UNIVERSITÀ DEGLI STUDI DI MILANO

IEO Istituto Europeo di Oncologia

# The future of European research and its impact on cancer inequalities

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# Disclosures

- Board Member : Ellipses
- Consultant: Lilly, Novartis, Seattle Genetics, Roche-Genentech, Pfizer, Gilead, Menarini, Exact Sciences
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- Stock ownership: None

# Outline

- Global clinical trials ecosystem
- Impact of EU regulations on clinical research
- Clinical research and value for national health systems
- Need to increase efficiency in clinical trials activation pathway to reduce inequalities

# Background

- Inequalities in socioeconomic and geographic factors influence referral and enrolment to clinical trials globally.

- This has implications for equity of access and generalisability of trial results internationally and warrants further study.

# EEA phase split

**Number of EEA commercial clinical trial starts by phase (2013, 2018-2023; Phase 1-4)**

| Phase | 2013 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|---|---|---|---|---|---|---|---|
| Phase 1 | 235 | 157 | 209 | 199 | 222 | 200 | 132 |
| Phase 2 | 401 | 524 | 482 | 510 | 601 | 501 | 373 |
| Phase 3 | 472 | 439 | 411 | 396 | 489 | 442 | 327 |
| Phase 4 | 133 | 133 | 150 | 172 | 172 | 139 | 88 |
| **Total** | 1241 | 1253 | 1252 | 1277 | 1484 | 1282 | 920 |

# Commercial trials by country

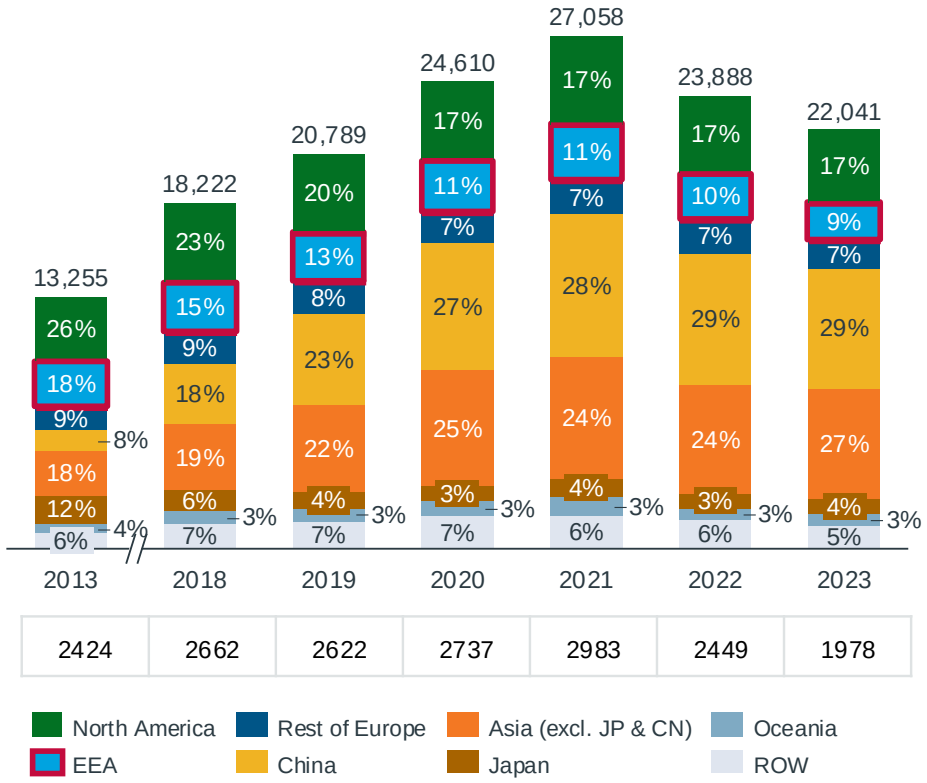
***Number of clinical trial starts in top 10 countries globally and 2018– 2023 trend***

| Country | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2018-2023 CAGR |
|---|---|---|---|---|---|---|---|
| US | 1850 | 1794 | 1920 | 2228 | 2051 | **1719** | -2% |
| China | 727 | 956 | 1103 | 1492 | 1440 | **1412** | 14% |
| Russia | 592 | 634 | 610 | 596 | 557 | **561** | -1% |
| Japan | 472 | 506 | 489 | 663 | 493 | **546** | 3% |
| Spain | 491 | 544 | 548 | 688 | 607 | **485** | 0% |
| South Korea | 491 | 483 | 497 | 590 | 489 | **444** | -2% |
| Australia | 436 | 446 | 530 | 607 | 485 | **444** | 0% |
| UK | 566 | 528 | 495 | 630 | 566 | **437** | -5% |
| Canada | 473 | 466 | 433 | 583 | 474 | **429** | -2% |
| Germany | 618 | 600 | 580 | 665 | 623 | **417** | -8% |
| ***EEA**** | 1253 | 1252 | 1277 | 1484 | 1282 | **920** | -6% |

*Limited data coverage on Lichtenstein, Malta and Iceland

# The global clinical trial ecosystem is evolving; Europe's share is declining, while Asia is emerging as a major location for new clinical trial starts

**Number of global clinical trial starts by region (2013, 2018-2023; Phase 1-4)**




Global trial starts grew year-on-year between 2013 and 2021. During this period, there has been a major evolution in geographical trial distribution. Post-2021, whilst absolute clinical trial starts have fallen back to pre-pandemic levels, relative geographic shares have remained broadly stable

- In 2013, North America, EEA, and the rest of Europe accounted for 53% of global clinical trial starts. As of 2023, this figure stood at 33%.
- During this period, Asia, and China in particular, has significantly grown its share of global clinical trial starts, with China moving from 8% of trial starts in 2013, to 29% in 2023

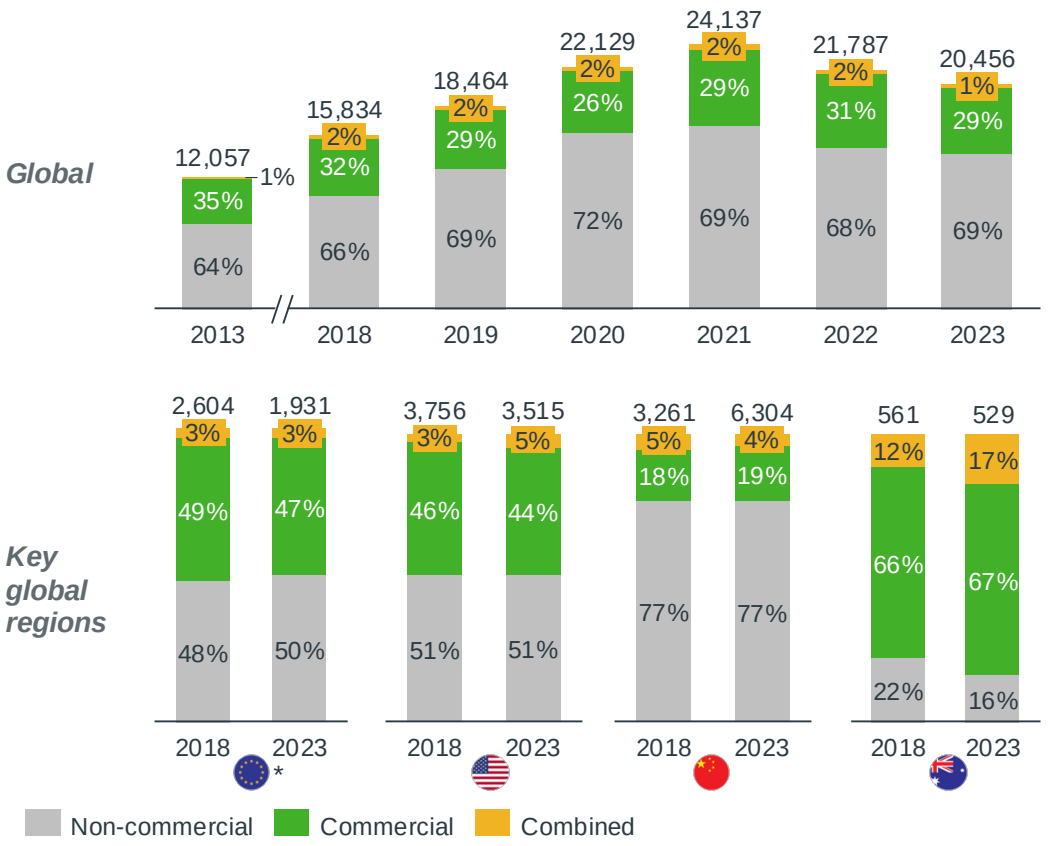
China's growth may be attributed to various factors, including National Reimbursement Drug List (NRDL) expansion, a large pool of treatment naïve patients, and an increase in China-headquartered companies sponsoring trials, especially in Phase I, oncology, and cell and gene therapy. However, China's clinical trial activity growth is primarily driven by trials conducted solely within China (single country trials).

Meanwhile, the relatively stable number of EEA trials, amidst the rising global trial numbers, has led to the EEA's share of trials decreasing from 18% in 2013, to 15% in 2018, to 9% in 2023.

