

# Clinical Trials in Europe

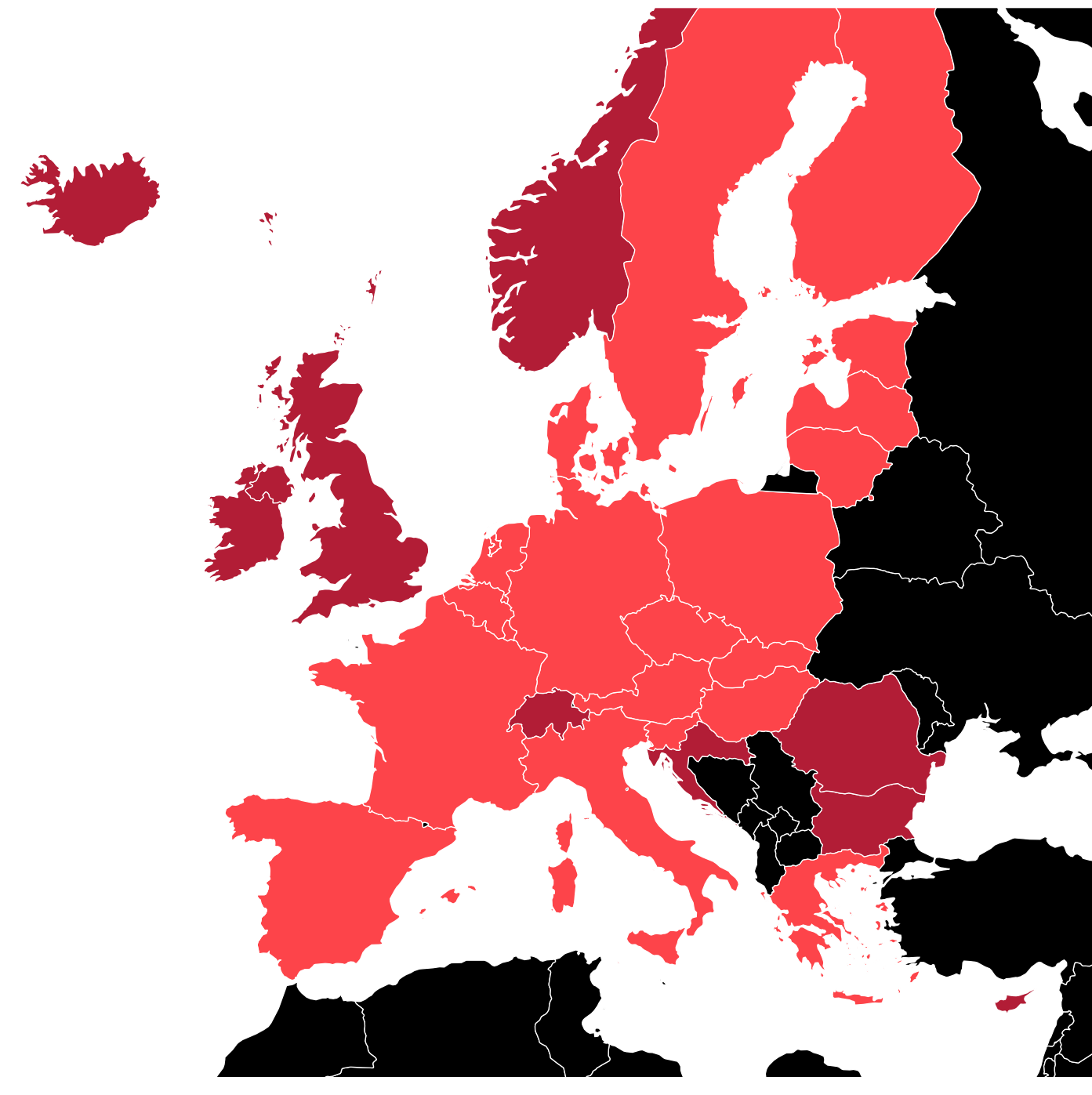
H1 2021 Research report

[Location Data](#) [Trial Data](#) [Sponsor Data](#) [Subject Data](#) [Data Search and Analysis](#) [About ACROSS](#)

## Location Data

For the purposes of this white paper, Europe is defined as macro-region incorporating 31 countries: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of Cyprus, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and still UK.

