，而近四分之三的美国民众则认为应当加强监管以控制药品价格。[80] 此外，在2022年年底进行的另一项民意调查中，询问了美国民众对于不同药品降价策略的支持情况 (图5) 。[81]

图5：2022年11月至12月美国公众对药品价格监管的意见

美国民众对以下各项药品降价措施的支持情况：



资料来源：KFF Health Tracking Poll (2022年11月29日至12月8日) [82]

缩小美国与其他国家的价格差距

通过减少管理支出和药品成本，能够显著缩小美国与其他发达国家在医疗支出上的差距。[83] 虽然制药公司表示，降价将对药品创新造成不利影响，[84] 但美国政府认为，制药公司在股票回购和分红方面的支出通常高于研发投入。[85] 同时，IRA对税收也有所影响。例如，对达到一定规模的公司征收1%的股票回购消费税和15%的公司替代性最低税。[86]

制药行业关注创新

PhRMA表示，其成员公司致力于为患者提供所需药物，而IRA却阻碍了创新与合作。[87] 在过去十年中，PhRMA成员公司每年在探索新疗法和新药研发方面的投资已增加一倍有余。[88]

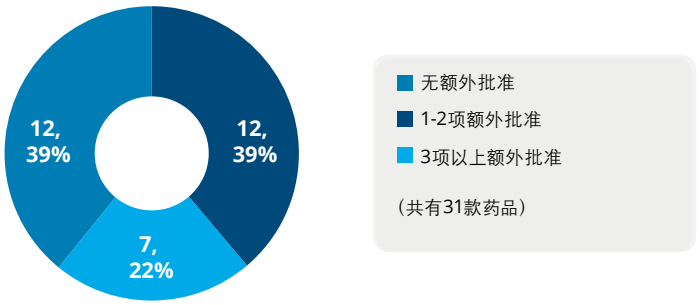
一种新药从研发到上市，制药公司平均需要投入23亿美元。[89] 2022年，全球排名前20的制药公司在研发方面的总投入高达1,390亿美元。[90]

PhRMA指出，IRA忽视了研发的性质，未考虑以下因素：

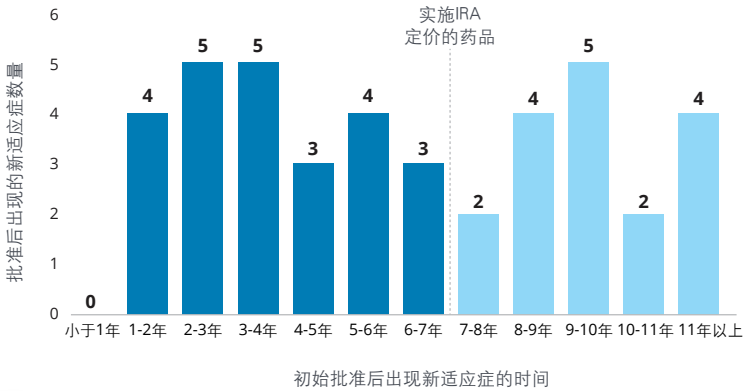
- 获得FDA初始批准后产生的创新成果（图6）——药品的新用途、新患者群体、新配方及新剂型。
- 新药和新疗法对患者的实际作用。
- 随着时间推移，药物的治疗价值因新用途批准而提升（如用于新的患者群体、新型疾病或疾病的新阶段）。[91]

图6：健康分析与研究合作组织（PHAR）报告：IRA定价对抗癌药物的影响

批准后出现不同数量新适用症的抗癌药品数量
2006-2012年获得FDA初始批准的小分子肿瘤药物



批准后出现新适应症的时间
2006-2012年获得FDA初始批准的小分子肿瘤药物



资料来源：PhRMA，PHAR研究

价格谈判框架的合宪性引发争议，相关组织提起诉讼

根据IRA的规定，对于拒绝参与价格谈判的制药公司，美国政府将根据其在美国市场的药品销售额征收一项新的消费税，税率从65%到95%不等。[92]

虽然选定的首批10种药品的制药公司都已签署了谈判协议，[93] 但PhRMA、许多制药公司、一些患者权益组织和其他团体仍对该措施的合宪性表示质疑，并提起了诉讼。[94] 全球结肠癌协会 (GCCA) 也加入了此次诉讼，因其担心IRA可能会妨碍结肠癌研究的进展，而该研究对越来越多50岁以下民众的健康至关重要。[95] GCCA首席执行官Andrew Spiegel表示，“在IRA的实施过程中，患者的声音和关切未能得到充分重视。”[96] 他指出，患者理应获得更优的待遇，这也是GCCA加入诉讼的原因。[97]

截至5月1日，法院已经驳回了PhRMA提起的诉讼，[98] 包括由阿斯利康发起的诉讼，这一裁决表明制药公司可能无法获得法律庇护。尽管如此，PhRMA已提起上诉。[99] 此外，一名新泽西州的联邦法官批准了百时美施贵宝、诺和诺德、诺华和强生这四家制药公司共同进行辩论。[100] 其他诉讼则仍待处理。[101]

对投资组合策略的影响

制药公司收入降低是否会对药品创新产生不利影响？[102] 药品价格下降确实会导致制药公司利润减少，影响其创新动力。[103] 由于规划的不确定性，IRA已经影响到研发决策和投资组合策略。部分公司正在重新考虑其研发投入，并放弃小分子药物投资。[104]

一项针对25家PhRMA成员公司的调研显示，四分之三的公司表示将取消处于早期阶段的研发项目，同时三分之二的公司表明，已经规划好但尚未启动临床开发阶段的项目也可能面临中断。此外，对于需要数年才能完成开发的新科学平台，超过半数的公司表示计划减少投资。[105]

美国国会预算办公室 (CBO) 的近期研究表明，在未来30年内，预计将有1,300种新药上市，但其中大约有13种 (即1%) 可能会因IRA引起的变动而无法进入市场。[106] 其他专家指出，新药的发现大多源自纳税人对学术研究和初创企业的支持。[107] 然而，鉴于成本考量，新药发现的推进及其研究主要依赖于制药行业的资助，而非生物技术公司。

Acumen Pharmaceuticals是一家创新型生物技术公司，专注于开发针对阿尔茨海默病的新型治疗方法，重点研究毒性β淀粉样蛋白低聚物。该公司获得了美国卫生与公共服务部 (HHS) 的资助，[108] 并在最近的“生物技术突破奖”中荣获“年度最佳单克隆抗体解决方案”的殊荣。[109] Acumen首席执行官Daniel O’ Connell表示，为引起人们对阿尔茨海默病的关注并满足市场需求，大型制药公司的参与和支持至关重要。

“我们正处于为阿尔茨海默病患者带来革命性治疗手段的初期阶段。大型制药公司如渤健、卫材和礼来正积极助力市场的建立。未来几年，随着数据的积累和时间的推进，新的机遇将逐渐出现。买家正在评估阿尔茨海默病市场的真正潜力。渤健、礼来等大型制药公司也在积极探索该领域。同时，如默克、艾伯维和百时美施贵宝等公司将根据这些初始药物产品的增长情况，寻找适合自己的市场切入点。这将在一定程度上促进公司间的合作与并购，从而推动阿尔茨海默病治疗领域的研发。

我们了解大型制药公司的业务领导层目前的想法，他们对阿尔茨海默病持一种“等待和观望”的态度。对于Acumen和我们所开发的单克隆抗体（mAb）技术而言，我们正处于一个全新的领域，没有任何先例可以参考。这个领域正在构建患者旅程和基础设施等方面。目前，我们的进展相当顺利，预计到明年这个时候，我们将更加确信该领域的商业潜力是确实存在且不断增长的。于我们而言，继续将我们的资产和项目定位为具有吸引力的差异化产品，并具备长期潜力，这非常重要。在整个过程中，大型制药公司扮演着重要角色，它们将创新成果转化为商业产品，确保患者能够获得预期的积极疗效。”

—**Acumen Pharmaceuticals首席执行官，Daniel O’ Connell**[110]

IRA需要关注各利益相关方之间的平衡

2024年，制药行业领导者应思考如何通过多样化的支付模式，促进产品的商业化进程。在未来几年中，由于IRA阻止特定类型的药物开发以及针对某些患者群体的治疗方法，患者将失去一些小众适应症的治疗机会。随着美国在变革性创新方面的引领作用，这些影响将波及全球。

毫无疑问，IRA将对美国乃至全球产生深远的影响，但确切的影响和具体时机尚需进一步观察。各方均提出了有力论据。制药公司渴望持续创新，也被激励这么做。患者期望药品价格合理，医护人员则希望患者能够负担得起必需的药物。美国政府由于在全球范围内承担了提供药物的主要财政负担，因此也希望药品价格更加公正。

药品定价压力影响日本药物创新

日本以开发创新药物而著称，但与世界其他地区一样，其近期所面临的药品定价压力也催生了改革需求。[111] 日本作为全球第三大制药市场，改革将给制药公司带来不确定性，同时也引发了公众对未来药物创新的关切。[112]

日本政府根据《药品价格标准》(DPS) 规定的价格为患者报销药品费用。DPS涵盖了国民健康保险 (NHI) 和日本厚生劳动省 (MHLW) 规定的所有药物。[113]

医疗服务资金来源：公立还是私营？

日本的医疗服务由政府资助，但具体的服务提供则主要由私营机构执行。[114] 英国的医疗体系以公立为主，而美国则更依赖于私营部门 (图7) 。

与其他发达国家相比，日本的医疗体系以其相对较低的医疗成本而著称。[115] 2022年，日本人均医疗支出为5,250美元，不足美国的一半。[116] 在日本，虽然患者需要承担一定的共付额，但自付费用设有上限。[117]

图7：各国医疗服务提供者及其资金来源

国家	主要的服务提供方	资金来源*2
	**私营** (公立：5%)*1	**公立** (公立：84%)
	**私营** (公立：23%)*2	**私营** (公立：51%)
	**公立** (公立：几乎100%)*2	**公立** (公立：79%)
	**私营** (公立：45%)*2	**公立** (公立：77%)
	**私营** (公立：25%)*2	**公立** (公立：78%)

注：*1为来源于日本MHLW 2021年数据；*2为来源于OECD 2020年数据。
资料来源：德勤分析

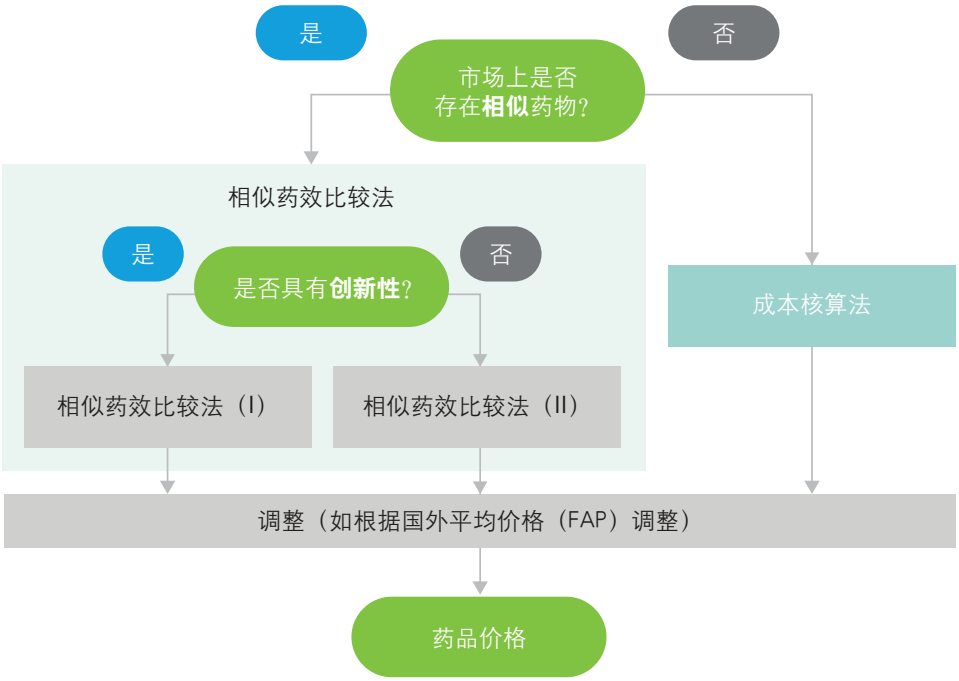
2023财年，日本DPS所涵盖的2,000种药品平均价格下降了9.4%，[118] 占当年DPS中上涨药品的36%。[119] 日本2023年药品价格降幅 (9.4%) 是美国2024年药品价格增幅 (4.7%) 的两倍，这反映了公共医疗系统国家与私营医疗系统国家之间的差异。[120]

市场准入和报销之间的新流程

美国政府最近开始通过价格谈判来确定药品价格，但日本是在1992年首批采用成本效益数据来为新药定价的国家之一。[121] 然而，日本在2019年实施的成本效益分析 (CEA) 制度正在考验其创新方面的声誉。[122]

简言之，新药和新疗法在最初评估时是基于其与市场上其他产品的相似性 (图8) 。若新药与现有产品相似且具备“创新性”，则根据日本的相似药效比较法 (SECM) I，对其实施可比定价。对于创新性较低的新药，则可运用SECM 2，考虑各种价值因素 (如市场接受度和特定用途) 进行溢价调整。若不存在可比药品，则采用成本核算法。[123] 药品标准上市后，将随时间推移对其进行成本效益分析或重新定价。[124]

图8：日本新药定价方式



资料来源：ISPOR亚太联合会，CRECON Medical Assessment Inc.

制药公司在卫生技术评估 (HTA) 过程中，需要对部分药品和医疗器械进行成本效益分析。[125] HTA旨在为决策者提供新型卫生技术的相关信息，包括药品、医疗器械、外科手术和其他卫生保健干预措施。[126]

专家们表示，制药公司面临的挑战包括评估自身是否需要成本效益分析，并确保自身具备CEA所要求的能力。这一额外步骤将引起报销过程的延迟和市场准入方面的挑战。

跨国HTA合作及其对欧盟的价值

在许多国家，HTA被广泛用于为药品报销和定价提供决策支持。生成式AI等新兴技术有望提升HTA报告的质量和效率。展望未来，跨国HTA合作将更加依赖于可比临床数据，以便更好地做出定价和报销决策 (图9) 。

图9：欧盟HTA流程与欧洲药品管理局 (EMA) 申请流程概述*

变更内容

1. 新联合科学咨询、**联合临床评估流程**、方法论文件
2. 更加早期的欧盟HTA**临床效益评估**
3. 不同成员国家的综合性需求
4. 与监管流程同时进行
5. 公开英文版文件

保持不变

1. **仍需进行本地HTA申报**
   - 本地申报需包含JCA报告，但并非强制性
   - 本地申报额外/补充材料
   - 本地申报经济材料
2. **本地定价和报销流程未发生变更**

◆ 监管里程碑　◆ 欧盟HTA里程碑

注：*流程及时间线尚未最终确定，预计2025年之前可能发生变动

资料来源：德勤分析

欧盟药品定价依据

许多国家（尤其是欧盟国家）早已采取基于价值的定价体系。欧盟和英国合计占据的市场份额（33%）位居世界第二，但如果以国家为单位，中国是第二大市场。

例如，挪威目前采用的药品定价体系是根据患者的质量调整寿命年来确定药物成本。其策略是通过谈判，基于新药的成本效益和医疗福利的分配方式来确定新药价格，从而控制药品成本。[127]

药品使用量不断增加，对全球药品定价透明度的呼声增强

随着全球药品使用量不断增加（图10），以及对药品定价透明度的呼声在全球范围内越发高涨，维持制药成本控制措施、药物创新和可负担性之间的平衡，是确保最佳定价和报销策略的关键所在。[128] 许多国家已经要求制药公司公开药品出厂价，即销售价格（图11）。

图10：2018–2028年各地区药物使用情况的历史数据和预测数据

注：预测限定日剂量（DDF）（单位：十亿）

资料来源：艾昆纬研究所，“Global Use of Medicines 2024, Outlook to 2028”，2024年1月。

图11：各国药品定价透明度增强措施

	政府采用的药品定价透明度增强措施（包括制药公司向政府申报价格）				药品定价机制		定价管理机构
	公布其他国家价格	出厂价	分销/物流费/批发价格	药房零售价格/医保目录（RL）	价格参考	价格谈判	
	✓	✓		✓ (RL)	✓	✓	专利药品价格审查委员会
		✓	✓	✓	✓	✓	国家发展和改革委员会
	✓	✓	✓	✓ (RL)	✓	✓	卫生部
		✓	✓	✓ (RL)	✓	✓	卫生部药品价格调控计划
	✓	✓		✓	✓		卫生、福利与体育部
		✓		✓ (RL)		✓	医疗保险计划、退伍军人事务部、医疗补助计划、健康维护组织、药品福利管理公司

*医疗保险计划、退伍军人事务部医疗计划和医疗补助最低价格计划承保的药品

资料来源：德勤分析

2024年，美国将与全球医疗体系齐心协力，致力于控制新药定价，同时保障并提升公众对创新药的可及性。美国的IRA将对部分制药公司巨头的研发资金分配和药品商品化策略产生重大影响。对药物创新和可及性的影响也将波及全球。

欧洲、日本和中国将持续关注新药成本效益评估，同时也面临新的挑战。这些地区需要着重考虑如何对细胞和基因疗法的效益进行评估和定价，因为这类治疗手段成本高昂，并且患者可在未来数年从中受益。只有制药行业与医疗生态系统之间相互合作才能实现双赢，确保为患者寻求治疗方法，同时预防和治疗对我们所有人产生影响的疾病。

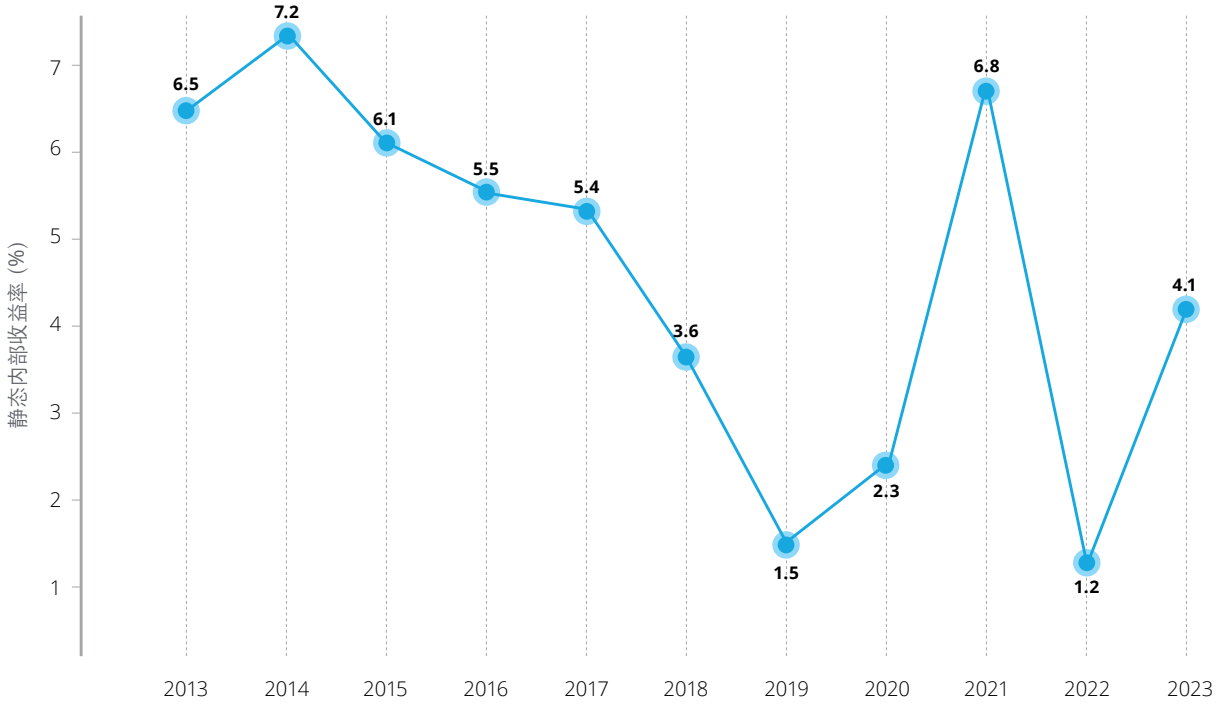
加速实现研发活动价值

2023年，大型制药公司的研发支出总额攀升至历史新高的1,610亿美元，占行业总投入的近三分之二[1]，比2018年增长了近50%。[2] 此外，这些公司的研发支出与净销售额的比例也上升至23.4%，刷新了历史最高纪录。[3]

自2010年起，德勤一直在持续发布关于医药创新回报率的研究报告，产出了一系列关于生物制药研发生产率的洞察。最新一期报告分析了2020年研发支出排名前20的制药公司。[4]报告结果显示，从2022年至2023年，这些制药公司的研发支出增长了4.5%，但单项资产从研发到上市的平均成本却基本不变，维持在22.84亿美元。[5]

今年的建模分析基于一个经过扩展的数据集，该数据集纳入了更广泛的资产类别和更长的追踪期限，结果显示内部收益率 (IRR) 从2022年的1.2%——是自我们开始这项分析以来的最低水平——上升至2023年的4.1% (图1) 。[6]

图1：后期管线IRR



资料来源：德勤，“Unleash AI’s potential: Measuring the return from pharmaceutical innovation – 14th edition”，2024年。

2024年，持续的监管变化和空前数量的高价值资产失去排他性将对生物制药行业的现有运营模式构成挑战。[7]《通货膨胀削减法案》（IRA）中的医疗保健条款带来了药品定价压力，同时影响研发决策和研发组合策略。[8] 十位研发领域的领导者接受了德勤采访，他们表示对法规变化的担忧已经超过了产品周期时间或研发成本问题。[9]

对于愿意使用创新技术的公司而言，科技进步带来了重大机遇，但迅猛的革新步伐也会带来挑战。[10] 随着AI技术（尤其是生成式AI）的进步，人类有望攻克复杂疾病生物学难题，加速药物发现过程，缩短研究周期，提升临床试验效率，并增加监管批准通过率。通过提高研发生产率和充分发挥AI的潜力，可以开辟新的价值创造途径。[11]

加快上市速度，加速价值实现

长期以来，制药公司一直将药品上市速度视为首要任务，旨在让患者更快地获得救命的治疗。[12] 2010年，德勤开始分析医药创新行业，发现仅有约十分之一进入人体试验阶段的新药最终获得了监管部门批准。[13] 尽管科学技术进步显著，但监管批准问题仍是生物制药行业所面临的重大挑战之一。[14]

“当面对癌症、心脏病等疾病时，患者需要的不是未来20年可能出现的治疗方法，而是立即有效的救治方案。”

—安进研发执行副总裁David Reese [15]

上市速度只是成功的因素之一，制药公司还应探索加速价值实现的途径。[16] 领先的生物制药公司正在整个价值链中采纳新的生成式AI/AI技术及其他数据创新技术，同时还寻求建立新的合作伙伴关系，与监管机构尽早开展合作，并利用外包策略来节省成本和时间。

> “我们25%的研发项目与合作伙伴共同进行，这种合作模式不仅使我们的研究生产率提高了一倍（根据每个临床候选项目所投入的资金来衡量），还使我们的首次人体试验项目数量实现了翻倍。”
>
> —**赛诺菲首席执行官Paul Hudson[17]**

采取敏捷思维

加速人员和流程部署

制药公司采取各种策略以加快价值实现，开始探索节约成本和获取竞争优势的个性化途径，[18] 即使在这个过程中，每个环节所实现的收益微乎其微。[19] 随着AI驱动的数字解决方案发展步伐日益加快，领导者们应当秉持敏捷的思维方式，着手重构运营模式。[20]

若要以敏捷方式加速价值实现，公司需要配备适当的人员和流程，以便根据市场动态快速调整策略。[21] 领先的公司正在制定策略，以缩短产品的研发、商业化和上市后监测等阶段所需的时间。[22]

> “我们正致力于从多个层面促进产品研发加速，包括采纳数字技术和创新研究设计，以及建立监管合作伙伴关系。我们的目标是助力每个药物研发团队充分利用这些加速因素，以加快研发进程。”
>
> —**安进研发转型副总裁Kimberly Clemenson[23]**

利用零食化AI提高工作效率

在2023年年末举行的BioCentury中国医疗健康峰会上，赛诺菲首席执行官Paul Hudson分享了赛诺菲如何利用“零食化AI”迅速获取数据，并为组织内众多员工提供AI辅助，以支持实时决策和报告。他指出，“零食化AI”确保了数据的完全透明性，能够提供即时、可信的反馈，避免了犹豫和粉饰——因为当数据结果令管理者感到不安时，他们会竭力避免向上级汇报。[24]

研发领域的AI使用率预计将增长106%

制药行业的研发创新能力毋庸置疑，但在技术革新方面却往往进展缓慢。[25] 生成式AI将众人的目光吸引到了AI发展现状上，促进了许多新举措。[26] 研究表明，目前AI在药物发现领域的使用率达到约16%，预计在未来三到五年内将增长106%。[27] 通过结合特定领域的大型语言模型、生成式AI、AI/机器学习、深度学习和数据分析技术，可以加速生物制药研发活动的价值实现。

研发能力是大型生物制药公司的首要价值贡献因素，为公司创造约30%-45%的价值。将AI应用于新药鉴别和加速药物开发过程，既能节约成本，又能提高收入。[28]

通过结合下一代AI技术与丰富的多组学数据，可以快速、自动地生成和验证从实验室到临床的假设，实现研发流程的完整闭环。[29] 目前，生成式AI可能改变生命科学组织在以下方面的决策：

- 疾病领域的投资选择
- 目标设定
- 开发的分子类型[30]

将生成式AI融入研发流程——从新靶标识别到监管批准

在从药物的新靶标识别到监管批准直至最终商业化的整个过程中，专家们期望生成式AI技术能够得到应用。[31] 组织在开始采用生成式AI技术时，应采取“稳妥策略”，确保在相对较短的时间内实现价值（图2）。[32] 这类低风险活动不但能加快研发进程，还能降低投资风险。[33]

图2：在研发领域采用生成式AI“稳妥策略”

	说明	业务价值	企业价值	“稳妥”体现在何处？
研发				
	生成科学文献摘要			
	生成便于使用的科学文献摘要	加速假设验证过程，**提高生产率**	+ 降低成本 + 提高收入	生成式AI能够排除干扰信息，以**最少的资源投入**直接得出洞察
	智能化撰写研究成果			
	自动化起草临床研究报告（CSR）	减少返工和自动化生成草稿，**提升速度**	+ 降低成本 + 规避成本	公司可利用**丰富的历史文档资源库**实现自动化创作

资料来源：德勤，“Realizing Transformative Value from AI & Generative AI in Life Sciences”，2024年。

下列模型阐述了随着生成式AI的发展，药物研发变革的三个阶段（图3）。专家们表示，在生成式AI的发展过程中，即使在风险较高的应用场景中，保持适当的人工参与对于在不冒重大风险的情况下提高生产率至关重要。[34]

图3：研发转型阶段

变革领域	阶段1 目前	阶段2 未来18个月	阶段3 未来5年
数据的管理和访问	• 基于特定业务流程的**非标准化数据源形成了一个脱节的生态系统** *例如：用于组学分析的RWE，用于临床研究的CTMS等*	• 可以在类似于**亚马逊的市场平台**上搜索和访问特定的研发数据或摘要 *例如：研究人员可以从历史临床试验数据中查找生物标志物分析数据，并提交访问请求*	• **动态数据网络结构**能够实现各职能部门数据资产的无缝连接，提供一个统一的真实数据来源 *例如： 临床医生可随时使用来自安全、商业和受监管系统的实时数据，以满足其需求*
洞察的生成和使用	• 离散分析模型生成洞察，再**由数据分析师进行解释**，以支持临床流程 • 科学家们**手动审查并整合科学文献**（如出版物、专利），得出研究洞察 *例如： 临床研究经理依靠数据分析师对选址分析模型的输出结果进行背景分析*	• 企业用户利用**生成式AI解读**复杂分析模型的**输出结果**，从而赋予企业更高的灵活性和更丰富的背景信息 • 科学家们可以从海量的科学文献中获取**总结性洞察**，从而快速调整研究重点 *例如：临床医生可与生成式AI聊天机器人进行互动，以了解患者的健康状况，进而优化临床试验的纳入标准*	• 几乎无需人工介入，即可将洞察随时**嵌入业务工作流程** • 对于外部研究得出的洞察，**迅速进行背景分析**并在企业内部传播 *例如： 研究、临床、财务、商务和监管团队可获取关于竞争对手专利的背景影响分析总结。*
研究活动的执行	• 由于**使用迭代式假设开发和计算密集型验证**，实验操作高度依赖人工且成本高昂 *例如：科学家们手动创建并验证各种假设，并且只有在确认某个假设失败后才会回到绘图板*	• 科学家们利用**AI驱动的模拟技术**，可同时生成、验证并优化成千上万种假设 *例如：科学家们通过快速试验和优化用于治疗乳腺癌的新分子，再生成3D生物分子结构*	• 研究人员通过**聚焦**对下游部门产生影响的**决策**，确定研究线索的优先次序 *例如： 研究人员根据监管批准的可能性和商业可行性，确定乳腺癌治疗的研究线索次序*
临床试验管理	• 复杂的试验流程和系统导致决策过程的**高度人工化、线性化和孤岛化，最终获得不尽如人意的结果** *例如：研究设计和选址决策脱节，导致试验执行延误，从而造成高昂的成本*	• 通过AI/生成式AI自动化技术，**精简和简化临床流程**，从而提高效率并改善体验 *例如：生成式AI助手通过结合下游患者招募和选址流程的洞察，优化研究设计决策*	• 使用生成式AI助手实现临床试验自主运行，**从而优化整个端到端价值链的输出结果** *例如： 通过实时监控参与者流失情况，得出相关洞察并提出建议，以便调整上游研究设计方案*
研发部门与其他职能部门的互动	• **各研发业务往往独立运作**，不同研发团队之间无法共享洞察 *例如： 上游研究人员几乎没有机会接触到临床数据和分析结果*	• **无缝连接数据和洞察**，加强各研发部门之间的协作 *例如： 研究、临床和监管团队可共同协作解决问题并开发新产品*	• 在超级互联的企业环境中，**所有职能部门协同工作**，优化企业的研究成果 *例如：研发、监管、商务和生产部门通力合作，顺利推出新药*
研发团队应对监管要求的方式	• 由于各地区的监管规则不同，需要当地的市场和流程团队经过非标准化且高度人工化的审查周期后进行**人为解释** *例如：监管团队需要耗费数周的时间，人工审核欧盟的最新临床法规，并评估这些法规对正在进行和即将进行的试验所造成的影响*	• 研发团队**广泛采用生成式AI功能**，以实现自动化法规监控、整合及影响评估 *例如：生成式AI助手能够识别并整合美国的临床试验多样性要求，并标记出受影响的研究*	• 通过在业务流程中嵌入**AI监管审查**，可减少人为错误并缩短监管审查周期 *例如：生成式AI助手可以确保新协议在起草过程中符合最新的监管政策*

资料来源：德勤分析

易如反掌：生成式AI替代人工流程

谷歌展示了其多模态平台Gemini的强大功能，可助力研究人员从科学文献中提炼所需资料。此前，这一过程通常依赖人工操作，既耗时又费力。[35] 在一个实证案例中，Gemini对20万篇学术论文进行了深度阅读，筛选出250篇相关研究成果，并从中提取出所需的关键数据，同时添加了注释并创建出图表——整个过程仅耗时约一小时。[36] 在短期内，生成式AI凭借其快速获取知识和替换人工流程的能力，在临床试验领域迎来了前所未有的应用机遇。[37]

> “在临床试验领域，充斥着大量重复且耗时的工作。生成式AI作为一种工具，能够加速处理部分任务。在生成式AI出现之前，申办者和研究机构需要经历漫长的人工流程。”
>
> **—AXON临床研究负责人Silvia De Carvalho [38]**

为提高研发生产率，药物发现和早期临床开发（从靶标选择到临床概念验证）成为了关注重点。[39] 通过合成数据的方法，可以加速获取所需数据，从而快速构建模型原型。当生成化学与工具平台以及人类的专家知识相结合时，不仅能加快药物设计速度，还能识别更优质的药物候选分子。在从头蛋白质设计领域（如抗体设计），生成式AI正积极推动研究进展。[40]

SyntheMol：生成式AI模型可为化学家提供实验室合成药物的配方

斯坦福大学医学院和麦克马斯特大学的研究团队正在采用一种新的生成式AI模型——SyntheMol，以合成新型分子。[41] 该模型已创建了六种新型药物的结构和化学配方，专门用于消灭鲍曼不动杆菌的耐药株，该菌株是主要的抗药性相关死亡病原体之一。

传统的计算模型通过筛选1亿种已知化合物才能获取部分结果，但这对于寻找出所有具有抗菌特性化合物来说，效果实在微不足道——据估计，这类药物分子的数量约为10的60次方。目前，该项目正在与其他科研团队协作扩展，旨在利用SyntheMol模型发现治疗心脏病的新药，并为实验室研究创造全新的荧光分子。[42]

尽管许多生物技术公司正在开发利用AI设计药物分子，但迄今为止，尚无任何药物获得美国食品药品监督管理局（FDA）的批准。[43] 原因在于收集和分析临床试验所需的数据，以证实这些药物的安全性和有效性，是一个耗时的过程。[44]

利用生成式AI加速临床试验进程

随着生成式AI的发展，在加速临床试验方面展现出多种潜力，具体包括：

- 自动化生成文件，提升工作效率；
- 增强患者参与度，提高保留率；以及
- 量身定制申报材料，确保监管合规性。[45]

追踪生成式AI应用的速度、生产率、质量和可持续性表现

在评估研发流程中生成式AI的潜在应用时，应结合考虑战略价值与应用速度、质量、生产率和可持续性等指标。[46] 用例表明，生成式AI可提高数据、资产和决策的质量，有利于降低研发各阶段的失败率。[47]

在短期内，生成式AI最显著的收益体现在生产率和质量上，其次是速度，而后是未来十年内的可持续性。[48] 基于这些指标，审慎考虑各个应用场景，有助于制定一套最优的“珍珠链战略”——将不同应用场景结合起来，以最大化生成式AI的价值。[49] AI的战略部署将贯穿整个研发价值链（图4）。

在构建数字化和AI投资的商业用例时，需要权衡短期成本与长期效益之间的关系。实施大范围的AI策略需要设立相应的管理职能，以便进行投资决策、评估所实现的效益，并监控AI应用可能带来的道德和法律风险。[50]

更多有关“珍珠链战略”的信息，请参阅《2024年全球生命科学行业展望》探索生成式AI和新兴技术的价值。

图4：AI在研发价值链中的战略应用

	AI的作用	价值因素
药物再利用	对临床试验和研究数据进行元分析，提出可靠的药物再利用假设	• 降低临床前成本 • 缩短上市时间 • 提升NDA批准率
AI驱动的药物发现	在评估药物毒性和疗效过程中，优化靶标和生物标志物识别，并筛选出候选药物名单	• 提高临床成功率 • 降低失败率 • 提升NDA批准率
快速设计与启动	自动化生成协议，起草研究文档（同意书、协议）并递交监管文件	• 缩短协议编撰时间 • 加快首次招募进程
数字化数据流	对试验数据进行整理和标准化处理，以创建自带分析结果的数据集，并在试验文档（如病例报告表）中自动化填充表格和图表	• 缩短各个研发阶段的耗时 • 按照既定时间锁定数据库 • 加快文档创建的速度
监管合规与申报	确定各地区的监管要求，生成文档草稿，同时了解竞争对手的监管策略	• 提升监管批准率
患者体验	采用战略提示工具提升受试者体验，革新招募和保留策略	• 降低受试者流失率 • 加快招募进程 • 降低因招募不足而导致的试验终止风险

资料来源：德勤英国，“Unleash AI's potential - Measuring the return from pharmaceutical innovation”，2024年4月。

制定生成式AI的短期目标

在小分子从头生成领域，生成式AI的价值创造已初步显现，下一波机遇将在临床领域出现，涉及运营、实施及患者体验等方面。[51] 短期内，企业不仅需要确认各职能部门在生产率提升方面所取得的早期成果，还应专注于数据的高效组织和管理。[52] 算法训练依赖于专有数据，因此其质量和完整性将成为差异化因素。随着生成式AI成为研发数据科学团队的核心能力，组织还应制定相关策略，以培养未来的员工队伍。[53]

加快临床试验速度

虽然基因治疗、AI技术等科技飞速发展，但临床研究仍面临以下挑战：

- 难以招募并保留具有代表性的患者群体；
- 对运营问题的响应不够迅速；
- 所依赖的数据源不完整或缺乏深度。

为实现临床试验转型，企业需要采用全新的工作模式，运用变革管理技巧，并建立合作伙伴关系和协作网络。因此，企业应培养具有高度专业技能的跨学科领导团队和AI专家团队，团队成员需具备创新能力，能够组织资源并指导他人。此外，企业的CEO和董事会成员也需要对AI持积极态度，以推动AI应用。[54]

开展CGT战略合作，加速价值实现

探索如何使罕见病患者快速获取创新疗法

2023年底，美国FDA批准了首个利用CRISPR基因编辑技术治疗镰状细胞病的细胞和基因疗法 (CGT) ——由福泰制药公司研发的Casgevy。[55] 该疗法被视为一项试验案例，用以评估这些创新药物抵达患者手中的速度 (专家们计划在2024年对结果进行追踪) 。[56] 有观点认为，如果在未来一年内，超过2%的患者 (约2,000名) 能从CGT中受益，这或许标志着该疾病治疗的一个转折点。[57] 据悉，美国共有10万名镰状细胞病患者 。[58] 追踪患者获取此类革命性药的速度，能够得出新的洞察并产生价值。[59]

> “我认为我们正处于该领域的转折点。从最初发现CRISPR技术，到荣获诺贝尔奖，再到如今成为获批产品，我们的进展速度之快，实在令人瞩目。”
>
> **—费城儿童医院血液科主任Alexis Thompson博士[60]**

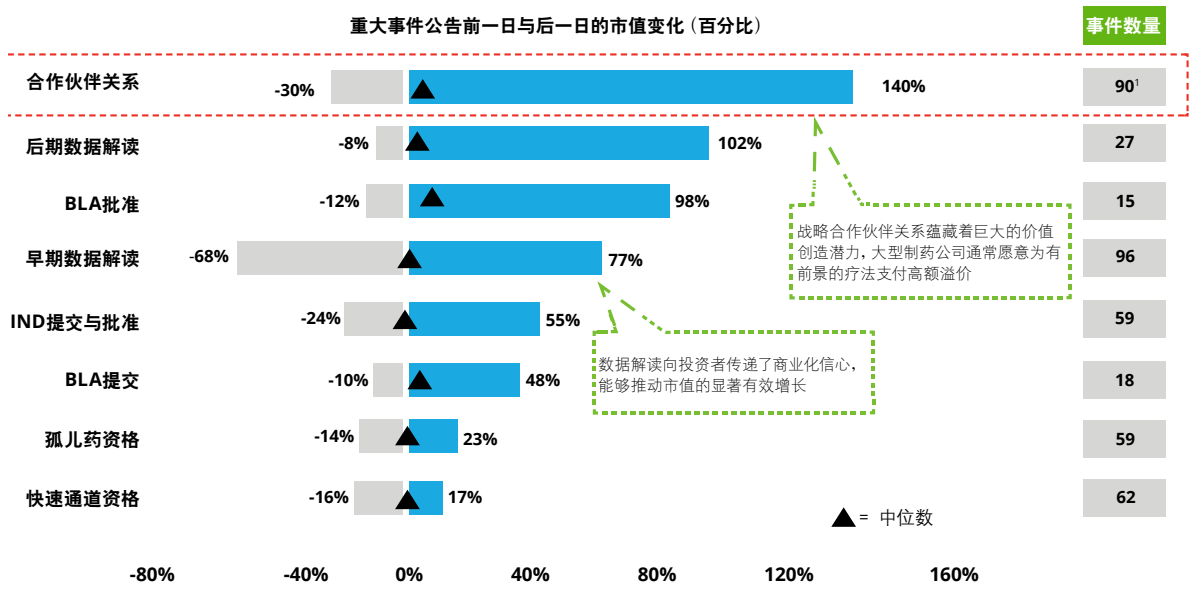
继Casgevy获批后，蓝鸟生物公司的Lyfgenia也获得了用于治疗镰状细胞病的CGT批准。[61] 2023年，蓝鸟生物公司表示，其Lyfgenia研究项目是迄今为止对镰状细胞病患者进行最长时间随访的临床试验——对47名患者进行了长达5年的跟踪研究。[62] 美国国家心肺血液研究所 (NHLBI) 指出，该公司的透明度和合作精神为其他技术的开发奠定了基础。[63] 该公司表示，获批的准入和报销策略将有助于扩大保险报销范围。[64]

成功的合作伙伴关系离不开商业与研发的协同

为德勤美国CGT市场指数研究团队指出，一家公司在获得监管批准后，距离推出商业化产品更进一步，投资者最关注此时的发展态势。[65] 战略合作伙伴关系成为推动市值增长的关键因素，一家公司若宣布与另一家公司 (通常是大型制药公司) 达成合作，其市值增长率最高可达140% (图5) 。[66]

图5：德勤CGT市场指数的价值驱动因素分析

有关CGT公司市值增长的驱动因素较少，现有数据仅更新至2023年。



资料来源：德勤美国分析。

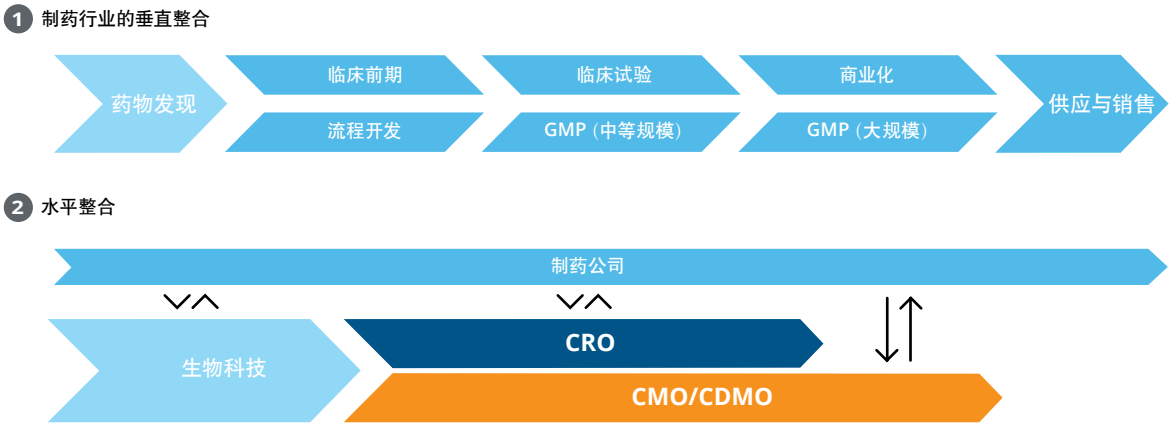
研究表明，最成功的合作伙伴关系往往融合了商业与研发安排，而非二者择一。这类合作通常将CGT公司的技术专长与大型公司的资产开发经验、临床试验专有技术、市场准入策略和分销渠道基础设施相互结合。[67]

此外，宣布建立生产合作关系并不会引起投资者的积极反应，但如果CGT公司与合同制造商合作，则能够比投资建设自有工厂获得更多的价值。[68] 总体而言，相较于在达到一个里程碑便止步不前的公司，那些将多个里程碑连贯结合的公司更能够实现持续的高价值创造。[69]

利用外包策略节省时间和成本

为加快产品上市速度，生物技术公司[70] 和制药公司都在增加外包的比重。[71] 与半导体领域一样，制药行业生态系统也形成了成熟的水平分工模式，其中生物技术公司和制药公司专注于药物研发和生产 (图6) 。[72]

图6：制药行业的横向分工



资料来源：版权所有 © 2022 Kurata、Ishino、Ohshima和Yohda，“CDMOs Play a Critical Role in the Biopharmaceutical Ecosystem,” Frontiers in Bioengineering and Biotechnology”，2022年3月21日。

随着众多制药公司采用数字化策略，以缩短研发周期和降低成本，更多公司开始构建战略联盟、外包业务或通过收购来加强药物早期及晚期研发能力。在早期药物发现和临床前药物开发阶段，合作研究协议/伙伴关系的数量迅速增加。在临床试验中，患者招募、临床实验室和诊断测试等领域更加倾向于采用外包策略。[73] 合同研究组织 (CRO) 的数量持续增长，[74] 制药公司逐步转向灵活生产模式，以适应不断变化的监管和市场需求。[75]

CRO数量增长推动实验研究

随着合同研究组织 (CRO) 与其他合同服务公司的兴起，制药公司可以快速获取化学专业技能，无需自行研发，这种模式提升了新药上市的速度。[76] 由于人工智能和机器学习在新药设计领域的辅助作用，提供“按需分子”服务的公司革新了实验方法。[77]

CRO的增长反映出小分子药物研发的复苏，研究人员正在探索利用小分子药物治疗目标疾病的新方法。[78] 2023年，销售额排名前十的畅销药物中，小分子药物和更大、更复杂的生物药各占据40%和60%的市场份额，其中几款生物畅销药占据主导地位。[79]

合同开发和生产组织（CDMO）的全球化

生命科学和医疗技术公司正在探索新的作业模式，期望在不影响研发和生产速度的情况下确保产品的安全性和质量。这些公司采用尖端技术，实施先进的流程自动化/连续生产技术，并结合实时监控和模块化设施设计，从而快速高效地调整生产流程，以适应不同的产品类型、产量规模和客户需求。[80]

欧洲的一些制药公司倾向于选择区域性CDMO服务，认为本地CDMO更接近市场、具备创新能力和丰富的人才资源，但中国和印度正在推动CDMO服务的全球化进程。根据预测，这两个国家的CDMO行业复合年均增长率将达到最高水平——中国为9.63%，印度为11.34%。[81]

C“R”DMO外包模式在全球兴起，推动疗法发展

由于制药公司追求效率提升和生产率，并寻求接入先进技术，对于能够提供全方位、端到端服务的外包技术解决方案的需求正不断增长。[82] 因此，制药公司开始寻求与合同研发和生产组织 (CRDMO) 合作。CRDMO自视为科技平台，并将“研究 (R)”这个要素融入到CDMO服务组合中。[83]

CRDMO机构开始在世界各地迅速发展，包括中国、新加披、美国和意大利等。CRDMO公司通过整合统一CRO与CDMO模式，为制药公司提供了加速新疗法上市的可性。[84]

“我们的愿景是在小分子药物领域构建端到端能力，并提供一体化解决方案。客户和市场都需要一站式服务和能够负责整个项目的合作伙伴。”

—**Angelini Pharma SpA精细化学品销售和业务拓展部门负责任人Giovanni De Filippo**[85]

新药的批准与上市

2023年，全球共推出了69种新型活性物质 (NAS)[86]，其中美国以55种位居首位 (2022年为37种)。[87] 过去五年，全球共推出362种NAS。[88] 中国NAS的上市数量呈上升趋势，但在国际市场的销售数量却逐渐减少，这表明中国NAS产业正逐渐转向国内市场。[89]

