

Synergy **orange** paper / 2019 spring / quarter 1



Clinical trials in Europe

Research report

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Foreword

The orange paper is a free publication produced by Synergy Research Group for the pharmaceutical industry since 2007. It pulls together data from numerous public sources into a single brief document to aid decision makers planning to conduct clinical trials. It is produced quarterly, with an annual summary at the close of each year.

All of the data within this document are actual on date: 04/04/2019



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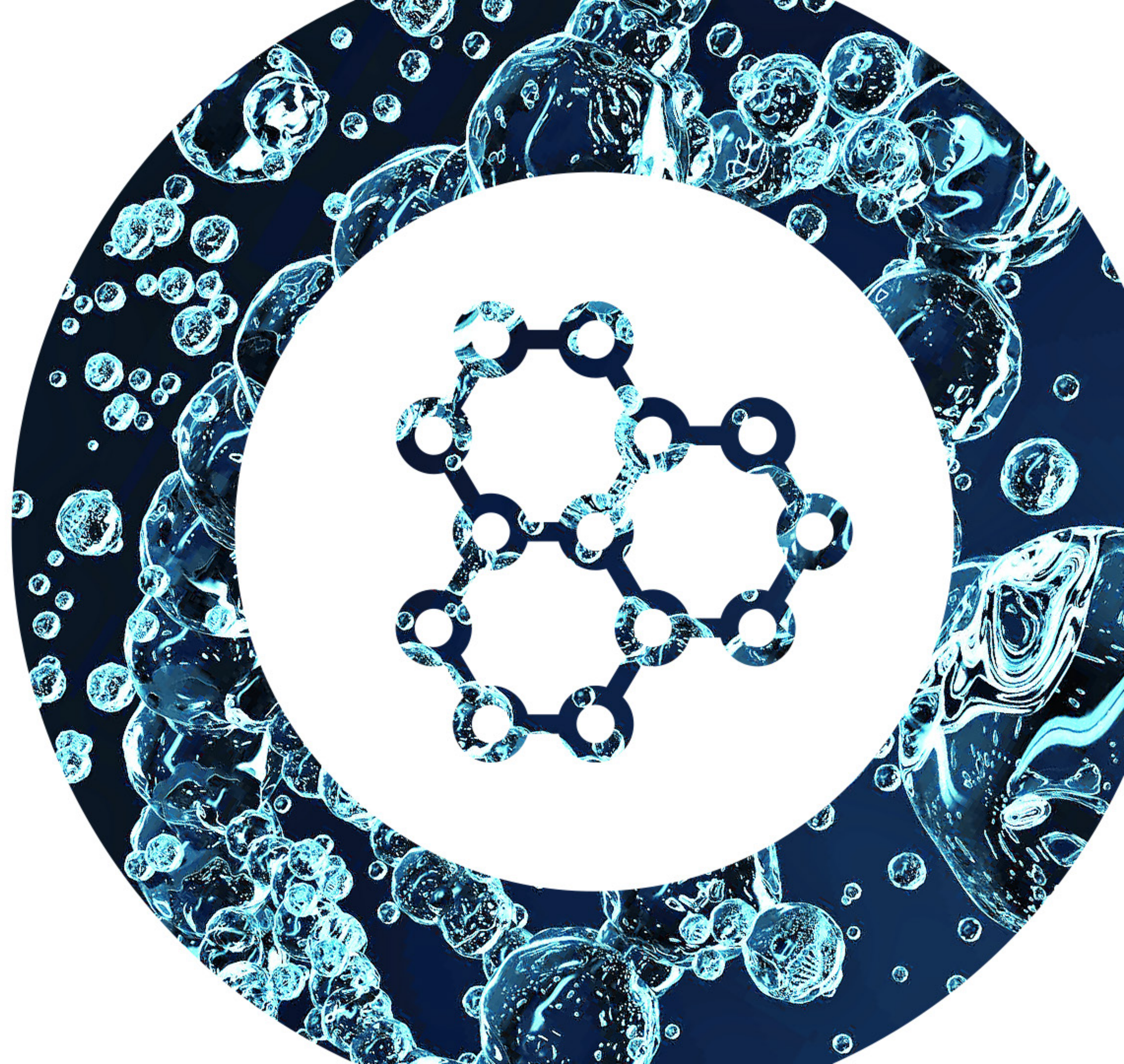


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Executive Summary

During Q1 2019 the official FDA website showed approvals for initiation of 7,201 new clinical trials of all types worldwide, including local and bioequivalence studies. 2,255 of them were initiated in 28 European Union countries, Switzerland and Norway. That represents an overall year to year decline of 28,85%.

Interventional clinical trials are the dominant type of research with 81% market share worldwide, 78% in Europe and 89% in the U.S. The most prevalent phase of clinical trials conducted worldwide by number of studies was Phase II. The dominant phase of clinical trials conducted across European sites by number of studies and subjects was Phase III.

In Europe the top-10 Sponsors combined account for 15% of total number of studies conducted in Q1 2019. In comparison, in the U.S. the top-10 Sponsors combined account for 16% of total number of studies.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 17 new drugs, including 2 generics, 2 biosimilar and 3 orphan medicines. 12 of these drugs received positive opinions and were approved to marketing.

In Q1 2019 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 29 new drugs, including 4 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

According to the U.S. FDA data, 3 FDA inspections were conducted in investigative sites located in UK (2 visits) and France (1 visit) during Q1 2019. All of the inspections ended with No Action Indicated (NAI) outcomes.



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Global Clinical Trials

Trial Data

During Q1 2019 the official FDA website showed approvals for initiation of 7,201 new clinical trials of all types worldwide, including local and bioequivalence studies with an overall year on year growth rate of 9% driven in large by an increasing number of trials in developing countries.

