

Synergy orange paper / 2019 summer / quarter 2



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: 01/07/2019



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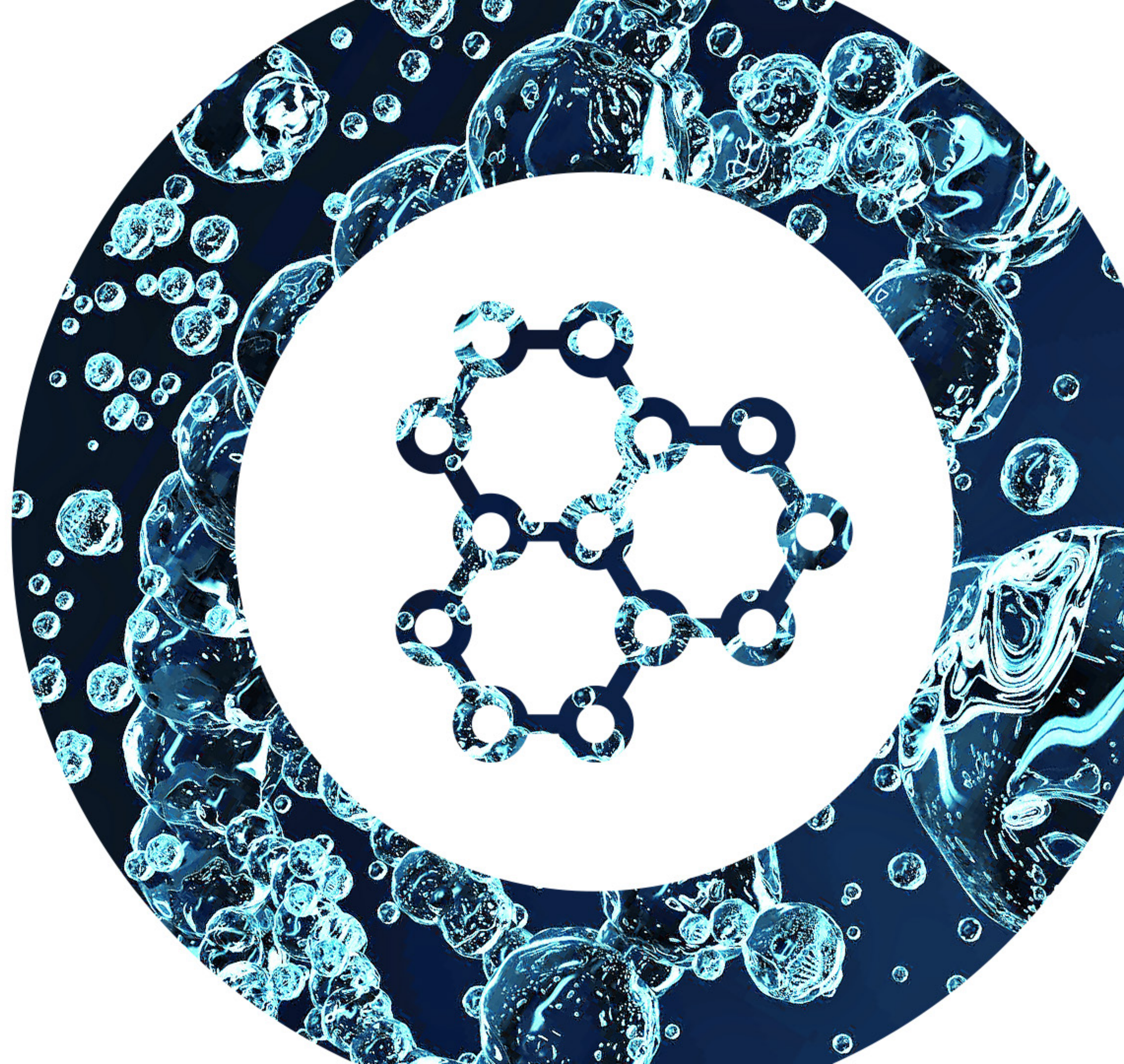


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Executive Summary

During Q2 2019 the official FDA website showed approvals for the initiation of 6,905 new clinical trials of all types worldwide, including local and bioequivalence studies. Of these, 2,144 were initiated in 28 European Union countries, as well as Switzerland and Norway. This represents an overall year on year decline of 32.6%

Interventional clinical trials are the dominant type of research with 81% market share worldwide, 77% 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 accounted for 16% of total number of studies conducted in Q2 2019. In comparison, in the U.S. the top-10 Sponsors combined accounted for exactly the same market share.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 21 new drugs, including 2 generics, 1 biosimilar and 1 orphan medicines. 18 of these drugs received positive opinions and were approved to marketing.

In Q2 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 U.S. FDA data, 9 FDA inspections were conducted across U.S. investigative sites whilst 3 FDA inspections were conducted across investigative sites located in Belgium, France and Czech Republic (1 inspection each) during Q2 2019.



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Section 1

Global Clinical Trials

Trial Data

During Q2 2019 the official FDA website showed approvals for initiation of 6,905 new clinical trials of all types worldwide, including local and bioequivalence studies with an overall year on year growth rate of 12% driven in large by an increasing number of trials in developing countries.

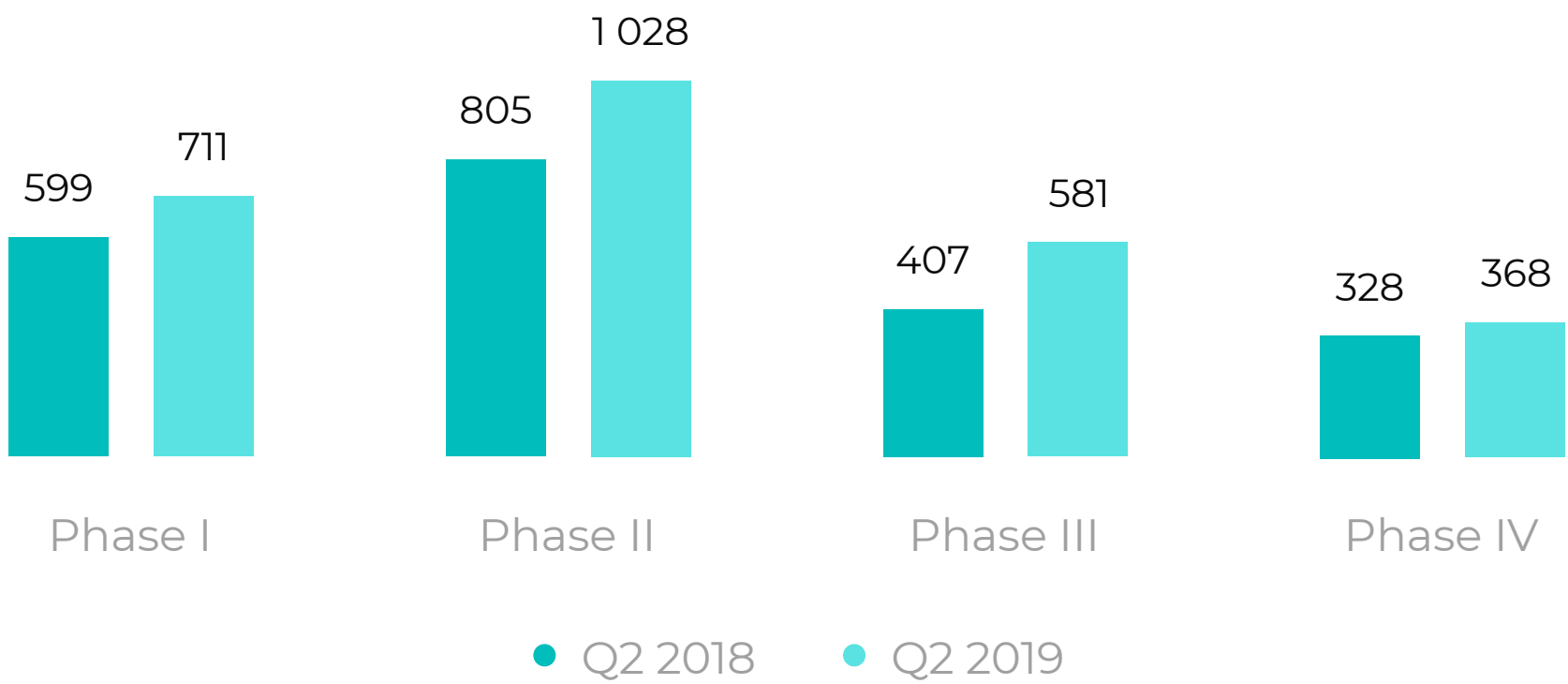
The combined market share of the U.S. and European countries by number of global initiated studies plunged from 88% in Q2 2018 to 63% in Q2 2019, with the U.S. having 32% and Europe having 31%.

