

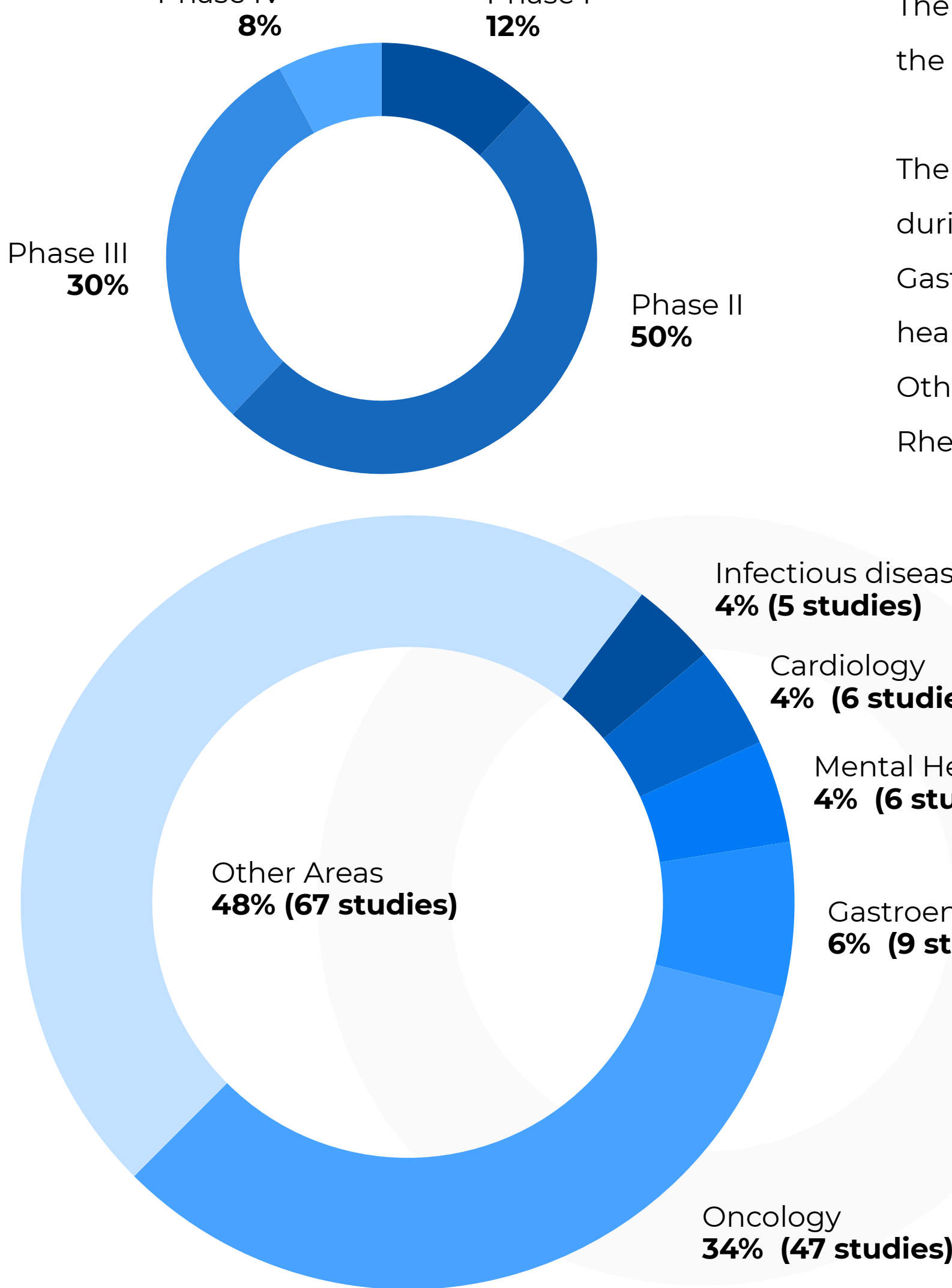
# Clinical Trials in Canada

Q3 2020 Research report

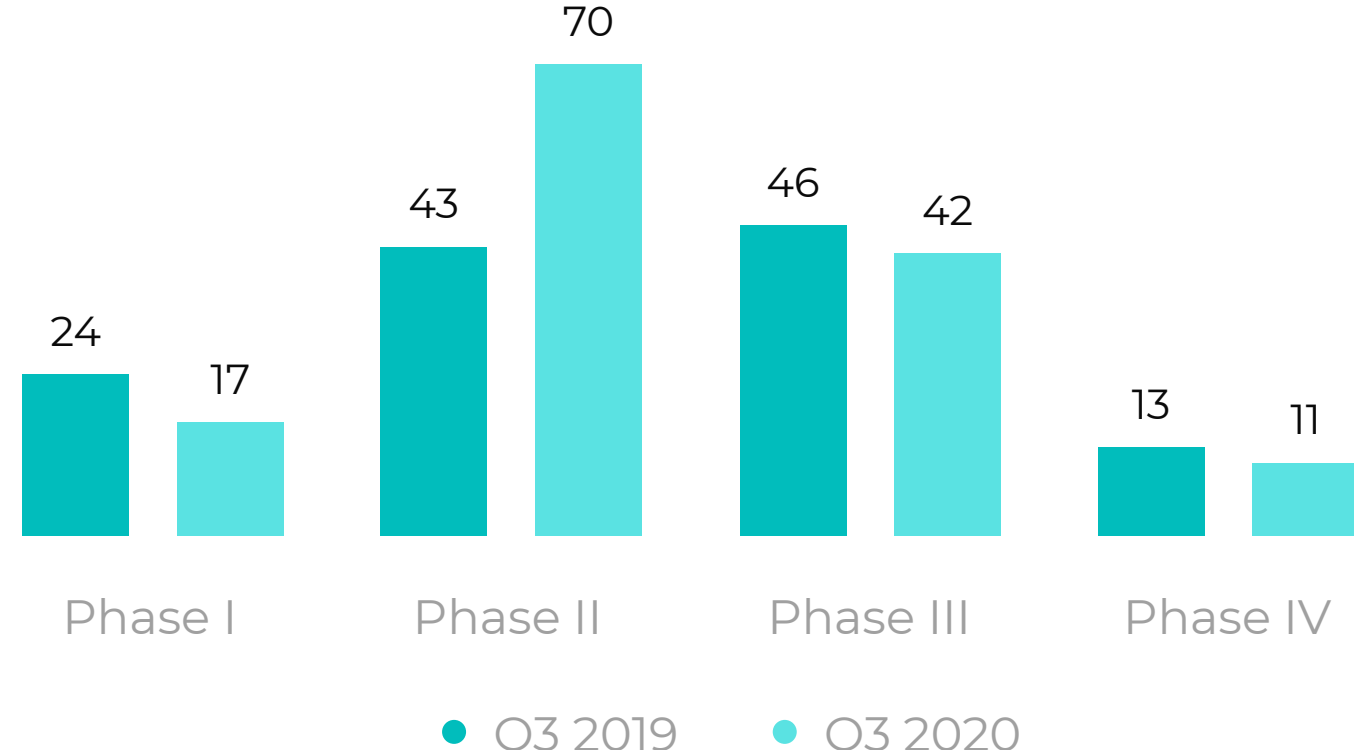
## Trial Data

During Q3 2020 there were 308 clinical trials initiated in Canada, including local and bioequivalence studies. That represents a 5% decline in comparison with the previous year when 325 studies were initiated. But if one excludes bioequivalence studies and studies without an FDA-defined Phase, there were only 140 clinical trials initiated during Q3 2020 compared to 126 studies initiated the previous year.