During the past three decades Europe has emerged as the most prominent region for conducting clinical trials, accounting for over 1/3 of the total number of studies conducted Worldwide in the first half of 2021.<sup>[1]</sup>



High level of Healthcare expenditures (as a proportion of GDP) – means not only significant market demand potential – but also widespread opportunities for the development and testing of innovative therapies. The majority of European countries have robust healthcare systems with high standards of quality and equally high levels of professional qualification for healthcare professionals involved in clinical research activities.

39% of commercial clinical trial sites participating in clinical trials are located in Europe – this equates to approximately 135,000 hospitals across Europe.<sup>[2]</sup>

The Top-5 European countries by the number of initiated clinical trials in the first half of 2021 were – UK, Germany, France, Spain and Italy – and they account for about 50% of European sites involved in clinical research activities.<sup>[3]</sup>

One Regulatory space is managed by the European Medicines Agency (EMA) – for all European Union (EU) countries, and one centralized database exists for all clinical trials initiated in EU countries – namely, EudraCT<sup>[4]</sup>. Thanks to the regulation regarding clinical trials with drugs of human use (EU Regulation 536/2014), the rules for conducting clinical trials are the same across the European Union.

There are also plenty of opportunities for conducting clinical studies and registration of treatments for Rare Diseases – thanks to the European Reference Networks.<sup>[5]</sup>

