HEALTHWORLD 2022

Building an Innovative Biotechnology Ecosystem: Incentives to Support and Attract Investments

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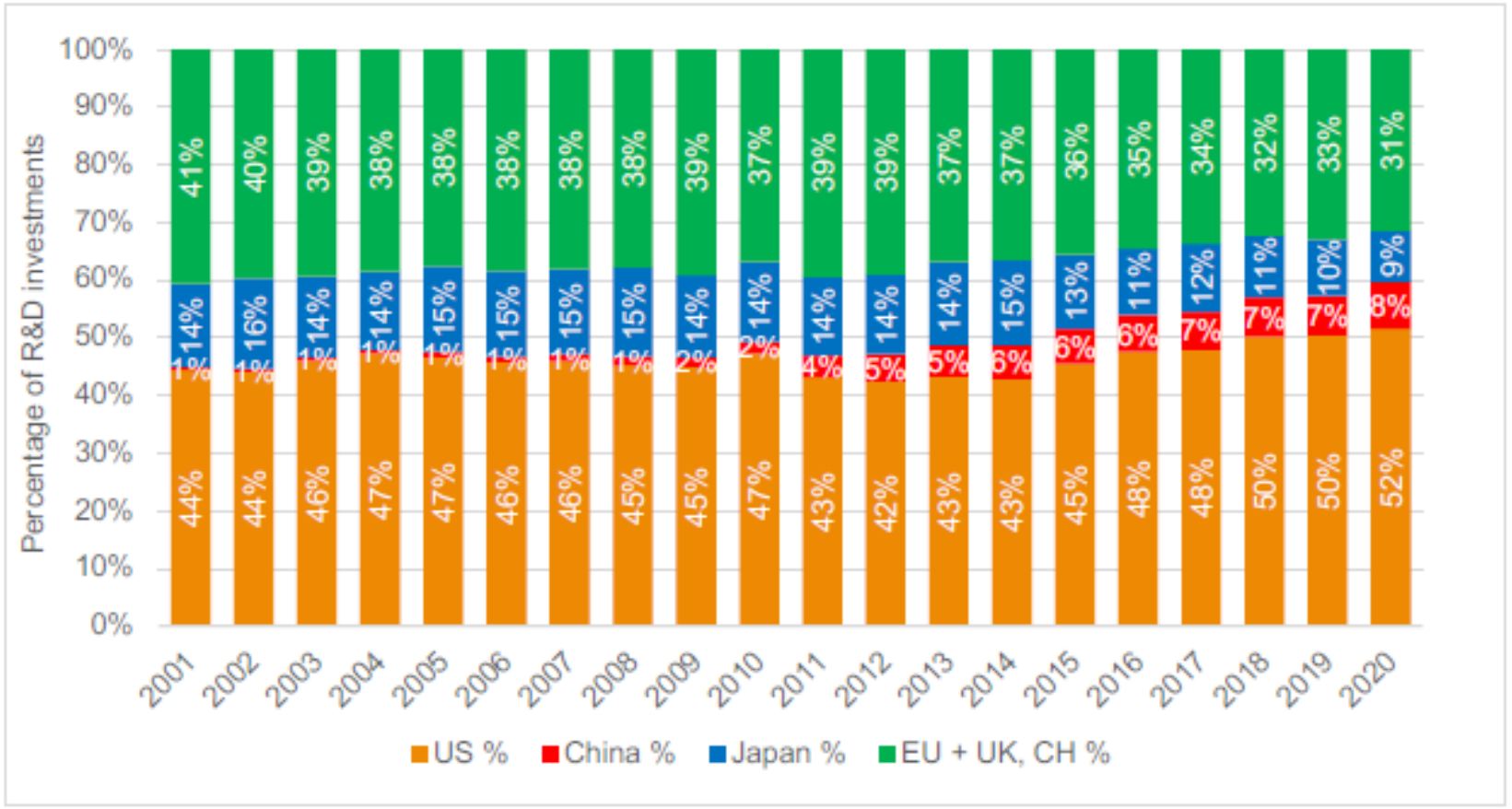
Biopharmaceutical R&D a very competitive area