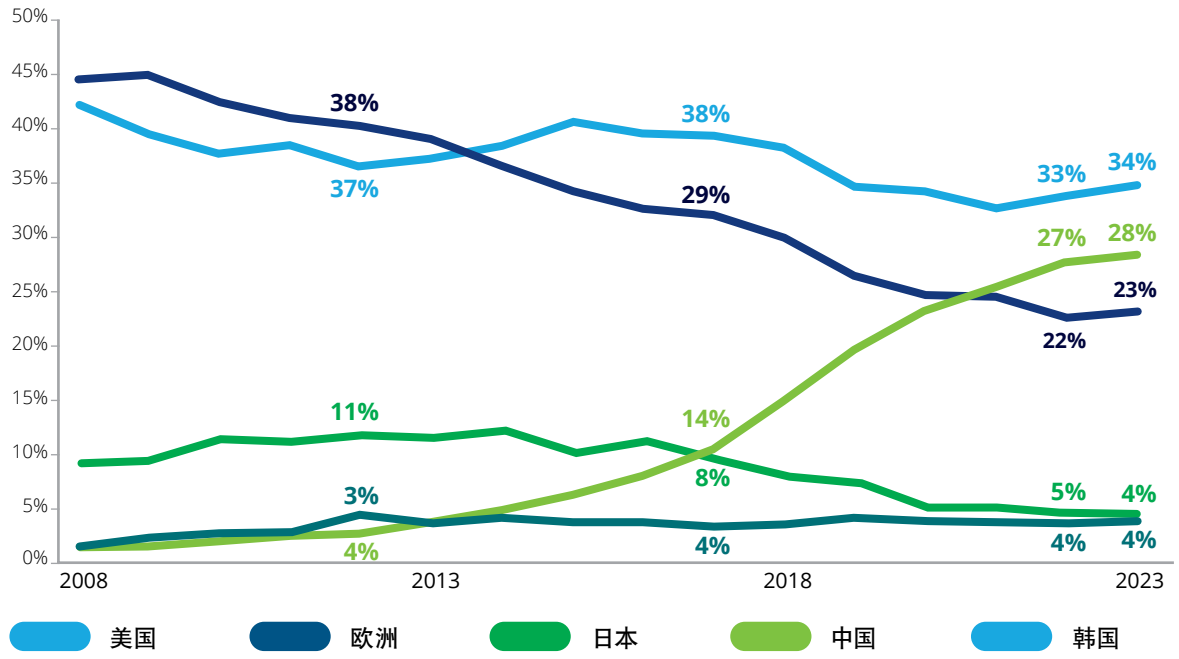
中国在研发领域超欧赶美

近年来，全球各地都在开展临床试验，其中亚洲的数量增长尤为显著。中国的NAS和临床试验数量已经超越欧洲，成为仅次于美国的全球第二大市场。[90] 尽管中国的NAS上市主要集中在国内，但中国参与的临床试验正日益走向全球化。

由于美国的临床研究活动逐渐向国际市场扩散，目前只有约三分之一的临床试验在美国本土进行。[91] 中国紧随其后，仅落后几个百分点。2023年，中国总部公司发起的临床试验占比为28%，这一数字相较于十年前的3%实现了显著飞跃 (图7)。[92]

值得注意的是，中国在全球各行业的研发支出中位居第二，达到17.8%，超过了欧盟的17.5%，这主要得益于中国科技行业的迅猛发展。[93] 对于中国的制药公司而言，高昂的研发和采购成本正在挤压其利润空间。[94]

图7：按公司总部所在地划分的第一至第三阶段临床试验数量 (2008-2023年)



资料来源：艾昆纬研究所，“2024年全球研发趋势”，2024年。

目前，美国在生物制药创新方面处于领先地位，这得益于其庞大的国内市场、强有力的知识产权保护、政府对药品定价的影响有限、有利的科研政策以及促进创新的产业集群。[95] 然而，美国正面临着不断上升的药品定价压力，其政策变动可能会削弱对知识产权的基础保护。[96]

批评者指出，美国曾在半导体和电信行业占据领先地位，但由于这些行业的衰退，美国从中吸取了经验教训。政策分析师建议，政策制定者不应将矛头对准制药公司，而应更多关注如何在全球制药行业竞争中取胜。[97]

为生物制药研发提供资金支持

生物制药研发活动的开展取决于不同地域之间以及公共和私营部门之间能否高效合作，这种深度合作过程将影响研发投资决策。[98] 最终，研发资金的充足与否将在很大程度上决定公司能否开发出符合患者需求的药物和治疗方法。[99]

近期，研究人员深入分析了医药研发的资金来源及其未来发展趋势。[100] 在总计3,000亿美元的药物研发支出中，大型制药公司几乎占了三分之二的比例。[101] 公共部门和非营利组织的投入则占支出总额的四分之一，即750亿美元。[102] 由此产生的重要科学研究成果将流向私营部门，使其进行更多研发投入。[103] 目前，风险投资约占总投入的十分之一。[104]

呼吁深入探究药物开发的生产率/价值创造

部分AI研究人员表示，应向学术界注入更多资金，以支持研究如何削减成本和提高制药研发生产率，因为目前关于如何切实创造价值的研究仍然比较匮乏。[105] 美国国会预算办公室 (CBO) 近期也呼吁开展更多研究。[106]

CBO使用药物开发模拟模型来评估立法提案，并将学术界和行业专家的反馈意见融入模型之中。生命科学和医疗技术领域的领导者应当注意，CBO近期表达了对以下问题的研究兴趣：

- 制药公司未来利润的变化将如何影响不同类型药物 (如小分子和大分子) 的开发；
- 新药数量的变化将如何影响健康结果；以及
- 价格谈判或加速药物审批等政策措施将如何影响制药公司对于哪些适应症进行药物审批的决定。[107]

开放趋势的变化：全球化与本地化及其对跨国企业的影响

生命科学和医疗科技公司日趋全球化，而全球经济正在走向新常态——全球化见顶回落。[1] 联合国最新发布的《世界开放报告2023》显示，“世界开放指数”下降0.4%，国家之间、行业之间、地区之间的开放程度越来越低。[2] 国家间相互依存程度的下降或给全球贸易与经济繁荣带来冲击。[3]

亚太地区因消费群体庞大、疾病发病率不断上升以及监管框架强而有力[4]，预计将在未来几年内实现最高增长，中国和日本将跻身制药和医疗器械市场最大经济体之列（图 1）。在亚太地区，我们看到全球第二大和第三大生命科学国家正在采取两种可以理解但截然不同的做法。中国正在推进以本国利益和技术发展为重的政策，[5] 而日本的贸易开放指数则达到了近47%的历史高点——从2021年到2022年上升了约10个百分点[6]。推动两国采取不同发展模式的多重因素包括贸易走廊、宏观政治动态、人才获取、对增长的看法以及知识产权保护。

图1：2019-2028年主要制药和医疗器械市场（按国家划分）增长预测

	按国家划分的前五大制药市场			按国家划分的前五大医疗器械市场		
国家	2019年销售额（十亿美元）	2023年销售额（十亿美元）E	2028年销售额（十亿美元）F	2019年销售额（十亿美元）	2023年销售额（十亿美元）E	2028年销售额（十亿美元）F
美国	453	571	704	165	205	262
中国	121	165	237	30	43	61
日本	106	100	163	33	33	43
德国	77	87	111	32	37	46
法国	41	47	57	18	20	24

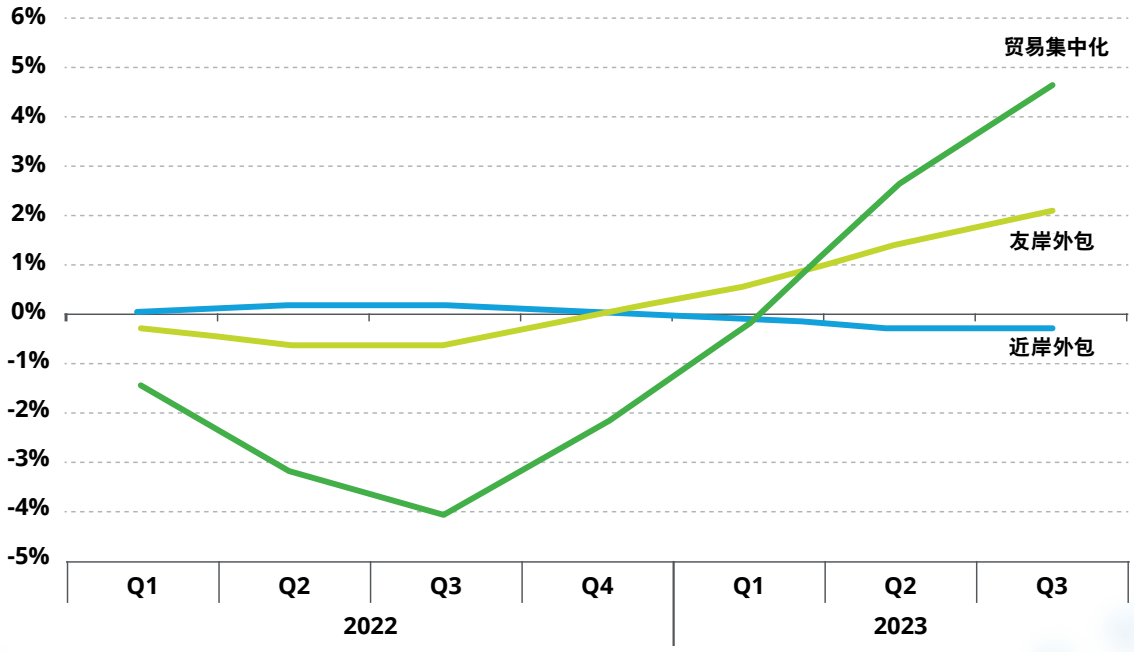
资料来源：经济学人智库（EIU）和Statista Market Insights

全球化并未消亡，只是在演变

全球连通性可基于贸易、资本、信息、人员、技术和思想的国际流动来衡量——尽管全球化并未消亡，但它正在改变。[7]

在新冠疫情期间，贸易和供应链对于医疗用品（包括疫苗）的提产和分销起到至关重要的作用。[8] 但在过去两年里，全球贸易集中化日趋明显，地缘政治更加封闭，各国的对外贸易依存度也不断降低（图2）。[9]

图2：全球贸易格局的地缘政治转向，2022年第一季度以来的双边贸易变化



资料来源：联合国贸易和发展会议（UNCTAD）发布的《2023年贸易和发展报告》

总体而言，国际贸易流动仍具活力，一些利益相关方则对“去全球化”的威胁提出质疑。[10] 跨境贸易额是衡量经济增长的重要指标，[11] 世界贸易组织 (WTO) 认为需要对近期趋势进行监测。[12]

预计2024年各地区增长仍将存在显著差异，[13] 这也是全球化趋势的一部分——全球化与本地化相融合，其中包括：

- 缩短供应链，
- 强调重建国内制造能力，以及
- 政府发挥更具战略性的作用。[14]

全球贸易概况

经历2023年的下滑之后，全球贸易增速有望在2024年回升3.3%。[15] 前文提到的中国和日本新出现的不同发展模式，在两国目前的贸易模式中亦有所体现。

专家表示，未来几年中国或仍是全球最大出口国，但其在全球经济中的出口主导地位正在接近顶峰。[16] 2022年至2023年，受对美出口缩减超20%的主要影响，中国的出口总额减少104亿美元，降幅为3.39%。[17] 然而，美国仍是中国最大的出口贸易伙伴，其次是越南、韩国和日本。2023年，中国扩大了贸易进口，美国、韩国和澳大利亚成为主要合作伙伴。[18] 中国的增长目标是迈入高收入国家行列，而不仅仅是提高国内生产总值 (GDP) 。[19]

按GDP计算，日本是第四大经济体，因为德国在2023年超越日本，成为仅次于美国和中国的第三大经济体。[20] 日本近四分之一的贸易是对华贸易，[21] 同时商品和服务出口也在扩大，2022年日本商品和服务出口额较疫情前水平增长4.1%。[22] 日本的出口额几乎与美国和中国持平。[23]

医药商品进出口比率

P医药贸易自2023年第三季度开始回暖，[24] 预计2024年全球医药市场规模将达到近1.2万亿美元。[25]

日本作为第三大医药市场，其医药产品进口额约为出口额的三倍 (图3) ，[26] 是美国药品的重要出口市场。[27] 从历史上看，日本通过扩大贸易和外商直接投资 (FDI) ，借助全球化的“外部力量”加速了经济增长。[28] 截至2021年，日本是美国最大的外商直接投资来源国，外商直接投资存量达7,210亿美元。[29]

中国的医药产品进出口水平相对均衡。[30] 目前，中美两国的医药产业依存度较高，美国主要对华出口半成品/成品药，中国则主要对美出口原料药。[31] 受癌症治疗特效药、抗生素等先进药物的推动，美国对华医药商品贸易进口额达102亿美元，出口额达93亿美元。[32] 尽管在某些领域取得了进展，但中国对美贸易仍面临诸多壁垒。[33]

图3：2021年中日医药商品进出口贸易额对比

医药商品	中国	日本
进口额	341亿美元	303亿美元
出口额	360亿美元	102亿美元

资料来源：经济合作与发展组织 (OECD)

中美科技战之阴霾仍将笼罩医疗技术和科技公司

预计到 2024年，美国医疗器械市场规模将达到1,820亿美元，中国医疗器械市场规模将达到363.8亿美元。[34] 美国是最大的医疗器械出口国和进口国；中国进口额排名第四，出口额排名第五；日本进口额排名第五。[35]

中国和日本是治疗型医疗器械所需半导体设备的主要出口国/地区；中国香港和美国则是主要进口国/地区。[36] 集成电路在半导体市场中占据主导地位，中国的集成电路进口数量正急剧下滑——2022年同比下降15.3%，2023年第三季度同比下降15.2%。[37]

中国国内生产和出口开始展现出更强的韧性。据预计，中国将在2024年中期引领芯片市场复苏，但美国也拟升级对华高端人工智能 (AI) 芯片出口管制。[38] 2023 年，日本也实施了对华出口管制，限制对华出售23种类型的芯片。[39]

日本半导体设备协会 (SEAJ) 称，受生成式AI高端芯片需求以及AI服务器领域投资的推动，日本芯片市场需求正在急剧增长。[40] 尽管今年年初芯片设备销售额有所下滑，但日本有望在2024年4月开启的新一财年 [41] 迎来27%的大幅增长。[42] 日本出台的新产业政策旨在重振本国半导体产业的国际竞争力。 [43]

中国也以“新型举国体制”推进科技攻关，包括鼓励本国半导体产业追赶全球竞争对手。[44] 部分人认为，目前美国实施的科技封锁正在刺激国内生态系统，[45] 激励中国自力更生实现技术突破。[46] 但在高端芯片制造领域，中国大陆仍落后于台湾和韩国市场两到三代。[47]

英特尔、通用电气、英伟达和高通等跨国企业正在游说政府官员寻找方法，以减轻出口管制所带来的打击。[48] 例如，英伟达于2023年12月在中国市场推出“降级版”芯片，以遵循美国的出口管制。[49]

> “跨国企业需要密切关注全球和中国本土环境，持续利用行业协会影响政府政策，并确保其中国战略始终能够适应外部变化。”
>
> **—某在华运营的跨国医疗科技公司首席执行官[50]**

生物技术外资审查趋严

中美两国在生物技术研发和贸易领域的竞争与合作不断升级，而美国外国投资委员会 (CFIUS) 正在加强中国对美国生物技术行业的投资审查。2024年，拥有“关键技术”或“敏感个人数据”的公司将面临更大风险并应做好准备，以应对CFIUS更为严格的外国投资交易审查。[51]

领军企业仍致力发展在华业务

面对地缘政治局势升级，许多顶级生命科学和医疗科技跨国企业表示，2024年其仍将致力发展在华业务，但预计也将面临更多的监管审查和市场准入挑战。[52] 随着降价影响的显现和内部优先事项的转变，跨国制药公司正在重塑业务模式。[53, 54]

在华运营的医疗技术和科技公司也在关注宏观经济形势，因其仍易受到供应链中断的影响。[55] 据德勤健康解决方案中心开展的首席高管调查显示，全球政治紧张局势是九成美国医疗器械公司高管在2024年最为关注的事项。[56]

> “中国医药市场规模将持续扩大，故其仍值得我们重点关注。未来增长或有所放缓（尽管我们的目标是在2024年实现两位数的增长）。目前，我们总部的领导团队对中国的看法非常‘持中’，既不看涨也不看衰。”
>
> **—某在华运营的跨国制药公司首席执行官[57]**

中国市场的机遇

中国市场的广阔规模吸引着跨国药企纷纷扩大其全球计划，[58] 而中国拟将2024年研发投入提高10%，以加速科技突破。[59] 中国有望在慢性病和罕见病治疗领域取得长足进展。[60] 对于罕见病的治疗，药品成本和可负担性仍需进一步的立法和政策支持。[61]

中国市场对于希望加强产业和供应链韧性的医疗器械公司而言亦极具吸引力。[62] 美敦力在华手术器械销量自2023年第三季度起迎来了强于预期的复苏。[63] 该公司称，带量采购（VBP）的影响“已基本过去，因其大部分产品组合已重新定价”。[64]

美敦力首席执行官Geoff Martha表示，公司将继续投资中国市场，因为“这是一个巨大的市场，并且仍在不断增长”。[65]

加快集中反腐工作

美敦力表示未受到反腐问题的影响，预计2024年反腐问题仍将是一项影响因素。[66] 中国中央政府的最新反腐行动包括中国国家卫生健康委（NHC）等14个部门联合启动的整治工作。[67] 研究显示，行贿受贿是医疗行业最普遍的腐败形式，而新政策将以“零容忍态度”反腐惩恶。[68] 虽然医疗机构最常被指受贿，但医药和医疗器械供应商也被曝存在行贿现象。[69]

根据德勤中国近期对反腐行动的研究，中国的整治工作不论是持续时长还是影响，都不仅限于短期，此项整治工作为期五年，其后续伴有定期的严格执行。[70] 在当下医药强监管趋势下，医药企业应立即搭建全面有效的企业合规体系以实现合法合规经营。[71] 在医疗反腐整改环境中，产品研发可以帮助制药公司提升在中国医疗体系中的竞争力。[72]

中国营商环境复杂

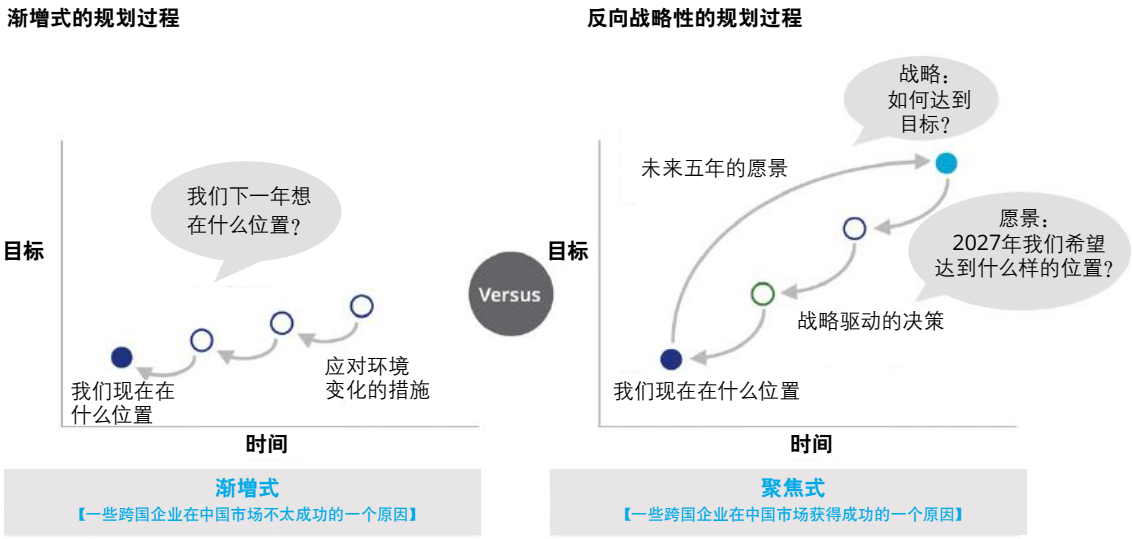
地缘政治、技术、法规和本地竞争的变化使在华运营的跨国企业面临诸多挑战。[73] 但勇于直面挑战的企业或将迎来新的市场和机遇。[74] 德勤中国从在华跨国企业的成功和不太成功的经历中发现，实施“聚焦”式策略好过被动及“渐增”式策略（图4）。[75]

迎接中国市场的挑战

对于在华跨国企业而言，中国市场机遇与挑战并存，尤其是日益激烈的本地竞争。中国对于知识产权（IP）的使用、强制技术转让以及许多市场准入问题仍可能阻碍跨国企业与中国本土企业平等经营。[76] 自中国政府于2015年提出《中国制造2025》战略计划以来，中国一直致力于提升在全球生物制药和先进医疗器械市场的份额占比。[77]

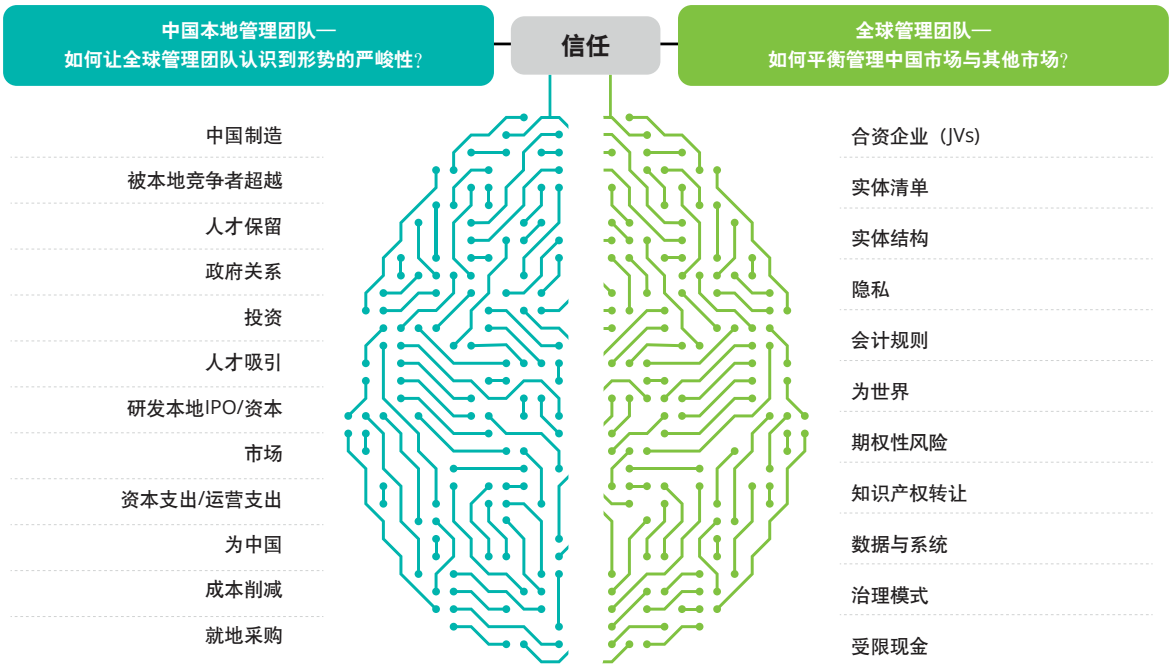
近年来，跨国企业的驻华办事处与境外全球总部之间的协调一直很棘手。在新冠疫情期间，跨国企业的全球领导团队无法造访中国，在缺乏面对面交流的情况下，一些跨国企业难以进行有效沟通。要在全球和本地管理团队之间建立信任并加强沟通，往往需要在中国和其他市场管理之间取得平衡，同时还要了解中国本地管理层的关键需求。（图5）。

图4：渐增式策略与聚焦式策略



资料来源：德勤中国《跨国企业本地化2.0》，2022年。

图5：在全球和本地管理团队之间建立信任



资料来源：德勤分析

中国希望在华经营的外国跨国企业趋于本土化，以支持本地发展。[78] 2023年底，辉瑞、赛诺菲和渤健等公司纷纷拟与中国公司建立合作，助其产品实现商业化。[79] 随着营销责任向其他公司转移，预计各领先制药公司将掀起一波裁员潮。[80]

“跨国企业需要制定稳健的行动计划来应对短期挑战（包括地缘政治冲突、带量采购、疾病诊断相关分组/按病种分值付费（DRG/DIP）、本地采购），同时也要看到中国的长期机遇，比如‘健康中国2030’规划、医疗服务‘广覆盖’，以及医疗支出占GDP比重或从2020年的约7%增至2030年的9%。”

—某在华运营的跨国医疗科技公司首席执行官[81]

中国药品和医疗器械定价的影响因素

中国的监管变化正在改变跨国企业的投资组合和业务模式，尤其是市场战略。[82] 中国的带量采购、DRG（打包付费）和DIP（按病种分值付费）定价计划，旨在通过由国家组织向省市或全国价格最低的中标企业进行集中采购，从而降低药品和医疗器械的成本。[83]

中国政府看到了降价带来的好处，因此扩大了集采产品种类。[84] 2023年底，中国启动第四批国家组织高值医用耗材集采，并拟于2024年年中进行招标。部分医疗器械迎来大幅降价——11种人工晶体类耗材平均降价58%，19种运动医学类耗材平均降价72%。[85]

2023年底，在第九批国家组织药品集采中，拟中选药品平均降价58%。在获得拟中选资格的260多种药品中，仅5种药品由4家外国公司供应。[86]

“到2024年，约80%的高值医用耗材将进行带量采购，而带量采购中标产品是中国患者在现行政策下可获得的主要产品。可以见得，中国患者对差异化、更优质、更先进的技术/创新产品有着明确的需求。跨国企业需要继续对政府施加影响，以通过公立医院评价体系、DRG/DIP支付和商业保险等方式，使患者能够获得这些产品。”

—某在华运营的跨国医疗科技公司首席执行官[87]

推进本地化战略计划

本地化是在华运营的永恒议题，跨国公司应推进其本地化计划，不仅要在中国市场上具备竞争力，还需要应对围绕供应链中断、技术和数据主权日益增加的风险。不存在可套用的万能公式，因为每家公司各自处于本地化进程不同的阶段（图6）。[88]

图6：跨国企业在中国推进本地化战略计划的各阶段

资料来源：德勤分析

在中国建立本地支持

预计生命科学和医疗科技跨国公司将对本地倡议表示支持。[89] “健康中国2030”是中国为改善公共卫生服务、医疗产业和食品药品安全而进行的卫生改革。其重点在于预防而非治疗。[90]

去年，辉瑞与中国签署了一项合作协议，以提高中国的医疗覆盖率，亦表明其对“健康中国2030”的支持。辉瑞与健康中国研究中心签署的战略合作备忘录旨在支持公共卫生研究，改善农村人口的健康状况。[91]

吸引人才回流，激活研发创新源泉

过去25年间，中国的研发支出占GDP的比重从0.56%上升到2.4%，根据目前的势头，未来十年很可能超过日本和德国。[92] 中国本土企业一直在研发上投入巨资，并因此在技术领域取得进步。[93]

为了在生物制药和医疗器械市场上占据一席之地，中国深知，成功源于创新而非模仿。近年来，中国启动了200多项人才招聘计划，在全球范围内吸引高素质的科学家。中国的“千人计划”（Thousand Talents Program，TTP）将受过西方教育的中国STEM研究人员招回中国。近期一项研究发现，“千人计划”成功用现金和实验室支持吸引了有前途的年轻科学家，但对于招揽高水平研究人员却不那么顺利。更成熟的研究人员偏爱西方，因为“行政干预”较少。[94]

不过，研究还表明，随着时间的推移，这类支持使得留学归国的研究人员的论文发表率超过了留在国外的同行，论文产出率提高了27%，包括在高水准期刊上发表论文。[95]

跨国企业在华设立研发中心超过1,600家，引进知识产权价值超过380亿美元。[96] 目前，中国鼓励外商投资在华设立研发中心，承担重大科研攻关项目。[97] 2023年8月，中国国务院印发《关于进一步优化外商投资环境 加大吸引外商投资力度的意见》（以下简称《意见》）。[98] 《意见》要求相关部门建立便利化的数据跨境流动安全管理机制。《意见》还提出，中国政府拟为外商投资企业的外籍高管、技术人员本人及家属提供入出境、停居留便利。[99, 100]

中国首席执行官谈2024年创新

针对在华跨国企业首席执行官的调查显示，[101] 许多受访者认为创新是在中国取得成功的主要驱动力，但对于创新的现状以及如何产生真正的创新却存在不同看法。部分受访者认为，数字创新已然在中国普及，而另一部分则表示，中国的AI应用现状和“可用工具落后于世界其他地区”。某制药公司首席执行官称，“国内创新的蓬勃发展为中国医药市场注入了新活力，但也加剧了竞争”。另一位首席执行官认为，“2024年最重要的举措将围绕中国患者和医疗机构的‘教育和参与’展开”。

> “跨国企业需要继续加快在中国推出创新产品，同时在特定领域创造差异化和价值主张，在价格和数量之间争取更好的平衡，并探索各种支付方式，以实现创新药物价值的最大化。”
>
> **—某在华运营的跨国制药公司首席执行官[102]**

日本积极推进全球化

日本制药公司不断扩大全球足迹

日本制药业一直致力推进全球化——通过并购、合作、更广泛的研发以及向新兴市场扩张来提高其全球影响力。它们对本土市场依赖程度较低，一半以上的收入来自海外市场。武田是日本最大的制药公司，目前在全球名列第17位，在全球80多个国家和地区开展业务，在全球化方面处于领先地位。[103] 历经20余载的全球扩张和服务战略部署，以及近10年来的全面转型，武田已从一家总部位于日本的杰出跨国企业，发展为一家“总部”遍布日本、美国和欧洲（瑞士）的全球企业。Christophe Weber是武田的首位非日本籍首席执行官，现已领导武田近十年。他在2021年接受采访时分享道：“当我在2014年加入公司时，我们的目标是进行两项重大变革。其一是转变研发能力，从而提高生产率。二是实现公司全球化，扩大规模，从而提高竞争力。”[104] 在此过程中，武田收购了多家跨国制药公司（如千年制药（Millennium Pharmaceuticals）、夏尔制药（Shire Pharmaceuticals）等），并积极推进全球化业务模式和战略。武田很早便致力走上全面全球化道路，在日本制药市场中独树一帜。[105]

安斯泰来制药集团是继武田之后，在日本境外设立最多办事处和领导层的公司，在全球约70个国家和地区开展业务。相比之下，由于研发中心主要集中在日本国内，盐野义（Shionogi）的海外业务发展较为有限。不过，大多数日本制药公司都在扩大在美国的业务，其次是亚太地区（APAC）和欧洲业务（图7）。

图7：日本制药公司（除武田外）的地理分布和足迹不断扩大

注：1. *亚太地区包括整个亚洲和大洋洲，不包括日本。2. 以上公司在各地区设有多个办事处。3. 大冢制药（Otsuka）和住友制药（Sumitomo Pharma）的部分研发中心和销售办事处与生产中心合并。

资料来源：德勤日本分析

在全球化进程中取得进展

美国和欧盟的制药公司在管理业务职能时，采用按疾病区域划分的职能管理方法（图8）。日本的早期制药公司则按地区进行管理。通过优先考虑地区业务拓展，这些公司希望扩大在某一地区或国家的市场份额。

日本较先进的制药公司已开始转向按全球职能而非地区进行管理。这种方法更加集中化，由总部确定任务和资源的最佳分配来实现多区域管理。

为了提高研发效率，一些公司正考虑将更多研发职能迁往日本以外的地区，但却面临人才稀缺问题。2024年，这些公司对具备全球专业知识的人才的争夺将更加激烈。

合作实现增长，形势乐观向好

2024年，随着领先的生命科学和医疗科技公司寻求在全球和日本本土发展的平衡，更多公司正在探索以合作推动增长。[106] 百时美施贵宝（BMS）计划在未来十年内将其日本业务规模扩大一倍，这不仅要依靠内部产品和产品线，还要通过合作来实现。[107] 目前，该制药巨头多达60%的研发管线来自外部，BMS准备进一步加强合作，以优化其产品组合。[108]

2022年，BMS在日本的销售额约为14亿美元，公司的“日本登月计划”旨在通过以下方法，在10年时间内将销售额翻一番：

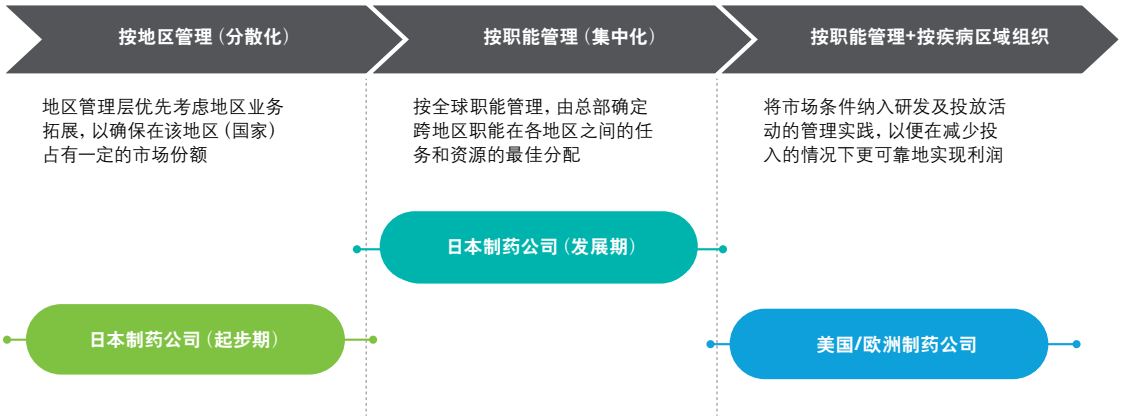
- 获得新药批准
- 扩充现有产品，包括扩展品牌系列
- 寻求外部创新[109]

推出系列产品也是增长计划的内容之一。[110] 在BMS已获美国食品药品监督管理局（FDA）批准的九种新药中，有三种已在日本获得批准，其他新药正在接受监管审查或处于中后期临床开发阶段。[111] 更多项目正在争取获得日本监管部门的批准，此外BMS计划扩大现有产品的市场投放。[112]

BMS在日本的研发战略是充分利用人工智能/机器学习（ML）的新用途，聚焦三大领域：

- 确定新的候选药物分子，提高研发成功几率
- 利用人工智能/机器学习加快临床试验，优化项目计划
- 将新技术纳入患者疗效研究[113]

图8：美国/欧盟和日本公司的全球化实践



资料来源：德勤日本分析

武田拟扩大新兴市场业务

作为日本最大、最国际化的制药公司，武田计划到2030年将其新兴市场业务规模扩大至90亿美元。[114] 其区域战略包括为全球85%的人口提供医疗服务和药品。[115] 世界卫生组织 (WHO) 战略专家咨询组 (SAGE) 近期建议在登革热疾病高发地区引进武田的登革热疫苗 “Qdenga”。 [116]

登革热是最常见的蚊媒病毒性疾病之一，每年造成超过3.9亿人感染，在100多个国家流行。[117] 巴西是首个通过公立医疗系统向公众提供武田疫苗的国家。[118] Qdenga目前也在欧洲、印度尼西亚、泰国、阿根廷等国销售。[119] 阿根廷目前正在经历20年来最严重的登革热疫情，仅2024年登记的感染人数就超过了10万。[120]

扩大日本市场的研发和国际合作

过去十年，生物制药行业在日本的研发投资超920亿美元，开发了1,500多种新药，为日本提供了逾14万个就业岗位。[121] 截至2024年第一季度，日本制药工业协会共有70家研究型制药成员公司，其 “2025行业愿景” 是到2025年为全球80亿人提供创新药物。[122]

启动创新战略转型

日本拥有全球独一无二的创新体系，在该体系下，所有新药均由现有制药公司开发，比如武田，它拥有日本制药公司中最高的研发预算。[123] 随着个性化医疗的兴起，治疗罕见病的新药不断问世，[124] 初创企业的崛起成为新药研发的重要途径。[125] 相较于其他国家，日本生命科学领域初创企业的实力历来较弱。[126]

日本通过 “日本生物经济战略” 开启了生物制药市场的战略转型，目标是到2030年建成世界上最先进的生物经济社会。[127] 日本政府已拨出相关款项，大举投资于生物制药、再生医学、细胞和基因疗法 (CGT) 以及先进治疗药物产品 (ATMP) 领域，从而推动生物制造技术发展。

与日本厚生劳动省 (MHLW) 牵头的 “远景规划” 相比，生物经济战略涵盖的范围更广，更注重于振兴日本制药业，尤其强调创新、全球竞争力和研发投资。[128] 加强与生物学学术研究机构的合作，是提高日本公司药物研发竞争力的途径之一。[129]

吸引新人才和研究人员

预计到2027年，日本的新药及专利药市场规模将超过720亿美元，成为仅次于美国的全球第二大市场。[130] 2023年，日本政府承诺设立一支约750亿美元的捐赠基金，供指定大学开展世界一流的研究并竞逐全球。其他组织也在创造新的资助机会。[131]

“我们专为年轻的研究人员提供资助，尤其是那些从国外归来、需要资金进行创业的有为青年。我们试图用少量的预算来培养优秀人才。”

—**日本生命科学基金会理事长林幸秀（Yukihide Hayashi）**

诸如生物物理学家Kazuhiro Maeshima这样的科学家，在返回日本之前，曾在海外从事多年的研究工作。Maeshima加入了位于静冈的国立遗传学研究所 (NIG) 的基因组动力学实验室，学术自由度之高令人向往。他表示：“基本上，我们可以随心做事，这在日本可能很罕见，但我们相信这是开展激动人心的研究的关键所在。”[132] Maeshima对国际合作也很感兴趣，目前正在与澳大利亚的同事合作，因为澳大利亚的研究社区虽相对较小，但质量很高。[133]

日本研发人才招聘掀热潮

与其他国家相比，日本研发人力资本增长历来缓慢。[134] 根据日本52家受访公司的反馈，2024年，在制药公司开放的应届毕业生招聘岗位中，研发岗占比40%。[135] 这一趋势在头部公司中更为明显，如中外制药 (Chugai Pharmaceutical)，其研发岗占总招聘岗位的80%；中外制药的新招员工数量也最多，达到155人。[136] 在第一三共制药（Daiichi Sankyo) 和小野制药 (Ono Pharmaceutical)，研发岗也占多数，占总招聘岗位的60%。[137] 在所有公司中，新增销售岗仅占20%。[138]

仿制药制造商日医工株式会社 (Nichi-Iko Pharmaceutical) 在经历了两年的招聘荒后，于2024财年重新开始招聘应届毕业生。[139] 25名新聘员工均被分配到生产和质量团队。[140] 岗位数量同比增加较多的公司还包括日本化药 (Nippon-Kayaku)（+42）、礼来 (Eli Lilly)（+17）和田边三菱 (Mitsubishi Tanabe)。[141, 142]

回顾2023财年，中外制药研发岗招聘的中层人员最多，占总招聘岗位的40%，未招聘销售人员。小野制药招聘的中层人员中，约20%从事研发工作。[143]

微软将在日本投资约29亿美元促进AI发展和就业

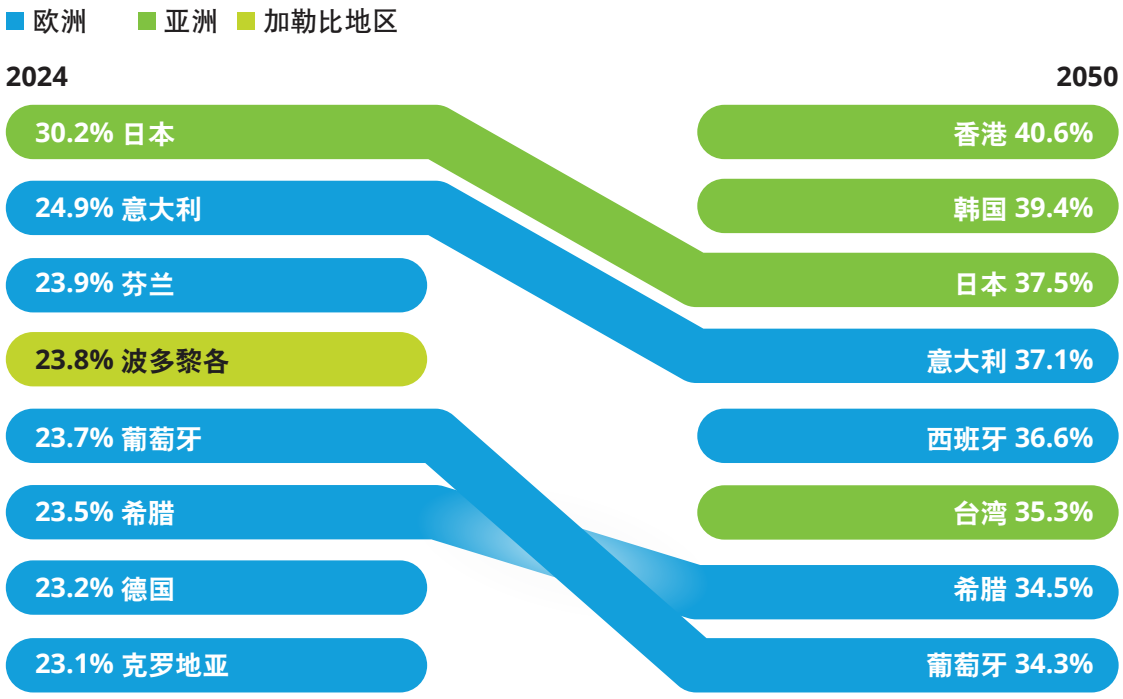
微软正计划在日本开展一项与AI相关的再培训计划，在三年内培训300万名工人，并在东京建立一个新的实验室，用于研发机器人和AI。[144] 根据该计划，微软将在日本东部和西部的两个现有基地安装先进的AI半导体。[145]

应对日本人口老龄化的挑战和社会风险

日本面临的最大挑战之一是老龄人口的增加——每10人中就有1人年龄超过80岁。[146] 目前，在人口超过100万的国家或地区中，日本65岁及以上人口的比例最高（图9）。[147] 在全球范围内，人口老龄化正成为政府和医疗生态系统面临的主要问题，因为到2050年，全球60岁以上人口将增加到近20亿。[148]

图9：全球老龄人口

2024年和2050年，在人口超过100万的国家及地区中，65岁及以上老年人口占总人口的比例预估。



资料来源：Statista，联合国人口司

出生率下降，企业为应对老龄化市场做出转变

随着人口老龄化加剧，日本2023年新生儿数量创新低，国家领导人正在评估人口危机以及人口老龄化对社会的未来影响。[149] 中国公布的数据也显示，2022年中国人口出现了六十年来的首次缩减。[150]

各大企业已纷纷着手应对这些转变。例如，日本尿布生产商王子控股 (Oji Holdings) 将于今年下半年停止生产面向国内市场的婴儿尿布，转而生产成人卫生用品，主要提供给养老院。[151]

老年人护理需求推动了创新技术的发展，如护理管理自动化。[152] 此类先进技术可助力老年人独立生活，并通过使用工具监控并满足老年人的需求，帮助减轻看护者和护理人员的负担。[153] 2024年，处于此类技术前沿的公司将从不断增长的需求中获益。[154]

用于辅助生活和老年护理的新型数字及AI技术

由松下打造的护理支援服务“Lifelens”，可通过技术增强的房间自动监控病人。日本公司Hitowa Care Services最新的养老院便采用了Lifelens服务，在其养老院每个房间均安装了摄像头以记录病人情况，同时使用AI系统对数据进行分析。[155] 该技术还使用传感器报告病人是否躺在床上，并监测病人的心跳。[156]

预计到2027年，日本的AI诊疗工具市场规模约为1.14亿美元。[157] 日本富有创研精神的医生正在协助开发新型AI医疗工具，以提高医生诊断的速度和准确性。[158]

例如，日本公司占据了全球内窥镜市场98%的份额，但根据内窥镜拍摄的图像诊断癌症极富挑战性。[159] 日本初创公司AI Medical Services (AIM) 开发了一款AI工具，并用20多万段高分辨率胃部视频对其进行训练，进而提升诊断准确性。[160] 胃癌仍然是全球第三大死因，在亚洲的发病率尤其高。[161] 亚裔美国人受到的影响也相对更大。[162] 日本和韩国作为胃癌高发国家，开展了全国性胃癌筛查计划。[163]

随着慢性病的增多，数字疗法得以普及。[164] 美国Welldoc和日本安斯泰来正合作开展一项临床试验，使用Welldoc的BlueStar数字健康应用程序进行糖尿病管理。[165]

增创数字服务机会，提高健康预期寿命

随着老年人对科技产品的接受度逐渐提高，企业因此有机会通过数字化触达更广泛的客户群，包括管理他们的健康。[166]通过帮助人们保持行动自如、远离衰弱性老年疾病，可延长其“健康预期寿命”。[167]

然而，当预期寿命增速快于健康预期寿命增速时，往往导致整个社会生活质量下降，医疗和社会保障成本上升。[168] 在日本面临步入老龄化社会的挑战之际，瑞士制药公司诺华等跨国公司正在日本医疗生态系统内寻求合作，以降低成本。[169] 心血管疾病是影响日本中老年人群的首要社会负担之一，诺华正努力提升人们对心血管疾病的认知，改善对心血管疾病的管理，并与日本各地区的学术界、地方政府部门和行业合作伙伴通力合作。[170]

日本的老年生活环境建立在过时的寿命预测模型之上，无法延长健康寿命。[171] 为有效应对老龄化社会，日本应考虑为预期活到九十多岁的人建立一个新的社会包容体系。[172] 本报告关于*“通过个性化体验和真正的共同决策改善患者疗效”*章节将深入讨论延长健康寿命这一话题。

在开放变化中前行

要在竞争异常激烈的全球环境中蓬勃发展，并在生命科学领域取得领先地位，离不开持续的政策支持和研发投资。[173] 开放趋势的变化——以及一个国家对其全球地位的认知——预计将持续影响内外部创新和医疗质量。成功的生命科学和医疗科技公司正在关注这些变化，持续提升地缘政治方面的专业知识，并制定战略和行动，以适应形势瞬息万变所带来的挑战。[174]

通过个性化体验和共同决策改善患者疗效

生命科学和医疗科技公司愈发重视通过更严谨的科学、更优质的体验来改善患者疗效。[1] 接受德勤美国调查的生命科学公司高管认为，其所在组织在2024年需要采取的主要行动是“提升患者体验、参与度和信任感”——与2023年相比，当下有更多公司将这一趋势视为头等要务。[2]

个性化护理和治疗支持提升患者体验，生命科学和医疗科技公司也拥有许多机会来改善整个患者旅程中的触点。[3] 然而，要想积极有效地改善患者的就医流程，就必须对该流程有全面、具体的了解，从而前瞻性地预测患者需求。[4] 随着就医流程日益数字化和个性化，其也将提供更加“直接”和无缝的诊疗体验。