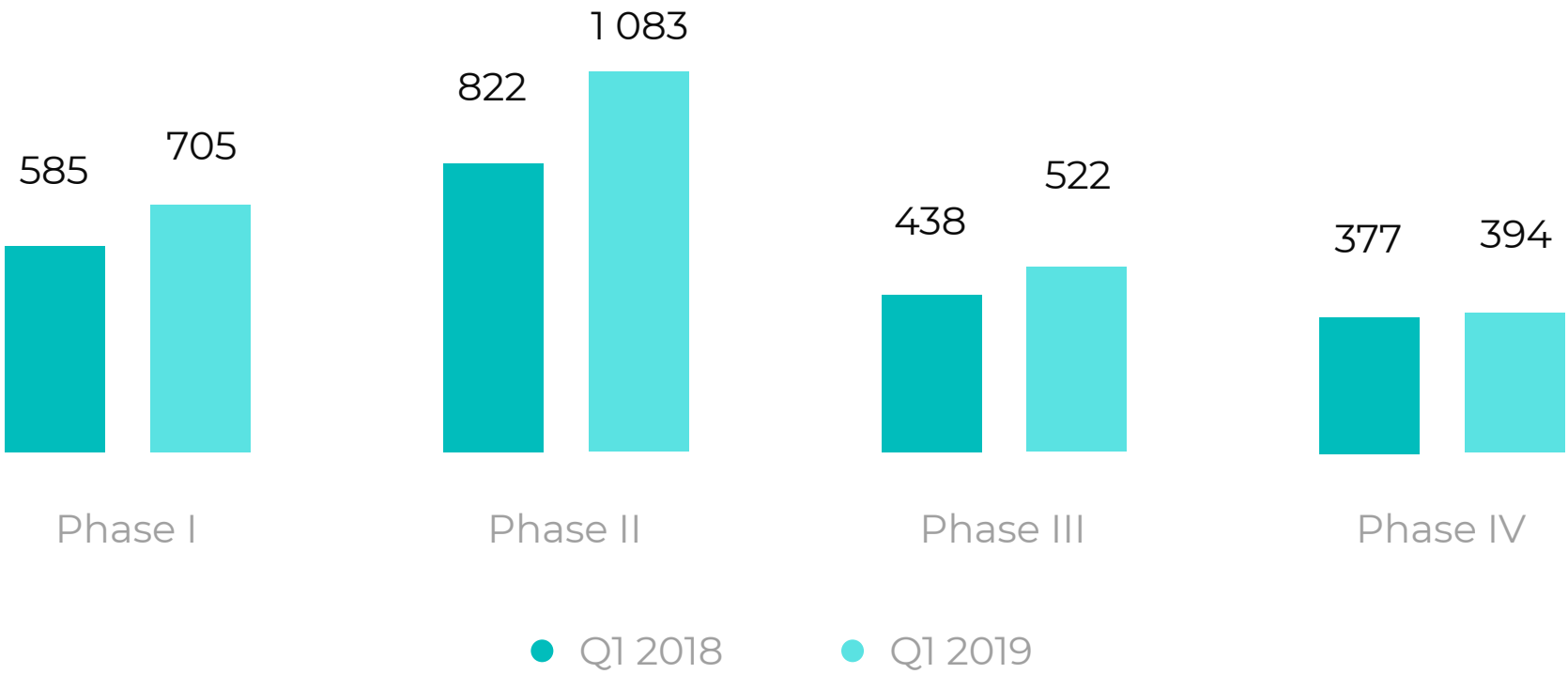
The combined market share of the U.S. and European countries by number of global initiated studies plunged to 63% in Q1 2019, with the U.S. having 32% and Europe having 31%.

81% of all global clinical trials initiated in Q1 2019 were Interventional Clinical Trials.

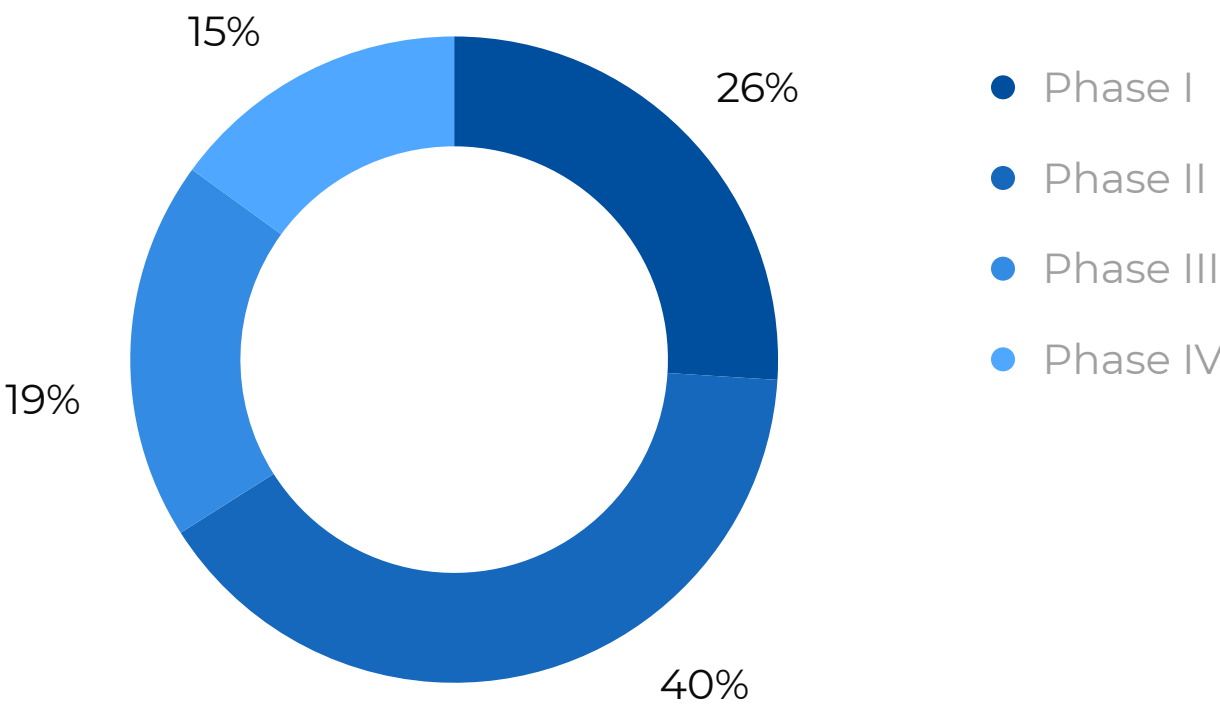


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Breakdown of Global Clinical Trials by Phase