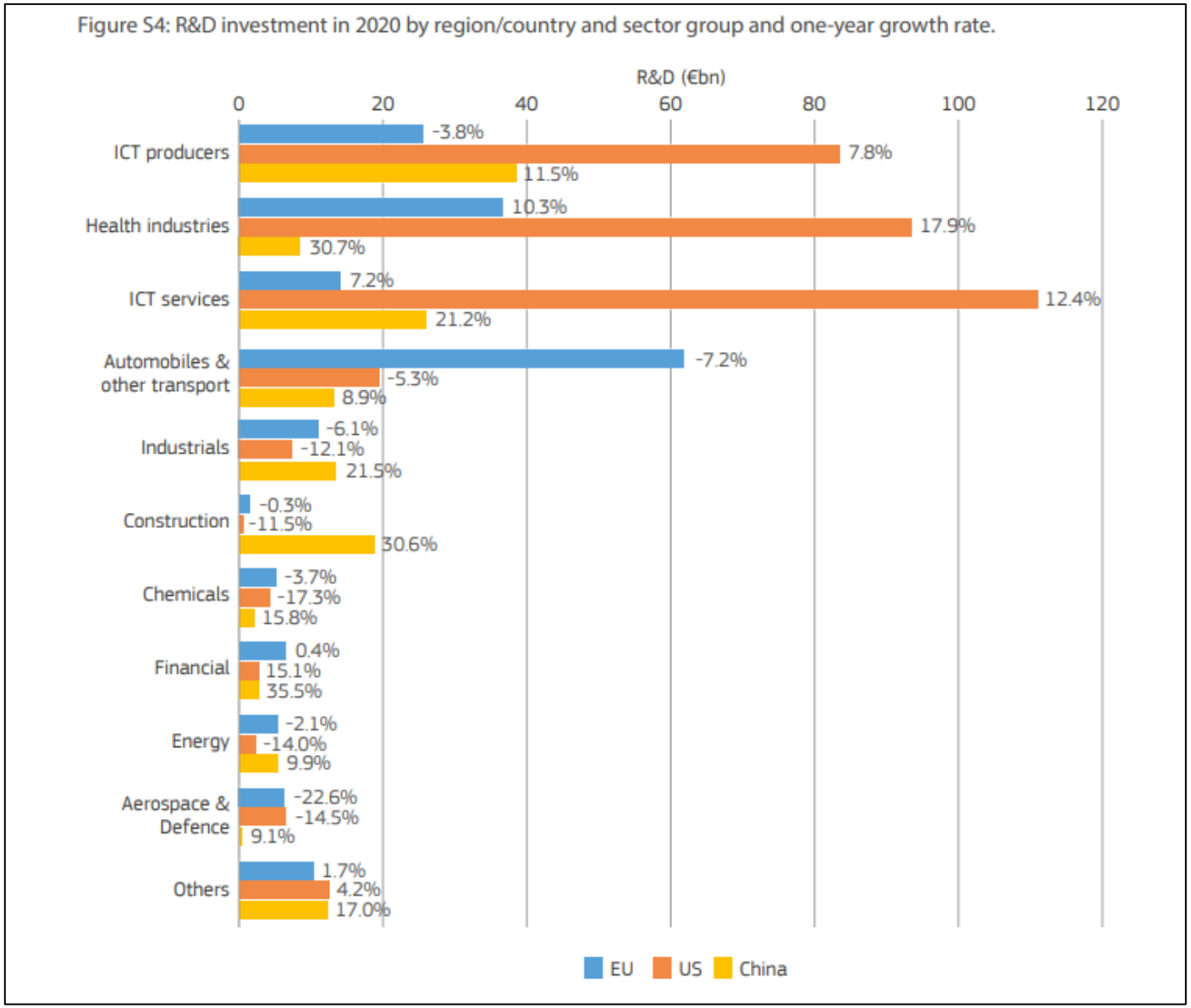
Figure 2: The US and China represent a growing share of biopharmaceutical R&D investments made in major markets

