

Synergy orange paper / 2019 spring / quarter 1



# Clinical trials in USA

Research report

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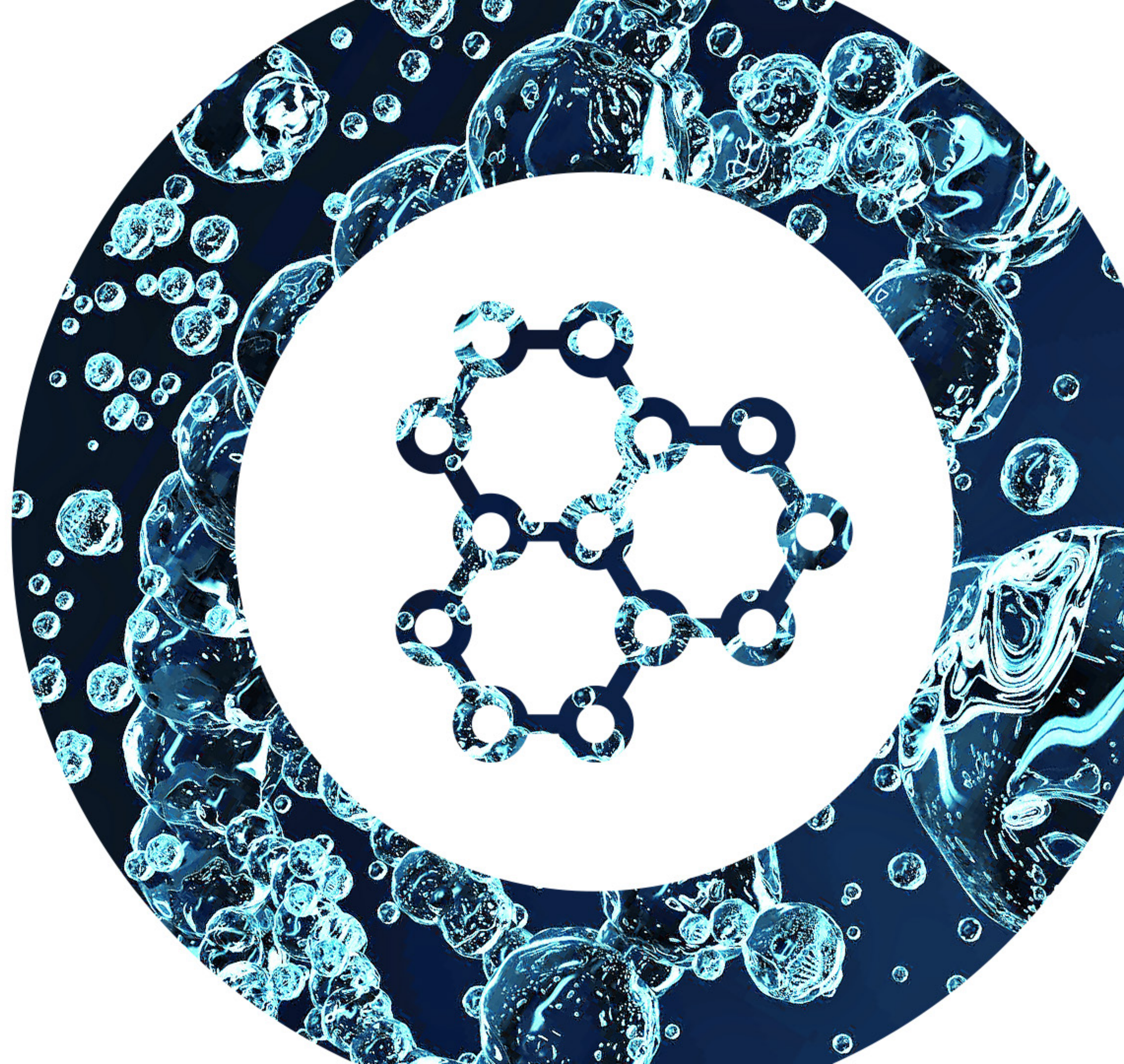
# Foreword

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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# 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. The number of studies initiated in the U.S. remained steady at 2,274 – a 0,5% increase in comparison with Q1 2018.

The dominant type of clinical trials conducted in Q1 2019 were Interventional Clinical trials with 81% market share worldwide and 89% market share in the U.S. The most prevalent phase of clinical trials conducted worldwide by number of studies was Phase II.

The total number of subjects enrolled in Clinical trials of all types in Q1 2019 reached 629 thousand of subjects. The most prevalent Therapeutic areas of Clinical trials were Oncology, Cardiology and Endocrinology.

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 U.S. FDA data, 32 FDA inspections were conducted across U.S. investigative sites whilst 3 FDA inspections were conducted across investigative sites located in UK (2 inspections) and France (1 inspection) during Q1 2019.



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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.