每名患者的经历都不尽相同，在支离破碎的医疗生态系统下生活的患者往往会感到沮丧。[5] 但现在，医患共同决策（SDM）过程能够明确患者偏好。根据英国全民医疗服务体系（NHS）所言，共同决策是一个基于证据选择诊疗方案的过程，同时也考虑患者的个人偏好、信仰和价值观。[6]

研究表明，共同决策的理论与实践之间仍存在差距。[7] 实施共同决策可以改善患者的报告结果 [8]，也是将以患者为中心的最佳护理与循证医学相关联的可能纽带。[9] 凭借更加个性化的医疗服务，在正确时间提供正确诊疗方案的时机已成熟。[10]

以技术实现个性化

2024年，生命科学和医疗科技公司考虑采用新兴技术，为患者提供更加个性化的就医体验。[11] 从预防到诊断、治疗和监测，许多机构都在尝试人工智能 (AI) 在整个患者旅程中的最新应用。[12]

患者旅程甚至可能在患者联系医疗机构之前就已经开始了。[13] 例如，通过识别哪些类型的患者更有可能罹患某种疾病，AI可提高未确诊患者对于可能将经历的临床治疗过程的认识，并有望加速这一进程。[14]

利用可穿戴设备、倾向性预测模型 (利用历史数据预测下一步行动) [15] 、健康评估工具以及新型生物标志物和筛查技术，早期干预也成为可能。有了更多数据，医疗专业人员 (HCP) 就能对患者有更为细致的了解。[16]

患者旅程日益受到关注

患者和医疗机构的新需求不断涌现

在医疗科技领域，成功的医疗机构正以超越物理设备、更全面的视角看待患者护理过程。[17] 越来越多的患者正在积极转变角色，选择根据个人的预防和健康偏好定制健康解决方案和服务，而不仅仅是治疗。[18] 患者还要求根据个人行为习惯定制便捷化护理，并对个人安全健康数据拥有更大的自主权。[19]

这种积极的患者角色 (即具有独特医疗需求的活跃消费者) 愿意考虑能够更好地满足其特定需求的解决方案，并催生出一个庞大的细分市场。[20]

首席患者体验官角色的转变

部分医疗公司在其首席高层中增设有首席患者体验官，而他们的工作重点正从提升住院患者体验，转变为改善整个患者旅程。[21] 约翰·霍普金斯大学医学院 (Johns Hopkins Medicine) 首席患者体验官Lisa Allen博士表示，尽管来自质量、统计和研究领域，但她将热忱全都付诸于患者和家庭。[22] 她说："很多医学研究者只是在研究疾病过程，而我更关注疾病会如何影响患者的生活。"[23] 南佛罗里达浸礼会医疗中心 (Baptist Health South Florida) 首席患者体验官、护理学硕士Patricia Rosello称，拥有从患者角度看问题的思维并关注整个患者旅程至关重要。[24]

> "你的影响力和协作能力将是关键所在，因为想要改善患者旅程，就需要所有这些能力和关系。你必须具备广阔的视野、高度的同理心和理解力。"
>
> —**南佛罗里达浸礼会医疗中心首席患者体验官、护理学硕士Patricia Rosello**[25]

随着患者旅程日益受到关注，首席患者体验官的角色也在不断演变，并愈发具有战略意义。[26]

将患者偏好和价值观纳入决策

在护理合作中，患者往往难以在其健康状况评估过程中感受到尊重。[27] 虽然通过病情交流和信息共享，患者或被告知并了解不同方案的风险、益处和可能的后果[28]，但如何将患者的价值观和偏好纳入共同决策过程中，却鲜有人知。[29]

制定“协作型”共同决策

制定协作型共同决策，意味着医患双方应当充分交流信息，以帮助患者就其护理做出个性化、知情的决定。[30] 这一过程应考虑患者期望的参与度和自主性，[31] 以及患者个人的价值观、目标、关注事项和期望的生活质量（QoL）。[32] 但是，实现价值观整合的方法目前并不明确。[33]

虽然协作型共同决策可以提高知情同意和患者信任，并使许多利益相关方受益，[34] 但其在日常实践中的应用仍然有限——即使在西方国家，协作型共同决策亦被视为一种理想状态。[35]

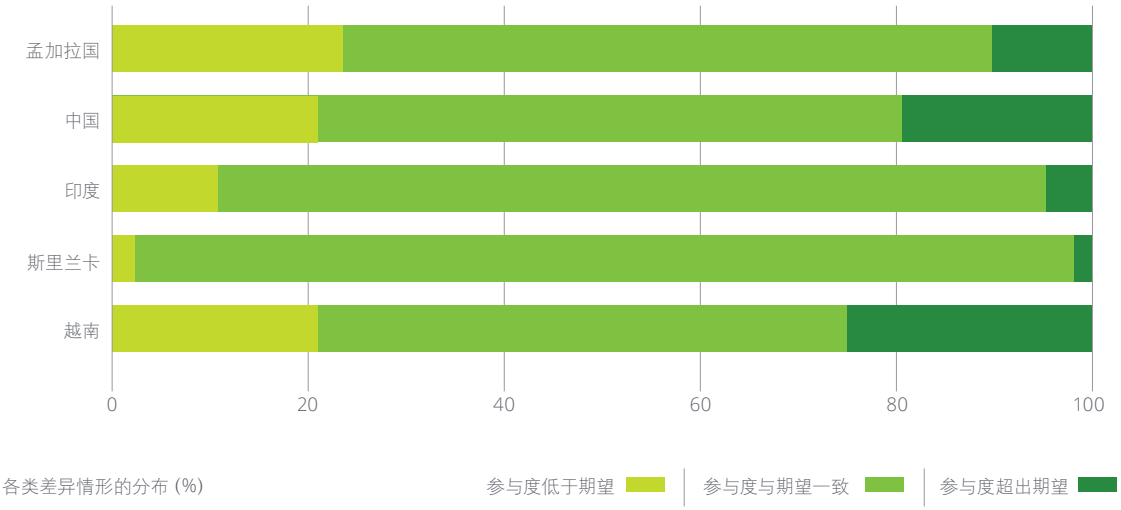
研究人员指出，医疗机构不应预设患者希望在决策过程中扮演的角色，并强调明确患者意愿的重要性。[36] 即使是年龄、教育程度和健康素养等特征，也并不一定是衡量患者参与意愿的一致指标，[37] 更何况文化和代际偏好也不尽相同。[38]

平衡“患者主导”与“医生主导”的护理观点

部分患者倾向于选择更主动参与的、或由“患者主导”的决策形式，研究自己的病情和可行的治疗方案。[39] 而部分患者则可能更喜欢传统的、由“医生主导”的决策形式，因其认为医生最了解自身情况。[40] 但医生如何平衡患者需求也存在主观意识，而不同医生的观点也同样千差万别。[41]

在埃塞俄比亚，研究人员发现，患者的期望角色与医疗机构对患者角色的认知之间存在差距，[42] 这表明医疗机构也处于“以人为本”模式与“家长”模式之间。[43] 一项针对亚洲多国的研究发现，各国患者在参与度期望方面存在不同程度的“一致性”（图1）。[44] 研究人员发现，这是首次针对中低收入国家癌症晚期患者在决策过程中的感知角色与患者预后之间的关联所展开的研究。共同决策与较高的幸福感和感知到的护理质量相关。[45]

图1：亚洲五国患者在决策过程中的感知角色与期望角色的（不）一致性分布



资料来源：Semra Ozdemir等人，“Patient-Reported Roles in Decision-Making Among Asian Patients With Advanced Cancer: A Multicountry Study”，2021年11月18日。

新医疗模式下的教育机会

目前应采取的进一步做法或许是深入了解不同医疗机构对患者参与共同决策的看法。[46] 一项针对荷兰住院医师的小型调研发现，年轻医生更倾向于传统的、由医生主导的决策方式。[47] 他们的决策似乎受到环境因素——他们的医学知识和共同决策知识——及其对医生职责的信仰和信念的影响。[48] 在试图为患者提供最佳循证治疗时，这些住院医师将共同决策与获得对其建议的知情同意混为一谈。[49]

教育应当成为新医疗模式的重要组成部分，国际合作生产卫生网络 (International Coproduction Health Network，ICoHN) 是一项支持患者、医护人员、学生和研究人员在不同实践社区中共同学习的倡议，以探索共同决策中的合作生产。[50]

共同决策为生命科学领域带来更大机遇

生命科学公司日益重视 “知情” 决策，以支持共同决策。[51] 知情患者往往更有可能积极参与决策过程，并更好地了解任何治疗的潜在结果和风险。[52] 此外，知情决策有助于建立信任，因为即使是最后选择将最终治疗决定权交给医生的患者，也仍希望获知高质量的诊疗信息。[53] 我们有机会提高对共同决策作用的认识，[54] 且有证据表明，共同决策可以促进适当护理、减少过度治疗、改善健康结果，进而降低医疗成本。[55]

使用患者决策辅助工具 (PDA) 可以帮助患者参与决策，从而提高决策过程的质量和对个人选择的满意度。[56] 想要开发能够提供治疗替代方案、潜在风险和益处等信息的PDA的生命科学公司，或会考虑如何满足患者的偏好和价值观。[57]

通过倡导共同决策并推动与临床医生、决策者、患者权益组织以及患者合作开发PDA，生命科学公司有机会表明，其对进一步尊重患者在决策过程中的权利和责任之战略的支持。[58]

一些AI工具或有助于增加共同决策实践——但这类工具的设计和使用也应考虑患者偏好。[59] 加拿大麦吉尔大学在AI和机器学习 (ML) 研究领域一直处于全球领先地位，[60] 该大学对多个国家用于促进共同决策的AI干预技术展开了一次范围审查。[61] 研究人员观察到，这些研究缺乏对患者价值观和偏好的重视。[62]

麦吉尔大学的研究人员发现，在共同决策相关研究中，没有一项研究将医疗机构或患者纳入AI干预技术的设计和开发中。他们建议，应该开展进一步研究，以加强和规范AI在共同决策不同阶段中的应用，并评估其影响。[63]

虽然AI在共同决策中的应用尚处于起步阶段，但AI和生成式AI (GenAI) 已取得多项进展，且均侧重于改善多个疾病领域的患者旅程——从辅助诊断到使用可视化和表征功能以向医疗专业人员提供支持，再到加速报销等等。有关生成式AI/AI力量和发展的进一步阐述，请参阅本报告的生成式AI相关章节。

优化患者体验的触点

患者体验触点是指患者在管理特定病症/病痛时与医疗生态系统进行互动（无论是现场服务还是通过网站、平台或应用程序进行在线互动）的任何点。[64] 触点的综合体验将影响患者对于所接受护理和就医过程的感知。[65]

患者旅程优化战略应在每个触点都加入患者视角。[66] 具体而准确地绘制患者旅程还有助于发现提高患者生活质量（QoL）的新机会，而不是将行动局限于紧急需求。[67]

每位患者的病程可划分为几个阶段，通常也是特定疾病的固有阶段。[68] 例如，癌症可能会遽然出现，治疗决定可能具有时效性，导致患者情绪高涨。[69] 糖尿病等慢性疾病则往往是逐渐恶化，一般可通过改变生活方式来预防或缓解。[70] 每位患者的病程有所不同，因此护理工作应注重统筹兼顾、应需而变。[71]

2024年，“以人为本的护理”仍将是各大医疗公司的工作重点，战略领导者应着眼于组织改善患者体验的任何潜在机会[72]——哪怕是一个触点的改进，都可能改变一个人的一生。

无法衡量即无法改进

医疗行业产生了大量真实世界数据（RWD），这些数据提供了关于患者、患者疾病、患者旅程和护理的宝贵见解。[73] 但是，高达80%的健康结果可能由非临床因素造成，如交通、教育、就业机会、营养食品和安全住房等。[74]

这种非临床数据被称为健康的社会决定因素（SDoH），传统的RWD通常无法捕捉到这些数据。[75] SDoH是指人们生活、学习、工作、娱乐和礼拜的环境条件，这些环境条件影响着广泛的健康和生活质量结果及风险。[76]

深入了解上述因素可助力有效改善患者旅程，因此，德勤展开投资，将Komodo的“医疗保健地图（Healthcare Map）”与其HealthPrism SDoH数据集（美国最大的SDoH数据集之一）相结合，以更全面地了解患者、其护理旅程及其结果。[77]

例如，数字医疗技术和移动电话的广泛使用，可以让中低收入国家患者和其他弱势患者，尽管交通不便，也能通过家庭监测设备、医疗保健应用程序、可穿戴技术和远程医疗服务积极参与护理。[78]

探寻数字触点机会

为照顾患者的个性化需求和关注事项，生命科学公司应当秉承以人为本的护理理念，采用个性化的互动方式，并通过数字方式与患者建立联系。[79]

数字驱动的个性化医疗有助于改善治疗的可及性。[80] 德勤ConvergeHEALTH Connect™可在患者旅程中创建增强型数字触点。[81] 通过典型对比，您可以观察到癌症和慢性病患者旅程的差异 (图2) 。[82]

罕见病患者旅程中的触点

罕见病患者多会经历艰难的诊断过程，并需多学科协作出具治疗方案。[83] 在此过程中，患者在诊断之前往往面临复杂的专家体系、检测限制和报销烦恼，更不必说治疗了。[84] 部分公司正在通过减负举措和个性化体验来改变现状。例如：

- **PANTHERx**简化了向罕见病患者提供药物的相关流程，并纳入了患者教育和依从性计划。RxARECARE团队专注于探究独特的疾病状态和患者可接受的特选药物。个性化护理团队自始至终负责账单流程，并处理突发事件，如更换损坏的冰箱、报销费用等，以减轻患者负担，避免患者因药物储存不当而延误治疗。[85]
- **MMIT**为制药和医疗公司提供患者访问数据和分析。Carolyn Zele是一位罕见病幸存者，现任该公司的市场准入专家。她时刻呼吁制造商了解患者的困境。“当患者处于最虚弱、最脆弱的时候，他们不应为诊断或护理协调问题而忧心，也不应为支付问题而多次向支付机构或制造商申诉。” Zele建议制造商应充分调查患者就医的曲折，深入了解现有的就医障碍。制药公司可通过深入了解患者旅程来改善治疗的可及性。[86]

图2：肿瘤患者与糖尿病患者旅程的联系比较

资料来源：德勤ConvergeHEALTH

肿瘤患者旅程中的触点

医疗服务需求日益增长的同时，全球癌症负担也在不断加重。据世界卫生组织报告，2022年全球新增癌症病例约2,000万例，预计2050年将达到3,500万例。[87]

全球约五分之一的人一生中会罹患癌症，但患癌者的平均寿命有所提高。[88] 数据显示，约5,350万人在确诊患癌后五年内仍然存活，[89] 但多数人因未得到必需的后续治疗，面临着持续的健康挑战。[90] 约九分之一的男性和十二分之一的女性死于癌症。[91] 肺癌、乳腺癌和结直肠癌是全球发病率最高的癌症。[92]

改善癌症的早期诊断

要改善癌症患者的生活体验，以人为本的护理不应只是“有就好”。[93] 患者希望轻松高效地了解癌症治疗的各个阶段，个性化的患者旅程应包括为患者及其亲人提供基于需求的服务。[94]

早期症状发现和及时就诊是癌症早期诊断的关键。[95] 如果癌症治疗延误或无法获得，存活几率便会降低，后续治疗难度和费用也将随之上升。[96]

在英国，大多数癌症都是在急诊室确诊的。[97] 只有乳腺癌和宫颈癌能在常规筛查中发现，结肠癌的发现率也较低。[98] 英国领先的慈善组织麦克米伦癌症援助机构 [99] 正在引入癌症电子风险评估 (ERICA) 试验。[100] 作为Skyline软件的一部分，ERICA正在测试六种工具在提高转诊率方面的临床效果，特别是在早期诊断阶段。[101]

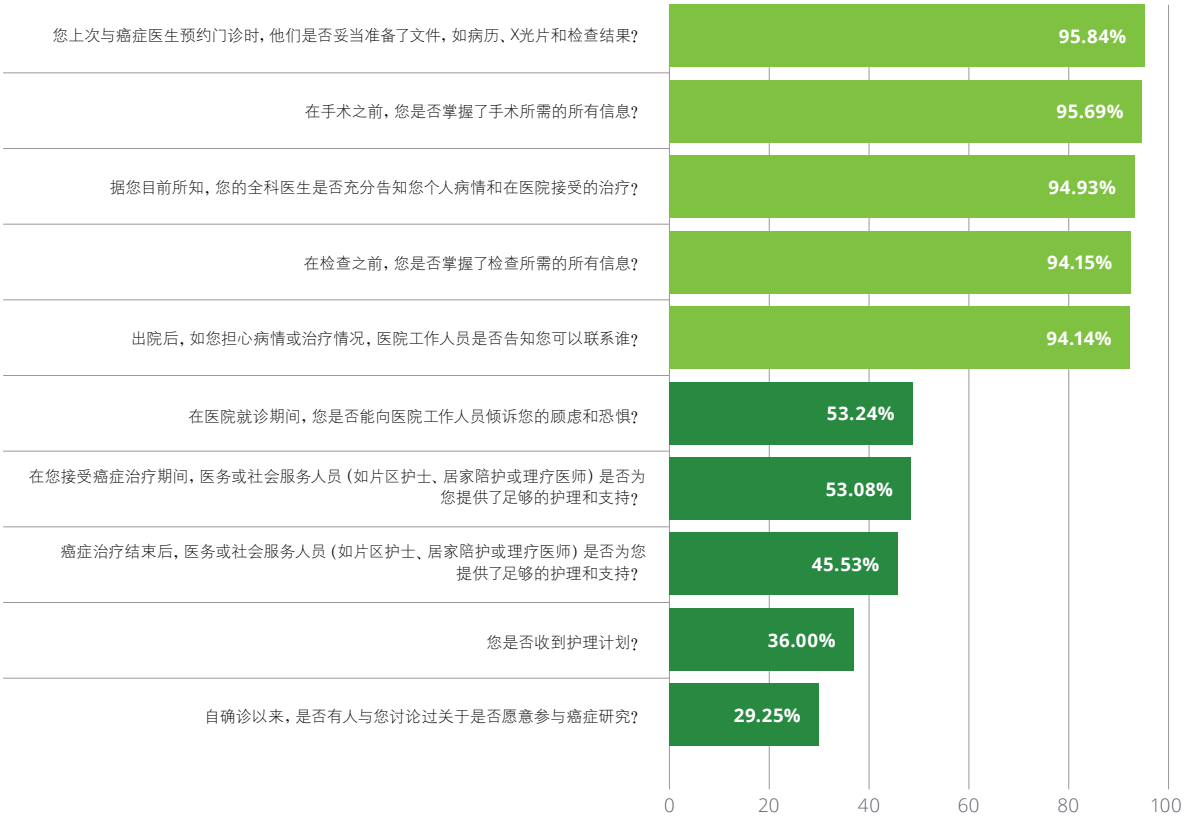
改善癌症患者的生活体验

一项关于英国癌症患者经历的全国性调查 (图3) 显示，不足54%的受访者表示英国国家医疗服务体系 (NHS) 在其住院治疗和后续治疗期间提供了情感支持 (图3) 。[102] 不到一半的受访者认为其在治疗后获得了所需的护理和支持，仅三分之一的受访者收到了护理计划。不到30%的受访者称其在确诊后进行了关于是否参与癌症研究的讨论。[103]

由于许多癌症患者的寿命延长，未来愿景的实现有赖于对癌症患者在治疗期间及之后提供的持续支持。[104] 癌症患者应始终能够以其认为有意义的方式充实地生活。[105]

德勤英国携手麦克米伦癌症援助机构在英国开展了一项关于重塑癌症患者未来医疗体验的研究。[106] 该研究于2023年1月报告了一项与癌症患者生活经历相关的未来愿景预测，包括当前医疗体系的哪些方面存在缺陷以及哪些方面需要采取行动 (图4) 。[107] 各组织不妨利用这一愿景进行情景规划，帮助实现癌症患者健康美好的未来。[108]

图3：关于英国国家医疗服务体系（NHS）癌症护理的患者体验调查



资料来源：Picker，全国癌症患者体验调查，2021年。数据和表格：2018年

图4：癌症患者的未来医疗和生活体验，以及行动战略

人们对癌症风险和症状的了解及认知

- 随着癌症筛查的普及，更多人能够**更深入地了解癌症风险和自身健康状况**，从而**更早发现癌症征兆和症状并采取行动**。
- 采取**因地制宜**的方法，**提高全民健康素养，增进全民对健康和健康服务的理解、认识和信任**，尤其是在医疗水平相对落后的社区。

以人为本的护理（包括关爱医护人员的福祉）

- 人们能公平地获得个性化的护理体验。
- 更加**重视个人需求**，并**衡量对癌症患者至关重要的结果**。
- **数字工具**的规模化应用可补充医护人力资源，为医患提供支持并满足其整体需求。更多技术将根据个人需求提供支持，最大限度地为癌症患者及其亲友带来积极影响。

与癌共存、战胜癌症及临终关怀*

- 随着癌症及其他长期疾病患者寿命延长，基层、**社区和二级医疗机构将加强协调，以提供全面支持**。
- 医疗机构的**工作方式也将发生重大转变**，从各科“单兵种作战”转变为多学科联合会诊。
- **大部分临终关怀将**从二级/三级医疗中心**转移至社区/家庭。死亡和临终关怀文化将发生转变**，癌症患者期望**就临终及其选择进行开诚布公的对话**。

护理地点

- **社区诊断**（包括血液检测和地方诊断）**将在癌症诊断中发挥更大效用**。
- **社区和家庭护理**将贡献更多力量，凭借创新解决方案（如化疗巴士、虚拟病房）并提升全科医护队伍的癌症知识水平，满足相对简单的癌症护理需求。
- 减少对专科中心的依赖，**提高其提供新型疗法**治疗复杂癌症的能力。
- 虚拟多学科联合会诊（MDT）实现三级医疗中心专家与本地广大医务人员的无阻沟通，**减少病人长途跋涉前往专科中心的需求**。

资料来源：德勤英国和麦克米伦癌症援助机构，“重塑未来癌症患者护理”，2023年1月。

癌症护理导航（包括治疗后）

癌症护理导航，是帮助癌症患者克服癌症护理过程中各种障碍的一种策略，其重要性正与日俱增。[109]最新证据表明，为患者提供导航式服务可提高患者的生活质量和对生存期护理的满意度，并减少积极治疗和生存期护理阶段的再入院率。[110] 缓和医疗的数据有限。[111]

多项计划有助于解决癌症防治中显著的种族、民族和社会经济差异，包括接受筛查的机会。[112] 生存计划还有助于提高治疗后患者的生活质量，帮助患者找到资源和社区。[113] 计划示例如下：

- **患者导航服务**：美国政府启动的“抗癌登月”计划优先考虑为癌症患者提供支持性服务，并强调扩大患者导航服务的重要性。[114] 该计划为患者、护理人员和家属提供个性化协助，通过护理协调和宣传，帮助他们了解并获得高质量和及时的癌症护理，持续到治疗后。[115]
- 美国首个患者导航计划于1990年由Harold Freeman博士发起，旨在改善纽约边缘化社区的健康状况。[116] 2023年底，美国医疗保险与医疗补助服务中心 (CMS) 最终确定了主要疾病导航 (PIN) 服务的代码，医疗机构凭此收取导航服务的费用。2024年初，七家大型私人医疗保险公司也同意承担癌症导航服务费用。[117]
- **合作促进医疗公平**：美国癌症协会 (ASC) 与辉瑞发起一项为期三年的计划，以改善美国医疗机会不平等的现状。目前，该计划正在努力提高人们对癌症筛查、临床试验机会、患者支持和综合癌症导航的认识，并提升这些服务的可及性。[118]
- **与非临床机构合作，实现医疗公平**：2023年底，ACS推出了ACS CARES（社区资源、教育和支持获取）计划，该计划旨在通过多渠道、定制化服务，为癌症患者和护理人员提供非临床患者导航支持。对于不太习惯使用数字工具的患者，该计划还在肿瘤诊所安排受过良好训练的大学生和研究生志愿者，帮助患者和护理人员获得非临床、个性化的面对面支持。德勤医疗公平研究院 (DHEI) 承诺提供100万美元，用于拓展该计划。
- **癌症幸存者计划**：体育锻炼是促进癌症康复的重要手段。[119] 在美国，“LIVESTRONG at the YMCA”癌症幸存者计划正引领癌症患者、康复者组成小组，提高其体能和健康水平，相互提供情感支持。[120] 根据耶鲁大学癌症中心和哈佛大学丹娜法伯癌症研究所的研究，该项专门计划参与者的体能和生活质量均得到了改善，与癌症有关的疲劳感也显著减少。[121] 该计划为期12周，在全国逾790个基督教青年会 (YMCA) 开展，服务于400个社区。[122]

生命科学和医疗科技公司可以考虑创建、赞助或以其他方式参与类似计划，以更好地了解癌症幸存者的心路历程和持续需求。例如，为一些健身计划活动提供可穿戴设备，为癌症幸存者提供往返医疗机构的交通服务，以及举办活动提高人们对心理健康辅导资源的认识，或解答有关参与临床试验的问题。

早期检测、康复和预防诊断需求与日俱增

越来越多的年轻人罹患癌症

自1975年以来，部分癌症的生存率大幅提高，从49%升至68%。[123] 例如，非霍奇金淋巴瘤患者的生存率现为74%，而50年前为47%。[124] 筛查技术的进步使得癌症得以在早期被发现和诊断，此时治疗产生积极结果的几率更高。[125]

但是，全球50岁以下人群的癌症发病率在三十年间激增80%。[126] 一位美国肿瘤学家10年前开始注意到这一趋势。她为一名从中国飞来的青少年进行治疗，这名青少年患上一种通常见于65岁及以上人群的胃肠道疾病，但癌症已到晚期，回天乏术。[127]

全球肿瘤学家正在接诊越来越多的年轻癌症患者。[128] 在全球范围内，40岁以下的年轻人最常见的癌症是乳腺癌，[129] 在美国，40岁以下的女性中有90%以上是在30岁至39岁之间被诊断出患有乳腺癌。[130] 在多个国家，十多种癌症的发病率正在上升。[131] 在美国，结直肠癌已成为50岁以下男性的首要死因。[132] 人们越发需要更好的筛查、认识和治疗。[133]

某些癌症（卵巢癌和白血病）患者也往往会经历不断的复发和缓解，[134] 这些疾病可与慢性病一样加以管理。[135] 随着各种癌症患者的寿命延长，慢性病患者的人数增加，重新评估患者自主权在慢性病和癌症中的作用，可能有利于重建信任和推进以患者为中心的护理。[136]

针对阿尔茨海默病早期诊断开展的新型生物标志物研究

中国已成为阿尔茨海默病患病人数最多的国家，有近1,000万病例。[137] 然而，超过21%的患者年龄在60岁以下且处于工作年龄，这就催生了早期筛查和诊断需求。[138] 目前，阿尔茨海默病（AD）影响着美国近700万人和全球约3,200万人。[139]

开发更多的生物标志物，是为阿尔茨海默病早期诊断带来最大希望的途径之一。[140] 除影像学检查和脑脊液（CSF）检测外，还迫切需要简单经济、无创易得的诊断工具（如血液检测）来诊断疾病。[141]

> “生物标志物领域目前发展迅速。血浆和血液生物标志物正在超越我们所看到的——与疾病阶段和病理存在高度相关性，这将有助于提高早期检出率，并有可能为患者量身定制治疗方案。”
>
> —**Acumen首席执行官Dan O’ Connell**[142]

Acumen的sabirnetug项目（ACU193）正在深入研究与阿尔茨海默病有关的关键生物标志物。[143] Sabirnetug（ACU193）是Acumen发现并开发的一种人源化单克隆抗体（mAb），可选择性靶向可溶性β淀粉样蛋白低聚物（AβOs）。[144] 越来越多的证据表明，可溶性AβOs是造成阿尔茨海默病神经退行性病变的最根本原因，sabirnetug旨在通过选择性靶向毒性可溶性AβOs直接解决这一病因。除能减缓疾病进程外，其另一显著特点是可能改善认知能力。[145] Acumen近期宣布，其ALTITUDE-AD研究（一项评估sabirnetug对于阿尔茨海默病早期患者疗效的II期试验）的首位患者已接受给药[146]

其他新型生物标志物研究包括视网膜成像、皮肤和唾液检测。此类生物标志物的检测尚处于探索阶段。[147]

智能设备实现更个性化的护理和康复

智能设备可远程收集用户数据并提供健康反馈，辅助得出更快、更个性化、更准确的医疗保健结论，因而用于加快诊断和康复进程。[148]

- **智能植入物**：捷迈邦美 (Zimmer Biomet) 的Persona IQ“智能膝关节”通过远程跟踪患者的活动范围、步态异常、功能、疼痛等，可检测患者的康复进展是否符合预期。[149] 其目标是减少再入院率和复诊率。该软件提供个性化的术后智能指标，通过护理管理平台和自动数据流与患者建立联系。 [150]
- **计算机视觉**：Senseye的新型心理健康诊断平台利用眼生理学表达的数字生物标记物来诊断心理健康。[151] 这种基于大脑的方法使用计算机视觉和专有的机器学习算法，可在任何智能手机上运行。[152] 该公司的首要目标是实现创伤后应激障碍 (PTSD) 的快速诊断。该设备旨在帮助临床医生进行个性化护理，并通过15分钟的眼部测试诊断创伤后应激障碍，省却使用其他评估方式进行为期数月的诊断。[153]

预防性护理和直接面向消费者的诊断服务

部分患者开始争取更多的自主权，生命科学公司正在探寻新的渠道和合作伙伴，以直接与患者互动，而不是仅仅依赖医护人员。[154] 更多直接面向消费者 (DTC) 的医疗服务正在推出，以便迅速应对患者的关切和偏好。[155] 随着这些服务日益高效普遍、经济安全，它们很可能会越来越受欢迎。

许多人认为血液检测和筛查程序可以提供信息并起到预防作用，但它们可能不在保险范围内，或者说，消费者可能不想等待或付费预约医生进行检测。[156] 患者可能听信他人所言认为某项检查没有必要 (而这项检查或许能救命)，[157] 还有一些检查可能是在浪费时间。[158]

- **DTC磁共振成像**：Prenuvo网站呼吁消费者“将健康掌握在自己手中”，警惕病情恶化，及时发现风险。[159] Prenuvo提供AI辅助扫描，包括全身磁共振成像扫描，可筛查500种疾病。 [160]

  女演员兼电视节目主持人Maria Menounos便是通过Prenuvo扫描技术在早期 (II期) 发现了癌症，现成为少有的胰腺癌幸存者之一。[161] 通过美国食品药品监督管理局 (FDA) 批准的扫描和其他筛查技术，大多数胰腺癌通常要到IV期才会被发现，而在这一阶段所发现疾病的五年生存率通常仅为1%。[162] 然而，2,500美元或更高昂的收费却令许多人望而却步，且关于扫描技术的风险也存在一些争议，包括假阳性情况可能导致不必要的流程及费用。
- **DTC实验室检测**：直接获取检验 (DAT) 或DTC实验室检测使个人能够直接从临床实验室订购自己的医学检验，并由实验室为其指定医生。[163] DAT受制于分散的监管环境，在某些司法管辖区可能无法使用。[164] 预计到2030年，DTC实验室检测市场规模将高达15.9亿美元，这标志着个性化诊断带来了医疗行业趋势的范式转变。[165] 有预测显示，2023年至2030年个性化诊断市场的复合年均增长率 (CAGR) 将达到10.8%。[166] 慢性病和性传播疾病发病率的上升，以及药物基因组学检测在DTC实验室检测领域的日益渗透，也成为该市场增长的驱动因素。[167] 相关挑战包括基因数据隐私、检测结果潜在误读以及专业医疗咨询需求。[168] 存在的其他问题，如样本完整性、监管问题、与传统实验室检测相比有限的检测组合以及缺乏报销机制，都可能阻碍增长。[169]

管理2型糖尿病的慢性病之旅

糖尿病是全球常见的、医疗费用高昂的慢性病之一，其发展速度之快超出许多医疗机构的管理能力。[170] 健康饮食和体育锻炼是糖尿病的控制要领，虽然一些干预措施已被证明能有效改变某些行为，但要实现可持续的长期效果仍面临挑战。[171]

过去十年，糖尿病患者旅程发生了变化，现已成为数字驱动个性化医疗的一部分。许多数字解决方案纳入了远程患者监测、行为和生活方式调整、辅导支持和营养性酮症管理等服务组合。[172]

用于治疗肥胖症和糖尿病前期的GLP-1类药物的发展，也将在2型糖尿病管理中发挥重大作用。有关GLP-1糖尿病药物发展的进一步阐述，请参阅本报告的“价值创造”章节。

糖尿病数字管理工具需要更多循证研究

最近的研究对用于跟踪和管理患者2型糖尿病的数字管理工具的有效性提出了质疑。[173] 彼得森健康技术研究所（PHTI）进行的研究表明，所评估的主要工具并不能带来有意义的临床效益，而且与常规护理相比，还会增加医疗支出。[174] PHTI称，使用这些工具仅能使人血红蛋白A1c (HbA1c) 小幅下降。[175]

PHTI希望提高期望和证据的标准，部分机构也认为需要对解决方案进行更严格的评估。[176] 但数字疗法联盟等一众机构对上述研究结论或方法表示不认同。[177]

研究的初步数据显示，一种“有前景的解决方案”——Virta Health，可能更有望带来有临床意义的益处。[178] 这家数字医疗公司旨在通过个性化营养疗法和远程医疗（包括电话保健）逆转2型糖尿病，同时控制患者的处方成本。[179] PHTI证实，如果患者能够坚持严格的饮食干预要求，Virta Health更有可能控制血糖和缓解病情。[180]

此外，Virta Health近日在《糖尿病治疗》杂志上发表了其关于营养疗法的研究报告，称该疗法有望成为GLP-1药物的替代疗法。[181] 许多患者在停用GLP-1药物后面临体重反弹的问题，Virta Health的研究结果可能会对希望改善会员健康状况的医疗服务机构及计划产生重大影响。[182]

支持慢病患者的自主权

慢性病管理的一个重要部分就是患者自主。[183] 糖尿病的自我管理通常会受到个人自主权和社会支持的影响。[184] 中国的研究人员发现，支持2型糖尿病患者自我管理，有助于患者保持自干预结束后六个月内的血糖控制。[185]

疾病或残疾患者的日常生活经历会影响他们对病痛的认识和理解。[186] 尊重和支持患者的自主权并不意味着医护人员认同或肯定患者的不同信仰和看法，但告知建议或提高患者的理解是必要之举。尊重患者及其自主表达，有助于建立信任。[187]

监管机构更注重衡量对患者最重要的因素

由于患者往往长期忍受病痛的折磨，清楚其症状的复杂性，因此美国FDA逐渐希望了解患者如何描述自身健康状况，以及如何在没有他人解释的情况下评估自身治疗效果。[188] 患者报告结局 (PRO) 和临床结局评估 (COA) 所提供的信息可用于帮助选择或开发工具，以衡量对患者最重要的因素，并制定未来政策。 [189]

目前并无对健康相关生活质量 (HRQoL) 评估的统一标准，也无有效方法将HRQoL数据纳入治疗药物评估。[190] 将HRQoL作为最终目标，可从患者的角度提供有关功效和治疗副作用的重要信息。[191]

在临床试验中将PRO和HRQoL作为标准实践，可以对正在开发的疗法进行更全面、以患者为中心的评估，并有助于指导患者和医护人员就临床护理中的治疗方案进行讨论。[192] 吉利德、赛诺菲、阿斯利康、渤健和卫材等领先制药公司正开始在艾滋病、慢性阻塞性肺病、糖尿病神经病变和阿尔茨海默病的临床试验中采用更新的方法来评估HRQoL。[193]

提高长寿生活质量，推动健康未来发展

长寿人口不断增加，生活质量的重要性也将日益凸显，[194] 中老年人对生活质量和长寿的偏好可能会影响他们的寿命。[195] 长寿研究方面的突破——人类为什么会衰老、如何衰老以及减缓衰老过程的干预措施——预示着部分人有可能远超过目前的预期寿命。[196]

延长健康寿命，而不仅仅是寿命

模式正在发生转变，从以疾病为中心的治疗方法转变为聚焦衰老、生物系统和健康根本机制的治疗方法。[197] 我们的目标是延长健康寿命，而不仅仅是寿命。[198]

老龄人口不断增加。[199] 部分人口寿命虽有所延长，但其身体机能和生活质量却双双下降。[200] 此外，数字化生活导致许多人久坐不动，从而增加了患病风险。[201]

以长寿为重点的治疗理念能否帮助改善现状？德勤美国针对10个治疗领域展开分析，发现了两种极端情况——正在恶化的疾病领域和正在改善的疾病领域 (图5) 。[202]

在15年的寿命跟踪调查中，由于生活方式的恶化 (肥胖、2型糖尿病) 和老年人口的增加，正在恶化的治疗领域的健康寿命和寿命都在缩短，这意味着因残疾和早亡所致的健康寿命/寿命损失年数在增加。[203] 衰老是神经和肌肉骨骼疾病的主要风险因素。癌症和心血管疾病治疗的进步是寿命延长的主要原因。[204]

新兴长寿生态系统

一个由生命科学、医疗保健和健康科技公司组成的生态系统正在不断兴起壮大，重点探究疾病和老龄化的根本原因及其解决方案 (图6) 。[205] 在全球范围内，风险投资者纷纷加大对旨在延长人类寿命和改善老龄化期间健康状况的创新解决方案的投资。[206] 例如，总部位于德国勒沃库森的拜耳旗下Leaps by Bayer (拜尔飞跃计划) ，截至2023年已向多家生物科技和健康相关公司投资约15亿美元，致力于推动老龄化和老年相关疾病领域的发展。[207]

图5：长寿疾病矩阵

分析说明

健康寿命和寿命

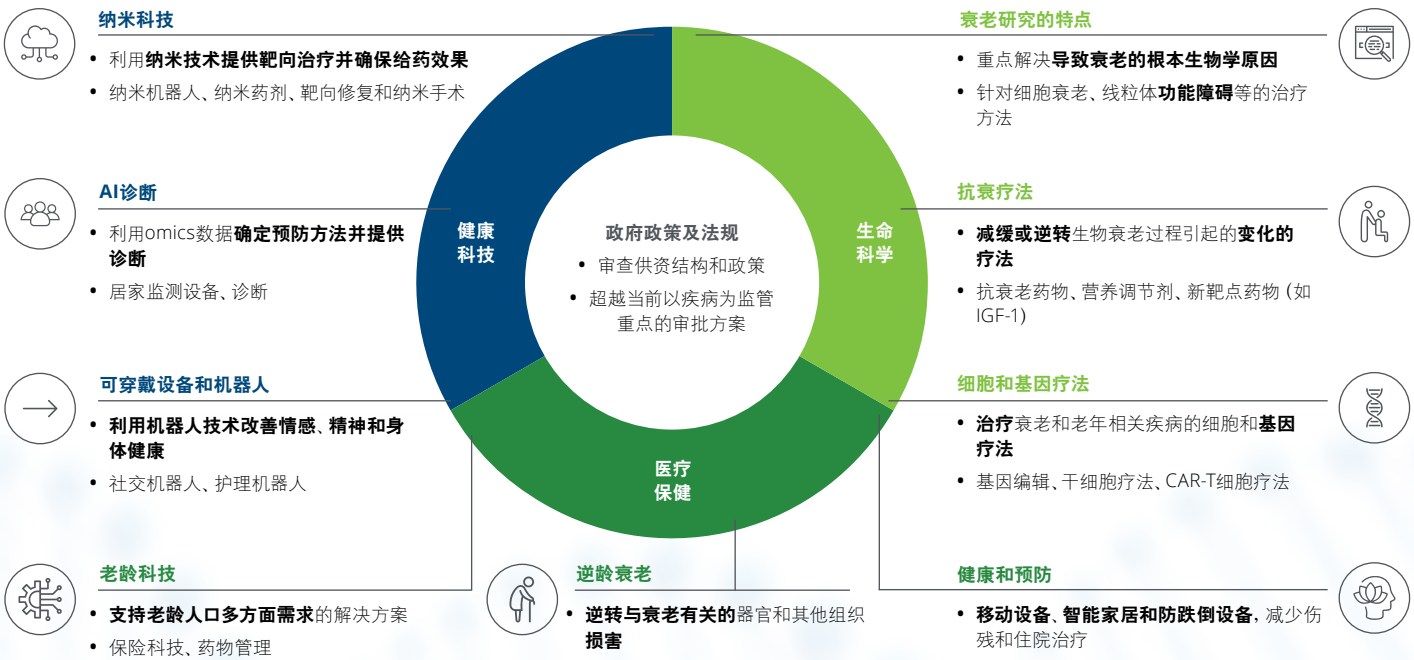
- 图表说明了2000年与2015年某疾病患者的差异，及其健康寿命或寿命情况。
- 例如，与2000年相比，2015年癌症患者的平均健康寿命和寿命明显更长。

药物批准

- 已批准药物数量可用于衡量生命科学行业在特定治疗领域的集中度。
- 疾病领域的集中度与健康寿命和寿命的改善之间不存在统计相关性。

资料来源：德勤美国 “Living a 140-year long and healthy life”，2021年。

图6：长寿生态系统



资料来源：德勤美国 “Living a 140-year long and healthy life”，2021年。

生命科学

我们预计，健康科技、生命科学和医疗保健之间的融合将持续支持生态系统不断发展壮大，以延长人类寿命。长寿研究将彻底改变医疗市场，而选择接受前瞻性长寿思维的生命科学公司认识到，健康未来是——治疗方法应能够预防疾病和促进健康，而非基于治疗的反应式护理。

医疗保健

医疗机构应优先考虑患者的健康，并制定超个性化的预防解决方案。由于个性化医疗能够提供以患者为中心的健康和医疗服务，并有可能提高疗效和降低成本，因此个性化医疗极有可能继续成为未来医疗保健的核心领域之一。

保险公司

公共和私营保险公司应重新审视其产品，并考虑增加服务和产品，为更长寿、更健康的人群提供支持。

健康科技

随着各公司利用现实世界的证据和数据，并充分把握向健康和个性化医疗的转变，健康科技正在迅速发展。新兴技术和数据驱动的决策开始加速快速诊断、治疗选择和实施。这些技术为老龄人口带来的诸多益处尤其不容小觑。

患者

健康老龄化因社会制度、教育、生活方式行为和健康素养不同而各异。[208] 很少有研究认识到老年人的自我护理行为有可能延长其晚年独立生活，而动机在长寿方面的作用在很大程度上也被忽视了。[209] 威尔士卡迪夫大学的研究发现，可选行为、自我反思和自主支持有助于预测长寿群体。[210] 随着各公司投资于长寿研究，其可能也将更深入地考虑患者自主权在健康老龄化中的作用。[211]

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尾注

价值创造：借助并购、建立合作伙伴关系、达成协作、寻找新的资本来源和调整投资组合等策略实现价值创造

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2024 Global Life Sciences Sector Outlook

Driving resiliency

Contents

Introduction

With the global pandemic firmly in the rearview mirror, life sciences companies are looking at key macro- and micro-economic drivers to guide their future growth. While the list of trends with wide-ranging global impact is broad, in this year, life sciences enterprises are paying particular attention to those more disruptive trends including increasing pricing pressures and changes in United States regulation, the acceleration of Generative AI (GenAI) adoption and impact, the geo-political environment, and as always, breakthrough science and outcomes. Companies are exploring how the evolution of GenAI can impact their operations and determining where to focus first and how to generate differential value. The potential of advanced technologies and these collaborations are directly integrated with life sciences companies' overall efforts to improve patient outcomes and inform their R&D decisions.

Companies are looking to the potential of GenAI to bring more value across the board—both in terms of cost reduction and revenue uplift. GenAI and other AI technologies, coupled with digital transformation tools, are poised to increase overall efficiencies and process innovation across many areas of the life sciences value chain. A top 10 biopharma company with an average revenue of US$65-75 billion could capture between US$5-7 billion of peak value by scaling the use of AI over 5 years.[1] The promise of AI and GenAI is expected to yield new partnerships in the rest of 2024 as large companies look to obtain technological capabilities, secure industry talent, and drive competitive advantage.

In the coming year, pharma companies will be finetuning strategies to create top-line value through strategic acquisitions with a cautious but active mergers and acquisitions (M&A) and capital environment expected as inflation is expected to lessen and interest rates likely stabilize. An active acquisition market may also offset loss of exclusivity patents, which could cost life sciences companies more than US$200 billion in revenue.[2] However, when it comes to M&A, companies should continue to expect regulatory scrutiny over antitrust concerns.

Partnerships and collaborations in conjunction with AI and GenAI are also driving new trends in accelerating the speed of time to value in R&D. With ongoing regulatory changes, pricing pressures, and loss of exclusivity in 2024, companies will need to harness the power of innovation[3] and leverage the potential of AI and GenAI to demystify complex disease biology, expedite drug discovery, cut study timelines, revitalize the clinical trial experience, and improve regulatory success. Leading biopharma companies are already adopting new AI/GenAI technologies and other data innovations across the value chain, while forming new partnerships, collaborating early with regulators, and outsourcing for cost and time savings.

Pharmaceutical trade started to rise in the third quarter of 2023,[4] and the global market for pharmaceuticals is expected to reach almost US$1.2 trillion in 2024.[5] During the pandemic, trade and supply chains were vital to increasing the production and distribution of medical supplies and vaccines,[6] however, in the past two years, global trade is noticeably more concentrated and geopolitically closed. This means major markets are increasingly relying on a smaller pool of trading partners[7] with attempts to protect and build local markets on the rise. As such, multinational corporations (MNCs) are lobbying government officials to find ways to temper the blow of export controls.[8]

MNCs are also working with governments to address drug pricing and value, which continue to come under scrutiny as pricing pressures are being felt globally.[9] While less-developed countries have voiced concerns over the unaffordability of medicines for decades, developed-world concerns around drug pricing are now pushing unaffordability to the top of the global health agenda.[10] In the rest of 2024, government-mandated pricing pressure and controls are expected to play an increased role in the affordability and accessibility of certain medicines.[11]

All of the above efforts underscore the foremost area of focus for life sciences companies: delivering better outcomes for patients. Companies have been focused on directly and indirectly improving patient experiences with the intent of ultimately improving their health outcomes. The data are bearing that out. Life sciences executives surveyed by Deloitte US believe that the leading action their organizations need to take in 2024 is "improving the patient experience, engagement, and trust."[12] With personalized care and treatments supporting better experiences, biopharma and medtech companies are exploring the many opportunities to improve touchpoints throughout the patient journey.[13] This includes a proactive and predictive approach to what patients need.[14] And as the process becomes more digitally enabled and personalized, it is also expected to become more "straightforward" and seamless. All of this will be to the benefit of patients and their long-term outlook.

In this outlook we examine what we see as disruptive trends like the impact of Gen-AI, the growth of the obesity market and treatment with GLP-1s, the IRA's first full year of impact as well as those trends which are more evolutionary in nature—like the continued complexity around navigating globalization in an uncertain geopolitical environment or the continue advancement of more personalized patient experiences. With geopolitical, economic, and regulatory landscapes still proving uncertain, life sciences will likely need to continue relying on innovation, agility, and collaboration as they build on their strong commitment to bettering the lives of patients.