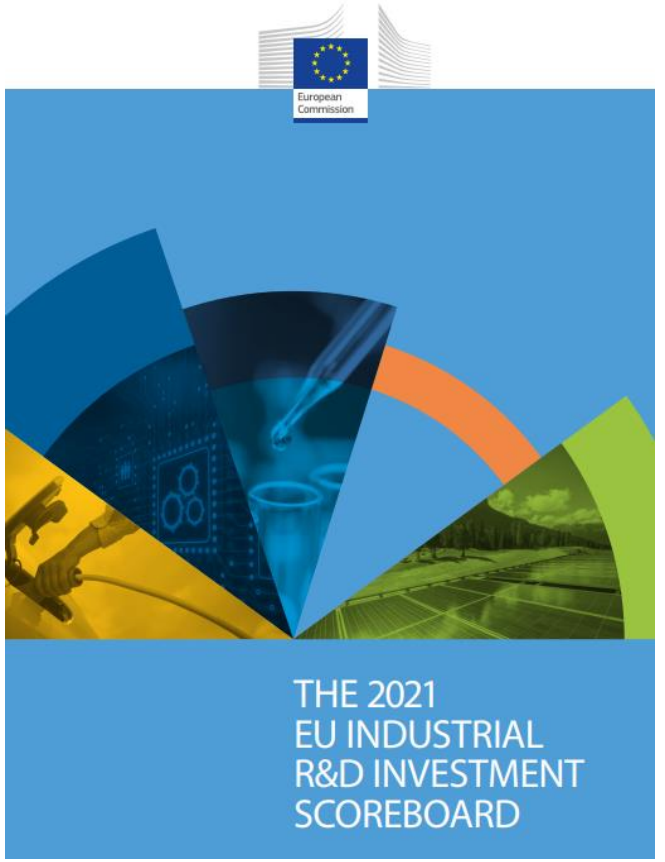


As Europe re-evaluates its pharmaceutical policy framework the challenge for the next decade(s) is **not if medical innovation will happen, but where it will happen**