81% of all global clinical trials initiated in Q2 2019 were Interventional Clinical Trials.

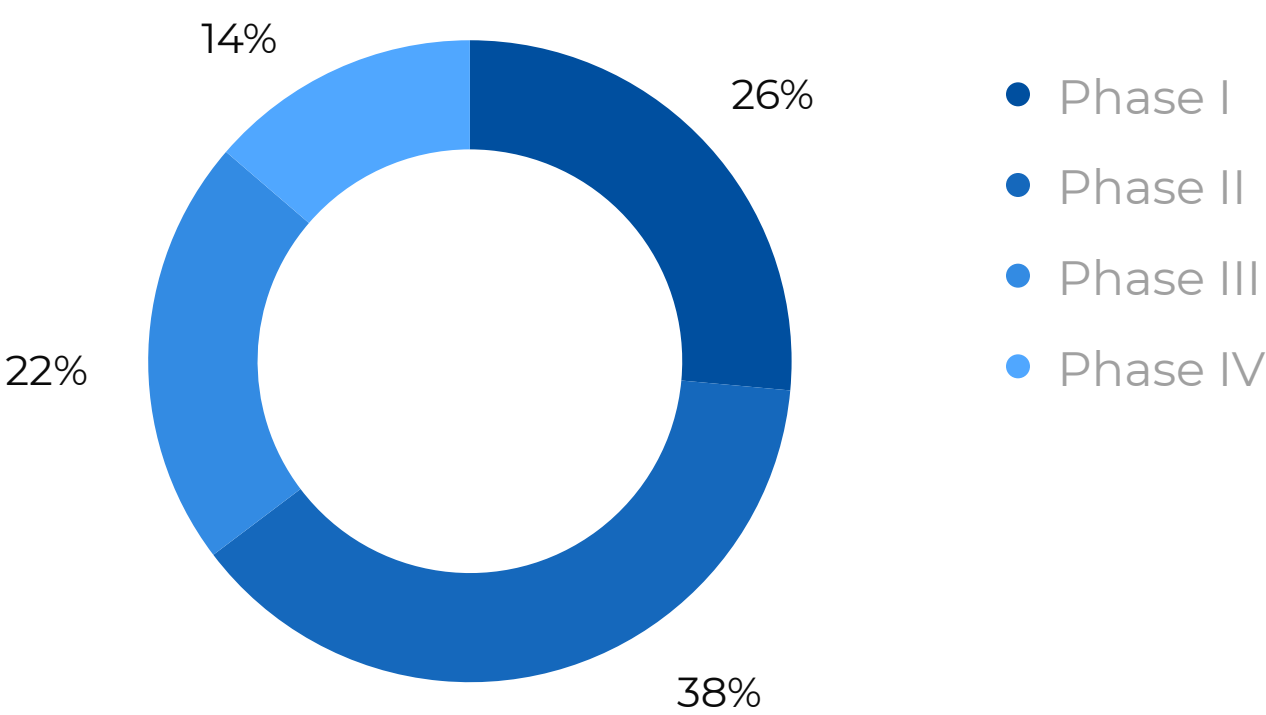


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Breakdown of Clinical trials by Phase