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Value creation: M&A, partnerships, collaborations, new sources of capital, and shifting portfolios

Cautious optimism in 2024

The economic and geopolitical climate will likely continue to impact decision-making in 2024.

Over the past year, life sciences and medical technology (medtech) companies have been managing inflation, rising interest rates (which can curtail access to capital), and slower economic growth. However, in 2024, inflation seems to be lessening, rates appear to be stabilizing, if not dropping, and growth is likely to be moderate—setting up a cautious, but still active mergers and acquisitions (M&A) and capital environment.

M&A activity collectively in biopharma, platforms, medtech, and diagnostics was brighter than many expected in 2023—with 254 M&A deals and US$209.8 billion in total announced value—eclipsing 2022 figures of US$143.5 billion.[1] The overall sector fared better than the overall M&A market where US and global total deal value across all sectors fell 11% and 18% respectively, compared to 2022.[2]

Valuations grew for life sciences companies in most stages of their life cycles over the past year. In 2024, pharma companies will be finetuning strategies to create top-line value with strategic acquisitions, while also planning for long-term bottom-line improvements, including divestitures and cost reductions.

While glucagon-like peptide 1 (GLP-1) obesity drugs have been a boon for pharmaceutical companies, their rise, along with macroeconomic headwinds, are creating uncertainty for medtech valuations, which were down US$300 million in 2023. However, fundamentals are strong, and medtech leaders are bullish on growth in 2024, given the improving supply chain situation.

M&A: Creating momentum

Pharma's megadeals put buying power on display

A primary driver of strength in 2023 were large/mega cap pharmaceutical companies with undeployed capital (figure 1).[3] Dealmakers are paying healthy premiums for assets with high commercial potential with oncology being the strongest therapeutic area attracting investment.[4] The top 10 megadeals closed in 2023 were each worth more than US$4 billion, led by multibillion dollar deals by Pfizer/Seagen (US$43 billion) and Bristol Myers Squibb/Karuna Therapeutics (US$14 billion).[5] A number of the leading acquisitions involved medicines either nearing regulatory approvals or in advanced testing.[6]

In 2024, companies should continue to expect regulatory scrutiny for a variety of investment activities. To facilitate the Pfizer/Seagen deal and address antitrust regulators' concerns, Pfizer agreed to donate the rights of royalties from sales of cancer drug Bavencio to the American Association for Cancer Research.[7] At the end of 2023, the US Federal Trade Commission (FTC) also settled its Amgen/Horizon Therapeutics acquisition challenge.[8]

"Blockbuster and mega blockbuster product opportunities are getting the most attention in M&A, and that will likely continue over the course of 2024. Once the best late stage assets are picked up—we should start to see more partnering and M&A for earlier stage assets, as there is a lot of interest in accessing new product growth opportunities."

—**Daniel O'Connell**, CEO, Acumen

Figure 1. 2023 M&A deal characteristics in life sciences by buyer groups

	Small/mid-cap	Large/mega cap	Private equity	Private strategic
Pharmaceuticals	**Pre-clinical oncology;** milestone payments are common, contingent on commercialization + regulatory	Acquisitions of companied with **approved oncology assets,** particularly in the **ADC space**	Driven largely by one acquisition in the **antibiotics space** seen as a platform for further growth	Acquisitions of **approved and late-stage rare disease assets**
MedTech & diagnostice	**Geographic expansion i**n orthoperdics and **consolidate play in spine**	Tuck-in deals across various therapeutic areas, including neurovascular, diabetes, and spine	Minimal activity	Large transaction in interventional urology; otherwise, limited tuck-in activity
CRO/CDMO/supplier	Strength in **cell and gene manufacturing** and supportive AI tools for biological drug develop-ment	Considerable investments in products used in **protein-based drug therapy development**	Significant capital deployed into both **CROs and CDMOs**	Small asset acquisitions of life sciences suppliers

Total deal value <$1B Total deal value $1-$5B Total deal value >$5B

Source: Deloitte analysis

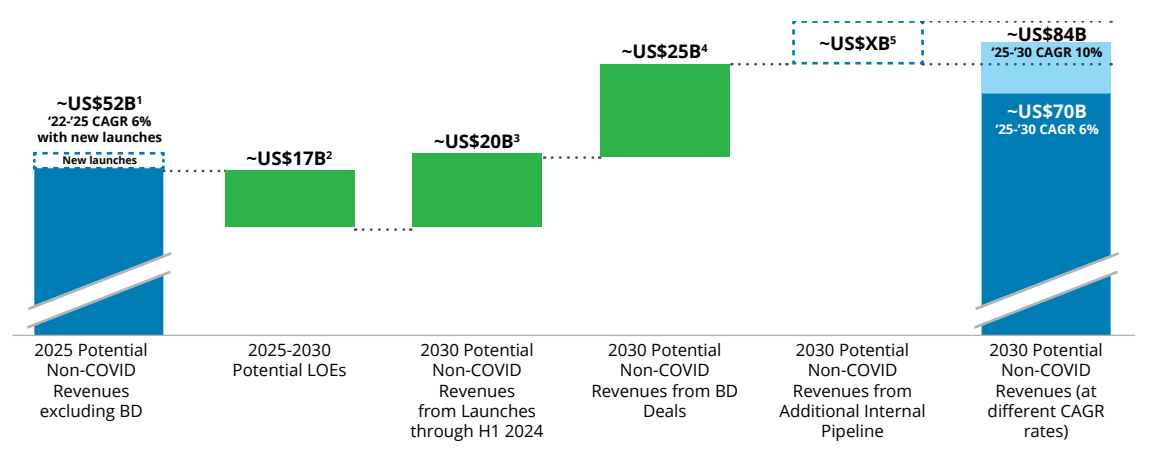
Over the next year, some big pharma companies will continue to look to M&A to plug portfolio gaps as a result of loss of exclusivity (LoE) across various therapeutic areas. In particular, late-stage development/early-stage commercial assets—that could contribute material revenue growth over the next few years—are expected to be attractive targets.[9]

Pharma M&A strategy highlight: Offsetting loss of exclusivity (LOE) with new acquisitions

Successful acquisitions may offset LOE patents for large pharmaceutical companies. Between 2022 and 2030, pharma companies will likely lose more than US$200 billion in revenue from the anticipated tectonic patent cliff.[10]

Pfizer, which faces US$17 billion in potential LOE between 2025 and 2030 and significant undeployed cash on their balance sheet from their COVID-19 portfolio, closed the largest M&A deal for biopharma in 2023. In its US$43 billion deal to acquire Seagen, Pfizer gained a market leader in antibody-drug conjugate technology to strengthen its position in oncology.[11] Pfizer projects an increase of US$3.1 billion in 2024 for top-line growth directly from the deal as well as bottom-line improvements over the long-term plan (figure 2).[12]

Figure 2. Pfizer's long-term plan to strengthen top-line growth after acquiring Seagen (illustrative)



Source: Pfizer, "Pfizer Invests $43 Billion to Battle Cancer," March 13, 2023

Pharma's near-term divestures/cost reductions

The immediate term may look bleaker as multiple pharma giants announce divestitures and cost reductions[13]—[14]including some work force cuts. Pipeline assets may be sold to other big pharma companies, while others sell to smaller companies and retain minority stakes. Given a few high-profile successes, this trend is likely to continue in 2024.[15]

As a result, freed-up capital may be deployed into accretive transactions.[16] While cautiously optimistic for 2024,[17] many experts expect that deal volume and value will pick up over the next year.[18]

Medtech returns to growth after 2023 divestitures

While pharma M&A activity was a bright spot in 2023, medtech and diagnostics M&A was not as strong. Over the past year, activity declined across M&A and venture, but the decline was not unexpected as medtech companies focused primarily on portfolio rationalization, divestitures, and cost transformation.[19] According to Deloitte US research, divestitures are being used to reduce debt and improve capital structures, generating improved balance sheets.[20]

Total deal value decreased nearly 45% year-over-year to US$13.5 billion, while deal volume actually accelerated. Some stakeholders continue to be optimistic about deal volume in 2024,[21] with companies targeting smaller deals in the US$200 million to US$800 million range.[22]

Regulators are also scrutinizing medtech deals. A protracted battle with regulators led to Illumina divesting its interest in Grail at the end of 2023.[23] Medtronic scrapped a US$738 million deal to buy South Korean-based EOFlow, an insulin patch-pump maker.[24]

In 2024, M&A is poised for a positive inflection point for improved activity as strategics and private equity alike re-enter the acquisition fold. M&A activity from medtech mega-cap players is likely to include high-growth small/mid-cap companies as well as emerging companies with interesting technology that could disrupt existing businesses.[23] Optimism is also being propelled by digital therapeutics and at-home diagnostics, growing use of biometric diagnostics, and speed to market.[24]

Private equity: Megadeals and tougher fundraising environment

More going private

More sponsor-backed companies may decide to go private instead of languishing at a below-IPO stock price in 2024.[27] Private equity (PE) investments in life sciences peaked in 2021 with 695 PE transactions totaling US$127.5 billion.[28] The space includes biotech and medical device companies as well as providers of related tools and services, like contract research organizations (CROs).[29]

Volume of P&E deals soars for life sciences suppliers

PE continues its interest in life sciences suppliers, deploying more than US$10 billion in capital into contract development and manufacturing organizations (CDMOs). M&A deal value across CROs/CDMOs/suppliers has jumped nearly 85% year over year to US$28.3 billion, while volume is up 50%. CDMOs are expected to attract more PE interest in 2024 and beyond as the need for highly specialized manufacturing facilities continues to increase.[30]

Tougher fundraising environment

Notable PE megadeals in 2023 included the US$7.1 billion privatization of biopharma CRO Syneos Health and the acquisition of veterinary drug maker Dechra Pharmaceuticals by Sweden's EQT for about US$6.1 billion, one of the biggest UK PE deals in 2023.[31] However, while EQT has been very successful in fundraising over the recent years, they are looking for new sources of capital, like private wealth, in a tougher overall fundraising environment.[32]

Venture capital: Billion-dollar fundraises amidst biotech challenges

Life sciences dealmaking in the startup space continues to decelerate after experiencing record highs in 2021 but is still above pre-pandemic levels. Venture capital (VC) remains active and resilient compared to many other fields,[33] and six funds that closed in the second half of 2023 now have more than US$6 billion to deploy into new investments in 2024.[34] A notable development to kick off startup investing in early 2024 is a US$3 billion raise by biotech creator Arch—a multibillion dollar deal that comes roughly two years after raising a similar amount.[35]

The pace of biotech IPOs stalled in 2023 with only 19 drugmakers pricing initial share sales.[36] Many experts are cautiously optimistic for 2024, and some anticipate a roller coaster year.[37] Six IPOs kicked off 2024, however, including a US$93.8 million deal for gene editing startup Metagenomi—one of the rare biotech companies to go public recently without a drug already in clinical trials.[38]

Biotech also hit a 10-year peak for bankruptcies with 18 companies filing for protection, preceded by 8 in 2022, and the next highest year in 2014, with 7.[39] Three companies already filed in early 2024, Humanigen, Athersys,[40] and Invitae (which is preparing for sale).[41]

Partnerships and collaborations: Expanding capabilities in tech and R&D

Integrating AI/ML

Representing a broader industry transition, there is a growing focus on precision medicine and personalized therapies that leverage advanced technologies, like artificial intelligence (AI) and machine learning (ML).[42] The promise of AI is expected to drive additional new partnerships in 2024 as large companies look to obtain new technological capabilities, secure industry talent, and drive competitive advantage.

Several AI-based drug development partnerships were signed in Q3 and Q4 of 2023.[43] The Verge Genomics/ Alexion (AstraZeneca Rare Disease) collaboration is worth US$42 million up front—consisting of a fee, equity, and near-term payments—and the potential for US$840 million in downstream royalties.[44] The collaboration will use CONVERGE®, Verge's AI-enabled approach for identifying novel drug targets for rare neurodegenerative and neuromuscular diseases.[45]

AbbVie made an upfront payment of US$30 million with potential milestone payments and royalties to AI/ML company BigHat Biosciences to commence an antibody research collaboration in oncology and neuroscience.[46]

Medtech companies continue to explore strategic collaborations across the health care ecosystem to leverage AI. GE HealthCare recently signed a US$44M contract with BARDA to develop AI-augmented ultrasound technology. A partnership was also formed with Mayo Clinic for innovation in medical imaging and theranostics—to enhance precision diagnosis and improve patient treatment using multi-modal data, AI, and digital health solutions.

Medtronic partnered with NVIDIA and Cosmo Pharmaceuticals to integrate NVIDIA's AI technologies into its GI Genius™ intelligent endoscopy module. They've also partnered with IBM Watson Health to develop AI tools for the diagnosis and treatment of heart disease.

R&D picking up steam and a multibillion-dollar deal

LoE is also driving market leaders to various types of partnerships. The top 20 highest value licensing, collaboration, and partnerships deals in 2023 were each worth at least US$1 billion—the total reaching about US$75 billion already by Q3 2023—with the largest transaction having a potential value of US$22 billion.[47]

Half the deals in the top 20 list for 2023 were around oncology assets and technology platforms, followed by cardiology and neurological diseases. In the booming area of antibody-drug conjugates, Merck and Co. and Daiichi Sankyo came together in a US$5.5 billion deal that has a potential lifetime value of US$22 billion.[48] The deal was the largest in a decade and unusual in that it involved a US$4 billion upfront cash payment. Daiichi Sankyo will retain rights for Japan, and the two giants will collaborate globally to develop candidates in other markets.[49]

In 2024, biotech companies with strong late-stage pipelines are ripe for acquisition and seeking exits.[50] But many small to mid-cap biotech companies facing a cash crunch are also looking to acquisitions, while a record number go bankrupt.[51] Partnerships are a growing trend and may be an alternative to M&A to boost values in 2024.

New sources of capital: Partnerships and strategic collaborations as alternatives to M&A for biotech

Tighter capital markets for small and midsize biotech companies in 2023 required many companies to find alternative ways of financing, including cutting costs and private investment. IPOs and public markets cooled, and venture funding investment was lower than in 2022 but still above pre-pandemic levels. At BIO Europe in late 2023, pharma companies made clear that substantial funding will be available for early-stage investment. However, biotech companies are still cautious and uncertain about how readily accessible funds will be.[52]

Addressing challenges with creativity and resourcefulness

Biotech companies are increasingly looking at partnerships and other creative collaborations as an alternative, or precursor, to M&A. The length of time to get regulatory clearances can be especially challenging, and many small to midsize biotechs have shorter cash runways for 2024 than in the past. In addition, prior to M&A, alliances and joint ventures may be used to demonstrate the viability of the business proposition, leaving regulators more comfortable with the arrangement.[53]

Reaping the benefits of partnerships and strategic collaborations

Some substantial benefits may be gained via joint efforts to acquire or have access to:

- New assets, like innovative science, platforms, and patents
- New capabilities and resources, like expertise, manufacturing, commercialization for large-scale indications, established infrastructures globally, and advanced technologies, e.g., AI
- New markets and patient populations
- Ecosystem-wide synergies and gap funding through public/private partnerships
- A trusted relationship that builds a pathway to future M&A

To find a symbiotic collaborator, companies need to first critically assess fit, complementary skills/resources, and the values/benefits that bring each partner to the table. But even when fit is determined and the deal has been structured and negotiated, the real work begins.

"Small to midsize biotechs may underestimate the resources and effort a partnership will take. When you have a limited resource base to start with, there are not a lot of departments to hand these things off to. Also, companies shouldn't underestimate the work it will take to build trust—and to stay true to the principles that were the basis for partnering in the first place,"

—**Renee Aguiar-Lucander,** CEO, Calliditas Therapeutics

Accessing new markets and new patient populations

For its first ever partnership, Calliditas Therapeutics set their sights on the world's second largest pharmaceutical market, China, in 2019. Calliditas entered into a licensing agreement with Everest Medicines to develop and commercialize its treatment for IgA nephropathy in Greater China and Singapore to address a huge patient need.[54] Chronic immune-mediated kidney disease is a major cause of kidney failure in China and other Asian countries, although considered a rare disease in the United States and Europe.

The partnership required Calliditas to remain agile—as clinical trial plans were disrupted by the pandemic—and work on the relationship differences between its own Scandinavian culture and that of China. For example, CEO Renee Aguiar-Lucander says her Swedish colleagues had a reluctance to say "no" when something could not be done. In many cultures, saying no may be viewed as problematic or impolite.[54]

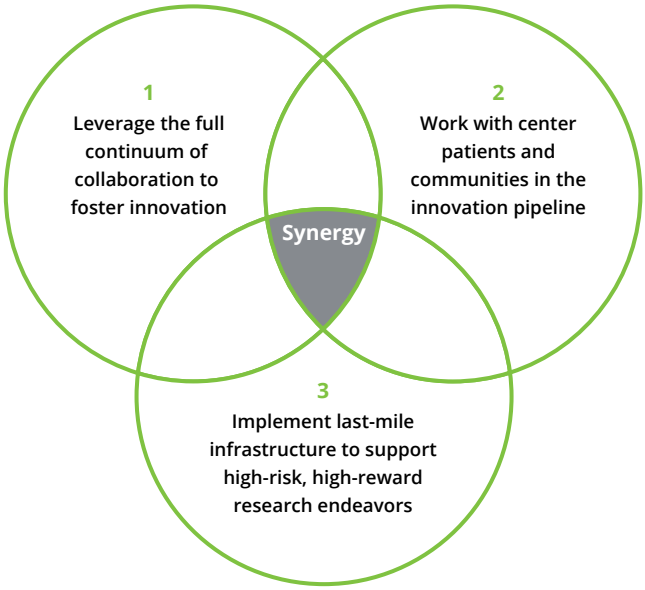
New sources of capital: Public/private partnerships for biomedical innovation

With tightened funding in the private sector, some companies find that government funding can become gap funding. COVID-19 provided an exemplary model for how governments can work with collaborators to advance care and treatment for all diseases, and, contrary to popular belief, government and nongovernmental institutional investment in biomedical areas does not reduce private spending on R&D.[56]

Beyond the pandemic, governments may continue to move disruptive ecosystem-wide solutions for biomedical innovation by:

- Prioritizing patients and communities in the innovation pipeline
- Leveraging the full continuum of relationships and partners
- Supporting funding and collaboration infrastructure for last-mile innovations[57]

Figure 3. Three synergy strategies for governments and collaborators



Source: Deloitte analysis

A government's ability to subsidize research and development in areas of unmet need may serve as a mechanism to drive research to the last-mile pipeline (figure 3).[58] Two mechanisms that some governments have used in the past could be key to de-risking high-risk research areas:

- **Push incentives** that reduce the cost of development by offering financial, tax, and technical incentives regardless of anticipated failure in the market

- **Pull incentives** that reward developments already considered relevant in the market and scientifically viable by helping ensure developers' financial viability into the future, even in inefficient markets[59]

Breakthrough biomedical innovations are not only possible but probable with government investment in the right infrastructure and incentives.[60]

New sources of capital: Medtech VCs launch new funds

After a downturn, VC investing in medtech started garnering renewed interest in mid-2023. Neuralink, Elon Musk's brain-reading startup (via implantable chips), and Beta Bionics, a low-touch automated insulin delivery system for diabetics, started an upturn with nine-figure deals.[61]

More selective investing

Venture capital investors are searching for visionary medtech founders to make more selective investments in 2024, and the digital health market could have promising opportunities for real innovators.[62] The most active category of medtech VC funding has been cardiovascular surgical devices. From 2020 through Q3 2023, Qiming Venture Partners is the leading medtech venture investor and Medtronic, the top acquirer (figure 4).[63]

Figure 4. Top medtech acquirers and VC investors from 2020 to 30 September 2023

Investor	Deal count	Investor type
Medtronic	5	Corporation
Boston Scientific	4	Corporation
Thermo Fisher Scientific	3	Corporation
Laborie Medical Technologies	3	PE-backed company
Philips	3	Corporation
Ottobock	3	PE-backed company

Investor	Deal count	pre-seed/ seed	Early-stage VC	Late-stageVC	Venture growth	Investor type
Qiming	49	0	25	22	2	VC
Hongshan	39	0	16	17	4	VC
Enterprise Ireland	34	3	7	14	10	VC
YuanBio Venture Capital	33	0	18	13	2	VC
European Innovation Council Fund	33	1	6	21	3	VC
Khosla Ventures	30	3	3	18	3	VC
Lilly Aisa Ventures	27	2	17	7	1	CVC
SOSV	27	6	2	18	1	VC
ShangBay Capital	26	3	14	7	2	VC
Johnson & Johnson Innovation - JJDC	24	0	7	13	4	CVC

Source: Pitchbook, Geography: Global

At the end of 2023, experts estimate the average cash balance at large medtech companies stood at approximately US$5 billion, up US$1.5 billion since early 2019.[64] Potential areas of M&A interest include mechanical circulatory support; transcatheter mitral and tricuspid valve repair and replacement; pulsed field ablation; peripheral vascular solutions; interventional devices to treat venous thromboembolism; and diabetes technology.[65] The left atrial appendage (LLA) closure market for reducing stroke is valued at US$1.4 billion and captured the interest of two companies, Johnson & Johnson and Medtronic, in separate deals. The LAA market is projected to reach US$6 billion by 2030.[66]

Tapping medtech giants' venture arms

Visionary startup founders may find opportunities through medtech giants' venture arms, like Boston Scientific and Johnson & Johnson.[67] For example, Johnson & Johnson Development Corporation (JJDC), Johnson & Johnson's venture arm, has innovation teams for early-stage startups around the globe—including in Shanghai, Boston, San Francisco, and London[68]—with its most notable exits including 23andMe, Nevro, and Grail.[69]

Intuitive Surgical's venture arm added a US$150 million fund in late 2023 bringing their total assets under management to US$250 million in 2024 across three investment areas:[70] Improving health care access and coordination; precision diagnostics and interventions; and secure, enriched digital health ecosystems.[71]

In addition to access and affordability, new business models that focus on early-detection and preventive care are drawing investment.[72] Also promising are digital health companies that focus on diagnostics to improve patient outcomes.[73]

New sources of capital: Medtech funding through government initiatives

The road to digital health and medtech innovation is being supported through many diverse economic initiatives with a growing focus on making medical services and devices for consumers more affordable and accessible.

Some examples of recent government biomedical or medtech initiatives around the globe include:

United States—The US administration recently designated 31 tech hubs across the country with 13 dedicated to either biomedical or medtech innovation. Some examples are the Greater Philadelphia Region Precision Medicine Tech Hub and Elevate Quantum Colorado.[74] Quantum computing has the potential to train AI in medical diagnostics more efficiently.[75]

Canada—Over CAD$2.1 million through PrairiesCan will help enable Alberta's health and medical technology sector to ramp up the commercialization of human mobility and home health innovations.[76]

Scotland—The Medical Device Manufacturing Centre (MDMC) has been awarded £3.35 million of additional funding from Scottish Enterprise to develop medical device innovation and improve the industry's sustainability.[77]

United Kingdom—The UK government is providing the National Health Service (NHS) with £21 million across 64 trusts to deploy new AI tools for the diagnosis and treatment of patients.[78]

Australia—The Australian government has set up an AUD$50 million fund for a combined AUD$115 million with Brandon BioCatalyst & ANDHealth towards a BioMedTech Incubator program.[79]

Shifting portfolios: Value creation in a new era of blockbuster drugs

Some companies are doubling down on oncology and specialty diseases, while others are committing to more prevalent chronic disease areas. In oncology, the Pfizer/Seagen deal escalated the excitement around antibody drug conjugates (ADCs), setting off a deal-making frenzy to snap up ADC assets and technologies.[80]

Merck, Daiichi Sankyo, BMS, and AbbVie all began making moves to access and/or expand their position in ADCs by the end of 2023. Japan's Daiichi Sankyo is also investing US$1.08 billion to create an "international innovation center" by 2030 in Germany and will equip the site to develop and manufacture future ADCs.[81] The size of ADC investments reflects a growing and increasingly valuable drug class that some proponents hope may eventually replace some forms of standard chemotherapy.[82]

Momentum is expected to continue, as the approach—using antibodies' specificity for targeted delivery of potent cytotoxic drugs—comes of age.[83] In 2024, deals from Johnson & Johnson/Ambryx and Roche/MediLink Therapeutics kicked off the year as well as smaller acquisitions and licensing.[84] Pharma and biotech interest is also attracting venture financing to ADC start-ups.[85]

In parallel, the market is rewarding those focused on more prevalent disease areas with the excitement over and growth of GLP-1 obesity drugs —a trend not seen in recent years. Those companies not active in either are finding themselves needing to explain their portfolio and scientific strategies.

At the 2024 J.P. Morgan Healthcare conference in January, Novartis found itself needing to explain the choice to double down on radioligand therapies (RLT), a platform where the company believes it can continue its established leadership for the long-term. Like ADCs, RLTs act like a guided missile but use a ligand to target cancer cells and kill them with a therapeutic radioisotope.[86] Novartis believes RLTs deliver better efficacy while producing less adverse events than ADCs.[87]

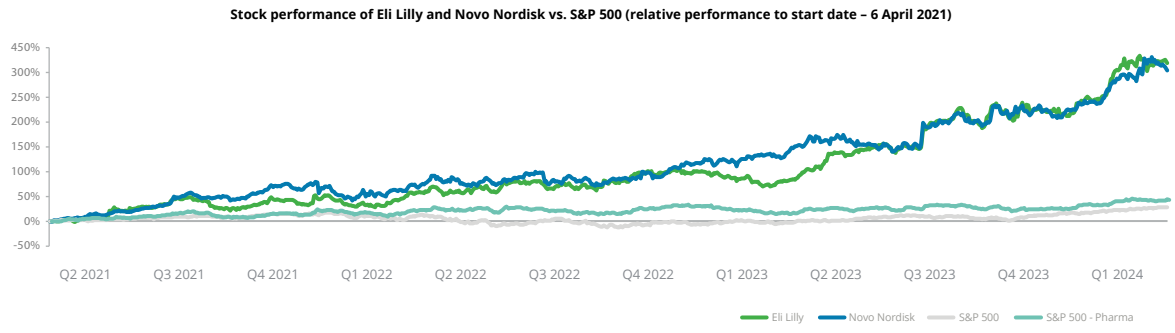
Rise of the GLP-1 weight loss boom, valuations, and market projections

Drugs originally developed to treat type 2 diabetes are now being formulated as popular weight loss drugs. Eli Lilly manufactures Mounjaro for diabetes (approved 2022) and its newly approved version for weight loss, Zepbound.[88] Novo Nordisk is also an obesity drug market leader with Wegovy (approved 2021) and Ozempic (approved 2022).[89]

Among biopharma market leaders, Novo Nordisk and Eli Lilly have some of the highest valuations due to long-term growth expectations and category leadership in metabolic diseases—including diabetes and obesity as the most prevalent. By the end of Q1 2024, Novo Nordisk's market capitalization reached a high of US$572.92 billion, rising from US$88.53 billion in late November 2016. Eli Lilly had a market cap high of US$740.30 billion, rising from US$74.1 billion in November 2016.[90]

The positive sentiment associated with the potential of their GLP-1 drugs is bringing Eli Lily and Novo Nordisk valuations on par with or greater than some leading tech growth stocks, like Tesla, as well as being disproportionate to the S&P 500 Pharma Index (figure 5). Analysts predict this upward trajectory to continue.

Figure 5. Stock performance of Eli Lilly and Novo Nordisk vs. S&P 500 and S&P 500 Pharma, Q2 2021 to Q1 2024



Source: Deloitte analysis

Experts say the treatment of obesity is on the verge of heading into mainstream primary care—comparable to the growth of hypertensive drugs that ballooned into a US$30 billion market in the 1990s.[91] The rising prevalence of lifestyle-related diseases is expected to continue to drive up overall GLP-1 agonist drug market projections. By 2030, the potential market is being priced anywhere from US$37 billion to more than US$100 billion.[92] While no one knows exactly how big it might be,[93] the surge is being driven by treatments for obesity and diabetes—a potential market of 30 million people in the United States alone by the end of the decade.[94]

In addition, GLP-1 agonists are being heralded as Science's "2023 Breakthrough of the Year" as potential new uses for the drugs emerge.[95] GLP-1s are showing promise for cardiovascular disease and investigations are underway for drug addiction, Alzheimer's, and Parkinson's diseases. These new uses may increase insurance coverage down the line.[96]

Growing high-quality concentrated revenue

Growing high-quality concentrated revenue, like Eli Lilly has achieved in the past four to six quarters, demonstrates an enviable road to value creation. Eli Lilly is making a long-term commitment in the obesity drug market with multiple obesity drug candidates in mid- and late-stage clinical development. At the end of 2023, the company also announced a multi-year partnership with startup Fauna Bio for obesity research with animal genomes, adding to the signs of a decade-long commitment to the market.[97] The result is Eli Lilly becoming the world's largest drugmaker by market cap—with 12% top-line growth and 20% bottom-line growth.

Addressing lack of reimbursement

Beyond the ability to meet the surging demand, another headwind to be navigated in 2024 and beyond is likely to be the lack of access and broader insurance coverage for obesity drugs. In the United States, lack of reimbursement for obesity treatments under government health care programs essentially makes these medications unaffordable.[98] Programs for low-income Americans do cover the drugs in some areas, but access is fragmented.[99]

Millions of older Americans on US Medicare cannot access the drugs, mostly because obesity drugs were originally classed as cosmetic in 2003; US lawmakers plan to push for a change in 2024.[100] If 10% of Medicare beneficiaries with obesity used a GLP-1, the annual cost to Medicare is estimated to be between US$13.6 billion and US$26.8 billion. But the total annual medical cost in the United States for obese adults averages US$1,861 higher than medical costs for people with healthy weight.[101]

Public and private payers could learn from guidelines in several EU countries, such as Norway, the Netherlands, Poland, and Italy.[102] These countries have reimbursement policies that may demonstrate a pathway to affordable coverage in the United States—slowing the progression of the disease. For example, some European coverage models deploy effective, but lower-cost medications for patients with lower BMI that do not meet the criteria for "obesity" but whose health could still benefit from treatment.[103]

Competition in weight loss market heats up, and digital health support services grow

Competitors and lower cost formulations that may also have potentially fewer side effects may be new entrants to the market. New products will need to distinguish themselves by clear advantages, and pharma companies have begun investigating:

- Novel molecular targets with alternate routes of administration

- Extended treatment intervals
- New double- and triple-agonist mechanisms[104]

Competition is already ramping up as Pfizer and Amgen are expected to release new data in 2024,[105] and several drugs in development may become attractive for acquisition. In late December 2023, Roche took over unlisted obesity drug developer Carmot Therapeutics in a US$2.7 billion upfront deal.[106]

Some smaller pharma companies are developing agents with novel mechanisms of action (MOAs), including Switzerland-based Aphaia Pharma and Japan's Shionogi.[107] Implications are expected for ingredients and support services. VCs are eyeing opportunities in weight care and management via both telemedicine and coaching as consumer interest soars (figure 6).[108]

Figure 6. Notable global VC deals for weight loss startups

Name	Close Date	Deal Size	Valuation	Deal Type	Location
Lark	10/13/2021	$100	$800.0	Late Stage	Mountain View
Calibrate	11/08/2022	$37.5	$365.0	Early Stage	New York
Zoe	11/01/2022	$34.8	$264.3	Late Stage	London
Nutrisense	06/28/2022	$25.0	$95.0	Early Stage	Chicago
Form Health	01/13/2023	$22.9	$6209	Early Stage	Boston
BooHee	11/21/2021	$15.6	$310.0	Late Stage	Shanghai
January AI	08/15/2022	$13.0	$28.8	Late Stage	Menlo Park
Nourish	01/20/2023	$9.3	$40.3	Seed	Austin
Intelliheath	02/15/2022	$8.5	$58.7	Seed	San Franciso
Veri	06/01/2022	$7.9	$12.5	Early Stage	Helsinki

Source: Pitchbook

GLP-1 proofing portfolios

While the rise of GLP-1 has created tremendous opportunities in obesity and obesity-related assets, some market leaders are also looking to GLP-1 proof their portfolios, flocking to "GLP-1-resistant" therapeutic areas like rare diseases, neurology, and oncology. Medtech companies may search for assets that are not impacted by GLP-1s or assets for which an increase in longevity could mean an increase in utilization.[109]

Extracting value from Generative AI and emerging technologies

Uncovering the realm of possibility

Generative AI (GenAI)'s release to the public quickly amassed adoption and delighted users, enchanted by chat-enabled interfaces and powerful new large language models (LLMs).[1] LLMs are foundation models—machine learning (ML) models pre-trained on a broad dataset that can be adapted to solve a range of problems, offering new ways to build applications or other foundational models.[2]

Early traction for GenAI was seen from consumer releases, but GenAI is quickly showing its potential to add contextual awareness and human-like decision-making to enterprise workflows.[3] This inventive era of GenAI advancement puts tremendous pressure on leaders to harness the technology's capabilities and promise, without being disrupted.[4] In the year ahead, extracting GenAI's value and managing its risks, while maintaining trusted enterprise status, are at the forefront of many leaders' strategic priorities.[5]

Amazon CEO Andy Jassy says that GenAI could be one of the most transformative technological transformations in decades,[6] while World Economic Forum (WEF) President Børge Brende, reminds leaders that the immense potential productivity gains underscore the need for responsible AI governance.[7]

The Winter 2024 Fortune/Deloitte CEO Survey of viewpoints—from the CEOs of some of the world's largest and most influential companies—shows there has been a marked increase in the adoption of GenAI.[8] The majority of CEOs (57%) intend to integrate new technologies into their business models to uncover growth opportunities, with a significant portion (56%) already leveraging GenAI to enhance efficiencies.[9]

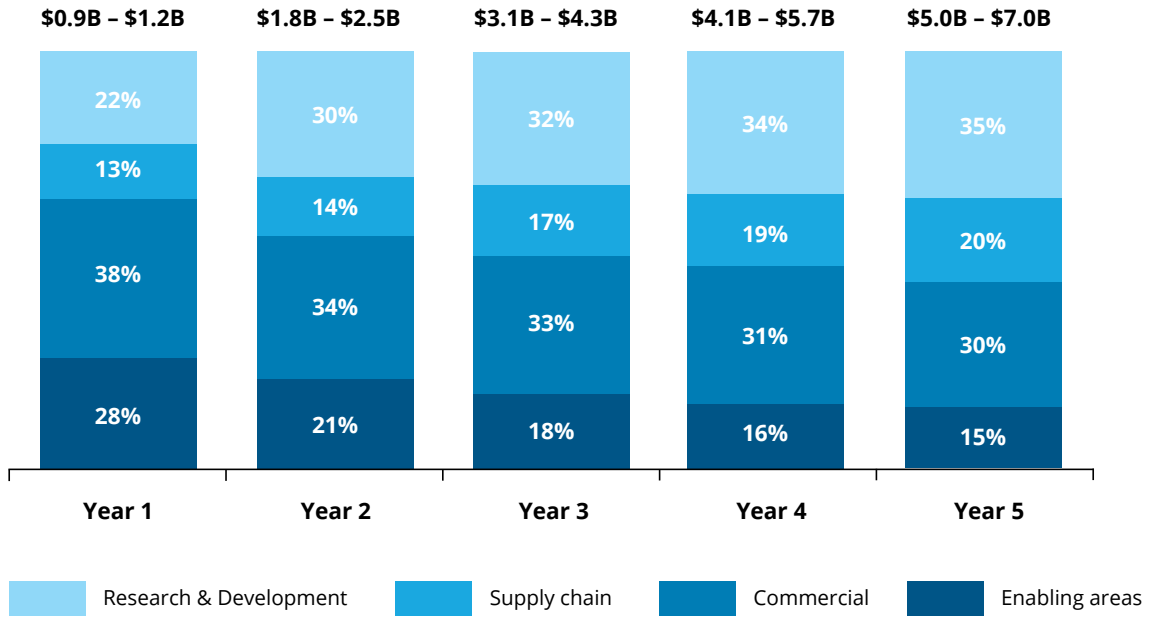
Creating competitive advantage

Increasing efficiencies and cost savings

In the next year, more than 90% of biopharma and medtech respondents surveyed by Deloitte say they expect GenAI to have some impact on their organizations.[10] GenAI and other AI technologies coupled with digital transformation tools are poised to increase overall efficiencies and process innovation across many areas of the life sciences value chain (figure 1).[11]

A top 10 biopharma company with an average revenue of US$65-75 billion could capture between US$5-7 billion of peak value by scaling the use of AI over 5 years. This varies depending on an organization's size.[12]

Figure 1. Average 5-year value accretion schedule of AI impact (percentage of peak value realized)



Assumptions:

01. Foundational data and infrastructure are in place to enable transformational use case development
02. Each function implements the full portfolio of transformational AI use cases (e.g., AI clinical trials, AI manufacturing, AI marketing)

Source: Deloitte, "Realizing Transformative Value from AI and Generative AI in Life Sciences," 2024.

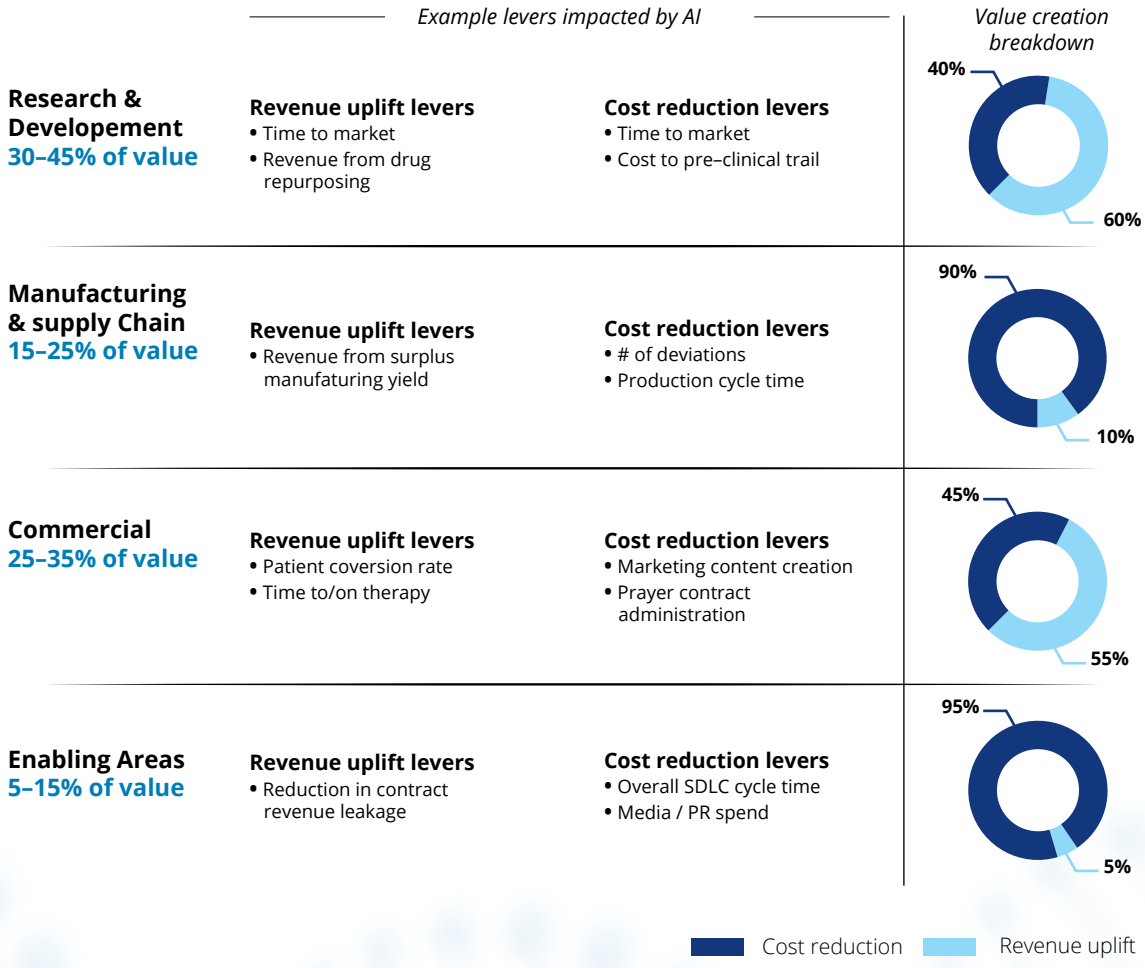
Creating value across the value chain

Are companies making choices for GenAI today that are going to create value and advantage? While it may be too early in the journey to declare, some approaches are gaining more traction and accelerating time to value vs. others.[13] Nearly 90% of value from the use of artificial intelligence in life sciences may be derived from three functional areas: research and development (R&D), manufacturing and supply chain, and commercial (figure 2).[14]

R&D represents the leading area for value opportunity at 30-45%. AI applied to novel drug identification and accelerating drug development could provide both cost savings and revenue uplift. Commercial may provide 25-35%, where marketing costs could be optimized and activities such as script utilization could be enhanced by AI. In manufacturing, supply chain, and enabling areas (including IT, HR, and finance) AI primarily provides opportunities for cost transformation through efficiency realization and vendor cost reductions.

How can organizations turn these impacts into competitive advantage? Greater speed and efficiency can enable redeployment of capital to other value creating areas. Greater effectiveness can help companies advance their science and engage their customers and patients comparatively with others. Ultimately, greater patient outcomes could be achieved.

Figure 2. Value creation breakdown by function



Source: Deloitte, "Realizing Transformative Value from AI and Generative AI in Life Sciences," 2024.

Finding synergies: Big pharma and big tech collaborating with GenAI

In 2024, many biopharma companies are looking for novel ways to marry the rich data sets of science with the latest GenAI technologies.[15] Alternatively, technology giants with advanced types of AI capabilities are looking to capitalize on the massive opportunities afforded by the life sciences and health care industry.[16] By 2025, 36 percent of the world's data is estimated to be generated by life sciences and health care.[17] Through GenAI, big pharma and big tech may be realizing these two sectors have more to gain from working together than by competing.[18]

Will GenAI create the trillion-dollar pharma company?

Evidence of tech titans' interest was on display with their formidable presence at the J.P. Morgan Healthcare Conference in early 2024.[19] Many tech company executives were looking to strike new deals with biopharma for GenAI/AI technologies, including NVIDIA, whose CEO attended the conference.[20] NVIDIA achieved a US trillion-dollar market cap status in 2023[21] and believes these generative technologies will also enable a drug maker to become the next trillion-dollar company.[22]

Pharma companies' collaborations with tech titans for GenAI

Tech titans are working with life sciences companies on more advanced GenAI in many areas that are constantly evolving, including the following:

NVIDIA: Provides a GenAI drug discovery cloud service, BioNeMo, to biopharma companies that want to create or customize their own generative models and then offer those as a Software-as-a-Service (SaaS) model to others via cloud APIs.[23] Some of NVIDIA's pharma relationships include Amgen, AstraZeneca, GlaxoSmithKline (GSK), and Roche subsidiary Genentech.[24,25]

Microsoft: Provides GenAI through Microsoft services, including Copilot, Microsoft 365 apps, Microsoft Azure, and Bing search engine.[26] Microsoft is collaborating on AI drug discovery with Novo Nordisk[27] and Novartis.[28] Some GenAI relationships in health care include Epic,[29] Siemens,[30] and health systems, like Mercy and Duke Health.[31]

Alphabet: Provides GenAI through Google services, including Gemini and Google Cloud. Its Target and Lead Identification Suite is designed to accelerate drug discovery and the Multiomics Suite to share mass amounts of genomic data in precision medicine.[32] Google Cloud is working on a GenAI relationship with Ginko Bioworks, for biosecurity and engineering biology,[33] and Insmed to bring about change in the drug development and commercialization process.[34] Insmed built a GenAI search capability for internal records leveraging Google Vertex AI Search that also allows categorized access to external medical articles.[35]

AWS: Gen AI on AWS Cloud allows integration with many leading foundations models—including Amazon, AI21 Labs, Anthropic, Cohere, Meta, and Stability AI—for uses such as generating new therapeutic candidates, better matching patients with the right clinical trials, powering patient engagement applications, and enhancing manufacturing oversight.[36] AWS is working with Novo Nordisk on protein structure prediction at scale; with Amgen on drug discovery and manufacturing;[37] and with Eversana to "pharmatize" AI across the life sciences industry, starting with a GenAI application for medical and regulatory content approvals.[38] AWS also worked with Pfizer on VOX, a proprietary GenAI platform for giving workers access to LLMs.[39] The company enhanced productivity by using GenAI to create first drafts of patent applications and medical and scientific content for human review and finalization.[40]

Democratizing a US$1 billion investment in phenomics with GenAI models

Founded in 2013, Recursion Pharmaceuticals is a leading AI-biotech company in what is now known as "techbio," advancing a clinical-stage pipeline in data-driven drug discovery.[41] Recursion uses its own operating system, Recursion OS, to turn drug discovery into a "search" problem—generating, analyzing, and deriving insight from massive biological and chemical datasets.[42] Its phenomics platform combines imaging and artificial intelligence for rapid validation and advancement of novel oncology targets.[43]

Looking to democratize its US$1 billion phenomics investment, Recursion is opening up access to years of proprietary work in hopes it will "move all of us forward faster."[44] The company's first in a potential series of GenAI foundation models—Phenom-Beta—is hosted on NVIDIA's BioNeMo platform.[45] In July 2023, Recursion also received a US$50 million investment from NVIDIA as part of a multi-year partnership to advance its AI technologies.[46] The aim is to leverage GenAI/AI technologies to benefit Recursion's own internal pipeline along with those of their partners, including Bayer for fibrotic diseases, and Roche/Genentech for oncology and neuroscience.[47]

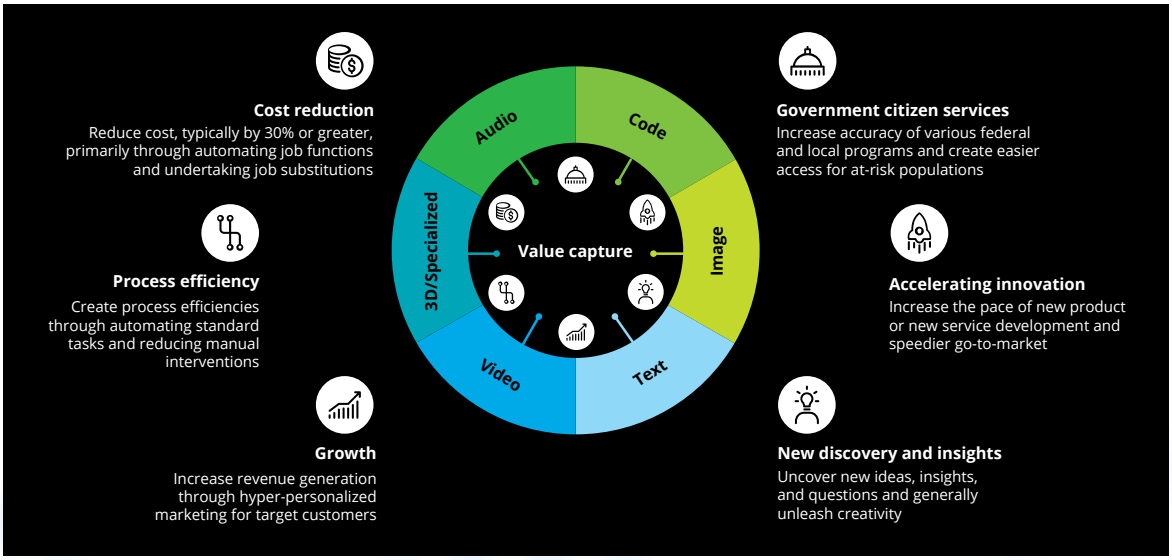
Understanding the technology to extract its value

Multimodal LLMs, the building blocks of artificial general intelligence (AGI)

Currently, multimodal LLMs are a step closer to mimicking human intelligence.[48] The ability to integrate audio, code, images, text, simulations, and videos with GenAI is already changing the way content is being generated and delivered and will likely remodel many types of consumer, business, and health care experiences (figure 3).[49,50]

Half of consumers surveyed by the Deloitte US Center for Health Solutions, report using GenAI in some capacity, and more than half believe GenAI could improve access to health care; 46% think it could make health care more affordable.[51]

Figure 3. Broad categories of value capture from GenAI



Source: Deloitte, "Realizing Transformative Value from AI and Generative AI in Life Sciences," 2024.

