

Synergy **Orange** Paper / 2019 Winter / Annual Report



# Clinical trials in Canada

Research report

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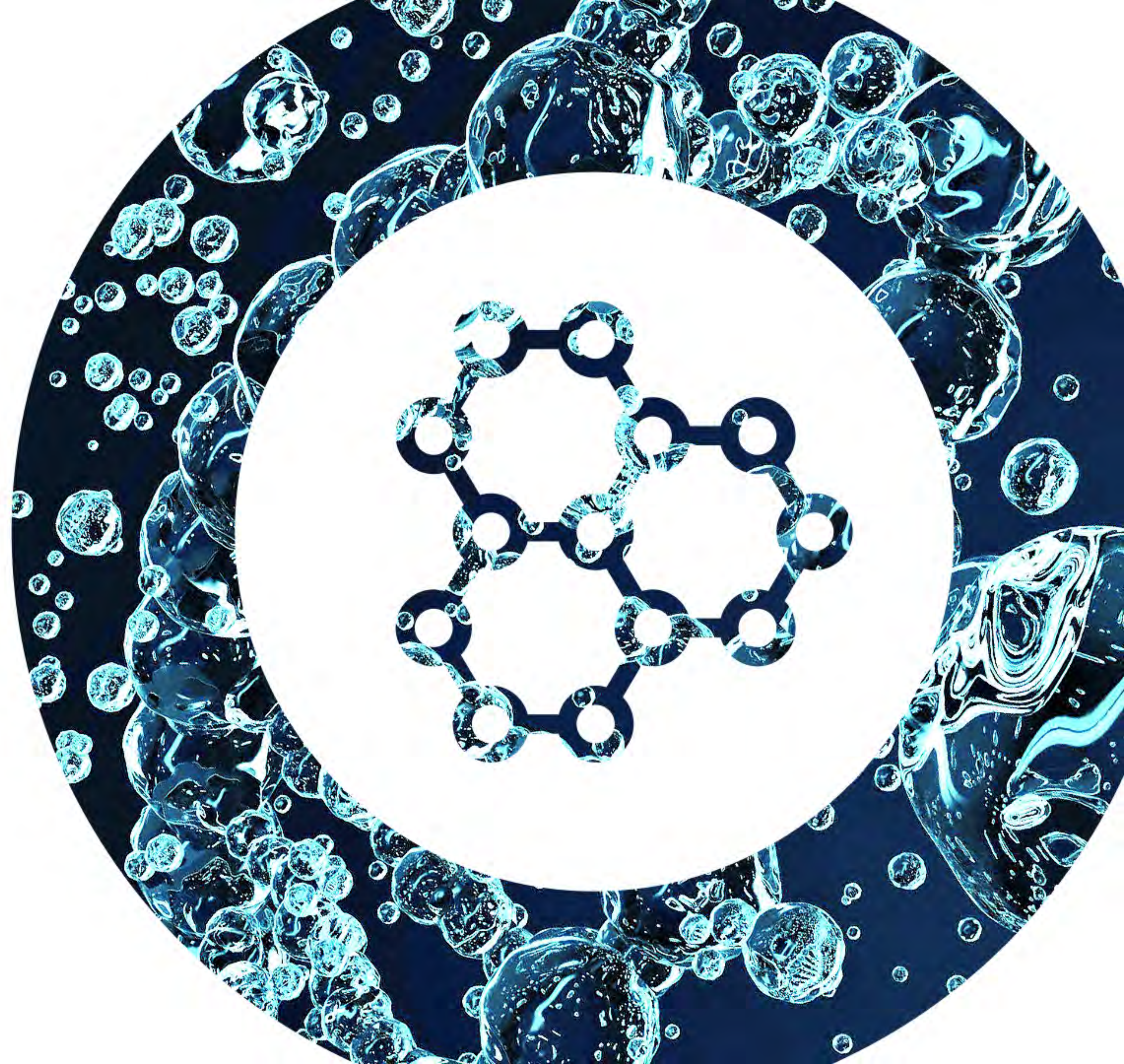
# Foreword

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: 01/01/2020



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# Executive Summary

During the Year 2019 the official FDA website showed approvals for the initiation of 27,303 new Clinical trials of all types worldwide, including local and bioequivalence studies, with an overall year on year growth rate of 8%.

The number of studies initiated in Canada dropped slightly to 1,343 with a 15% decline rate in comparison with the previous year.

The dominant type of clinical trials conducted in the Year 2019 were Interventional Clinical trials with 78% market share worldwide and 87% 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 29% of the total number of clinical trials with an FDA-defined Phase, and for 37% 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 16% of enrolled subjects.

The total number of subjects enrolled in clinical trials of all types in the Year 2019 reached 3.4 million of subjects worldwide and 0.2 million of subjects in Canada. The most prevalent Therapeutic areas of Clinical trials in Canada were Oncology, Dermatology, Infectious diseases, Endocrinology and Rheumatology.

During the Year 2019 the Health Products and Food Branch of Health Canada authority approved 79 new drug applications.

At the same time the authority reviewed 279 applications for marketing authorization for new medical devices with positive results.

According to U.S. FDA data, the FDA conducted 20 inspections at Canadian investigative sites during the Year 2019, wherein 19 inspections ended with No Action Indicated (NAI) outcomes, and one inspection ended with a Voluntary Action Indicated (VAI) outcome.



