

Synergy **Orange** Paper / 2020 Spring / Quarter 1



Clinical trials in Canada

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: 02/04/2020



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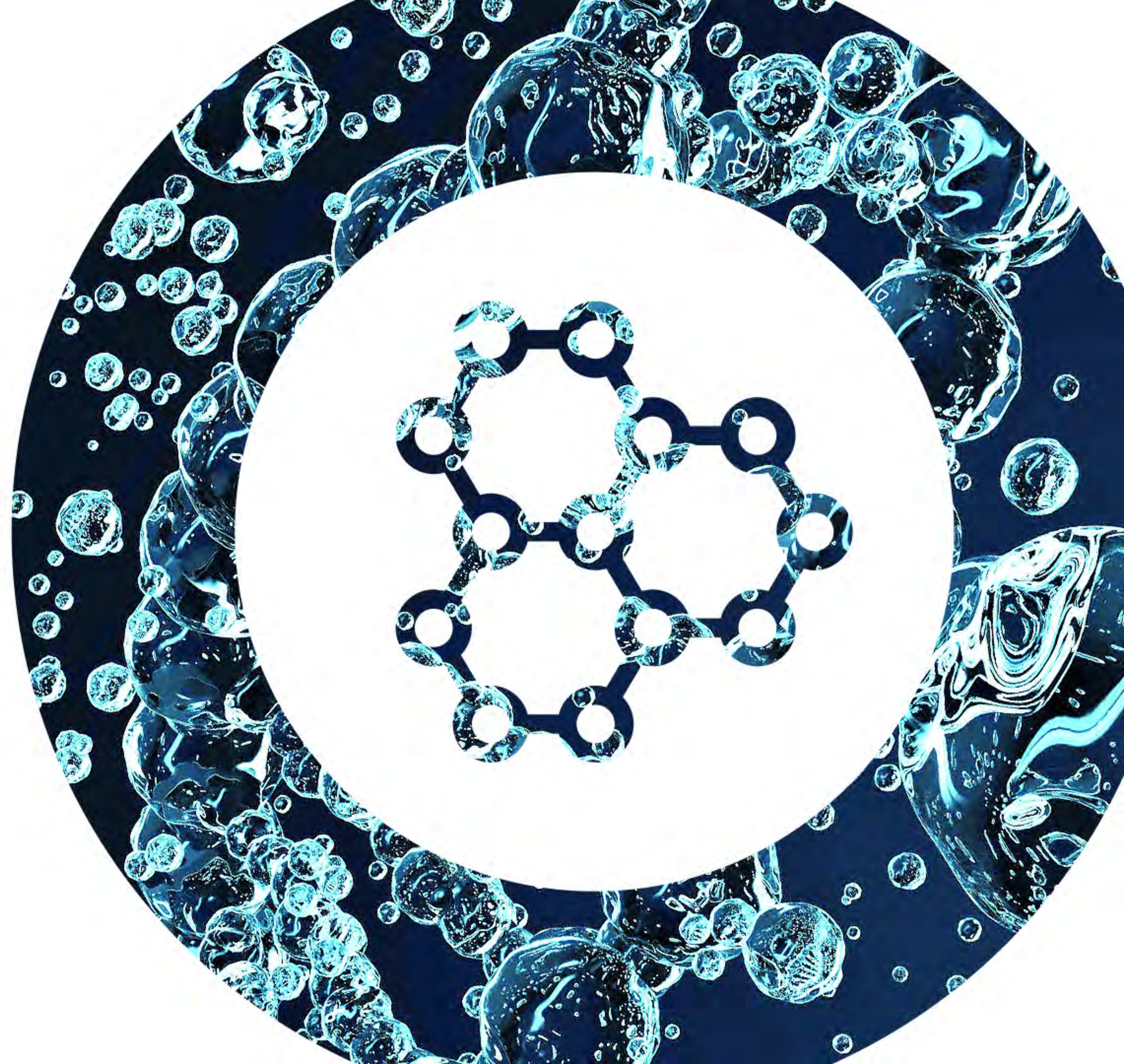


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Executive Summary

During Q1 2020 the official FDA website showed approvals for the initiation of 7,599 new Clinical trials of all types worldwide, including local and bioequivalence studies, with an overall year on year growth rate of 6%. The number of studies initiated in Canada plunged to 287 with a 27% decline rate in comparison with the previous year.

The dominant type of clinical trials conducted in Q1 2020 were Interventional Clinical trials with 78% market share worldwide and 85% market share in Canada. The most prevalent phase of clinical trials conducted by number of studies were Phase II worldwide and Phase III in Canada.

In Canada the Top-10 Sponsors combined accounted for 31% of the total number of clinical trials with an FDA-defined Phase, and for 33% of all subjects enrolled during the year. In comparison, in the U.S. the top-10 Sponsors combined accounted for 16% of initiated studies and for 23% of enrolled subjects.

The total number of subjects enrolled in clinical trials of all types in Q1 2020 reached 649,046 subjects worldwide and 33,561 subjects in Canada. The most prevalent Therapeutic areas of Clinical trials in Canada were Oncology, Infectious diseases, Neurology, Gastroenterology and Cardiology.

During Q1 2020 the Health Products and Food Branch of Health Canada authority approved 2 new drug applications.

At the same time the authority reviewed 16 applications for marketing authorization for new medical devices with positive results.

In Q1 2020 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 29 new drugs, including 8 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

According to U.S. FDA data, there was one FDA inspection conducted in the Canadian investigative sites during Q1 2020. In January 2020 the FDA representatives inspected the clinical trial related activity of Pharma Medica Research site in Scarborough with a No Action Indicated (NAI) outcome.

Section 1

Global Clinical Trials Trial Data

During Q1 2020 the official FDA website showed approvals for initiation of 7,599 new clinical trials of all types worldwide, including local and bioequivalence studies with an overall year on year growth rate of 6% driven in large by an increasing number of trials in developing countries. At the same time according with the official FDA website there were only 2,678 studies with clearly defined study Phase I – IV.

