

The importance of venture capital in Europe's life science ecosystem

Executive summary

As policymakers are currently shaping the future of pharmaceutical legislation in Europe, it is important to consider how the risk of eroding existing incentives for innovation will further exacerbate the decline in Europe's performance. We find that:

- Whilst Europe remains a world-leading region for life sciences innovation, there are risks that it is already falling behind. **US biotechnology companies invested 11 times more in R&D than EU companies in R&D in 2020.**
- Venture capital (VC) investment is an essential component of the life sciences innovation ecosystem, but the capital landscape in Europe is comparatively weak. **VCs in Europe raise 3-4 times less capital than VCs in US.**
- Europe now not only needs to compete with the US for funding, but also with China. **Capital raised in China now exceeds that in Europe and the average financing per round is 2-3 times greater.**
- Weaker VC funding flows to Europe create a "Death Valley" stage in early development whereby investors move out of Europe into regions where funding availability is greater in order to bring new promising therapies to market. **US companies launched over twice as many new molecular entities between 2017 and 2021 than European companies.**

With the ongoing revision of the EU's pharmaceutical legislation, there is now an opportunity to renew Europe's position as a leader in global biopharmaceutical research and entrepreneurial commercialisation and to ensure that European patients have access to the latest advancements in life sciences. Key policy enablers for a stronger innovation ecosystem in Europe include:

1. **Conserving strong intellectual property policies** to encourage continued high-risk investments into development of innovative technologies
2. **Recognize the value of innovative medicines** to appropriately value risk-taking by creating a healthy market.
3. **Enhance support for the early-stage innovation ecosystem** in order to advance the translation of academic breakthroughs into innovative medical technologies for patients in Europe.

Introduction

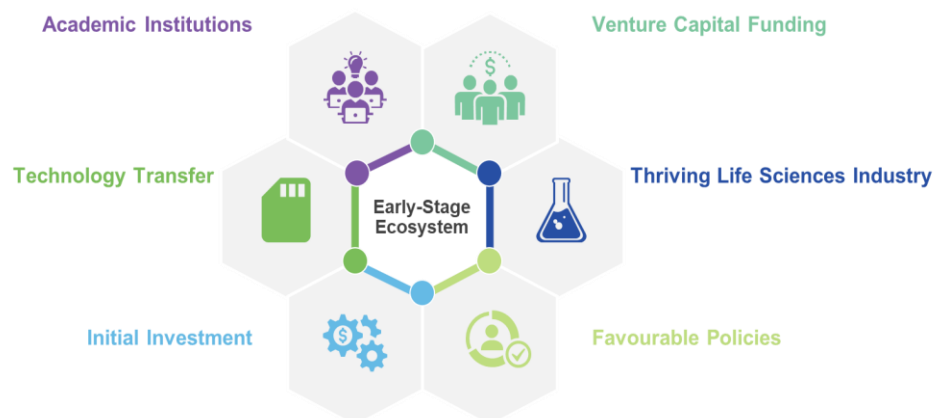
Europe is a leading hub of life sciences innovation. The continuous growth of European innovation, particularly in the life sciences, contributes to the development of EU strategic autonomy and stronger global competitiveness.¹ Investment in the life sciences has brought substantial benefits in terms of access to the latest scientific advancements, as well as economic benefits in terms of growth in expenditure and employment in the sector.² The pharmaceutical industry provides 800,000 direct jobs and an almost €110 billion trade surplus.³ Fostering a strong life sciences sector is critical as the pharmaceutical industry is one of the most R&D-intensive industries globally. However, Europe remains well behind the US in the level of innovative activity it attracts and is falling behind growth in other regions such as China. This is not a new trend, and it has long been acknowledged that a key driver of this trend is Europe's comparatively weaker culture around the basic-to-translational research stage and the ecosystem for early innovative activities (Figure 1), which is underpinned by venture capital (VC) investment.⁴

VC plays an important role in life sciences investment, enabling the risk-taking that is critical to the development of new medicines, vaccines and devices. Historically, VC-backed firms exhibit less under-pricing – the practice of listing an initial public offering at a price below its real value to increase demand – than their non-VC backed competitors.⁵ This implies that sponsors of VC-backed firms are confident in their valuation. VC investment has also exhibited higher growth than other private and public investors, with a 14.2% compound annual growth rate between 2011 and 2019.⁶ The importance of VC in Europe was recently brought to the forefront during the COVID-19 pandemic, during which German-based BioNTech, in partnership with Pfizer, developed the first fully approved COVID-19 vaccine. Prior to this successful development programme, BioNTech had raised some of the largest VC rounds in European biotech history (reaching \$1.4bn in seed and VC funding rounds by 2019), enabling it to develop its mRNA technology.⁷ Risk capital is particularly important during times of global economic instability; as the current global recession and cost of living