Clinical Trials Regulations may be found on the EMA website.<sup>[6]</sup>

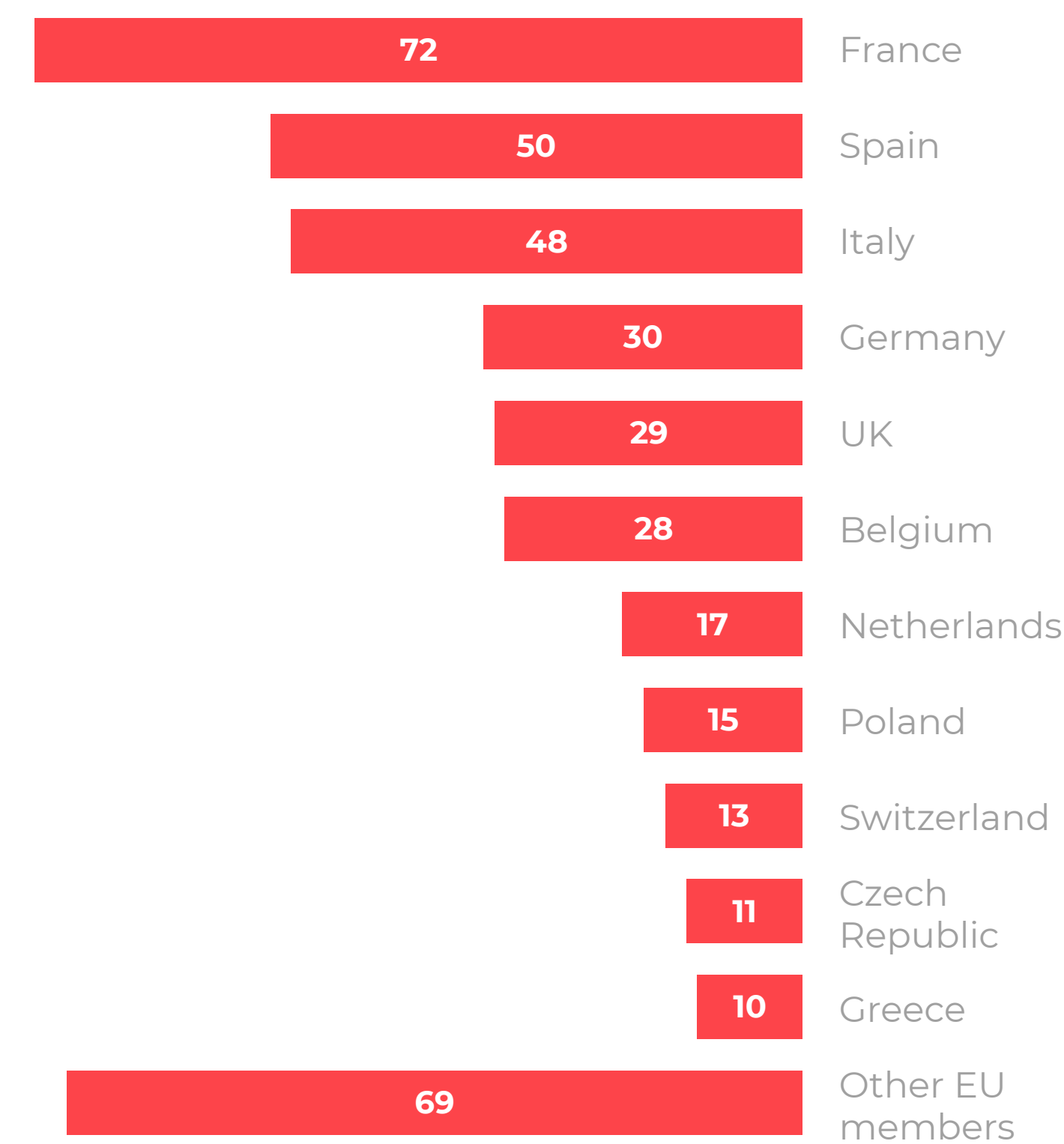
## Trial Data

During the first half of 2021 there were 6,180 clinical trials initiated in European countries including local and bioequivalence studies. This represents a 34% growth in comparison with the previous year when a total of 4,629 studies were initiated.