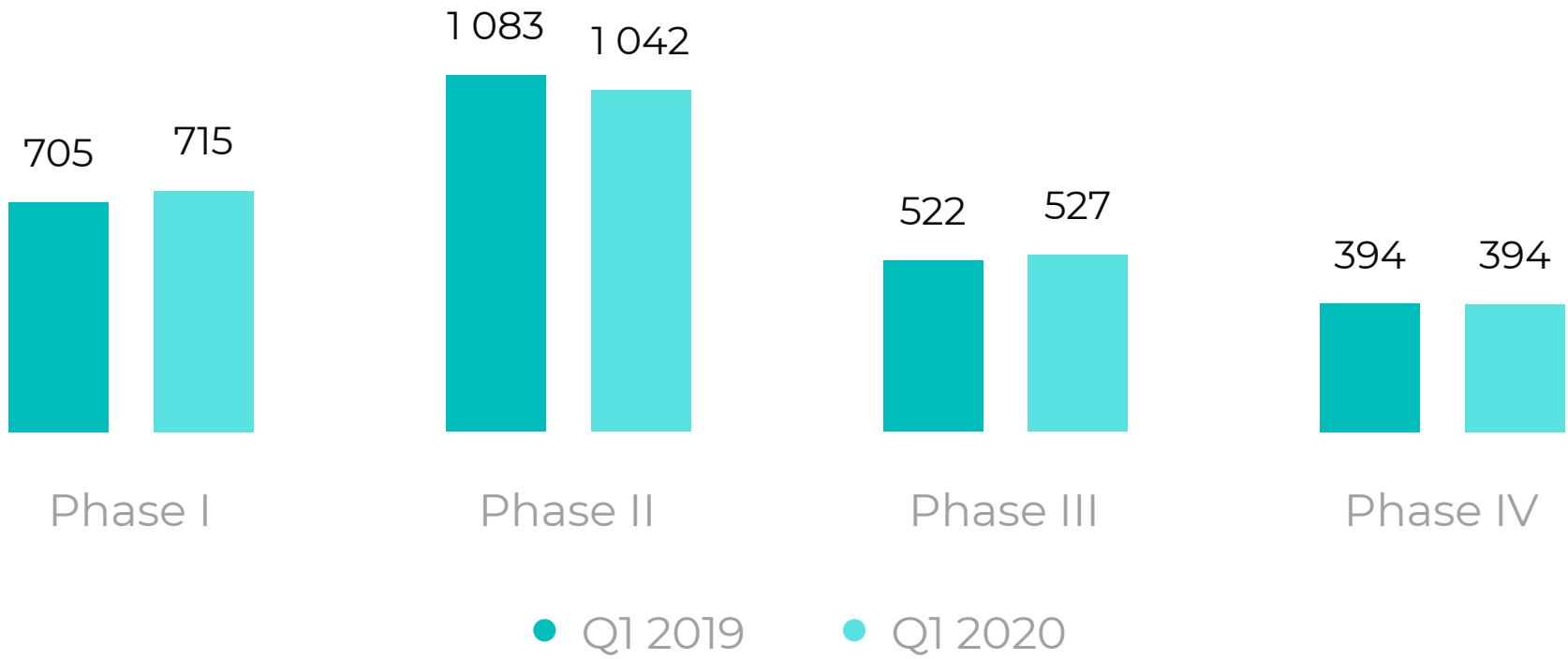
The combined market share of the U.S. and European countries by number of global initiated studies dropped slightly from 63% in Q1 2019 to 61% in Q1 2020, with the U.S. having 31% and Europe having 30%.

78% of all global clinical trials initiated during Q1 2020 were Interventional Clinical Trials.

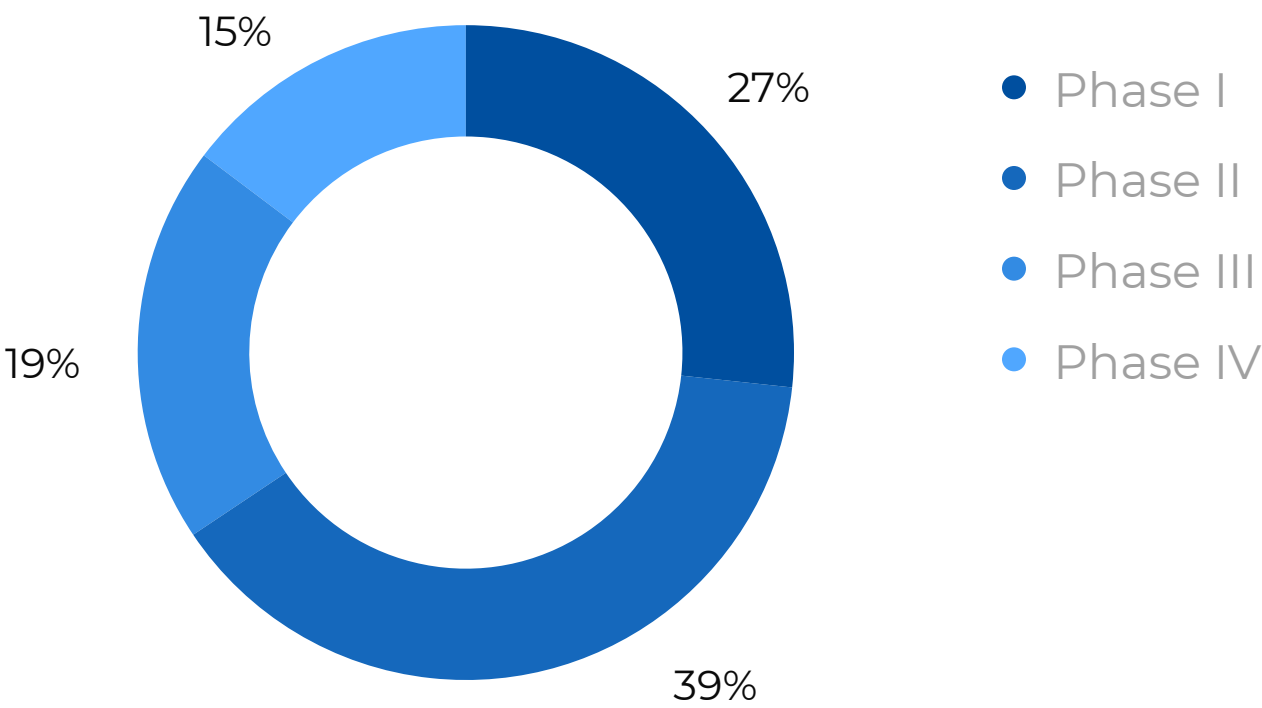


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Breakdown of clinical trials by Phase during Q1 2020