Note: Medical device trials and terminated/suspended trials were excluded. ROW includes LATAM, Middle East & Africa. Rest of Europe includes Russia. Trial with sites in multiple regions were counted once for each region.
Abbreviations: CAGR: compound annual growth rate, ROW: rest of world
Source: Clinical Trial Repository (Access Date: April 30th, 2024). IQVIA Expertise; IQVIA Institute

# The EEA has a broadly even split of commercial and non-commercial trials; both the EEA and US have seen a slight fall in commercial share since 2018

**Number of global clinical trial starts by sponsor type (2013, 2018-2023; Phase 1-4)**




Global clinical trials are predominantly sponsored by non-commercial stakeholders, with a relatively stable 70% -30% split over time, however there is significant regional variation.

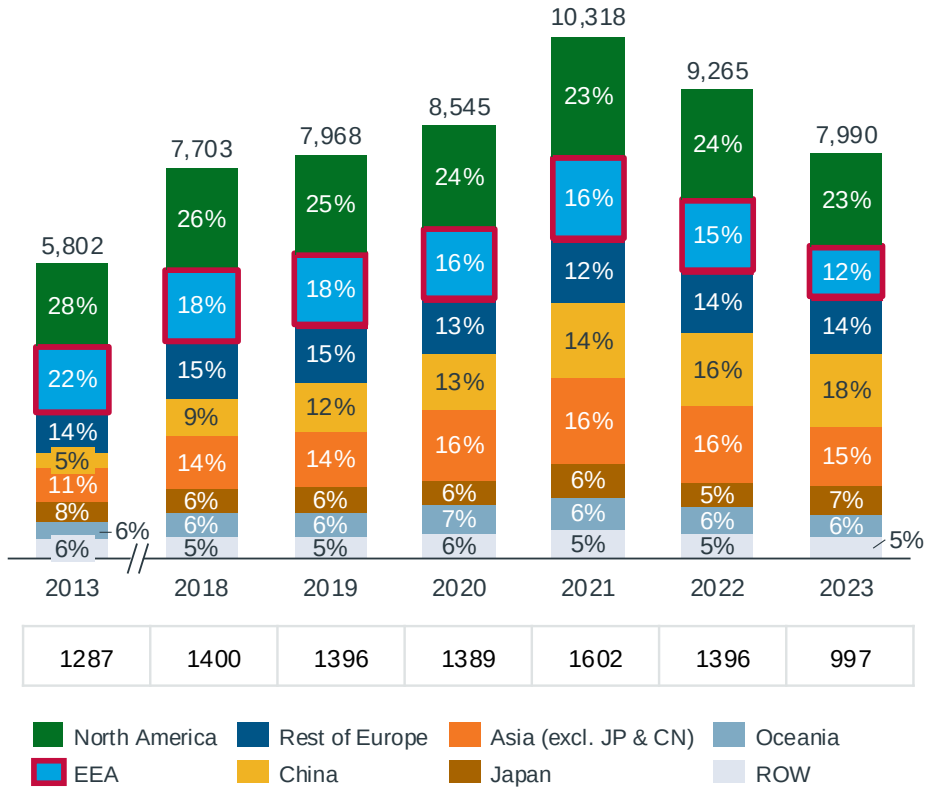
- Within EEA and the US, the split of commercial vs. non-commercial trials is broadly even, however, there has been a 2-percentage point decline in commercial share since 2018 in both regions
- In China, over three quarters (77%) of the trials have a non-commercial [illegible] country trials, which are more likely to have a non-commercial sponsor
- In Australia, the opposite is true, where commercial trials constitute the majority. Industry reports suggest Australia is viewed as an attractive location for clinical trials, due to its medical & research expertise, dedicated infrastructure (particularly for Ph1 trials) and a streamlined regulatory and ethics approval process, and benefitting from geographic proximity to Asia

[illegible] 60%. European level commercial value (49%, 47%) counts multi-country EEA trials once, to allow comparison to comparator countries

Note: Combined sponsors: any trials with more than one type of sponsor (non-commercial, EBPs, mid pharma, large pharma); Medical device trials and terminated/suspended trials were excluded.
Source: Clinical Trial Repository (Access Date: April 30th 2024); MTPConnect. (2021). Australia's Clinical Trials Sector; IQVIA Expertise; IQVIA Institute

# EEA clinical trial starts were broadly stable in 2018-2022, and fell in 2023; this represents a fall in global share from 18% to 12% between 2018-2023

**Number of global commercial clinical trial starts by region (2013, 2018-2023; Phase 1-4)**




Note: Medical device trials and terminated/suspended trials were excluded. ROW includes LATAM, Middle East & Africa. Rest of Europe includes Russia. Trial with sites in multiple regions were counted once for each region.
Abbreviations: CAGR: compound annual growth rate, ROW: rest of world
Source: Clinical Trial Repository (Access Date: April 30th, 2024).

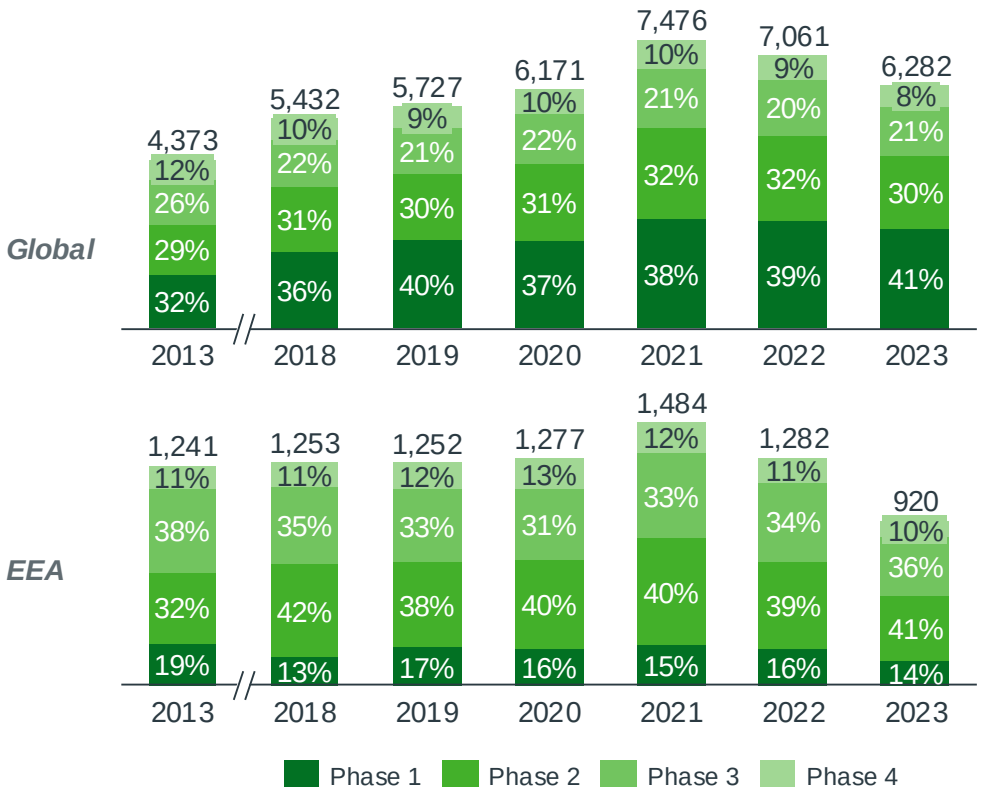
**Top countries holding the highest number of commercial trials (2018-2023, Phase 1-4)**

| Country | 2018 | 2023 | CAGR |
|---|---|---|---|
| US | 1850 | **1719** | -2% |
| China | 727 | **1412** | 14% |
| Japan | 472 | **546** | 3% |
| Spain | 491 | **485** | 0% |
| South Korea | 491 | **444** | -2% |
| Australia | 436 | **444** | 0% |
| UK | 566 | **437** | -5% |
| Canada | 473 | **429** | -2% |
| Germany | 618 | **417** | -8% |

- The number of commercial clinical trial starts has increased by 38% over the last decade. Meanwhile, EEA's share of total commercial trials declined from 22% (2013), to 18% (2018), to 12% (2023)
- This performance has been driven by two key trends:
  - A flat-lining or decline in absolute trial starts, in many EEA countries
  - Significant growth in absolute trial starts in China, Japan, and other non-Western markets
- The US remains the largest single country for commercial clinical trial starts; with China rapidly closing the gap
- However, underlying these trends is an increase in the number of single country commercial trials in the US and China. Europe's fall in global share is significantly less pronounced when considering *multi-country* commercial trials only (see slide 16),

# EEA has a relatively high share of Phase 2 & 3 trials, which are important for patients; however, the decline in Phase 1, may limit future trial opportunities

**Number of global commercial clinical trial starts by phase (2013, 2018-2023; Phase 1-4)**




Global commercial growth has mainly been fueled by the rise in Phase 1 trials, which have seen a 4.5% growth (2018-2023 CAGR), higher compared to overall 4% growth of commercial clinical trials

In the EEA, the trend contrasts with the global picture, as most trials are in Phase 2 and 3, with a slight decrease in Phase 1 trials in 2023.

Whilst Phase 2 and 3 trials are particularly important for patients, a reduction in Phase 1 trials may lead to a reduced 'pipeline' of future trials, particularly in areas where specialized knowledge or equipment is required to deliver the investigational therapy, which may be established during Phase 1.