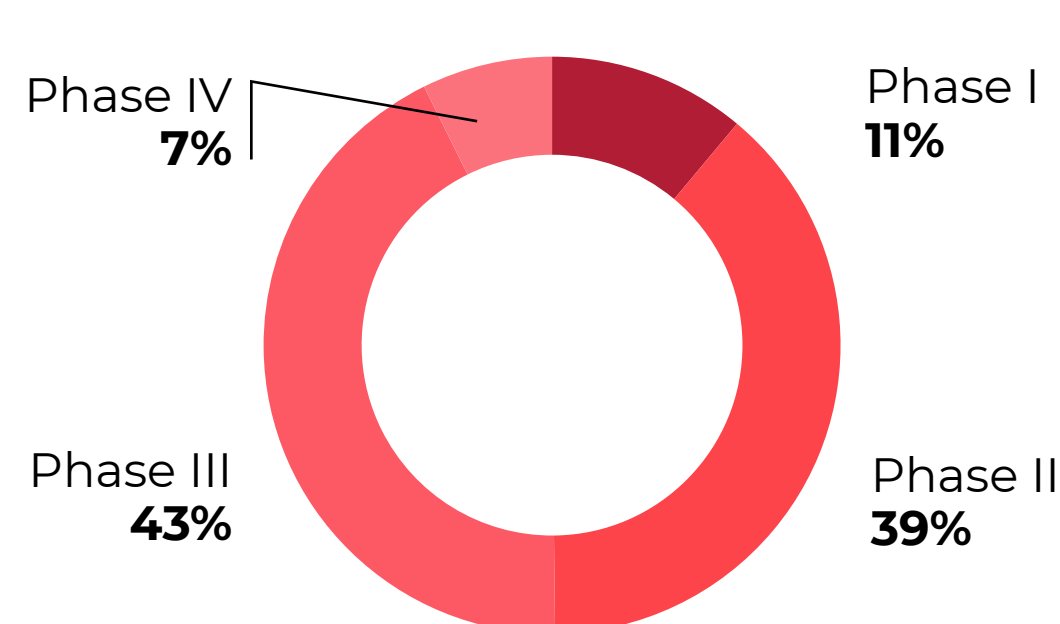
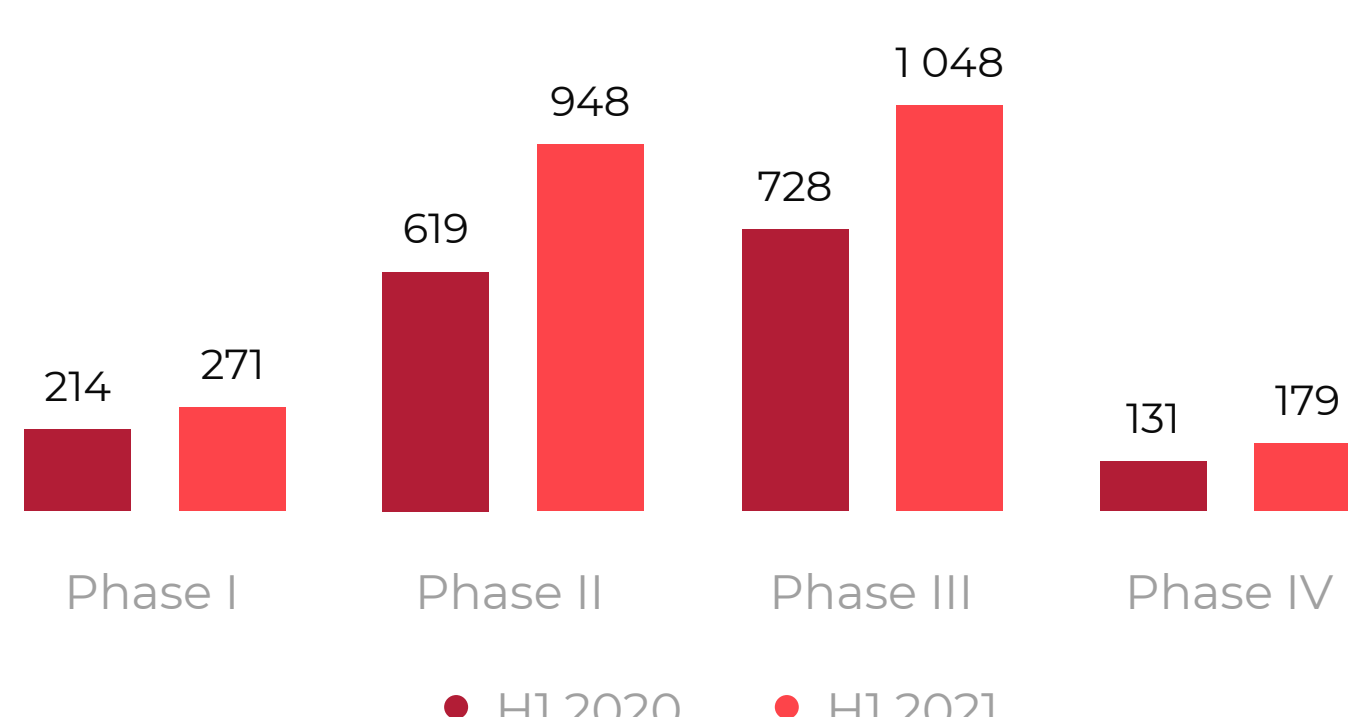
However, if one excludes bioequivalence studies and studies without an FDA-defined Phase, there were only 2,446 clinical trials initiated during the first half of 2021 compared to 1,692 studies initiated in previous year with year on year jump rate of 45%.

The largest number of clinical trials initiated in European countries during the first half of 2021 were related to Oncology, Infectious Diseases, Cardiology, Endocrinology and Gastroenterology. Other prominent therapy areas included Dermatology and Rheumatology.

### Clinical Trials with COVID19-related Nosologies in European countries (H1 2021)



### Breakdown of Clinical Trials in European Countries by Phase (H1 2021)



The most active countries involved in various COVID-19 treatments were France (72 studies), Spain (50 studies), Italy (48 studies), Germany (30 studies) and UK (29 studies). The total number of COVID-19 trials represents 6% of the total number of clinical studies initiated in Europe during the first half of 2021.