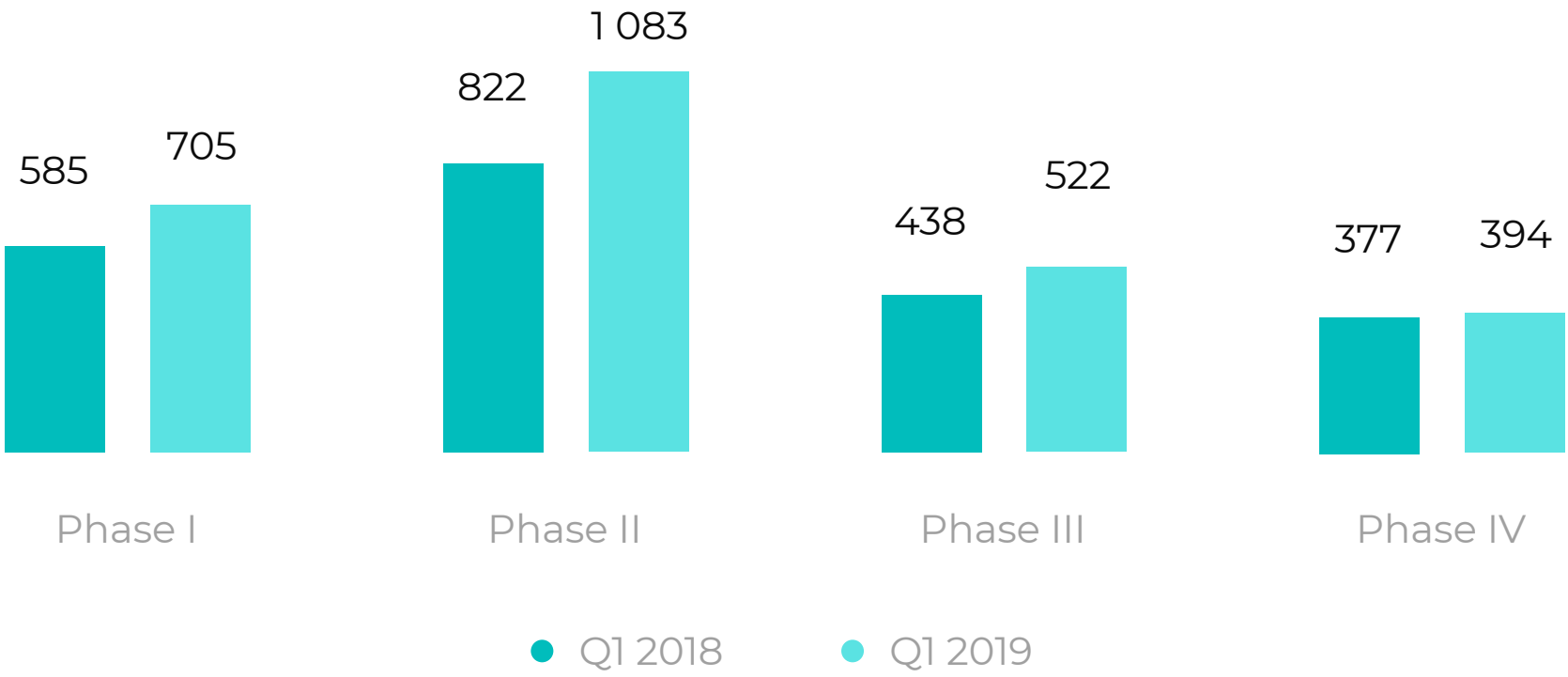
The combined market share of the U.S. and European countries by number of global initiated studies plunged to 63% in Q1 2019, with the U.S. having 32% and Europe having 31%.

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

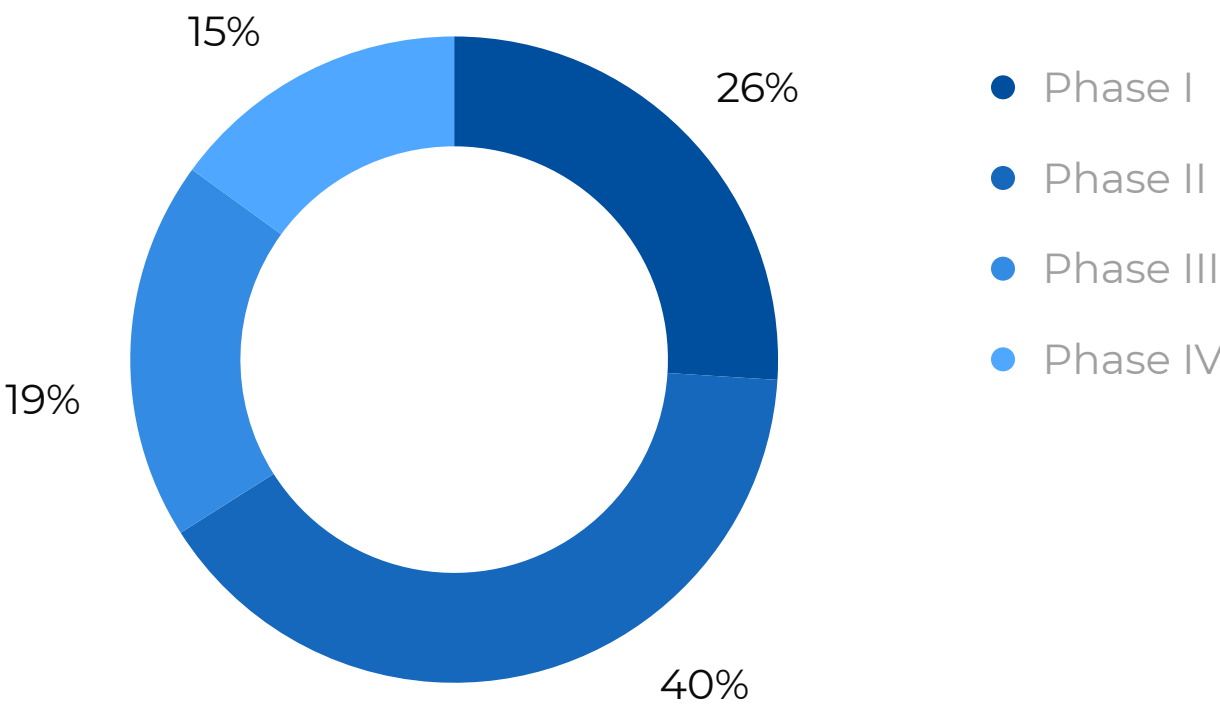


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Breakdown of Global Clinical Trials by Phase