Percentage breakdown of global clinical trials by Phase

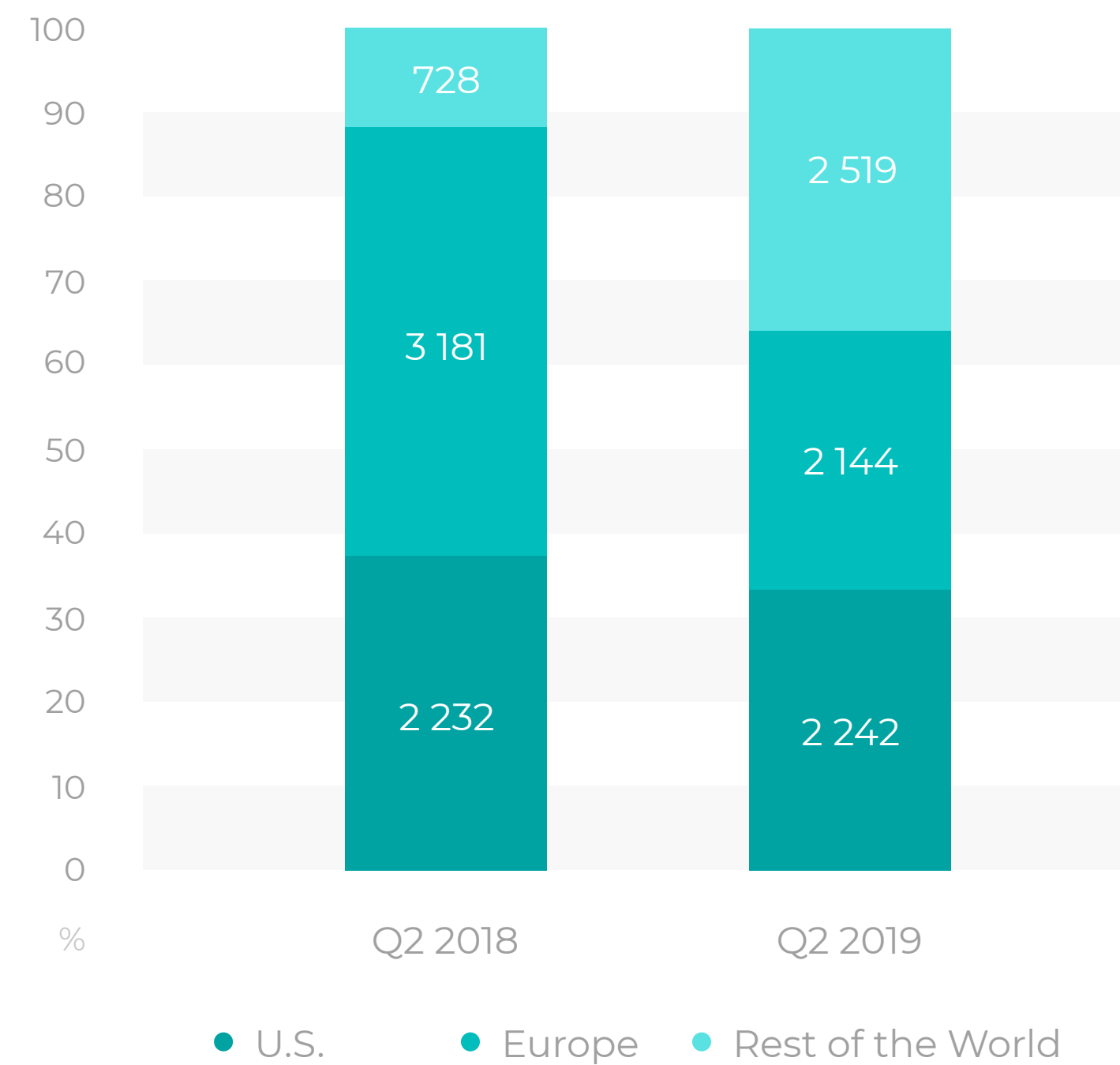
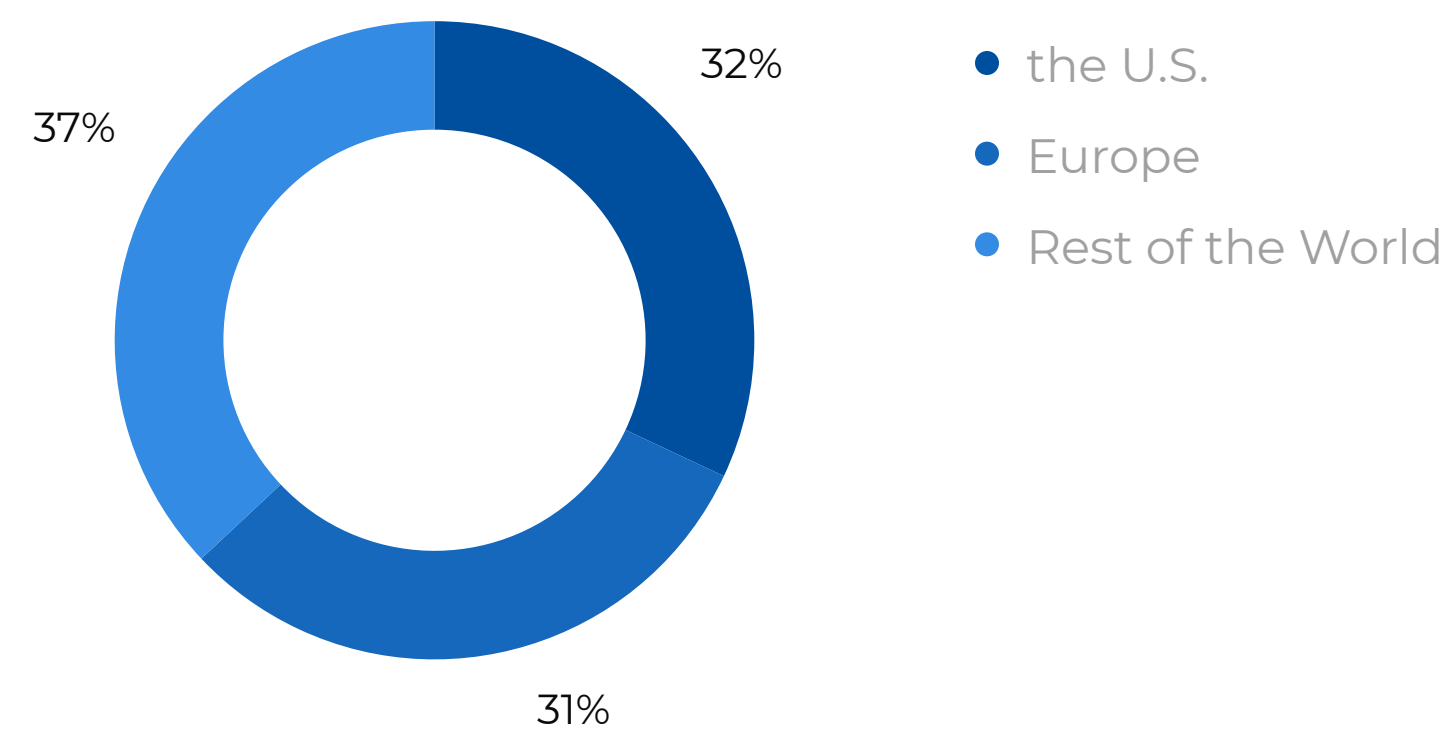


Trial Data

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 Q2 2019 changed in comparison to Q2 2018. Notably, the market share of leading European countries by number of initiated studies dropped from 52% to 31% in Q2 2019.