Percentage breakdown of global clinical trials by Phase

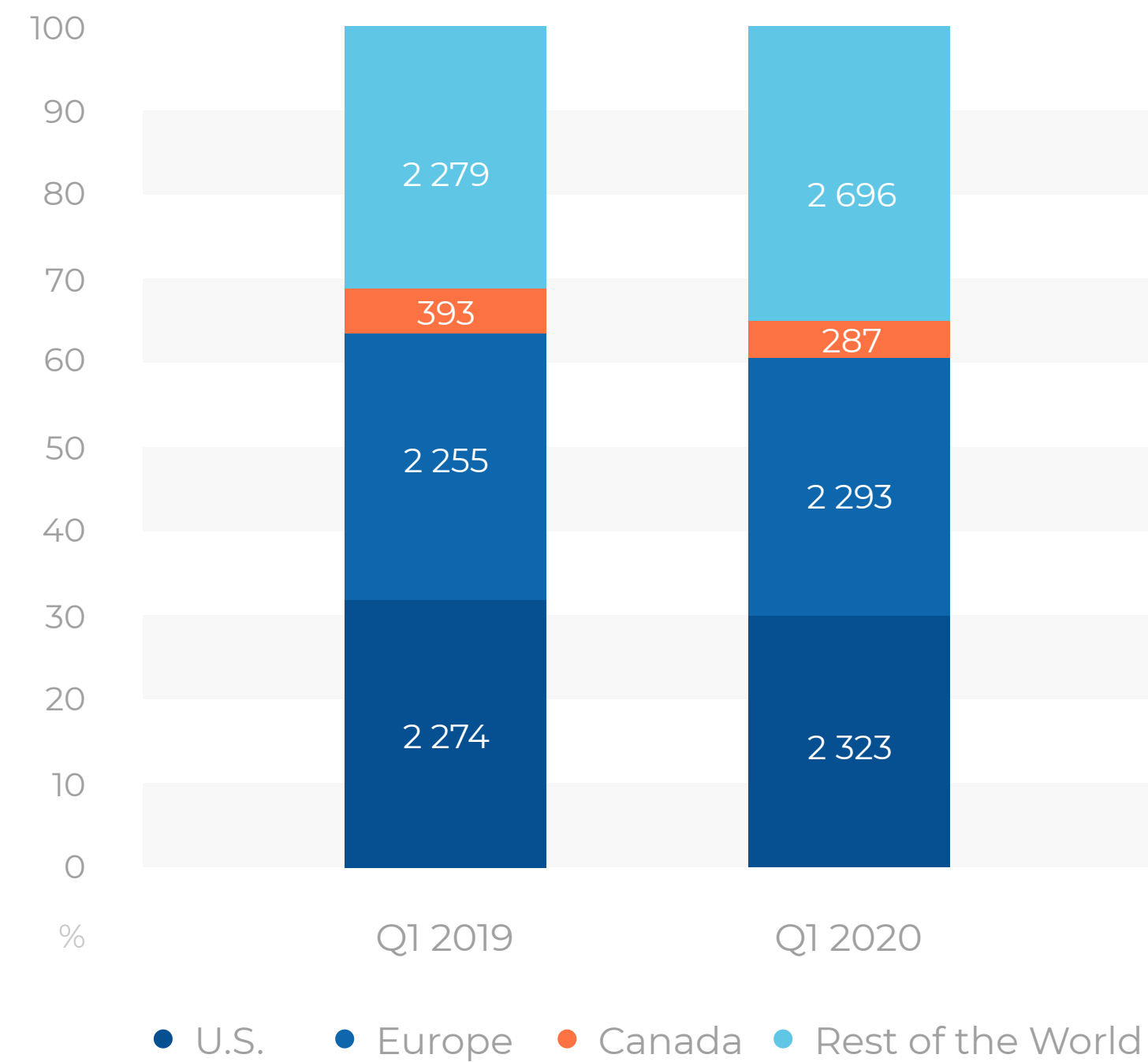
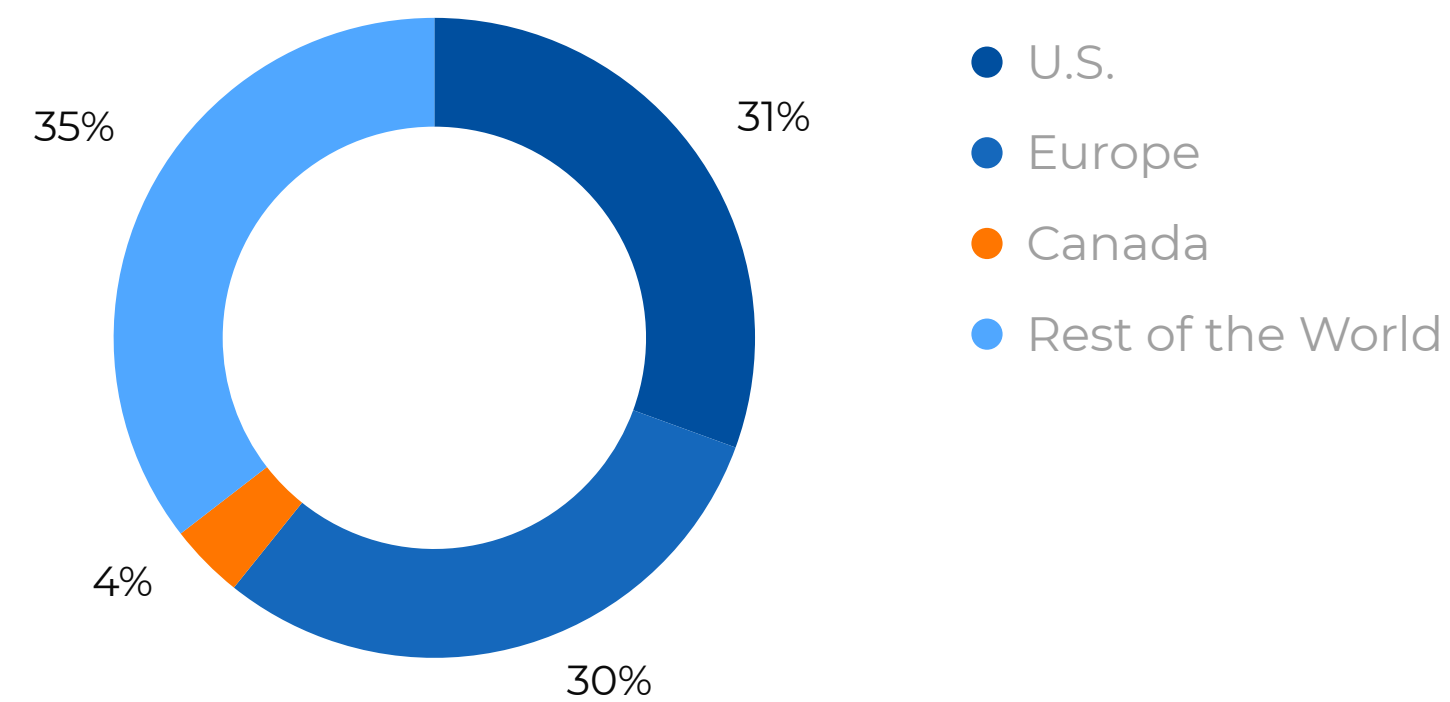