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- 1 European Commission (2020). Pharmaceutical strategy for Europe. Available at: https://health.ec.europa.eu/system/files/2021-02/pharma-strategy_report_en_0.pdf
 - 2 Copenhagen Economics (2018) Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe. Available at: <https://copenhageneconomics.com/wp-content/uploads/2021/12/copenhagen-economics-2018-study-on-the-economic-impact-of-spcs-pharmaceutical-incentives-and-rewards-in-europe.pdf> [Accessed November 2022]
 - 3 European Commission (2020) Pharmaceutical Strategy for Europe. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN> [Accessed November 2022]
 - 4 Karpa, W. and Grginović, A. (2020). Long-term perspective on venture capital investments in early stage life-science projects related to health care. *Economic Research-Ekonomska Istraživanja*. 33(1):2526-2540.
 - 5 Patzelt (2012). Portfolio Strategies of Life Science Venture Capital Firms in North America and Europe. Available at: <https://www.tandfonline.com/doi/abs/10.1080/08276331.2009.10593444>
 - 6 LEK (2022). The financial ecosystem of pharmaceutical R&D.
 - 7 <https://www.investeurope.eu/about-private-equity/private-equity-in-action/biontech/> [Accessed October 2022]

crisis continues to take its toll in Europe's economy, attracting VC investment into Europe will not only preserve the current benefits brought by the life sciences sector, but also encourage sustainable growth for future innovation.

Figure 1: Components of a healthy early-stage life sciences innovation ecosystem



The innovation policy environment in Europe is at a crossroads. Policymakers are currently undergoing extensive legislative discussions to review the incentives for innovation in Europe. Thus, immediate action and firm action is required to reevaluate the risk that erosion of incentives would have on further exacerbating the observed decline in Europe's performance relative to other regions, requiring full attention and swift action from policymakers. In this paper, we describe declining patterns of VC investment and early-stage innovation in Europe and review the risks and opportunities for strengthening the surrounding innovation ecosystem.

What is the current health of the early-stage life sciences ecosystem in Europe?

There are several industry-wide trends that indicate the declining health of European investment in the life sciences.

The ability of VCs to raise funds is lower in Europe: Total capital raised by healthcare-focused VC funds increased in Europe over the past 10 years, with a CAGR of 24% between 2012 and 2021. However, in absolute terms, **VCS in Europe raised a total capital of only \$6bn in 2021**; this lags substantially behind funds raised in the US (\$20bn) and in China (\$8.6bn).⁸ Although the average size of funds in Europe is comparable to the US, there are many fewer funds active in the sector. For example, between 2012 and 2022, there were 230 early-stage healthcare funds and 393 late-stage funds set up in the US. In Europe, there were only 67 early-stage and 108 late-stage funds respectively.⁹

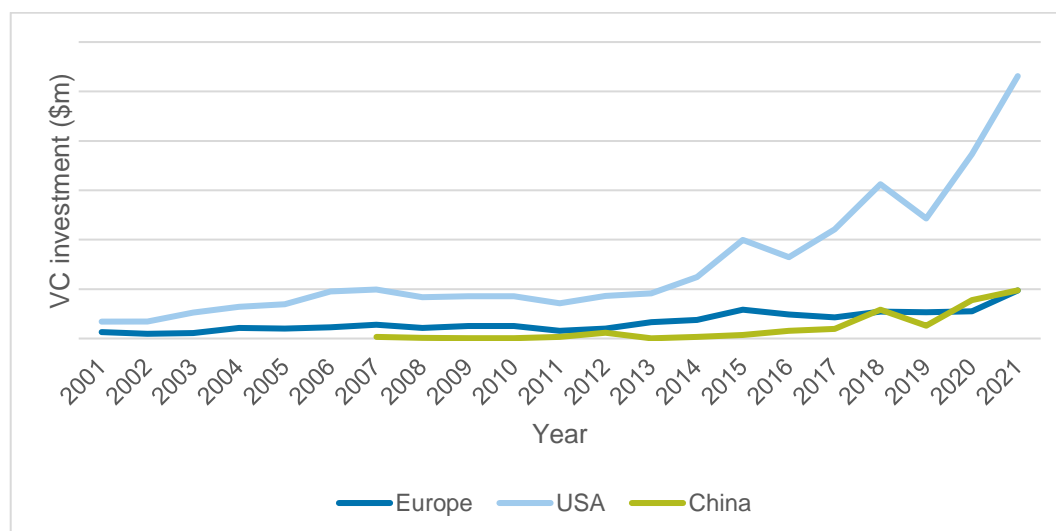
⁸ McKinsey (2022). "Uncharted Waters Can European Biotech Navigate Through Current Headwinds?". Available at: <https://go.biocentury.com/rs/731-BYF-828/images/BioEquity%20McKinsey%20Report%202022.pdf> [Accessed October 2022]