Percentage Breakdown of Global Clinical Trials by Phase



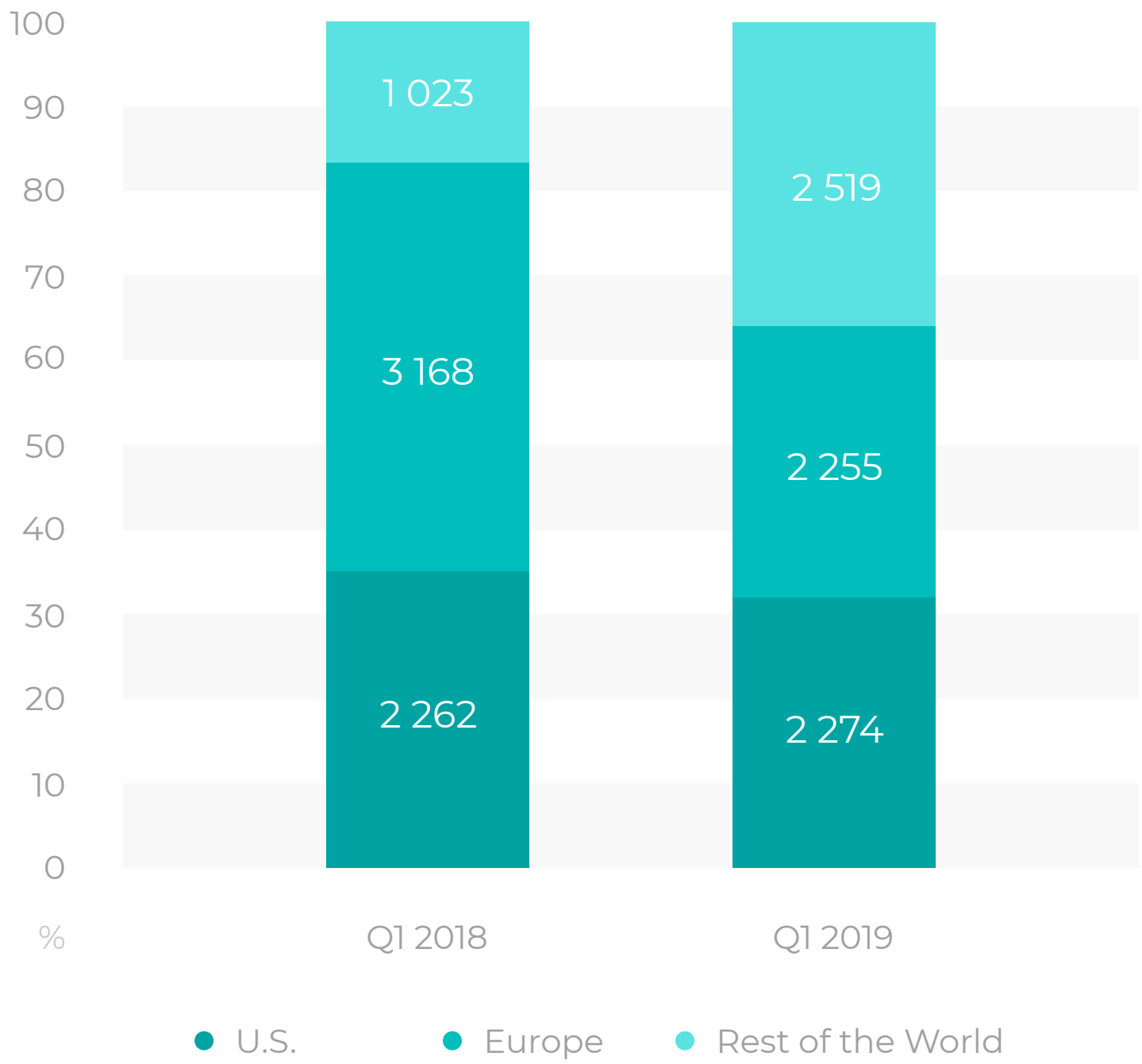
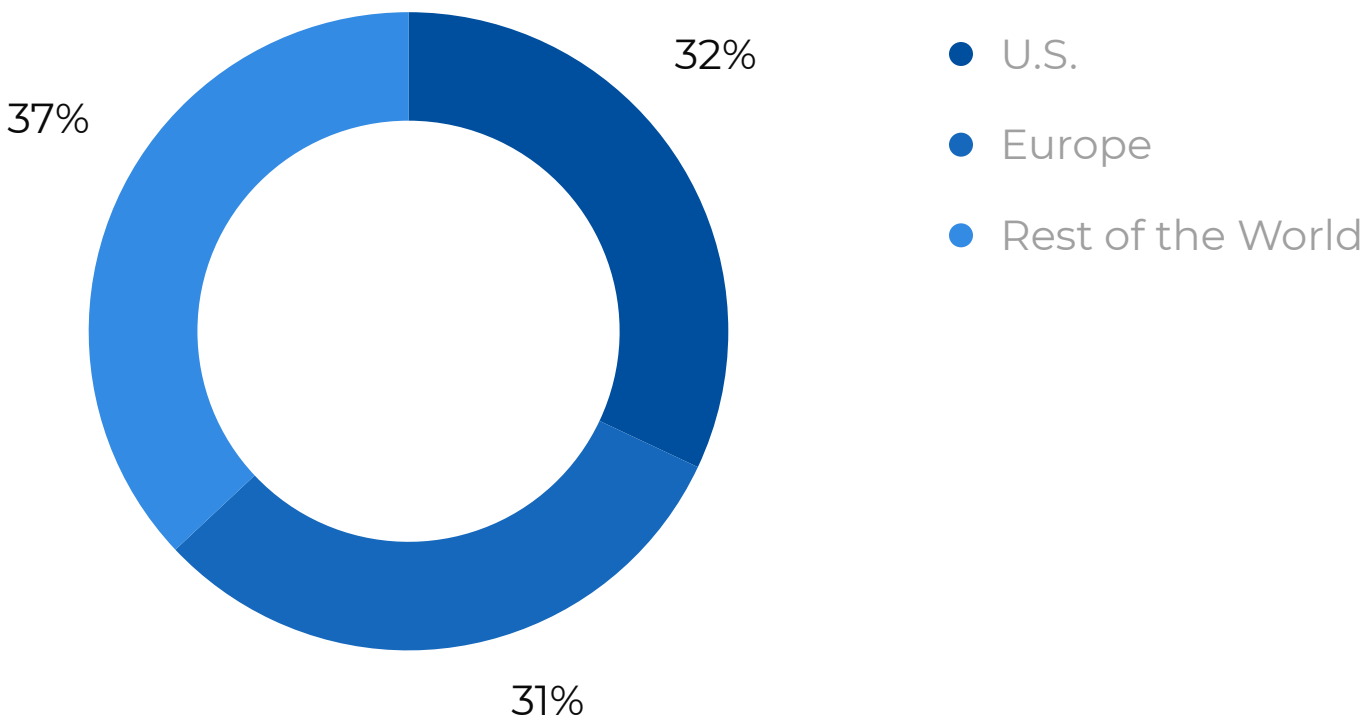


