Assessing the clinical trial ecosystem in Europe

Excerpts from the Final Report

Katarina Nedog, EFPIA, for ACT EU Multistakeholder Annual event
22 October 2024

EFPIA & Vaccines Europe worked with IQVIA to assess the European clinical trial ecosystem

+ Clinical Trial Development and Trends

- Non-commercial & commercial clinical trials – global perspective: share and 2013, 2018-2023 trend
- Non-commercial vs commercial split, trial phases split – global perspective: share and 2013, 2018-2023 trend
- Share of commercial clinical trials – global, European and Member States perspective
  - › therapeutic areas, paediatric, rare disease, cell and gene therapy clinical trials
  - › single vs multi-country trials
- Immunisation clinical trials - global, European and Member States perspective

+ Clinical Trial Ecosystem Robustness

- Europe vs US timelines (oncology, rare and infectious diseases), Start-up timelines

+ Impact & Benefit of Clinical Trial Activity

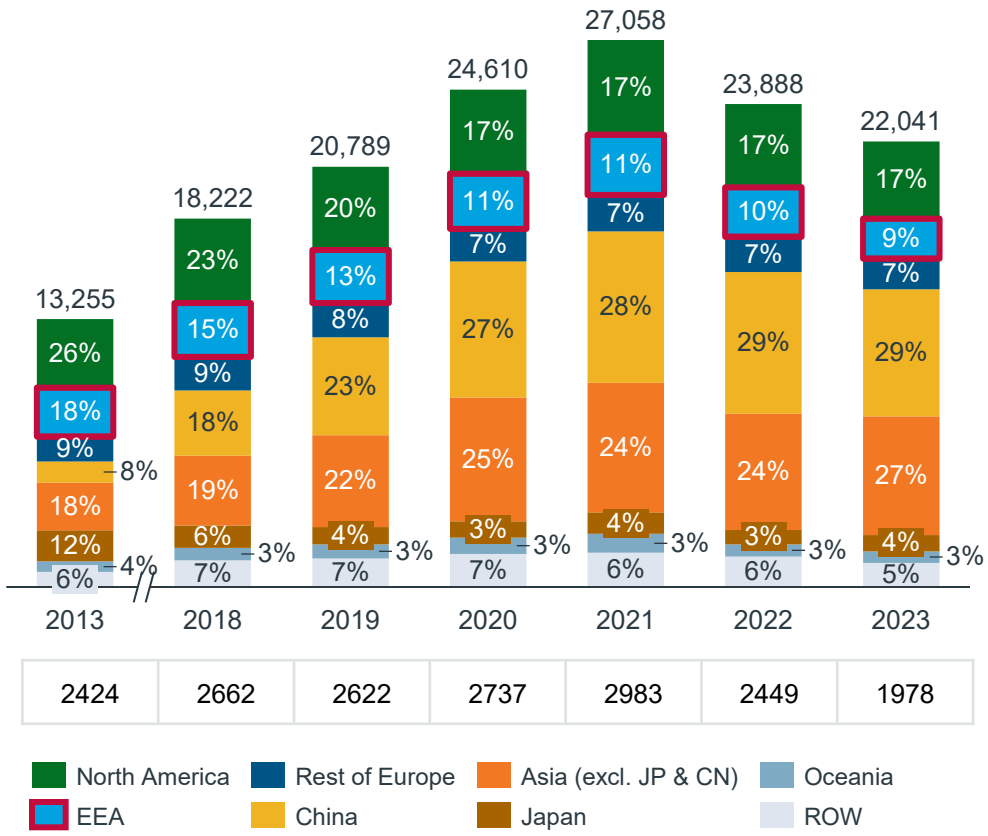
- On patients, healthcare systems and society