Percentage Breakdown of Global Clinical Trials by Phase

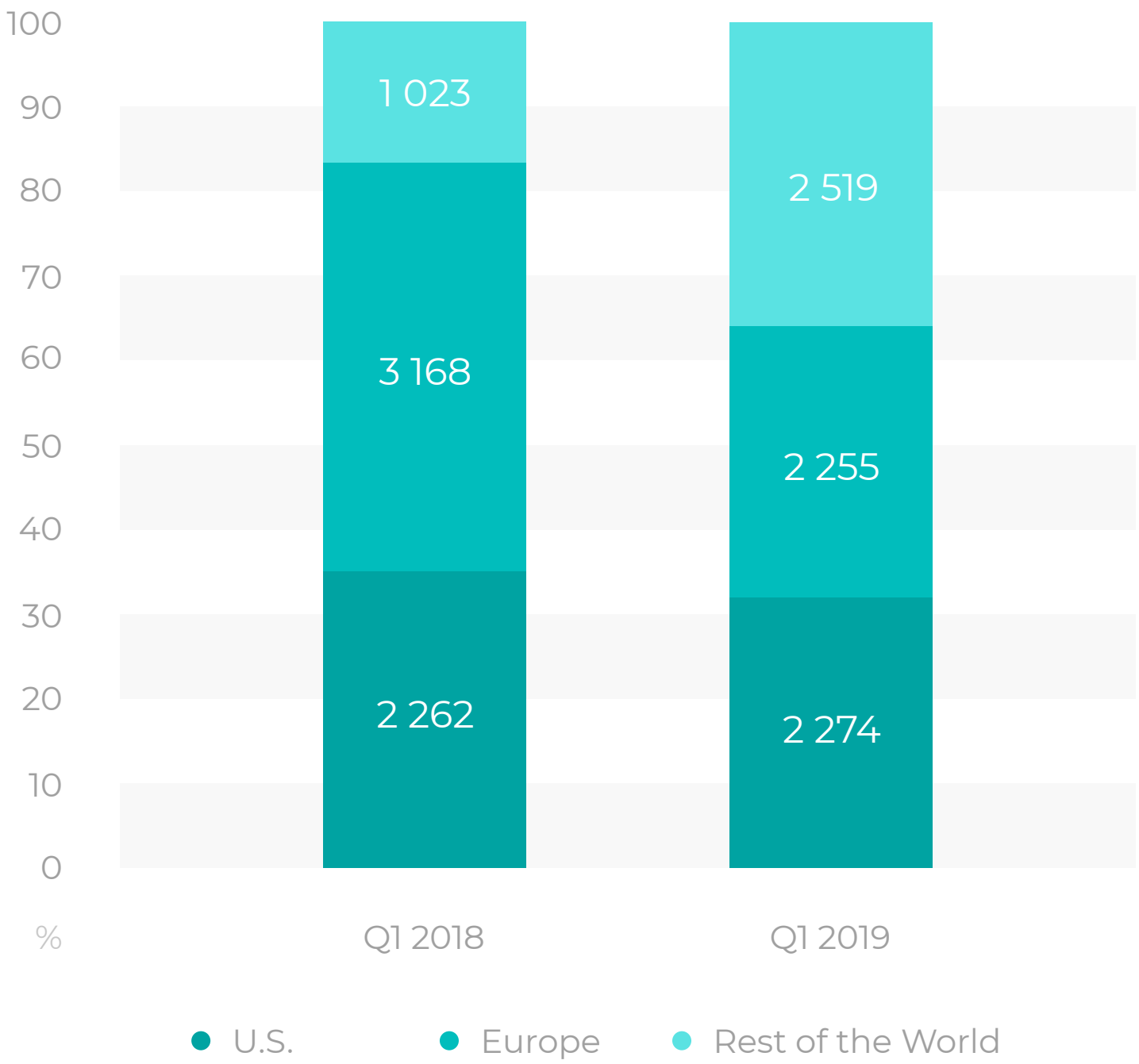
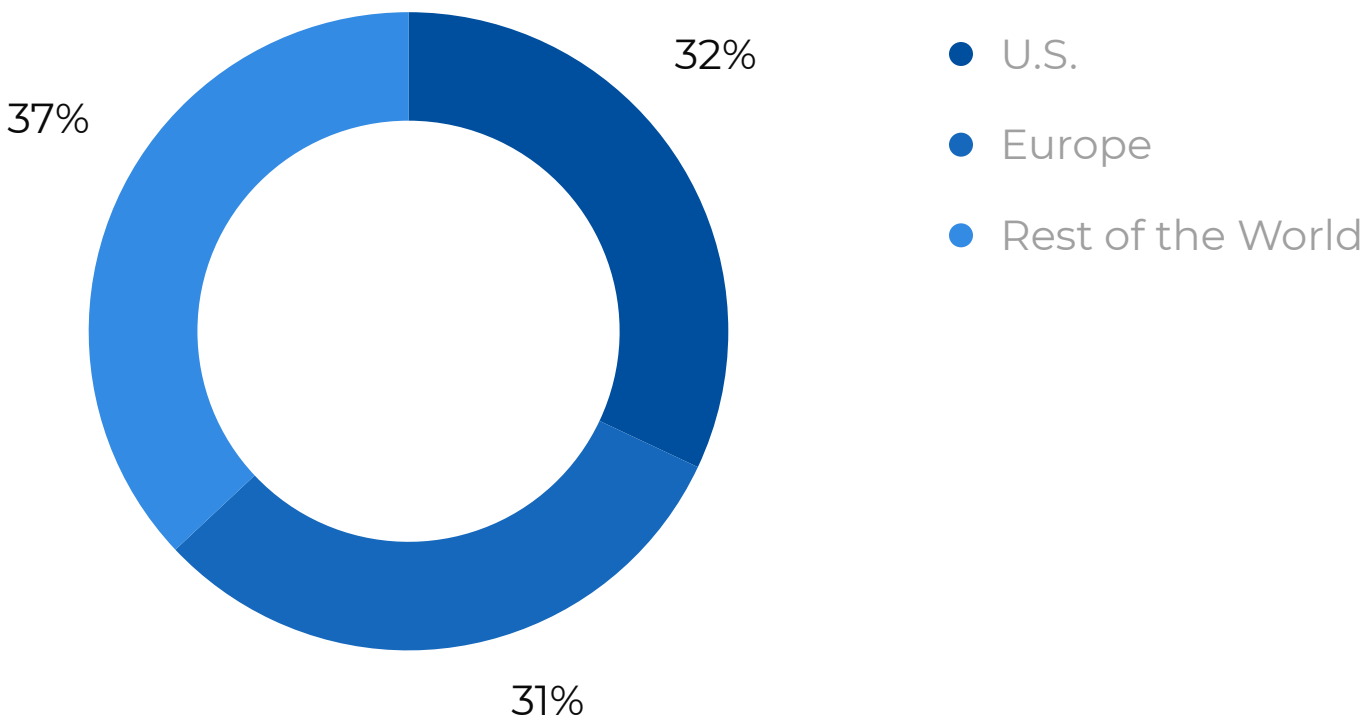