# Global Clinical Trials

## 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



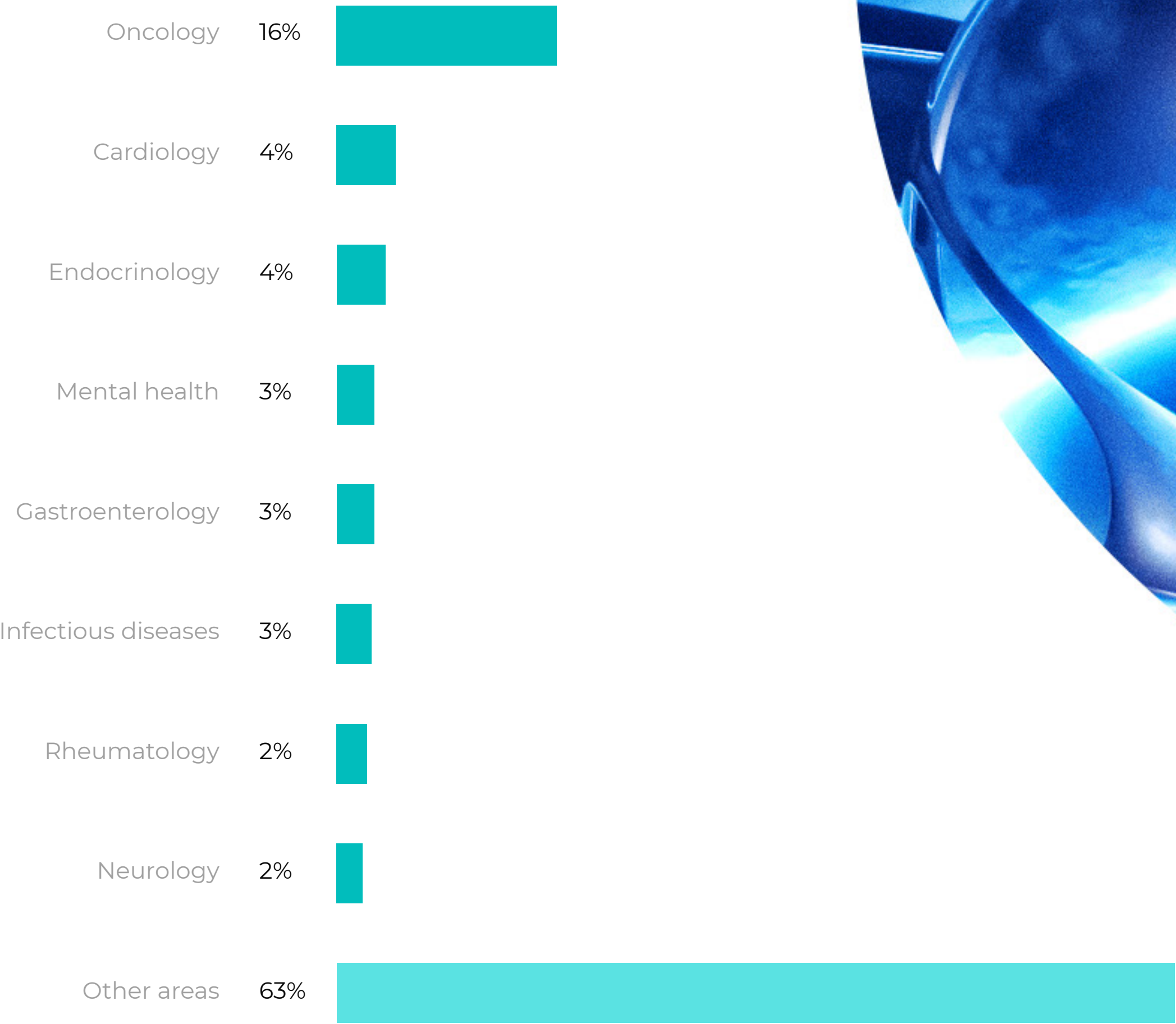


# Global Clinical Trials

## 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.



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# 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%