+ Case studies

- Spain
- Denmark

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

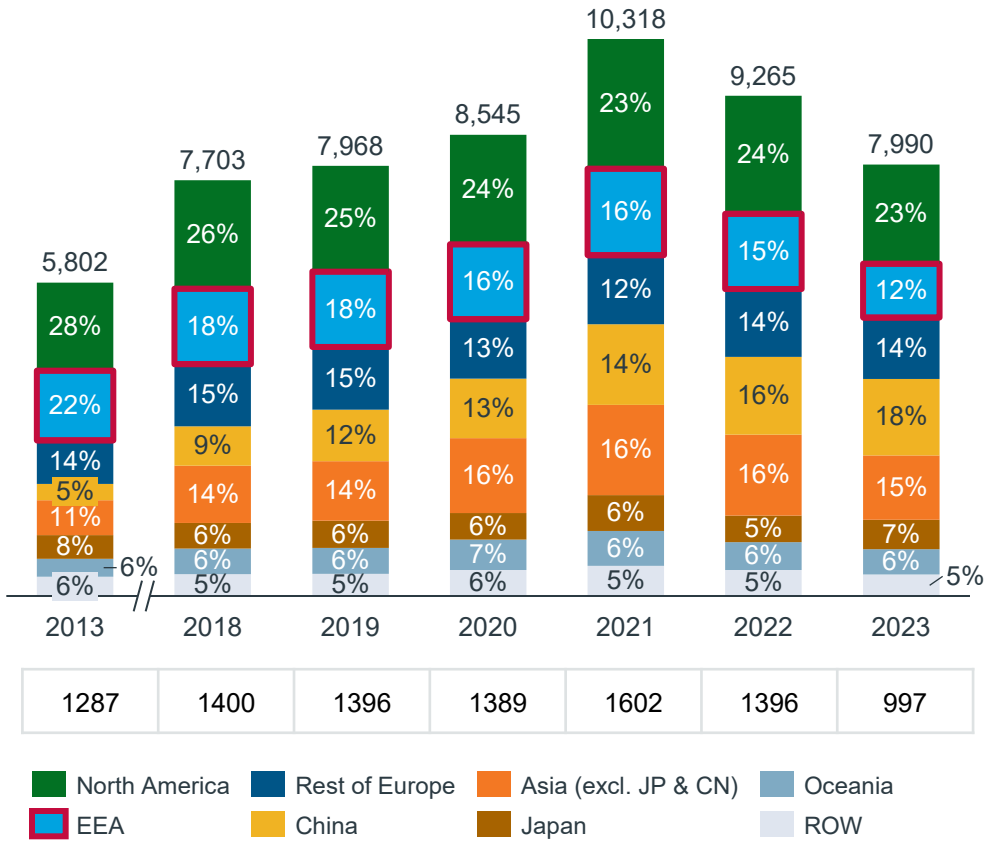
China's growth may be attributed to various factors, including National Reimbursement Drug List (NRDL) expansion, a large pool of treatment naïve patients, and an increase in China-headquartered companies sponsoring trials, especially in Phase I, oncology, and cell and gene therapy. However, China's 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

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)



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

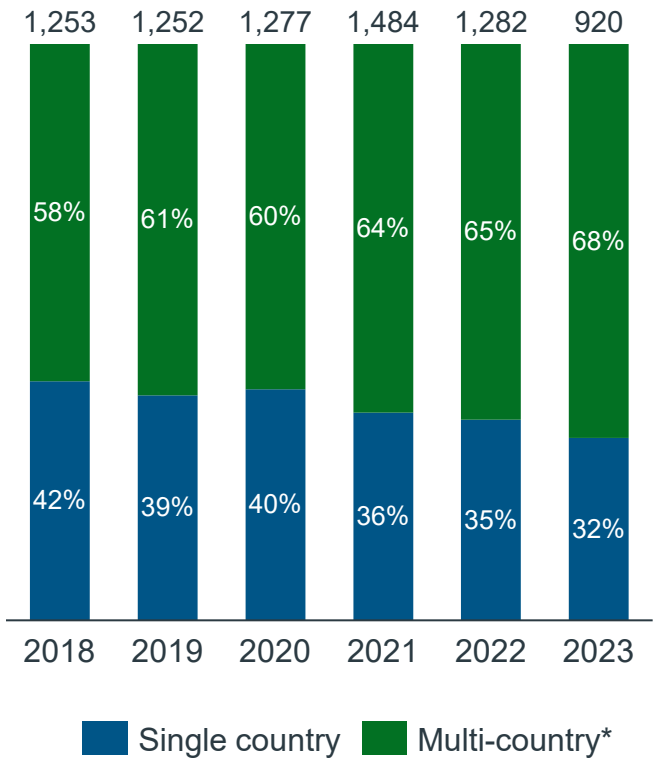
Top countries holding the highest number of commercial trials (2018-2023, Phase 1-4)

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.