Global Clinical Trials Trial Data

Breakdown by Region of Origin

The proportion of clinical trials between different global regions (i.e. U.S., Europe and Rest of the World) in Q1 2020 remains almost the same in comparison to Q1 2019.

Percentage breakdown of global clinical trials by Region

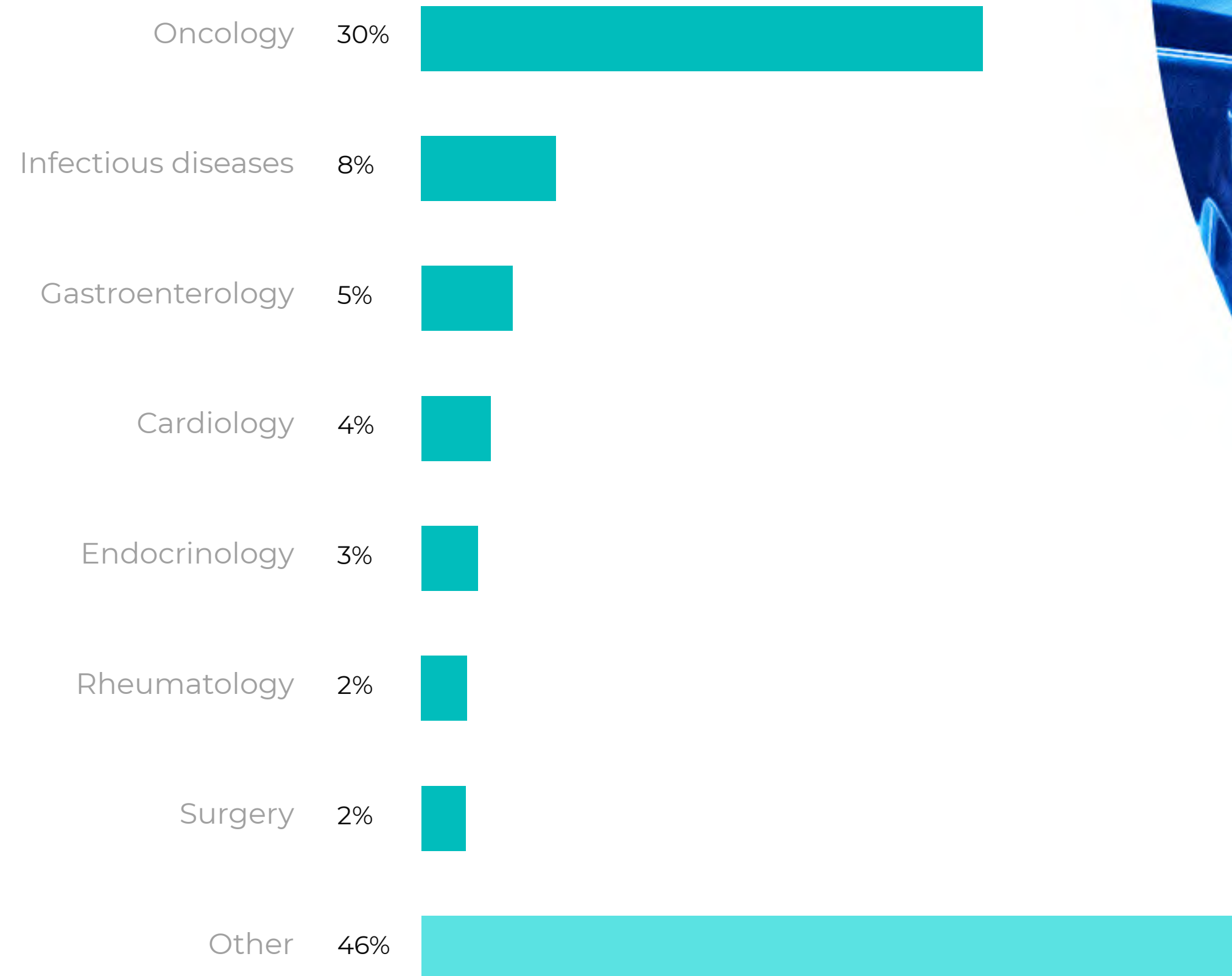


Global Clinical Trials Trial Data

Therapeutic Areas of global clinical trials

In Q1 2020 the largest number of studies were initiated in Oncology (823 studies), Infectious diseases (197 studies), Gastroenterology (134 studies) and Cardiology (102 studies).

More than one therapeutic area could be assigned to a trial. Observational Clinical trials and Clinical trials without FDA-defined phases (from I to IV) were not included in this chart.