Global Clinical Trials

Trial Data - Breakdown by Region of Origin

The proportions between different global regions (i.e. U.S., Europe and Rest of the World) for trials conducted in Q1 2019 changed in comparison to Q1 2018. Notably, the market share of leading European countries by number of initiated studies dropped from 48% to 31% in Q1 2018.

Percentage Breakdown of Global Clinical Trials by Region of Origin

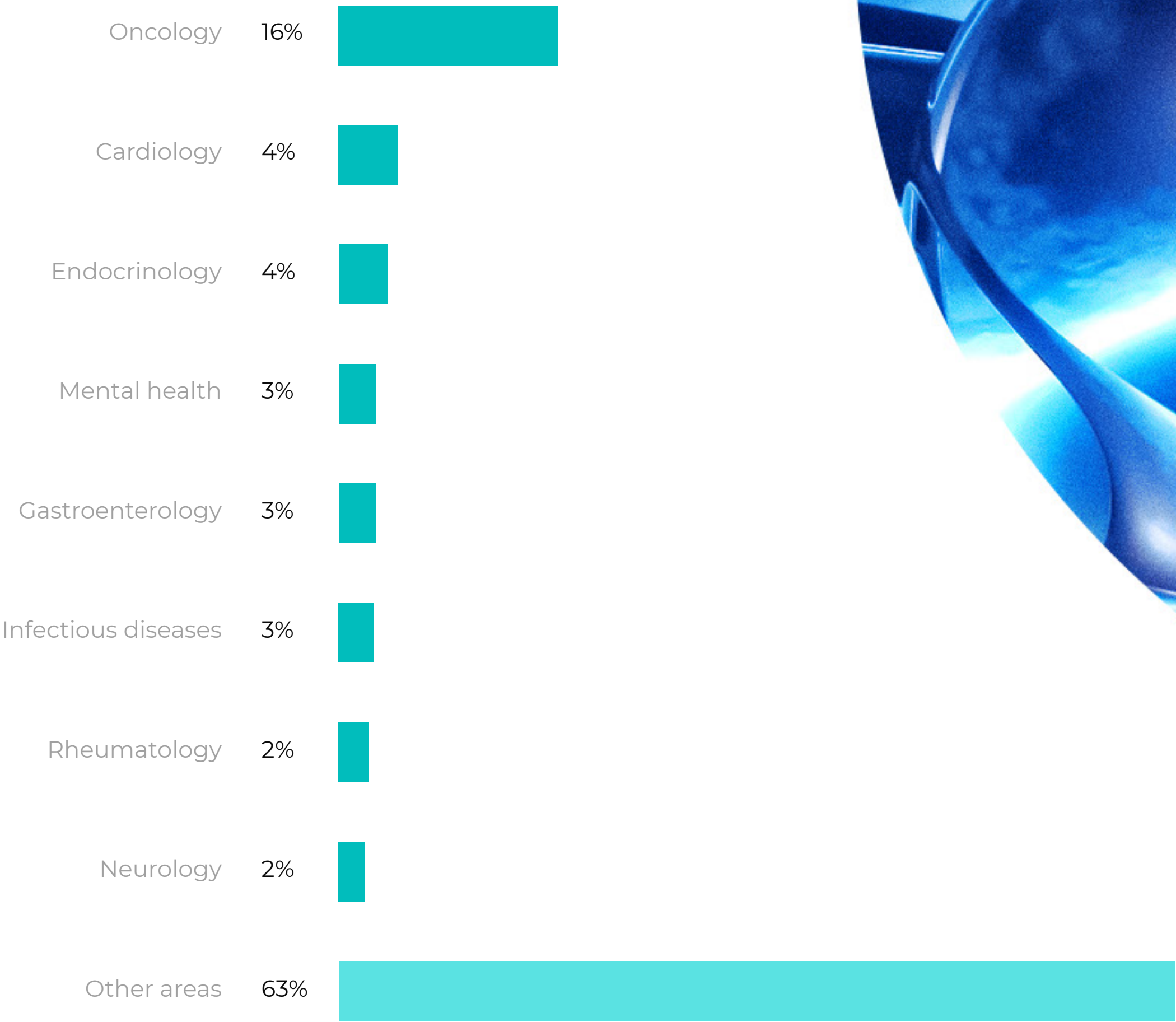


Global Clinical Trials

Global Clinical Trials by Therapeutic Area

In Q1 2019 the largest number of studies were initiated in Oncology (1,170 studies), Cardiology (318 studies), and Endocrinology (257 studies).

Note: More than one therapeutic area could be assigned to a trial. BE studies were not included in any therapeutic area group.



Global Clinical Trials

Sponsor Data

The Top-10 list of global Sponsors of Clinical Trials worldwide remains unchanged for the past 5 years – this fact may be explained by the significant and continuously increasing amount of investment required for research and development of new drugs.

However, it's remarkable that the combined market power of these leading pharmaceutical corporations accounts for just 12% of all interventional clinical trials where the study Phase has been identified, and just 10% of all enrolled subjects.