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

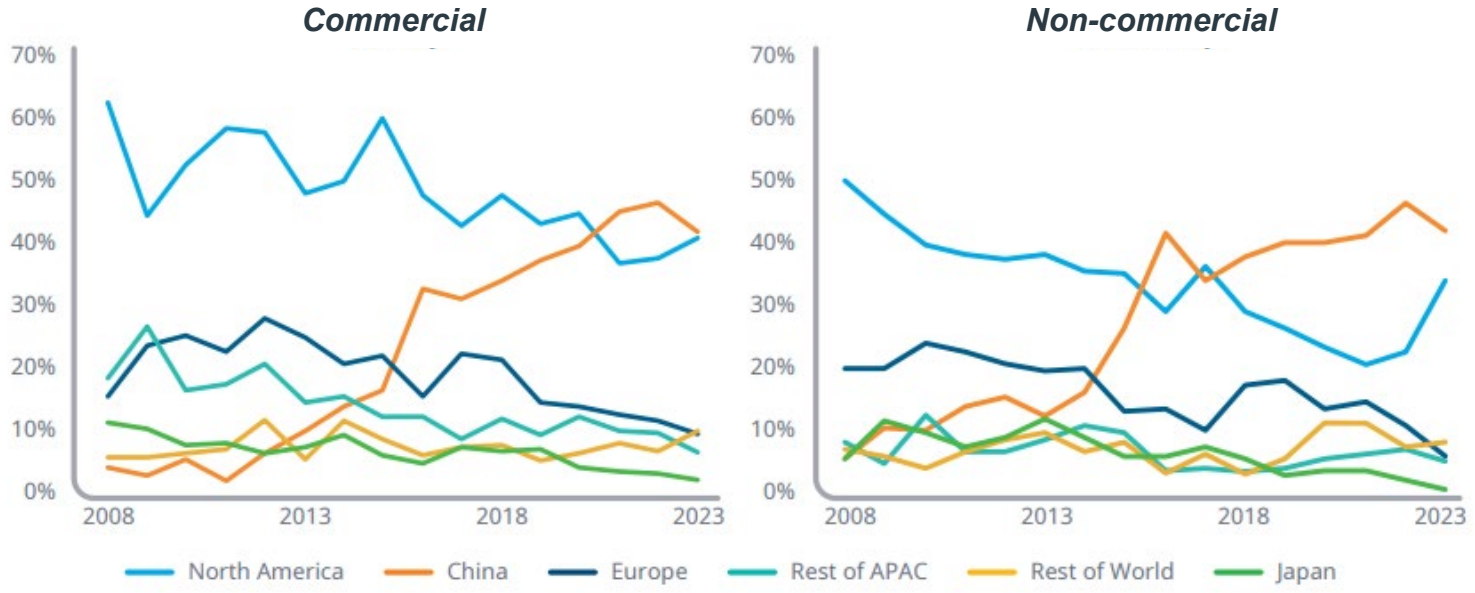
Note: Phase 1-4 commercial trials considered. Medical device trials and terminated/suspended trials were excluded. Trial with sites in multiple EEA countries were counted once within EEA. *Multi-country trials defined here as involving at least one EEA country, and not excluding those with a non-EEA 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)

Europe's share of Cell and Gene Therapy trials has decreased since 2013, whilst China has experienced rapid growth in the last decade

Cell and Gene Therapy (CaGT) spotlight

Share of cell and gene therapy trial starts by geography (2013-2023)