Simple uses of GenAI, like generating ideas and design artifacts, can be "no regrets bets" for organizations to de-risk investments and accelerate progress when kickstarting their GenAI programs.[52] More advanced use cases start incorporating more modalities and technologies.[53] Each modality, like text or video, is a potential value-driver for a use case; expanding modalities increases the potential benefits of a use case.[54]

For example, a use case for unlocking cures in drug discovery may provide value-drivers through both simulations and images (figure 4). The potential benefits in this use case are GenAI's ability to analyze and learn from vast amounts of data, including images, which can lead to more targeted and effective treatments. The ability to run simulations with GenAI to select the best potential drug candidates minimizes the need for real-world iterations.[55]

Because multimodal AI systems can interpret multiple types of data together, such as textual and image data, their development and validation require collaborative efforts between a number of disciplines.[56] Leaders should bring together a cross-disciplinary team of people with the domain knowledge to think creatively about potential use cases.[57] (See Deloitte's AI Institute's Generative AI Dossier to explore more use cases.)

Moving beyond use cases to a string-of-pearls strategy

LLMs and other foundation models are starting to unlock a slew of high-value applications. About two-thirds of life sciences companies surveyed say they are building GenAI use cases, and 36% say GenAI will impact their strategy in the year ahead.[58]

Vertical-specific use cases for life sciences are likely to command a premium due to the dependence on proprietary data. Incorporating proprietary content into a generative model can be accomplished by fine-tuning an existing LLM or training an LLM from scratch.[59] In 2024, new economies may be created for access to proprietary data and synthetic data.[60]

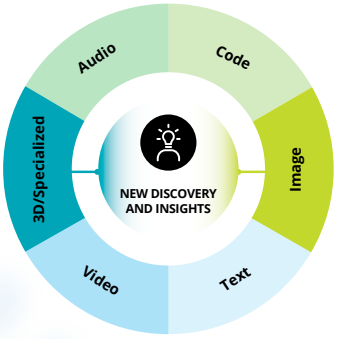
While each individual GenAI use case may generate some improvements, stringing together multiple use cases—along with other digital tools like machine learning and Internet of Things (IoT)—could transform entire processes, and that is where the value gets unlocked. This string-of-pearls strategy could be applied to everything from research to clinical development to customer engagement and patient experience. Each individual use case connects to another use case, and another, etc.[61]

Figure 4. Example of a use case in drug discovery to identify new drug candidates

Unlocking the cures

(New Drug Discovery/Generation)

Generative AI can be used to model the structure and function of proteins and biomolecules, accelerating the identification and validation of molecules and the creation of new drug candidates.



Issue/opportunity

Despite advancements in medical treatments, numerous diseases still lack effective solutions due to the complex, costly, and time-consuming process of drug discovery and verification. The challenge of drug development lies not just in iscovering potential treatments but also in the rigorous verification of their effectiveness, a process that is both costly and time-consuming. Compounding these issues are the unique complexities of clinical trials, which need to account for diverse populations, varied interactions with other treatments, and potential side effects. Furthermore, the rarity of some diseases creates additional hurdles due to limited data from fewer patients, making the development even more challenging.

How Generative AI can help

Cost reduction

The use of Generative AI in the verification of drugs during clinical development could significantly reduce costs. This is due to its ability to run simulations and select the best potential candidates for further testing, thereby minimizing the need for extensive real-world iterations.

Promoting public health

Generative AI has the potential to significantly improve public health by accelerating the discovery of better treatments and cures for diseases. Its ability to analyze and learn from vast amounts of data can lead to more targeted, effective treatments, directly benefitting patients and, by extension, society at large.

Enabling collaboration

Generative AI can facilitate improved communication and knowledge sharing across research groups. It can process and make sense of data from various sources, breaking down data silos and opening new opportunities for collaboration and innovation in experimentation.

Source: Deloitte, "The Generative AI Dossier," 2024.

String-of-pearls strategy in action, GenAI in scientific research

Thinking of use cases in the context of workflow, functional area, and greater mission to be accomplished can help assemble a string of use cases. Each "pearl" should have some major contribution that will make the main goal possible to achieve, thereby enhancing the power of the whole.[62]

String-of-pearls for expanding scientific research productivity and global collaboration

How can GenAI help?

1. Serves as a brainstorming research partner, providing the ability to search a broader knowledge base, including proprietary data
2. Summarizes scientific literature for meta-analyses[63]
3. Processes and makes sense of data from various sources
4. Breaks down silos, to facilitate communication and knowledge sharing across research groups and geographies
5. Assists in writing research papers, grants, literature reviews, and non-technical summaries of data
6. Creates presentations in multiple modalities
7. Translates work, making it shareable across geographies (figure 5)[64]

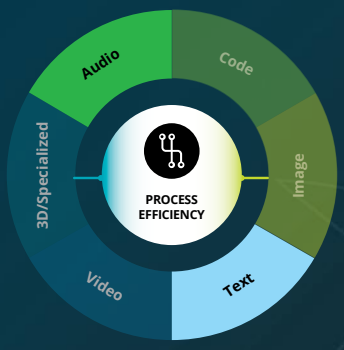
Figure 5. One use case in the string-of-pearls for expanding scientific research collaboration

Language translation at scale

(Content localization)

Gen AI can be used to quickly and easily scale content across regions by translating and converting text and audio into regional languages.

Issue/opportunity
The ability to create and translate content at scale can be a competitive differentiator for multinational enterprises, but it can also command significant time and resources, and rapid, on-demand translation may be difficult to achieve.



How Generative AI can help

Tools for custom localization and quality assurance
Generative AI can be used to help organize and manage complex file types, analyze content before translation to optimize localization, and integrate glossaries, term bases, and language tools into workflow.

Content personalization across industries
AI-powered content personalization can supercharge localization efforts by improving engagement, building brand loyalty, and increasing conversions.

Speech recognition during translation
Generative AI can be leveraged to enable voice user interfaces (VUI), transcribe video and audio content into text, and simultaneously translate spoken content into the target language.

Source: Deloitte, "The Generative AI Dossier," 2024.

How can the language translation use case be expanded to provide more than two value-drivers of text and audio? GenAI could not only convert text to audio in multiple languages, but also generate a supporting video in another language—adding another value-driver to support sharing content across geographies and on more platforms.

Adopting an evolutionary AI mindset

As leaders start looking beyond siloed pilots and individual use cases, they could consider how GenAI can be part of an enterprise-wide transformation that not only fundamentally changes the way work is done and value is created, but also addresses compliance, privacy, regulation, and trust.[65] Successfully driving large-scale AI transformation requires an evolutionary mindset across the AI journey (figure 6).

Integrating GenAI into the enterprise tech stack

Ultimately, decision-makers should develop a strategy that harmonizes its existing AI enterprise strategy with GenAI, while considering GenAI's capabilities and limitations.[66] Getting the most from GenAI may require enterprise-wide infrastructure and platforms spanning the entire tech stack.

This includes secure cloud infrastructure, foundation models, modernized data platforms that manage high quality, context-rich data, and low-code/no-code platforms—to build and scale applications, in addition to establishing practices such as Large Language Model Ops (LLMOps) and Cloud Cost Management.[67]

Foundation models, the model layer of GenAI

Foundation models differentiate the GenAI tech stack from previous AI (figure 7).[68] Just as Microsoft's Win32 offers APIs for developers to access base-level hardware and OS functions, the model layer is designed to connect application developers to optimized hardware for adoption and democratization of GenAI.[69] Experts say foundation models will form the basis of GenAI's future in the enterprise.[70]

These foundation models are often available to developers via closed and open APIs, where developers can fine-tune them with additional training data to improve context, relevance, and performance for specific use cases and verticals.[71] In the model layer, closed-source model providers, like Cohere and Google host and manage models built on a vast data corpus and charge for consumption. Open-source models providers, like Meta and Stability.ai, are managed by communities and are monetized when they are fine-tuned or are based on usage costs as a function of the size of a company.[72]

Figure 6. AI value journey

Mindset evolution

Move beyond the end less cycle of near term proof of concepts, and place long term bets on AI in key areas

Leadership evolution

Goal leaders against measurable AI targets and value goals in order to drive AI evangelism and accountability

Investment evolution

Treat AI investments as core enablers of enterprise business strategies and not as experimental investments

Cultural evolution

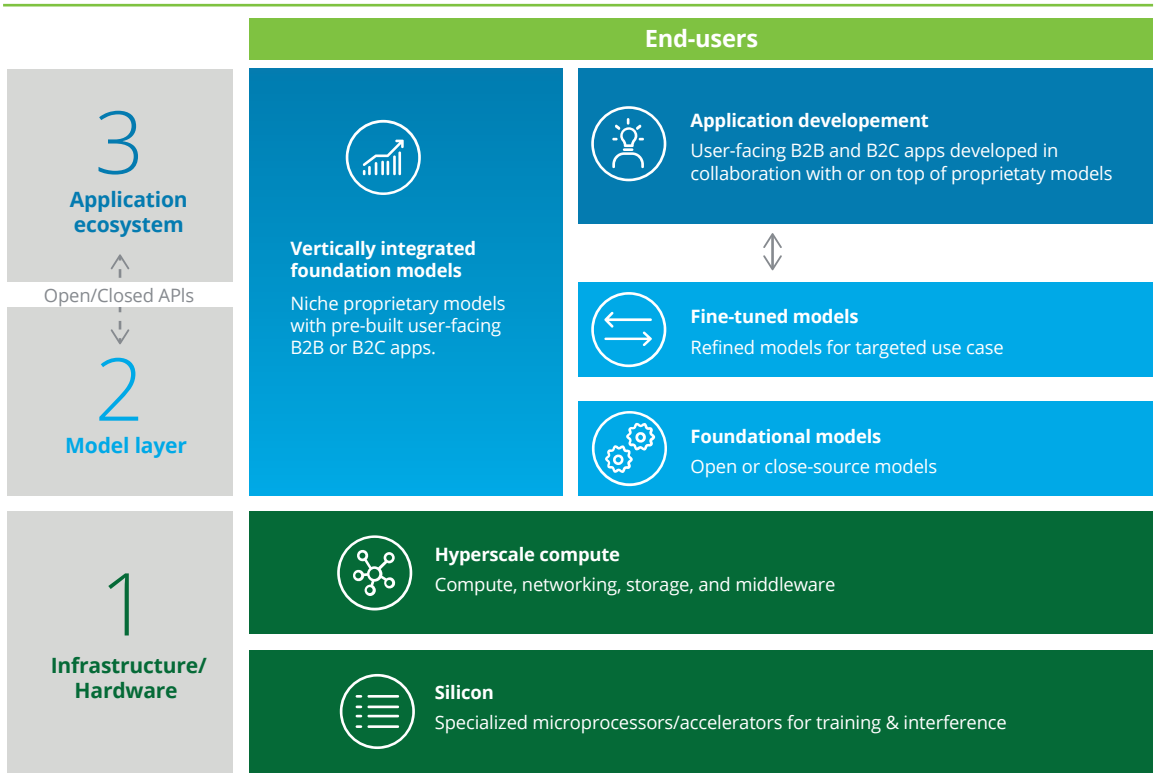
AI should not be looked at like a tool, but as a skill that all employees will need to possess to maximize efficiency

Execution evolution

Evolve beyond front and back office methods and adopt a "two in the box" approach where business & IT are goaled together

Source: Deloitte, "Realizing Transformative Value from AI and Generative AI in Life Sciences," 2024.

Figure 7. GenAI Tech Stack



Source: Deloitte, "A new frontier in artificial intelligence," 2023.

Establishing operational efficiencies

Once these models are built, organizations need to establish operational capabilities around LLMOps. LLMOps focuses on unique needs of these models: compute, transfer learning, human feedback, tuning cost/performance, new metrics, prompt engineering, and building LLM pipelines. LLMOps tackles complexity of development of LLMs for efficiency, scalability, and risk reduction while scaling the applications into production.

In addition to LLMOps, another critical component is cloud cost management. This enables organizations to leverage the potential of GenAI while optimizing cloud resource consumption and maximize investments.

Managing risks, setting up the right base model

Deploying on premises (on-prem) and private LLMs

There are risks in deploying GenAI models across the enterprise, particularly LLMs, and there are several ways they can be deployed:

- Via a service provider, as a SaaS model, avoiding any configuration or installation issues
- Deployed on an organization's private cloud or network, "on-prem," enabling control and management of API configuration[73]

On-prem LLMs are installed on the organization's infrastructure and available to users who have access to the organization's network and the application. Some on-prem systems are isolated or "air-gapped" from open access to the internet but may be connected via secure means.

In 2024, some life sciences companies will also be looking to private LLMs for a walled garden to protect their data from going into the public domain and to control costs.[74] GenAI trained from a private LLM operates within a controlled environment and the dataset can be curated to align with specific guidelines, quality standards, and desired outcomes.[75] Companies that build solutions on private, rather than general purpose, LLMs could also have the most impact.[76]

Managing LLMs with orchestration startups

As more organizations put GenAI into action and face a myriad of choices, orchestration startups are predicted to play an outsize role in 2024. These startups are attracting significant venture capital interest[77] and designed to orchestrate the many tasks of managing LLMs, including:

- Simplifying model selection
- Choosing and fine-tuning models
- Integrating multiple LLMs into a single service
- Deploying applications at lower costs
- Creating platforms that democratize access to LLMs[78]

Managing regulatory uncertainty, instituting governance

Closing the AI trust gap

The capability many people find so captivating is GenAI's ability to mimic human thinking and behavior. Of course, human thinking and behavior aren't always perfect, predictable, or socially acceptable—and the same is true for technology.[79] Experts say keeping humans in the loop remains critical to check and validate the accuracy of AI and to address problems as they arise.[80]

Society expects guardrails to be in place so people can trust what AI has to offer.[81] Trust is not an inherent quality of AI but instead the product of AI governance, risk mitigation, and the intentional alignment of people, processes, and technologies across the enterprise.[82]

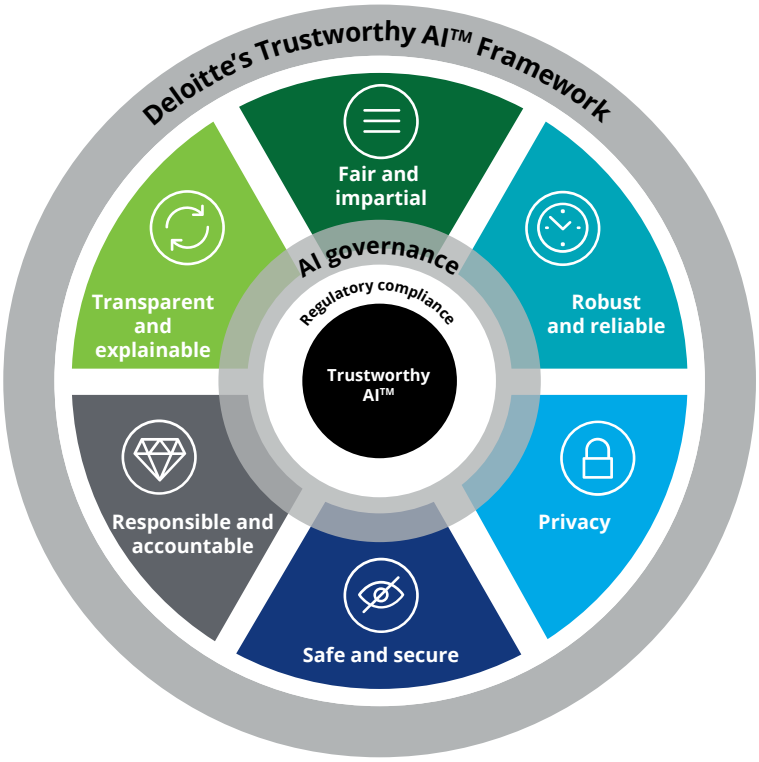
AI-experienced executives Deloitte surveyed across industries globally in December 2023 expressed a variety of concerns about GenAI risks, including the need to:

- Manage hallucinations and model bias,
- Assess potential intellectual property issues, and
- Ensure transparency and explainability.[83]

By 2026, more than 80% of enterprises are predicted to be using GenAI and/or deploying GenAI-enabled applications in production environments.[84] Business users should have a real understanding of GenAI and keep end users in mind--not rely solely on AI engineers and data scientists to contend with the risks and the consequences of trusting a tool.[85] Uncertainty around regulatory and legal challenges is expected to affect the development of the overall market.[86] According to one survey of technologists, 41 percent say that they are concerned about the ethics of AI tools that their company uses.[87] In another study of consumers and buyers in 25 countries, more than half of respondents don't trust their companies to use AI ethically.[88] Almost 70 percent of these respondents believe advances in AI make it even more important to be able to trust companies.[89]

Organizations can complement innovation with a strategy that also builds customer trust and brand equity. Deloitte developed its Trustworthy AI Framework to help organizations adhere to emerging regulations (figure 8).[90]

Figure 8. Trustworthy AI Framework



Source: Deloitte, "Trustworthy AI," 2022.

Private: Privacy is respected. User data is not used or stored beyond its intended and stated use and duration and users are able to opt-in/out of sharing their data.

Transparent and explainable: Users understand how technology is being leveraged, particularly in making decisions; decisions are easy to understand, auditable, and open to inspection.

Fair and impartial: The technology is designed and operated inclusively—for equitable application, access, and outcomes.

Responsible: The technology is created and operated in a socially responsible manner.

Accountable: Policies are in place to determine who is responsible for the decisions made or derived with the use of technology. Because an AI model has no autonomy or intent, it cannot be held accountable in any meaningful sense.[91]

Robust and reliable: The technology produces consistent and accurate outputs, withstands errors, and recovers quickly from unforeseen disruptions and misuse.

Safe and secure: The technology is protected from risks that may cause physical, emotional, environmental, and/or digital harm to individuals or communities.[92]

Appointing a chief AI officer (CAIO)

Forward-thinking enterprises are already appointing a chief AI officer (CAIO) to lead their business visions and manage reputational, regulatory, and legal risks.[93] An effective AI governance framework can help identify potential risks and gaps in capabilities, validate performance, and safeguard the business.[94]

While AI shares some practices with IT governance, it is a distinct discipline that benefits from both technical and non-technical stakeholders.[95] The US government is expecting US federal agencies to appoint CAIOs and introduce new governance approaches to ensure their use of AI is lawful, secure, and transparent.[96]

Of particular concern for life sciences is that LLMs have the potential to pose substantial risk with respect to proprietary or sensitive information that passes through these systems, despite current safeguards. Moreover, when existing foundation models are fine-tuned with a company's own data, experts say companies should double down on data governance, especially if an outside vendor is used for fine-tuning.[97]

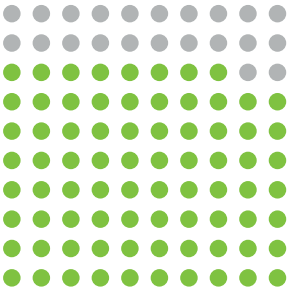
Companies may also consider creating a "sandbox," an isolated environment that allows employees to explore the capabilities of GenAI tools without sharing their prompts or the data with developers. Developers, as well as users, need to apply monitoring and feedback processes—helping ensure quality of the outputs generated and to encourage continuous improvement while companies determine what level of transparency is best.[98]

Anticipating future regulatory challenges

A string-of-pearls approach could also be utilized effectively in the context of regulatory—by aligning multiple technologies and geographies for a harmonized regulatory environment.[99] While a global set of regulations may not be feasible, the potential of global guardrails based on countries' regulatory approaches may provide regulatory clarity and could be beneficial.[100] A global collaborative and clarity of the regulatory environment can help accelerate the AI journey and adoption across regions.[101]

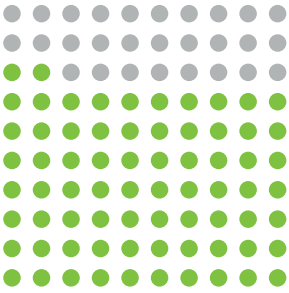
Research finds AI-experienced directors and C-suite executives are looking for more regulation and collaboration globally (figure 9).[102] A rapidly changing regulatory landscape and the speed of GenAI innovation can create a challenging environment for those building technologies and those looking to manage them.

Figure 9. Leader support for GenAI regulation and collaboration



78% more regulation

Agree the widespread proliferation of generative AI tools / applications will require **more regulation of AI** by governments



72% more collaboration

Agree there is not enough **global collaboration** with respect to ensuring the responsible development of all AI-powered systems

Source: Deloitte, "State of Generative AI in the Enterprise," January 2024.

Some LLMs and foundation models are already testing the limits of regulations, including the EU's Digital Services Act.[103] Companies can incur risks if they do not have safeguards that help ensure that these technologies are used effectively, responsibly, and legally.[104]

Almost half of organizations (47%) responding to the State of Generative AI in the Enterprise, survey report monitoring regulatory requirements as part of their risk management efforts. Many express concerns that widespread use of GenAI will concentrate power and increase economic disparity.[105]

2023 saw lawmakers agree on a vision. But in 2024 we can expect to see policies start to morph into concrete action and tech companies being held accountable. In particular, the emphasis is expected to be on content labeling, watermarking, and transparency.[106]

United States: The US set out its most sweeping set of AI rules and guidelines in an Executive Order (EO) issued by the US government on 30 October 2023.[107] In addition to AI safety and security, it includes a requirement that developers share safety test results for new AI models with the US government if the technology could pose a risk to national security. However, the EO lacks specifics on how the policies will be enforced.[108] Some highlights of the EO include:

- **Labeling guidance:** Requires the US Department of Commerce to develop guidance for labeling AI-generated content in hopes that labeling the origins of text, audio, and visual content will make it easier for consumers to know what's been created using AI online.
- **Labeling and watermarking tools:** Asks AI developers to develop labeling and watermarking tools that federal agencies may also adopt. Stakeholders say there are currently no fully reliable ways to label text or investigate whether a piece of content was machine generated. There is also no requirement to use these tools.[109]

In 2024, the new US Artificial Intelligence Safety Institute will be responsible for executing most of the policies called for in the order. Similar to the EU's AI Act, we are likely to see an approach that grades AI by type, uses, and the level of risk they pose.[110]

European Union: The world's first comprehensive law is the EU AI Act.[111] The new rules establish obligations for GenAI/AI providers and users depending on their level of risk. Many AI systems may pose minimal risk, but the European Parliament believes they need to be assessed.[112] Critical infrastructure and other high-risk organizations are required to do AI risk assessments and adhere to cybersecurity standards.[113]

AI systems that pose "unacceptable risk" are those that are considered a threat to people and will be banned (there may be some exceptions for law enforcement).[114] Critical infrastructure and other high-risk organizations will need to do AI risk assessments and adhere to cybersecurity standards.[115]

GenAI technologies that are general purpose, like Gemini by Google and ChatGPT, have transparency requirements to:

- Disclose that the content was generated by AI
- Design the model to prevent it from generating illegal content
- Publish summaries of copyrighted data used for training[116]

With limited-risk AI systems, transparency requirements call for providing enough information to allow users to make informed decisions. Users must be able to understand that they are interacting with an AI and have an opportunity to decide whether they want to continue using it or not.[117]

Most importantly, the EU AI Act ushers in binding rules on transparency and ethics.[118] Companies building open-source AI models are exempt from most of the AI Act's transparency requirements, unless their models

are as computing-intensive as GPT-4.[119] As other countries decide on policies, the EU's comprehensive regulations are poised to serve as a blueprint for overseeing the technology,[120] and tech companies are likely to have two years to implement the rules.[121]

Singapore: Another blueprint being looked at around the world is Singapore's approach to AI governance that was initiated in 2019.[122] IMDA, Singapore's Information Media Development Authority, recently developed "AI Verify," an AI governance testing framework and software toolkit to support the current state of AI.[123]

As governments continue to chart the course to mitigate AI's risk to society, enterprise-wide risk awareness—including AI literacy and individual responsibility—will play an increasing role in day-to-day operations with the advent of GenAI. To promote the necessary AI understanding, CIOs and business leaders could support business users with resources, enhance existing workforce training and learning sessions, and foster an enterprise culture of continuous learning.[124]

(See more at Deloitte's AI Institute.)

Looking ahead

To move beyond proofs-of-concept and scale, companies may need to upgrade enterprise technology and integrate GenAI into redesigned work processes. Organizations should identify where GenAI might make the most impact and build incremental digitization, moving beyond basic productivity use cases to higher order opportunities, such as new, differentiating services or business models.[125] In addition, a sound governance model can help drive adoption, ensure accountability for outcomes, and help to realize value.[126]

Strategy questions for life sciences and medtech stakeholders regarding GenAI

01. Does our organizational approach to GenAI have a value creation and advantaged mindset?
02. How can we best scale up and build a foundation for longer-term value creation?
03. Are we sufficiently diversified in terms of the ecosystem partners we are working with? There are multiple different solutions and capabilities—how do we balance focus and diversification?
04. What guardrails does our organization need to ensure responsible use of GenAI and how do we stay aligned with shifting societal expectations?
05. What do we need to do to ready our talent and organization to adapt to transformed ways and technologies?

Pricing pressures rising globally, threats of impacts on R&D innovation worldwide

Accelerating medicines spending

Drug spending and growth is expected to accelerate globally over the next few years but varies across countries.[1] Spending for medicines is largely correlated with degrees of economic development and should be considered in the context of a country's overall health care expenditures[2] and health expenditures in the context of GDP.[3] Use of medicines is typically higher in higher income countries than in lower income countries (figure 1).[4]

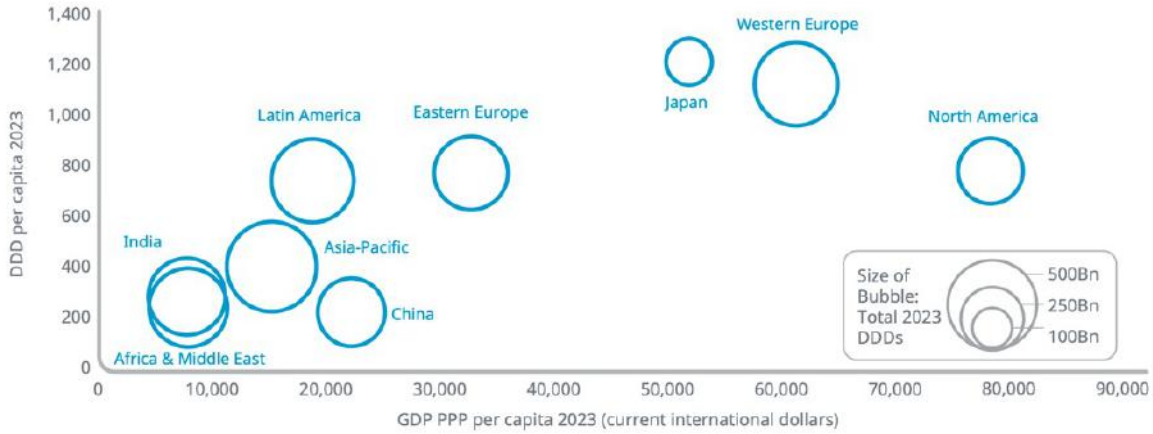
Some countries are more volume driven, while others are focused on the adoption of innovation in medicines.[5]

Specialty medicines are projected to represent more than 40% of global spending by 2028, with more than half of total spending in leading developed markets.[6]

Both population-driven volume growth—and a shift in the mix of medicines to higher cost products—is expected in North America, Eastern and Western Europe, Latin America, Africa, and the Middle East over the next five years. At the same time, China's drug spending looks to be less volume-oriented and more focused on expanding access to novel drugs, while Japan's spending is not likely to change as innovation is offset by annual price cuts.[7]

Figure 1. Per capita use of medicines

Defined Daily Doses (DDD) per capita by region compared to per capita gross domestic product (PPP), current international dollars



Source: IQIVIA Institute, December 2023; The World Bank, July 2023; International Monetary Fund, October 2023

Drug pricing pressures worldwide

Drug pricing and value continue to come under scrutiny as pricing pressures are being felt globally.[8] In 2024, government-mandated pricing pressure and controls are expected to play an increased role in the affordability and accessibility of certain medicines.[9] It's a complex topic, governed in wide ranging ways across the world, and requires taking multiple stakeholder perspectives in balance.

Direct drug pricing negotiations by the US government are underway for the first time in the US.[10] While the US government has a range of policy initiatives aimed at addressing drug pricing, the health care provisions of the Inflation Reduction Act (IRA)[11] are raising concerns among some drugmakers.[12]

In Europe, there is similar price consciousness. For example, in the UK, a new price regulation agreement–the voluntary scheme for branded medicines pricing and access (VPAS)—was reached to control the level of spending on innovative drugs.[13] VPAS sets a cap on the total allowed sales value of branded medicines to the UK National Health Service (NHS) on an annual basis.[14] The cap grows at an agreed rate of 2% per annum, but any medicine sales above the cap are required to be paid back to the UK Department of Health and Social Care (DHSC) via a levy.[15]

In Asia, Japan has steadily reduced prices every other year, ranging from around 2% to 9.4% after the latest fiscal year-over-year (FYoY) 2023 review.[16] China is leveraging its large population for its volume-based procurement strategy, significantly reducing prices while saving approximately US$36.3 billion at the end of 2021.[17]

Developed-world concerns around drug pricing are pushing the unaffordability of medicines to the top of the global health agenda as discussed at the World Health Assembly (WHA) in 2023.[18] Less-developed countries have voiced concerns over unaffordability of medicines for their health systems for decades. In 2024, the Access to Medicines Foundation is enhancing regulatory coordination in low- and middle-income countries (LMICs). The organization's updated biennial report is expected in 2024 and is expected to assess how pharma companies monitor the number of patients with access to their essential health care products in LMICs.

Implications of the US Inflation Reduction Act

The impact of pricing and access to medicines leads the list of concerns of more than half of US life sciences companies in 2024, according to a survey by Deloitte US.[19] Over the next five years, the IRA is expected to have implications for how the industry makes decisions and allocates resources in both research and development (R&D) and commercial efforts with corresponding implications for access to drugs across the world. The US holds almost a 43% share of the global pharma market and is home to some of the largest pharma companies worldwide.[20]

The IRA may have a positive effect for patient affordability given reduced out-of-pocket expenses for patients in Medicare Part D, and negotiated drugs are expected to be provided to patients at the negotiated price. Furthermore, smoothing is slated to begin in 2025, capping Medicare Part D out-of-pocket prescription drug costs at $2,000 annually.[21] As a result, it's anticipated that there may be major changes to commercial insurance design over the next few years, including pressures to incorporate patient out-of-pocket costs on net vs. list prices.

There can be material implications for drug companies with respect to gross-to-net, total molecule value—particularly for negotiated assets, price adjustments, and capital allocation for R&D and business development (BD).

A downstream effect is expected from the IRA on the operations and financials of health insurance plans, pharmacy benefit managers (PBMs), pharmacies, employers, hospitals, health systems, and other providers in the US. The price-negotiation provisions, for example, will likely impact the drug-acquisition price for providers and pharmacies and their reimbursement rates, in addition to rebates. Amongst all the players, the effects of lower negotiated prices put pressure on business practices.[22]

There may also be unintended consequences, such as differences for small molecule vs. biologic drugs as well as orphan drug dynamics (multiple vs. single orphan drug exclusion). Several negotiated drugs expect to have generics/biosimilars introduced within 12-24 months or less. In order to not create financial incentives that could deter biosimilars from entering the market, the IRA provides for a delay in selecting drugs for negotiation.[23]

Government's in-depth reviews on the drugs selected

An in-depth review of the first 10 drugs selected for negotiation is provided by the US Department of Health and Human Services (HHS)—the "Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs." Drugs selected represent nearly 20% of spending in the Medicare Part D drug benefit and were approved by the FDA more than seven years ago.[24]

According to the report, prices for the 10 drugs selected had more than doubled from 2018 to 2022, from US$20 billion to about US$46 billion, an increase of 134%.[25] In addition, the rate of growth in spending for these 10 drugs was more than three times as fast as for all Medicare Part D drugs over the same period.[26] List prices being negotiated factor into both insurance premiums and patient out-of-pocket costs.[27]

First 10 drugs selected for price negotiations

Drugs selected represent nearly 20% of spending in the Medicare Part D drug benefit and were approved by the US Food & Drug Administration (US FDA) more than seven years ago.[28] In 2024, the US administration is moving forward on seeking price cuts for 10 drugs covered by US Medicare that are commonly prescribed to older and disabled Americans; another 60 will be negotiated by 2029 (figure 2).[29] The first round includes medications for diabetes, heart-failure, arthritis, psoriasis, Crohn's disease, ulcerative colitis, blood thinners, and treatment for blood cancers. "Orphan" drugs for rare diseases, which treat conditions affecting fewer than 200,000 people, were excluded.

Drugs purchased at pharmacies under Medicare Part D are part of the first two years of negotiations, with Medicare Part B drugs, those administered by doctors, being added in 2028. Prices for the first 10 drugs are expected to be revealed by September 2024.[30]

In addition to the drug negotiation program, the IRA requires drugmakers that sell drugs through Medicare to pay rebates to the US government for drugs increasing in price faster than the rate of consumer inflation. As part of the rebate provision, prices for 48 prescription drugs included in Medicare Part B beneficiary coinsurances may be lower starting between 1 January 2024–31 March 2024.[31]

Government view, focus on cost savings

The drug negotiation program is estimated to potentially save Medicare US$100 billion[32] of the US$237 billion in overall savings projected for the IRA's drug pricing provisions over the next decade.[33] The US government believes Americans should not be paying two to three times more than what people

Figure 2. First 10 drugs up for Medicare price negotiation cuts in 2024

Drug	Type of medication	Pharma company
Eliquis	Blood thinner	Pfizer and Bristol Myers Squibb
Xarelto	Blood thinner	Janssen Pharmaceuticals, Inc., part of Johnson & Johnson, and Bayer
Jardiance	Diabetes, heart failure	Boehringer Ingelheim and Eli Lilly
Januvia	Diabetes	Merck & Co.
Farxiga	Diabetes, chronic kidney disease	AstraZeneca and Bristol Myers Squibb
Novolog	Diabetes	Novo Nordisk
Enbrel	Arthritis, psoriasis	Immunex, a subsidiary of Amgen
Stelara	Psoriasis, Crohn's disease, ulcerative colitis	Janssen Biotech Inc., part of Johnson & Johnson
Entresto	Heart failure	Novartis
Imbruvica	Cancers of the blood	Pharmacyclics, an AbbVie Company, and Janssen Biotech Inc., part of Johnson & Johnson

Source: US Department of Health and Human Services

in other Organisation for Economic Co-operation and Development (OECD) countries pay for the same drugs—even when accounting for rebates and discounts.[34]

A recent US Senate Health, Education, Labor, and Pensions (HELP) Committee staff report highlighted the high cost of drugs in the US compared to other countries.[35] The issue is complex, and there are many variables to consider. For example, HELP's focus is on gross prices that are part of the negotiations. Manufacturer gross drug prices for brand name originator drugs are significantly higher in the US than other countries—422 percent of prices in comparison countries in 2022.[36]

What the drug manufacturer receives, the "net" price, can be up to 75% less. Negotiated and statutory rebates to third-party payers are the largest share of gross-to-net differences.[37] In the first three quarters of 2023, net prices for brand-name drugs dropped for the sixth year in a row, with real, inflation-adjusted net prices falling -7.4% in 2023.[38]

Comparisons of gross prices shape public perception, and for 158 million Americans with employer-based plans, premium contributions and out-of-pocket costs, like those for prescription drugs, are taking up an increasing portion of US household budgets.[39] The US government increases demand for prescription drugs by subsidizing employment-based health insurance in addition to being the primary funder of basic research in biomedical sciences.[40]

Pharma industry view, focus on pharmacy benefit manager reform

Drug manufacturers point to PBMs as needing significant reform.[42] A concern for the Pharmaceutical Research and Manufacturers of America PhRMA is that the US government's policy presents barriers to transparency and accountability. Prescription drugs are the only part of the US health care system where the difference between list and net prices is monetized as rebates that are redistributed via intermediaries to payers.[43] PhRMA President and CEO Stephen Ubl says reforms should shift focus to ensure that rebates companies negotiate with intermediaries (like PBMs) are passed onto patients at the pharmacy counter.[44]

PBMs were introduced into the system to manage benefits for health plans, and while they were

Where does the money go? Gross-to-net price differences

A drug's net price represents the actual revenues that a manufacturer earns from a drug after paying rebates, applying discounts, and other reductions.[41] Gross-to-net price differences for brand-name drugs include:

- Rebates, discounts, and fees to commercial payers and plans
- Rebates and coverage gap discounts in Medicare Part D
- Rebates to the Medicaid program
- Discounts under the 340B Drug Pricing Program
- Manufacturers' payments to drug channel participants, including administrative and other fees to PBMs as well as fees and discounts to pharmacies, wholesalers, and other purchasers
- Patient assistance and copayment support funds

supposed to lower health care costs,[45] manufacturers' list prices actually increased to accommodate rebates.[46] PBMs' use of pharmaceutical rebates allows multiple players in the supply chain to potentially benefit financially at the expense of patients and control patients' access to certain drugs.[47] In addition, PBMs own their own pharmacies, and many believe this ownership creates huge conflicts of interest—hurting competition and distorting pricing.[48]

The US House of Representatives launched a report in 2023 that found:

- PBMs often require burdensome prior authorization that may cause lengthy delays to approve prescriptions.
- With lengthy delays, some patients may suffer, and even die, while they await authorization.[49]
- Some patients first have to fail to respond to a more expensive drug, even if a cheaper alternative exists because the PBM may have a financial incentive to compel the more expensive drug.[50]

Provisions in the US Department of Health & Human Services (HHS) November 2020 final rule on pharmacy benefit managers' rebates should eliminate rebates in favor of point-of-sale discounts in the Medicare Part D and Medicaid managed care organization programs.[51] Essentially, the rule is designed to remove the anti-kickback safe harbor for rebates.[52] However, implementation of the rule was deferred, and the IRA has extended the time to implement the rule until 2032. [53]

Industry stakeholders are also concerned about the disproportionate power and influence of the three largest PBMs that control over 80% of all prescription drug access and reimbursement in the US.[54] In 2022, these PBMs excluded more than 1,150 medicines from their standard commercial insurance formularies, representing a nearly 1,000% increase in exclusions since 2014, including medicines that would provide patients needed treatments at lower costs.[55]

Experts say out-of-pocket costs for many patients have risen as leading PBMs logged double-digit profit growth.[56] Enforcers, like the US Federal Trade Commission (FTC), and lawmakers in Congress have started focusing on PBMs with hearings and bills, and PBMs will likely remain on the hot seat.[57]

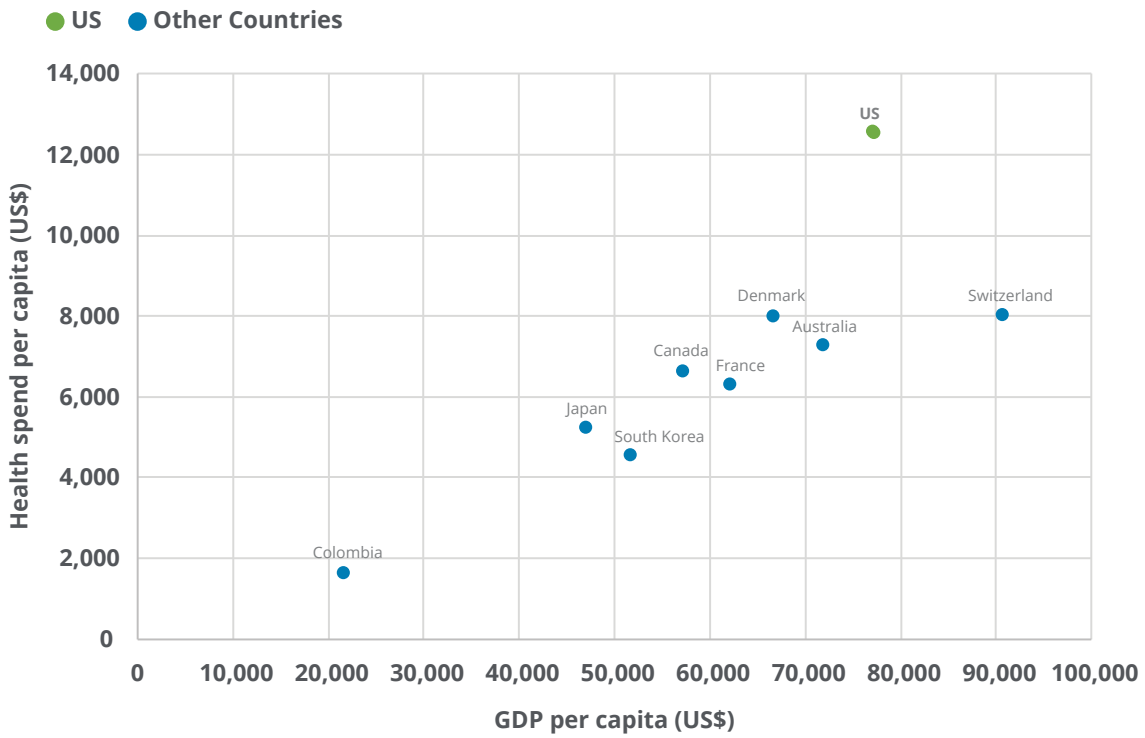
"The US is the only country where our members are capturing less than 50 cents on the dollar of the list price of the medicine, with the rest being absorbed very efficiently by other actors in the supply chain."

—**Stephen Ubl**, President and CEO of PhRMA[58]

Drug pricing in the context of per capita health expenditures and GDP

The US spends considerably more per capita on health expenditures than peer nations, spending about US$12,500 in health expenditures per capita, with a GDP per capita of approximately US$77,000 in 2022 (figure 3).[59] Switzerland and Germany have the next highest health expenditures per capita, at about US$8,000 each per capita in 2022; GDP per capita in 2022 was higher for Switzerland at about US$90,000, and close to US$67,000 in Germany.[60]

Figure 3. GDP per capita and health consumption spending per capita, US dollars, 2022 (current prices and PPP adjusted),



Source: Petersen KFF Health Tracker, analysis of OECD data

As an example of the wide range in prices paid for essential medicines across the world, in 2019, the median price paid for 60 tablets of the blood thinning medication Eliquis by a sample of private health insurers was US$440 in the US, US$162 in Switzerland, and US$96 in Germany in 2019 (figure 4).[61] The price in the US was 4.5 times more than in Germany.[62]

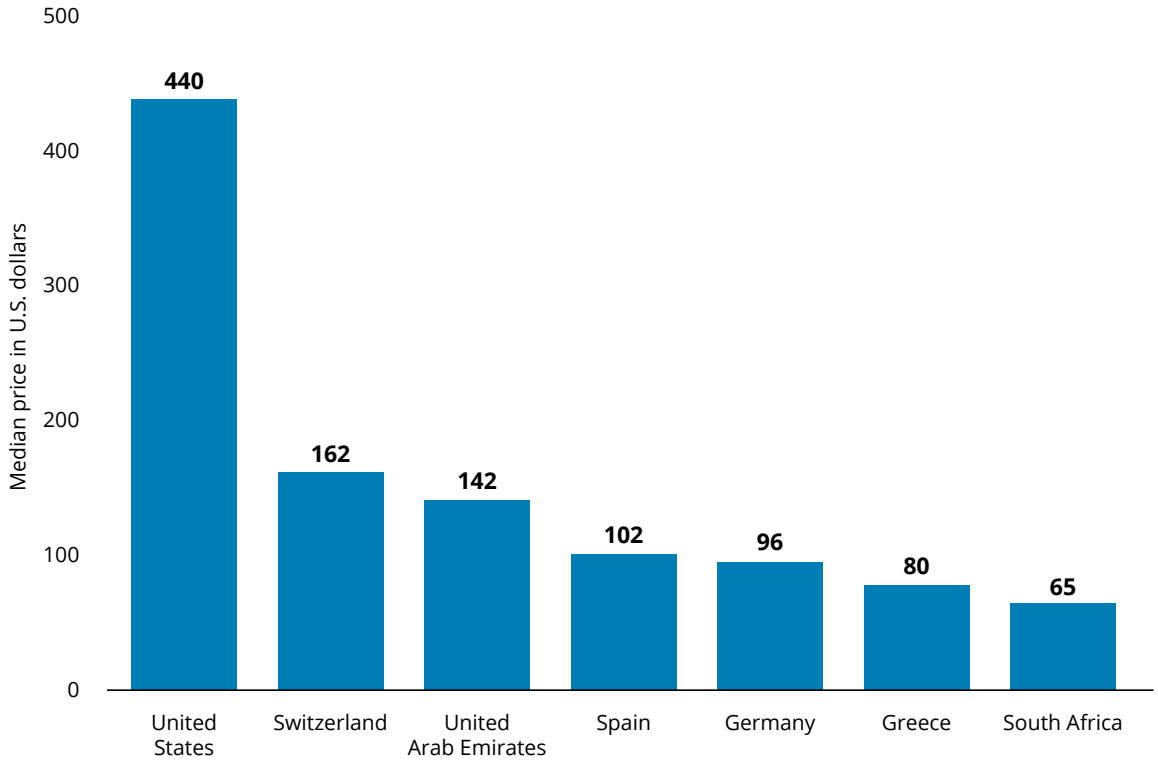
The Bristol Myers Squibb (BMS) customer savings and support webpage promotes that Eliquis is covered by 90% of commercial and Medicare Part D plans, but out-of-pocket copays vary. The webpage offers a US$10 copay card to apply towards any copay for patients deemed eligible to receive it, which could be those who have insurance and still have a copay or those without insurance.[63]

Discounted prices advertised for 60 tablets of Eliquis by GoodRX, available to consumers from leading pharmacies in the US, are in the range of about US$592 to US$626—a savings of 9% to 17% off the retail price.[64] GoodRX's discount and coupon prices are

based on contracts between a pharmacy (or pharmacy purchasing group) and a PBM that provide the prices and are a best estimate.[65] Some patient assistance programs (PAPs) also provide those with limited incomes access to free or low-cost prescription drugs from the drug manufacturer.[66]

As we point out in the patient section of this outlook, some patients do not even know who manufactures their drugs, and more than one company is associated with many drugs. Finding the best available price and discount is not just a patient problem, it can become an administrative cost and burden on health care professionals (HCPs), pharmacists, communities, and the health care system as a whole if patients cannot afford the medicines they need and risk suffering additional health consequences.[67]

Figure 4. Median prices paid for Eliquis by a sample of private health insurers in select countries in 2019



Notes: Prices are for Eliquis (apixaban 5mg) – 60 pills. The source compared the median prices paid by a sample of private health insurance companies for 34 specific health care services in 11 countries in 2019. Health cost comparisons among various countries are complicated by differences in sectors, fee schedules, and prices may not be representative of prices paid by other plans in that market. The limitations were minimized by selecting services with very specific definitions and wording survey questions to match the procedures that are the basis of the US payment system.