Top-10 Global Sponsors by Total Number of Studies Initiated in Q1 2019

Nº	Company Name	No. studies	No. subjects
1	Merck	60	11 107
2	Bristol-Myers Squibb	46	3 006
3	AstraZeneca	42	7 563
4	Pfizer	35	5 733
5	Novartis	31	5 460
6	Janssen	26	5 903
7	Eli Lilly	25	8 728
8	Boehringer Ingelheim	24	6 116
9	Takeda	24	3 240
10	Sanofi	21	6 204
Combined market share of top-10 companies		12%	10%

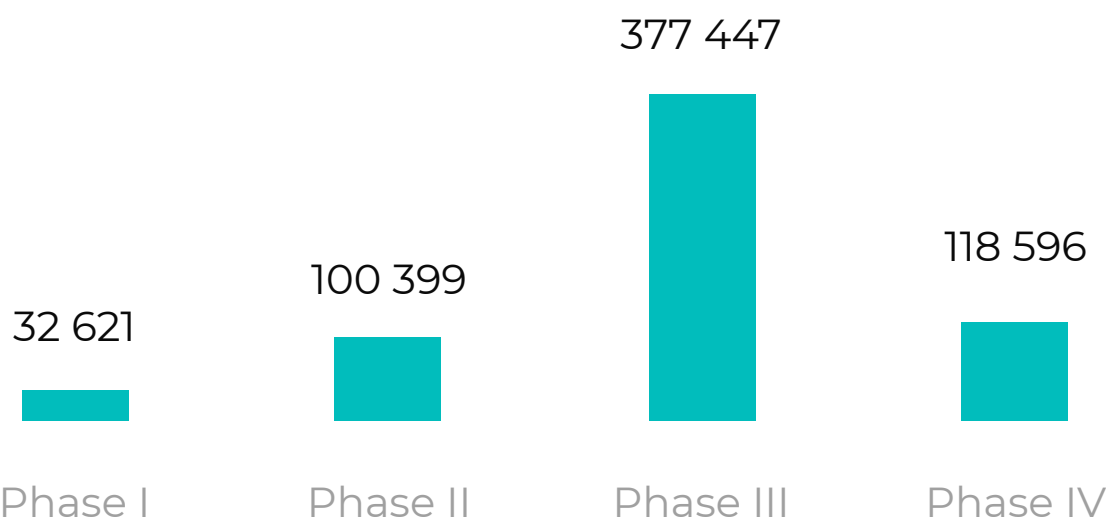
Global Clinical Trials

Subject Data

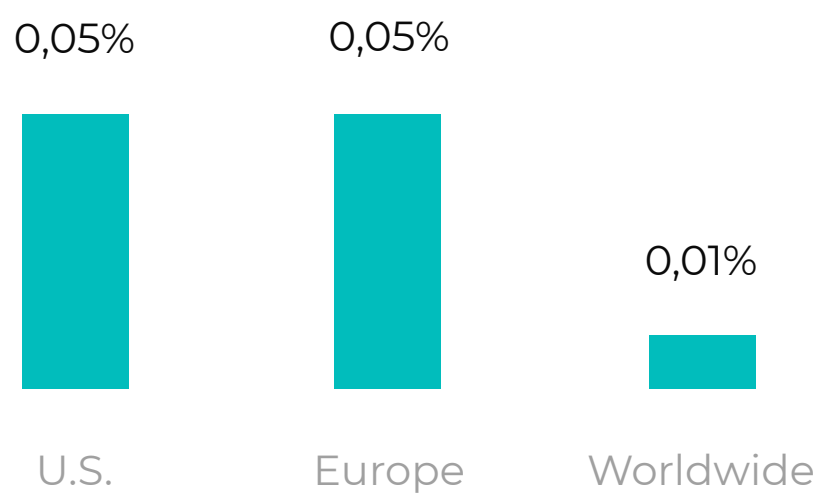
The total number of subjects enrolled in Clinical trials of all types in Q1 2019 reached 629,063 subjects.

The majority of subjects were enrolled in Phase III trials, and the largest proportion of the global subject population were from Europe. However, the share of subjects participating in clinical trials remains extremely low in comparison with overall size of the population – with approximately 0,01% Worldwide.