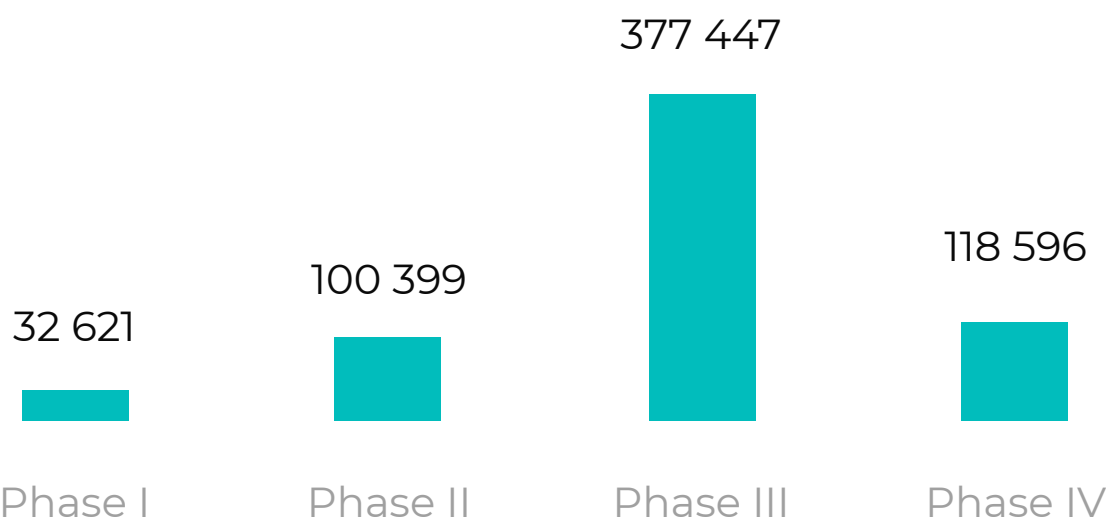
# Global Clinical Trials

## Subject Data

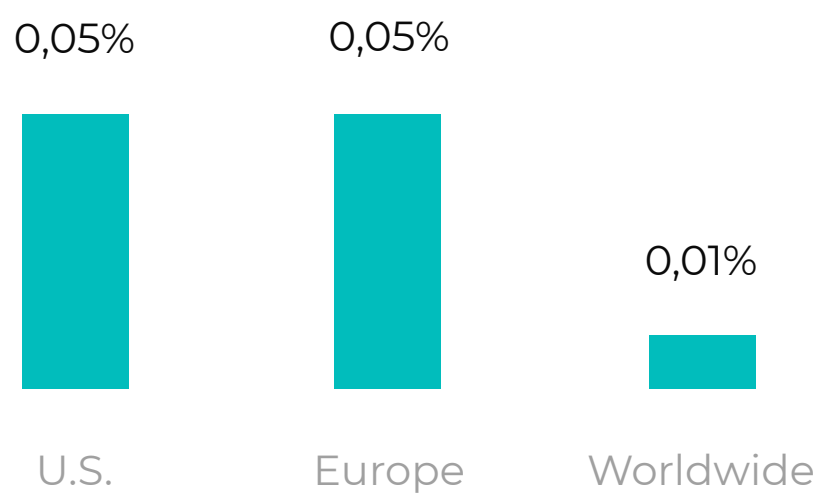
The total number of subjects enrolled in Clinical trials of all types in Q1 2019 reached 629,063 subjects.

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 the U.S.

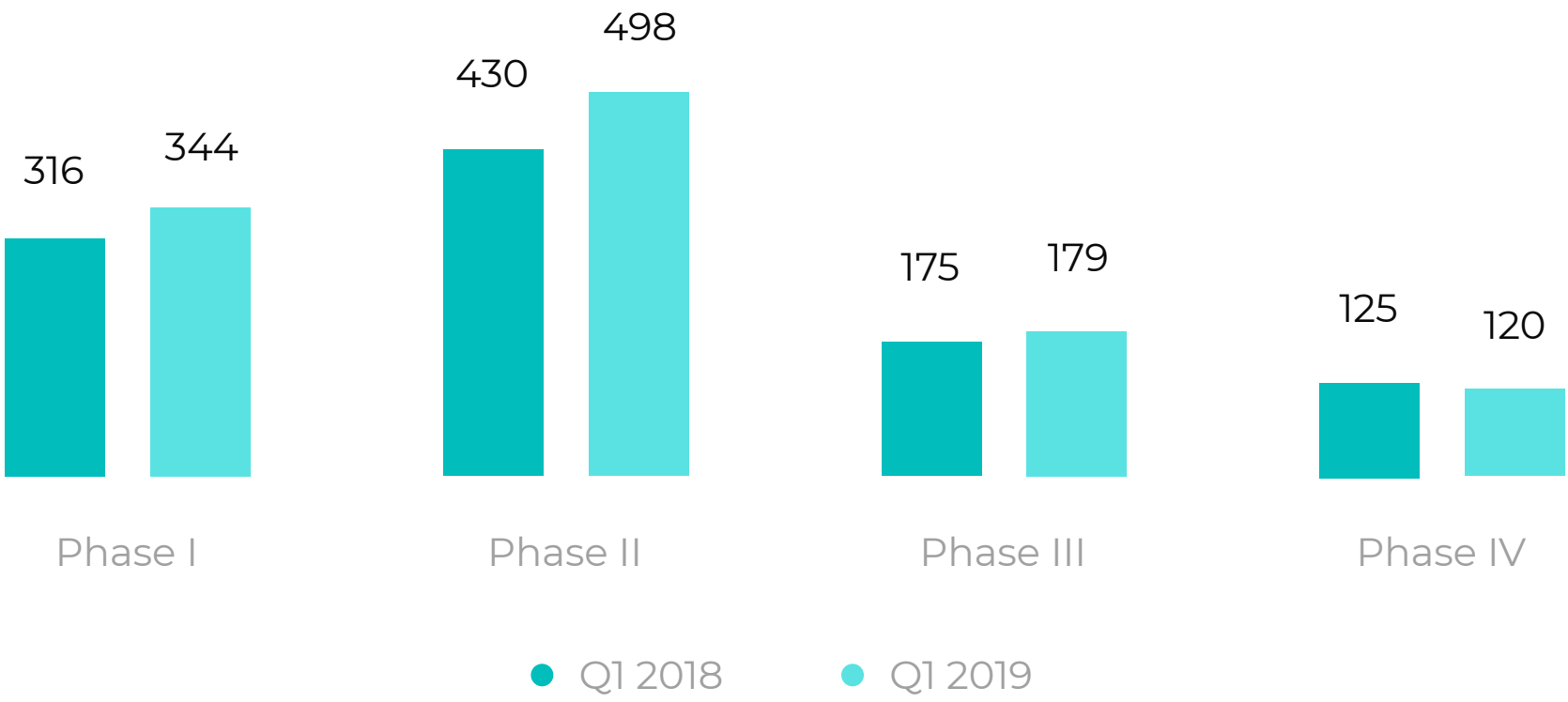
## Trial Data

During Q1 2019 there were 2,274 clinical trials initiated in the U.S. including local and bioequivalence studies. That closely matches the previous year when 2,262 studies were initiated.