Percentage Breakdown of Global Clinical Trials by Region

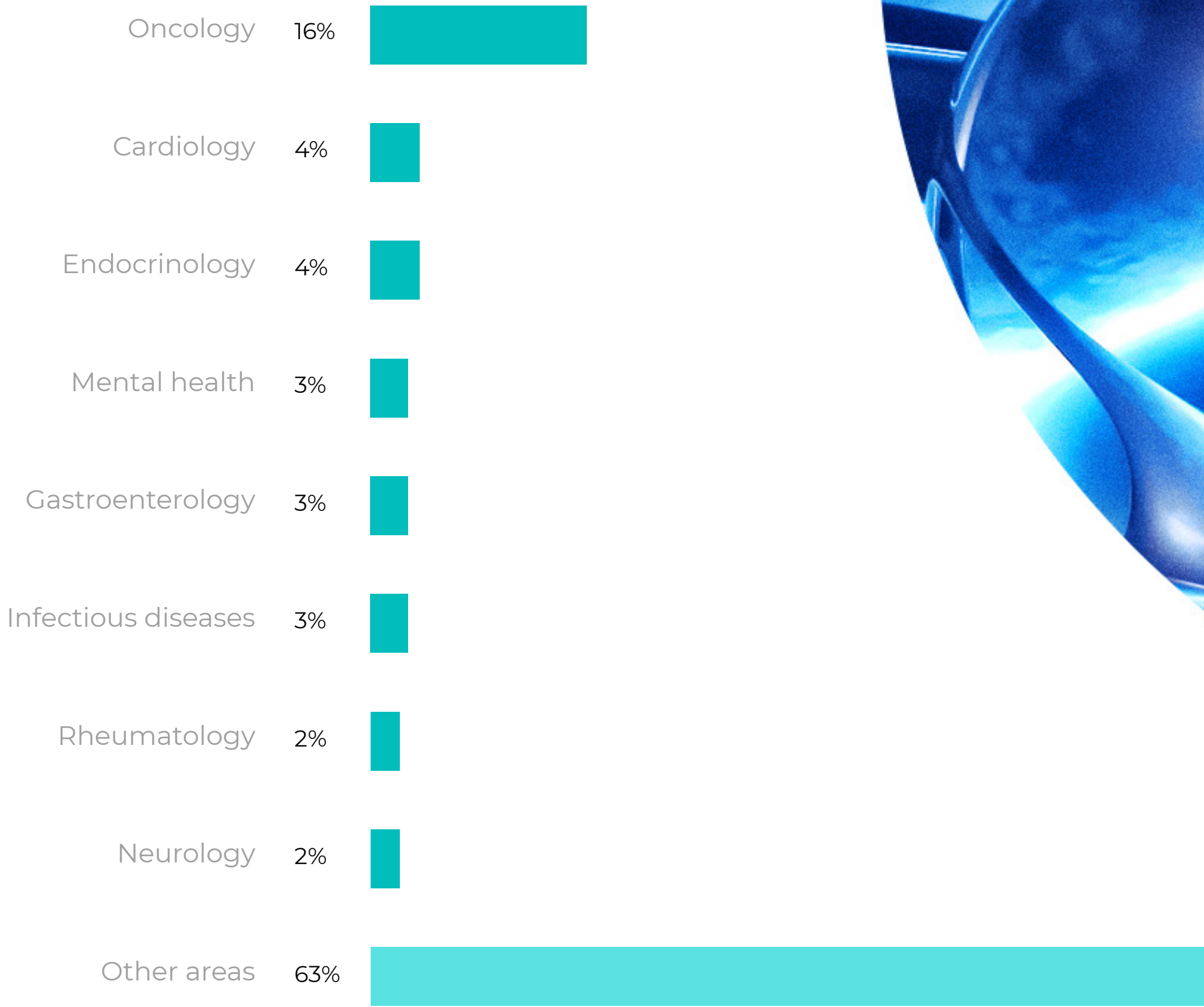


Trial Data

Therapeutic Areas of Global Clinical Trials

In Q2 2019 the largest number of studies were initiated in Oncology (1,115 studies), Cardiology (288 studies), Endocrinology (249 studies) and Mental health (240 studies).

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



Global Clinical Trials

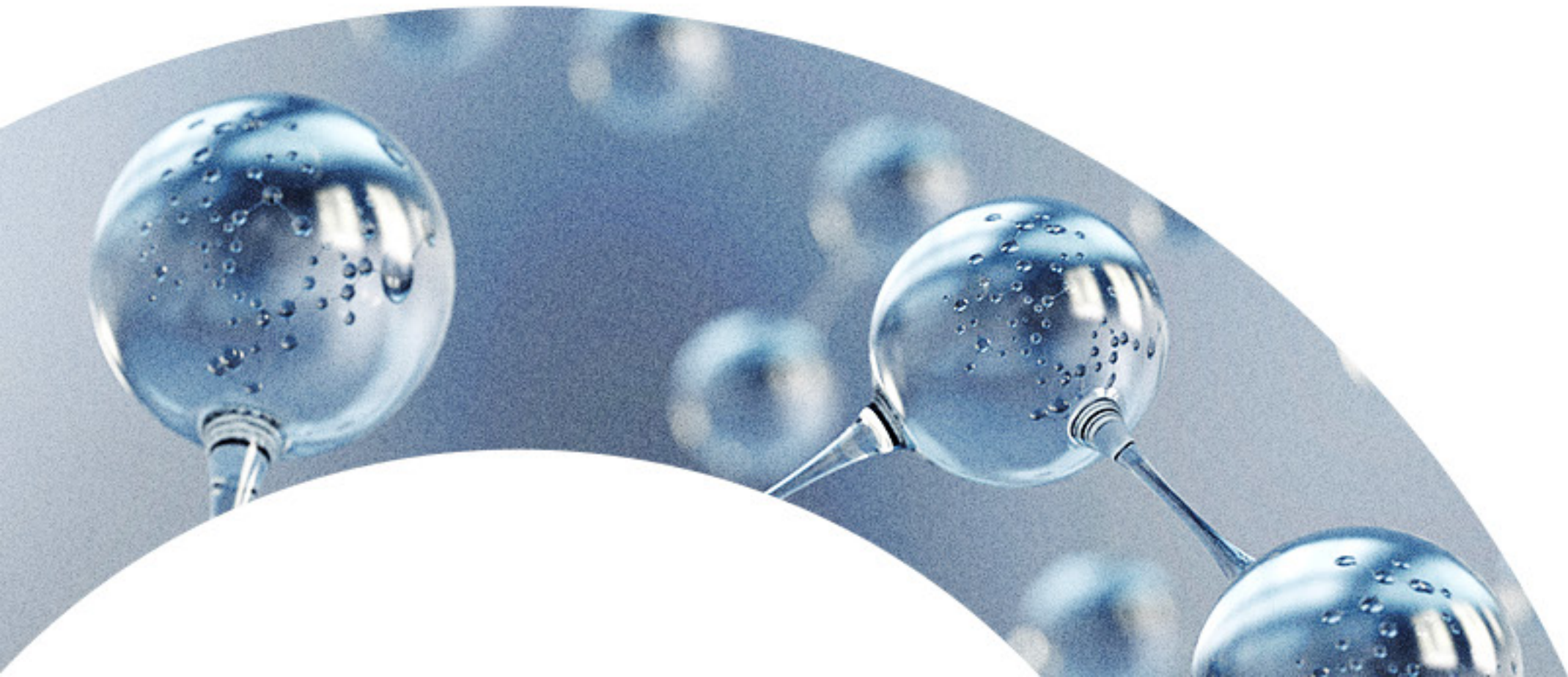
Sponsor Data

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 13% of all interventional clinical trials where the study Phase has been identified, and just 6% of all enrolled subjects.

Top-10 Global Sponsors by Total Number of Studies Initiated in Q2 2019

Nº	Company Name	No. studies	No. subjects
1	Merck	65	24 815
2	Bristol-Myers Squibb	45	5 429
3	AstraZeneca	41	5 834
4	Pfizer	35	4 216
5	Novartis	35	5 701
6	Eli Lilly	34	13 078
7	Janssen	25	9 299
8	AbbVie	22	2 479
9	Amgen	21	16 657
10	Boehringer Ingelheim	18	1 615
Combined market share of top-10 companies		13%	6%