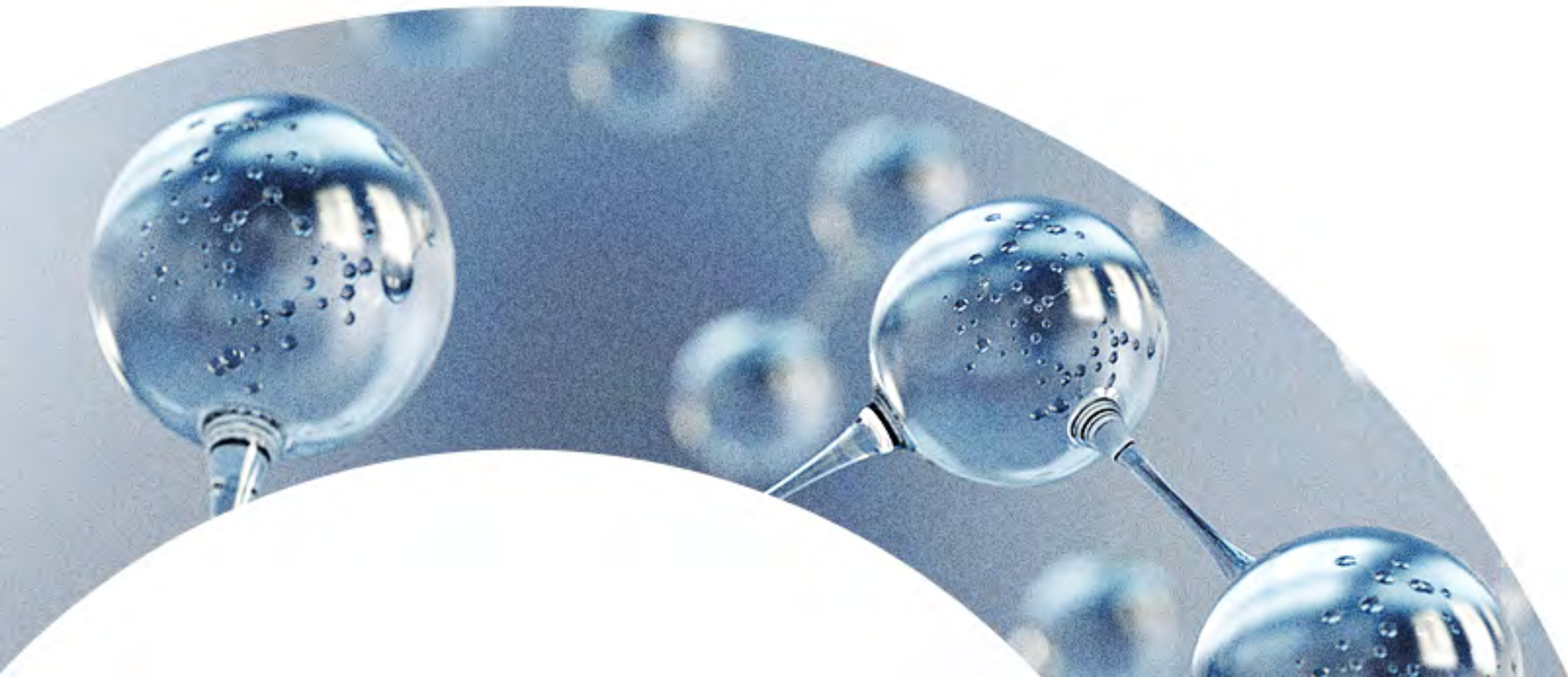
Global Clinical Trials Sponsor Data

The Top-10 list of global Sponsors of Clinical Trials worldwide remained almost unchanged for the past 7 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 11% of all interventional clinical trials worldwide where the study Phase has been identified, and just 9% of all enrolled subjects.

Top-10 global sponsors by Total Number of Studies Initiated in Q1 2020

Nº	Company Name	No. studies	No. subjects
1	Merck	46	15 877
2	Janssen	37	6 044
3	Pfizer	37	2 639
4	Bristol-Myers Squibb	33	2 528
5	AstraZeneca	29	4 001
6	Eli Lilly	28	3 973
7	Bayer	23	7 009
8	Novartis	23	3 812
9	AbbVie	22	3 299
10	Sanofi	21	9 930
Combined market share of top-10 companies		11%	9%



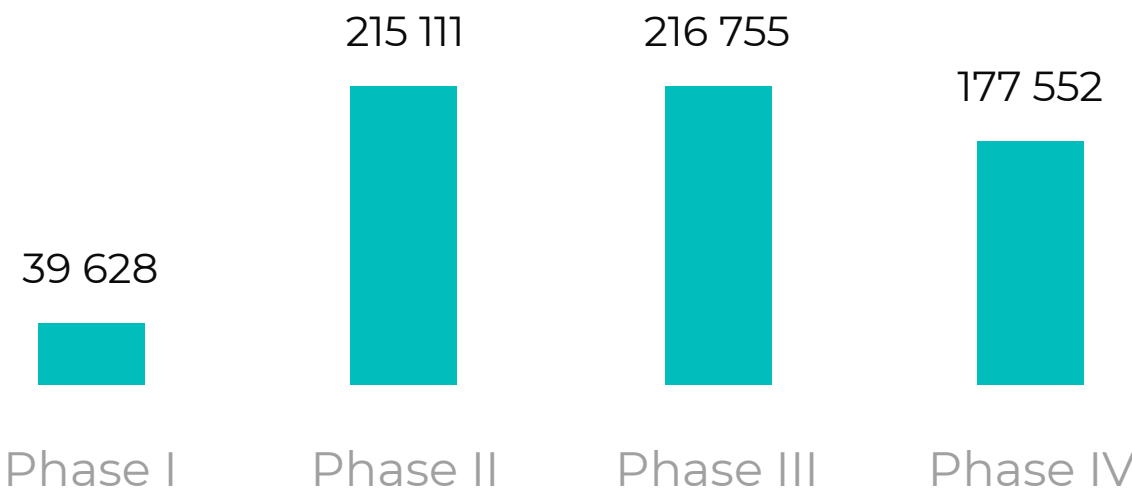
Global Clinical Trials Subject Data

The total number of subjects enrolled in Clinical trials worldwide of all types in Q1 2020 reached 649,046 subjects.