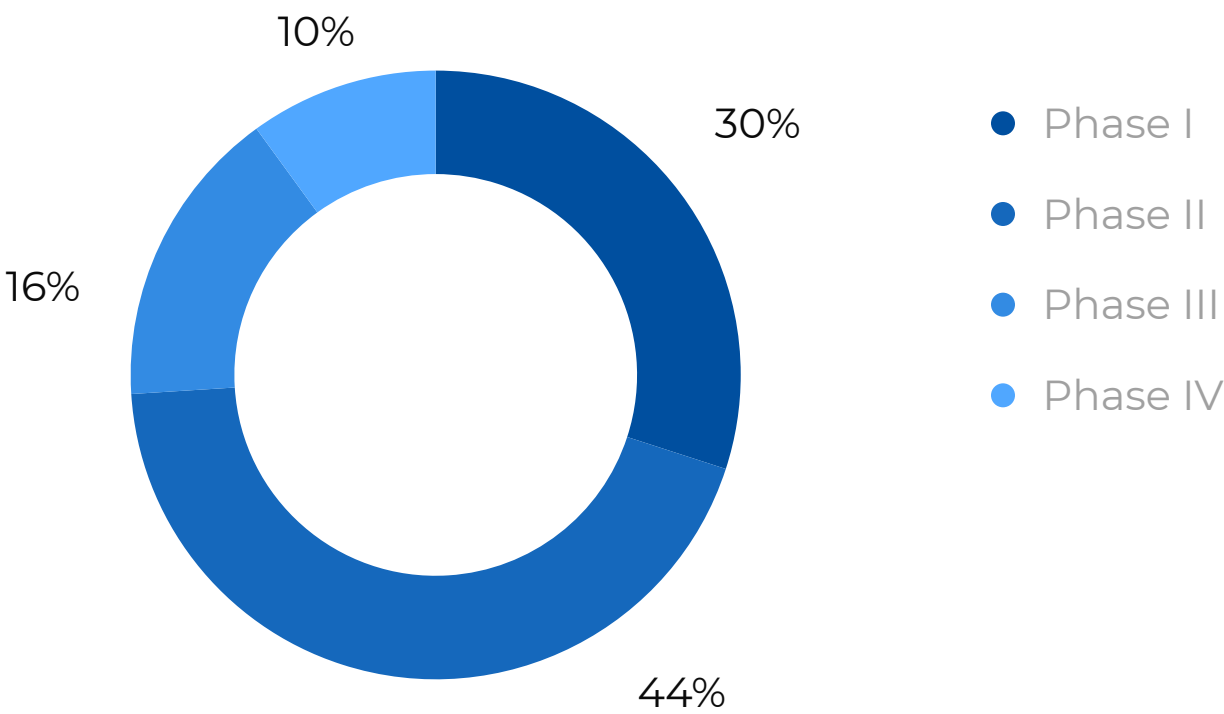
The most prevalent type of clinical trials conducted in US sites were interventional studies with a 89%market share.

The most frequent phase of clinical trials conducted across US sites by number of studies was Phase II.