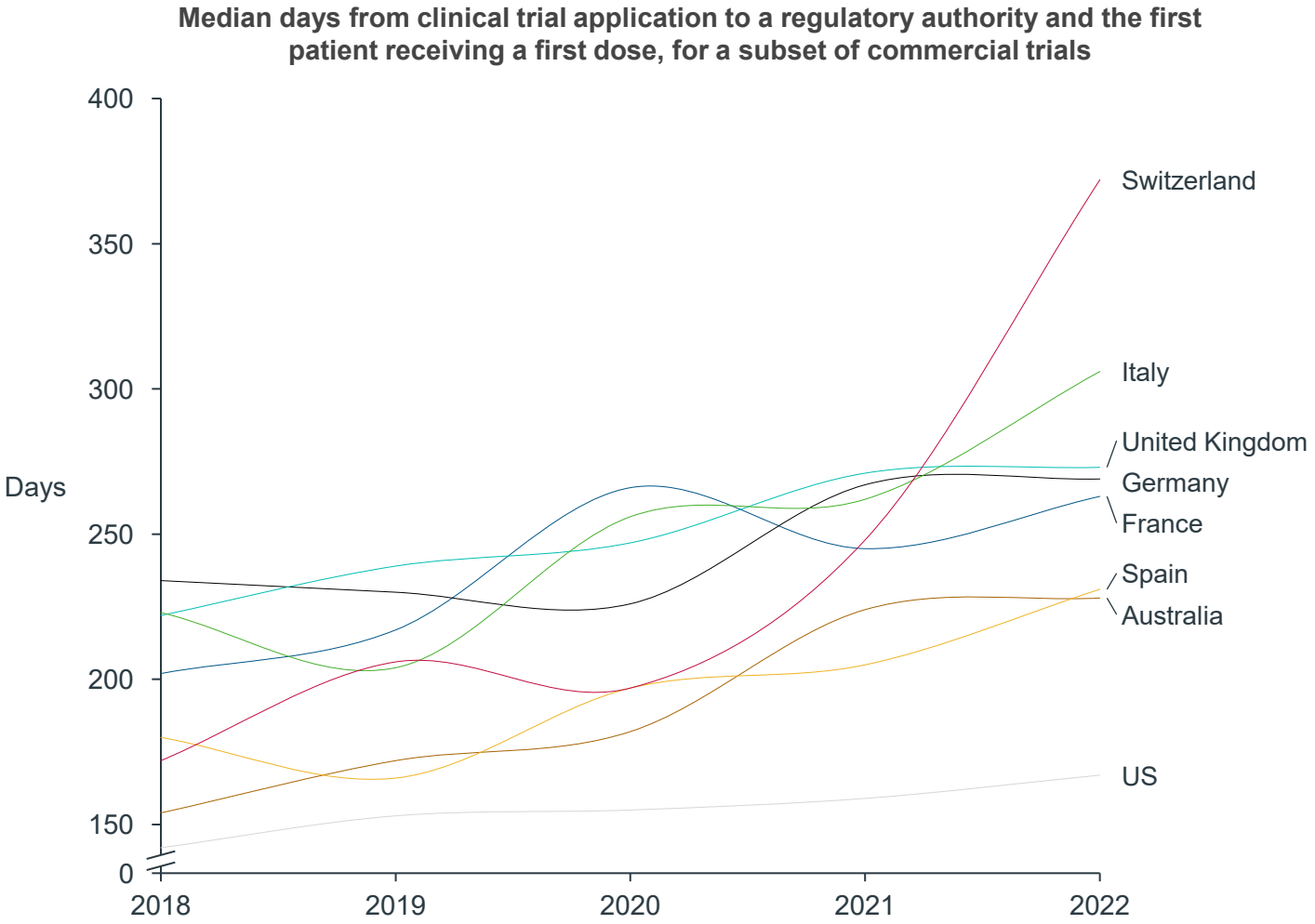
Europe's participation in global cell and gene therapy trials has steadily decreased since 2013.