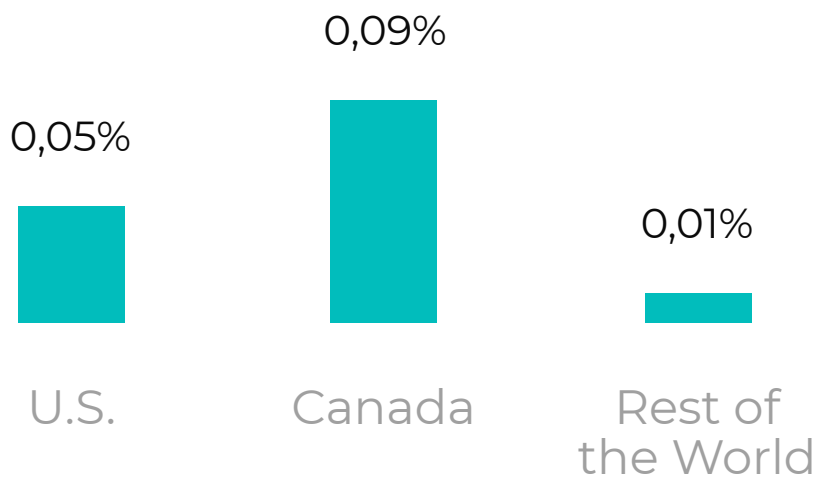
The majority of subjects were (or planned to be) enrolled in Phase II and Phase III trials, and the largest proportion of the global subject population were from the U.S. and Canada.

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 in Q1 2020



Breakdown of Number of Subjects
Enrolled as a % of Population



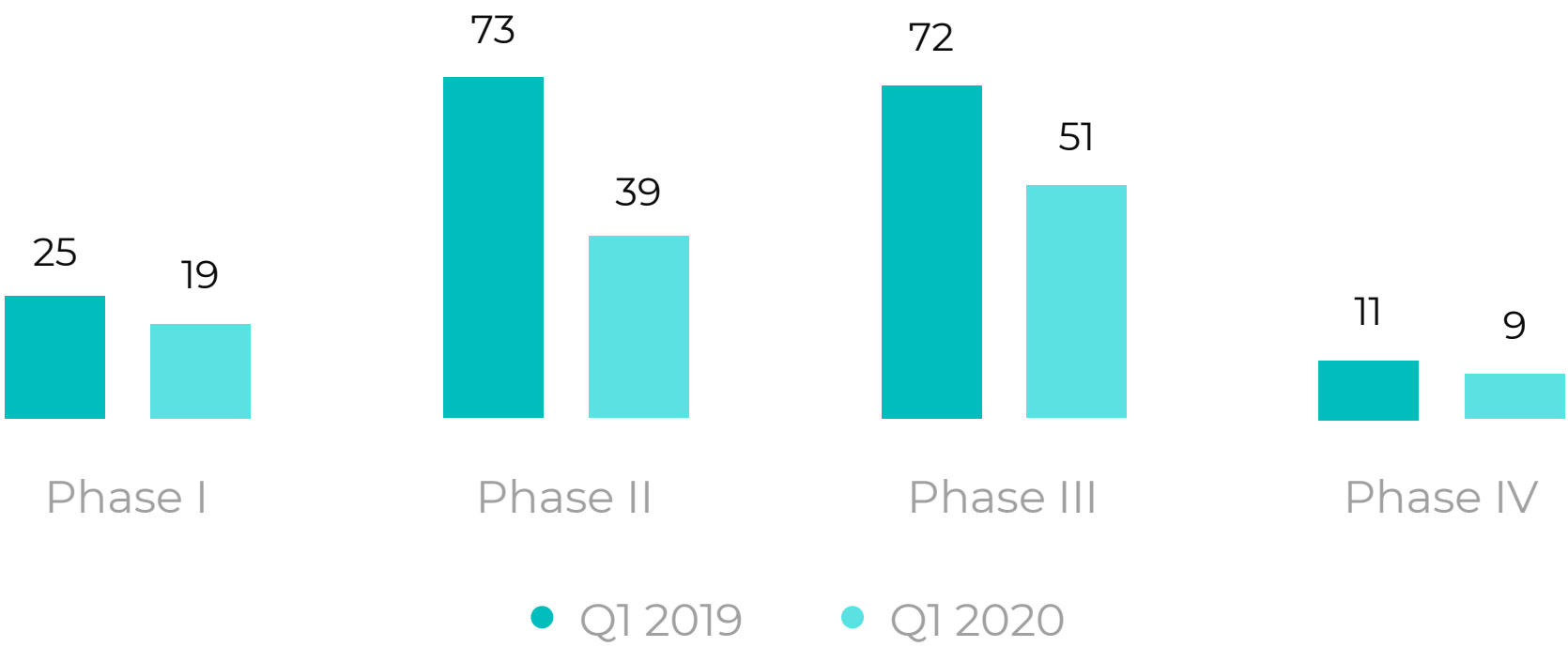
Clinical Trials in Canada Trial Data

During Q1 2020 there were 287 clinical trials initiated in Canada including local and bioequivalence studies. That represents a 27% decline in comparison with the previous year when 393 studies were initiated. But if one exclude bioequivalence studies and studies without FDA-defined Phase there were only 118 clinical trials initiated during Q1 2020 compared to 181 studies initiated in previous year.