Section 1

# Global Clinical Trials Trial Data

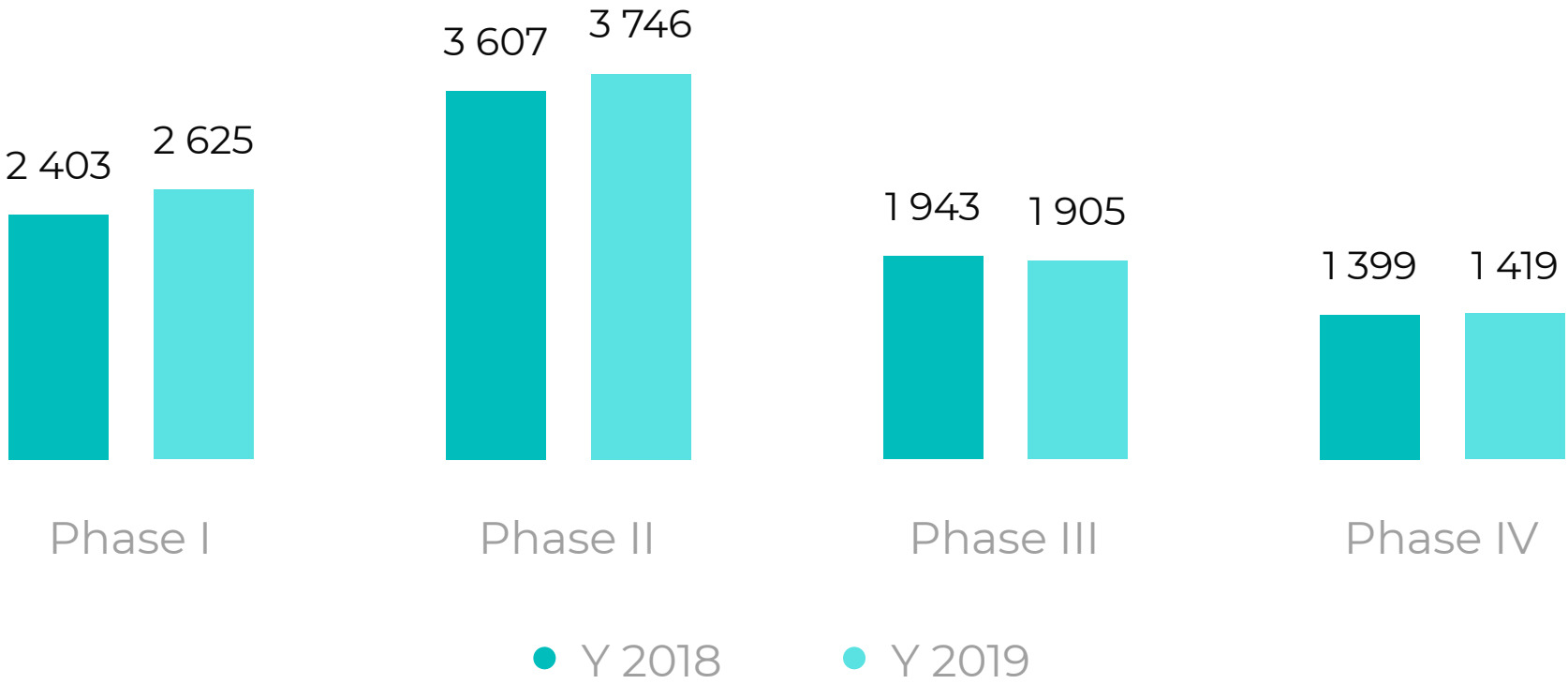
During the Year 2019 the official FDA website showed approvals for initiation of 27,303 new clinical trials of all types worldwide, including local and bioequivalence studies with an overall year on year growth rate of 8% driven in large by an increasing number of trials in developing countries. At the same time according with the official FDA website there were only 9,695 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 75% in the Year 2018 to 72% in the Year 2019, with the U.S. having 33% and Europe having 39%. 78% of all global clinical trials initiated during the Year 2019 were Interventional Clinical Trials.

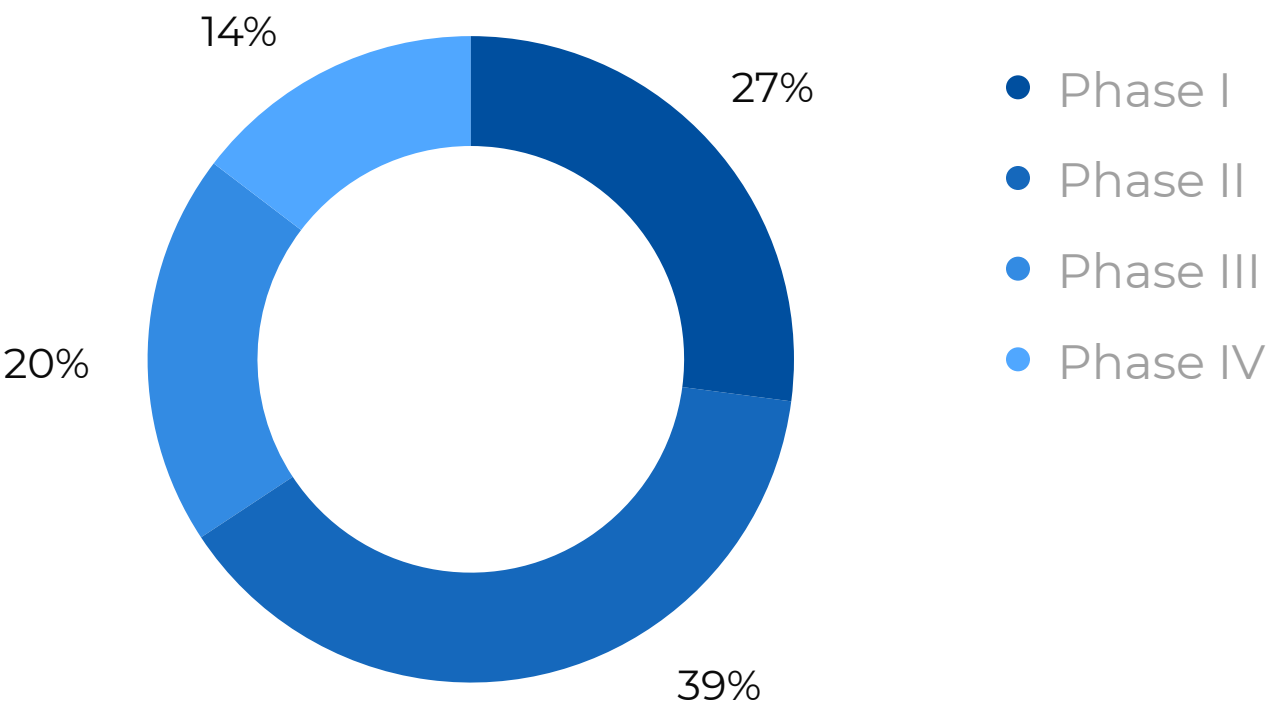


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Breakdown of global clinical trials by Phase during Y 2019