⁹ McKinsey (2022). "Uncharted Waters Can European Biotech Navigate Through Current Headwinds?". Available at: <https://go.biocentury.com/rs/731-BYF-828/images/BioEquity%20McKinsey%20Report%202022.pdf> [Accessed October 2022]

As a result, funding flows to European companies are weaker: In 2021, **biotech companies in Europe raised only \$7.9bn, one-quarter of the \$31bn raised by US companies.**¹⁰ In France and Germany, major hubs of biopharmaceutical investment activity, only \$427m and \$132m respectively were raised in VC funding from October 2021 through October 2022. When compared to the number of financing rounds driving this investment, this equates to an average of \$39m and \$22m per round in France and Germany respectively. Over the same time period, the average VC financing per round in China was \$67m – **2-3 times greater than that observed in major European markets.**¹¹

Looking over a longer timeframe, a decline can be observed in Europe’s international competitiveness in the strength of its VC ecosystem. In 2001, VC financing in Europe represented a 28% share of total VC financing across the US, Europe and China. **Twenty years later, this share has fallen to 13%.**¹² Whilst the US has consistently accounted for around 75% of this share, rapid maturation of the VC environment in China has led to Europe falling to third place.

Figure 2: Trends in life sciences VC investment over time



Source: CRA analysis of data obtained from EvaluatePharma [Accessed October 2022]

For many biopharma companies, raising capital during preclinical development and phase 1, the so-called “Death Valley”, poses a significant challenge (Figure 3). VC investors are

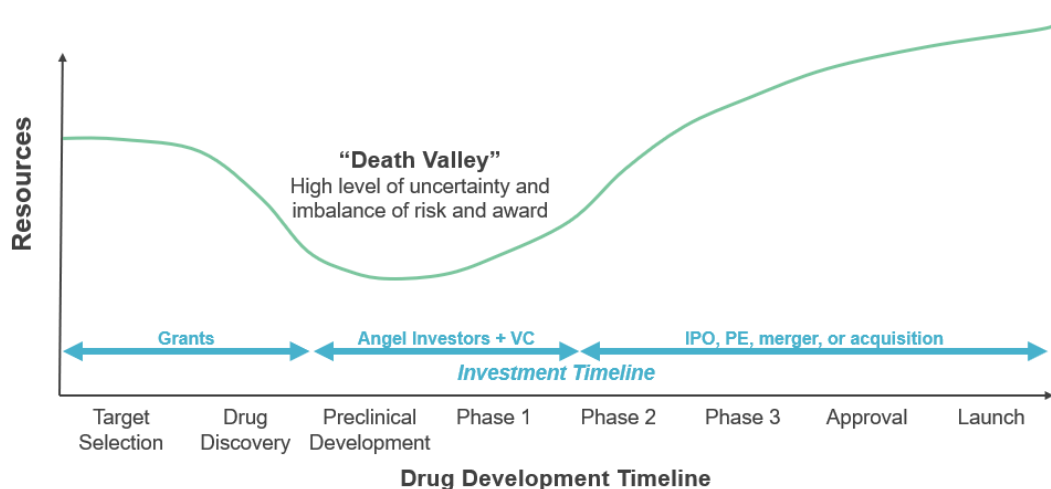
¹⁰ McKinsey (2022). “Uncharted Waters Can European Biotech Navigate Through Current Headwinds?”. Available at: <https://go.biocentury.com/rs/731-BYF-828/images/BioEquity%20McKinsey%20Report%202022.pdf> [Accessed October 2022]

¹¹ CRA analysis of data obtained from EvaluatePharma in October 2022. Analysis included total VC investment and number of financing rounds in major markets from October 2021 to October 2022.