Breakdown of Clinical Trials in the U.S. Q1 2019 by Phase



Percentage Breakdown of Clinical Trials in the U.S. by Phase





# Clinical Trials in the U.S.

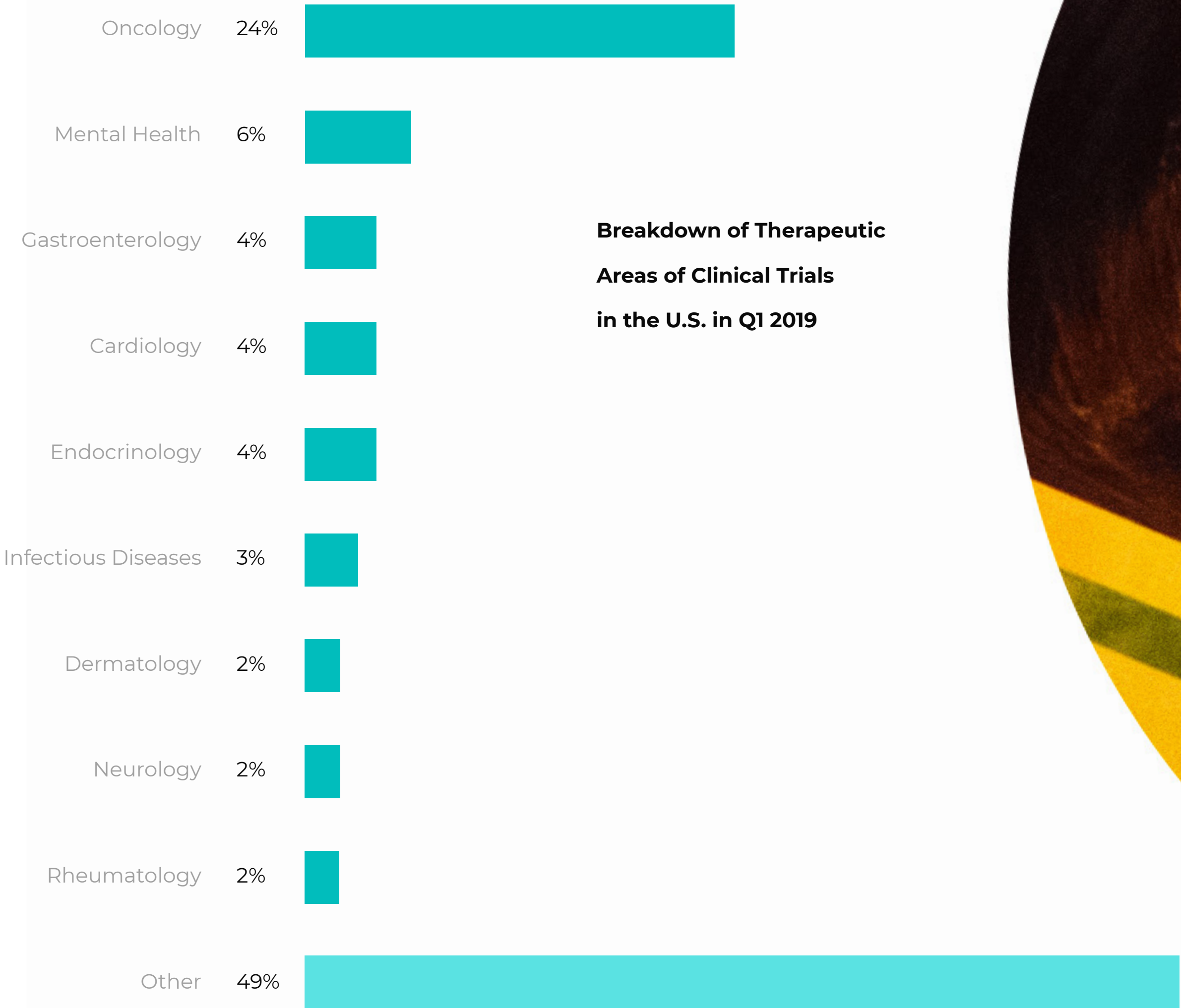
## Trial Data

The largest number of clinical trials initiated in the U.S. in Q1 2019 were related to Oncology (488 studies), Mental health (110 studies), Cardiology (85 studies), Endocrinology (77 studies) and Gastroenterology (73 studies). Other popular areas included Infectious diseases, Dermatology, Surgery and Geriatrics.

The majority of Clinical trials conducted in the U.S. in Q1 2019 were Interventional.



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# Clinical Trials in the U.S.

Sponsor Data



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Top-10 Sponsors  
of Clinical trials  
in the U.S. in Q1 2019

Nº	Company Name	No. studies	No. subjects
1	Merck	30	4 638
2	Bristol-Myers Squibb	29	1 663
3	Eli Lilly	19	7 727
4	AstraZeneca	19	5 879
5	Pfizer	18	3 549
6	AbbVie	17	3 839
7	Janssen	15	3 964
8	Hoffmann-La Roche	14	3 745
9	Genentech	13	1 302
10	Takeda	13	1 106
Combined market share of these companies		16%	31%



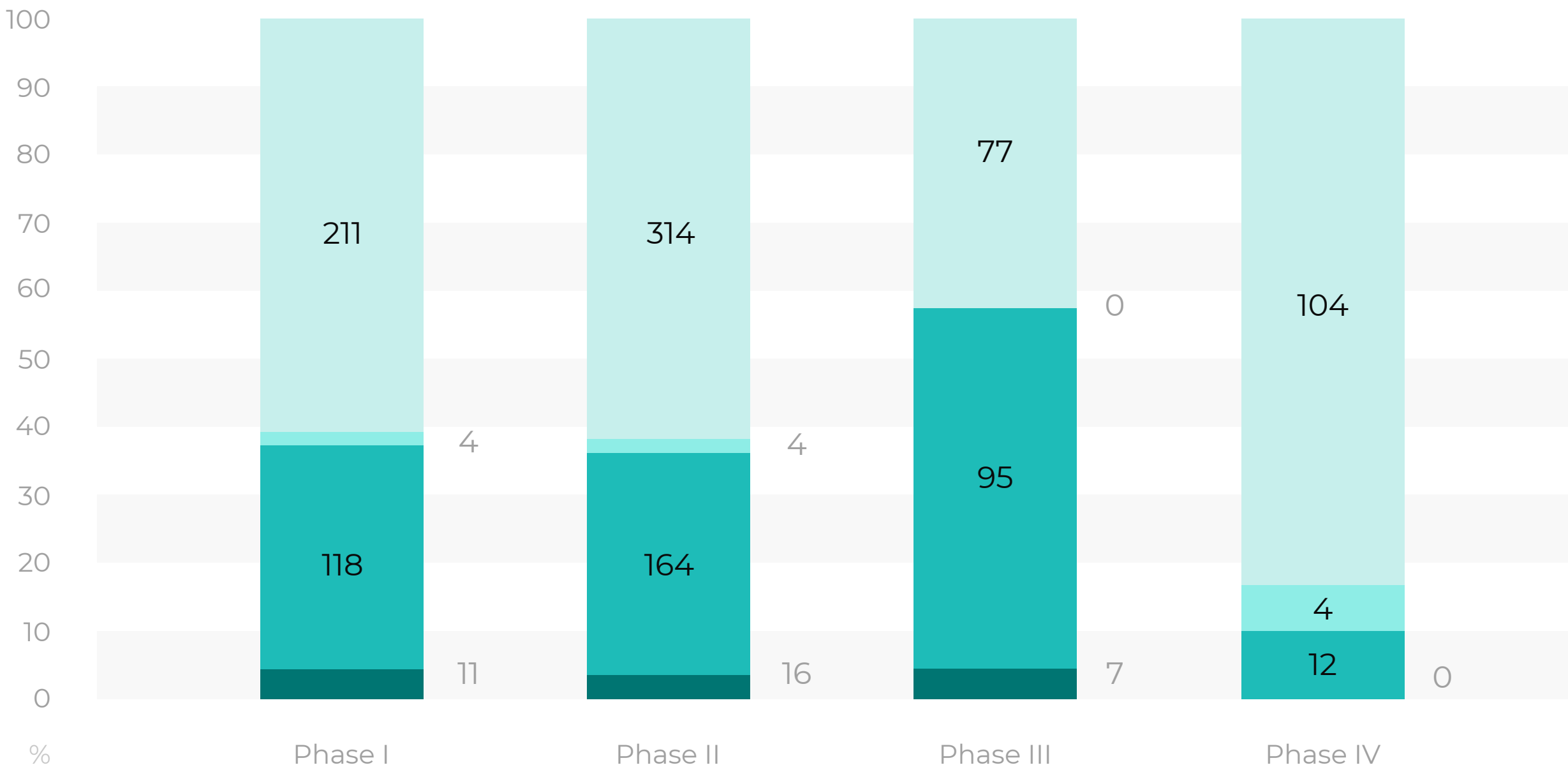
# Clinical Trials in the U.S.