Source: Statista, 12 August 2022

CMS hosts patient "listening sessions" in support of Medicare negotiations

Concern about high copays were expressed at the patient listening session for Eliquis—hosted by the US Centers for Medicaid and Medicare Services (CMS)—and open to the public online.[68] These live-streamed listening sessions are opportunities for patients, patient advocacy groups, caregivers, and others to provide feedback on the values of particular drugs.[69] Ten sessions were held in Q4 2023, one for each drug being negotiated.[70]

Transcripts for the sessions are available on the CMS website,[71] including a transcript for the Eliquis session.[72] One medic, representing Doctors for America as its Vice Chair for Access to Affordable Care, points out that high copays for Eliquis are not insignificant for seniors on a fixed income.[73]

Area of high public interest and opinion

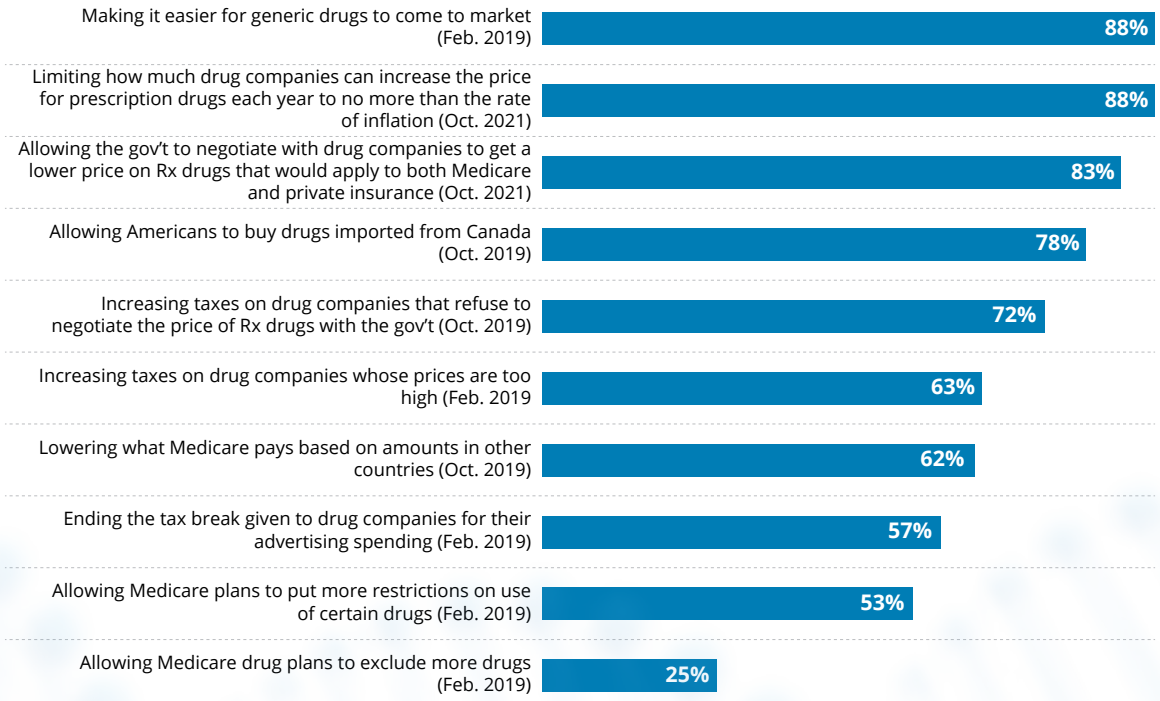
The pharma sector faces growing public scrutiny and media attention regarding drug pricing transparency and affordability.[74] More than 900 name brand drugs have price increases taking affect at the beginning of 2024.[75] But the median wholesale acquisition cost (WAC) increase of 4.7% is now the lowest percentage increase in more than a decade, down 0.1% from 2023.[76]

Many believe the pharmaceutical industry is viewed unfavorably due to the rising (and total) cost of prescription drugs.[77] Research organizations have been polling public opinion in the US for decades,[78] and 93% of Americans feel drugmakers would still make enough money if prices were lowered.[79]

A 2023 poll found that 82% say the cost of prescription drugs is unreasonable, and almost three-quarters of Americans feel there should be more regulation to limit the price of drugs.[80] An end of the year 2022 poll queried Americans regarding support of various proposals for lowering drug costs (figure 5).[81]

Figure 5. Tracking US public opinion on drug cost regulation, November-December 2022

Percent who favor each of the following actions that would keep prescription drug costs down:



Source: KFF Health Tracking Poll (29 November-8 December 2022)[82]

Reducing the price differences between the US and other countries

Reductions in administrative burdens and drug costs could substantially reduce the difference between US and peer nation health spending.[83] While drug manufacturers say price cuts can negatively affect innovation,[84] the US government's view is that companies spend more on stock buybacks and dividends than they do on research and development (R&D).[85] Accordingly, the IRA has tax implications, including a 1% share buyback excise tax and a corporate alternative tax of 15% for companies meeting the thresholds.[86]

Pharma industry view, focus on innovation

According to PhRMA, members want to get patients access to the medicines they need, but believe the IRA is a threat to innovation and collaboration.[87] PhRMA member companies have more than doubled their annual investments in the search for new treatments and cures over the last decade.[88]

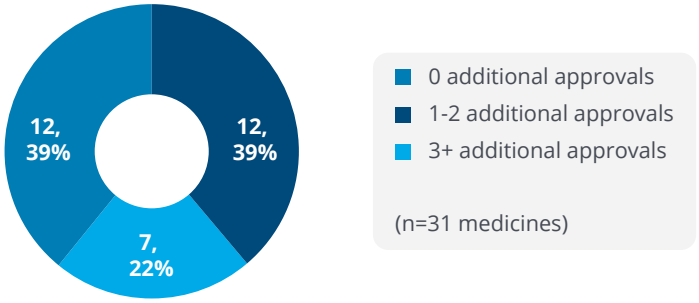
From discovery to launch, drug manufacturers spend an average of US$2.3 billion to bring a new drug to market.[89] The top 20 global pharmaceutical companies collectively spent US$139 billion on R&D in 2022.[90]

PhRMA states that the IRA ignores the nature of the R&D process by not considering:

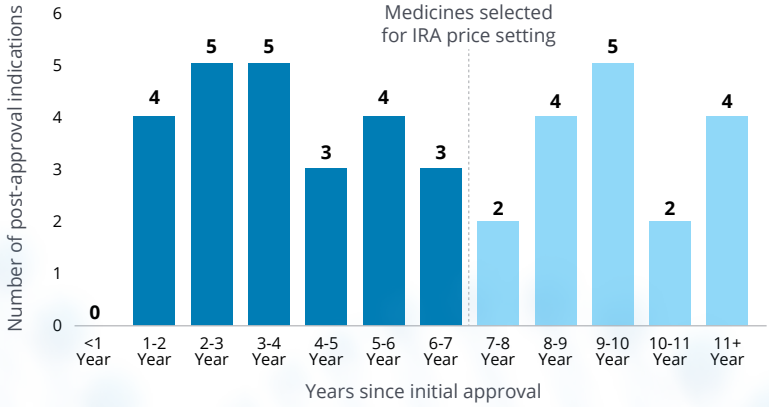
- Innovations that occur past the time of their first USFDA approval (figure 6)—new uses for medicines, new patient populations, new formulations, and new dosage forms.
- The real-life impact new drugs and treatments can have on patients.
- The increase in therapeutic value over time as medicines are approved for new uses—such as in new patient populations, for use with new diseases or new stages of disease.[91]

Figure 6. IRA's price setting impact on cancer medicines, research from the Partnership for Health Analytics and Research (PHAR)

Number of cancer medicines by number of post-approval indications
For small molecule oncology medicines receiving initial FDA approval between 2006-2012



Timing of post-approval indications
For small molecule oncology medicines receiving initial FDA approval between 2006-2012



Source: PhRMA, research from PHAR

Lawsuits argue the constitutionality of the pricing negotiation framework

As part of the IRA, a new US excise tax, ranging from 65%-95% on all US sales by a pharmaceutical manufacturing company, may potentially be applicable to pharmaceutical manufacturers who do not enter into a negotiation program with the US government to determine maximum prices.[92]

While all the companies representing the first 10 drugs selected signed agreements to negotiate,[93] PhRMA, drugmakers, some patient advocacy groups, and others, initiated lawsuits against the constitutionality of the measure. [94] The Global Colon Cancer Association (GCCA) joined PhRMA's lawsuit because it believes that the IRA could thwart progress in colon cancer research that is affecting more Americans under 50.[95] According to GCCA Executive Director Andrew Spiegel, "The IRA is implementing a process where patient voices and concerns have no real seat at the table." [96] He says patients deserve better, and that's why GCCA joined in the lawsuit.[97]

As of 1 May, the courts have rejected the PhRMA lawsuits including one brought by AstraZeneca[98]—signaling that the pharmaceutical manufacturers may not secure legal protections. However, PhRMA filed an appeal,[99] and a federal judge in New Jersey is permitting four other drugmakers—BMS, Novo Nordisk, Novartis, and Johnson & Johnson—to combine their arguments.[100] Additional lawsuits are still pending.[101]

Impacts on portfolio strategies

Will less revenue mean less drug innovation?[102] Lowering US drug prices may impact incentives to innovate because drugmakers are likely to be less profitable.[103] The IRA is already affecting R&D decision-making and portfolio strategies as there is uncertainty around planning. Some companies are rethinking R&D investments—shifting away from small molecule investments.[104]

In a survey of 25 participating PhRMA members, three-quarters say early-stage pipeline projects are likely to be cancelled and two-thirds say pipeline projects that are planned, but not yet in clinical development, will likely no longer be pursued. More than half expect to reduce spending on new scientific platforms that may take many years to develop.[105]

Nonetheless, recent research by the Congressional Budget Office (CBO) expects that about 13 out of 1,300 new drugs, or 1%, over the next three decades would not make it to market as a result of changes brought about by the IRA.[106] Other experts say novel discoveries are mostly the result of taxpayer investments in academic research and startups.[107] However, how those new discoveries are accelerated and studied is predominantly funded by the pharma sector, not biotechs, given the cost.

Acumen Pharmaceuticals is an innovative biotech company specializing in novel Alzheimer's disease therapeutics, with a focus on toxic amyloid beta oligomers. Acumen received funding from the US Department of Health & Human Services (HHS),[108] and recently was awarded "[the 2023] Monoclonal Antibody Solution of the Year" by the BioTech Breakthrough Awards program. [109] Acumen CEO Daniel O'Connell says that in order to really bring attention to Alzheimer's disease, and meet the market's needs, it will require the support of large pharma companies.

"We are in the early days of launching disease modifying treatments for Alzheimer's disease patients. Large pharma companies, like Biogen, Eisai and likely Eli Lilly are helping to establish the market. Over the next few years, with additional data and time, opportunities will start to open up. Buyers are trying to assess how big the Alzheimer's market is really going to be. Large pharma companies, like Biogen and Eli Lilly have added to the mix. Depending on the drug growth trajectory with those initial products, companies like Merck, maybe AbbVie and BMS, will be looking for their play. That is going to contribute to some level of partnering and M&A that will further catalyze growth of the Alzheimer's space.

Knowing the mindset within the business leadership of these big pharma companies right now, there is a "wait and see, show me" kind of attitude for Alzheimer's disease. For Acumen, and our mAb (monoclonal antibody), it's a greenfield; there is no prior precedent. The field is in the process of establishing the patient journey, the infrastructure, etc. It's going reasonably well, and by this time next year, we're going to be convinced that the commercial possibilities are very real and growing. It'll be an important time for us to continue to position our asset and program as one with attractive differentiation and long-term potential. And there's an important role for the larger pharmaceutical companies to play in bringing these innovations to commercialization and ultimately have the envisioned patient impact."

—**Daniel O'Connell**, CEO at Acumen Pharmaceuticals
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IRA impact requires a balanced view from stakeholders

In 2024, pharmaceutical leaders should consider ways to make products more commercially accessible through different payment schema. In the next few years, patients may lose out for niche indications as the IRA is discouraging the development of some types of medicines and treatments for certain patient populations. These effects are likely to spread throughout the world as the US leads transformative innovation.

No doubt the impacts of the IRA will be profound in the US as well as globally, but the precise impact and timing is still unfolding. All sides present strong arguments. Pharma wants to keep innovating—and be incentivized to do so. Patients want fair prices and HCPs want patients to be able to afford their necessary medicines. And the US government wants more equitable prices—as it is carrying a large share of the burden to make these drugs available globally.

Pricing pressures challenge Japan's innovative reputation in medicines

While Japan is known for developing innovative medicines, recent pricing pressures, akin to those in other parts of the world, are also driving reforms.[111] Reforms are creating uncertainty for pharmaceutical companies in the world's third-largest pharma market as well as concerns over the future of innovation.[112]

The Japanese government reimburses patients for drugs at prices specified in the Drug Price Standard (DPS). The DPS covers all medications dispensed by the National Health Insurance (NHI) and stipulated by Japan's Ministry of Health, Labour and Welfare (MHLW).[113]

Health care funding sources, public vs. private

Health care in Japan is publicly funded, while health care delivery is primarily done through private institutions.[114] In the UK, the health care system is mostly public, while predominately private in the US (figure 7).

Japan's health care system is known for maintaining relatively low health care costs compared to other developed countries.[115] In 2022, its health expenditure per capita was US$5,250, less than half of that for the US.[116] While patients in Japan have copays, there are caps on out-of-pocket expenses.[117]

Figure 7. Countries' health care service provider and its financial resource

Country	Primary service provider	Financial source*2
	Private (Public: 5%)*1	**Public** (Public: 84%)
	Private (Public: 23%)*2	**Private** (Public: 51%)
	Public (Public: almost all)*2	**Public** (Public: 79%)
	Private (Public: 45%)*2	**Public** (Public: 77%)
	Private (Public: 25%)*2	**Public** (Public: 78%)

Note: *1=Japan's MHLW data, 2021; *2=OECD, data, 2020
Source: Deloitte analysis

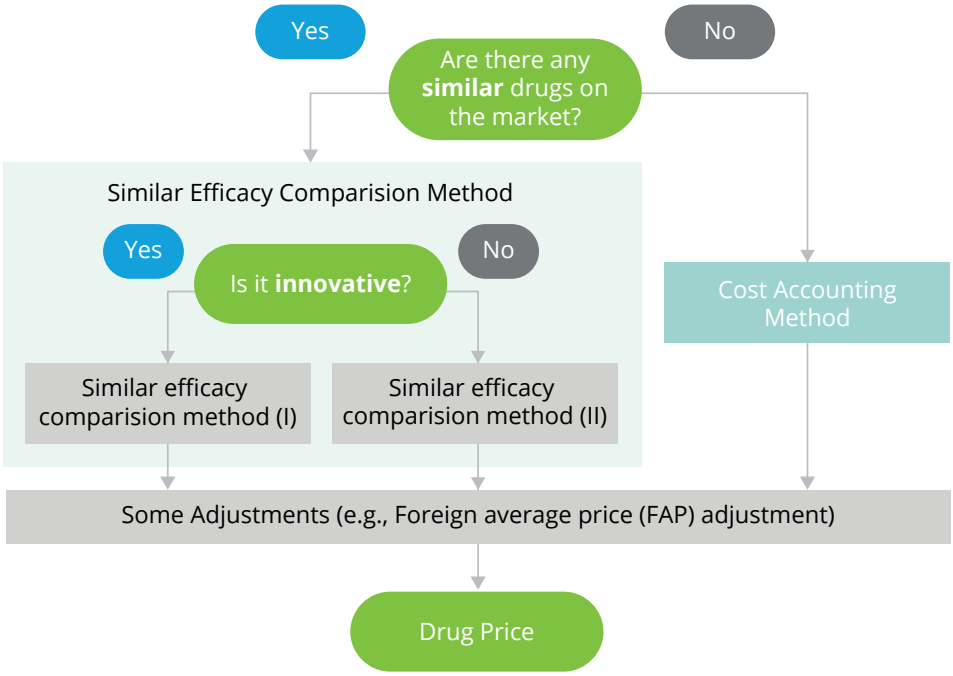
In FY2023, Japan's average drug price decreased 9.4% for 2,000 drugs in the DPS,[118] accounting for 36% of products increased in the FY2023 DPS.[119] This 9.4% decrease in 2023 for Japan's drug prices is twice the size of the 4.7% drug price increase in the US for 2024, reflecting some of the differences between countries with publicly funded health care systems and private.[120]

A new layer between market access and reimbursement

While the US government recently started considering value assessments through price negotiations, Japan was one of the first countries to introduce cost-effectiveness data for pricing new pharmaceutical products in 1992.[121] But a new Cost-Effectiveness Analysis (CEA) implemented in 2019 is testing the country's reputation for innovation.[122]

In a simplified overview, new drugs and treatments are originally evaluated for their similarity to other products in the market (figure 8). If similar and "innovative," the new product is priced comparably, according to Japan's Similar Efficacy Comparison Method (SECM) I. For less innovative products, SECM 2 adds premium adjustments for various values, like marketability and specific use. If there are no comparable drugs, a cost accounting method is used.[123] After the drug standard listing, drugs may be subject to a CEA or repricing over time.[124]

Figure 8. Pricing methods for new drugs in Japan



Source: ISPOR Asia Pacific, CRECON Medical Assessment Inc.

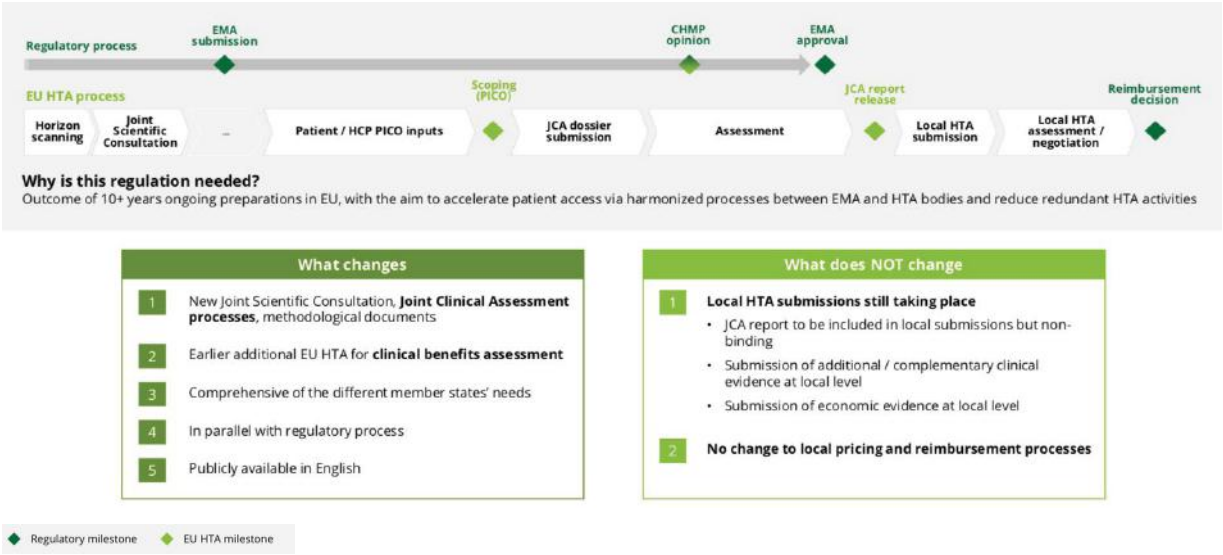
Drug manufacturers may be required to undergo a CEA for certain medicines and medical devices as part of the Health Technology Assessment (HTA) process.[125] HTAs aim to inform decision makers about relevant aspects of new health technologies, including pharmaceuticals, medical devices, surgical procedures, and other health care interventions.[126]

Experts say some of the challenges for drug manufacturers include assessing whether they will be subject to a CEA, and then ensuring they have the capabilities to show they meet CEA requirements. This extra step presents a delay in reimbursement and market access challenges.

Cross-country HTA collaborations, and value in the European Union (EU)

In many countries, HTA is used to inform reimbursement and pricing. New technologies, like Generative AI (GenAI), have the potential to improve HTA submissions. In the near future, cross-country HTA collaborations are expected to require more comparative clinical data for pricing and reimbursement decisions (figure 9).

Figure 9. Overview on European Union (EU) HTA process in parallel with European Medicines Agency (EMA) submission process*



Note: * Process and timeline are not final and expected to change until 2025

Source: Deloitte analysis

Providing evidence for value in the EU

Evidence for a value-based system already has precedent in many other countries, particularly throughout the EU. Collectively, the EU plus the UK represent the second largest pharma market (33%), even though China is the second largest by country.

For example, Norway currently has a system that gives a drug its cost based on the patient's quality-adjusted life year. Their approach seeks to control costs by negotiating the prices of new drugs based on their cost-effectiveness and how health benefits are distributed.[127]

Rising use of medicines and calls for global pricing transparency

A good balance—between pharma cost containment measures, innovative medicine, and affordability—is critical to achieving optimal pricing and reimbursement, as the use of medicines is only expected to rise globally (figure 10)[128] along with global calls for pricing transparency. Many countries already require their manufacturers to declare ex-factory pricing—the manufacturer's selling price—in their initiatives (figure 11).

Figure 10. Historical and projected use of medicines by region, 2018–2028

Note: Forecasted Defined Daily Doses (DDF) in billions

Source: IQVIA, "Global Use of Medicines 2024, Outlook to 2028", January 2024.

Figure 11. Approaches used for drug price transparency by various countries

	Approach used on drug price transparency to government (through price declaration practices of pharma companies)				Drug price setting mechanism		Governing bodies for price setting mechanism
	Report other countries' price	*Ex-factory price*	*Distribution/ logistics fee/ wholesale*	*Pharmacy retail price/reimbursement list (RL)*	*Price referencing*	*Price negotiation*	
Canada	✓	✓		✓ (RL)	✓	✓	*Patented Medicine Prices Review Board*
China		✓	✓	✓	✓	✓	*National Development and Reform Commission*
Germany	✓	✓	✓	✓ (RL)	✓	✓	*Ministry of Health*
United Kingdom		✓	✓	✓ (RL)	✓	✓	*Pharmaceutical Price Regulation Scheme, Department of Health*
Netherlands	✓	✓		✓	✓		*Ministry of Health, Welfare and Sports*
United States		✓		✓ (RL)		✓	*Medicare, Department of Veteran Affairs, Medicaid, Health Maintenance Organization and Pharmacy Benefit Managers*

*Drugs covered under Medicare, Department of Veteran Affairs' health plans and Medicaid Best Price Program

Source: Deloitte analysis

In 2024, the US joined attempts by health systems around the world to control spending on new drugs, while also ensuring and improving access to innovative medicines for their populations. The IRA in the US is expected to have significant implications on how some of the largest pharma companies allocate funds for R&D and commercialize their drugs. Impacts on innovation and access could be felt globally.

In Europe, Japan, and China, the focus on how to evaluate the cost benefit of new medicines will likely continue—with new challenges. In particular, they will need to focus on how to value and price the benefits for cell and gene therapies as a class of expensive drugs with patient benefits over multiple years. Only through collaboration between industry and the health ecosystem can patients be assured that there is a win-win for finding cures and preventing and treating the diseases that affect all of us.

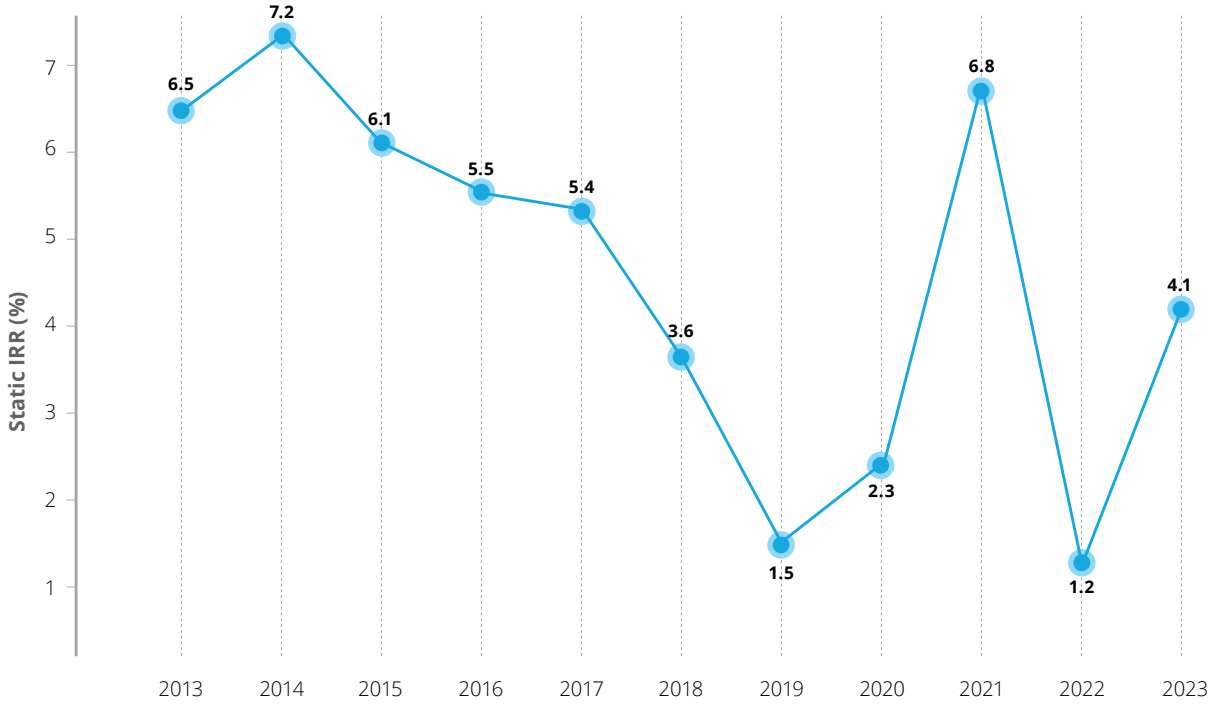
Accelerating speed of time to value in R&D

Large pharmaceutical companies account for almost two-thirds of total pharma research and development (R&D) investments[1] and spent a record total of US$161 billion in 2023—an increase of almost 50% since 2018.[2] As a percentage of companies' net sales, spending reached a historic high of 23.4%.[3]

Since 2010, Deloitte's series on Measuring the return from pharmaceutical innovation has provided insights into the productivity of biopharma R&D and has now evolved to include the top 20 pharma companies by R&D spend (determined in 2020).[4] For this cohort, R&D spend increased 4.5% from 2022 to 2023, while the average R&D cost to progress an asset from discovery to launch remained flat in this period at US$2.284 billion per asset.[5]

This year's modeling, based on a dataset that includes an expanded scope of assets and line extensions, shows the internal rate of return (IRR) rising to 4.1% in 2023 from 1.2% in 2022—the lowest point for the cohort since our analysis began (figure 1).[6]

Figure 1. Internal rate of return of the late-stage pipeline



Source: Deloitte, "Unleash AI's potential: Measuring the return from pharmaceutical innovation – 14th edition," 2024.

In 2024, ongoing regulatory changes and loss of exclusivity of an unprecedented number of high-value assets are expected to challenge the existing biopharma operating model.[7] Pricing pressures from the Inflation Reduction Act's (IRA's) health provisions are already impacting R&D decision-making and portfolio strategies.[8] Ten R&D leaders interviewed by Deloitte expressed more concern about changing regulations than cycle times or R&D costs.[9]

Scientific and technological advancements present a significant opportunity for those willing to harness the power of innovation, but the rapid pace of innovation can also be a challenge.[10] Advances in AI, including Generative AI (GenAI), have the potential to demystify complex disease biology, expedite drug discovery, cut study timelines, revitalize the clinical trial experience and improve regulatory success. Realizing productivity improvements and unleashing AI's value could provide new sources of value.[11]

Not just speed to market, but accelerating time to value

Speed to market has long been a leading priority for drug developers to accelerate patient access to life-saving therapies.[12] Since Deloitte first started analyzing pharmaceutical innovation in 2010, still only about one in ten new drugs entering human trials obtains regulatory approval.[13] Despite many advances in science and technology, this remains one of the leading challenges for the biopharma industry.[14]

"When you're facing an illness like cancer or heart disease, you don't want therapies 20 years from now—you want them now."

—**David Reese**, Executive Vice President, Research and Development, Amgen [15]

Speed to market is only part of a success formula; companies should also be looking at ways to accelerate time to value.[16] Leading biopharma companies are adopting new GenAI/AI technologies and other data innovations across the value chain, while forming new partnerships, collaborating early with regulators, and outsourcing for cost and time savings.

"Twenty-five percent of our projects entail working with partners, which has doubled research productivity as measured by dollars spent per clinical candidate and doubled our first-in-human entries."

—Paul Hudson, CEO, Sanofi[17]

Adopting a more agile mindset

Accelerating people and processes

By adopting strategies to accelerate time to value, companies can start on their individual path to potential cost savings and competitive advantage[18] even if small gains are made in each step of the process.[19] With the pace and development of AI-enabled digital solutions only expected to accelerate, leaders should start reengineering with an agile mindset.[20]

Accelerating time to value in an agile manner means having the people and processes in place to change and adapt swiftly in response to market forces.[21] Successful companies are building strategies to reduce the time it takes to advance across the stages of R&D, commercialization, and post-marketing surveillance. [22]

"We are applying speed levers in multiple areas, from digital technology and innovative study designs to regulatory partnerships. Our goal is to help each drug development team integrate as many of these levers as possible to accelerate progress."

—Kimberly Clemenson, Vice President, R&D Transformation, Amgen[23]

Snackable AI for improving business functions

At the BioCentury China Healthcare Summit in late 2023, Sanofi CEO Paul Hudson discussed how Sanofi uses "snackable AI" to get rapid access to data by providing many people across the organization with "bits" of AI for real-time decision-making and reporting. He says snackable AI offers radical data transparency and may provide immediate and trustworthy feedback without hesitation or sugarcoating–unlike managers who may delay delivering data to leaders when uncomfortable with the results.[24]

Use of AI in R&D expected to grow 106%

While the pharma industry is innovative in R&D, it is also true that it is often slow at embracing technological revolutions.[25] However, GenAI has brought more widespread attention to the current state of AI and jumpstarted many new initiatives.[26] Research shows that AI currently accounts for approximately 16% of drug discovery efforts and is

predicted to grow by 106% over the next three to five years.[27] It is the combination of domain specific LLMs, GenAI, AI/ML, deep learning, and data analytics that is positioned to accelerate time to value across biopharma R&D.

The R&D function represents the top value opportunity for large biopharma companies representing 30-45% of value creation. AI applied to novel drug identification and accelerating drug development could provide both cost savings and revenue uplift.[28]

Combining next-generation AI technologies with rich multi-omics data may close the loop across the R&D pipeline with rapid, automated generation and testing of hypotheses from bench to bedside.[29] Currently, GenAI may reshape the way life sciences organizations decide:

- Which disease areas to invest in,
- Which targets to pursue, and
- Which molecules to develop.[30]

Incorporating GenAI in R&D, from novel target identification to regulatory approval

Experts have ambitions to apply GenAI technologies to novel target identification through to regulatory approval, and into commercialization.[31] To kickstart their GenAI programs, organizations should employ "no regrets bets" that can deliver value in a relatively short timeframe (figure 2).[32] These types of low-risk activities can accelerate progress, while de-risking investments.[33]

Figure 2. GenAI's "no regrets bets" in R&D

	DESCRIPTION	VALUE TO THE BUSINESS UNIT	VALUE TO THE ENTERPRISE	WHY THIS IS NO REGRETS
Research & Development	**Scientific literature summarization**			
	Generates easy-to-consume summaries of scientific literature	**Greater productivity** from faster hypotheses testing	+ Cost reduction + Revenue uplift	GenAI can cut through research noise and go straight to insights with **minimal resource investment**
	Intelligent study deliverable authoring			
	Automate the drafting of clinical study report (CSR) deliverables	**Greater speed** from less rework and automated drafting	+ Cost reduction + Cost avoidance	Companies have a massive **treasure trove of past documents** that can be tapped into to automate creation

Source: Deloitte, "Realizing Transformative Value from AI & Generative AI in Life Sciences," 2024.

The following model illustrates three horizons of innovation in pharma R&D with the development of GenAI (figure 3). Throughout the evolution of GenAI, experts say that keeping a human-in-the loop where possible will be critical to maximizing productivity gains without significant risks, even in high stakes applications.[34]

Figure 3: R&D transformation horizon

Areas of Change	Horizon 1 Today	Horizon 2 18 Months	Horizon 3 5 Years
How Is data managed and accessed?	**Disjointed ecosystem of non-standardized data sources** aligned to specific business processes *Example: RWE for omics analysis; CTMS for clinical study conduct processes etc.*	**Amazon-like marketplace** where purpose-built R&D data products or extracts can be searched and accessed *Example: Research scientists can search for biomarker analysis data from past studies clinical trials data and request access*	A **dynamic data fabric** that seamlessly connects data assets across functions to provide a single source of truth *Example: Clinicians can readily leverage real-time data from safety, commercial, and regulatory systems to meet their business needs*
How are insights curated and consumed?	Insights are generated from discrete analytical models and **interpreted by data analysts** to support clinical processes Scientists **manually review and synthesize** scientific literature (e.g., publications, patents) to create research insights *Example: Clinical study managers rely on data analysts to contextualize outputs of site selection analytical models*	Business users leverage **GenAI to interpret outputs** of complex analytical models that provide them with more flexibility and context Scientists can access **summary insights** from vast amounts of scientific literature enabling them to rapidly adapt research priorities *Example: Clinicians can interact with GenAI chatbots to understand population health insights to optimize inclusion criteria*	Insights are **readily-embedded into business workflows** with little to no-need for human intervention Insights from external research are **rapidly contextualized and disseminated** across the enterprise *Example: Research, Clinical, Finance, Commercial, Regulatory teams are provided with contextualized impact summaries of a competitor's patent*
How are research operations conducted?	Experiments are highly manual and expensive due to **iterative hypothesis development and compute-intensive validation** *Example: Scientists manually create and test hypothesis, going back to the drawing board only after confirming failed hypotheses*	Scientists use **AI-powered simulations** to parallelize generation, testing, and optimization of thousands of hypotheses *Example: Scientists generate 3D biomolecular structures by rapidly testing and optimizing new molecules to treat breast cancer*	Research scientists prioritize leads by **amplifying decisions** with impact on downstream functions *Example: Researchers prioritize leads for treating breast cancer based on likelihood of regulatory approval and commercial viability*
How are clinical trials managed?	Complex trial processes and systems result in **highly manual, linear, and siloed decision-making leading to suboptimal outcomes** *Example: Disjointed decisioning around study design and site selection lead to expensive delays in trial execution*	Clinical **processes are streamlined & simplified** through AI / GenAI automation to deliver efficiency and experience gains *Example: GenAI copilots optimize study design decisions by incorporating insights from downstream patient enrollment and site selection processes*	Clinical trials are autonomously run through GenAI copilots that **optimize outcomes across the end-to-end value chain** *Example: Real-time participant attrition insights generate recommendations to modify upstream study design choices*
How does R&D interact with other functions?	**Operations within different part of R&D are often siloed** and insights are not shared across all R&D teams *Example: Clinical data and analytics are rarely readily available to upstream research scientists*	**Seamless data and insight connectivity** enables greater collaboration across all R&D functions *Example: Research, clinical, and regulatory teams work together to solve problems and create new products*	Hyper-connected enterprise where all **enterprise functions work together** to optimize enterprise outcomes *Example: R&D, regulatory, commercial, and manufacturing functions collaborate to seamlessly launch new drugs*
How do R&D organizations navigate regulatory landscapes?	Diverse regulatory rules are **manually interpreted** by local market and process teams in non-standardized, highly manual review cycles *Example: Regulatory teams spend weeks manually reviewing new clinical regulations in EU and assessing impact on ongoing and upcoming trials*	R&D teams leverage **GenAI capabilities** at scale to automate monitoring, synthesis, and impact assessment of regulations *Example: GenAI copilots identify and synthesize trial diversity requirements in the US and flag impacted studies*	Business processes limit human error and regulatory cycle time by building **AI-enabled regulatory checks** into processes *Example: GenAI copilots ensure new protocols are compliant with the latest regulatory policies during the drafting process*

Source: Deloitte analysis

Low-hanging fruit, GenAI replacing many manual processes

Google demonstrated the capabilities of its multimodal platform, Gemini, to aid research scientists in extracting data from scientific literature, often an arduous, time-consuming process done by hand.[35] In one example, Gemini read through 200,000 papers, filtered relevant studies down to 250, extracted the key data needed, annotated, and created graphs—and the entire process took about an hour.[36] In the near term, the ability to access knowledge rapidly and transform manual processes opens up an opportunity for GenAI in clinical trials.[37]

"The clinical trial space is an area where we have a lot of repetitive and very time-consuming tasks. GenAI is really a tool that enables an acceleration in some of these tasks, where before it would be a very manual prolonged process for both sponsors and sites."

— Silvia De Carvalho, Clinical Studies lead at AXON

To achieve the necessary increases in R&D productivity, some of the sweet spots are drug discovery and early clinical development, from target selection to clinical proof-of-concept.[39] Synthetic data is one way to accelerate access to data to start prototyping models quickly, and generative chemistry combined with a platform of tools and human expertise may help speed up drug design and identify better candidates. Work is being done with GenAI in de novo protein design, such as antibody design.[40]

GenAI model, SyntheMol, creating recipes for chemists to synthesize drugs in the lab

Researchers at Stanford Medicine and McMaster University are utilizing a new GenAI model for synthesizing molecules, dubbed SyntheMol.[41] The model created structures and chemical recipes for six novel drugs aimed at killing resistant strains of Acinetobacter baumannii, one of the leading pathogens leading to antibacterial resistance-related deaths.

Older computational models were able to yield some results by sifting through 100 million known compounds. However, this only scratched the surface in finding all the chemical compounds that could have antibacterial properties—estimated as close to 10^{60} possible drug-like molecules. The work is being expanded with other research groups, using the model for drug discovery for heart disease and to create new fluorescent molecules for laboratory research.[42]

While a number of biotech companies are developing AI-designed drug molecules, none have received US Food & Drug Administration (FDA) approval.[43] It will take time to collect and analyze the data needed to demonstrate the safety and efficacy of these drugs through clinical trials.[44]

Accelerating clinical trials with GenAI

As it develops, GenAI offers several possibilities for accelerating clinical trials, including:

- Automating document generation activities to increase velocity,
- Increasing study retention by amplifying patient engagement, and
- Improving regulatory engagement with tailored submissions.[45]

Tracking speed, productivity, quality, and sustainability of GenAI applications

Reviews of potential applications for GenAI along the R&D pipeline should consider linking strategic value to metrics in speed, quality, productivity, and sustainability.[46] Use cases that improve the quality of data, assets, and decision-making have the potential to reduce failure rates across R&D phases.[47]

Productivity and quality may offer the largest gains provided by GenAI in the near term, followed by speed, then sustainability over the next decade.[48] Considering individual use cases along these metrics may help determine an optimal string-of-pearls strategy—where use cases are combined to unlock the full value of GenAI.[49] Strategic applications of AI can be found all across the R&D value chain (figure 4).

When developing the business case for investment in digital and AI, the short-term costs need to be balanced against the long- term efficiency gains. Executing large-scale strategies requires setting up a governance function for making investments, assessing value realized, and monitoring ethical and legal risks from the use of AI.[50]

For more information on the string-of-pearls strategy, read the **Extracting value from Generative AI and emerging technologies** section of the 2024 Global Life Sciences Sector Outlook.

Figure 4. Strategic applications of AI across the R&D value chain

	Role of AI	Value levers
Drug repurposing	Perform meta-analysis of clinical trial and research data to generate high quality hypothesis for drug repurposing	• Reduced pre-clinical costs • Reduced time to market • Higher NDAs
AI-driven drug discovery	Optimize target and biomarker identification and shortlisting candidates while assessing toxicity and therapeutic efficacy	• Improved clinical success rate • Lower failure rates • Higher number of NDAs
Rapid design and setup	Automated protocol generation, drafting of study documents (consent form, agreements) and regulatory submissions	• Lower average protocol authoring time • Lower average time to first enrollment
Digital data flow	Collate and standardize trial data elements to create analysis-ready data sets and to auto-populate tables and charts in trial artifacts (e.g., case report forms)	• Reduced total time per phase • On-time database lock • Faster documentation creation
Regulatory intent and submission excellence	Identify regulatory requirements across geographies, generate drafts of dossiers, and understand competitor regulatory strategy	• Higher regulatory success
Participant experiences	Enhancing participant experiences with strategic nudges to revolutionize recruitment and retention strategies	• Reduced drop out rate • Faster recruitment • Lower terminations for insufficient recruitment

Source: Deloitte UK, "Unleash AI's potential - Measuring the return from pharmaceutical innovation," April 2024.

Setting near-term GenAI objectives

Small molecule de novo generation is already delivering value, and the next wave of opportunities being developed are in the clinical arena, from operations and delivery to patient experience.[51] In the near term, organizations should look to organize data more effectively, in addition to identifying early wins from productivity gains across functions.[52] The quality and comprehensiveness of proprietary data that these algorithms are trained on are expected to be a differentiator. As GenAI becomes a core capability within R&D data science teams, organizations should also have strategies in place for developing their future workforce.[53]

Accelerating speed in clinical trials

The pace for scientific and technological advancements is accelerating, from gene therapy to AI, but challenges in clinical research remain, including:

- The ability to recruit and retain a representative patient population
- The delayed response to operational problems
- The reliance on incomplete or un-insightful data sources

Ultimately, transforming clinical trials could require companies to work in very different ways, drawing on change management skills as well as partnerships and collaborations. This may require companies to develop highly skilled interdisciplinary leadership and AI experts who can innovate, organize, and guide others as well as AI-friendly CEOs and board members to push for the adoption of AI.[54]

Strategic CGT partnerships trigger speed to value

Discovering how fast novel treatments can reach rare disease patients

In late 2023, the US FDA approved the first cell and gene therapy (CGT) treatment using CRISPR gene-editing technology to treat sickle cell disease—Vertex Pharmaceuticals' Casgevy.[55] The treatment is being viewed as a test case for how fast these trailblazing medicines can reach patients (in 2024, experts will be tracking the results).[56] Some suggest that if more than 2%, or about 2,000 US sickle cell patients, benefit from CGT over the next year, it may be a marker of progress for the disease. [57] There are 100,000 sickle cell disease patients in the US.[58] Tracking the speed at which revolutionary medicines reach patients may provide new insights and value.[59]

> "I think this is a pivotal moment in the field. It's been really remarkable how quickly we went from the actual discovery of CRISPR, the awarding of a Nobel Prize, and now actually seeing it being an approved product."
>
> **— Alexis Thompson,** M.D., Chief of the Division of Hematology at Children's Hospital of Philadelphia[60]

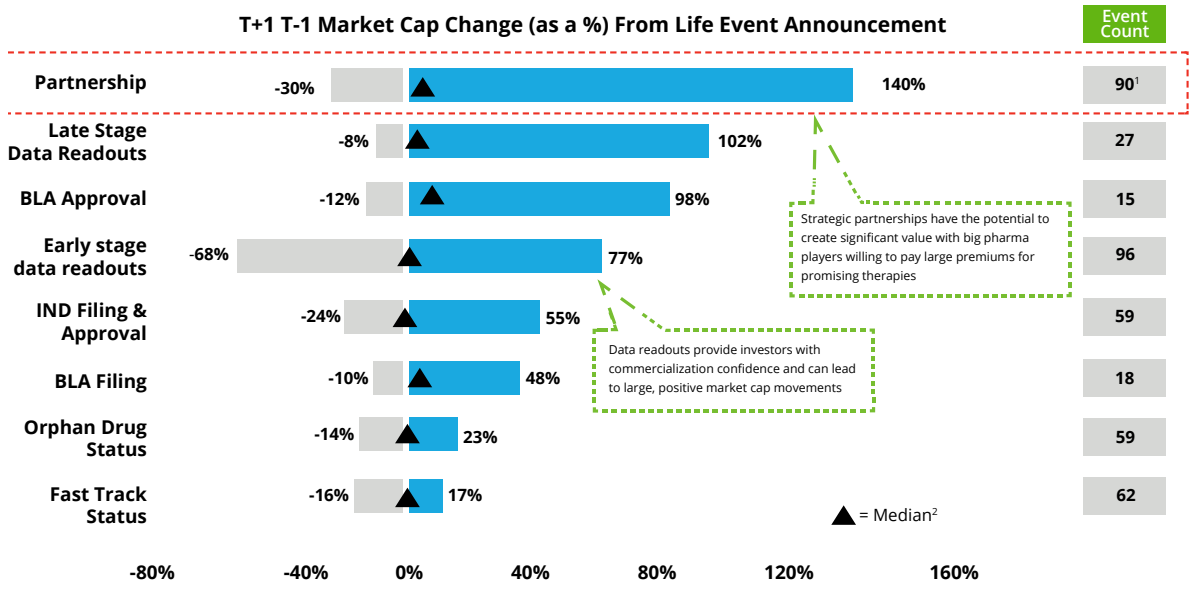
The Casgevy approval was quickly followed by another CGT approval for sickle cell disease, Bluebird Bio's Lyfgenia.[61] In 2023, Bluebird Bio said that its study for Lyfgenia was the longest follow-up of sickle cell patients to date—following 47 patients over 5 years[62]—and the National Heart, Lung, and Blood Institute (NHLBI) points to its transparency and collaboration as laying the groundwork for other technologies to follow.[63] The company says a validated access and reimbursement strategy is driving a favorable insurance coverage landscape.[64]

Successful partnerships involve a combination of commercial and R&D arrangements

What moves the needle for CGT investors after regulatory approvals is what happens when a company is closer to having a commercial product, according to Deloitte US' CGT Market Index research team.[65] Strategic partnerships top the list of triggers, with market cap increasing by as much as 140% for companies announcing partnership arrangements with another, typically large pharma company (figure 5).[66]

Figure 5. Deloitte CGT Market Index™ value triggers

Limited number of triggers correlate with an increased market value for CGT companies, data as of 2023



Source: Deloitte US analysis

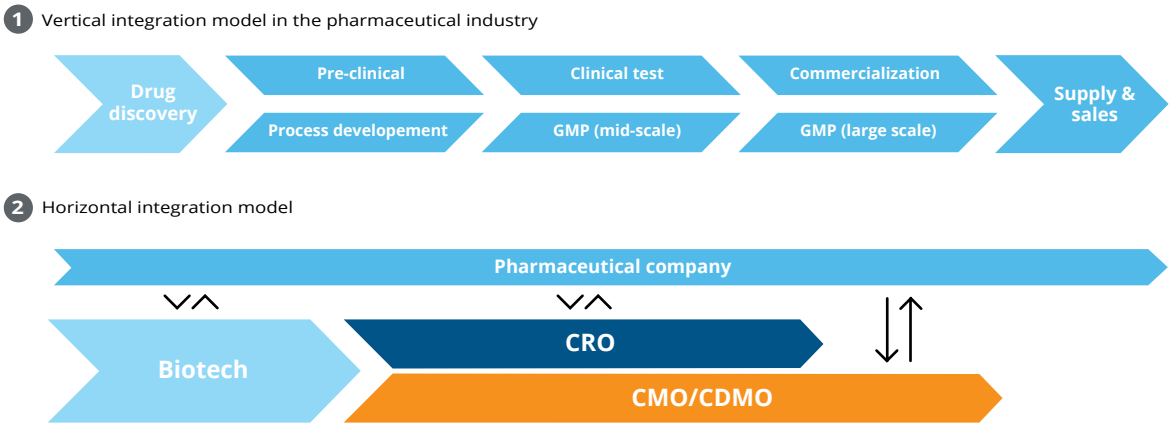
Research demonstrates that the most successful partnerships involve a combination of commercial and R&D arrangements, not one or the other. These partnerships typically combine the technological expertise of CGT companies with the asset development experience, clinical trial know-how, market access, and distribution channel infrastructure of larger companies.[67]

On the other hand, manufacturing partnerships did not trigger positive results, while contract manufacturers did derive more value than a company undertaking construction of its own costly facility.[68] Overall, companies stringing together multiple milestones realized continued high-impact value creation multiples over those hitting just one milestone and then moving on.[69]

Outsourcing for time and cost savings

Outsourcing is on the rise for both biotech[70] and pharma companies to accelerate speed to market.[71] Like the semiconductor segment, the pharmaceutical ecosystem has a mature horizontal division model of drug discovery and manufacture by biotech and pharmaceutical companies (figure 6).[72]

Figure 6. Horizontal division of roles in pharma



Source: Copyright © 2022 Kurata, Ishino, Ohshima, and Yohda, "CDMOs Play a Critical Role in the Biopharmaceutical Ecosystem," Frontiers in Bioengineering and Biotechnology, 21 March 2022.