Analysis from IQVIA Institute suggests EEA has seen relative or absolute decline in most categories of trials, such as:

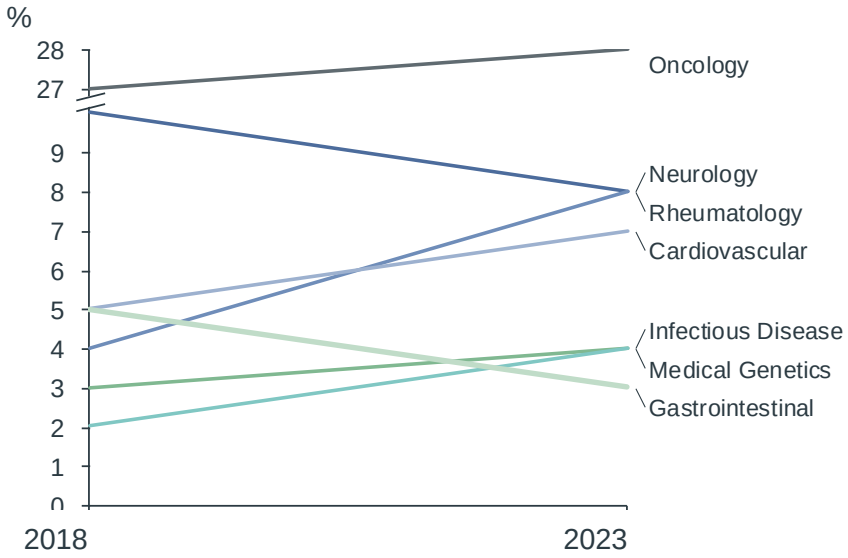
- Phase 1 oncology and Phase 2/3 oncology
- Cell and Gene Therapy (CaGT)
- Biosimilars
- Rare diseases

Conversely, China has grown its global share, particularly through an increase in Phase 1 oncology, Phase 2/3 oncology, and cell and gene therapy trials

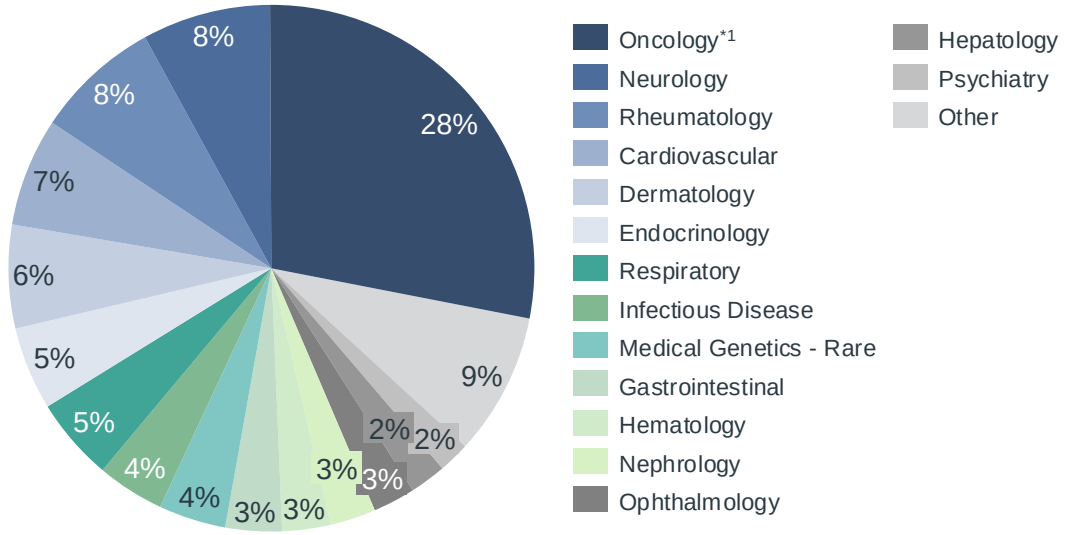
Note: Phase 2 includes Phase 1/2, 2a & 2b trials, Phase 3 includes Phase 2/3. Medical device trials and terminated/suspended trials were excluded. Trial with sites in multiple EEA countries were counted once within EEA
Abbreviations: CAGR: compound annual growth rate
Source: Clinical Trial Repository (Access Date: April 30th 2024)

# Within EEA commercial trials, oncology remains the dominant therapeutic area; cardiovascular and rheumatology increased share, whilst neurology fell

**Share of commercial clinical trials by therapy area, within EEA (Phase 1-4, 2018-2023)**




**Share of commercial clinical trials by therapy area (Phase 1-4, EEA, 2023)**

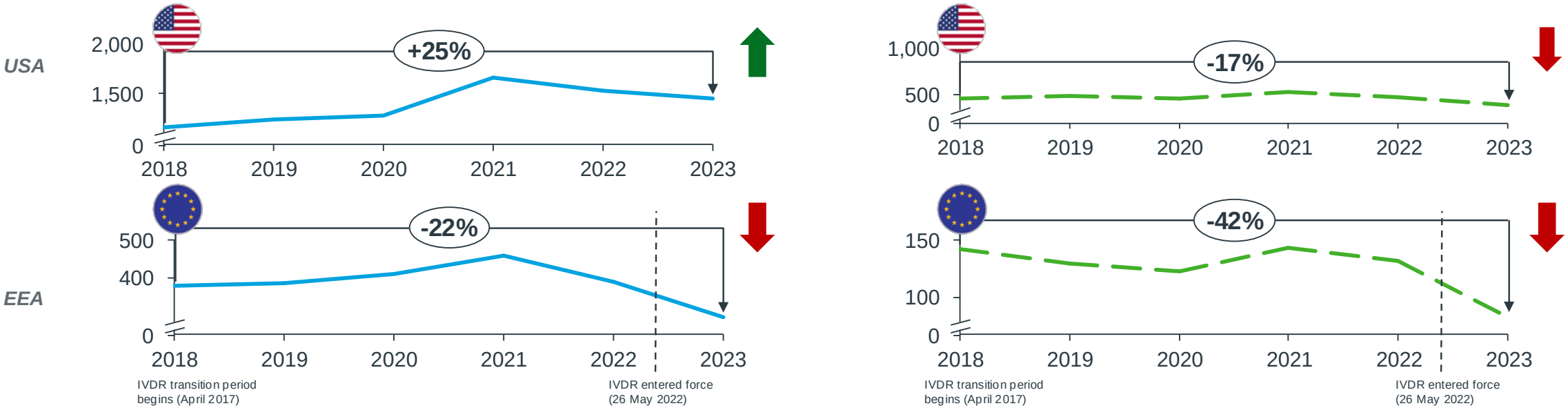



Oncology remains the largest TA for EEA trials, accounting for more than 25% of new trial starts. Neurology is the second largest TA, though has seen a fall in activity in recent years. These trends broadly reflect the global TA picture. Infectious-disease trials are slightly lower than global average, and rheumatology higher than the global average. Recent EEA share growth is seen in cardiovascular, rheumatology and infectious diseases, at the expense of neurology and gastrointestinal trials.

Note: Phase 1-4 commercial trials considered. Medical device trials and terminated/suspended trials were excluded. Trial with multiple therapy areas are counted once per therapy area.
*1 Oncology includes haematology-oncology treatments; *2 The rank is based on the absolute number and the share of the given year. Abbreviations: TA: therapy area, CV: cardiovascular
Source: Clinical Trial Repository (Access Date: April 30th 2024)

# In oncology and neurology, the EEA has experienced contrasting trends to US; IVD regulation, among other factors, may have influenced trial decisions

**Total number of commercial oncology and neurology trial starts in 2018-2023; Phase 1-4**



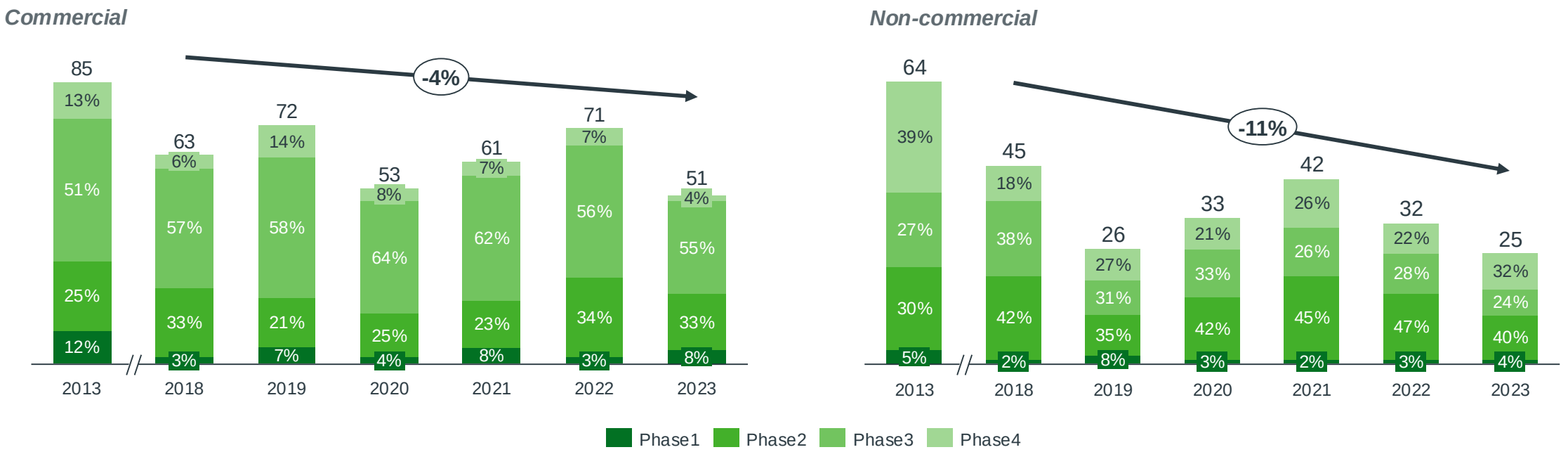

In the EEA, despite the 'Beating Cancer Plan', oncology trial starts have fallen consistently since 2021, and are now below 2018 levels. This contrasts to the US, which saw an increase in 2021, and levels have been maintained. The fall in EEA may be driven by several factors. In the EU, the in-vitro diagnostic regulation (IVDR) transition period began in 2017, which introduced more stringent requirements for the designation of Notified Bodies, with increased control and monitoring by the national competent authorities and EU Commission. This regulation affects clinical trials using in-vitro diagnostics (e.g., for patient selection, allocation and monitoring), which is particularly relevant to oncology trials, though can affect many TAs.