Charles River Associates Report, Sep 2022

Investments from Health industries key for EU

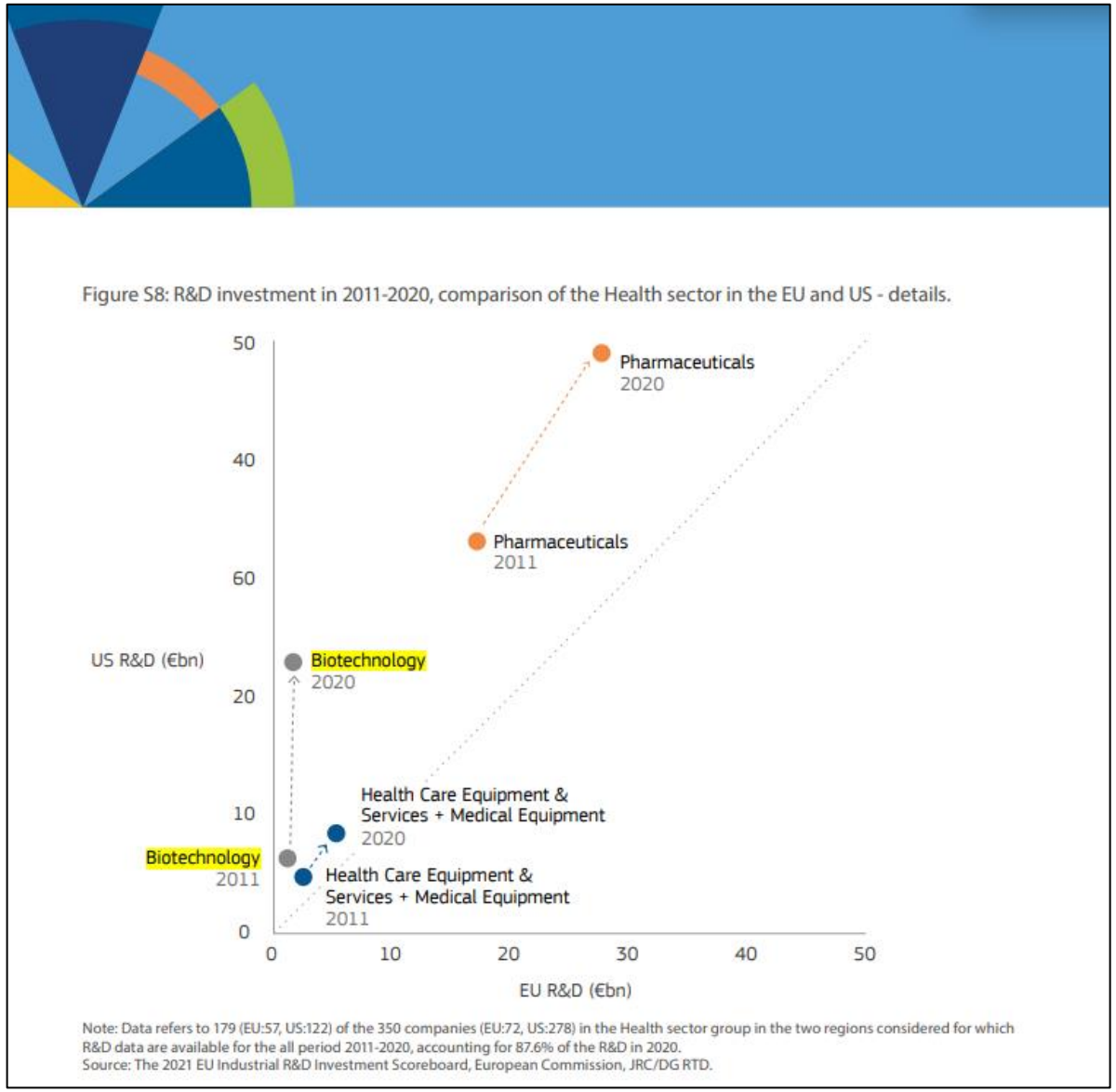




Need for investments in Biotechnology a priority for EU

2021 EU Industrial R&D Investment Scoreboard:

Among key challenges "to rebuild **a strong Health sector with increasing focus on biotechnology"**



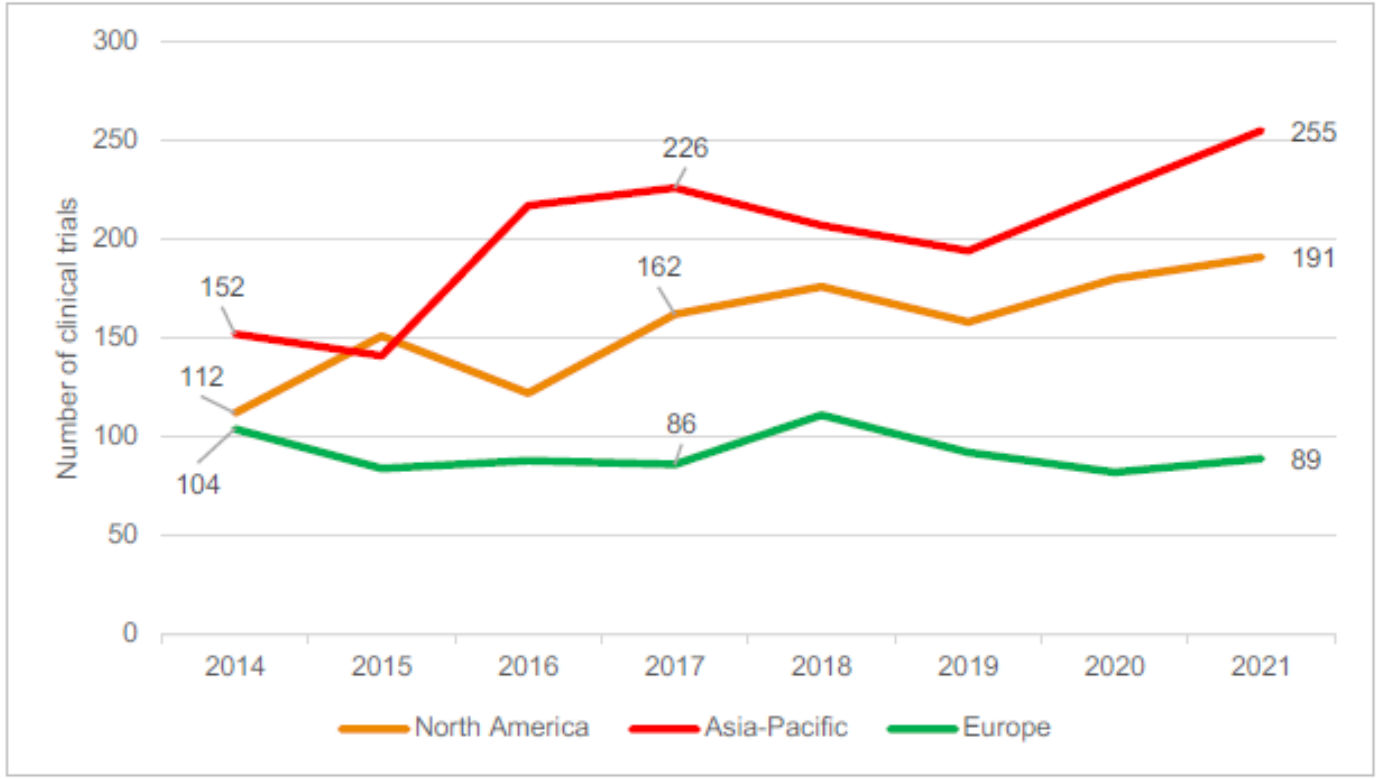
In biotechnology, the R&D growth of the US companies was remarkably higher; in 2020 they outperformed their EU counterparts in terms of R&D investment (11 times larger) and number of companies (166 vs 20)