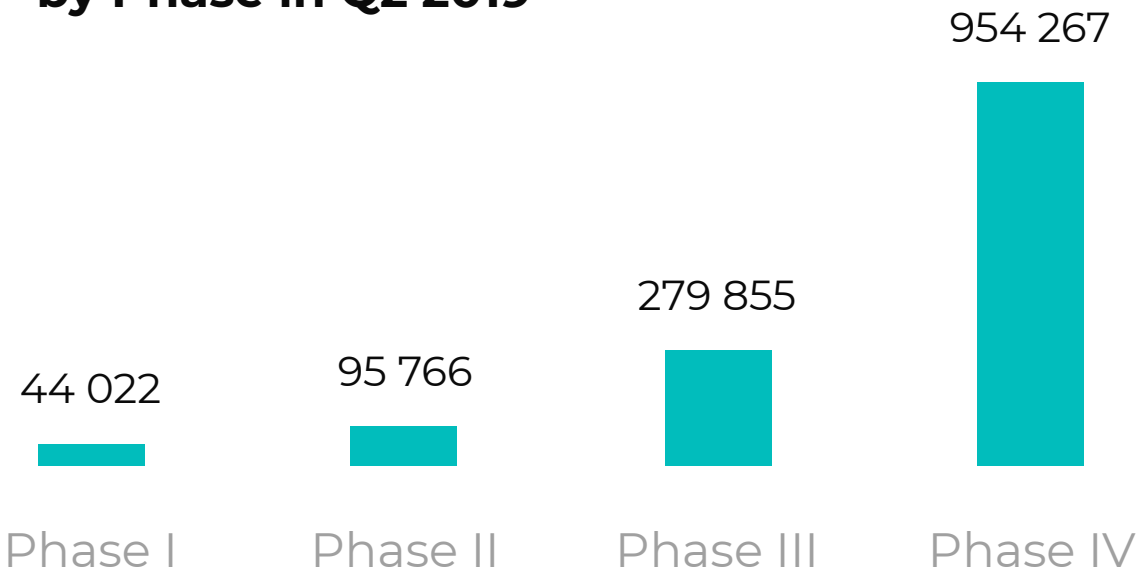
Global Clinical Trials

Subject Data

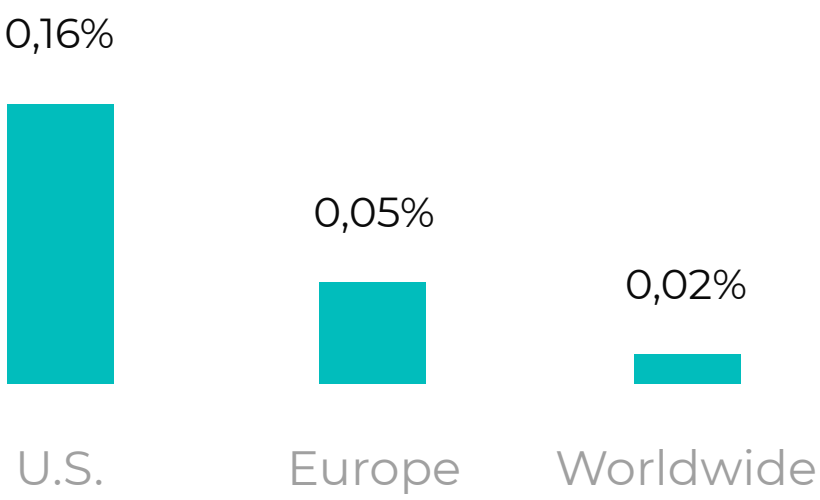
The total number of subjects enrolled in Clinical trials of all types in Q2 2019 reached 1,373,910 subjects.

The majority of subjects were (or planned to be) enrolled in Phase IV trials, and the largest proportion of the global subject population were from the U.S. However, the share of subjects participating in clinical trials remains extremely low in comparison with overall size of the population – with approximately 0.02% Worldwide.

Number of Subjects Enrolled Worldwide
by Phase in Q2 2019



Breakdown of Number of Subjects
Enrolled as a % of Population



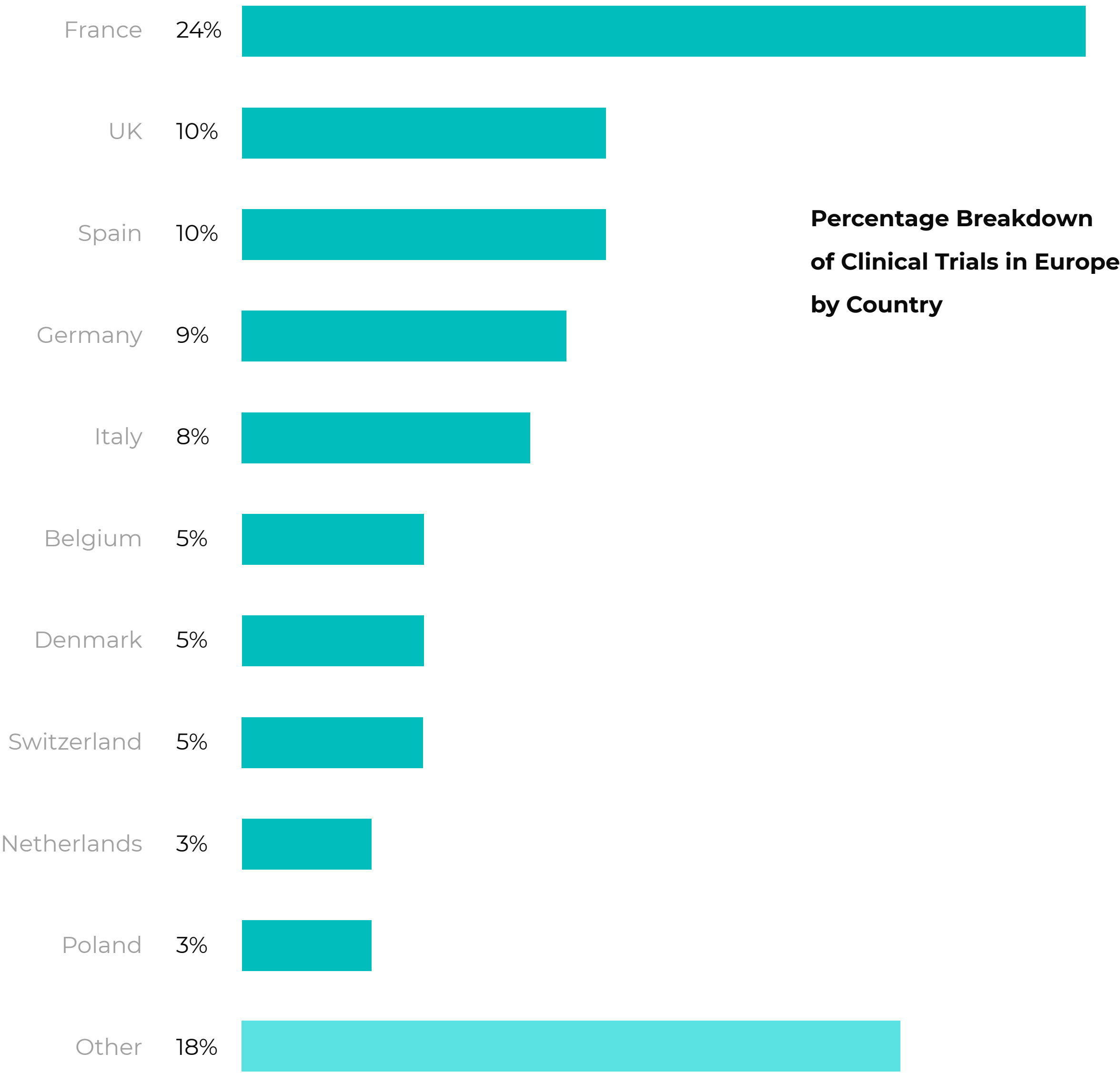
Section 2

Clinical Trials in Europe

Trial Data

According to U.S. FDA data, 2,144 clinical trials were initiated in 28 European Union countries, as well as Switzerland and Norway during Q2 2019, including local and bioequivalence studies with an overall year on year decline of 32.6%

The leading countries by the number of clinical trials initiated in Q2 2019 were France, UK, Spain, Germany, Italy, Belgium, Denmark, Switzerland, Netherlands.