Percentage breakdown of global clinical trials by Phase



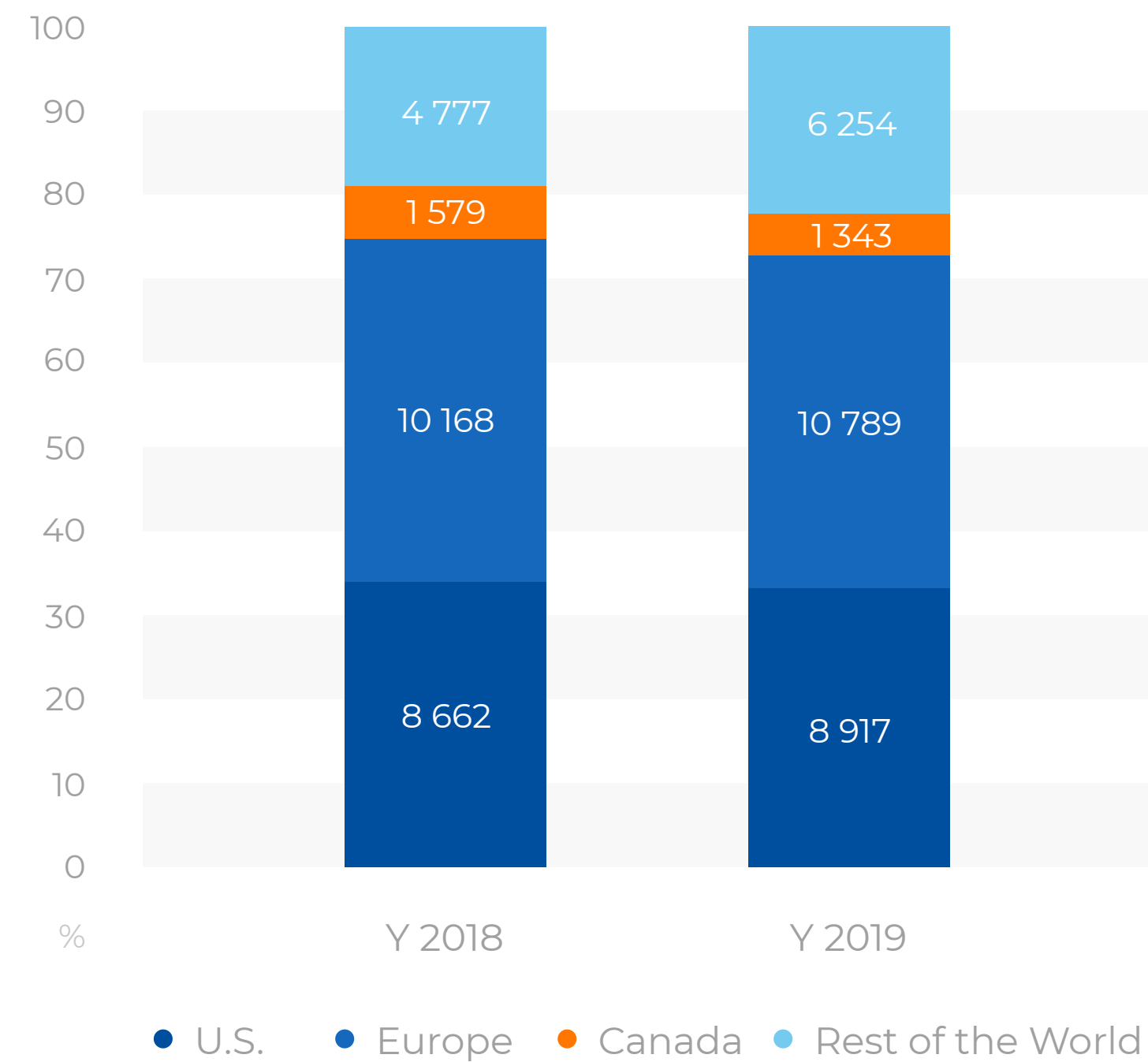
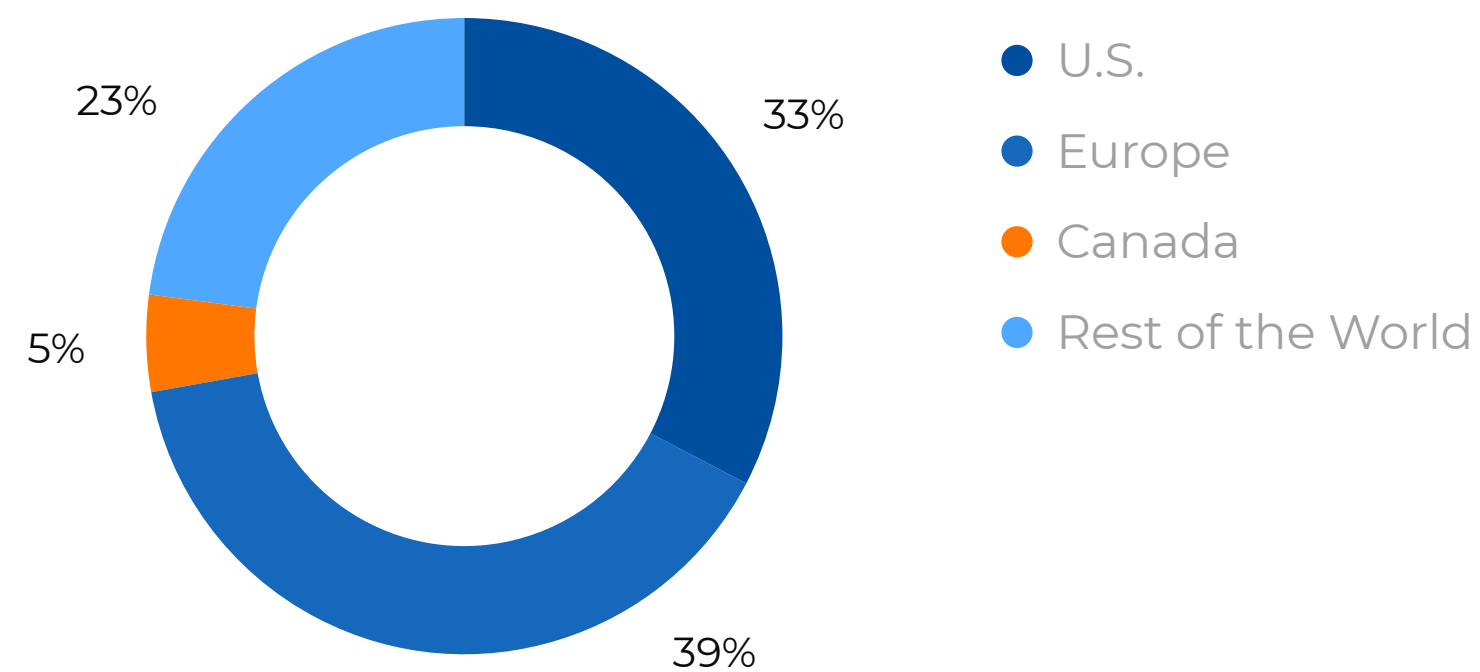