Significant gap on ATMP research for EU vs China and US

…the pattern of clinical trial locations varies for different types of technology, focusing on the trends for advanced therapy medicinal products (ATMPs) as an example of a new therapeutic solution. The number of trials conducted in the **US and Asia-Pacific region grew by 70% and 67%,** respectively, between 2014 and 2021. Meanwhile, the **number of ATMP trials in Europe appears lower and stagnant** despite overall growth of the global clinical development pipeline.

…whilst Europe continues to be an attractive location for pharmaceutical companies to conduct clinical trials **for more traditional medicinal technologies, this is not the case for all new therapeutic solutions**, including but not limited to ATMPs

Figure 5: The location of Advanced Therapy Medicinal Products (ATMP) clinical trials differ from the overall geographic pattern of biopharma clinical trial activity



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Lessons learned / drivers for China growth on R&D

- China has dramatically improved its position in terms of scientific infrastructure, over the last fifteen years. US universities awarded twice as many doctorates in STEM fields (18,289) as Chinese universities (9,038) in 2000. **In 2019, Chinese universities produced 49,498 PhDs in STEM fields, while US universities produced 33,759**

(focus on education and scientific infrastructure)

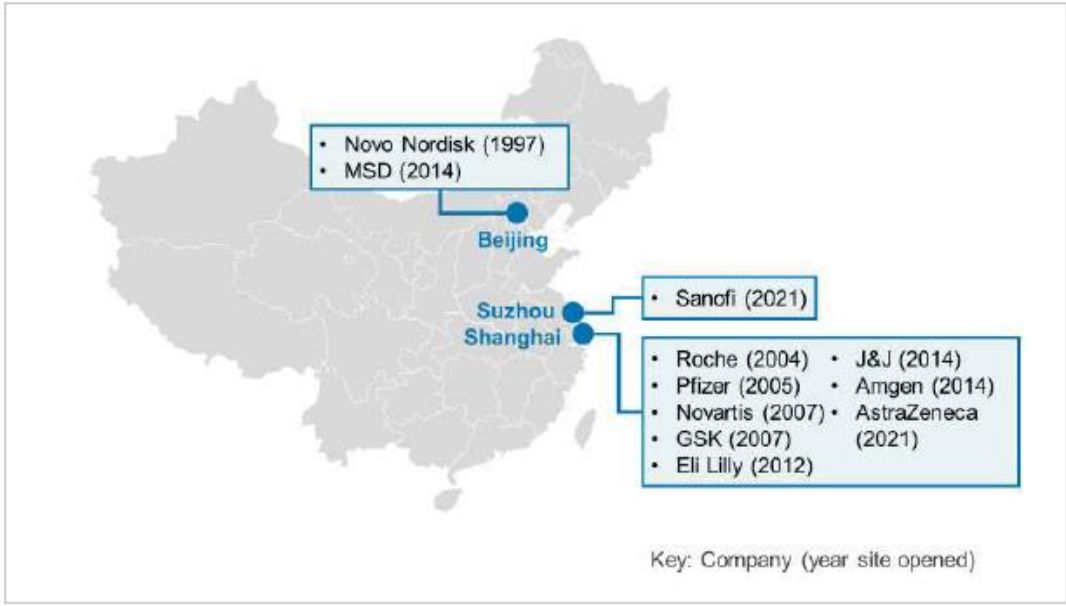
- This is clearly, partly due to the growth of the Chinese economy and the growing **importance of the Chinese pharmaceutical market**. China's pharmaceutical market has been constantly growing in recent years. It is estimated to reach $161.8 billion by 2023 and take a 30% share of the global market