A fall in new starts in neurology in the EEA may be driven by a combination of local policy factors (including IVDR), but also broader industry trends (reduced biopharma R&D investment in 2022, recent R&D challenges in neurology).

Note: Phase 1-4 commercial trials considered. Medical device trials and terminated/suspended trials were excluded. Trial with sites in multiple EEA countries were counted once within EEA.
Abbreviations: TA: therapy area, IVDR: In Vitro Diagnostic Regulation
Source: Clinical Trial Repository (Access Date: April 30th 2024)| EU Beating Cancer Plan

# Within the EEA, there has been a decline in both commercial and non-commercial paediatric sponsored trials, suggesting systemic challenges

**Number of EEA paediatric clinical trial starts by phase (2013, 2018-2023, Phase 1-4)**




In the EEA, both commercial and non-commercial paediatric disease clinical trials declined over last 6 years, with commercial trials falling by 4% and non-commercial trials seeing a steeper decline (11% reduction). A decline in paediatric research has been highlighted by Evelina London Children's Hospital, which showed:

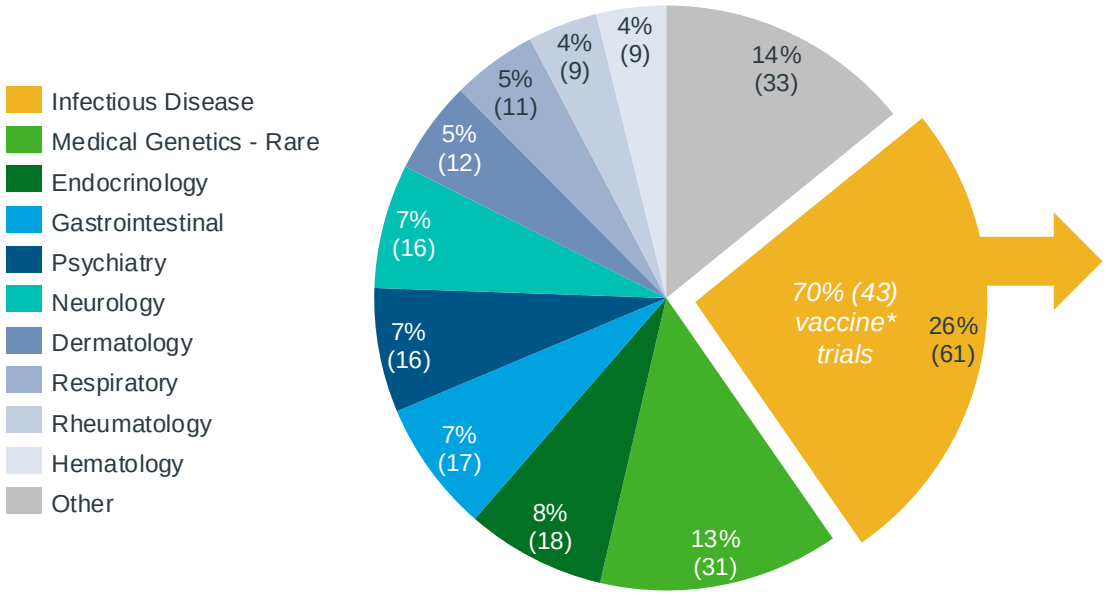
- 30% reduction in research outputs for child health compared to pre-pandemic level, with the number of paediatric clinical trials published falling each year at an increasing rate.
- Similar trends in Europe and US, across all childhood conditions except respiratory diseases, with Europe and the UK having the greatest reductions globally

Note: Phase 2 includes Phase 1/2, 2a & 2b trials, Phase 3 includes Phase 2/3. Medical device trials and terminated/suspended trials were excluded.
Source: Clinical Trial Repository (Access Date: April 30th 2024)

# Most commercial paediatric trials are focused on infectious diseases and rare diseases; ‘paediatric-only’ oncology trials are relatively limited

Paediatrics Spotlight

**Global commercial paediatric trial starts in 2023 (Phases 1-4, top 10 TAs, n=214)**




***Commercial paediatric infectious disease vaccine trial starts in 2023****

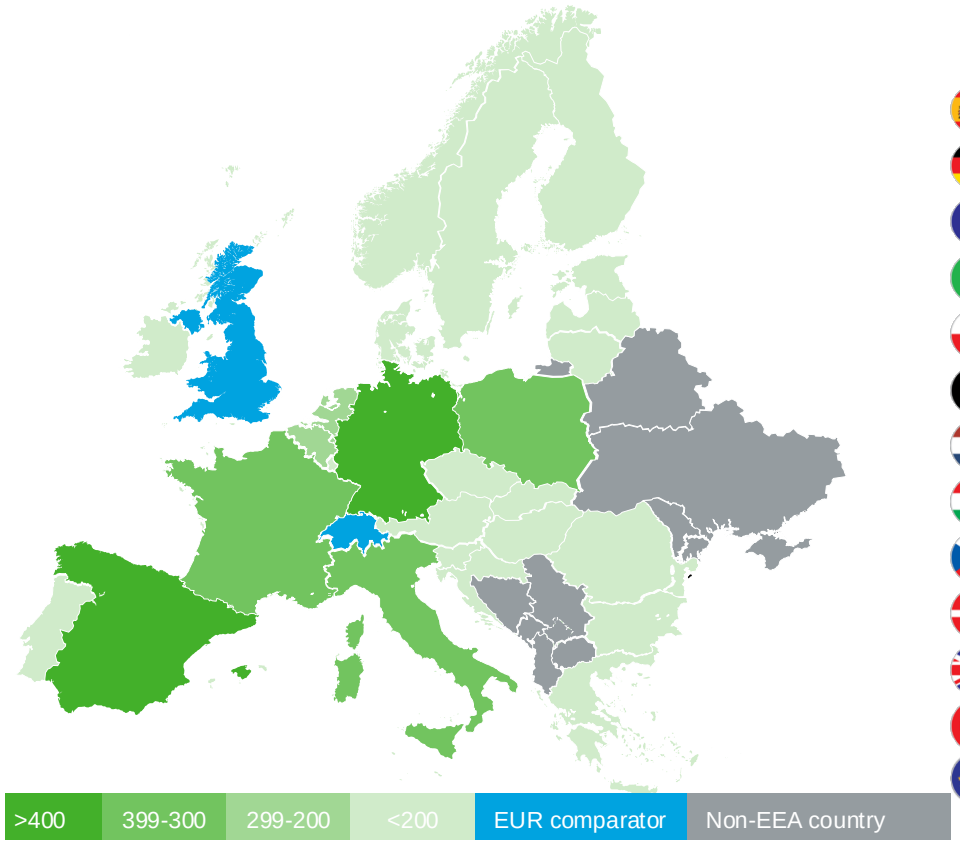
| Country | #trials | %share |
|---|---|---|
| CN | 13 | 23% |
| JP | 7 | 12% |
| US | 6 | 11% |
| ZA | 3 | 5% |
| IN | 3 | 5% |
| PH | 2 | 4% |
| PL | 2 | 4% |
| ES | 2 | 4% |
| ID | 2 | 4% |

| | | |
|---|---|---|
| North America | South America | Europe |
| Asia | Oceania | Africa |

Note: Medical device trials and terminated/suspended trials were excluded. Trial with multiple therapy areas are counted once per therapy area.
*Trial with sites in multiple countries were counted once per country. Abbreviations: TA: therapy area
Source: Clinical Trial Repository (Access Date: April 30th 2024)

# Across all commercial trials in the EEA, there is variation in country-level performance; Spain recently overtook Germany in clinical trial starts

**Number of EEA commercial clinical trial starts in 2018 and 2023, top 10 countries**




| | 2018 | 2023 | CAGR |
|---|---|---|---|
| | 491 | **485** | -0.2% |
| | 618 | **417** | -7.6% |
| | 439 | **389** | -2.4% |
| | 378 | **343** | -1.9% |
| | 332 | **300** | -2.0% |
| | 305 | **218** | -6.5% |
| | 282 | **210** | -5.7% |
| | 205 | **161** | -4.7% |
| | 199 | **147** | -5.9% |
| | 156 | **118** | -5.4% |
| | 573 | **439** | -5.0% |
| | 120 | **107** | -2.3% |
| | 1253 | **920** | -6.0% |