¹² CRA analysis of data obtained from EvaluatePharma in October 2022. Analysis included total VC investment in the US, China and Europe from 2000 to present.

critical at this time because public research and development grants are limited to pilot proposals and further drug development is needed for large-scale company financing. **The “Death Valley” is often the turning point at which investors move from European markets to American markets**, derailing the capacity of European biopharma companies’ who intend to commercialise innovative products. Europe’s lengthy IPO process and longer approval times for new products make “Death Valley” investments less attractive compared to the US.¹³ An analysis of five EU VCs and five US VCs showed that US VCs invested more heavily in the preclinical stages, uplifting companies from the “Death Valley”.¹⁴ Meanwhile, EU VCs tended to invest during clinical stages when alternative forms of funding were already starting to become available.

Figure 3: Illustrative representation of the life sciences innovation journey



Source: Adapted from “The financial ecosystem of pharmaceutical R&D report” (LEK, 2022).¹⁵

It is also interesting to look across subsectors. Since 2007, EU companies developing medical devices and equipment have received the most funding from VCs (\$49bn), followed by biotech firms (\$41bn), and drug development (\$25bn).¹⁶ Medical devices and equipment often have fewer barriers to commercialisation, driven by the shorter length of time for products to enter the market.¹⁷ The decreased risk makes this market comparatively more attractive for VC investment. Thus, the depth and breadth of the “Death Valley” can vary across not only geographic regions, but also subsectors within Europe.

¹³ Karpa, W. and Grginović, A. (2020). Long-term perspective on venture capital investments in early stage life-science projects related to health care. *Economic Research-Ekonomska Istraživanja*. 33(1):2526-2540.

¹⁴ LEK (2022). The financial ecosystem of pharmaceutical R&D.

¹⁵ LEK (2022). The financial ecosystem of pharmaceutical R&D.

¹⁶ Karpa, W. and Grginović, A. (2020). Long-term perspective on venture capital investments in early stage life-science projects related to health care. *Economic Research-Ekonomska Istraživanja*. 33(1):2526-2540.

¹⁷ Fleming (2015). The Decline Of Venture Capital Investment In Early-Stage Life Sciences Poses A Challenge To Continued Innovation. *Health Affairs* 34(2):271-276

Limitations in the funding ecosystem result in less innovative activity occurring in Europe: Emerging biopharmaceutical companies (with less than \$500m in annual sales and less than \$200m in annual R&D spend) represent 65% of the total global drug development pipeline. **US-headquartered companies currently account for 46% of that share**, with European companies representing **only 20%**.¹⁸ In terms of magnitude of investment, the EU Industrial R&D Investment Scoreboard finds that **US biotechnology companies invested 11 times more** in R&D than EU companies in R&D in 2020.¹⁹

The strength of the biotech industry in the US is reflected in patent grant trends: almost **12,000 pharmaceutical and biotechnology patents were granted in the US in 2020, versus just over 6,000 in Europe** (of which around 2,600 were granted to US companies).²⁰ Similarly, US companies launched over twice as many new molecular entities between 2017 and 2021 than European companies (159 NMEs from US versus 72 from European companies).²¹

This contrasts with the trends observed in academic research, where Europe performs strongly. Over the last 15 years, **Europe has consistently performed well in terms of number of top-ranking academic institutions for life sciences**. Between 2016-2019, 10 of the top 25 universities ranked by proportion of publications ranking in the top 10% of their field were based in Europe.²² However, 14 of the remaining 15 countries on the list were American universities.²³ While European research quality is comparable to US in that regard, the publication output of European universities is much lower than US and China. Based on number of publications of universities in the biomedical and health sciences between 2016-2019, US and Chinese schools have 11 and 7 universities on the top 25 list respectively, while Europe only has three.²⁴

18 IQVIA Institute for Human Data Science (2022). "Emerging Biopharma's Contribution to Innovation". Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports/emerging-biopharma-contribution-to-innovation> [Accessed October 2022]

19 European Commission (2021). "The 2021 EU Industrial R&D Investment Scoreboard". Available at: <https://iri.jrc.ec.europa.eu/scoreboard/2021-eu-industrial-rd-investment-scoreboard> [Accessed October 2022]

20 CRA analysis of World Intellectual Property Organisation (WIPO) database. Total values stated represent patents originating from companies in Europe, China, the US and Japan.