# Global Clinical Trials Trial Data

## 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 the Year 2019 remains almost the same in comparison to the Year 2018.

## Percentage breakdown of global clinical trials by Region



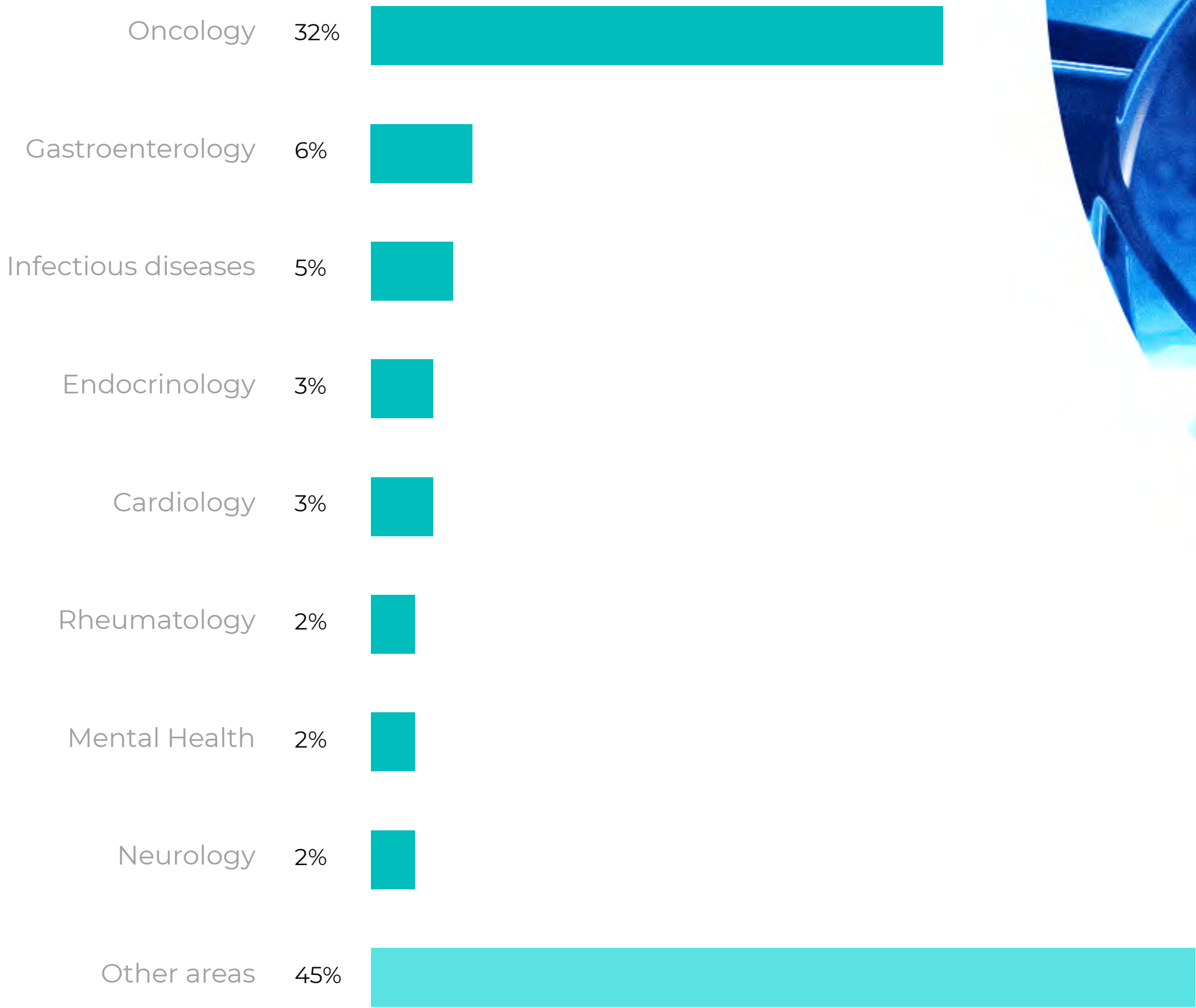


# Global Clinical Trials Trial Data

## Therapeutic Areas of Global Clinical Trials

In the Year 2019 the largest number of studies were initiated in Oncology (3,055 studies), Gastroenterology (536 studies), Infectious diseases (430 studies) and Endocrinology (331 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 6 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 worldwide where the study Phase has been identified, and just 13% of all enrolled subjects.