All but three EEA countries* saw a fall in the absolute number of trial starts in 2023 vs 2018

Spain, Germany, France and Italy remain the largest countries for clinical trial activity within the EEA

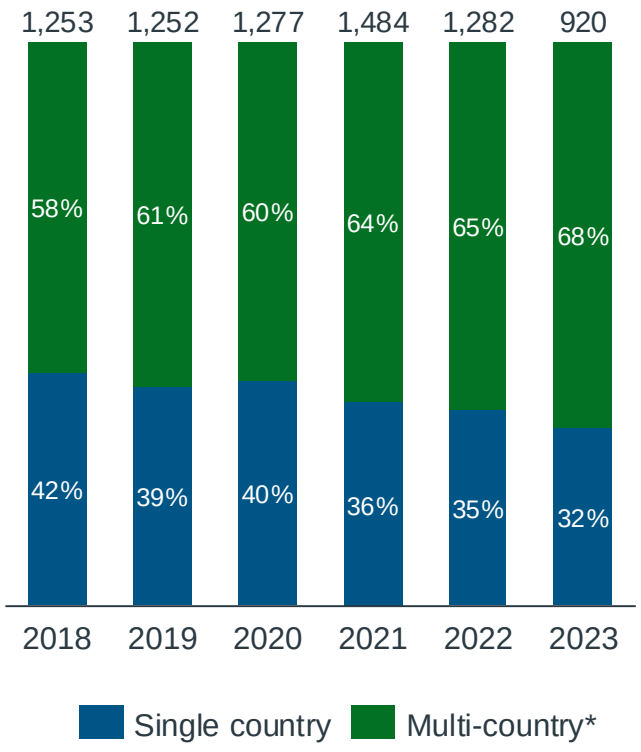
- In Spain, over the past decade, investment in clinical trials has risen at an average annual rate of 5.3%, climbing from EUR 470 million in 2011 to nearly EUR 800 million in 2021. Factors attracting investment may include quality of Spain's healthcare system, successful implementation of new European legislation on clinical trials, and an effective commercial/ non-commercial clinical trial collaboration model
- The recent decline in German trials is attributed, in part, to extensive negotiation times between companies and research institutions, and highly stringent data protection laws, which may slow patient recruitment efforts

*Slovakia, Portugal and Greece

Note: Limited data coverage on Lichtenstein, Malta and Iceland; Phase 1-4 commercial trials considered. Medical device trials and terminated/suspended trials were excluded. *[1] 2018-2023 CAGR
Source: Clinical Trial Repository (Access Date: April 30th 2024); Farmaindustria, TaylorWessing

# An increasing number of EEA trials are delivered in multiple countries, contrasting a recent global shift towards more single-country trials

**Share of single- vs. multi-country* commercial trials started in EEA in 2018-2023**




**Top 10 EEA countries holding the highest number of single country commercial trials**

| Country | #trials | %share |
|---|---|---|
| France | 58 | 20% |
| Germany | 46 | 16% |
| Spain | 35 | 12% |
| Netherlands | 28 | 10% |
| Italy | 26 | 9% |
| Belgium | 20 | 7% |
| Sweden | 14 | 5% |
| Denmark | 13 | 4% |
| Poland | 10 | 3% |
| Norway | 8 | 3% |

Northern Europe
Central and Eastern Europe
Southern Europe
Western Europe

In EEA, more than two-thirds of trials are 'multi-country' (defined as trial sites in more than one country) with this trend increasing since 2018

This finding, alongside a declining absolute number of trials, may suggest that

- There is an increasing capability to conduct trials in a range of EEA countries
- Multiple EEA countries are required to reach the desired patient population

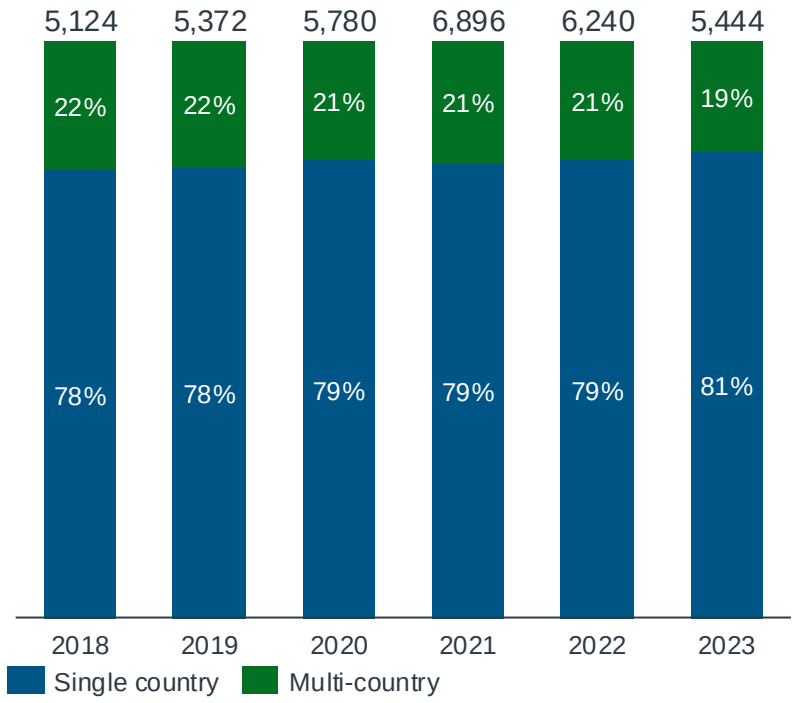
However, other commercial and operational factors may be driving this trend

France, Germany and Spain remain the EEA countries with the greatest number of single-country trials, likely due to population size, healthcare infrastructure and research centers

Note: Phase 1-4 commercial trials considered. Medical device trials and terminated/suspended trials were excluded. Trial with sites in multiple EEA countries were counted once within EEA. *Multi-country trials defined here as involving at least one EEA country, and not excluding those with a non-EEA country as part of the trial. NB/ A similar trend is seen when restricting multi-country trials to EEA only
Source: Clinical Trial Repository (Access Date: April 30th 2024)