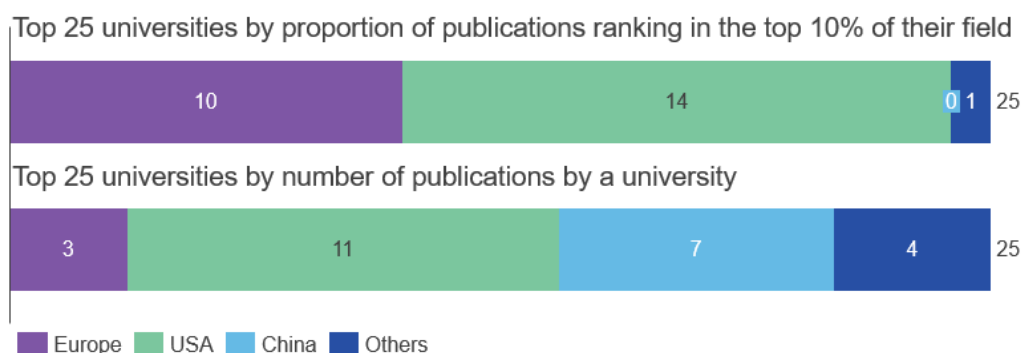
21 CRA analysis of SCRIP data on file.

22 CRA analysis of data obtained from CWTS Leiden Ranking. Available at: <https://www.leidenranking.com/> [Accessed November 2022]

23 CRA analysis of data obtained from CWTS Leiden Ranking. Available at: <https://www.leidenranking.com/> [Accessed November 2022]

24 CRA analysis of data obtained from CWTS Leiden Ranking. Available at: <https://www.leidenranking.com/> [Accessed November 2022]

Figure 4: Worldwide university rankings in the biomedical and health sciences 2016 – 2019



Source: Adapted from CWTS Leiden Ranking²⁵

Despite this, the overall quality and strength of European research provides a strong foundation for a healthy life sciences innovation ecosystem in Europe. In 2021, United Kingdom, Germany, Italy, and France were within the top 10 countries of the world with the most published pharmacology, toxicology and pharmaceuticals documents.²⁶ The research-based pharmaceutical industry consistently indicates that they aim to establish their own centres for research and drug development in proximity to existing world-leading academic centres of excellence.²⁷ The gap between **the strength of Europe's academic performance and the relatively weaker support for its biotech and pharmaceutical industries** has frequently been linked to the gap in VC funding.

What could reverse the downward trends in Europe's early-stage innovation ecosystem?

A number of theories have been put forward to explain the lower levels of VC investment in Europe, including the uncertainty of returns for biotechnology and pharmaceuticals in Europe, combined with market fragmentation and slower speed of access for new technologies.²⁸

This reflects the basic logic of VC decision-making: investors provide capital to a specific company only when the potential return on investment is sufficient compared to the

²⁵ CRA analysis of data obtained from CWTS Leiden Ranking. Available at: <https://www.leidenranking.com/> [Accessed November 2022]

²⁶ CRA analysis of data obtained from SJR World Ranking. Available at: <https://www.scimagojr.com/countryrank.php?area=3000&year=2021> [Accessed November 2022]

²⁷ Bramley-Harker, E. et al. (2007) Key Factors in Attracting Internationally Mobile Investments by the Research-Based Pharmaceutical Industry. London, UK: NERA Economic Consulting.

²⁸ Karpa, W. and Grginović, A. (2020). Long-term perspective on venture capital investments in early stage life-science projects related to health care. *Economic Research-Ekonomska Istraživanja*. 33(1):2526-2540.

investment risk.²⁹ With this equation in mind, there is opportunity for swift and decisive actions to retain and drive an increase innovation in Europe—such as by protecting intellectual property policies—and yield continued economic and health benefits through development commercialisation of new technologies.

1. Conserve and improve intellectual property policies

In Europe, there is a heritage of strong IP protection for life sciences innovation. A clear example is seen in the level of research into new orphan drugs, which benefit from ten years of post-launch market exclusivity under the current IP framework in Europe. It was found that over half (724) of the 142 orphan drug products developed between 2000-2017 would not have been economically viable without this framework.³⁰ In addition to IP protections acting as a signal for innovators to develop and launch innovative medicines in Europe, IP rights have also strongly benefited the European economy.³¹

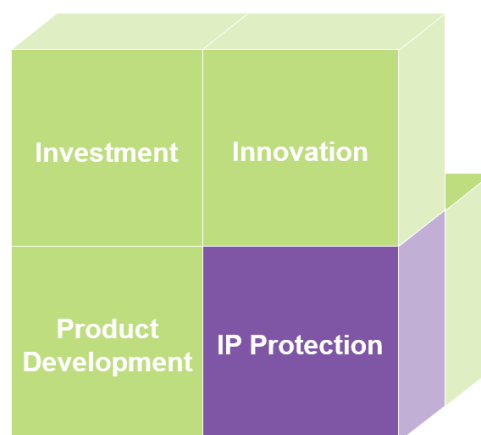
Intellectual property (IP) protections are critical for early-stage companies seeking to raise investments and investor interest. IP is a cornerstone for investment activities, propping up and supporting innovation, further investment, and product development (

Figure 5). Numerous studies have shown that VC firms are much more likely to fund companies with patentable innovations because of the associated risks and costs of life sciences R&D and the tangible nature of patents. All capital investments risk the possibility of failure. But in the case of IP, the investment is more insured because the patent itself could one day pay out, potentially with a different business model or a different company.