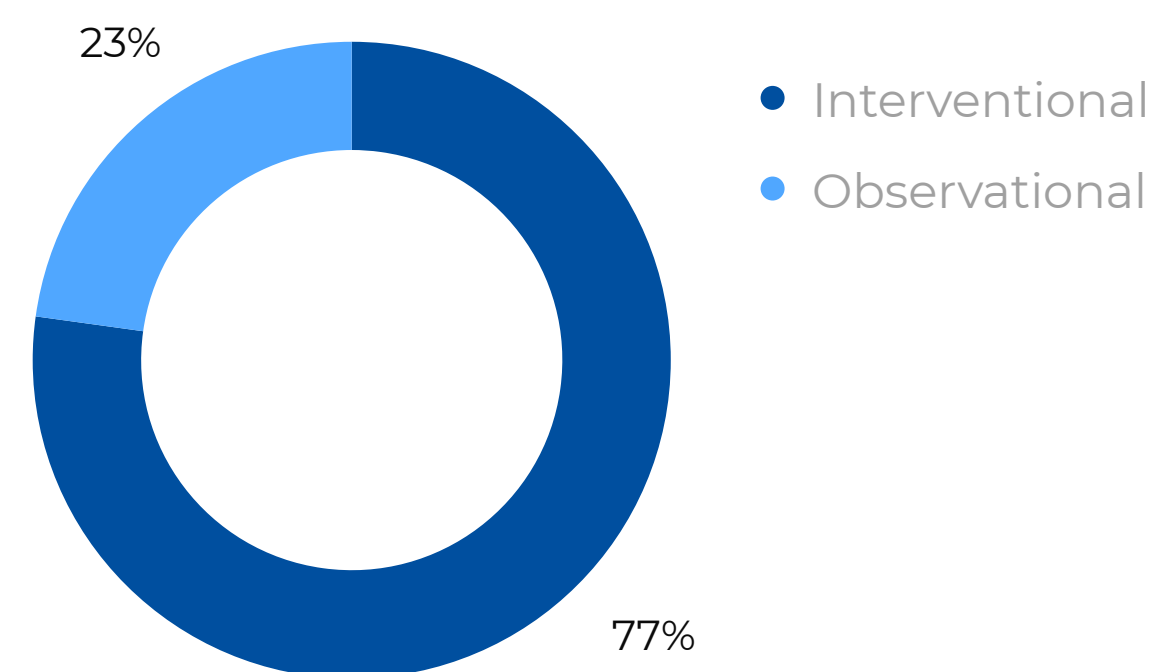
Clinical Trials in Europe

Trial Data

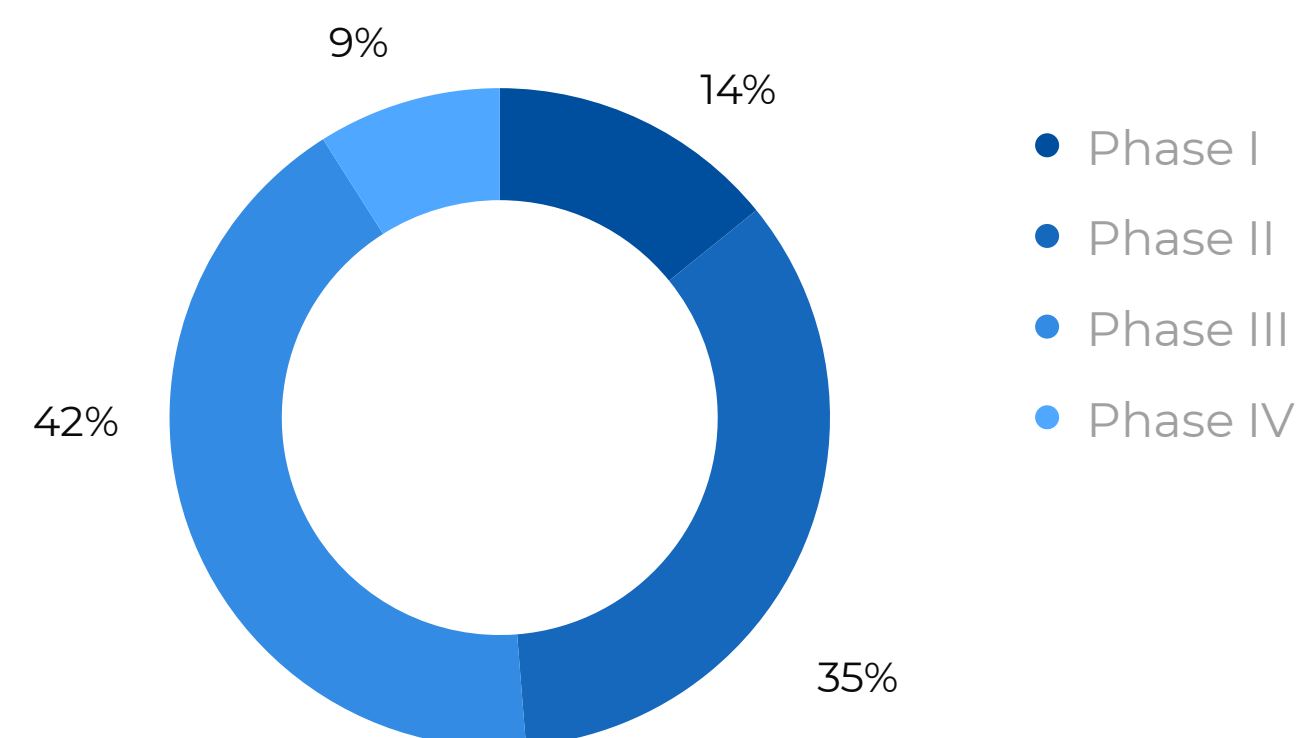
The most prevalent type of clinical trials conducted across European sites were Interventional studies.

The most frequent phase of clinical trials conducted across European sites by total number of studies was Phase III.

