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An overview of key trends in Research and Development (R&D)

Overview of key R&D trends

1. Life Science pipeline pivots to digital heath therapies and personalised healthcare

Digital Health Therapies and Personalised Healthcare are shaping the future market

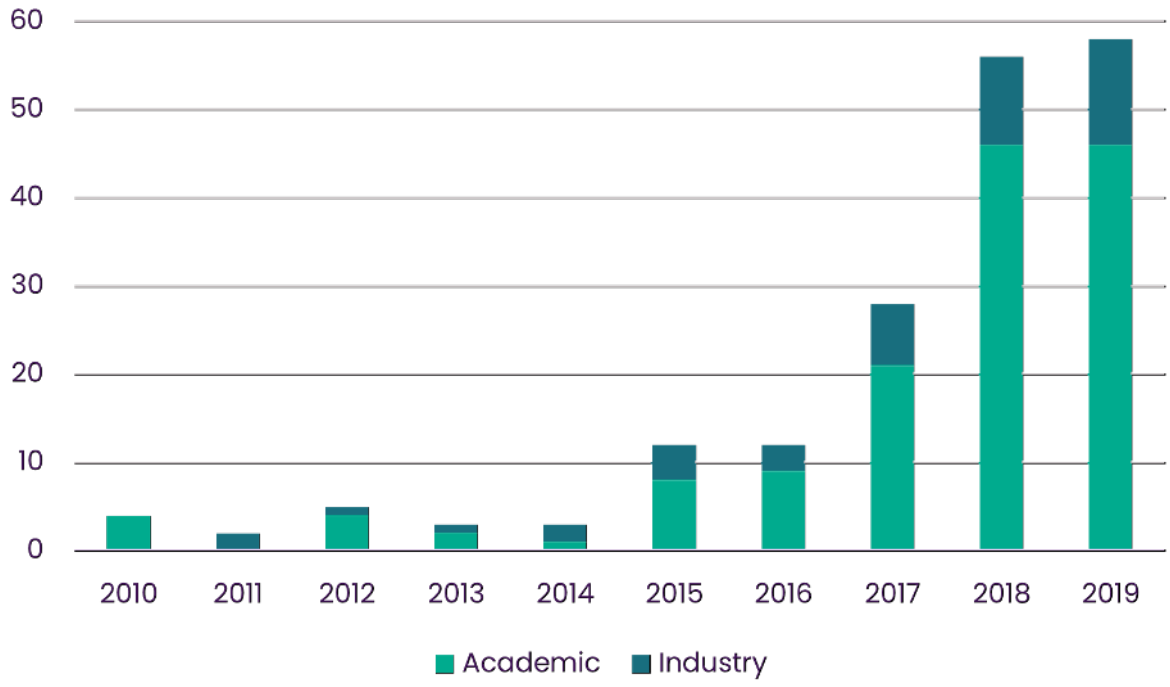
Personalised Healthcare (PHC) is shaping the pipeline as more players seek to capitalise on opportunity:

- **PHC sector is forecast to grow at a rate of ~12% CAGR over the next 10 years**, to over 5trn USD in value.[1]
- **This growth is accompanied by that of companion diagnostics (CDx), a critical component of personalisation**. The CDx market is anticipated to grow at ~23%[2] over the next 5 years, which is double the rate of the PHC sector as CDx providers ramp up activities to keep up.
- **Pipeline evolution is driven by sales of Advanced Therapy Medicinal Products (ATMPs)** (excluding COVID vaccines) which has grown by over 60% since 2017.[3]

Digital Health Therapies are becoming a stronger presence in the pipeline of the future:

- Digital transformation of R&D is defining the future with the **increasing maturity of artificial intelligence, virtual reality and IoT, enabled by decentralised clinical trials** helping to increase patient access.[4]
- **Emerging class of digital therapeutics (DTx) driven (Fig 1)[5] by increasing focus on preventive care and self-testing**, fueled by growing prevalence of chronic diseases and availability/maturity of smart consumer technologies.[4]
- **Most DTx clinical development is focused on psychiatry indications**, followed by **oncology, addiction, neurology and endocrinology (diabetes management)** as emerging opportunity areas.[6]