# Globally, US, China, India and Japan are driving the rise in single-country trials

**Single- vs. multi-country commercial trials, global, Phases 1-4, in 2018-2023**



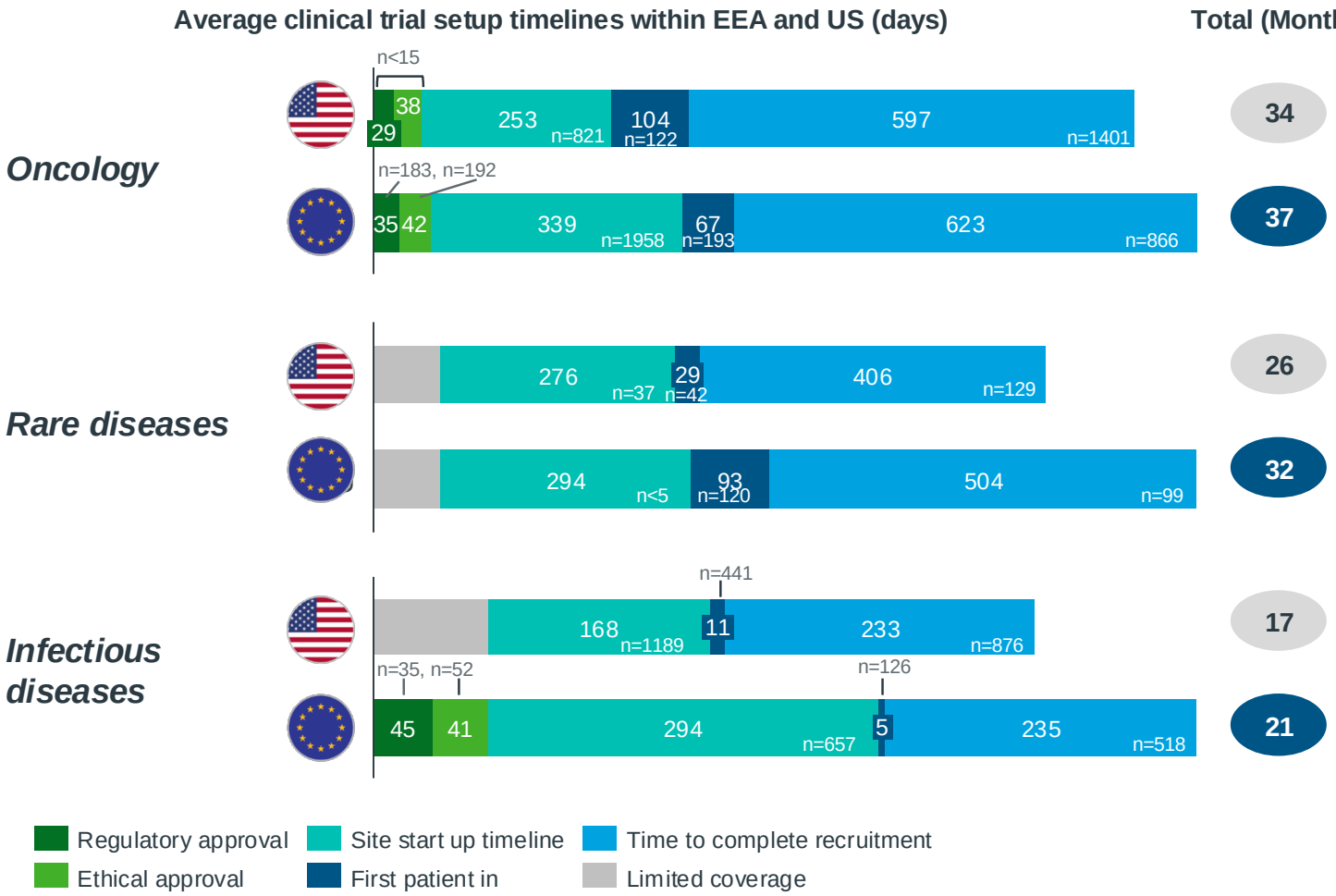

**Single-country commercial trials initiated in 2023, Phases 1-4, top 10 countries globally**

| Country | #trials | %share |
|---|---|---|
| China | 1194 | 27% |
| US | 921 | 21% |
| India | 321 | 7% |
| Japan | 298 | 7% |
| South Korea | 179 | 4% |
| Iran | 131 | 3% |
| Australia | 110 | 2% |
| UK | 74 | 2% |
| Canada | 72 | 2% |
| Thailand | 71 | 2% |

| | | |
|---|---|---|
| North America | South America | Europe |
| Asia | Oceania | Africa |

- Globally, across phases, there has been an increase in the number of single-country trials, with China, US, India, Japan driving this trend
- Approximately 50% of singe-country trials are located in China and US, likely due to their large patient pool, number of local companies, regulatory requirements, and future market demand

Note: Phase 1-4 commercial trials considered. Medical device trials and terminated/suspended trials were excluded.
Source: Clinical Trial Repository (Access Date: April 30th 2024)




Source: Clinical Trial Repository (Access Date: April 30th 2024)

Clinical trial set up timelines vary across regions and TAs. In this analysis, five steps were measured:

- Regulatory approval ; Ethical approval; Site 'start-up' Recruitment (first patient in) ; Recruitment (last patient in)

Of the five steps, site startup timeline and recruitment duration required the longest period in all three TAs explored (oncology, rare disease and infectious diseases).

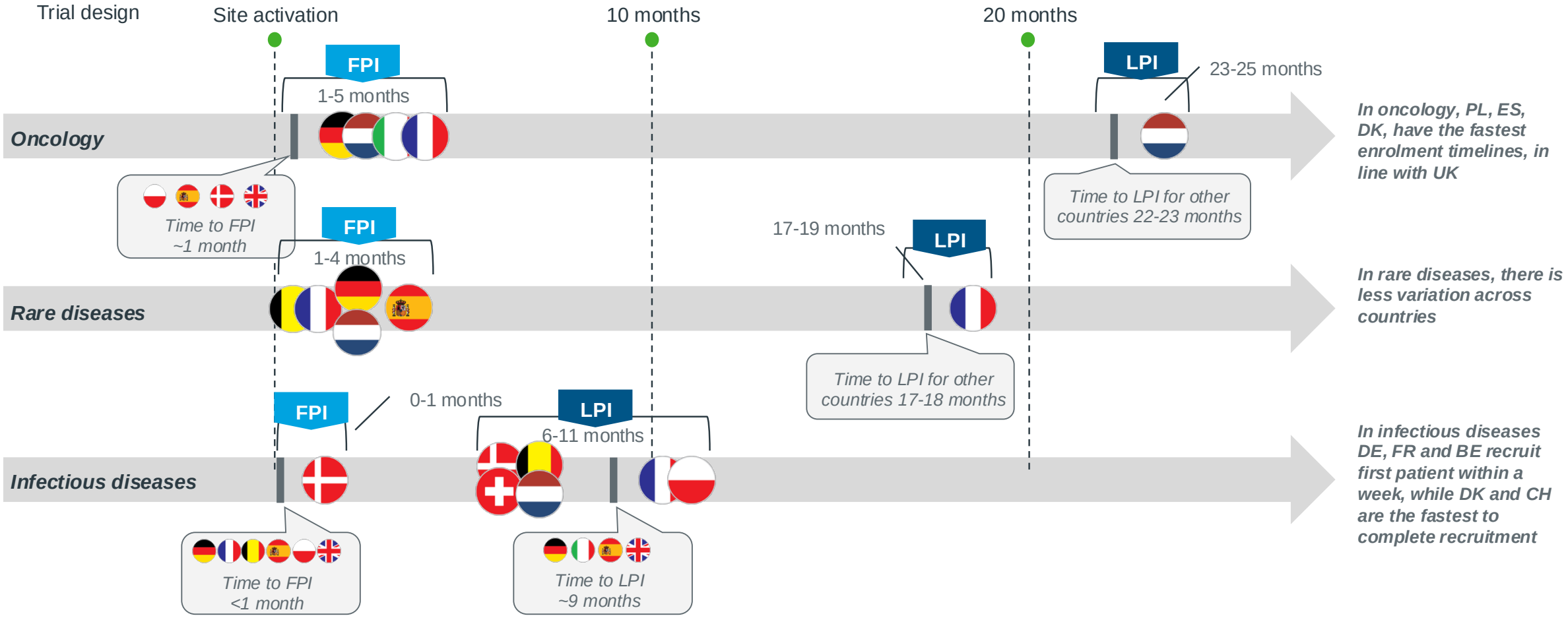
Across each therapy area, EEA timelines were longer than the equivalent US values. In infectious diseases (ID), site-start up timelines in EEA were notably longer than US. Within ID, there is variation between vaccine and non-vaccine trials. Vaccine trial start-up times were significantly longer in the US (vs. non-vaccine ID trials), but only slightly longer in the EEA

Across TAs, there is country-level variation within the EEA:

- Focusing on oncology, which represents the largest TA for clinical trials, Poland, Spain and Denmark show the fastest enrolment timelines, with a similar performance to the UK.

# Within EEA, there is significant variation across countries, with Poland, Spain and Denmark showing fast recruitment rates

**Clinical trial setup timelines within EEA and European comparator countries**




Source: Clinical Trial Repository (Access Date: April 30th 2024)

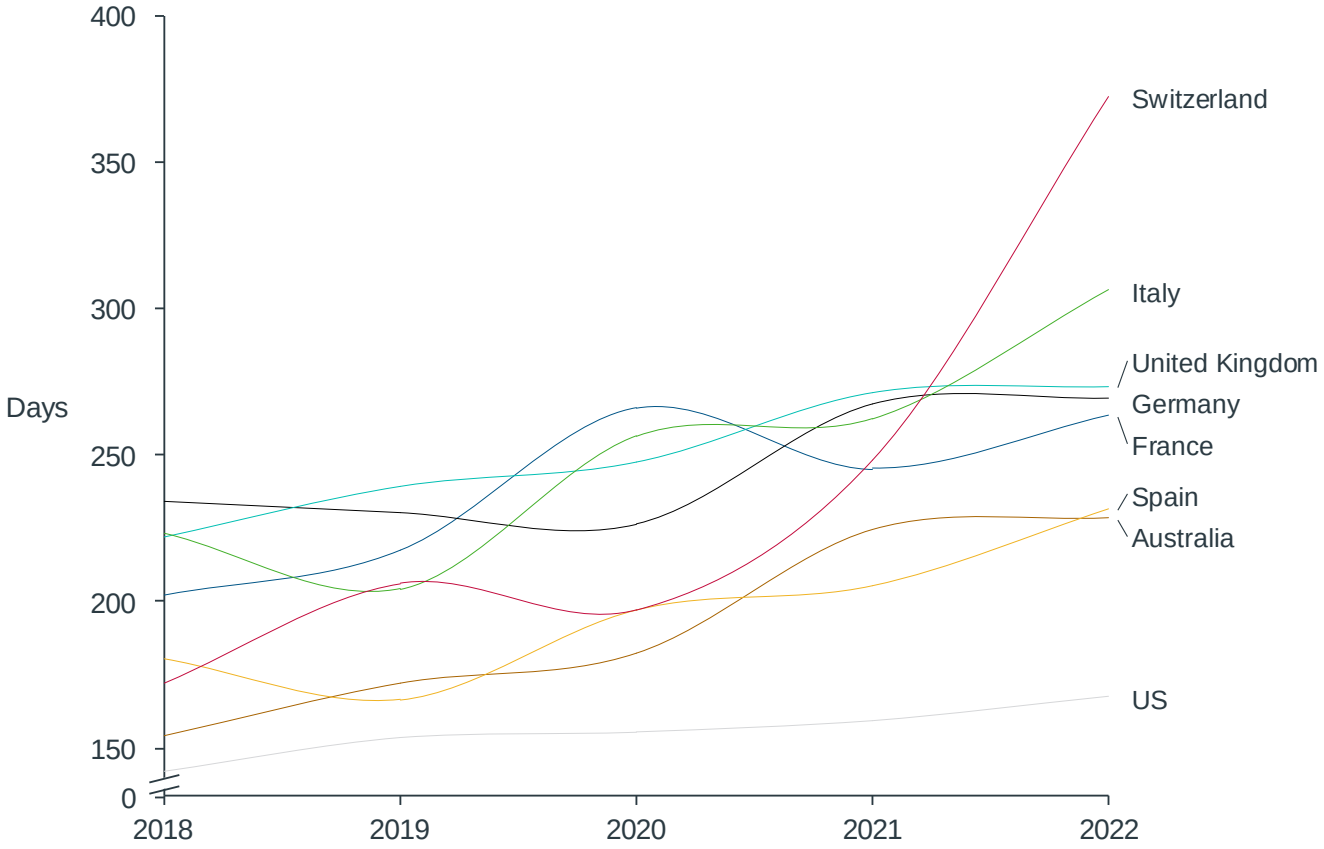


FPI First patient in

LPI Last patient in (recruitment completed)