29 Karpa, W. and Grginović, A. (2020). Long-term perspective on venture capital investments in early stage life-science projects related to health care. *Economic Research-Ekonomska Istraživanja*. 33(1):2526-2540.

30 Dolon (2020) “Estimated impact of EU Orphan Regulation on incentives for innovation”. Available at: <https://dolon.com/rare-knowledge/publications/estimated-impact-of-eu-orphan-regulation-on-incentives-for-innovation> [Accessed November 2022]

31 EPO and EUIPO (2022) “Intellectual property rights intensive industries and economic performance in the European Union”. Available at: [https://documents.epo.org/projects/babylon/eponet.nsf/0/33DCE530D888258BC12588D7004539D1/\\$File/ipr-intensive_industries_and_economic_performance_in_the_EU_2022_en.pdf](https://documents.epo.org/projects/babylon/eponet.nsf/0/33DCE530D888258BC12588D7004539D1/$File/ipr-intensive_industries_and_economic_performance_in_the_EU_2022_en.pdf) [Accessed November 2022]

Figure 5: IP as a cornerstone of investment

To incentivise risk-taking, returns on investment arising from intellectual property are a key attribute. Stronger IP protection also synergistically boosts the value of VC; evidence has shown that the impact of VC investment on companies' level of innovative activity is greater when IP protection is stronger.³² Given that companies will typically first file for IP protection in their home country, the strength of the IP regime will affect the investment by VC companies.

However, there is now a risk that the life sciences IP framework in Europe may be weakened. COVID-19 has intensified the debate surrounding IP and access to medicines, despite many economies do not even have basic IP systems in place. For example, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides exempts least-developed countries from implementing IP rules, and yet access needs for essential medicines remain high.^{33,34} The venture capital and life sciences industries share the European Commission's goal of supporting broader patient access to innovative medicine in Europe. And yet, evidence indicates that the costs of weakening of IP protection are substantial and would impact global availability of new medicines.³⁵ A joint study by Copenhagen Economics and the European Commission found that in Europe, longer effective IP protection of pharmaceuticals stimulates R&D into new medicinal products. This is also linked to the location of sales: the length of the protection

³² Guo, D. and Jiang, K. (2022) Venture capital investment, intellectual property rights protection and firm innovation: evidence from China. *Entrepreneurship & Regional Development*. 34(5-6):434-470.

³³ World Intellectual Property Organization (WIPO) Magazine (2017). "Perspectives on access to medicines and IP rights". Available at: https://www.wipo.int/wipo_magazine/en/2017/06/article_0002.html [Accessed November 2022]

³⁴ Gyimah, F. T., & Dako-Gyeke, P. (2019). Perspectives on TB patients' care and support: a qualitative study conducted in Accra Metropolis, Ghana. *Globalization and health*, 15(1), 1-9.

³⁵ FTI Consulting (2022) "The role of intellectual property in the biopharmaceutical sector". Available at: <https://www.ifpma.org/resource-centre/the-role-of-intellectual-property-in-the-biopharmaceutical-sector/> [Accessed November 2022]

period provided in EU markets where companies sell their products has a positive impact on their domestic spend on pharmaceutical R&D. However, the study also found that the average effective protection period in Europe has decreased by two years over the last two decades.³⁶

The US is the world-leader in life sciences innovation and, perhaps unsurprisingly, the world-leader in the strength of its IP framework.³⁷ The value of the US's IP system was most recently put into perspective during the COVID-19 pandemic, following which the US Chamber of Commerce have emphasised that “without strong and clear IP rights, it is unlikely that any of those products and technologies—or the underlying science—that have been so essential to keep societies functioning and fighting the COVID-19 pandemic, would exist”. In China, where weaker IP protections have historically acted as a deterrent to investment from multinational pharmaceutical companies, the strengthening of IP protection over recent years has had an observable impact on improving the level of innovative activity, the outputs of this innovative activity, and the number of innovative medicines reaching Chinese patients.³⁸ A number of weaknesses remain in China's IP policies, such as high patent invalidation rates, restrictive patentability criteria and lack of effective implementation of patent term extensions. This imposes a limitation on the amount of innovative activity occurring in China, particularly by multinational companies. In Europe, where IP protections currently remain strong, the risks of a backwards trend are substantial.