During this period, China has seen a dramatic rise in CaGT trials since 2013, to become the leading region. This trend may be attributed to a favourable regulatory environment, funding streams, and strategic focus on these technologies

Between 2014-2022, The US share of CaGT trials declined, though the US remains the second-largest region for commercial and non-commercial trials. Since 2021, there has been a notable increase in non-commercial CaGT trials in the US, suggesting the US is increasing its focus in this area

Note: ATMP: Advanced Therapy Medicinal Products
Abbreviations: ATMP: advanced therapy medicinal product, CaGT: cell and gene therapy
Source: Strengthening Pathways for Cell and Gene Therapies, IQVIA Institute

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



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

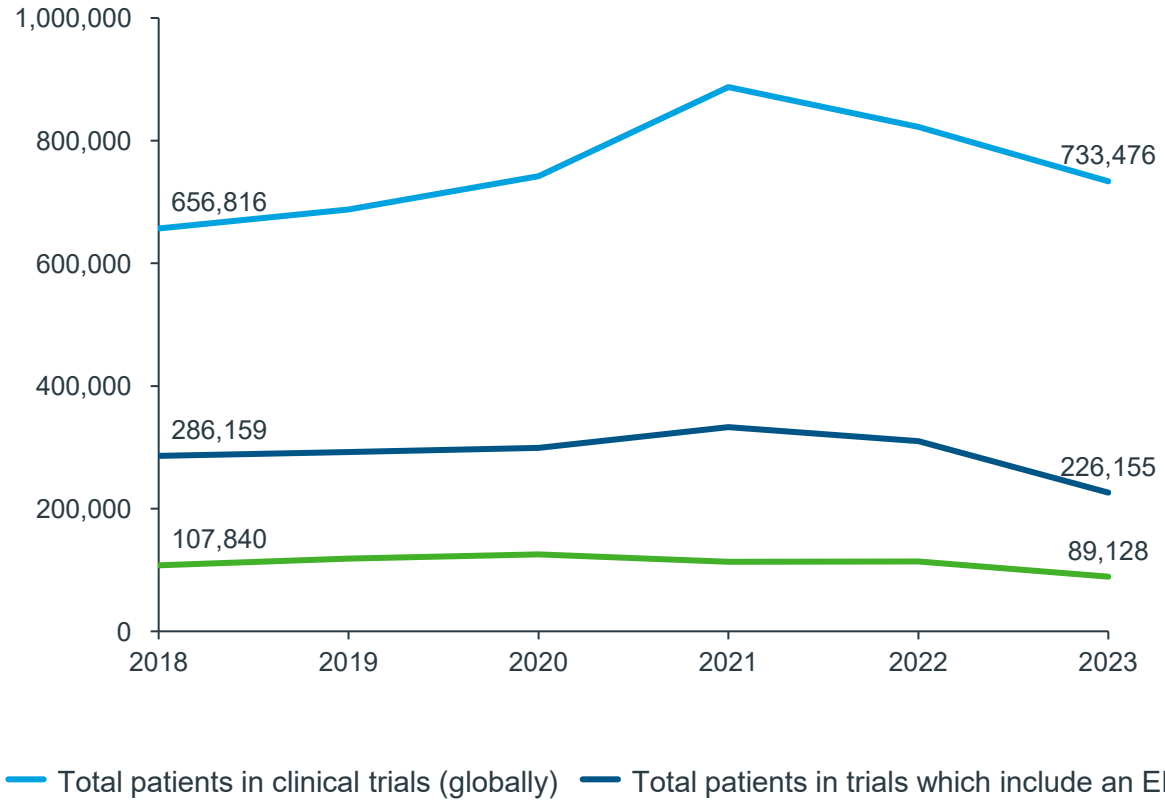
Whilst also slowing, in absolute terms, US and Australia have faster timelines than most major EEA countries, with US increasing the gap to the EEA in recent years

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

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

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)

Where Clinical Trials take place matters

The value and impact of conducting clinical trials in Europe extend well beyond benefiting patients.

Patients

Clinical trials can provide patients with access to innovative medicines up to 5-10 years before commercial launch

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

Healthcare systems

Clinical trials bring revenue, cost-savings, clinical skills, improve clinical outcomes, healthcare performance and increase staff satisfaction.

Data estimates that EEA health systems benefit from between 1-1.5 billion EUR in trial payments and drug cost savings every year.

Society

Clinical trials improve the health and well-being of society as a whole.

They bring economic investment and benefits to GDP, valued in the multi-billion EUR range.

The full report is available on EFPIA website

Publication of the report: 22 October 2024

In case of any inquiries, please contact the EFPIA Communication Team: communications@efpia.eu