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



Breakdown of Clinical Trials by Phase (Canada)



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

The largest number of clinical trials initiated in Canada during Q3 2020 were related to Oncology (47 studies), Gastroenterology (9 studies), Cardiology (6 studies), Mental health (6 studies) and Infectious diseases (5 studies). Other prominent therapy areas included Hematology, Rheumatology and Surgery.

Breakdown of Clinical Trials by Therapeutic Area

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

"Other Areas" include Neurology, Ophthalmology, Mental health, Cardiology, Rheumatology, and Geriatrics

## Sponsor Data

By country of origin, the U.S. accounted for the largest number of pharmaceutical sponsored clinical trials in the Q3 2020 in Canada. The headquarters of the sponsor companies conducting clinical trials in Q3 2020 in Canada were evenly split between the US (5 companies) and Europe/UK (5 companies).

Observational trials and trials without FDA-defined phases (from I to IV) were not counted in the following ranking. Combined market share shown as a percentage of both international and Russian sponsors.

Top-10 Sponsors of Clinical trials in Canada in Q3 2020

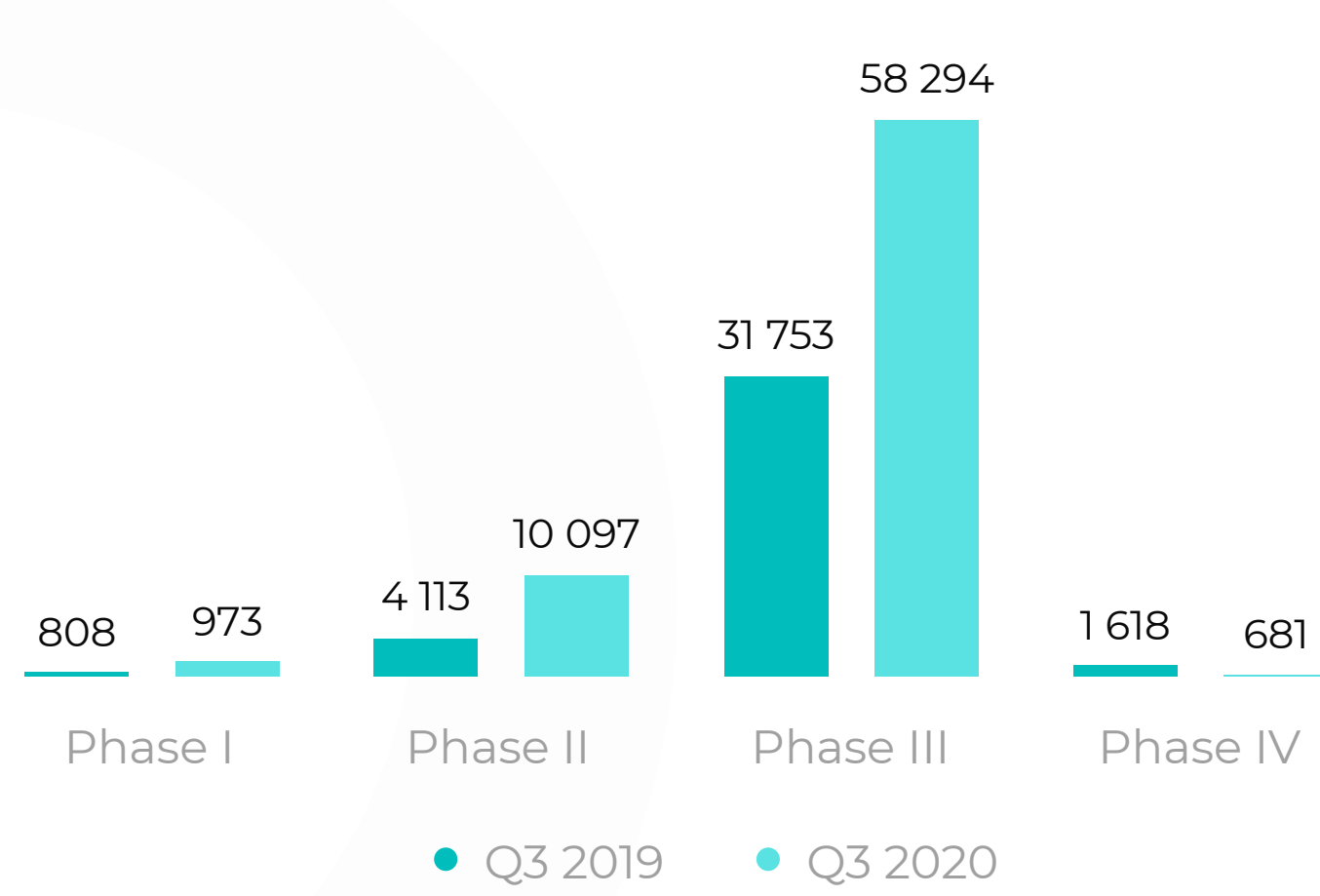
Nº	Company Name	Studies	Subjects
1	AstraZeneca	9	3 950
2	Janssen	6	2 886
3	AbbVie	6	1 694
4	Bristol-Myers Squibb	6	1 685
5	Pfizer	5	974
6	Bayer	4	6 984
7	Hoffmann-La Roche	4	2 910
8	Boehringer Ingelheim	4	1 464
9	Celgene	4	352
10	Merck	3	735
Combined share		36%	34%

## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in Q3 2020 (including multi-center international studies) jumped from 38,292 subjects in Q3 2019 to 70,045 subjects in Q3 2020 with year on year growth rate of 83%. The most prevalent Phase of clinical trials by total number of participating subjects was Phase III.

Studies indicated by sponsors as Phase I-II were counted as Phase II; Phase II-III – as Phase III, Phase III-IV – as Phase IV.

Breakdown of number of Subjects enrolled by Phase



## Regulatory Data

During Q3 2020 the Health Products and Food Branch of Health Canada authority approved 4 new drug applications.

Source: Health Canada

Appr.Date	Drug (Active Ingredient)	Company
02/07/2020	Energair Breezhaler (Indacaterol Acetate, Glycopyrronium Bromide, Mometasone Furoate)	Novartis
15/07/2020	Tomvi (Etomidate)	Sterimax
27/07/2020	Veklury (Remdesivir)	Gilead Sciences
31/07/2020	Firdapse (Amifampridine Phosphate)	Catalyst Pharmaceuticals

FDA inspections

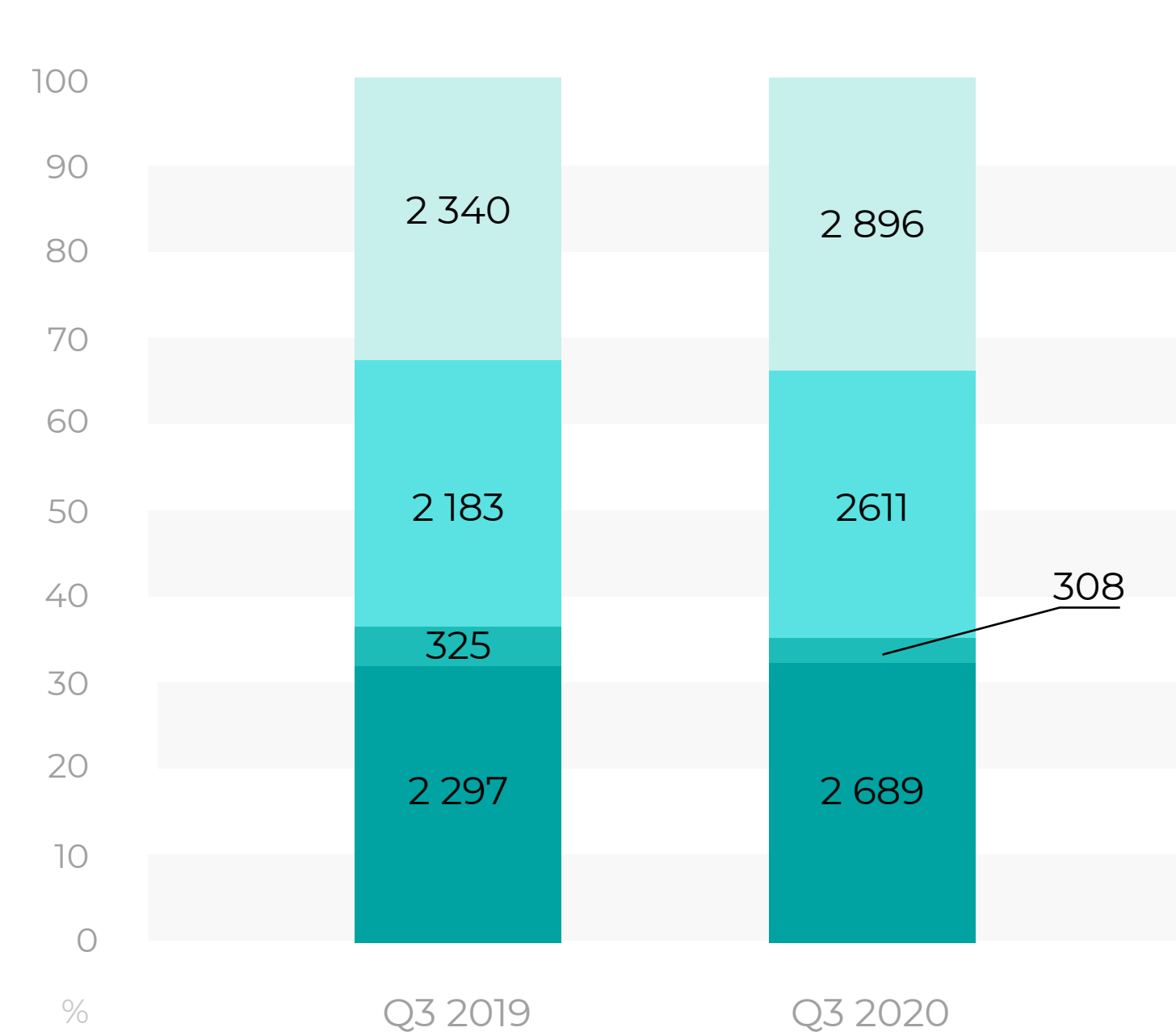
According to U.S. FDA data, there were no FDA inspections conducted in the Canadian investigative sites during Q3 2020.

## Worldwide Clinical Trials

During Q3 2020 the official FDA website showed approvals for initiation of 8,504 new clinical trials of all types worldwide, including local and bioequivalence studies with an overall year on year growth rate of 19% driven in large by an increasing number of trials in developing countries. According with the official FDA website there were only 3,300 studies with clearly defined study Phase I – IV.