Fig 1. Trends in interventional Digital Therapeutics (DTx) trials. Clinical development activity has increased substantially in recent years[5]
(Source: Evidera 2020)



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2. Portfolio rationalisation and targeted therapies take centre stage

Increased focus on repurposing of assets and Advanced Therapy Medicinal Products (ATMP)

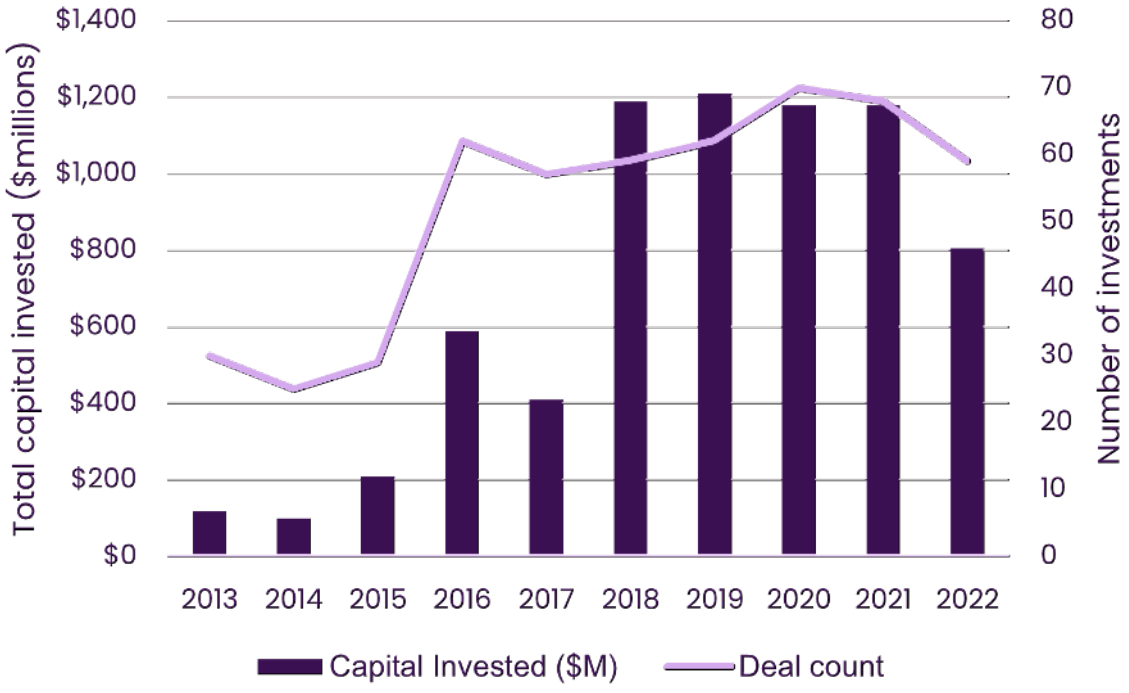
Continued portfolio rationalisation and evolution, with more focus on repurposing of assets:

- Repurposing **brings products with an established safety profile to new indications** or patient groups,[1] while continuing to drive organisational efficiencies aimed at releasing cash for re-investment.
- The pandemic saw a number of drugs repurposed to treat COVID-19, e.g., baricitinib, remdesvir, tocilizumab, dexamethasone.[2]
- **Real-world data / real-world evidence is a key enabler** and area of substantial opportunity. Regulators are developing and publishing guidance to support its use. The FDA has published a range of guidance documents, and the EMA has included this in its strategy to 2025.[3]

Increasing focus on Advanced Therapy Medicinal Products (ATMPs) as targeted therapies take centre stage:

- **More than double the number of ATMPs approved in the last 5 years** than in the previous 9 years.[4]
- A key driver of this trend is the **maturing of regulatory mechanisms, pricing & reimbursement pathways and supply chains**, which all lower the barriers to entry.
- **Gene therapies are currently leading the charge and will dominate in the next few years** as R&D coalesces around this technology to make the next big leap; and M&A activities targeting cell and gene therapies increase (Fig 2). However, even cell and gene companies aren't immune to market conditions, as evidenced by the dip in performance in 2022.[5]