Number of Subjects Enrolled Worldwide by Phase



Breakdown of Number of Subjects Enrolled as a % of Population



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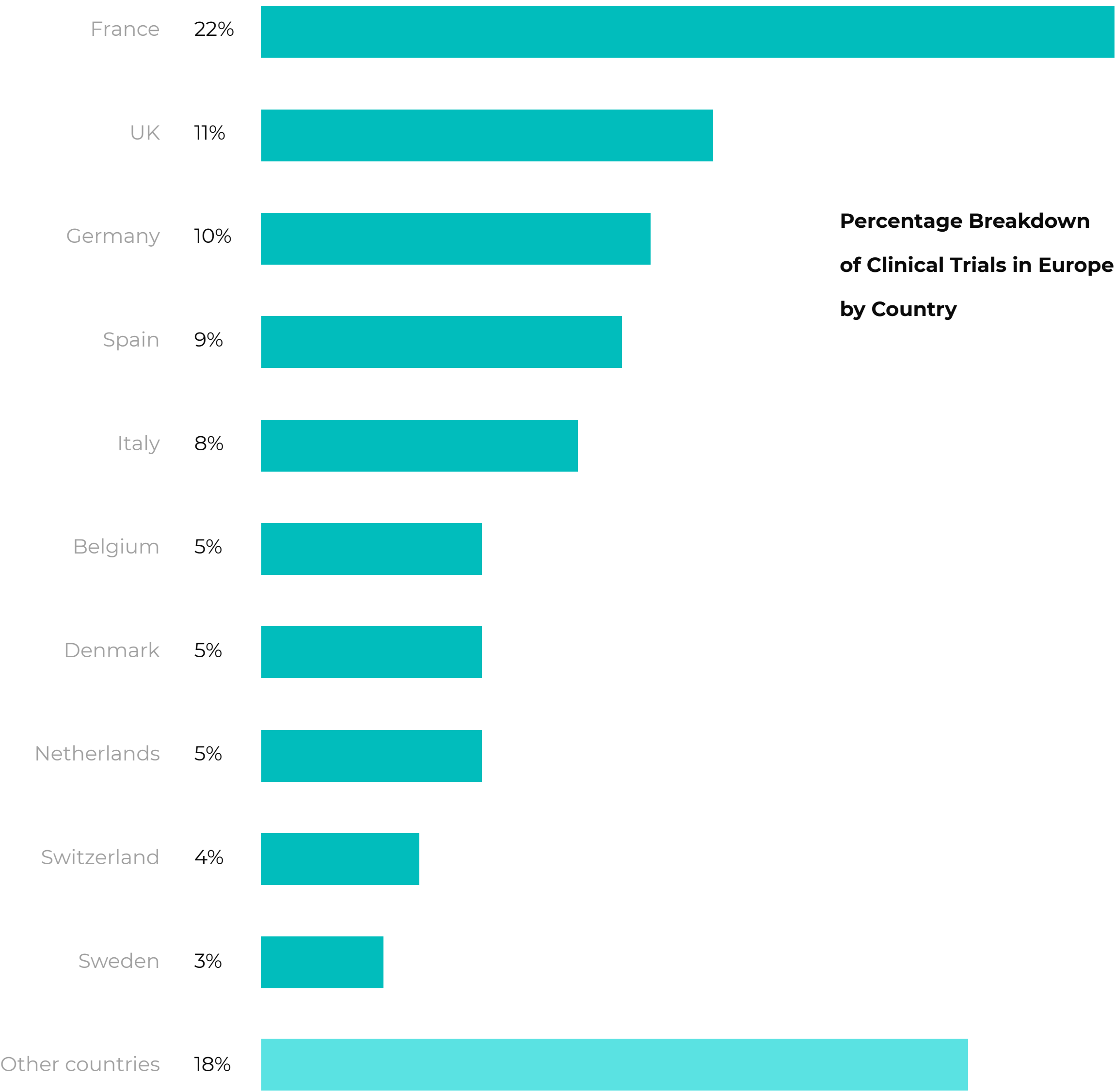


Clinical Trials in Europe

Trial Data

According to U.S. FDA data, 2,255 clinical trials were initiated in 28 European Union countries, Switzerland and Norway during Q1 2019, including local and bioequivalence studies with an overall year on year decrease of 28,8%.

The leading countries by the number of clinical trials initiated in Q1 2019 were France, UK, Germany, Spain, Italy, Belgium and Denmark.



Clinical Trials in Europe

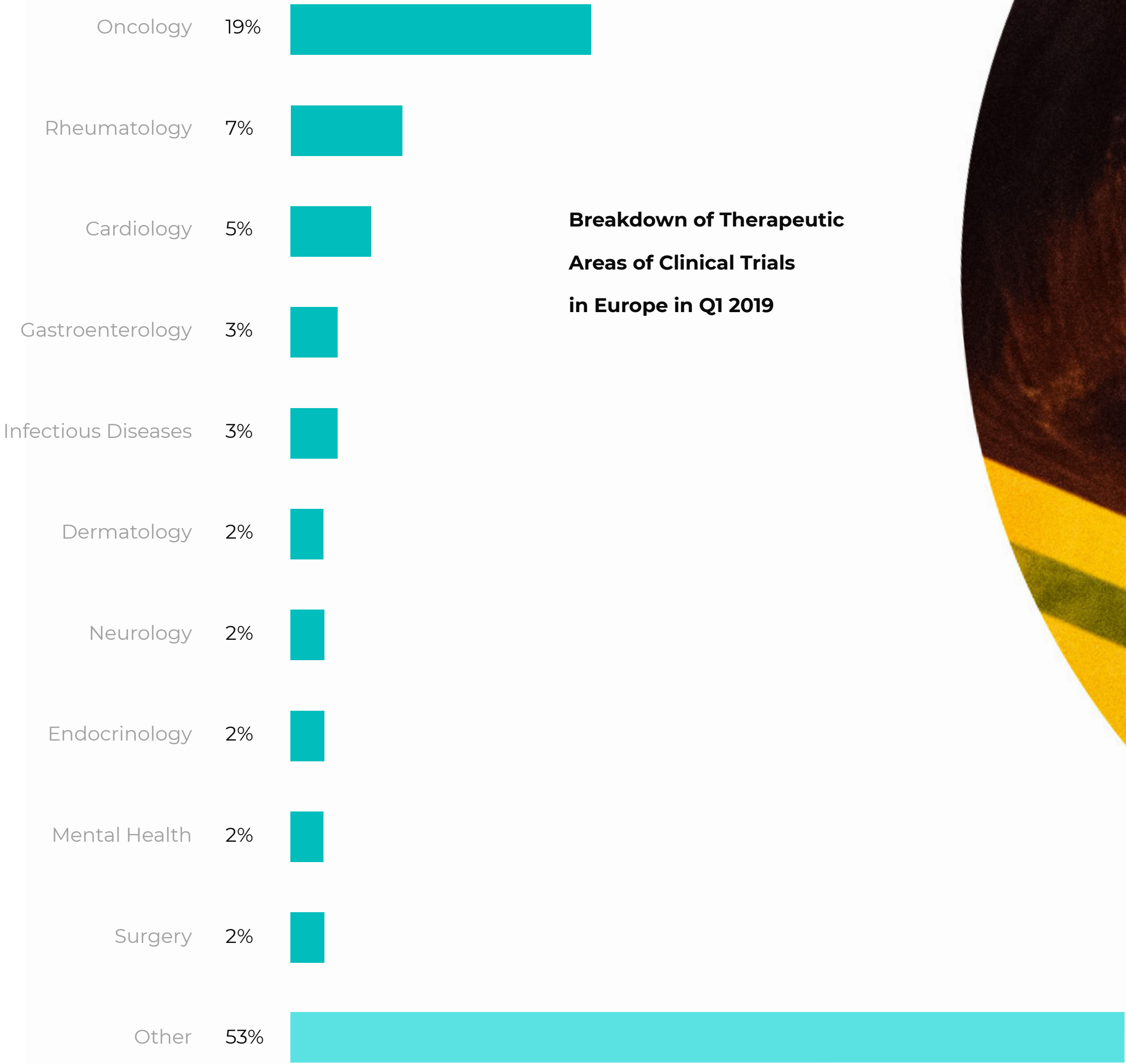
Trial Data

The largest number of Clinical trials initiated in 28 European Union countries, Switzerland and Norway in Q1 2019 were related to Oncology (325 studies), Rheumatology (114 studies) and Cardiology (86 studies).