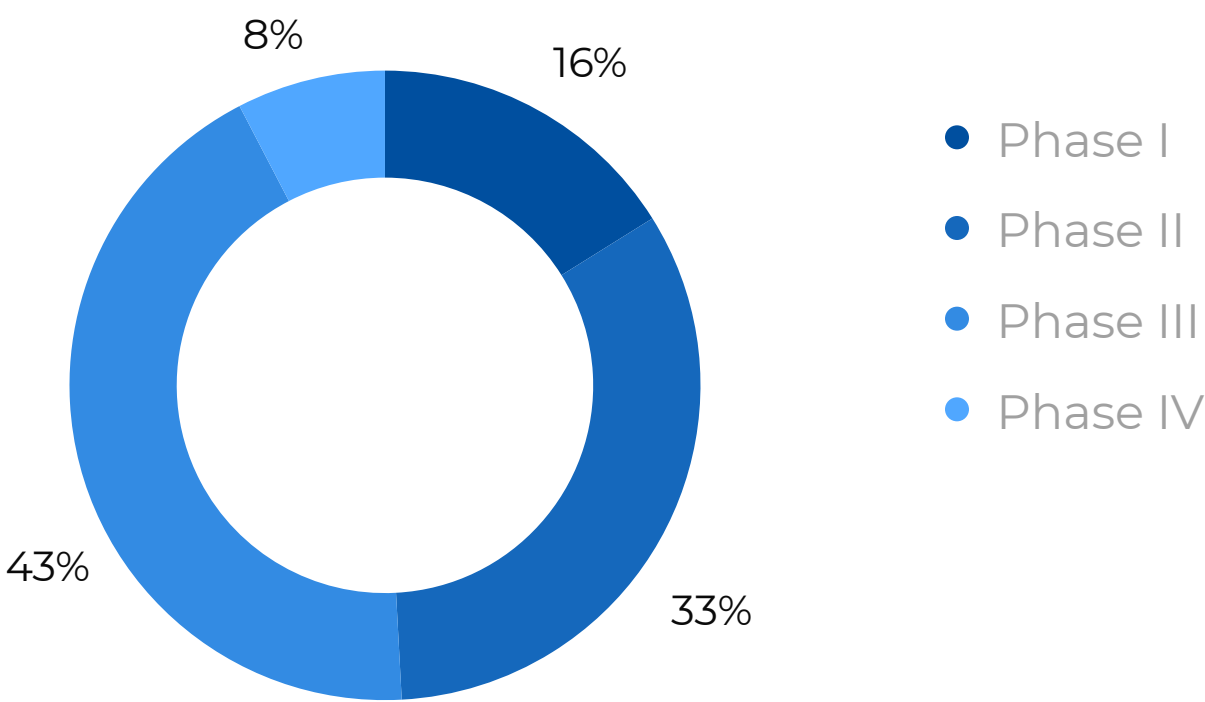
The majority of clinical trials conducted in Canada were interventional studies with a 85% market share.

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

Breakdown of clinical trials in Canada during Q1 2020 by Phase



Percentage breakdown of clinical trials in Canada by Phase

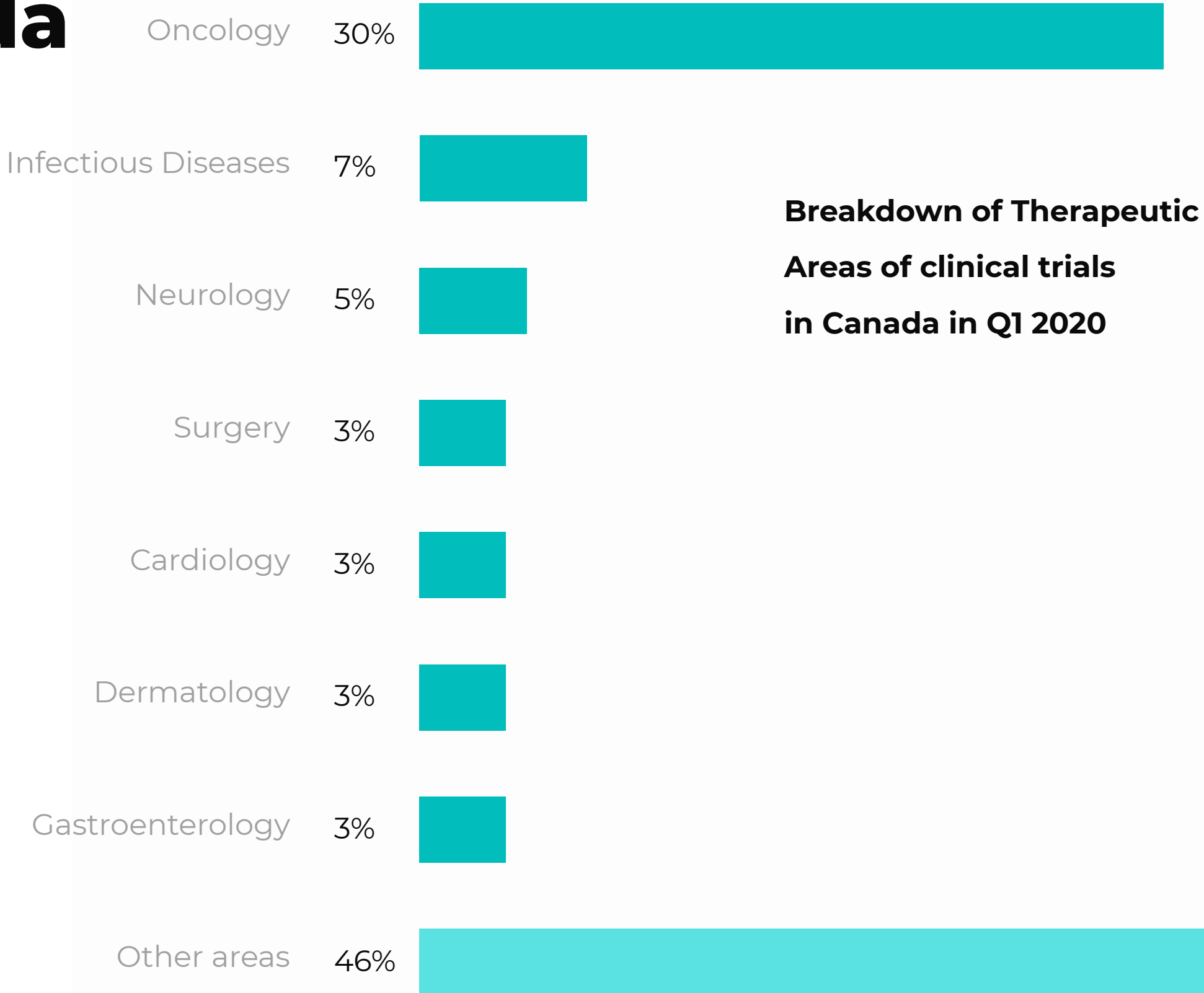


Clinical Trials in Canada Trial Data

The largest number of clinical trials initiated in Canada during Q1 2020 were related to Oncology (36 studies), Infectious diseases (8 studies), Neurology (5 studies), Gastroenterology (4 studies) and Cardiology (4 studies). Other prominent therapy areas included Dermatology, Surgery and Ophthalmology.

The majority of Clinical trials conducted in Canada in Q1 2020 were Interventional.

More than one therapeutic area could be assigned to a trial. Observational Clinical trials and Clinical trials without FDA-defined phases (from I to IV) were not included in this chart.