Fig 2. First time investments in cell & gene companies
(Source: PitchBook, RSM US)



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3. The power of strategic partnerships

The appeal of the Alliance proposition in generating value and the need for regulatory collaborations

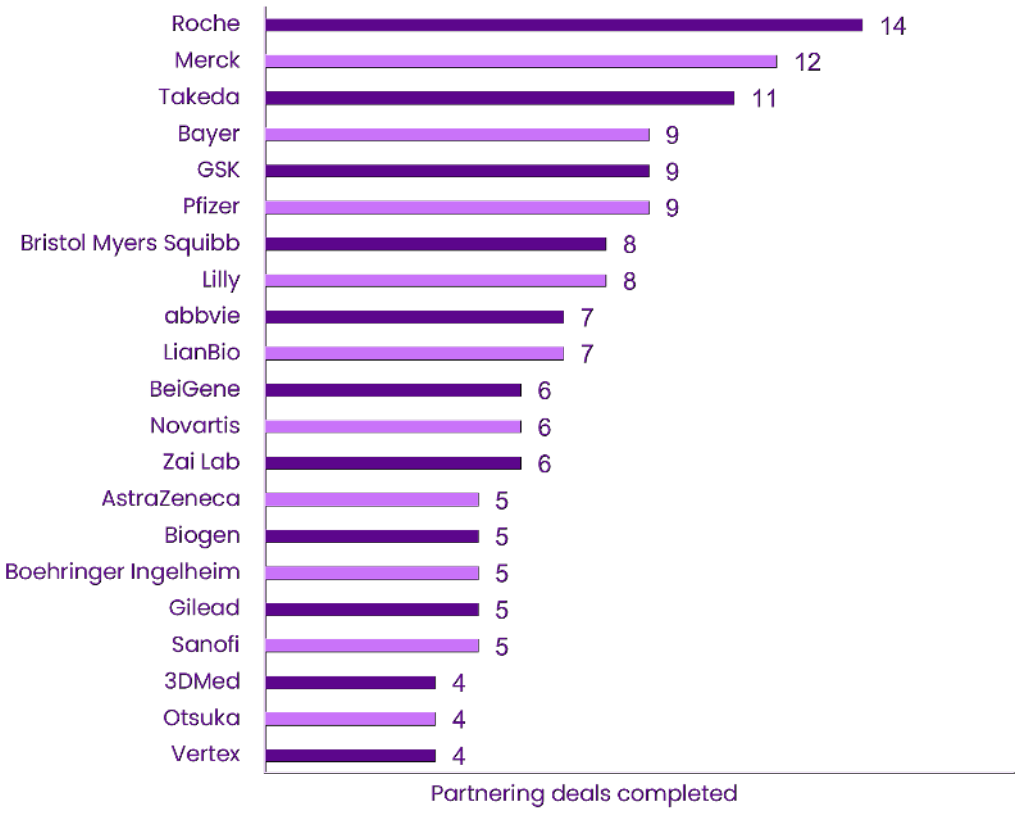
Accelerating speed to market with more innovative and effective partnership models:

- **Innovation in partnerships and collaboration** is key to delivering on the opportunities that emerged from pandemic experience. Partnerships and collaborations in new areas, including R&D, manufacturing and supply chain, commercialisation and regulatory policy, e.g., Oxford-AZ COVID partnership, Pfizer-Biontech. This approach is being applied to more ordinary settings and defining a new normal.[1]
- **Partnerships and alliances have developed as a critical avenue of value generation** (Fig 3) with partnership deals presenting exciting liquidity and risk mitigation opportunities for early-stage companies and growth opportunities for established players.[2]

Strengthening regulatory collaborations as a critical enabler of access to next generation therapies:

- Ongoing conversation with key opinion leaders, industry and regulatory experts make it clear that **closer collaboration between industry and regulators is a key enabler of the emerging landscape of next generation therapeutics** such as digital therapies and ATMPs.[3]
- **Regulators are seeking to work more closely together** to keep pace with rapid science-based technological and medicinal product innovation, as well as to promote availability of appropriate development pathways to support access. Continued engagement with the (bio)pharmaceutical industry is deemed critical.[4]

Fig 3. Multinational strategics seek to solidify pipelines through partnering activities
(Source: Outcome Capital)



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4. Large pharma driving health equity and Environmental, Social and Governance (ESG) agendas for life sciences

Delivering access to patients with increased diversity and geographies is helping to increase social impact and reset global pharma's reputation

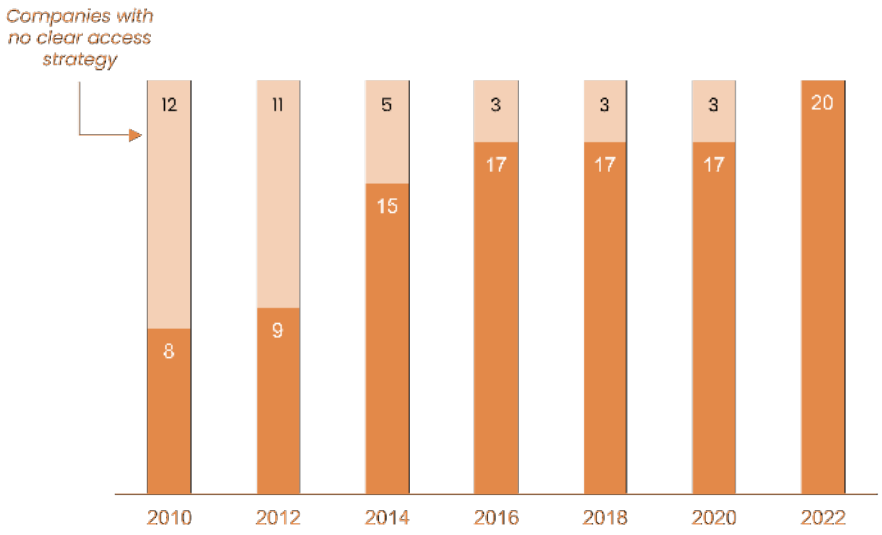
Elevating health equity to deliver more access to more patients, with more diversity, across more geographies:

- **All 20 of the largest pharma companies included in the Access to Medicine Index in 2022 have newly implemented access to medicine strategies** (versus 8 in 2010) (Fig 4). Previously, a number of these companies only had general commitments to improve access to medicine rather than a clear, integrated strategy.[1]
- **Demonstrating patient centricity through optimal access to medicine continues to be important,** as more companies adopt a systematic approach and pharmaceutical giants position themselves as leaders in this space.[2]
- **WHO's Special Initiative for Action on Social Determinants of Health for Advancing Equity** is a first-of-its-kind global and multi-stakeholder initiative with the goal **to improve the social determinants of health for at least 20 million disadvantaged people in at least 12 countries by 2028.**[3]

Leading the ESG agenda to invest in a sustainable future and reset the pharmaceutical reputation narrative:

- **Large pharmaceutical companies are driving the sector's sustainability agenda,** with carbon negative targets to be achieved by 2030.[4]
- **Environmental sustainability references in company filings increased by 114% within one quarter.** Similar increases are seen across social media communications, job postings and discussion of environmental topics.[4]
- **Pharma 4.0 is driving a more mature sustainable future** through the supply chain, including opportunities for improved patient focus and drug personalisation to minimise waste.[5]
- **Investors and regulators are increasing scrutiny of ESG topics** such as diversity in clinical trials, access to healthcare and drug pricing, and the environmental impact of drugs and their packaging.[6]

Fig 4. Clear signs of progress as all 20 companies now have an access-to-medicine strategy
(Source: 2022 Access to Medicines Index)



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5. Shift in geographical focus to Asia

Asia, and China in particular, offer numerous opportunities for investment and a favourable R&D environment for pharma organisations