(importance of pharma market)

- **China is strengthening its Intellectual Property (IP) laws** in order to strengthen and support the pharmaceutical industry. Many of China's laws governing patents, trademarks, copyrights, and others, have recently been amended

(importance of strong IP framework)

Figure 11: The majority of large multinational pharmaceutical companies now have an R&D centre in China



Sources: Company websites and press releases[74]

Key Drivers for R&D pharma investment

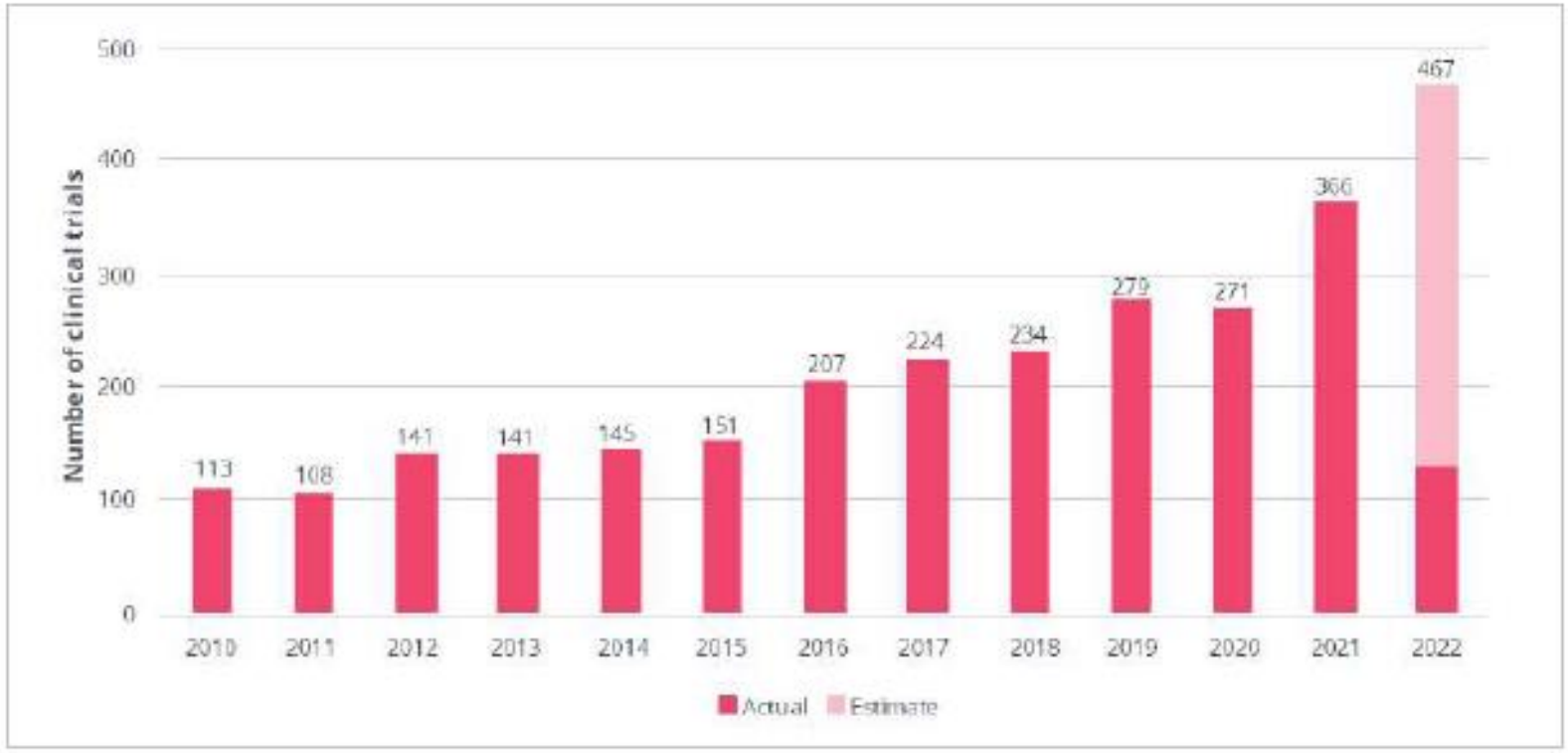
- Studies indicate that **quality of the scientific ecosystem** takes precedence over cost for research hub location decisions.
- co-location with world-leading academic **centers of excellence, research scientists** and **skilled research staff** are key drivers of location
- **Ability for these centres of academic excellence to collaborate with industry** and translate academic research into successful candidates for the clinic is also key.
- **Cost is consistently ranked as one of the least important factors** in research location
- **Digital infrastructure:** To modernize processes and keep pace with the digital evolution of the industry, particularly post-COVID-19, pharmaceutical companies look towards countries with a supportive digital ecosystem (opportunity for Greece- trend to become a digital technology hub in the region)