## Sponsor Data

It's worth highlighting that the biggest amount of investments in clinical trials of new drugs in the U.S. is as a result of cross-institutional partnerships between the pharma business and state institutions (National Institute of Health, U.S. Federal agencies, etc).

- Cross-institutional cooperation
- U.S. Federal agencies
- Sponsors (corporate funding)
- U.S. National Institutes of Health

U.S. Clinical Trials - Funding Sources





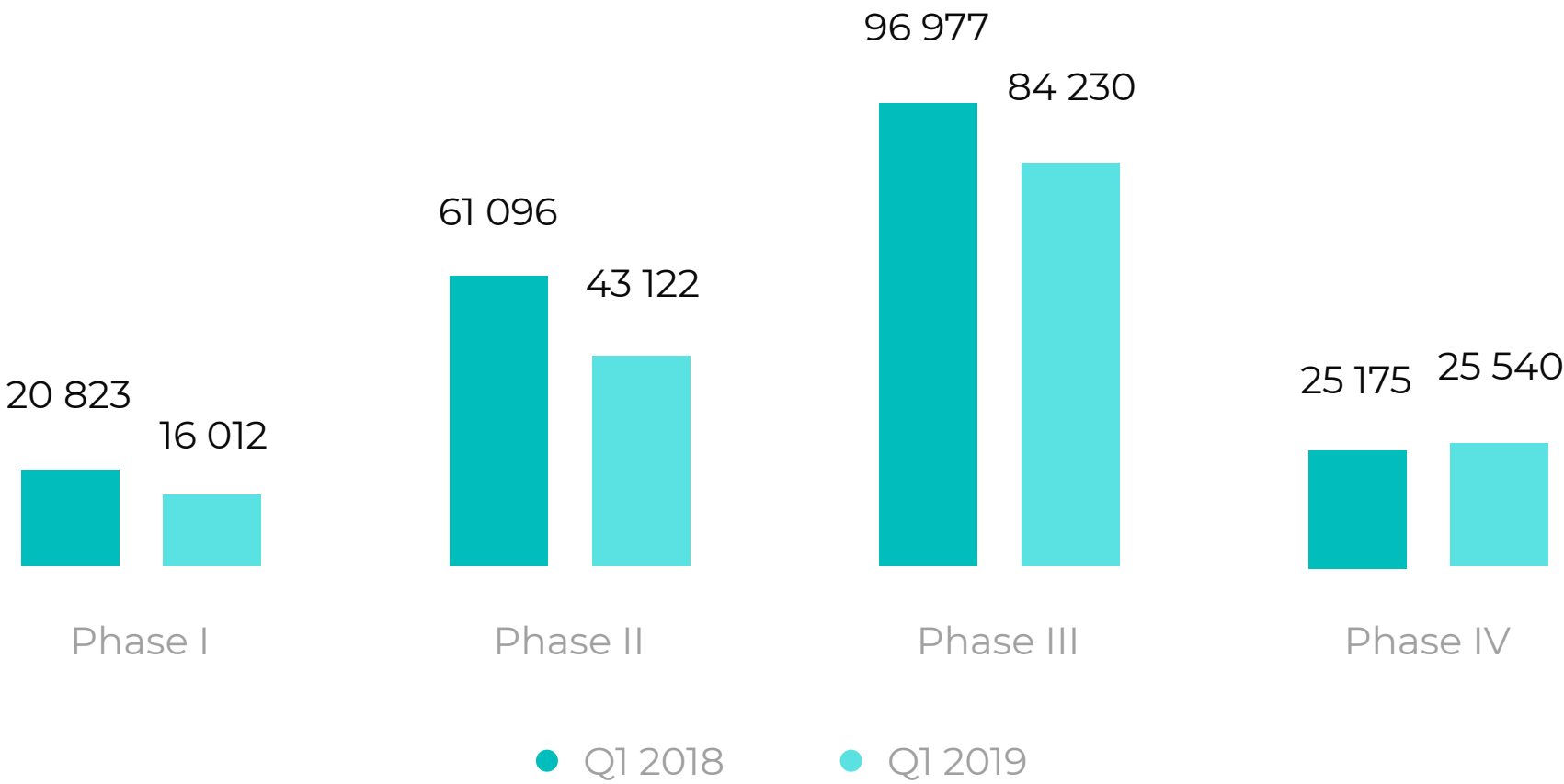
# Clinical Trials in the U.S.

## Subject Data

The overall number of subjects involved in clinical trials initiated in the U.S. in Q1 2019 shrank to 168,904 subjects with a year on year decline rate of 17%.

The most prevalent Phase of clinical trials by total number of participating subjects was Phase III.

Breakdown of Number of Subjects  
Enrolled in U.S. Clinical Trials by Phase





# U.S. Regulatory Data

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

# U.S. Inspection Data

According to U.S. FDA data, 32 FDA inspections were conducted across U.S. investigative sites during Q1 2019. Twenty seven inspections resulted with No Action Indicated (NAI) outcomes, and 5 inspections resulted with a Voluntary Action Indicated (VAI) outcome.

Nº	Appr. date	Drug (active ingredient)	Company
1	02.13.2019	Egatennda (Triclabendazole)	Novartis
2	03.19.2019	Zulressonda (Brexanolone)	Sage Therapeutics
3	03.20.2019	Sunosinda (Solriamfetol)	Jazz Pharmaceuticals
4	03.26.2019	Mayzentnda (Siponimod)	Novartis

Source: FDA

CDER - New Molecular Entity (NME) Approvals – Q1 2019





# 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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