# However most Western countries, including the US, are seeing a slow-down in trial set-up and recruitment, potentially driven by increased trial complexity

**Median days from clinical trial application to a regulatory authority and the first patient receiving a first dose, for a subset of commercial trials**




Clinical trial set-up timeline has been increasing since 2018, in most Western markets. This may be attributed to increasingly complex trials, with a wider set of endpoints, with more granular patient recruitment requirements, and longer negotiations with hospital centers

Between 2021-22, Switzerland saw a notable significant increase in set-up timelines. As a non-EU country, Switzerland has not adopted EU's Clinical Trial Regulation, and follows local clinical trial regulations and processes

Within major EEA countries, Spain retains the shortest trial set-up timelines, though faced a 25% deceleration since 2018

Whilst also slowing, in absolute terms, US and Australia have faster timelines than most major EEA countries, with US increasing the gap to the EEA in recent years

Source: Office of Life Sciences, UK Government, 2024; ABPI

# Clinical trials are extremely valuable to patients, providing early access to medicines and the opportunity to push boundaries of scientific knowledge

*Impact on patients*

***Clinical trials provide early access to innovative medicines***

Clinical trials can provide patients with **access to innovative medicines up to 5-10 years** before commercial launch[1,2]

***In some cases, clinical trials provide the only treatment option***

For **rare disease patients, clinical trials play a particularly important role** in providing treatment opportunities[3]

***Clinical trials allow patients to contribute to society and the future of healthcare***

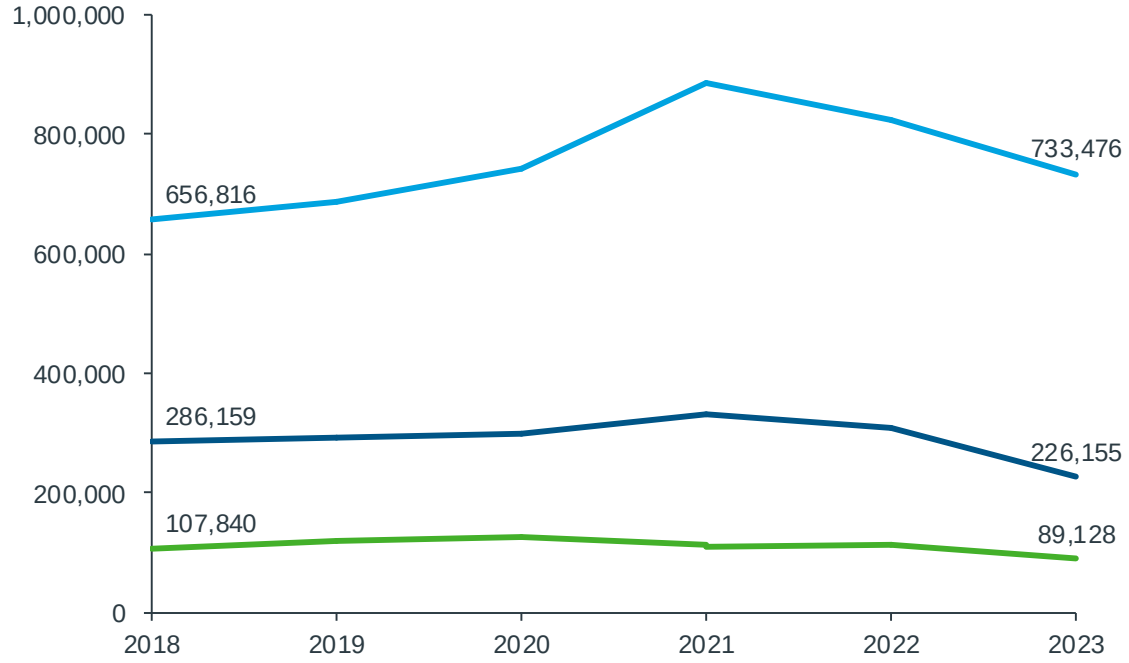
In addition to potential personal benefit, many patients take **comfort and pride in contributing medical knowledge**[2]

Source: 1. CRUK, 2. NIH 3. NORD

# In recent years, the EEA has seen a decline in the number of patients enrolled into clinical trials, contrasting to global growth

## *Impact on patients*

**Total patient numbers enrolled into commercial global, EEA-only and EEA-included trials (2018-2023)**




**Change in patients 2018 vs.2023**

70,000 more patients in clinical trials globally

60,000 fewer patients in trials involving an EEA country

20,000 fewer patients in EEA-only trials

Total patients in clinical trials (globally) | Total patients in trials which include an EEA site | Total patients in EEA-only trials

Between 2018 and 2023, global enrollment of patients into commercial clinical trials increased by 12%, despite falling back from the major boost seen during the COVID pandemic

Conversely, in the EEA, there has been a decline in the number of patients enrolled in 'EEA-only' trials (-20%) and 'EEA-included trials' (-22%)

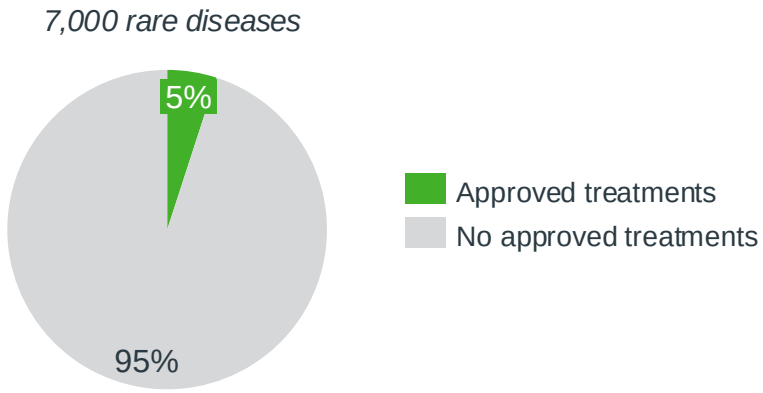
These trends follow a similar pattern to clinical trial starts, confirming that the fall in trials has not been compensated by 'larger' trials with greater number of enrolled patients

Note: Phase 1-4 commercial trials considered. Medical device trials and terminated/suspended trials were excluded.
Source: Clinical Trial Repository (Access Date: April 30th 2024)

# For patients with rare diseases, a decline in patient numbers is particularly concerning, given the critical role trials play in providing treatment options

## *Impact on patients - Rare Disease Spotlight*

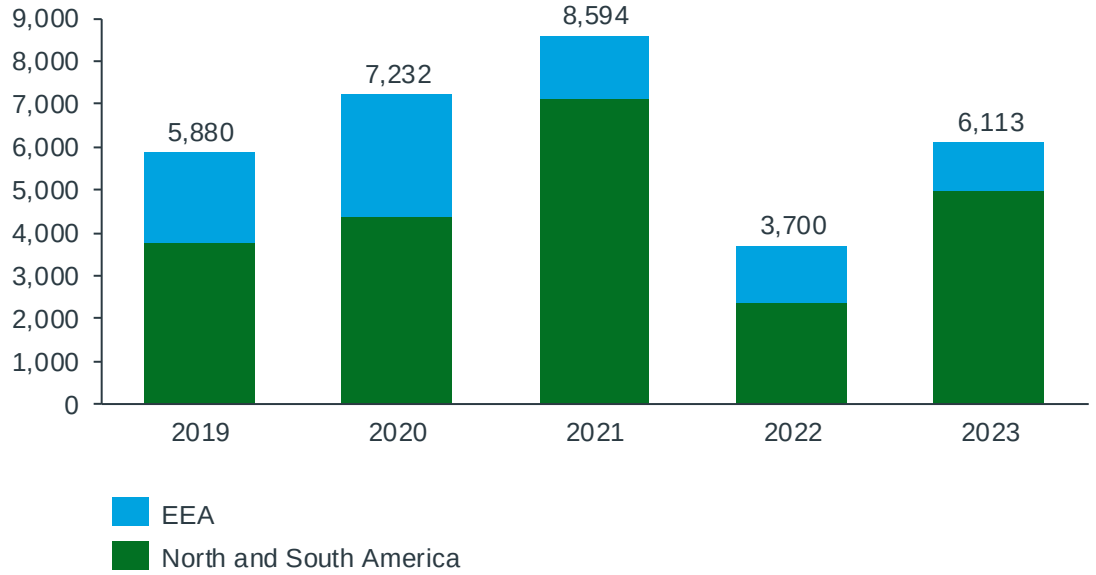
**Share of rare diseases with and without approved treatment options**




Approximately 30 million individuals in Europe are affected by rare diseases, and rare conditions are often associated with a high disease burden, with nearly 50% of cases diagnosed in early childhood

The development of new therapies is essential for improving patient outcomes, with clinical trials frequently serving as the primary option in the 95% of rare diseases with no approved treatments

**Number of patients enrolled into rare disease trials EEA and North and South America in 2019-2023**




Thousands of rare disease patients are receiving treatment options through clinical trials each year in the EEA and US, so a decline in rare disease trials would limit options for many patients

Note: Number of patients enrolled in rare diseases clinical trials: multi-country trials including sites in other than indicated regions were excluded
Sources: NORD Rare Disease; FDA, European Commission

# Healthcare systems may miss out on revenue, cost-savings, clinical skills, and staff satisfaction associated with clinical trials

## *Impact on healthcare systems*

Clinical trials bring direct financial benefit to healthcare systems through two mechanisms

- Revenue derived from running clinical trials
- Cost-savings associated with 'research-access' to innovative medicines

In 2018/19, the NHS received on average £9,000 per patient recruited to a commercial clinical trial and saved over £5,800 in drug costs for each of these patients. This equates to income of £355 million and cost savings of £28.6 million in 2018/19.