Enhanced role of digital technology

Growing adoption of new technologies like artificial intelligence, big data analytics, blockchain, clinical trial payments, and patient engagement solutions.

COVID-19 pandemic has improved the **adoption of virtual clinical trials**. There have been a number of interesting initiatives relating to the use of these technologies in clinical trials in Europe, for example, the Innovative Medicines Initiative (IMI)'s 'Trials@Home' project, which aims to conduct a pan-EU pilot on innovative, technology-led decentralized clinical trial designs.

Number of clinical trials employing digital technologies or virtual interactions



Sources: Trialtrove® (Pharma Intelligence), March 2022. Trialtrove consolidates data from over 58,000 distinct trial intelligence sources.

The role of local pharma market in attracting R&D pharma investment

Much of the literature recognized that there is also strategic commercial consideration in determining the location of clinical trial programs:

- In markets which the **new medicine is seen as a considerable asset**.
- A major commercial market may be an attractive location for a clinical trial due to the advantages associated with **familiarizing clinical key opinion leaders with a new product**
- The Helsinki Declaration revision of 2013 stipulates **patients participating in a clinical trial must retain post-trial access**, which is now factored into decisions on where to initiate clinical trials
- **A restrictive pricing and access environment for innovative therapies** can stagnate the standard of care in a market, as physicians may be treating patients with older, low-cost therapies rather than newer high-cost therapies. This could prevent a company from conducting a clinical trial in such a market in the future because **the outdated clinical guidelines used may not reflect what a comparator arm needs** to be in an innovative clinical trial

How are all these translated for Greece?

Drivers	Thoughts / trends
Centers of excellence and skilled research staff	Initiatives like the recent "Hellenic Institute of Human Genomics" in FORTH
Academic excellence to collaborate with industry	Initiatives like the "Hellenic Institute of Advanced Studies" can show the way
Supportive digital ecosystem	Tech companies and Pfizer CDI shaping digital ecosystem
Market which the new medicine is seen as a considerable asset	Yes for patients, researchers, HCP, but mostly as threat for decision makers
Where patients participating in a clinical trial retain post-trial access	RRF Innovation Fund can play a key role
Where pricing and access environment pro innovative therapies	A real HTA/Nego process should be based on value
Where industry has resources available for biotechnology R&D	Limited room due to high paybacks

RRF: "This disguised borrowing mechanism has the additional effect of **depriving national economy of significant resources for private investments"**