The majority of clinical trials conducted in the European countries were interventional studies with a 74% market share. The most frequent phase of clinical trials conducted across European countries by number of studies was Phase III.

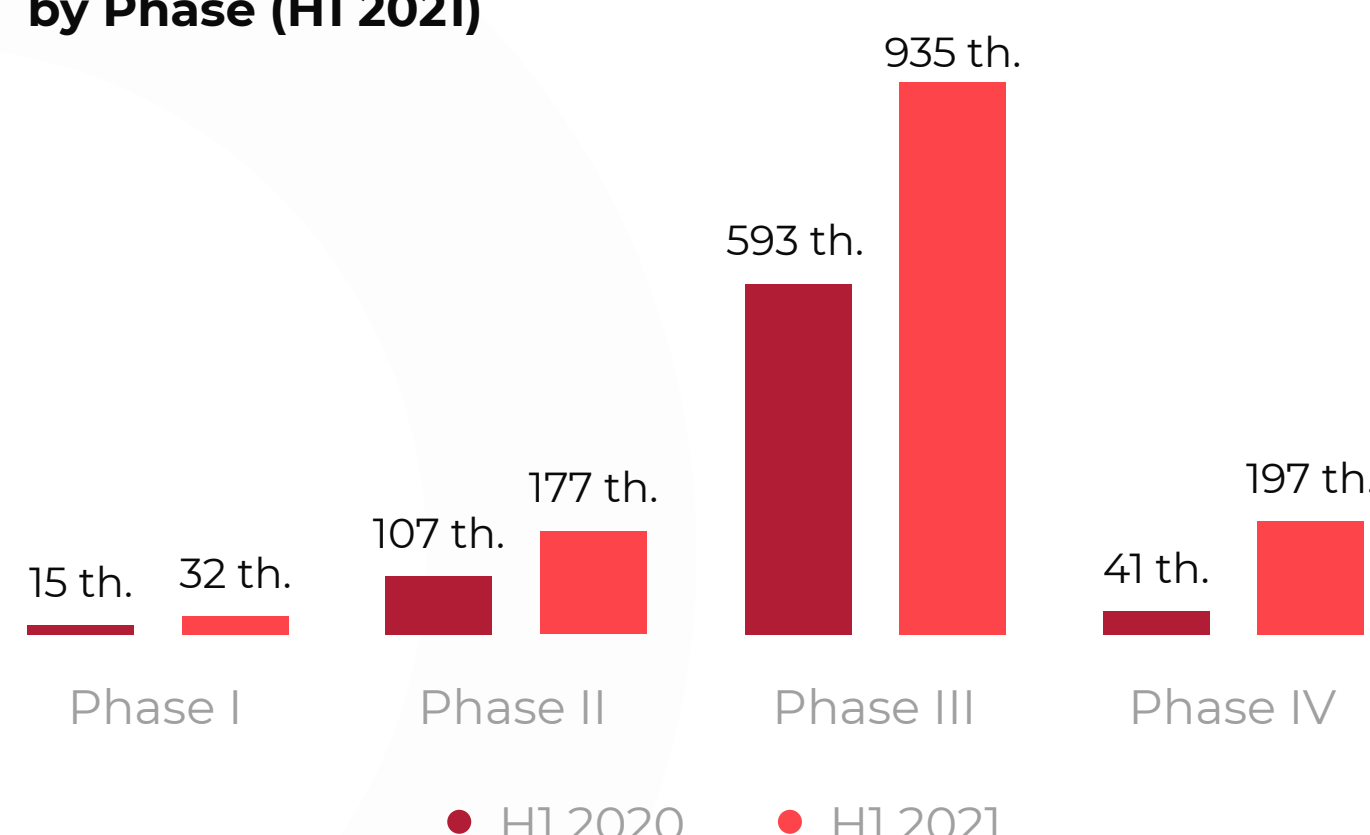
The “Other EU members” bar includes Austria, Sweden Denmark, Hungary, Bulgaria, Portugal, Ireland, Norway, Romania, Finland, Croatia, Estonia, Lithuania, Slovakia, Slovenia, Latvia and Luxembourg.

## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in the European countries during the first half of 2021 (including multi-center international studies) jumped from 756,224 subjects in the previous year to 1,340,662 subjects in the first half of 2021 with a year on year jump rate of 77%. Within the European region, the most prevalent Phase of clinical trials by total number of participating subjects was Phase III.

\* Studies indicated by sponsors as Phase I-II were counted as Phase II; Phase II-III – as Phase III, Phase III-IV – as Phase IV.

### Breakdown of Number of Subjects Enrolled / Planned to be Enrolled in European Countries by Phase (H1 2021)



## Sponsor Data

During the first half of 2021 there were more than 200 Pharmaceutical companies worldwide which sponsored clinical studies with FDA-defined Phase I – IV and which were initiated in European countries. The leaders were the Multi-National Corporations (MNCs) – both domestic (i.e., European), like AstraZeneca, Novartis, Bayer, Janssen, Hoffmann-La Roche, Boehringer Ingelheim,

GlaxoSmithKline and Sanofi – and overseas (primarily, from the U.S.) – for example, Merck, AbbVie, Pfizer, Bristol-Myers Squibb and Amgen. These MNCs traditionally conduct large multi-center international clinical trials across many countries – and dominate the local clinical trial market scene of many countries across the world.



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## H1 2021 Research report

## Data Search and Analysis Approach

All of stats data used in this document were downloaded from [ClinicalTrials.gov](https://clinicaltrials.gov) website as a .CSV file with the download options listed in the table below.

.CSV file export was completed with the following options:

Number of studies [to download]: all studies.

Select table columns: All available columns.

Select file format: Comma-separated values.

Nº	Item Name	Fields in Pivot Table	Details
1	Breakdown of Clinical trials by Regions (H1 2021)	NCT, Country	
2	Breakdown of Clinical Trials in European Countries by Phase (H1 2021)	NCT, Phases	Exclude “Not Applicable” and empty values in “Phase” field
3	Percentage Breakdown of Clinical Trials in EU by Phase (H1 2021)	NCT, Phases	Exclude “Not Applicable” and empty values in “Phase” field
4	Breakdown of Interventional vs. Observational Trials in EU (H1 2021)	NCT, Study Type	
5	Clinical Trials with COVID-19-related Nosologies in EU (H1 2021)	NCT, Conditions	Use “COVID” keyword in “Conditions” field
6	Breakdown of Number of Subjects Enrolled in EU by Phase (H1 2021)	NCT, Phases, Enrollment	See below *

\* Exclude “Not Applicable” and empty values in “Phase” field. Use “Number of values” by “NCT Number” field. Use “Sum” by “Enrollment” field. Use decreasing sorting of the table by “NCT Number” field.

If you want to use the same source .CSV file used in this report – just let us know via [info@across.global](mailto:info@across.global) and we’ll send it to you.

## About The White Paper

The White Paper is a free publication produced by ACROSS Global (CRO) Alliance for decision makers in the pharmaceutical industry. The document pulls together data from numerous public sources into a single brief document to aid decision makers planning to conduct clinical trials.

All of the data contained in this document are actual as of 12-JULY-2021.

For more information or if you would like to review a .CSV file of the data extracted from [ClinicalTrials.gov](https://clinicaltrials.gov) (used in this White Paper) please write to: [info@across.global](mailto:info@across.global).

## About ACROSS Global

ACROSS Global is a global alliance of local contract research organizations successfully operating in 98 countries and covering more than 25 therapy areas.

High recruitment rates combined with innovative technology allows ACROSS partner companies to offer our clients conduct faster, more cost-effective studies without sacrificing quality for our clients.

All clinical studies conducted by ACROSS Partners conform to Good Clinical Practice (GCP) as well as local and international regulations ensuring the highest level of quality of the final study data.

We apply continuous improvement methodology to our working practices and IT infrastructure – and replace outdated R&D strategies by novel, more efficient approaches to clinical research.