Other popular areas included Gastroenterology, Infectious diseases, Dermatology and Neurology.



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Clinical Trials in Europe

Sponsor Data



Top-10 Sponsors of Clinical trials in Europe in Q1 2019

Nº	Company Name	No. studies *
1	AbbVie	85
2	Janssen	51
3	AstraZeneca	47
4	Hoffmann-La Roche	40
5	Merck	31
6	Novartis	20
7	Boehringer Ingelheim	15
8	Eli Lilly	15
9	Celgene	14
10	Takeda	10

Combined market share of these companies **15%**

* A single Clinical study may have multiple Sponsors , each operating in a number of countries. If a study spans multiple countries for a particular sponsor, that study counts as several separate projects, one for every country.

Observational Clinical trials and Clinical trials without FDA-defined phases (from I to IV) were not counted in this ranking.

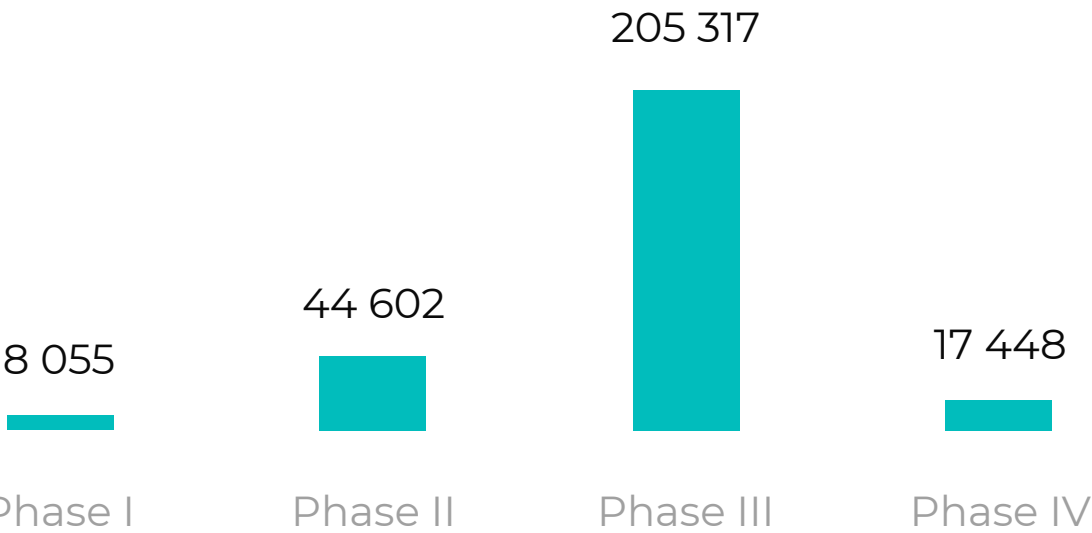
Clinical Trials in Europe

Subject Data

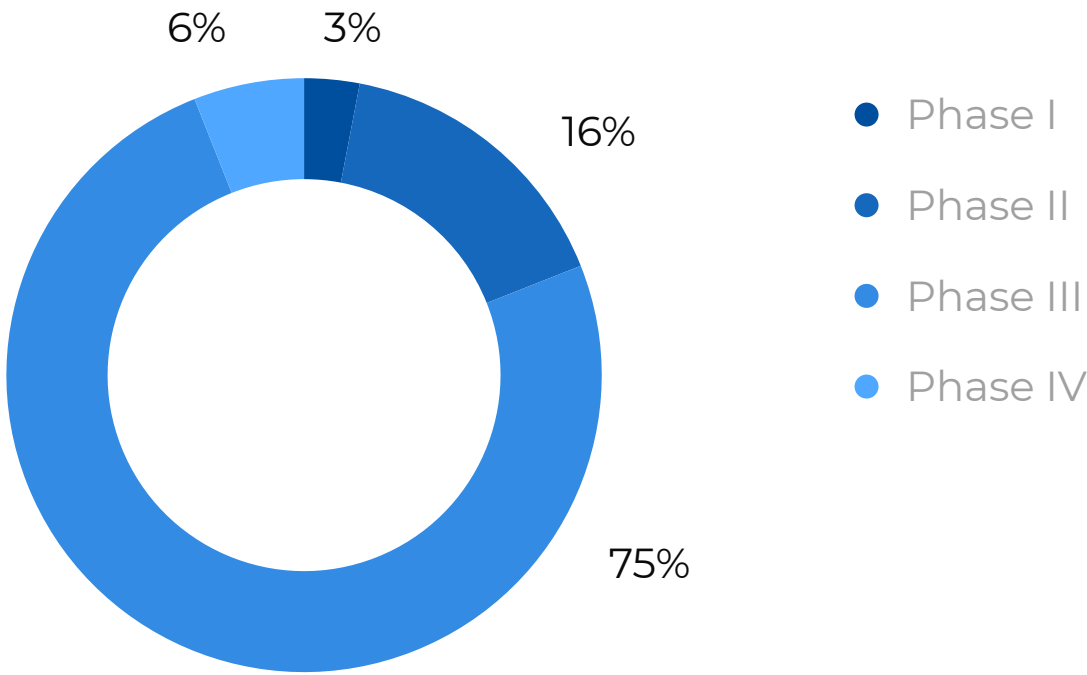
Overall the total number of subjects involved in Clinical trials initiated in 28 European Union countries, Switzerland and Norway in Q1 2019 amounted to 275,422 subjects.

The dominant phase by total number of subjects enrolled during Q1 2019 was Phase III.