Interventional vs. Observational Clinical Trials in Europe in Q2 2019



Percentage breakdown of Clinical Trials in Europe in Q2 2019 by Phase

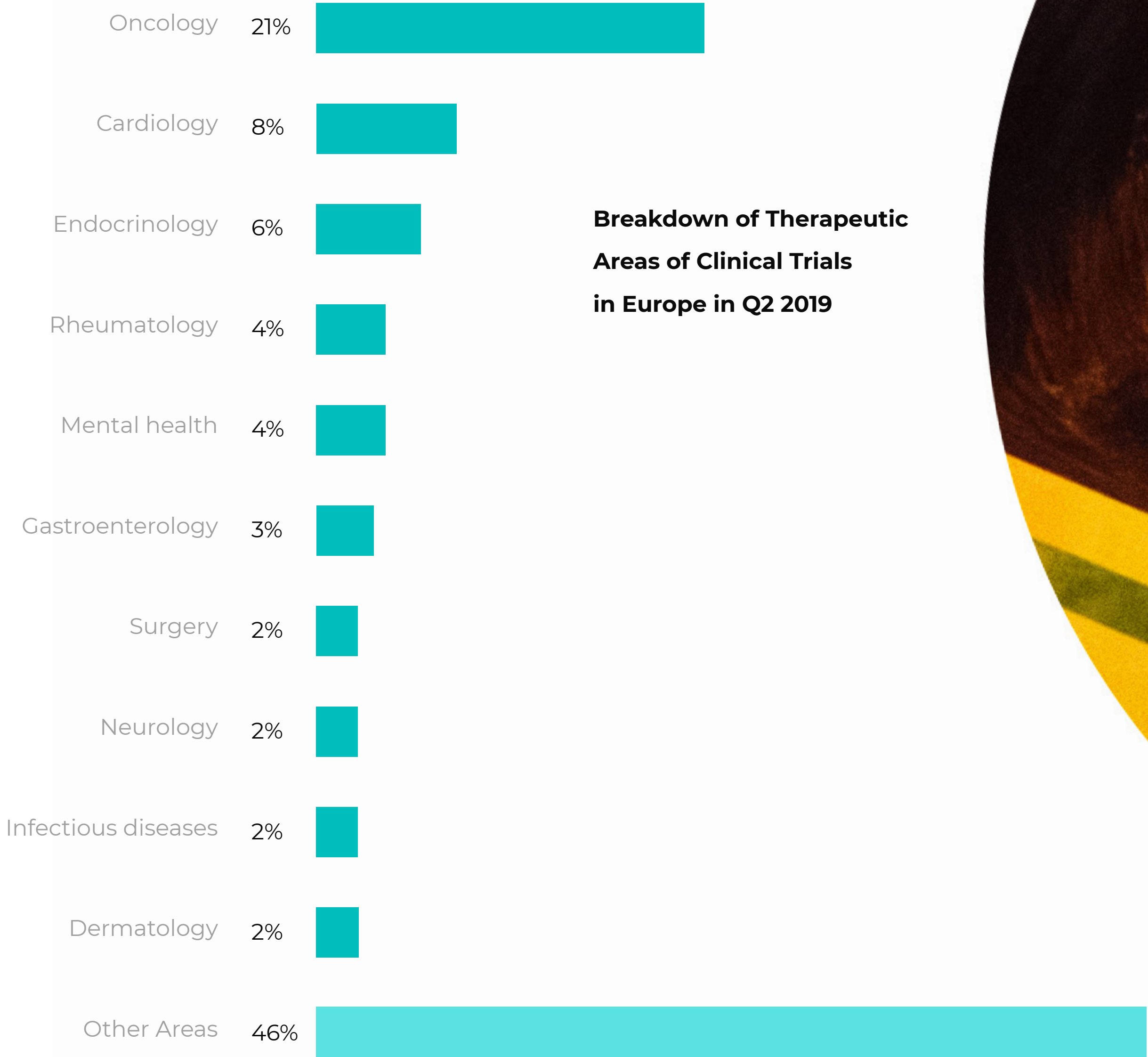


Clinical Trials in Europe

Trial Data

The largest number of Clinical trials initiated in 28 European Union countries, as well as Switzerland and Norway in Q2 2019 were related to Oncology (353 studies), Cardiology (127 studies) and Endocrinology (93 studies).

Other prominent therapy areas included Rheumatology, Mental health, Gastroenterology, Surgery and Neurology.



Clinical Trials in Europe

Sponsor Data



Top-10 Sponsors
of Clinical trials
in Europe in Q2 2019

Nº	Company Name	No. studies *
1	Eli Lilly	82
2	Janssen	46
3	Novo Nordisk	42
4	Merck	40
5	AstraZeneca	40
6	Novartis	25
7	Amgen	22
8	Bristol-Myers	22
9	Hoffmann-La Roche	18
10	Bayer	14

Combined market share of these companies **16%**

* 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



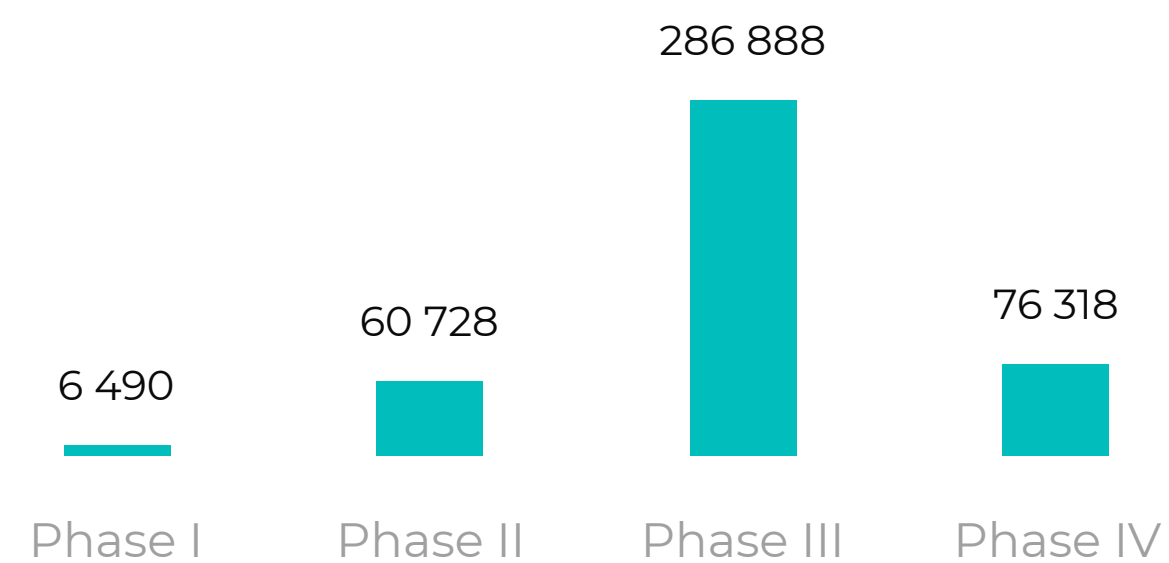
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Subject Data

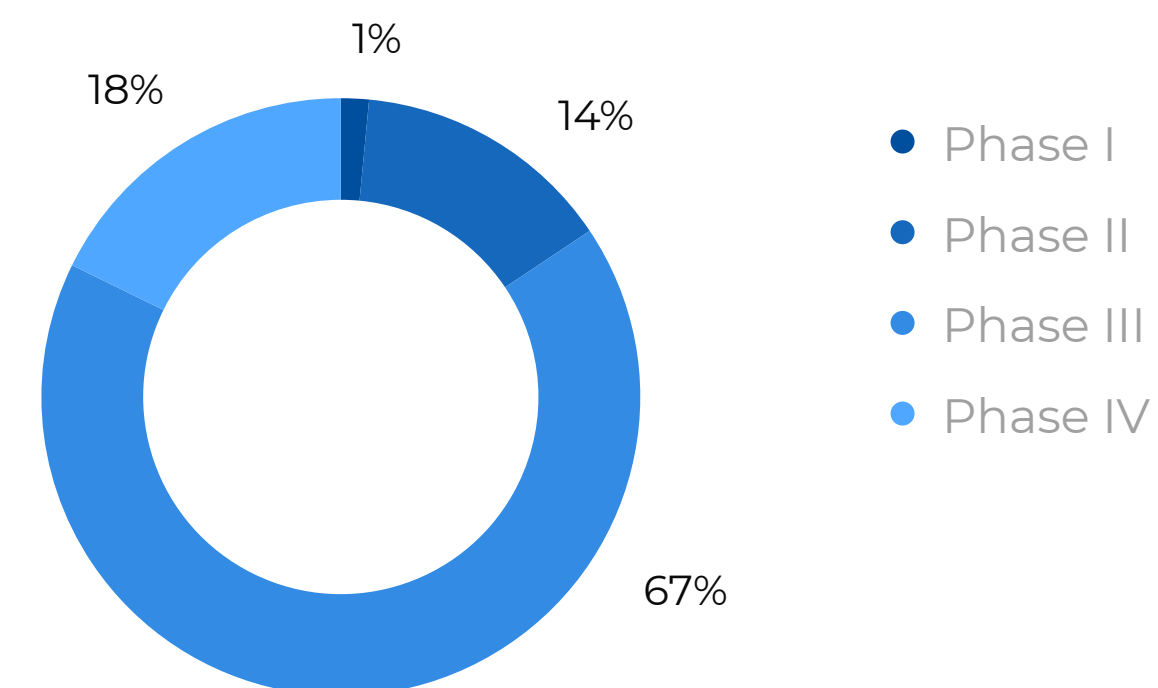
Overall the total number of subjects involved in Clinical trials initiated in 28 European Union countries, as well as Switzerland and Norway in Q2 2019 amounted to 430,424 subjects

The dominant phase by total number of subjects enrolled during Q2 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 Q2 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 21 new drugs, including 2 generics, 1 biosimilar and 1 orphan medicines.