Policy recommendation 1 – Conserve strong IP protection in Europe

Protecting intellectual property to increase risk capital investments: The European Commission should continue to uphold current IP and incentive schemes to encourage life science innovators to continue to undertake high-risk investments into the development of life-changing and life-saving technologies for patients.

2. Recognise the value of innovative medicines

Related to the influence IP protections have on venture capitalists' willingness to take on financial risk in life sciences R&D, there is also a consideration as to whether the innovative technology under development will be appropriately valued once launched, thereby bringing a viable return on their investment.

This may, in part, explain why the strength and level of activity of the early-stage innovation ecosystem in the US exceeds that in Europe. Academics have linked the strong

³⁶ Copenhagen Economics (2018) “Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe”. Available at: <https://copenhageneconomics.com/wp-content/uploads/2021/12/copenhagen-economics-2018-study-on-the-economic-impact-of-spcs-pharmaceutical-incentives-and-rewards-in-europe.pdf> [Accessed November 2022]

³⁷ U.S. Chamber of Commerce's Global Innovation Policy Center (2022) “2022 International IP Index: Competition for Tomorrow”. Available at: <https://www.uschamber.com/intellectual-property/2022-international-ip-index> [Accessed November 2022]

³⁸ Ding, J et al. (2011) From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. *Journal of Technology Management & Innovation*. 6(2).

performance of the life sciences sector in the US in attracting VC investment to the access environment. For example, a recent analysis found that the US Food and Drug Administration (FDA) approved 95% of new oncology therapies faster than the European Medicines Agency (EMA), with a median delay in Europe of 241 days.³⁹ Across the EU and European Economic Area (EEA), the average time to reimbursement for innovative treatments is 511 days following EMA approval.⁴⁰ Not only does this mean that European patients face delays in access to new innovative therapies, but it makes it less attractive for VC investors to seek opportunities that focus on the Europe market relative to the US.⁴¹ Life sciences companies choosing to locate in the US is a clear signal of the importance of the US marketplace, reassuring VC investors regarding the focus on successful commercialisation.

Furthermore, the value placed on investments that reach the market by Member State payers often does not consider the nature of risk capital allocation. Despite successful implementation of new optimisation strategies, there is still a greater than 90% failure rate for drug candidates that have made it to preclinical stages.⁴² Thus, the amount of invested capital for a single innovative medicine that reaches commercialisation is not representative of the vast amounts of sunk costs in life sciences R&D. The expected batting averages for early-stage investments by VCs are roughly “1/3, 1/3, 1/3”—a third at a loss, a third returning to principal, and the remaining third delivering returns.⁴³ This strategy stipulates that the remaining third that delivers returns must surpass the investments made at a loss. Therefore, basing valuation of innovative medicines on the costs associated with bringing that product to market does not account for the upstream dynamics of VC investment and of failed R&D projects.

Policy recommendation 2 – Recognise the value of innovation

Fairly valuing life science technologies to create a viable market: The EMA and Member State payers should value risk-taking initiatives in the life sciences by providing fair assessments and expanding access of new products and technologies, encouraging the continued growth of a healthy pipeline.

39 Lythgoe, M. P. et al. (2022) Cancer Therapy Approval Timings, Review Speed, and Publication of Pivotal Registration Trials in the US and Europe, 2010-2019. *JAMA Netw Open*. 5(6):e2216183.

40 EFPIA (2022) “Shortening the WAIT - Patient Access to Medicines in Europe”. Available at: <https://www.efpia.eu/news-events/the-efpia-view/efpia-news/shortening-the-wait-patient-access-to-medicines-in-europe/> [Accessed November 2022]

41 Karpa, W. and Grginović, A. (2020). Long-term perspective on venture capital investments in early stage life-science projects related to health care. *Economic Research-Ekonomska Istraživanja*. 33(1):2526-2540.

42 Sun, D., Gao, W., Hu, H., & Zhou, S. (2022). Why 90% of clinical drug development fails and how to improve it?. *Acta Pharmaceutica Sinica B*.