Clinical Trials in Canada Sponsor Data

By country of origin, the U.S. accounted for the largest number of pharmaceutical sponsored clinical trials in the Q1 2020 in Canada. The headquarters of the sponsor companies conducting clinical trials in Q1 2020 in Canada were evenly split between the US (5 companies) and Europe / UK (5 companies).

Observational clinical trials and clinical trials without FDA-defined phases (from I to IV) were not counted in this ranking. More than one Sponsor company may be involved in a single clinical trial.

Top-10 Sponsors of clinical trials
in Canada in Q1 2020

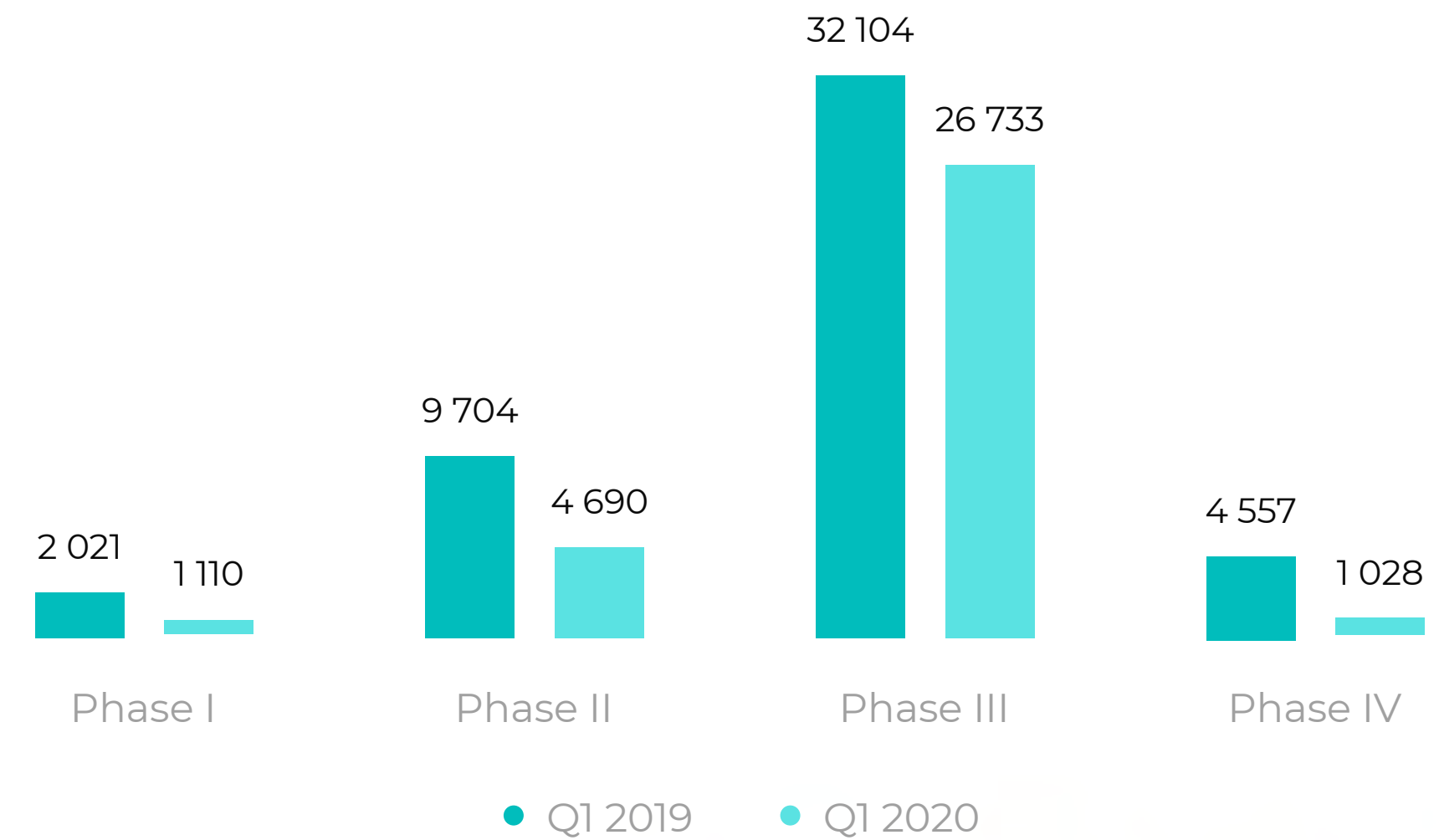
Nº	Company Name	No. studies	No. subjects
1	Merck	5	2 366
2	AbbVie	5	1 882
3	Bayer	4	1 138
4	AstraZeneca	4	1 045
5	Hoffmann-La Roche	4	890
6	Q-Med	3	950
7	Eli Lilly	3	830
8	Bristol-Myers Squibb	3	718
9	Sanofi	3	716
10	Arcutis Biotherapeutics	2	550
Combined market share of these companies		31%	33%

Clinical Trials in Canada Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in Q1 2020 (including multi-center international studies) plunged from 48,386 subjects in Q1 2019 to 33,561 subjects in Q1 2020 with year on year decline of 31%.

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

Breakdown of Number of Subjects Enrolled
in clinical trials in Canada by Phase



Canadian Regulatory Data

During Q1 2020 the Health Products and Food Branch of Health Canada authority approved 2 new drug applications. At the same time the authority reviewed 16 applications for marketing authorization for new medical devices with positive results.

Canadian Inspection Data

According to U.S. FDA data, there was one FDA inspection conducted in the Canadian investigative sites during Q1 2020. In January 2020 the FDA representatives inspected the clinical trial related activity of Pharma Medica Research site in Scarborough with a No Action Indicated (NAI) outcome.

Nº	Appr. date	Drug (active ingredient)	Company
1	13/01/2020	Oshuvo (Teriparatide)	AVIR Pharma
2	24/01/2020	Drax Exametazime (Exametazime)	Jubilant DraxImage

Health Products and Food Branch of Health Canada authority approved New Drug Applications – Q1 2020



About **Synergy**

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

From year to year our company is consistently in the TOP-10 of market leaders by the numbers of conducted clinical studies and enrolled patients.

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

We ensure the highest level of quality of SOPs and of final study data for all clinical studies conducted by our company. We're continuously working on improvements of our SOPs, study risk management and IT infrastructure – replacing outdated R&D strategies by novel, more efficient approaches to clinical research.



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