Three drugs received negative opinions and as such 18 drugs received positive opinions and were approved for marketing.

Nº	Appr. date	Drug (active ingredient)	Company
1	26.04.2019	Grasustek (Pegfilgrastim)	Juta Pharma
2	26.04.2019	Ambrisentan (Ambrisentan)	Mylan
3	26.04.2019	Talzenna (Talazoparib)	Pfizer
4	26.04.2019	Nuceiva (Botulinum toxin Type A)	Evolus Pharma
5	26.04.2019	Sixmo (Buprenorphine Hydrochloride)	L. Molteni & C. dei Fratelli Alitti Società di Esercizio

Source: EMA

Nº	Appr. date	Drug (active ingredient)	Company
6	29.05.2019	Ultomiris (Ravulizumab)	Alexion
7	29.05.2019	Temybric Ellipta (Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate)	GlaxoSmithKline
8	26.04.2019	Libtayo (Cemiplimab)	Regeneron
9	26.04.2019	Striascan (Ioflupane (123i))	CIS Bio International
10	26.04.2019	Xromi (Hydroxycarbamide)	Nova Laboratories
11	26.04.2019	Dovato (Dolutegravir Sodium; Lamivudine)	ViiV Healthcare
12	29.05.2019	LysaKare (L-Arginine Hydrochloride/ L-Lysine Hydrochloride)	Advanced Accelerator Applications
13	29.05.2019	Posaconazole AHCL (Posaconazole)	Accord Healthcare
14	29.05.2019	Posaconazole (Posaconazole)	Accord Healthcare
15	29.05.2019	Cufence (Trientine Dihydrochloride)	Univar
16	27.06.2019	Giapreza (Angiotensin II Acetate)	La Jolla Pharmaceutical
17	27.06.2019	Azacitidine (Azacitidine)	Celgene
18	27.06.2019	Lacosamide (Lacosamide)	UCB Pharma

Source: EMA

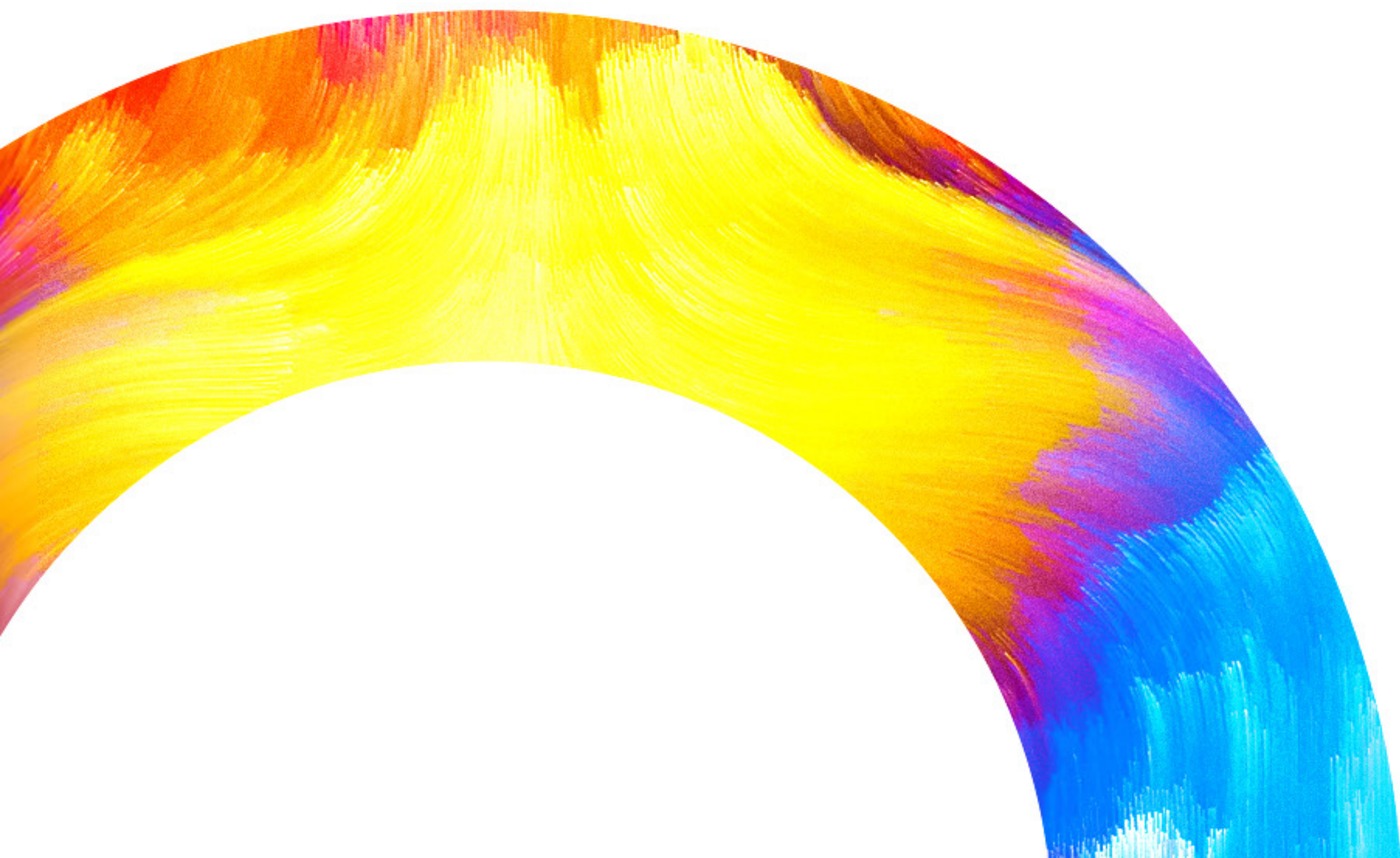
European Inspection Data

According to U.S. FDA data, 3 FDA inspections were conducted at investigative sites located in European countries in Q2 2019. One inspection was carried out in Belgium, one inspection was executed in Czech Republic, and one inspection was performed in France.

Two of three inspections ended with No Action Indicated (NAI) outcomes and one inspection resulted with a Voluntary Action Indicated (VAI) outcome.

Nº	Country	Company / Investigator Site Firm Name	Outcome
1	Belgium	Pfizer Clinical Research Unit, Hopital Erasme	NAI
2	Czech Republic	Jiri Vyhnal, MD	NAI
3	France	Laurent Servais, M.D., PhD.	VAI

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 offer 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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