Observational clinical trials and clinical trials without U.S. FDA-defined Phases (from I to IV) were not included in this ranking. More than one Sponsor company may be involved into a Clinical trial.

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

Nº	Company Name	No. studies	No. subjects
1	Merck	185	49 629
2	Bristol-Myers Squibb	152	74 375
3	AstraZeneca	139	21 153
4	Pfizer	118	73 483
5	Novartis	111	23 632
6	Janssen	109	28 713
7	Eli Lilly	106	32 948
8	Sanofi	70	94 157
9	Boehringer Ingelheim	67	19 466
10	GlaxoSmithKline	66	19 276

Combined market share of top-10 companies **12%** **13%**





# Global Clinical Trials Subject Data

The total number of subjects enrolled in Clinical trials worldwide of all types in the Year 2019 reached 3,406,266 subjects.

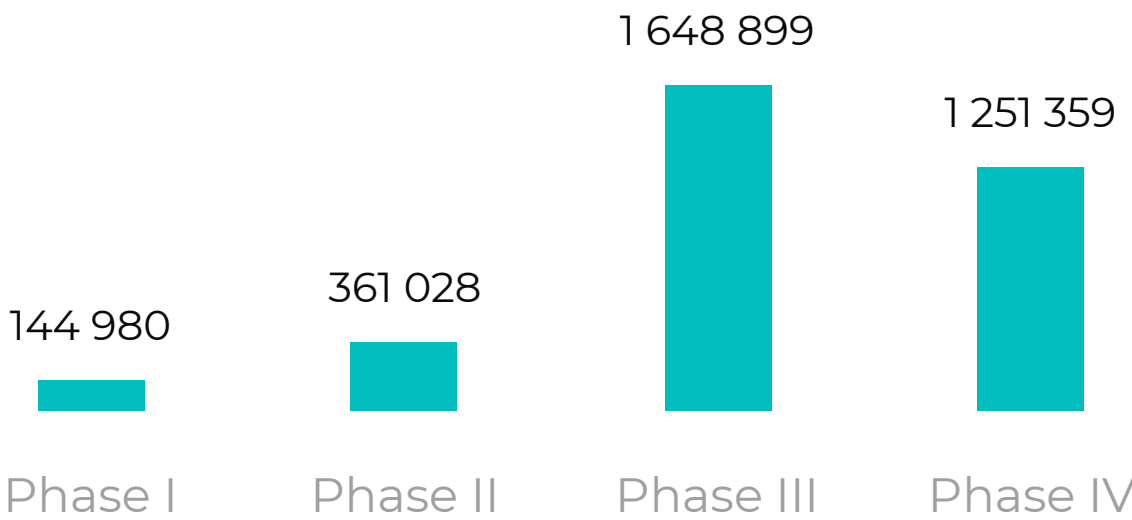
The majority of subjects were (or planned to be) enrolled in Phase III trials, and the largest proportion of the global subject population were from the U.S. and Canada.

However, the share of subjects participating in clinical trials remains extremely low in comparison with overall size of the population – with approximately 0,04% Worldwide.

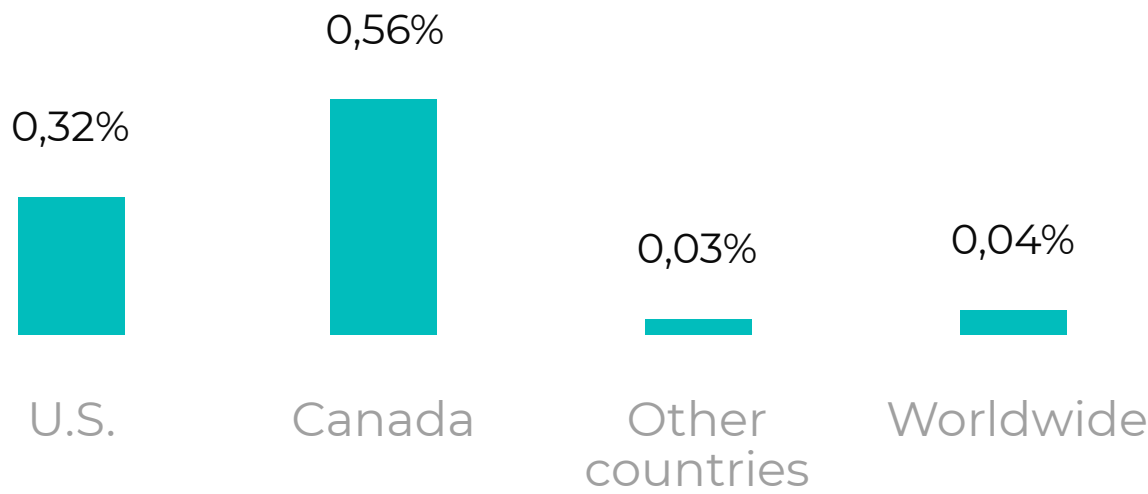


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Number of Subjects Enrolled Worldwide  
by Phase in Y 2019