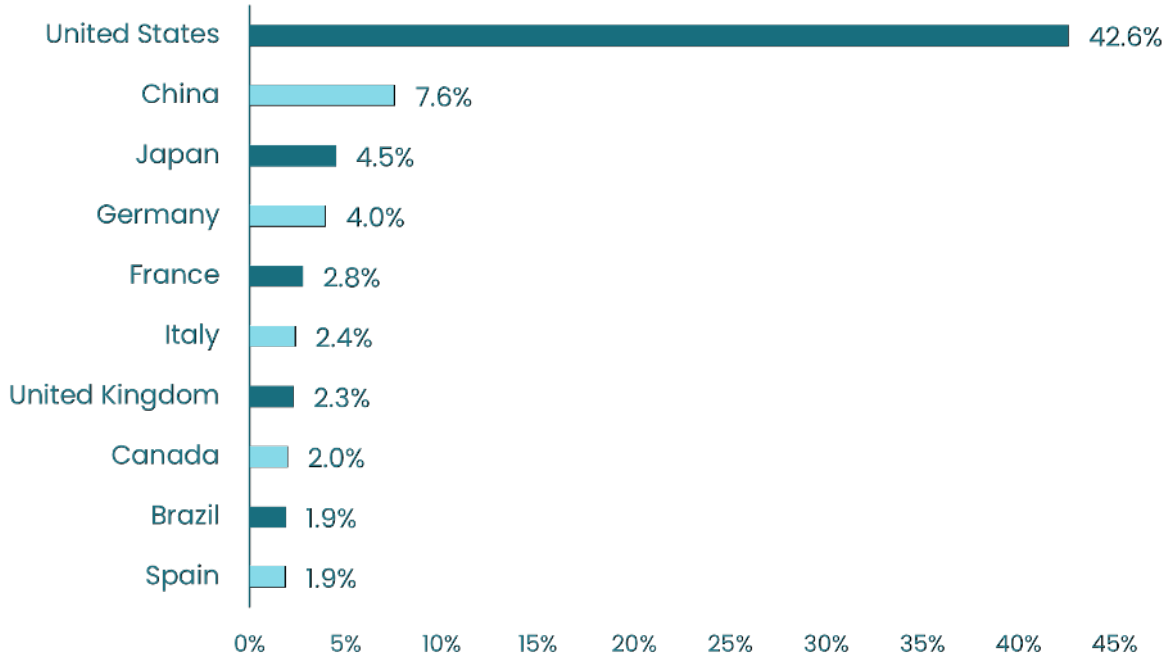
Asia is no longer a laggard when it comes to pharma:

- China, India, and other key markets in Asia have long been labelled as "emerging" markets; however, that is no longer the case[1]. In terms of market size and scale, **China and Japan now stand as the second- and third-largest pharmaceutical markets in the world**, respectively.
- China, in particular, has seen **strong and consistent annual double-digit growth** over the past decade, underpinned by ongoing infrastructure build-up, increasing healthcare spending and coverage, and an encouraging regulatory environment which has given **Contract Research Organisations,** who provide clinical trial services for medical device and pharma companies, **room to grow following a trend of outsourcing and cost savings by large pharma[2].**
- From **a sales perspective however, there is still room for pharma organisations to grow** and expand within the Asian market. **Asia still remains a relatively untapped market, given the sizeable patient population**, when compared with the US for example who account for roughly 50% of global pharma sales revenue[3]. Hence, it makes economic sense to have more clinical trials and drug development activities based in Asia.

Expansion of CROs will be key to future Asian pharma growth:

- The Asia-Pacific Contract Research Organisation (CRO) market is expected to **grow at a CAGR of 8.34%** from 2023 to 2028[4].
- This growth will be **fuelled by favourable government policies, the lower cost of conducting clinical trials in the region, and increased consolidation and competition** (of the roughly 5,000 small and medium manufacturers in the Chinese pharma sector) driven by regulatory reforms.

Fig 5. Market share of the leading global pharmaceutical markets 2022
(Source: Statista 2023)



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