Scaled to EEA level, this suggests European health systems benefit from 1-1.5bn EUR from clinical trial payments and drug cost savings.

Based on studies of healthcare system performance, research and clinical trial activity is seen to impact:

**Job satisfaction:** staff involved in research have greater job satisfaction and staff turnover is lower in research active hospital groups

**Clinical outcomes:** research active hospitals have lower mortality rates (extending beyond research participants)

**Healthcare performance:** operational improvements have been seen from the creation of academic research placements

Clinical academic research is associated with **improved patient and carer experiences.**

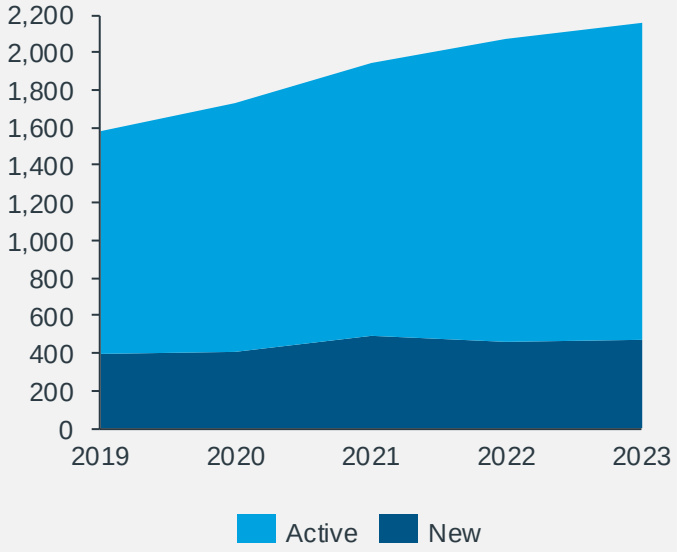
# However, for sites able to capitalise on opportunities, clinical trials drive financial benefits and direct opportunities cutting-edge patient care

## *Impact on healthcare systems – Positive trends at a major Spanish site*

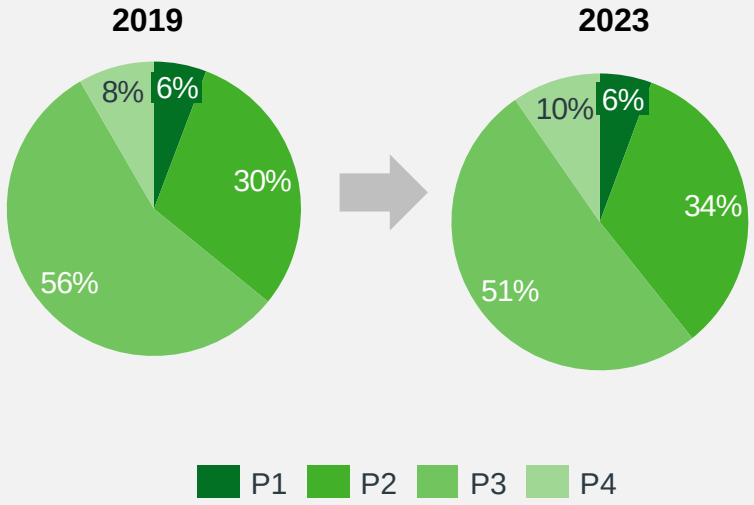
Vall d'Hebron is a major hospital and academic campus in Barcelona, seen as a leader in clinical research. **Contrasting to the wider EEA trend, the center has seen growth in clinical trials since 2019.** Hospital beds are located close to laboratories, supporting direct translation research. The center is viewed positively by industry leaders as a key site for trial delivery

### Key statistics

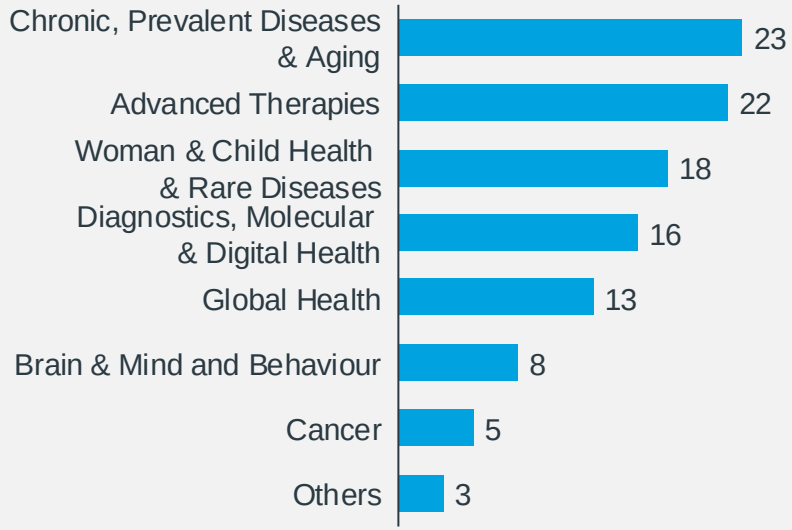
**Active and new clinical studies per year**




**Trial split by phase**




**Trial split by TA group (%)**




Sources: Vall d'Hebron

# A thriving clinical trial ecosystem brings multi-billion Euro economic benefit, but requires coordinated government investment and policy implementation

*Impact on economy and society*

## Contribution to economic growth

*in selected EEA and non-EEA markets*

- **Based on a report in Denmark, EU clinical trials add +€130,000 to GPD per trial[1]**
- **A UK report estimates +£1.8 billion in gross value added (GVA)** to the UK economy, due to commercial clinical trials[2]

## Government health R&D Investment

*in selected EEA and non-EEA markets*

- **US government allocated 2x % GDP to health R&D than Germany and Spain,** and 19x Belgium, highlighting major variation in foundational support within and outside of Europe[5]

***Clinical trial policy and investment cycle***

## Private sector investment

*in selected EEA and non-EEA markets*

- In 2017, a **major CRO opened a 'Prime Site' in Barcelona (its first in Southern Europe)**, with a commitment to offer all trials run by the CRO to this Center. **This provides a major source of international trials to Spain[3]**
- **In UK, Singapore, Australia, a range of companies are developing vaccine manufacturing capacity, and committing to delivering local clinical trials through a range of public-private sector agreements[4]**

## Clear policy and fast adoption

*in selected EEA and non-EEA markets*

- **Spain was the first in the EU country to adopt the Clinical Trial Regulation,** leading to a harmonization of national procedures and a greater commitment to rare disease and paediatric research[6]
- In 2023, to arrest declining clinical trial performance, UK committed to policy changes to reduce commercial clinical trial **approval times,** deliver a national approach to **trial contracting,** provide **'real-time' data on commercial clinical activity** in the UK, and establish a **common approach to contacting patients** about research

Sources: 1. Copenhagen Economics; 2. NIHR (UK); 3. Vall d'Hebron Hospital 4. (a) (b) (c) .5 Office of Life Sciences (UK); 6. Farmaindustria; 7. UK Government (Lord O'Shaughnessy review);

# Conclusions

- Recent European level and member state policy initiatives have attempted to increase the capabilities and attractiveness of t he clinical trial ecosystem.
- Whilst Europe is a strong performer in commercial multi-country clinical trials, it is losing global share, particularly to Asia and other regions (falling from 25% in 2013, to 19% in 2023).
- As a result of the declining share of trials, Europe has also seen a fall of the global share of patients enrolled into clinical trials.

# Conclusions

- Sustain or increase government funding into health R&D and support full adoption of CTR across member states.
- Action should be taken ensure approvals, site-start up, and recruitment speeds do not fall further, which could increase the ‘competitive-gap’ with the US. As a result of the declining share of trials, Europe has also seen a fall of the global share of patients enrolled into clini cal trials.

# What to do

- The full impact of Clinical Trial Regulation is yet to be established, however, CTR has so far failed to improve Europe's competitiveness, and there are continued challenges with CTIS implementation . Despite the ambition of harmonized standards and common procedures for regulatory and ethical approvals, the capacity and motivation at member state level to implement these changes is inconsistent.
- Future EU and members state funding should focus on creating "ready-to-go" clinical trial networks, that are open to working with the private sector, to attract clinical trials to Europe.