As many pharma companies adopt digital practices to shorten development timelines and reduce R&D costs, more are forming strategic alliances, outsourcing, or acquiring early and late-stage capabilities. There appears to be proliferation of collaborative research agreements/partnerships in the early drug discovery and preclinical drug development stages. In clinical trials, patient recruitment and clinical lab and diagnostics testing areas are seeing more outsourcing.[73] The number of contract research organizations (CROs) are growing,[74] and pharma companies are turning to flexible manufacturing in response to changing regulatory and market needs.[75]

Proliferation of CROs facilitate experimentation

CROs and other contract service firms allow chemical expertise to be acquired rather than developed, which may enhance speed to market.[76] These molecule-on-demand firms have altered experimentation as artificial intelligence and machine learning help to design new drugs.[77]

The growth in CROs is behind a renaissance in small molecule discovery with developers learning novel ways to use small molecules to target disease.[78] In 2023, sales of the top 10 selling drugs were split 40/60 between small molecules and larger, more complicated biologics where sales were dominated by a few biologic blockbusters.[79]

Globalization of contract development and manufacturing organizations (CDMOs)

Life sciences and medtech companies are considering new ways of working to help ensure product safety and quality without sacrificing speed. Companies adopting cutting-edge technologies, employing advanced process automation/continuous manufacturing, and incorporating real-time monitoring and modular facilities designs, may quickly and efficiently adapt production processes to accommodate varying product types, volumes, and customer demands.[80]

While some pharma companies in Europe favor regional CDMO services for close proximity to markets, innovation capabilities, and talent, CDMO services are being globalized by China and India. These two countries are projected to experience the largest CAGR growth in the CDMO industry—9.63% in China and 11.34% in India.[81]

C "R" DMO outsourcing model emerges globally to accelerate therapies

As drug makers seek to increase efficiency and productivity and gain access to advanced technologies, there is a growing demand for outsourcing technology solutions that provide more integrated end-to-end services.[82] Drug makers are starting to seek out contract research development manufacturing organizations (CRDMOs). These operators consider

themselves science and technology platforms that also bring the "R," or research, into the CDMO mix.[84]

CRDMO facilities are starting to spring up around the world—including in China, Singapore, the US, and Italy. By consolidating and unifying the CRO and CDMO models, companies see an opportunity to accelerate the time it takes to bring new therapies to market.

"Building end-to-end capabilities and offering integrated solutions in the small molecule space is our vision. Clients and the market want a one-stop shop and a partner who can take care of the entire project."

—Giovanni De Filippo, Fine Chemicals Sales & BD head, Angelini Pharma SpA[85]

New drug approvals and launches

A total of 69 novel active substances (NASs) were launched globally in 2023,[86] led by the US, with 55 compared to 37 in 2022.[87] Over the past five years, NAS launches around the globe totaled 362.[88] The tally of NAS launches in China is on the rise, but an increasing number are not available outside China, reflecting an increasingly domestic industry.[89]

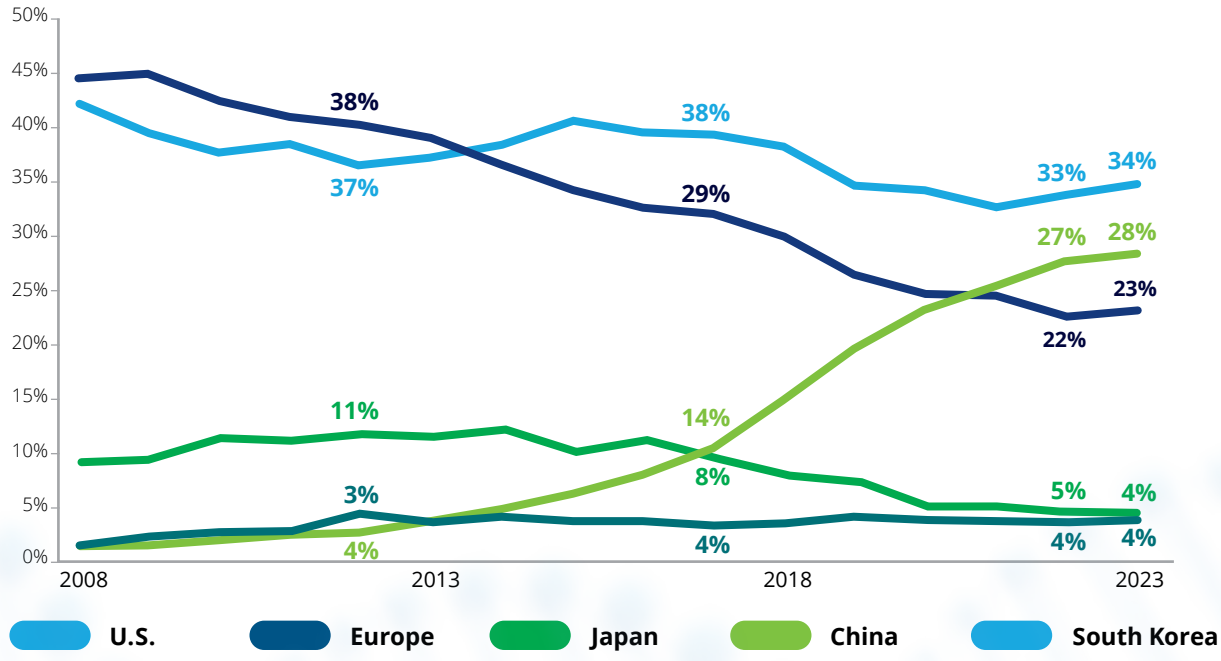
China eclipsing Europe and gaining on the US in R&D

Clinical trial starts are increasingly global with Asia experiencing the largest growth in recent years. China moved ahead of Europe in NAS launches as well as in clinical trials to reach the number two spot behind the US globally.[90] While China's NAS launches are domestic, China's clinical trials are increasingly global.

Only about a third of all clinical trials are being held in the US as the US clinical research footprint shifts overseas.[91] China is only a few points behind the US, with 28% of all clinical trial starts from China-headquartered companies in 2023—a significant jump from only 3% a decade ago (figure 7).[92]

Notably, China also reached the number two spot for worldwide R&D expenditures across all industries, surpassing the EU (17.5%) with 17.8%, mainly as a result of its tech sector.[93] For China's pharma companies, high expenditures on R&D and procurement are shrinking profit margins.[94]

Figure 7. Number of Phase I to III trial starts based on company headquarter location, 2008-2023



Source: IQVIA, "Global trends in R&D 2024," 2024.

Currently, the US leads biopharmaceutical innovation, supported by its large domestic market, IP protections, limits on government drug price setting, supportive science policies, and supportive innovation clusters.[95] However, the US is experiencing rising drug pricing pressures and US policies may weaken foundational IP protections.[96]

Critics point to lessons learned as a result of the US decline in semiconductors and telecommunications, where the US originally held leadership positions. Policy analysts suggest policymakers should not attack pharmaceutical companies but focus more on how to win the global battle for pharmaceutical sector competitiveness.[97]

Funding biopharma R&D

How biopharma R&D unfolds depends on the ability to effectively partner across geographies and between the public and private sectors. This highly collaborative process can affect decision-making about R&D investments.[98] Ultimately, financing for R&D can play a major role in whether the medicines and treatments that patients need are developed.[99]

Researchers recently explored how pharmaceutical R&D is financed and how this may evolve in the future.[100] Of the total US$300 billion spent on pharmaceutical R&D, large pharmaceutical companies represent almost two-thirds of investments.[101] Public and not-for-profit sectors contribute a quarter of the total (US$75 billion).[102] These essential scientific advances may then flow downstream for private R&D sector investment.[103] Venture capital currently accounts for about a tenth of the total investment.[104]

Calls for more research into drug development productivity/value creation

Some AI researchers say that more funding should go to academia to study ways to cut costs and improve pharmaceutical R&D productivity as there is scant research on how value is actually created.[105] The US Congressional Budget Office (CBO) also recently called out a need for more research.[106]

The CBO uses a simulation model of drug development to analyze legislative proposals and incorporates feedback from academic and industry experts to inform its model. Life sciences and medtech leaders should be aware that the agency recently expressed interest in researching:

- How changes in the future profits of pharma companies might affect the development of drugs with differing characteristics (e.g., small and large molecules),
- How changes in the number of new drugs can affect health outcomes, and
- How policies—such as price negotiation or accelerated drug approvals—could affect companies' decisions about which indications to target for approval.[107]

Shifting trends in openness: Globalization vs. localization and impacts for multinational companies

Life sciences and medtech companies are increasingly global, and the global economy is moving toward a new normal—a shift away from peak globalization.[1] The United Nations' latest "World Openness Report 2023" shows "world openness" falling 0.4%—a downward trend amidst a growing move away from openness between countries, sectors, and regions.[2] Declining interdependence between countries may have negative consequences for global trade and overall prosperity.[3]

The Asia-Pacific (AP) region is expected to yield among the highest growth over the next several years—due to its sizable consumer base, increasing disease incidence, and supportive regulatory frameworks[4]—and China and Japan are among the largest economies in the pharma and medical device markets (figure 1). In AP we see two understandable but diverging approaches being taken by the second and third largest life sciences countries in the world. China is advancing policies that prioritize its own national interests and technologies,[5] while Japan's trade openness is at its highest level historically—at almost 47% and up about 10 points from 2021 to 2022[6]. The multiple factors driving these diverging models include trade corridors, macro political dynamics, access to talent, views on growth, and IP protection.

Figure 1. Top pharma and medical devices markets by country, growth forecast 2019 to 2028

	Top 5 Pharma Market by Country			Top 5 Medical Device Market by Country		
Country	2019 Sales (US$ B)	2023 Sales (US$ B) E	2028 Sales (US$ B) F	2019 Sales (US$ B)	2023 Sales (US$ B) E	2028 Sales (US$ B) F
US	**453**	**571**	**704**	**165**	**205**	**262**
China	**121**	**165**	**237**	**30**	**43**	**61**
Japan	**106**	**100**	**163**	**33**	**33**	**43**
Germany	**77**	**87**	**111**	**32**	**37**	**46**
France	**41**	**47**	**57**	**18**	**20**	**24**

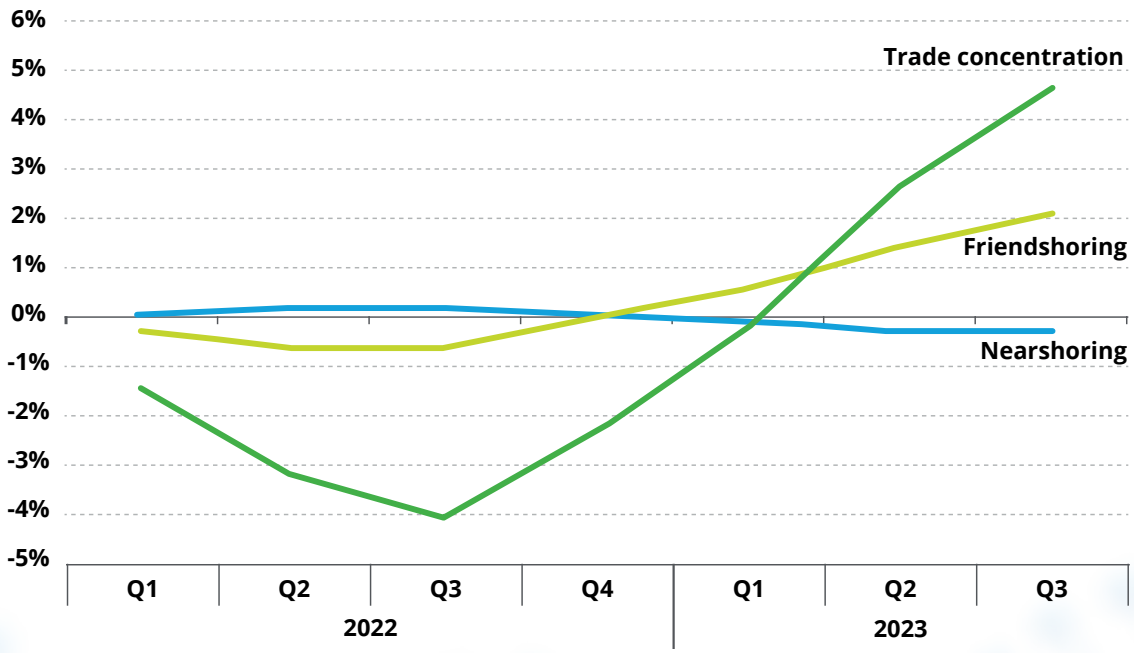
Source: EIU and Statista Market Insights

Globalization is not dead, but changing

Global connectedness may be measured by the flow of trade, capital, information, people, technology, and ideas—and while globalization is not dead, it is changing.[7]

During the pandemic, trade and supply chains were vital to increasing the production and distribution of medical supplies, including vaccines.[8] However, in the past two years, global trade is noticeably more concentrated and geopolitically close, relying on a smaller pool of trading partners (figure 2).[9]

Figure 2. Global trade patterns' geopolitical turn, bilateral trade changes since Q1 2022



Source: UNCTAD, United Nations Trade Update 2023

On the whole, international trade flows are still proving resilient, while some stakeholders question the threat of ***deglobalization***.[10] The volume of cross-border engagement is a valuable measure for economic growth,[11] and the World Trade Organization (WTO) believes recent trends need monitoring.[12]

In 2024, marked difference in growth among regions is expected to continue,[13] part of the glocalization trend—a blend of ***globalization*** and localization, involving:

- shorter supply chains,
- an emphasis on re-establishing domestic manufacturing capacity, and
- a more strategic role for government.[14]

Tracking trading patterns

After a dip in 2023, the expectation for growth in global trade is rising—3.3% growth is projected for 2024.[15] The two emergingly divergent models in China and Japan, highlighted earlier, are also demonstrated by their current trading patterns.

Experts say China is likely to remain the world's leading exporter for the near future, but its export dominance in the global economy may be peaking.[16] Between EOY 2022 and EOY 2023, China's exports decreased by US$10.4 billion or -3.39%, primarily impacted by a decrease of over 20% in exports from China to the US.[17] However, the US remains China's top trading partner in exports followed by Vietnam, South Korea, and Japan. China increased imports in 2023, with the US, South Korea, and Australia as leading partners[18] China's growth objectives point to becoming a high-income economy, rather than simply raising GDP.[19]

Japan is the fourth largest economy by GDP, as Germany moved ahead of Japan in 2023 to claim third place behind the US and China.[20] Almost a quarter of Japan's trade is with China,[21] and Japan's export of goods and services is on the rise—climbing 4.1% in 2022 above pre-pandemic levels.[22] Japan exports almost equal to both the US and China.[23]

Pharmaceutical goods import and export ratios

Pharmaceutical trade started to rise in the third quarter of 2023,[24] and the global market for pharmaceuticals is expected to reach almost US$1.2 trillion in 2024.[25]

Japan, the third largest pharmaceutical market, imports about three times the pharmaceutical products it exports (figure 3)[26] and is a critical export market for US pharmaceuticals.[27] Historically, Japan has accelerated economic growth with "external" globalization through expansion of trade and outward foreign direct investment (FDI).[28] As of 2021, Japan is the largest source of overall FDI into the US, with an FDI stock of US$721 billion.[29]

China has a relatively equal level of pharmaceutical product imports and exports.[30] Currently, the US and China are relying more on each other for pharmaceuticals, with the US exporting semi-finished/end products and China exporting API.[31] The US imports US$10.2 billion in pharmaceutical goods from China, while exporting US$9.3 billion to China, driven by advanced medicines such as cancer treatments and antibiotics.[32] Despite progress in some areas, barriers for trade with US companies remain challenging.[33]

Figure 3. Comparison of 2021 pharmaceutical imports and exports, China, and Japan

Pharmaceutical Goods	China	Japan
Imports	US$34.1B	US$30.3B
Exports	US$36.0B	US$10.2B

Source: OECD (Organization for Economic Co-operation and Development)

US-China tech wars continue to affect medtech and technology companies

Revenue in the medical device market is projected to reach US$182 billion for the US and US$36.38 billion in China, in 2024.[34] The US is the top exporter and importer of medical instruments; China is fourth in imports, fifth in exports; and Japan is fifth in imports.[35]

China and Japan lead exports for semiconductor devices that are essential for therapeutic medical devices; Hong Kong, China, and the US lead imports.[36] Integrated circuits dominate the semiconductor market, and China experienced sharp declines in these imports—a drop of 15.3% in 2022 and 15.2% through Q3 2023 YoY in the number of units.[37]

Domestic production and exports are starting to show more resilience. In 2024, China is expected to lead chip recovery mid-2024, but the US plans more export controls on high-end AI chips.[38] In 2023, Japan also introduced export controls, limiting 23 different types of chips sales to China.[39]

The demand for chips that are optimized for Generative AI and investment in AI-supporting servers is bolstering demand in Japan, according to the Semiconductor Equipment Association.[40] Despite being down at the beginning of the year, Japanese chip gear sales are forecast to climb 27% in the fiscal year[41] that starts in April 2024.[42] Japan's new industrial policies are aimed at restoring the international competitiveness of its semiconductor industry.[43]

China's "new whole-nation system" was also put into place to advance its R&D, including spurring its semiconductor industry to catch up with global competitors.[44] Some believe current US tech bans are stimulating a domestic ecosystem[45] and motivating China to deliver on its own technological breakthroughs.[46] But China still lags two to three generations behind Taiwan and South Korea in manufacturing the most advanced chips.[47]

Multinational corporations (MNCs)—like Intel, GE, NVIDIA, and Qualcomm, among others—are lobbying government officials to find ways to temper the blow of export controls.[48] For example, NVIDIA introduced less powerful chips in China in December 2023 to comply with US export restrictions.[49]

> "MNCs need to monitor the global and China local environment closely, continue to leverage industry associations to influence government policy, and keep their China strategy adaptable to external changes."
>
> —**Medtech** CEO of MNC operating in China[50]

Heightened scrutiny for biotech foreign investments

China and the US share ties in biotech R&D and commerce, and the Committee on Foreign Investment in the United States (CFIUS) is increasing scrutiny of Chinese investment in the US biotech industry. Companies with "critical technology" or "sensitive personal data" are at greater risk and should be prepared for potential CFIUS challenges in 2024, related to foreign transactions for investment.[51]

Market leaders remain committed to business in China

As geopolitical tensions rise, many top life sciences and medtech MNCs report they remain committed to China in 2024, but expect more regulatory scrutiny and market access challenges.[52] Pharmaceutical MNCs are reworking business models[53] as they watch price cuts play out and internal priorities shift.[54]

Medtech and technology companies operating in China are also monitoring the macroeconomic situation as they remain susceptible to disruptions in supply chains.[55] Global political tensions in 2024 are the primary concern of 90% of US medical device executives in a survey of C-suite executives by the Deloitte Center for Health Solutions.[56]

> "The China pharma market will remain a very important focus for us, as its size and scale will continue to rise. The growth will be slower going forward (although we have the ambition to grow double digits in 2024). Currently our HQ leadership team has a very 'balanced' view on China—neither bullish nor negative."
>
> —**Pharmaceutical** CEO of MNC operating in China[57]

Opportunities in the China market

For pharmaceutical MNCs, the vast size and scale of the China market is a magnet for expanding global plans,[58] and China is raising R&D investment by 10% in 2024 to speed up scientific and technological breakthroughs.[59] There is an opportunity to make considerable progress in the development of treatments for chronic as well as rare diseases.[60] For the treatment of rare diseases, drug cost and affordability are in need of further legislative and policy support.[61]

China is also an attractive market for medical device companies looking to strengthen their industrial and supply chain resilience.[62] Since Q3 2023, Medtronic started showing stronger-than-expected recovery for its procedure volume in China.[63] The company reports that the impact of value-based procurement (VBP) is "largely behind us as the majority of its product portfolio has been repriced."[64] Medtronic CEO Geoff Martha says that the company is continuing to invest in China because "it's a big market, and it's growing."[65]

Acceleration of centralized anti-corruption efforts

Medtronic says it has not been affected by anti-corruption issues, which are expected to continue to be a factor in 2024.[66] China's latest anti-corruption campaign by the central government in China includes rectification efforts by 14 government agencies, including China's National Health Commission (NHC).[67] Research shows bribery has been the most common form of corruption in the medical sector, and new policies reflect a "zero-tolerance attitude."[68] While healthcare providers are most often cited as taking bribes, pharmaceutical and medical equipment suppliers are also said to be paying the bribes.[69]

China's rectification efforts are not likely to be short-term in duration or impact—possibly lasting for five years followed by rigorous and regular enforcement, according to recent research into the anti-corruption campaign by Deloitte China.[70] With tightened pharmaceutical regulation, pharmaceutical companies should urgently construct comprehensive and effective corporate systems to facilitate compliant business operations.[71] In the context of rectification, product R&D can help pharmaceutical companies improve their competitiveness in China's health care system.[72]

Operating in China is complex

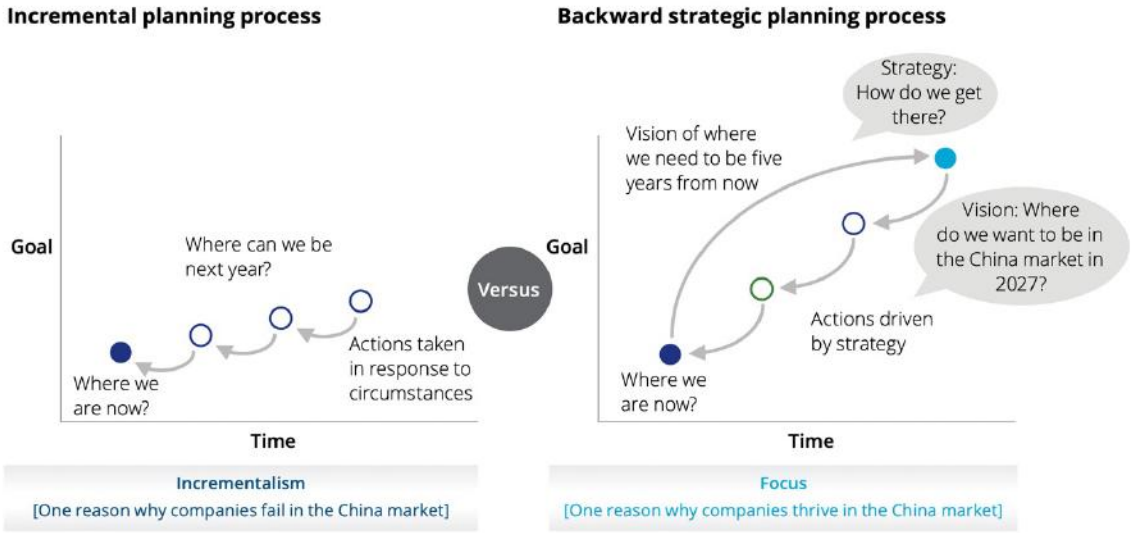
Changes in geopolitics, technology, regulations, and local competition makes operating in China challenging for MNCs. But addressing these challenges may open up new markets and opportunities.[74] From the experiences of successful and unsuccessful MNCs in China, Deloitte China finds that it may be better to implement a strategy that is focused, as opposed to one that is reactive and incremental (figure 4).[75]

Meeting the challenges of the China market

Alongside opportunities, MNCs operating in China face challenges, especially due to growing local competition. China's use of intellectual property (IP), forced technology transfer, and many market access matters may still impede multi-national firms from operating on equal footing with local Chinese firms.[76] Since the government of China introduced the "Made in China 2025" strategic plan in 2015, China has had its sights on capturing a much larger share of the biopharma and advanced medical device markets.[77]

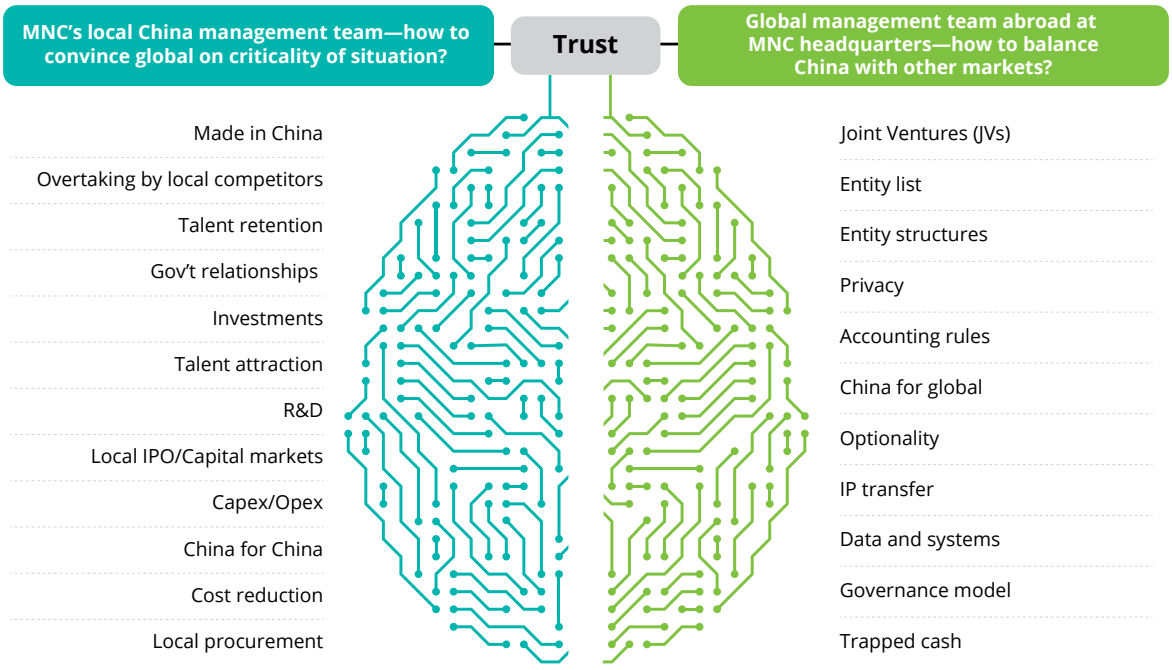
In recent years, alignment between an MNC's corporate office in China and its global headquarters outside of the country has been tricky. During the COVID-19 pandemic, MNCs' global leadership teams were unable to visit China, and without face-to-face interaction, some found challenges in effective communication. To bridge trust and improve communication between global and local management teams often includes balancing China with other markets, while also understanding the critical needs of local management in China. (figure 5).

Figure 4. Incremental vs. focused strategy



Source: Deloitte China, *MNC Localization 2.0*, 2022

Figure 5. Bridging trust between global and local management teams



Source: Deloitte analysis

China expects foreign MNCs operating in China to become more localized and support local growth.[78] Toward the end of 2023, Pfizer, Sanofi, and Biogen all tapped local collaborators to help commercialize their products in China.[79] As marketing responsibilities shift to other firms, job cuts are expected at each of the leading drugmakers.[80]

"MNCs need to work out a balanced action plan to address the short-term challenges—geopolitical conflicts, volume-based procurement (VBP), diagnosis-related group/diagnosis-based intervention packet (DRG/DIP), 'buy local'—while also seeing China's long-term opportunities, like 'Healthy China 2030,' therapy penetration to cover a broader population, and the potential growth in health care expenditures as a percentage of GDP, from about 7% in 2020 to 9% in 2030."

—**Medtech** CEO of MNC operating in China[81]

Drug and device pricing impacts in China

China's regulatory changes have been altering portfolios and business models for MNCs, and in particular, go-to-market strategies.[82] China's VBP, DRG (fixed payment), and DIP (price-adjusted payment) pricing plans seek to reduce the cost of drugs and devices by awarding large volume sales to tender winners with the lowest price in cities, provinces, or the country.[83]

As the Chinese government sees the benefits of these price cuts, it has expanded product categories.[84] At the end of 2023, China rolled out its fourth national high value consumables VBP, and tenders expect to be carried out in mid-2024. Some medtech devices saw dramatic price reductions—11 artificial intraocular lens products averaged 58% in price cuts, and 19 sports medicine products averaged 72% in price cuts.[85]

Drug products also underwent price cuts in late 2023, averaging 58% as part of the ninth national pharma VBP. Of more than 260 drug products undergoing preliminary bids, only five are supplied by four foreign companies.[86]

"By 2024, about 80% of high-value consumables will go through VBP, and VBP-winning products are the major products that China patients can have access to under the current policy. We saw there are clear needs from China patients for differentiated, better quality, and more advanced technology/innovation products. MNCs need to continue to influence the government to enable this offering to patients through the public hospital evaluation system, DRG/DIP payment exception, and commercial insurance, etc."

—**Medtech** CEO of MNC operating in China[87]

Advancing a localization strategic plan

Localization has been a continuous theme in the evolving China market, and MNCs should be advancing their localization plans—to not just be competitive in the China market but also to address the increasing risks surrounding supply chain disruption and technology and data sovereignty. There is no one-size-fits all formula, and each company is at a different stage (figure 6).

Figure 6. Stages of advancing a localization plan in China for MNCs

Source: Deloitte analysis

Building local support in China

Life sciences and medtech MNCs are expected to show support for local initiatives.[89] The Healthy China 2030 initiative is China's health reform to improve the country's public health services, medical industry, and food and drug safety. Its focus is on prevention rather than treatment.[90]

Recently, Pfizer demonstrated its support of Healthy China 2030 by signing an agreement with China to cooperate on improving the country's health coverage. The memorandum of understanding with the Health China Research Center plans to support public health research and improve the health of rural populations.[91]

Bringing talent back home, attracting new sources of R&D innovation

Over the last 25 years, China's R&D spending to GDP share has risen from 0.56% to 2.4% and is likely to surpass Japan and Germany in the next decade, given its current momentum.[92] Local Chinese companies have been spending relentlessly on R&D and, as a result, are making advances on the technology front.[93]

To capture its share of biopharma and medical device markets, China knows it must innovate, not just copy, to succeed. In recent years, it launched more than 200 talent recruitment programs to attract high-caliber scientists globally. China's Thousand Talents Program (TPP) recruits Western-educated Chinese STEM researchers back to China. A recent study found TPP to be successful in attracting promising young scientists with cash and lab support, but less successful in luring high-caliber researchers. These more established researchers prefer the West for less "administrative intervention."[94]

However, the research also shows that over time, the support has enabled returning foreign-educated researchers to surpass their peers who stayed abroad in publishing productivity. Productivity rose 27%, including publication in high-caliber journals.[95]

There are more than 1,600 MNC R&D centers operating in China, and more than US$38 billion worth of intellectual property has been imported.[96] Currently, China is encouraging foreign investors to establish R&D centers in China to undertake major scientific research projects.[97]

In August 2023, the China State Council released "***Opinions to Further Optimize the Environment for Foreign Investment and Increase Efforts to Attract Foreign Investment***".[98] The opinions in the policy call for relevant departments to develop a convenient management mechanism for cross-border data transfer security. The policy also conveys that the Chinese government intends to facilitate the entry-exit and residence of foreign executives and technical personnel (and their families) from foreign-invested enterprises.[99, 100]

China CEO insights on innovation in 2024

In surveying CEOs from MNCs operating in China,[101] many identified innovation as a primary driver for success in China, but there were various views on the state of innovation and how to generate true innovation. Some felt that digital innovation has been applied widely, while others say that the state of AI and "the tools available are behind what is done elsewhere in the world." One pharmaceutical CEO says that the "vibrant growth of domestic innovation injects new vitality into the China pharmaceutical market, but also intensifies competition." Another believes that "the most important initiatives for 2024 will be around 'education and engagement' of patients and health care providers in China."

> "MNCs need to continue to accelerate innovative product launches in China while at the same time creating differentiation and value propositions in specific areas, striking a better balance between price and quantity, and exploring various payment methods in order to maximize the value of innovative drugs."
>
> —**Pharmaceutical** CEO of MNC operating in China[102]

Active globalization efforts in Japan

Expanding footprints of Japanese pharma companies

The Japanese pharmaceutical industry has been actively participating in globalization efforts and activities—increasing their global presence through M&A, collaborations, broader R&D, and expansion into emerging markets. They are less dependent on local revenue, generating more than half of their revenue outside of Japan. Takeda, the largest pharmaceutical company in Japan and currently 17th largest in the world, leads in its globalization efforts with a global presence in more than 80 countries.[103] With over 20 years of a deliberate strategy to expand and serve globally and more recently- 10 years of comprehensive transformation already underway, Takeda is an 'exceptional' Japanese head quartered company but one which is really a globally "headquartered" across Japan, the US and Europe (Switzerland). Takeda has been led by Christophe Weber, its first non-Japanese CEO, for almost 10 years. He shared in an interview in 2021, "When I joined the company in 2014, the ambition was to make two big changes. One was to transform the R&D capabilities so we could improve productivity. The second was to globalize the company, to increase scale, so we could be more competitive."[104] During this journey, Takeda has acquired multiple other multi-national pharmaceutical companies (e.g., Millennium Pharmaceuticals, Shire Pharmaceuticals among others) and committed to a global enterprise business model and strategy. Its early commitment to a comprehensive globalization path is distinctive in the Japanese pharmaceutical market.[105]

After Takeda, Astellas Pharma has the maximum presence outside Japan, both in terms of facilities and leadership locations, and conducts business in approximately 70 countries around the world. In contrast, Shionogi has a more limited presence outside Japan, as its R&D centers are concentrated in Japan. However, most of the Japanese pharmaceutical companies are expanding their presence in the US followed by Asia-Pacific (APAC) and Europe (figure 7).

Figure 7. Geographic presence and expanding footprint of Japanese pharma companies (beyond Takeda)

Notes: 1. APAC—Asia Pacific, includes all of Asia and Oceania, except Japan. | 2. CEE—Central and Eastern Europe. | 3. Firms have multiple offices across regions. 4. For Otsuka and Sumitomo Pharma, some of the R&D facilities are combined with manufacturing hubs.

Source: Deloitte Japan analysis

Making progress in the globalization journey

US and EU pharmaceutical companies utilize a functional management approach in managing business functions, organized by disease region (figure 8). Early-stage pharmaceutical companies in Japan are managed by region. By prioritizing regional business expansion, these companies are looking at increasing market share in a region or country.

More advanced pharmaceutical companies in Japan have started the move towards managing by global function, rather than region. This approach is more centralized where multiple regions are managed by the headquarters across an optimal distribution of tasks and resources.

To increase R&D productivity, some companies are looking at moving more R&D functions outside of Japan, but talent is scarce. In 2024, these companies can expect increased competition for talent with global expertise.

Growing optimism for growth through collaborations

In 2024, as leading life sciences and medtech companies look to balance both a global and local perspective in Japan, more are exploring collaborations to drive growth.[106] Bristol Myers Squibb (BMS) aims to double the size of its Japan business over the next decade, driven not only by its internal products and pipeline but also through partnerships.[107] Currently, as much as 60% of the drug giant's development pipeline is externally sourced, with BMS poised to further promote collaborations that bolster its portfolio.[108]

BMS in Japan generated sales of approximately US$1.4 billion in 2022, and the company's "Japan Moonshot program" is designed with the aim of doubling this revenue over 10 years by:

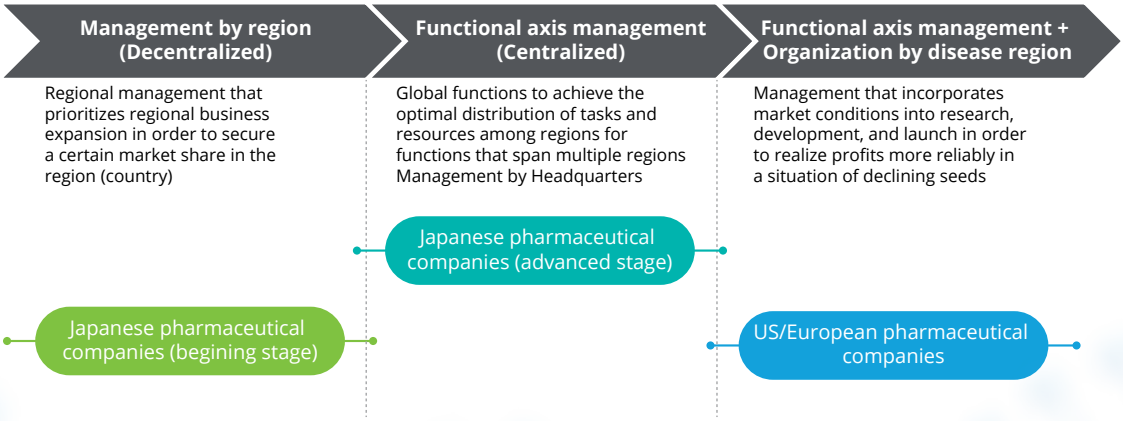
- Gaining new drug approvals
- Growing existing products including through label expansions
- Accessing external innovation[109]

A string of product launches are also part of the doubling plan.[110] Of nine new medicines already approved by the US FDA, three have attained the green light in Japan, and others are either under regulatory review or in mid- to late-stage clinical development.[111] There are more programs underway pursuing regulatory approval in Japan as well as plans to expand access to existing products.[112]

BMS's R&D strategy in Japan is leveraging new uses for AI/ML, focusing on three areas:

- Identifying new molecular candidates to improve the odds of success
- Tapping into AI/ML to accelerate clinical trials and create better programs
- Incorporating new technologies into patient outcome studies[113]

Figure 8. Approaches between US/EU and Japanese companies as they globalize



Source: Deloitte Japan analysis

Takeda's expansion into emerging markets

Already Japan's largest and most global pharmaceutical company, Takeda is moving forward on a plan to grow its emerging market business to US$9 billion by 2030.[114] Its regional strategy includes delivering health care and medicines to 85% of the world's population.[115] The World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE) recently recommended Takeda's dengue vaccine, QDENGA, for introduction in areas with a high dengue disease burden.[116]

Dengue fever is among the most common mosquito-borne viral disease, causing more than 390 million infections per year, and is endemic in more than 100 countries.[117] Brazil was the first country to make Takeda's vaccine available in the public health system for children and adults.[118] QDENGA is also currently available in countries in Europe, Indonesia, Thailand, and Argentina.[119] Argentina is currently undergoing its worst dengue outbreak in 20 years with over 100,000 infections registered in 2024 alone.[120]

Expanding R&D in Japan and international collaborations

The biopharmaceutical industry has invested more than US$92 billion in R&D in Japan over the last decade, developing over 1,500 new medicines and supporting over 140,000 jobs in Japan.[121] As of Q1 2024, 70 research-oriented pharmaceutical members make up the Japan Pharmaceutical Manufacturing Association, whose "Industry Vision 2025" is to provide innovative drugs to 8 billion people worldwide by 2025.[122]

Embarking on a strategic turnaround for innovation

Japan has an internationally unique innovation system in which all new drugs were created by incumbent pharmaceutical companies, like Takeda, which has the largest R&D budget of the Japanese pharma companies.[123] There is a shift taking place with the rise of personalized medicine towards first-in-class drugs for orphan diseases,[124] with the establishment of start-ups as an important pathway for new drug R&D.[125] The start-up sector in the life sciences has been historically weaker in Japan than elsewhere.[126]

Japan has started a strategic turnaround for the biopharmaceutical market with the "*Japan Bioeconomy Strategy*," which aims to transform Japan into the world's most advanced bioeconomy society by 2030.[127] The government of Japan has allocated funds to promote biomanufacturing technologies with significant investments in biopharmaceuticals, regenerative medicine, cell, and gene therapies (CGTs) and advanced therapy medicine products (ATMPs).

The Bioeconomy Strategy encompasses a broader spectrum than the "*Vision Plan*," spearheaded by the Ministry of Health, Labor, and Welfare (MHLW), which is focused specifically on revitalizing Japan's pharmaceutical sector with particular emphasis on innovation, global competitiveness, and R&D investment.[128] Strengthening collaboration with biology research in academia is a way to improve the drug discovery competitiveness of Japanese companies.[129]

Attracting new talent and researchers

The Japanese market for new and patented pharmaceuticals is expected to reach more than US$72 billion by 2027, making it the second largest in the world after the US.[130] In 2023, the Japanese government committed to investing circa US$75 billion in an endowment fund for select universities to produce world-class research and compete globally. Other organizations are also creating novel funding opportunities.[131]

"We specialize in young researchers, especially those who have returned from abroad and need funding for start-ups. We are trying to nurture those that will become excellent researchers in the future, with a small budget."

—Yukihide Hayashi, head of the **Life Science Foundation of Japan**

Scientists, like biophysicist Kazuhiro Maeshima, benefited from years of research overseas before returning to Japan. Maeshima joined the Genome Dynamics Laboratory at the National Institute of Genetics (NIG), based in Shizuoka, with one attraction the level of academic freedom. "Essentially, we can do what we want. This may be pretty rare in Japan, but we believe it's a critical factor in performing exciting research," he says.[132] Maeshima is also interested in collaborating internationally, and currently is working with colleagues in Australia because of their relatively small, high-quality research community.[133]

Focus on R&D hiring in Japan

Japan's human capital for R&D has been growing more slowly than its peers.[134] In 2024, R&D now accounts for 40% of jobs for new grads hired at pharmaceutical companies, according to responses by 52 companies surveyed in Japan.[135] The trend was more evident at top-tier companies, like Chugai Pharmaceutical, where R&D dominated with 80% of new hires; Chugai also had the most hires with 155.[136] At Daiichi Sankyo and Ono Pharmaceutical, R&D jobs were also the majority, accounting for 60% of hires.[137] For all companies, new sales jobs accounted for just 20%.[138]

The generics manufacturer Nichi-Iko Pharmaceutical resumed hiring new grads for FY2024 after a two-year drought.[139] All 25 new hires were assigned to the production and quality team. [140] Others leading increases in the number of jobs YoY included Nippon-Kayaku (+42), Eli Lilly (+17) and Mitsubishi Tanabe[141, 142]

Looking back at FY2023, Chugai hired the most mid-career personnel in R&D, accounting for 40% of jobs, and no sales hires were made. About 20% of Ono Pharmaceutical's mid-career hires were for R&D jobs.[143]

Microsoft to invest approximately $2.9 billion to boost AI and jobs in Japan

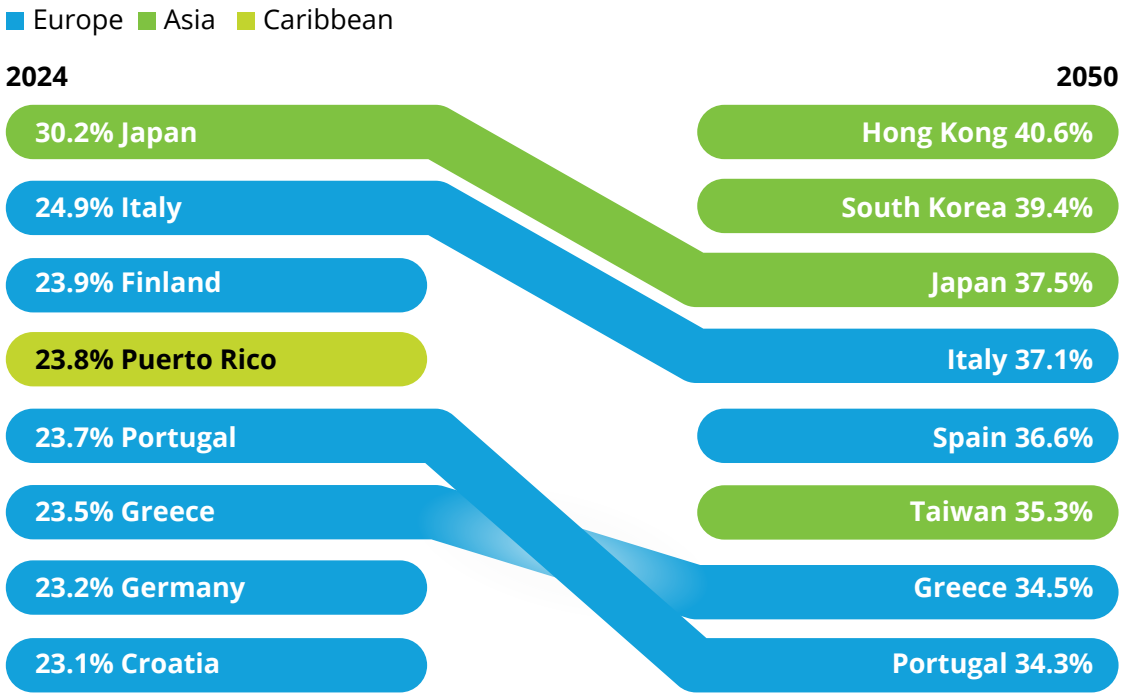
Microsoft is planning an AI-related reskilling program in Japan that will train 3 million workers over three years. The investment also includes setting up a new Tokyo-based lab for R&D in robotics and AI.[144] Under the plan, Microsoft plans to install advanced AI semiconductors at two existing facilities in eastern and western Japan.[145]

Meeting the challenges of an aging population in Japan and risks to society

One of the biggest challenges facing Japan is the rise in its aging population—one in 10 people are over 80 years of age.[146] Japan currently has the highest percentage of citizens aged 65 or older among countries or territories with over a million people (figure 9).[147]Around the world, aging is becoming a leading issue for governments and health care ecosystems as the number of people worldwide over 60 years of age will rise to reach nearly 2 billion by 2050.[148]

Figure 9. World's oldest populations

Estimated share of a population in countries and territories with over a million people aged 65 or older, in 2024 and 2050.