Breakdown of Number of Subjects  
Enrolled as a % of Population



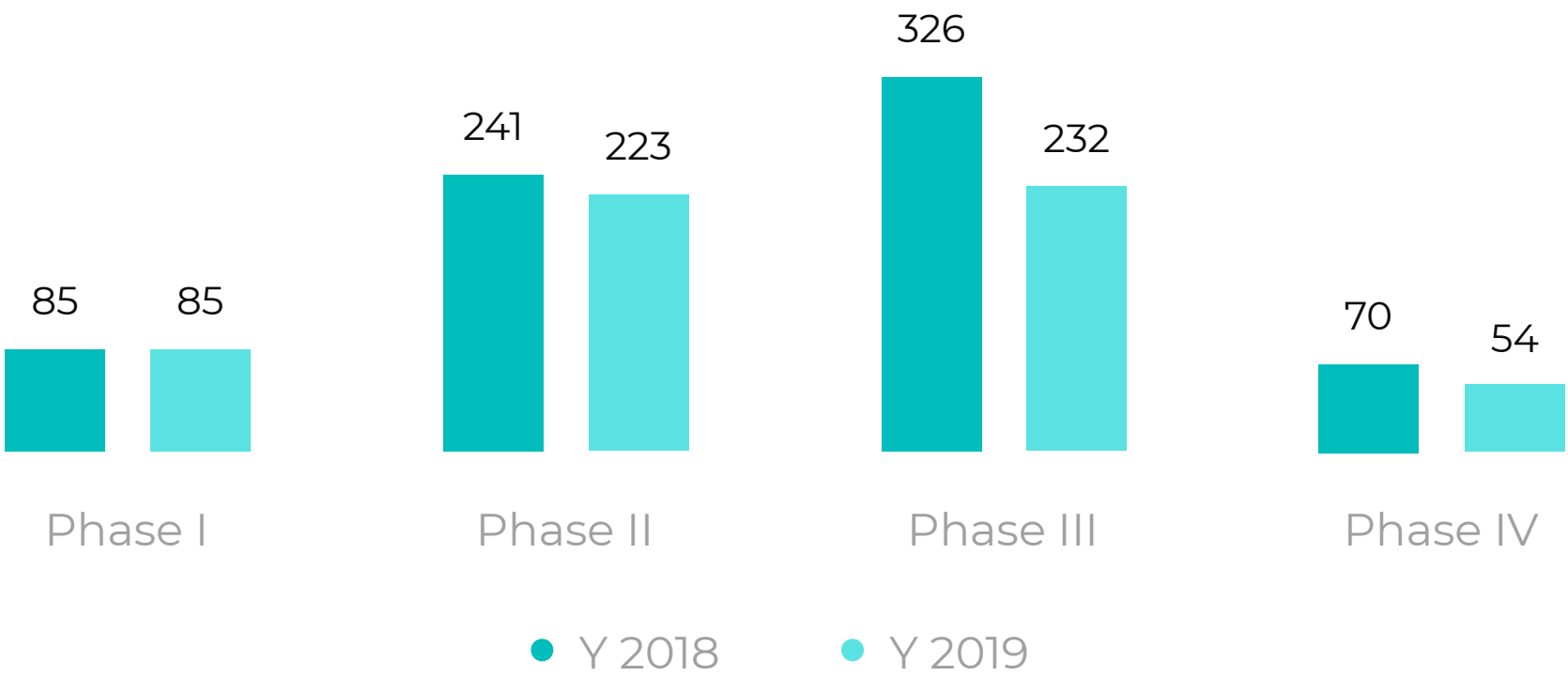


# Clinical Trials in Canada Trial Data

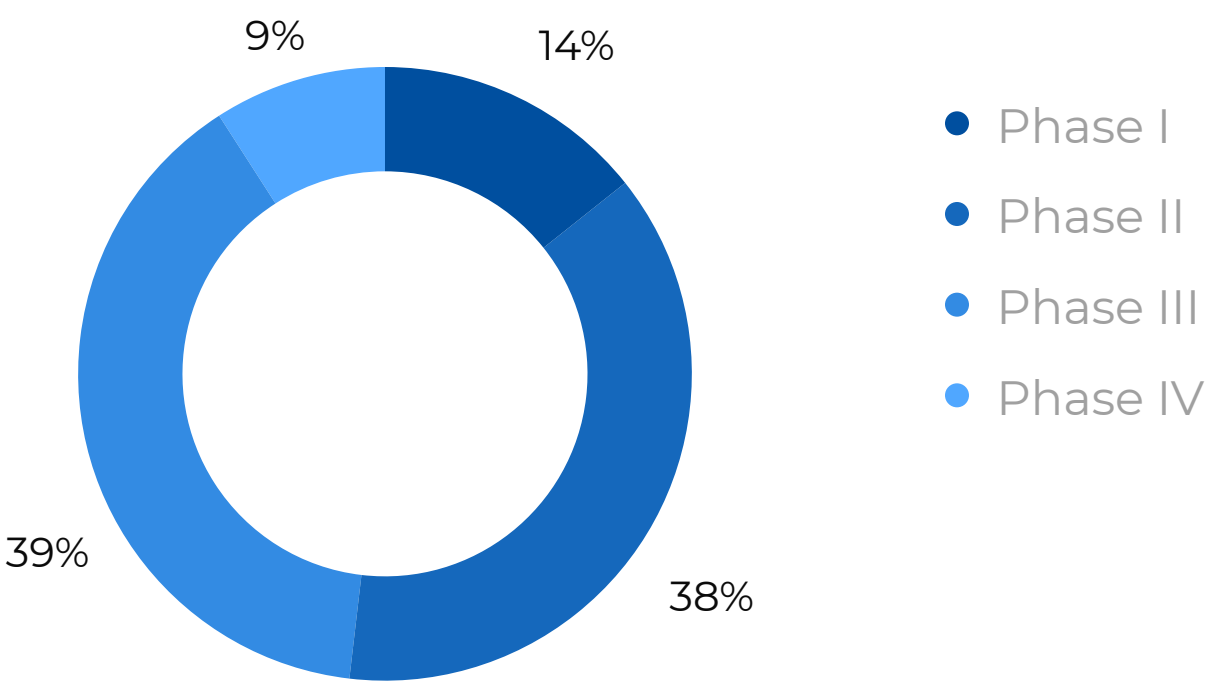
During the Year 2019 there were 1,343 clinical trials initiated in Canada including local and bioequivalence studies. That represents a 15% decline in comparison with the previous year when 1,579 studies were initiated. But if one exclude bioequivalence studies and studies without FDA-defined Phase there were only 594 clinical trials initiated during the Year 2019 compared to 722 studies initiated in previous year. The majority of clinical trials conducted in Canada were interventional studies with a 87% market share.