43 Industry Ventures (2017). “The Venture Capital Risk and Return Matrix”. Available at: <https://www.industryventures.com/insight/the-venture-capital-risk-and-return-matrix/> [Accessed November 2022]

3. Enhance support for the early-stage innovation ecosystem

Another element that has been attributed to the US's dominance in life sciences innovation is its robust mechanisms to connect basic research with entrepreneurship and commercialisation. This goes back to the Bayh-Dole Act, introduced in 1980, conferring IP rights to universities and non-profit research institutions for innovations created with the support of federal funding. This had the impact of elevating the role of US universities in the life sciences innovation ecosystem and catalysed a wave of innovative activity. Importantly, in the first two decades of the Act's operation, over 2,200 companies were created to develop and commercialise the IP generated within the universities.⁴⁴ Furthermore, the US VC infrastructure is much more favourable for earlier successful divestments, attracting VC fundraising. Other regions lag behind with respect to exit stage, the use of convertible securities, the replacement of former management and deal syndication, overall contributing to faster divestment processes for US VC-backed investments.⁴⁵

In China, there has also been a significant policy focus on encouraging the growth of basic research and translation of that research into new technologies that can be brought to patients. Although VC financing in China has historically been weak, various government programmes have aimed to support academic research and growth of emerging companies. For example, the Major New Drug Creation Program, initiated in 2008, provided financial support of close to USD \$1 billion to support companies in developing new drugs with independent IP rights.⁴⁶

In Europe, there is strong academic infrastructure for producing high-quality life science basic research. However, it has often been acknowledged that Europe lags behind in the available support for translating this research into new technologies and promoting commercialisation of these technologies. Recognising that European research institutions were not yet as effective as their US equivalents in commercialising research results, the European Commission launched the 'Capacity-Building in Technology Transfer' in 2013 which catalysed a wave of best practice sharing between technology transfer offices across European institutions.⁴⁷ There are strong examples of a healthy research-to-commercialisation ecosystem within Europe, for example Ablynx, which was established as a spin-out of the Vlaams Instituut voor Biotechnologie (VIB) and the Free University of Brussels (VUB). Ablynx received seed funding of €2 million, and 16 years after its creation

44 Rabitschek, J. H. and Latker, N. J. (2005) Reasonable Pricing – A New Twist for March-in Rights Under the Bayh-Dole Act. *Santa Clara High Technology Law Journal*. 22(1):149.

45 Karpa, W. and Grginović, A. (2020). Long-term perspective on venture capital investments in early stage life-science projects related to health care. *Economic Research-Ekonomska Istraživanja*. 33(1):2526-2540.

46 Ding, J. et al. (2011) From Imitation to Innovation: A Study of China's Drug R&D and Relevant National Policies. *Journal of Technology Management & Innovation*. 6(2).

47 ALLEA (2019) "The Need for Intellectual Property Rights Strategies at Academic Institutions". Available at: https://allea.org/wp-content/uploads/2019/11/The_Need_for_IPR_Strategies_at_Academic_Institutions_ALLEA_2019-1.pdf [Accessed November 2022]

was acquired by Sanofi for \$4.8 billion.⁴⁸ However, it has often been acknowledged that Europe still lags behind other regions in the level of available support for translating academic research into new technologies and promoting commercialisation of these technologies.

Policy recommendation 3 – Enhance support for early-stage innovation

Supporting an integrated ecosystem to enable commercialisation and access: The European Commission should take advantage of opportunities during implementation of the Pharmaceutical Strategy (its first in over 50 years since the first pharmaceutical legislation was implemented in the EU) to foster new approaches and modern attitudes to advance the translation of academic outputs into innovative medical technologies that can reach European patients.

Summary

With the ongoing revision of the EU's pharmaceutical legislation, there is now an opportunity to renew Europe's position as a leader in global biopharmaceutical research and entrepreneurial commercialisation and to ensure that European patients have access to the latest advancements in life sciences. This will likely require a focus on proactive policymaking that considers the innovation ecosystem holistically. There are three key policy themes that will be pivotal in guiding these discussions (Figure 6) to avoid the risk that the degree of innovative life sciences activity in Europe declines.

The Life Sciences Acceleration Alliance (LSAA) represent the shared voice of investment, scientific and corporate leaders dedicated to strengthening life sciences research and development in Europe. LSAA are committed to working with policymakers to explore new opportunities for improving the early-stage life sciences ecosystem in Europe and ensuring innovative treatments are available to European patients.

48 ALLEA (2019) "The Need for Intellectual Property Rights Strategies at Academic Institutions". Available at: https://allea.org/wp-content/uploads/2019/11/The_Need_for_IPR_Strategies_at_Academic_Institutions_ALLEA_2019-1.pdf [Accessed November 2022]

Figure 6: Summary of policy factors to encourage early-stage innovation