Breakdown of Number of Subjects Enrolled in European Clinical Trials by Phase



Percentage Breakdown of Subjects Enrolled in European Clinical Trials by Phase



European Regulatory data

In Q1 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 17 new drugs, including 2 generics, 2 biosimilar and 3 orphan medicines.

Five drugs received negative opinions and as such 12 drugs received positive opinions and were approved for marketing.

Nº	Appr. date	Drug (active ingredient)	Company
1	01.31.2019	Atazanavir (Atazanavir)	KRKA
2	01.31.2019	Kromeya (Adalimumab)	Fresenius Kabi Deutschland
3	01.31.2019	Idacio (Adalimumab)	Fresenius Kabi Deutschland
4	01.31.2019	Vizimpro (Dacomitinib)	Pfizer
5	02.28.2019	Palynziq (Pegvaliase)	BioMarin International
6	02.28.2019	Dectova (Zanamivir)	GlaxoSmithKline
7	02.28.2019	Zynquista (Sotagliflozin)	Sanofi
8	02.28.2019	Ondexxya (Andexanet Alfa)	Portola Pharmaceuticals
9	02.28.2019	Waylivra (Volanesorsen)	Akcea Therapeutics
10	03.01.2019	Lorviqua (Lorlatinib)	Pfizer
11	03.01.2019	Pazenir (Paclitaxel)	Teva Pharmaceutical Industries
12	03.01.2019	Zynteglo (Autologous CD34+ Cell Enriched Population)	Bluebird Bio

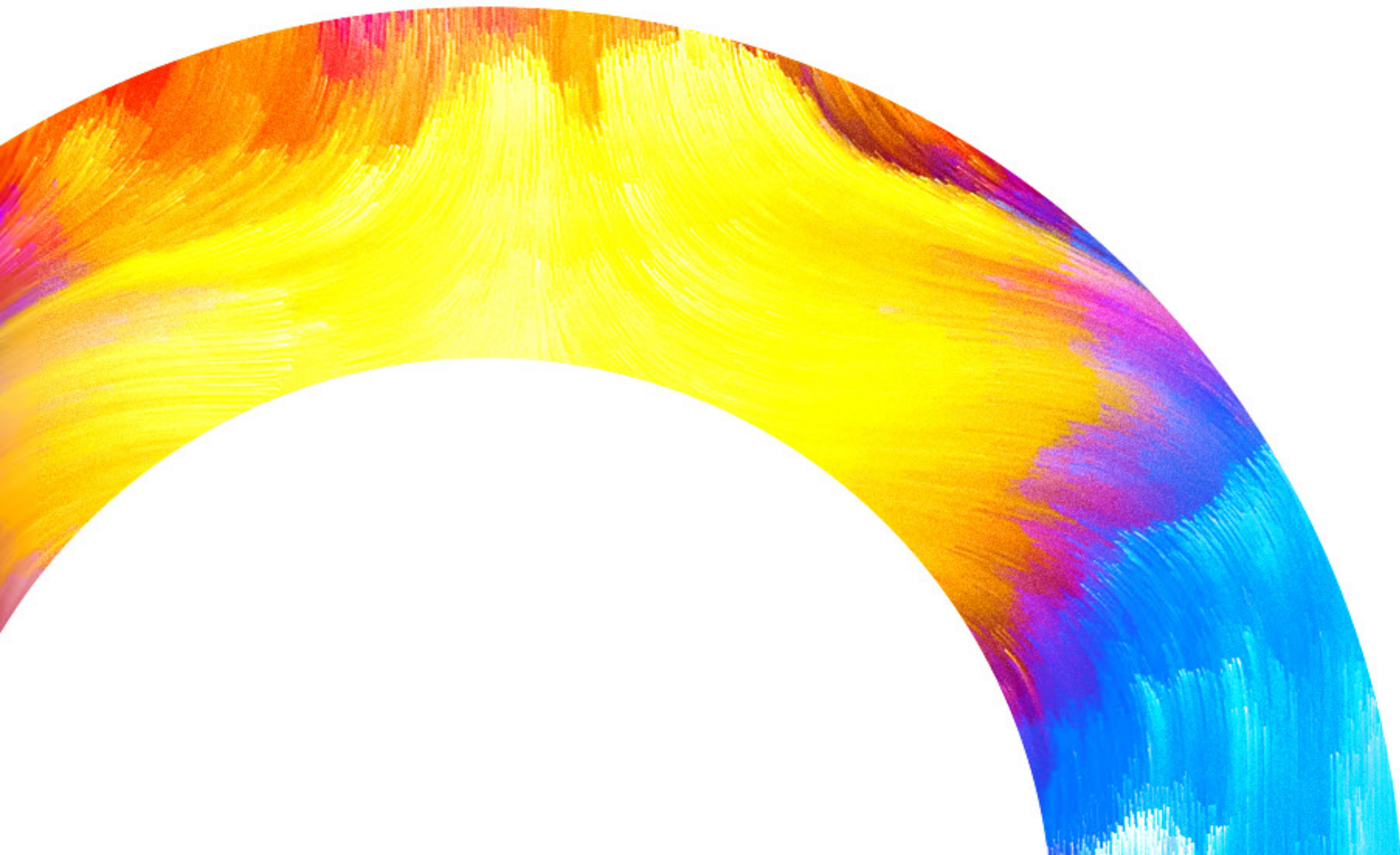
Source: EMA

European Inspection Data

According to U.S. FDA data, 3 FDA inspections were conducted at investigative sites located in European countries in Q1 2019. Two inspections were carried out in UK and one inspection was performed in France. All three inspections ended with No Action Indicated (NAI) outcomes.

Nº	Country	Company / Investigator Site Firm Name	Company
1	France	Yohann Lorient, M.D.	NAI
2	UK	Hendrik-Tobias Arkenau	NAI
3	UK	Was Mansoor, M.D.	NAI

Source: FDA



About Synergy

Synergy Research Group is a contract research organization successfully operating in Russia, Kazakhstan, Ukraine and Canada since 2002.

The high recruitment rates of the emerging markets combined with innovative technology allows Synergy to our clients conduct faster, more cost-effective studies without sacrificing quality for our clients.

We have replaced outdated R&D strategies by novel, more efficient approaches to clinical research.



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