The most prevalent type of clinical trials conducted in Canadian sites were interventional studies with a 87% 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 Y 2019 by Phase



Percentage breakdown of Clinical Trials in Canada by Phase





# Clinical Trials in Canada Trial Data

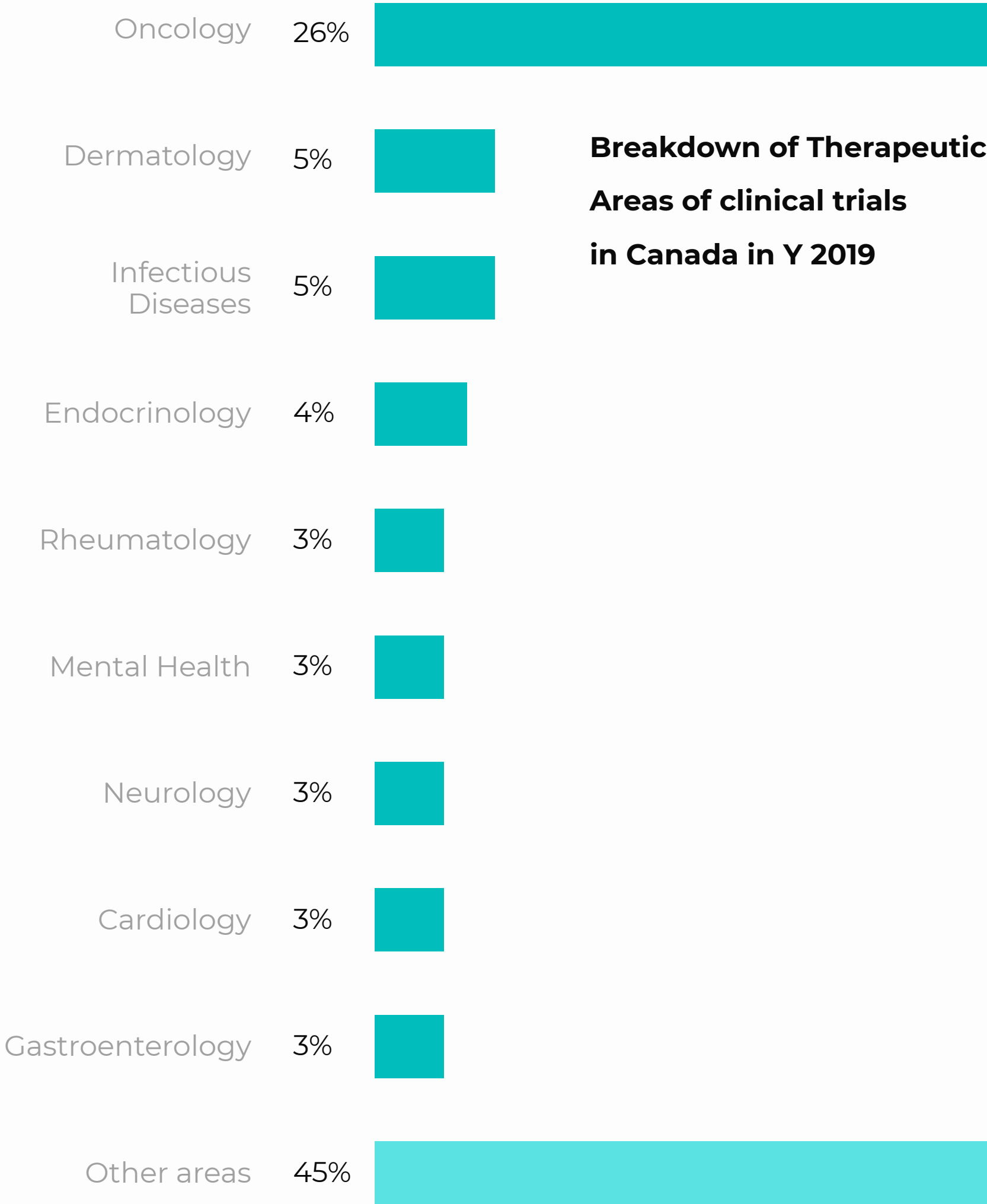
The largest number of clinical trials initiated in Canada during the Year 2019 were related to Oncology (157 studies), Dermatology (31 studies), Infectious diseases (27 studies), Endocrinology (24 studies) and Rheumatology (19 studies). Other prominent therapy areas included Neurology, Mental health, Cardiology and Gastroenterology.

The majority of Clinical trials conducted in Canada in the Year 2019 were Interventional studies with a 87% market share.

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.



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# 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 Year 2019 in Canada. The headquarters of the sponsor companies conducting clinical trials in the Year 2019 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 Y 2019