Source: Statista, United Nations Population Division

Births dropping, companies making shifts to address aging market

As more people age, the number of births in Japan dropped to new lows in 2023, and leaders are assessing the demographic crisis as well as the future impacts to society with an aging population.[149] China also released data showing that its population shrank in 2022—for the first time in six decades.[150]

Companies are starting to address these shifts. For example, Oji Holdings, a maker of diapers in Japan, is wrapping up its domestic output of infant diapers later this year to boost production of sanitary items for adults, mainly in nursing homes.[151]

The demand for elderly care is driving the development of innovative technologies, like automation for managing care.[152] These advancements support independent living and can help reduce the burden on caregivers and nursing staff by using tools to monitor and address senior's needs.[153] In 2024, companies at the forefront of such technologies are poised to benefit from the growing demand. [154]

New digital and AI technologies for assisted living and elderly care

Lifelens, created by Panasonic, allows tech-enhanced rooms to automatically monitor patients. Hitowa Care Services' newest retirement home is a Lifelens partner

in Japan and uses cameras in each of its rooms to record patients while an AI system analyzes the data.[155] The technology also uses sensors that report whether a person is in bed or not and can keep track of the patient's heartbeat.[156]

The Japanese market for diagnostic and therapeutic AI health care tools is projected to be worth around $114 million by 2027.[157] Entrepreneurial physicians in Japan are helping to develop new AI health care tools for improving the speed and accuracy with which doctors can make diagnoses.[158]

For example, Japanese companies hold a 98% share of the global market for endoscopes but diagnosing cancer from images captured by endoscopy is highly challenging.[159] Japanese startup AI Medical Services (AIM) has developed an AI tool to improve diagnostic accuracy by training on more than 200,000 high-resolution videos of the stomach.[160] Gastric cancer remains the third leading cause of death worldwide, and its incidence is particularly high in Asia.[161] Asian-Americans are also more affected.[162] Japan and Korea have national stomach cancer screening programs because the incidence of gastric cancer is so high.[163]

Digital therapeutics are also seeing more adoption as chronic diseases rise.[164] US-based Welldoc and Japan's Astellas Pharma are collaborating for a clinical trial using Welldoc's BlueStar digital health app for diabetes management.[165]

More opportunities for digital services to promote a healthy life expectancy

Increasing adoption of technology among the older generation presents opportunities for businesses to reach a wider customer base through digitalization, including managing their health.[166] By helping people stay mobile and free of debilitating age-related diseases, they can enjoy a better "healthy life expectancy."[167]

However, when life expectancy grows faster than healthy life expectancy, the result is often lower quality of life and higher medical and social security costs.[168] MNCs, like Swiss pharma company Novartis, are looking for ways to lower costs in Japan by collaborating within the health care ecosystem as it faces the challenges of an aging society.[169] Novartis is working to raise awareness and improve management of cardiovascular disease—one of Japan's top social burdens affecting its middle-aged to elderly population. The Swiss company is collaborating with academia, local government authorities, and industry partners in various regions within the country.[170]

In Japan, the senior life environment is built on an outdated model of life span, instead of extending health span.[171] To deal effectively with its aging society, Japan should consider a new socially inclusive system for people expected to live into their nineties or more.[172] Extending healthy life span is further discussed in the patient section of this outlook, "***Achieving better patient outcomes with personalized experiences and authentic shared decision making***".

Moving forward amidst shifts in openness

To flourish in a hypercompetitive global environment and achieve leadership in life sciences requires sustained supportive policies and investment in R&D.[173] Shifting trends in openness— and how a country views its place in the world—are expected to continue to influence internal and external innovation and quality of care. Successful life sciences and medtech companies are paying attention to these shifts and remaining equipped with geopolitical expertise, while also developing strategies and actions to adapt to the challenges of this changing landscape.[174]

Achieving better patient outcomes with personalized experiences and shared decision-making

Life sciences and medtech organizations are increasingly focused on achieving better patient outcomes, not only through more rigorous science, but through better patient experiences.[1] Life sciences executives surveyed by Deloitte US believe that the leading action their organizations need to take in 2024 is "improving the patient experience, engagement, and trust"—and the trend is now a higher priority for more companies than it was in 2023.[2]

Personalized care and treatments support better experiences, and there are many opportunities for life sciences and medtech companies to improve touchpoints throughout the patient journey.[3] However, effectively and positively influencing a patient's journey requires a thorough and specific understanding of that patient's journey in order to be proactive and predictive about what patients may need.[4] As the process becomes more digitally enabled and personalized, it is also expected to become more "straightforward" and seamless.

Every patient's experience is different, and a patient's lived experience in a fragmented health care ecosystem may cause frustration.[5] The process of shared decision-making (SDM) can better illuminate what patients may prefer. According to the UK's National Health Service (NHS), SDM is a process that involves selecting tests and treatments based on evidence, while also considering the person's individual preferences, beliefs, and values.[6]

Studies show that there is continued need for improvement between the theory and practice of SDM.[7] Practicing SDM can improve patient-reported outcomes[8] and is also a possible link between the best of patient-centered care and evidence-based medicine.[9] The process is ripe for more personalization to deliver the right solution at the right time.[10]

Personalization through technology

In 2024, life sciences and medtech organizations are considering novel ways to make experiences across the patient journey more customized for patients through technology.[11] Many are experimenting with advancements in artificial intelligence (AI) all across the patient journey—from prevention to diagnosis, treatment, and monitoring.[12]

A patient's journey may start even before a patient contacts the provider.[13] For example, by identifying which patient types are more likely to have a certain disease, AI can raise awareness of the clinical journey that undiagnosed patients may undergo and potentially expedite progress in the journey.[14]

Early interventions are also being made possible through wearables, predictive and propensity modeling (using past data to predict the next action),[15] health assessment tools, and new types of biomarkers and screenings. With more data, health care providers (HCPs) can have a more granular view of the patient.[16]

Growing focus on the patient journey

New patient and provider needs are emerging

In medtech, successful organizations are embracing a more holistic view of the patient care journey beyond the physical device.[17] More patients are taking an active role in their health care journey and turning to health solutions and services tailored to their prevention and wellness preferences over treatment alone.[18] Patients are also demanding customized and convenient care adapted to personal behaviors and routines, with greater ownership of their secure health data.[19]

This engaged patient persona creates a powerful market segment of active consumers with distinct health demands, willing to consider solutions that may better meet their specific needs.[20]

Changing role of chief patient experience officers

Some health care companies have added a chief patient experience officer to their C-suite, and their focus is evolving from the inpatient experience to improving the patient's entire health care journey.[21] Lisa Allen, Ph.D., chief patient experience officer at Johns Hopkins Medicine says she came from the world of quality, statistics, and research, but her passion was really being patient- and family-centered.[22] "A lot of people were just studying the disease process, and I was asking how it was affecting people's lives," she says.[23] Patricia Rosello, M.S.N., R.N., chief patient experience officer at Baptist Health South Florida, says it is crucial to have a passion to see things from a patient's perspective and look at the whole patient journey.[24]

> "Your ability to influence and be very collaborative is going to be key because it takes all these different relationships to make any journey a better journey for a patient. You have to have that broad perspective and a high level of empathy and understanding."
>
> —**Patricia Rosello**, M.S.N., R.N., Chief Patient Experience Officer, Baptist Health South Florida[25]

With more focus on the patient journey, the role for chief patient experience officers is evolving and becoming increasingly strategic.[26]

Integrating patient preferences and values in decision-making

Care collaboration, where patients feel respectfully engaged in the evaluation of their health, is inconsistent.[27] While it is expected that patients should be informed and understand any risks, benefits, and possible consequences of different options through discussion and information sharing,[28] it is less understood how to integrate an individual patient's values and preferences in the process of SDM.[29]

Making SDM "collaborative"

Making SDM collaborative means there is a bidirectional exchange of information between patients and providers that helps patients make individualized, informed decisions about their care.[30] The process should consider a patient's desired level of involvement and autonomy[31] as well as an individual patient's values, goals, concerns, and desired quality of life (QoL).[32] But the path to values integration is not well defined.[33]

While SDM practiced collaboratively can improve informed consent and patient trust, as well as benefit many stakeholders,[34] its application in daily practice is still limited—even in the Western world, where collaborative SDM is championed as an ideal.[35]

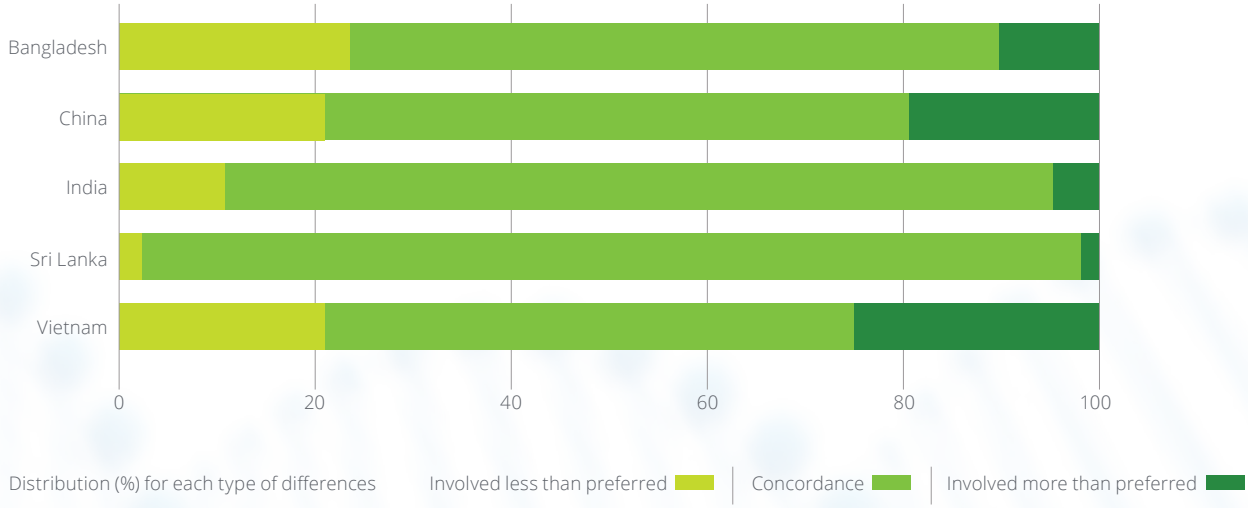
Researchers say that providers should not make assumptions about a patient's desired role in decision-making and stress the importance of clarifying patients' desires.[36] Even characteristics such as age, education, and health literacy skills may not be consistent indictors for how involved a patient wants to be,[37] and cultural and generational preferences vary.[38]

Balancing views for patient-led vs. provider-led care

On one end of the spectrum, some patients want a more active, or "patient-led" form of decision-making, researching their conditions and treatments available.[39] On the other end, patients may prefer a more traditional "physician-led" style, assuming the doctor knows best.[40] But how providers can balance these needs also depends on the providers' own views, which are equally as varied.[41]

In Ethiopia, researchers identified a gap between patients' expectations and providers' perception of the patient's role,[42] showing that providers also exist somewhere on a spectrum between person-centered care and paternalistic care.[43] A multi-country study in Asia found varying degrees of "concordance" between countries over the amount of involvement patients prefer (figure 1).[44] Researchers found this to be the first study to examine the associations of perceived roles in decision-making and patient outcomes among advanced cancer patients in low- and middle-income countries. Joint decision-making was associated with higher well-being and perceived quality of care.[45]

Figure 1. Distribution of discordance/concordance between perceived and preferred roles in decision-making in five Asian countries



Source: Semra Ozdemir, et al., "Patient-Reported Roles in Decision-Making Among Asian Patients With Advanced Cancer: A Multicountry Study," 18 November 2021.

Opportunity for education in a new paradigm of care

One step forward may be gaining a better understanding of various providers' perceptions of patient involvement in SDM.[46] A small study of medical residents in the Netherlands found that young doctors preferred more traditional, physician-led, decision-making.[47] Their decision-making appeared to be affected by contextual factors—their medical knowledge and knowledge about SDM—and by their beliefs and convictions about their professional responsibilities as a doctor.[48] While trying to provide patients with the best possible evidence-based treatment, these residents confused SDM with acquiring informed consent for their recommendations.[49]

Education can be an important part of a new paradigm of care, and the international coproduction health network (ICoHN) is an initiative supporting learning in different communities of practice with patients, practitioners, students, and researchers to explore coproduction in SDM.[50]

Bigger opportunities for life sciences in SDM

Life sciences companies are increasingly focused on "informed" decision-making to support SDM.[51] A well-informed patient is more likely to actively participate in the decision-making process and better understand the potential outcomes and risks of any treatments.[52] In addition, informed decision-making may help build trust, as even patients who ultimately opt to defer a final treatment decision to a provider are still interested in quality information.[53] There is an opportunity to increase awareness about the role of SDM,[54] and evidence shows that SDM can promote appropriate care, decrease overtreatment, meliorate health outcomes, and thereby, may reduce health care costs.[55]

The use of patient decision aids (PDAs) can help patients participate in decisions to improve both the quality of the decision-making process and satisfaction with their choices.[56] Life sciences companies that develop PDAs with information on treatment alternatives, potential risks, and benefits might consider how a patient's preferences and values could be addressed.[57]

By championing SDM and facilitating collaborative PDA development with clinicians and decision-makers, patient advocacy groups, and patients, life science companies have an opportunity to show support for strategies that further respect patient rights and responsibilities in the decision-making process.[58]

Some AI tools may prove beneficial to increasing the practice of SDM—but the design and use of these tools should also incorporate patient preferences.[59] McGill University in Canada, which has been a leader in AI and machine learning (ML) research globally,[60] conducted a scoping review of AI interventions that were used to facilitate SDM across several countries.[61] Researchers observed a lack of emphasis on patients' values and preferences in the studies.[62]

McGill researchers found none of the studies on SDM included health care providers or patients in the design and development of the AI interventions. They suggest further research should be conducted to strengthen and standardize the use of AI in different steps of SDM and to evaluate its impact.[63]

While AI in SDM is in its infancy, there are multiple advances in AI and Generative AI (GenAI) that focus on improving patient journeys across multiple disease areas—from better diagnostics and use of visualization and characterization functionality to support HCPs, faster reimbursement, and more. See the GenAI section of the Outlook for further elaboration on the power and growth of GenAI/AI.

Optimizing touchpoints in the patient experience

A patient experience touchpoint is any point at which a patient interacts with the health care ecosystem as they manage a given condition/affliction, whether through an in-person service or online, through a website, platform, or app.[64] The sum of all these touchpoints influences a patient's perception of the care they receive and the patient journey.[65]

Strategies to optimize the patient journey should integrate the patients' perspective at each touchpoint.[66] Specifically and accurately mapping the patient journey can also help identify new opportunities to improve a patient's quality of life (QoL), not limiting actions to acute needs.[67]

Every patient journey can have several stages that are considered inherent to a specific disease.[68] For example, cancer can present suddenly and decisions regarding treatment can be time sensitive, causing a patient's emotions to run high.[69] Chronic diseases, like diabetes, typically progress gradually and may often be preventable or mitigated with lifestyle changes.[70] Every patient's individual journey can also differ within their disease, and care should be holistic and able to adapt to needs as they change over time.[71]

In 2024, as person-centered care continues to be a priority, strategic leaders should be looking at possibilities for their organization to improve patient experiences[72]—even one touchpoint improvement may make a difference in someone's life.

What can't be measured, can't be improved

The health care industry generates a tremendous amount of real-world data (RWD) that provides valuable insights on patients, their diseases, and their patient journeys and care.[73] But up to 80% of health outcomes can be driven by nonclinical factors, such as access to transportation, education, job opportunities, nutritious food, and safe housing.[74]

This nonclinical data—referred to as social determinants of health (SDoH)—aren't typically captured in traditional RWD.[75] SDoH are the environmental conditions where people live, learn, work, play, and worship that affect a wide range of health and quality-of-life outcomes and risks.[76]

These factors need to be better understood to more effectively enhance a patient's journey, which is why, for example, Deloitte has invested in combining Komodo's Healthcare Map with its HealthPrism SDoH data set—one of the largest SDoH data sets in the US—to develop a more comprehensive view of patients, their care journeys, and their outcomes.[77]

For example, digital health technologies and the widespread use of mobile phones can enable, those in low- and middle-income countries, and other disadvantaged patients, to actively participate in their care, despite transportation challenges, through home monitoring devices, health care apps, wearable technology, and telehealth services.[78]

Finding opportunities for digital touchpoints

Because patients have individualized needs and concerns, life science organizations should respond to patients with a personalized engagement approach that put them at the center of care and connects them digitally.[79]

Digitally powered personalized health care plays a part in helping improve access to treatments.[80] Deloitte's ConvergeHEALTH Connect ™ creates enhanced digital touchpoints across patient journeys.[81] In a stylized manner, you can observe the differences in patient journeys for cancer and chronic disease (figure 2)[82]

Touchpoints in the patient journey for rare disease

In rare diseases, patients may endure challenging diagnostic journeys and often require multifaceted treatment plans.[83] The process typically requires a patient navigate a convoluted system of specialists, testing restrictions, and reimbursement hassles before they're even diagnosed, much less treated.[84] Some companies are working to make a difference by mitigating the burden and personalizing the experience. For example:

- **PANTHERx** streamlines the process associated with getting rare disease medications to patients and incorporates patient education and adherence plans. RxARECARE teams specialize in unique disease states and the select medications patients will receive. Personalized care teams work to ease a patient's burden by taking care of the billing process from start to finish and handling contingencies, like getting a damaged refrigerator replaced, and getting costs reimbursed so a patient won't miss a treatment due to improper storage.[85]
- **MMIT** provides patient access data and analytics to pharmaceutical and health care companies. Carolyn Zele is a rare disease survivor that now works as a market access specialist for the company. She says that she advocates daily for manufacturers to understand the plight of patients. "When patients are at their weakest and most vulnerable, they shouldn't have to fight for a diagnosis or help coordinating their own care. They shouldn't have to file multiple appeals to a payer or manufacturer to help pay for their treatment," she says. Zele advises manufacturers to map the twists and turns of the patient journey to become deeply familiar with the existing access barriers. Pharmaceutical companies may improve access to treatments with a deeper understanding of the patient journey.[86]

Figure 2. Comparison of patient connect across oncology and diabetes patient journeys

Source: ConvergeHEALTH by Deloitte

Touchpoints in the patient journey in oncology

Amidst a mounting need for care services, the cancer burden is growing globally. For 2022, the World Health Organization reports that an estimated 20 million new cancer cases were diagnosed, and it projects 35 million new cases will be diagnosed in 2050.[87]

Approximately one in five people develop cancer in their lifetime, but people are living longer after cancer.[88] Data shows an estimated 53.5 million are still alive five years following a diagnosis,[89] but many aren't getting the follow-up care they need and face continued health challenges.[90] Of those that die from the disease, about one in nine are men, and one in 12 are women.[91] Lung, breast, and colorectal cancer are the most prevalent cancers.[92]

Improving early diagnosis in cancer

To improve the lived experiences of cancer patients, person-centered care should be more than a "nice to have."[93] Patients want to be able to navigate all stages of their cancer care easily and efficiently, and personalized patient journeys should include a needs-based approach for the patient as well as their loved ones.[94]

Early symptoms and indications of cancer with prompt presentation are key to early diagnosis.[95] When cancer care is delayed or inaccessible, chances of survival are lower, more problems are associated with treatment, and costs are higher.[96]

In the UK, the majority of cancers are diagnosed in an emergency room.[97] Only breast and cervical cancer, and to a lesser degree, colon cancer, are found during routine screenings.[98] Macmillan Cancer Support, a leading UK charity organization,[99] is introducing the electronic risk assessment for cancer (ERICA) trial.[100] ERICA is testing six tools as part of Skyline software for clinical effectiveness in improving referral rates particularly in early stages of diagnosis.[101]

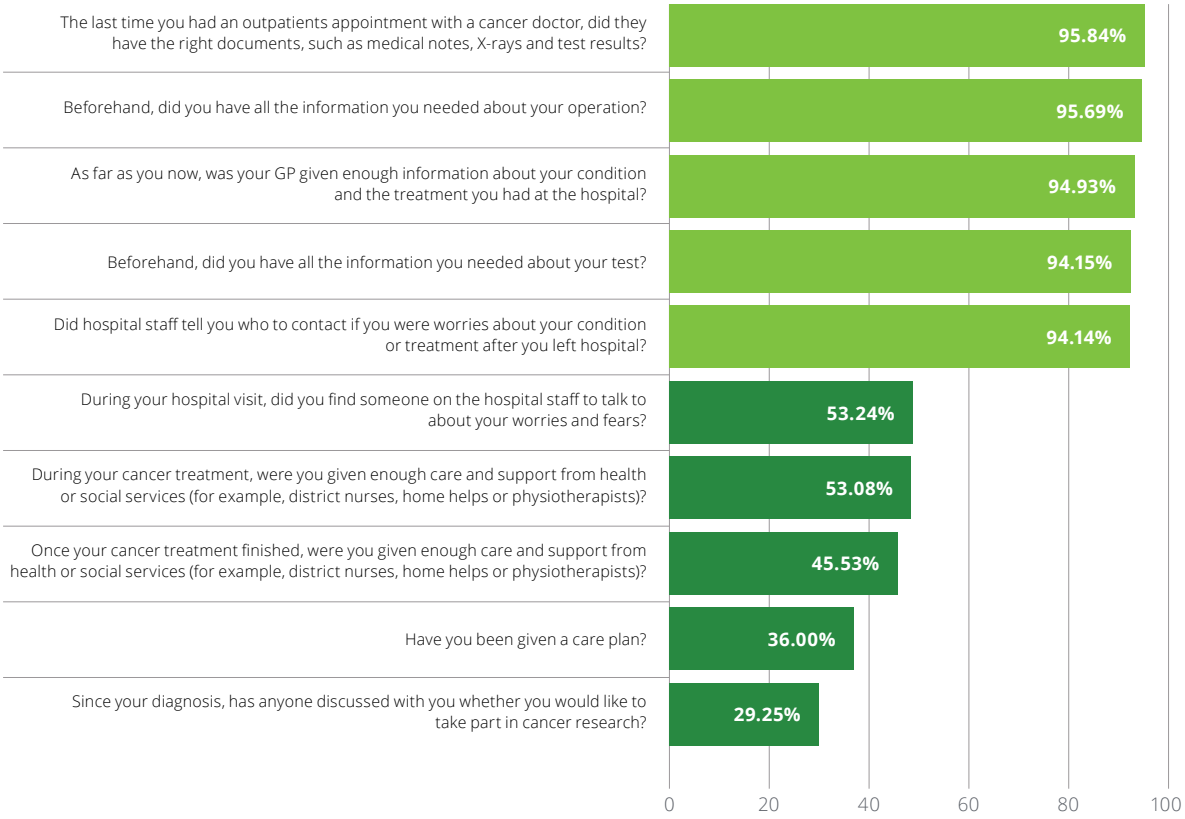
Improving the lived experience with cancer

In a national survey of cancer patient experiences in the UK (figure 3), the NHS fell below 54% in meeting patients' needs for emotional support during hospital care and subsequent treatment (figure 3).[102] Less than half of the patients surveyed felt they had the care and support needed after treatment, including only one-third saying they were given a care plan. An opportunity appears to exist to discuss participation in cancer research as less than 30% say this was discussed with them at any time following diagnosis.[103]

As many people are living longer with cancer, a future vision relies upon ongoing support for people living with cancer during treatment and beyond.[104] People with cancer should always be able to live life fully—in a way that is meaningful for them.[105]

Deloitte UK and Macmillan Cancer Support conducted research in the UK on shaping the future health care experience for people with cancer.[106] One forecast of the January 2023 report was the future ambition related to the lived experience of cancer patients, including where the system is failing and where action is needed (figure 4).[107] Organizations may want to engage this vision for scenario planning to help make a better future of health for cancer patients a reality.[108]

Figure 3. Patient experience survey, National Health Service (NHS) England cancer care



Source: Picker, National cancer patient experience survey, 2021. Data and tables: 2018

Figure 4. The future of health and the lived experience in cancer, strategies for action

People's understanding and awareness of cancer risks and symptoms

- More people will have a **better understanding of cancer risk and their own health generally**. This will likely mean more people are **seeking action sooner over cancer signs and symptoms**, as they have increased access to screening tests which are accepted widely.
- A **customized/localized** approach will be taken to **increase health literacy and raise understanding, awareness, and trust**, particularly in less represented communities.

Person-centred care (including well-being)

- People will have equitable access to a personalized care experience.
- There will be greater **emphasis on the needs of the individual and measuring outcomes that matter to people living with cancer**.
- The use of **digital tools** at scale will complement the workforce to support people and meet their holistic needs. A greater range of technologies will allow support to be tailored to each individual's needs, maximizing the impact for people living with cancer and the people that matter to them.

Living with and beyond cancer and end of life care*

- As people live longer with cancer alongside other long-term conditions, primary, **community and secondary care will coordinate better to provide holistic support**.
- There will be **big shifts away from siloed working** to a more multidisciplinary and cluster medicine way of working.
- **A large part of end-of-life care will move** from secondary/tertiary centres **to community/home settings.** There will be a **cultural shift regarding death and dying**, and people living with cancer will expect to have **open conversations about end of life and their choices**.

Location of care

- **Community diagnostics –** including blood tests and local diagnostics – **will play a much greater role in diagnosing cancer.**
- There will be an increased role for **community and home-based care** to support treatment for less complex cases of cancer care, including innovative solutions (e.g., chemotherapy buses, virtual wards) underpinned by increased cancer knowledge in the generalist workforce.
- This will decrease reliance on specialist centres and increase their capacity to **deliver novel therapies** to treat complex cancers.
- **And there will be a reduced requirement for patients to travel long distances to specialist centres,** with virtual multidisciplinary teams (MDTs) connecting specialists in tertiary centres with the wider workforce locally.

Source: Deloitte UK and Macmillan Cancer Support, "Shaping the future of cancer care," January 2023.

Navigating cancer care, including after treatment

Cancer care navigation is growing in importance and is a strategy for helping cancer patients overcome barriers across the cancer care continuum.[109] Emerging evidence suggests that providing patients with navigation services improves quality of life and patient satisfaction for care in the survivorship phase and reduces hospital readmission in both the active treatment and survivorship care phases.[110] Palliative care data is limited.[111]

Other programs help to address the significant racial, ethnic, and socioeconomic disparities in cancer, including access to screenings.[112] After treatment, survivorship programs also help improve quality of life and help patients find resources and a community.[113] Examples of these programs include:

- **Patient navigation services:** In the US, the Biden Cancer Moonshot program is prioritizing supportive services for people affected by cancer, including championing the importance of expanding patient navigation services.[114] The program is providing personalized assistance to patients, caregivers, and families to help identify and resolve barriers to high-quality and timely cancer care through care coordination and advocacy, even after treatment.[115]
- The first patient navigation program in the US was launched in 1990 by Dr. Harold Freeman to improve health outcomes in marginalized communities in New York.[116] In late 2023, the US Centers for Medicare & Medicaid Services (CMS) finalized codes for Principal Illness Navigation (PIN) services so providers can receive payment for navigation services. In early 2024, seven large private health insurance companies also agreed to cover the cost of cancer navigators.[117]
- **Collaborating for health equity:** The American Cancer Society (ASC) and Pfizer launched a three-year initiative targeting improvement in health outcomes in medically underrepresented communities across the US. Efforts are underway to enhance awareness of and access to cancer screenings, clinical trial opportunities, patient support, and comprehensive cancer navigation.[118]
- **Collaborating for health equity with non-clinical support:** In late 2023, the ACS launched ACS CARES (Community Access to Resources, Education, and Support), a new multi-channel, customizable program to deliver non-clinical patient navigation support to cancer patients and caregivers. For those not as comfortable with digital tools, the program also places trained college and graduate student volunteers in oncology clinics to help patients and caregivers receive non-clinical, individualized in-person support. A US$1 million commitment from the Deloitte Health Equity Institute (DHEI) is helping to expand the program.
- **Cancer survivorship program:** Physical activity is an important part of cancer recovery.[119] In the US, the "LIVESTRONG at the YMCA" cancer survivorship program organizes small groups of people living with, through or beyond cancer to improve their strength and fitness, while also gaining emotional support from peers.[120] According to research from the Yale Cancer Center and Dana-Farber/Harvard Cancer Institute, participants in the specialized program experience improved fitness and quality of life, as well as significant decreases in cancer-related fatigue.[121] The 12-week program is offered at over 790 YMCAs and serves 400 communities around the country.[122]

Life sciences and medtech companies might consider creating, sponsoring, or otherwise getting involved with these types of programs to gain a better understanding of the cancer survivor's journey and ongoing needs. For example, some opportunities might include engaging wearables as part of activities in the fitness program, providing transportation to and from facilities for cancer survivors, and hosting events that raise awareness of mental health support resources or answer questions about clinical trial participation.

Growing demand in diagnostics for early detection, rehabilitation, and prevention

More younger people getting cancer

Survival rates for some cancers have improved dramatically since 1975, rising to 68% from 49%.[123] For example, people with non-Hodgkin lymphoma now have a 74% survival rate compared to 47%, 50 years ago.[124] Improved screening has also led to detection and diagnosis of cancers at earlier stages, when treatment has a higher chance of producing a positive outcome.[125]

But cancer is starting to affect more adults younger than 50 years of age, with an 80% rise in the cancer rate from three decades ago.[126] One US oncologist started noticing the trend 10 years ago. She was asked to treat a teenager that flew in for treatment from China for a gastrointestinal disease typically found in people 65 years or older, but the cancer was too advanced to treat.[127]

Oncologists around the world are seeing more younger patients with cancers uncommon for young people.[128] Worldwide, the most common cancer for young adults under 40 is breast cancer,[129] and more than 90% of women under 40 in the US are diagnosed between 30 and 39.[130] More than a dozen types of cancers are rising in multiple countries.[131] In the US, colorectal cancer has become the leading cause of death for men under 50.[132] There is a growing need for better screening, awareness, and treatments.[133]

Patients with certain cancers, like ovarian cancer and leukemia, also often experience ongoing recurrence and remission,[134] and these diseases may be managed like a chronic illness.[135] As people live longer with various cancers, and the number of people with chronic disease increases, reevaluating the role of patient autonomy in chronic disease and cancer may prove beneficial in rebuilding trust and advancing patient-centered care.[136]

New biomarker research underway for earlier diagnosis of Alzheimer's disease

China has become the country with the largest number of Alzheimer's patients with nearly 10 million cases.[137] However, more than 21% are under the age of 60 and are working age, creating a demand for earlier screening and diagnosis.[138] Currently, Alzheimer's disease (AD) affects nearly 7 million people in the US and approximately 32 million people worldwide.[139]

The development of more biomarkers offers one of the most promising paths to early diagnosis for AD.[140] Beyond imaging and cerebrospinal fluid (CSF) tests, an urgent need exists for simple, inexpensive, noninvasive, and easily available diagnostic tools such as blood tests to diagnose the disease.[141]

> "The biomarker space right now is advancing rapidly. Plasma and blood biomarkers are moving beyond what we've seen—more highly correlated with stage of disease and presence of pathology and will contribute to improved and earlier detection and the possibility of tailoring treatments for patients."
>
> —**Dan O'Connell**, CEO, Acumen Pharmaceuticals[142]

Acumen's sabirnetug program (ACU193) is developing a deeper understanding of key biomarkers related to AD.[143] A humanized monoclonal antibody (mAb), sabirnetug (ACU193) was discovered and developed based on its selectivity for soluble amyloid-β oligomers (AβOs).[144] By selectively targeting toxic soluble AβOs, sabirnetug aims to directly address a growing body of evidence indicating that soluble AβOs are a primary underlying cause of the neurodegenerative process in Alzheimer's disease. One of its distinguishing factors is the potential for cognitive improvement, in addition to slowing the disease progression.[145] Acumen recently announced the first patient dosed in the company's ALTITUDE-AD study a Phase 2 trial evaluating sabirnetug in early AD patients.[146]

Other emerging biomarkers include retinal imaging and skin and saliva tests. Tests with these types of biomarkers are exploratory.[147]

Smart devices for more personalized care and rehabilitation

Smart devices are being used for quicker diagnosis and rehabilitation by enabling remote collection of user data and providing health-related feedback for faster, more personalized, and more accurate health care conclusions.[148]

- **Smart implants:** Persona IQ "The Smart Knee" by Zimmer Biomet is being used to detect if a patient is progressing as expected through rehabilitation by remotely tracking range of motion, gait disturbance, function, pain, etc.[149] The goal is to reduce readmissions and revisions. The software provides personalized post-operative smart metrics that connect patients through a care management platform and automated data flow.[150]
- **Computer vision:** Senseye's novel diagnostic platform for mental health uses digital biomarkers for mental health expressed by eye physiology.[151] The brain-based methodology uses computer vision and a proprietary machine learning algorithm that works on any smartphone.[152] The company's first target is post-traumatic stress disorder (PTSD). The device was designed to help clinicians personalize care and diagnose PTSD with a 15-minute ocular test, rather than over months using other forms of evaluation.[153]

Preventative care and direct-to-consumer diagnostic services

As some patients strive for more autonomy, life sciences companies are exploring new channels and partners to engage directly with patients rather than relying solely on HCPs.[154] More direct-to-consumer (DTC) health services are launching to address patient concerns and preferences more expeditiously.[155] As these services become more prevalent, effective, safe, and cost effective, it's likely that they will grow in popularity.

There are blood tests and screening procedures that many feel are informative and preventative, but they may not be covered by insurance, or alternatively, consumers may not want to wait, or pay, for a doctor's appointment to get access.[156] Patients may be told that a test is not necessary, when it might prove lifesaving,[157] and others may be a waste of time.[158]

- **DTC MRI:** On **Prenuvo** website, consumers are called to "put their health in their own hands," so they can catch conditions before they are a crisis.[159] Prenuvo offers AI-assisted scans, including a Whole-Body MRI scan, that screens for 500 conditions.[160]

  Actress and television host Maria Menounos is now one of the rare pancreatic cancer survivors after her cancer was detected early—at stage 2—with a Prenuvo scan.[161] With US Food and Drug Administration (FDA)-approved scans and other screenings, most pancreatic cancer is not typically discovered until stage 4, and diseases discovered at this stage commonly have a prognosis of a 1% survival rate at five years after discovery.[162] However, at USD$2500 and up, the access to such scans are extremely limited and there's some debate about the risks of these scans, including false positives which may lead to unnecessary procedures and costs.
- **DTC lab testing:** Direct access testing (DAT) or DTC lab testing enables individuals to order their own medical tests directly from a clinical laboratory, which assigns their own HCP to the order.[163] DAT is subject to a fragmented regulatory landscape and may not be available in some jurisdictions.[164] The DTC lab testing market is projected to reach a hefty US$1.59 billion by 2030, signifying a paradigm shift in health care dynamics due to personalized diagnostics.[165] Forecasts for the period, 2023 to 2030 show a Compound Annual Growth Rate (CAGR) of 10.8%.[166] Some drivers include the rising incidence of chronic as well as sexually transmitted diseases and the increasing penetration of pharmacogenomic testing within the DTC laboratory testing realm.[167] Challenges include genetic data privacy, the potential for misinterpretation of test results, and the need for professional medical counseling.[168] Other issues—like sample integrity, regulatory concerns, limited test portfolios compared to conventional laboratory testing, and the lack of reimbursement schemes—are likely to be headwinds to growth.[169]

Managing the chronic disease journey in Type 2 diabetes

Diabetes is a worldwide epidemic and an expensive chronic condition that continues to increase faster than many HCPs can manage.[170] Healthy eating and physical activity are critical to diabetes management, and while some interventions have proven effective at changing certain behaviors, there are still challenges in achieving sustainable long-term results.[171]

The patient journey in diabetes has changed over the last decade and is now part of digitally powered personalized health care. Many digital solutions include combinations of remote patient monitoring, behavior and lifestyle modification, coaching support, and nutritional ketosis.[172]

The growth of the GLP-1 class of medications for the treatment of obesity and pre-diabetes will also play a disruptive role in the management of Type 2 diabetes. For further insights on the growth of GLP-1 diabetes drugs, see the Value Creation section of the Outlook.

More evidence-based research needed for diabetes digital management tools

Recent research is calling into question the effectiveness of digital management tools used to track and manage patients' Type 2 diabetes.[173] Peterson Health Technology Institute (PHTI) conducted research that asserts that the leading tools evaluated do not deliver meaningful clinical benefits and increase health care spending relative to usual care.[174] PHTI says users of these tools achieve only small reductions in hemoglobin A1c (HbA1c) compared to those who do not use the tools.[175]

PHTI hopes to raise the bar on expectations and evidence, and some agree that there needs to be a more rigorous assessment of solutions.[176] But many, including the Digital Therapeutics Alliance, pushed back on conclusions drawn or the methodology used for the study.[177]

Initial data in the research showed that one "promising solution," Virta Health, might be more likely to deliver clinically meaningful benefits.[178] The digital health care company aims to reverse Type 2 diabetes through personalized nutrition therapy and remote medical care, including telehealth, while also controlling prescription costs for patients.[179] PHTI affirmed that glycemic control and remission are more likely with Virta Health if patients can maintain the rigorous dietary requirements of the intervention.[180]

In addition, Virta Health recently published its own research on its nutritional therapy in Diabetes Therapy showing it to be a potential off-ramp to GLP-1 drugs.[181] Many face the prospect of regaining weight after stopping GLP-1 medications, and Virta Health's results potentially have major implications for employers and plans looking to improve members' health outcomes.[182]

Supporting patient autonomy in chronic disease

An important part of managing a chronic disease is patient autonomy.[183] Diabetes self-management often requires personal autonomy and a supportive social environment to influence outcomes.[184] Researchers in China found that supporting patient autonomy in Type 2 diabetes could help patients achieve glycemic control—not only at the end of intervention but up to six months after.[185]

Patients' personal experiences concerning everyday life with disease or disability shape their knowledge and understanding.[186] Respecting and supporting patient autonomy may not mean providers agree with or confirm a patient's different beliefs and perceptions, but it may be necessary to inform or develop that patient's understanding. Being respectful and seeing the patient view as an expression of their autonomy helps to build trust.[187]

Regulators heightened interest in measuring what matters most to patients

Because patients often live with their disease or condition for long periods of time, and clearly understand the intricacies of their symptoms, the US FDA is increasingly looking to understand how patients describe their health status and assess their outcomes without interpretation from others.[188] Input from patient-reported outcome measures (PROs) and clinical outcome assessments (COAs) can then be used to help select or develop tools to measure what matters most to patients as well as shape future policy.[189]

To date, health-related quality of life (HRQoL) is assessed inconsistently and there is no validated method to integrate HRQoL data into the assessment of therapeutic agents.[190] Including HRQoL as an endpoint may offer crucial information on functional abilities and treatment side effects from the patient's perspective.[191]

Utilizing PROs and HRQoL as standard practice in the clinical trial setting could provide a more comprehensive, patient-centered assessment of therapies under development and help guide patient-provider discussions around treatment options in clinical care.[192] Leading pharma companies like Gilead, Sanofi, AstraZeneca, Biogen and Eisai are starting to include newer methods to assess HRQoL for clinical trials in HIV, COPD, diabetic neuropathy, and Alzheimer's disease.[193]

Advancing the future of health with quality of life in longevity

The importance of quality of life is expected to expand as more people live longer,[194] and people's preferences for quality of life versus longer life as they age may influence their longevity.[195] Breakthroughs in the study of longevity—why humans age, how they age, and interventions to slow the aging process—suggest the possibility of some humans significantly surpassing current life expectancies.[196]

Extending health span, not just life span

A paradigm shift is underway—from disease-focused treatments to those that address the underlying mechanisms of aging, biological systems, and wellness.[197] The goal is to extend health span, not just life span.[198]

The number of aging adults is on an increasing trajectory.[199] Some people may be living longer, but they are doing so with less physical function and a reduced quality of life.[200] Also, a digital life has led many to a sedentary life resulting in an increased risk of disease.[201]

Can longevity-focused concepts help improve the current status quo? Deloitte US analyzed 10 therapeutic areas to uncover two extreme scenarios—disease areas that are deteriorating and those that are improving (figure 5).[202]

In tracking life span over a period of 15 years, deteriorating therapeutic areas saw reduced health span and life span, signifying more years of life with a disability as well as premature death, driven by worsening lifestyle behavior (obesity, Type 2 diabetes) and the growing elderly population.[203] Aging is the leading risk factor for neurological and musculoskeletal disorders. Treatment advances for cancer and cardiovascular disease have been the primary contributors to life span improvement.[204]

Emerging longevity ecosystem

A growing ecosystem of life sciences, health care, and health tech companies is emerging focused on solutions that address underlying drivers of disease and aging (figure 6).[205] Globally, venture capital funding is increasing support for the immense potential of innovative solutions aimed at extending human life and improving health during aging.[206] For example, LEAPS by Bayer, headquartered in Leverkusen, Germany, has invested about US$1.5 billion as of 2023 in various biotech and health-related companies and is dedicated to propelling advancements in aging and age-related diseases.[207]

Figure 5. Longevity disease matrix

Analysis explained

Health and life span

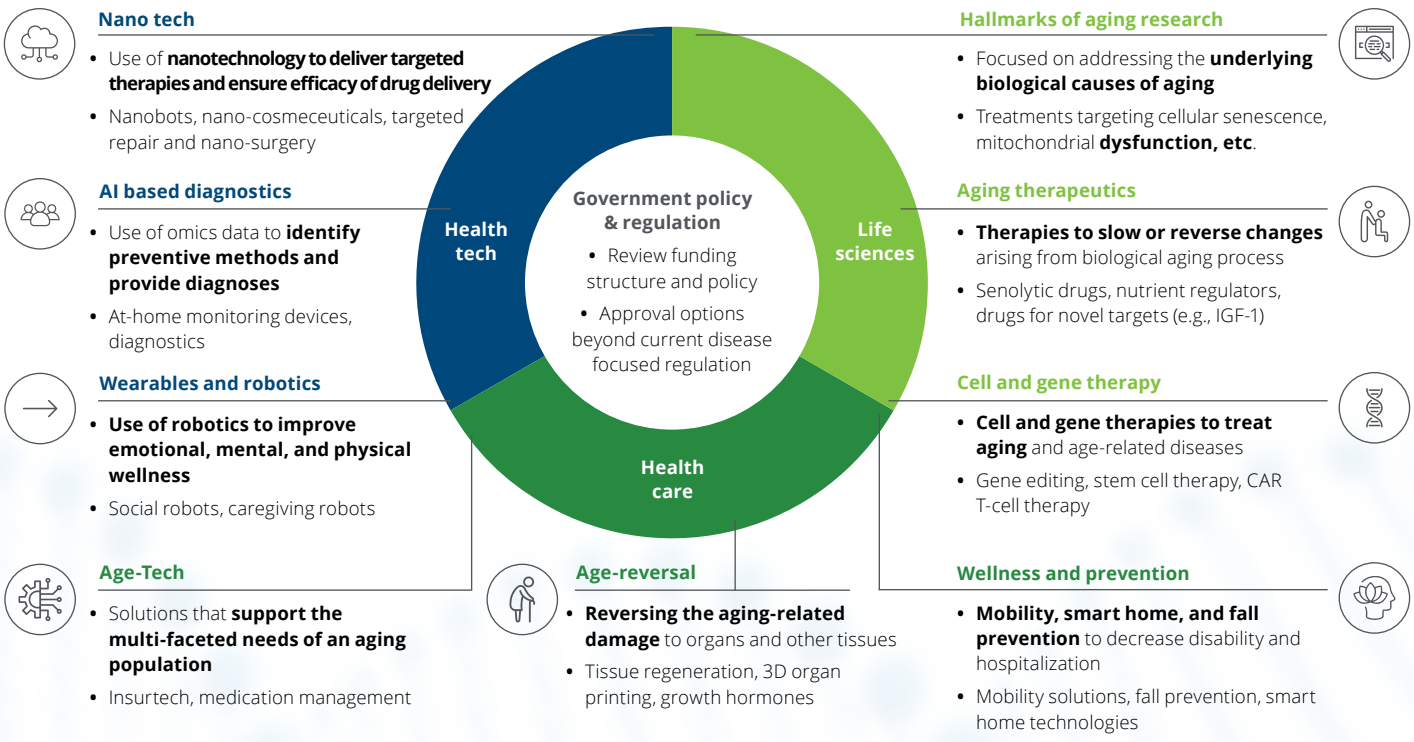
- Chart illustrates the difference of a patient with a disease in 2000 vs. 2015 and whether they experience a better health or life span in the latter.
- For example, the average cancer patient experienced a materially longer health and life span in 2015 (vs. 2000).

Drug approvals

- Number of drug approvals was used as an analogue for the life sciences industry's concentration on a given therapy area.
- No statistical correlation exists between disease area concentration and improvement in health and life spans.

Source: Deloitte US, "Living a 140-year long and healthy life," 2021.

Figure 6. The longevity ecosystem



Source: Deloitte US, "Living a 140-year long and healthy life," 2021.

Life sciences

We expect the convergence between technology, life sciences, and health care to continue supporting a growing ecosystem in pursuit of extending human longevity. Longevity research is poised to revolutionize the therapeutics market, and life sciences companies that opt to embrace a forward-thinking longevity mindset recognize that the future of health is one where therapeutics enable prevention and well-being over treatment-based reactionary care.

Health care

Health care providers should prioritize patient wellness and create hyper-personalized preventative solutions. Because personalized medicine enables a patient-centric approach to well-being and care delivery that has the potential to improve outcomes and reduce cost, personalized medicine is highly likely to continue gaining traction as a prominent feature of the future of health care.

Insurers

Public and private insurance payers should reexamine their offerings and consider adding services and products that also support populations with longer, healthier life spans.

Health Tech

Health tech is rapidly advancing as companies leverage real-world evidence and data and capitalize on the shift to well-being and personalized medicine. Emerging technologies and data-driven decisions are starting to accelerate rapid diagnosis, treatment selection, and delivery. The many benefits of these technologies on the aging population, especially, should not be underestimated.

Patient

Healthy aging varies according to social systems, education, and knowledge about lifestyle behaviors and health care.[208] Few studies have recognized the potential of self-care behaviors among older adults to prolong independence later in life, and the role of motivation has largely been ignored with regard to longevity.[209] Research from Cardiff University in Wales finds that choiceful behavior, self-reflection, and supported autonomy helped to predict who would live longer.[210] As companies invest in longevity research, they might also more deeply consider the role of patient autonomy in healthy aging.[211]

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