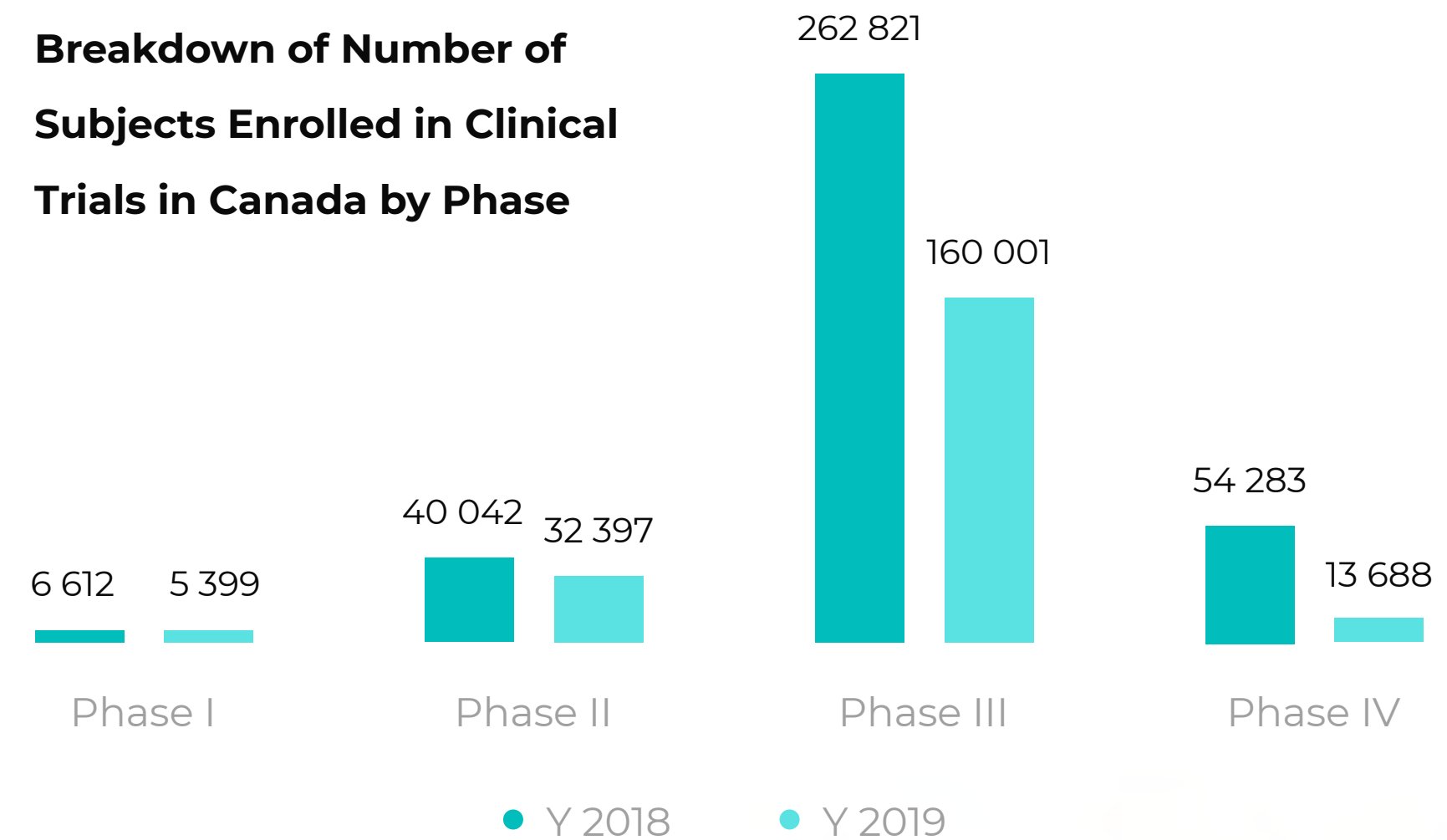
Nº	Company Name	No. studies	No. subjects
1	Merck	33	17 752
2	AstraZeneca	23	10 092
3	Bristol-Myers Squibb	21	13 382
4	AbbVie	16	4 641
5	Hoffmann-La Roche	14	7 982
6	Eli Lilly	13	11 538
7	Celgene	13	2 950
8	Novartis	13	2 849
9	GlaxoSmithKline	12	3 961
10	Pfizer	12	3 391
Combined market share of these companies		29%	37%



# Clinical Trials in Canada Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in the Year 2019 (including multi-center international studies) plunged from 363,758 subjects in the Year 2018 to 211,485 subjects in the Year 2019 with year on year decline of 42%.

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





# Canadian Regulatory Data

During the Year 2019 the Health Products and Food Branch of Health Canada authority approved 79 new drug applications. During the Year 2019 the authority also reviewed and approved 279 applications for marketing authorization for new medical devices.

In Q4 2019 the Health Products and Food Branch of Health Canada authority approved 10 new drug applications. During the same period the authority also reviewed and approved 47 applications for marketing authorization for new medical devices.

Nº	Appr. date	Drug (active ingredient)	Company
1	12/04/2019	Defitelio (Defibrotide Sodium)	Jazz Pharmaceuticals
2	11/28/2019	Mylotarg (Gemtuzumab Ozogamacin)	Pfizer
3	11/25/2019	Kadcyla (Trastuzumab Emtansine)	Hoffmann-La Roche
4	11/22/2019	Adcetris (Brentuximab Vedotin)	Seattle Genetics
5	11/22/2019	Flucelvax Quad (Surface Antigen, inactivated, prepared in Cell Cultures)	Seqirus
6	11/15/2019	Zonovate (Turoctocog Alfa)	Novo Nordisk
7	11/13/2019	Cimzia (Certolizumab Pegol)	UCB Canada
8	11/06/2019	Bavencio (Avelumab)	EMD Serono
9	10/25/2019	Darzalex (Daratumumab)	Janssen
10	10/08/2019	Nucala (Mepolizumab)	GlaxoSmithKline

**Health Products and Food Branch of Health Canada authority approved New Drug Applications – Q4 2019**



# Canadian Inspection Data

According to U.S. FDA data, the FDA conducted 20 inspections at Canadian investigative sites during the Year 2019, wherein 19 inspections ended with No Action Indicated (NAI) outcomes, and one inspection ended with Voluntary Action Indicated (VAI) outcome.

Nº	City	Company / Investigator Site Firm Name	Outcome
1	Montreal	Laboratoire BNK Canada	NAI
2	East York	Ronnie Aronson, M.D.	NAI
3	Richmond Hill	Apotex	NAI
4	Red Deer	Josias S. Badenhorst, M.D.	NAI
5	Toronto	Dr. Arun Ravindran, MBBS MSc., PhD	VAI
6	Quebec	Syneos Health	NAI
7	Scarborough	Lambda Therapeutic Research	NAI

Source: FDA

Nº	City	Company / Investigator Site Firm Name	Outcome
8	Montreal	Andre Lacroix, M.D.	NAI
9	Montreal	Syneos Health	NAI
10	Scarborough	Lambda Therapeutic Research	NAI
11	Laval	Biotrial Bioanalytical Service	NAI
12	Cambridge	Novocol Pharmaceutical	NAI
13	Calgary	Geoffrey Gotto, M.D.	NAI
14	North York	BioPharma Services	NAI
15	Quebec	inVentiv Health Clinique	NAI
16	Mont-Royal	Altasciences Company	NAI
17	Laval	Algorithme Pharma	NAI
18	Brampton	Harpreet Bajaj, M.D.	NAI
19	Scarborough	Hilltop Research	NAI
20	Vancouver	Donna Hogge, 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.

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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