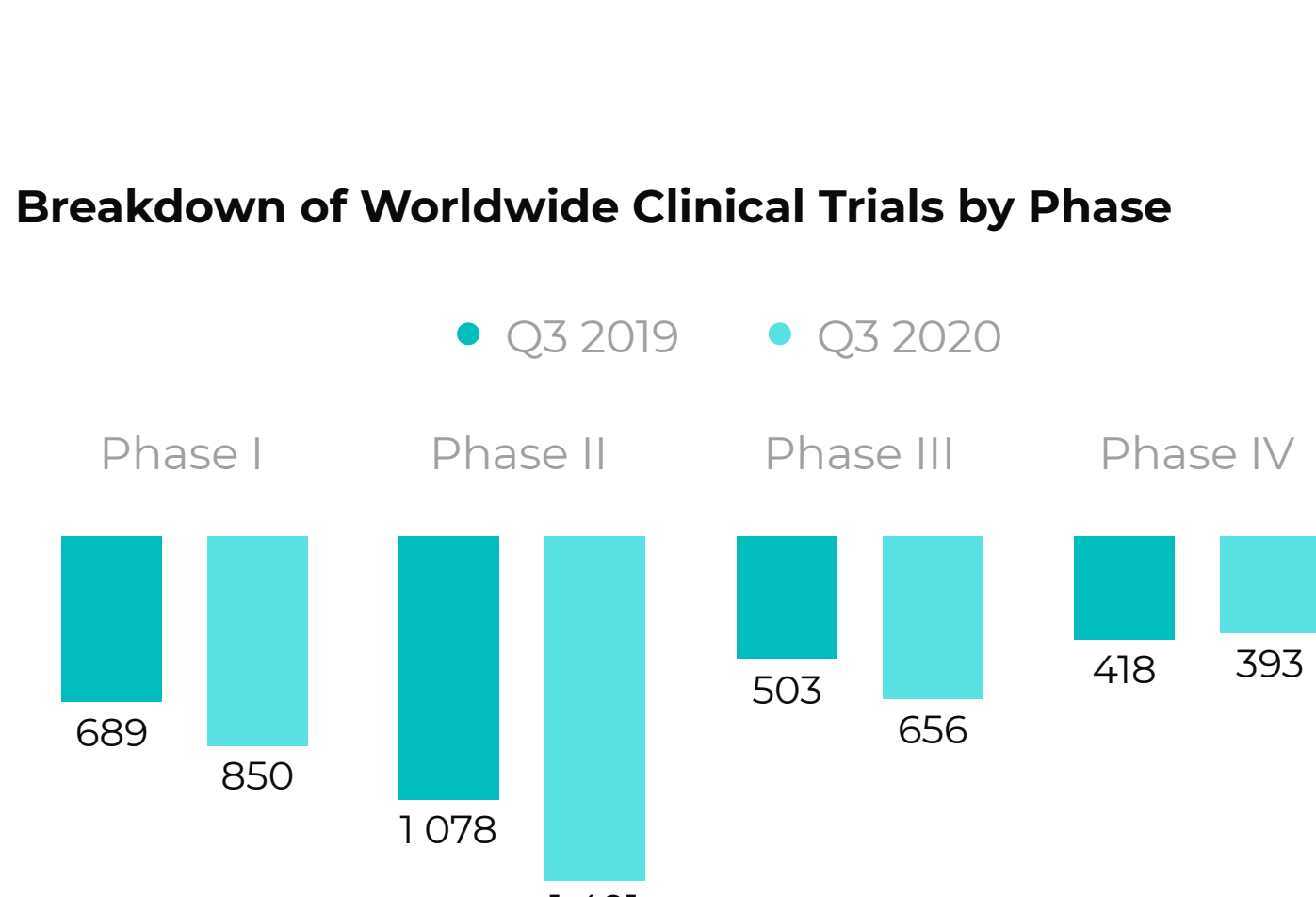
The combined market share of the U.S. and European countries by number of global initiated studies remains almost the same with 62%, with the U.S. and Europe both having 31%.

79% of all global clinical trials initiated during Q3 2020 were Interventional Clinical Trials.



The proportion of clinical trials between different global regions (i.e. U.S., Europe and Rest of the World) in Q3 2020 remains almost the same in comparison to Q3 2019.

Breakdown of Worldwide Clinical Trials by Phase



The Top-10 list of global Sponsors of Clinical Trials worldwide remained almost unchanged for the past 9 years – this fact may be explained by the significant and continuously increasing amount of investment required for research and development of new drugs. But in Q3 2020 the new Chinese challenger – Jiangsu HengRui Medicine company – appeared in this ranking for the first time.

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 5% of all enrolled subjects.

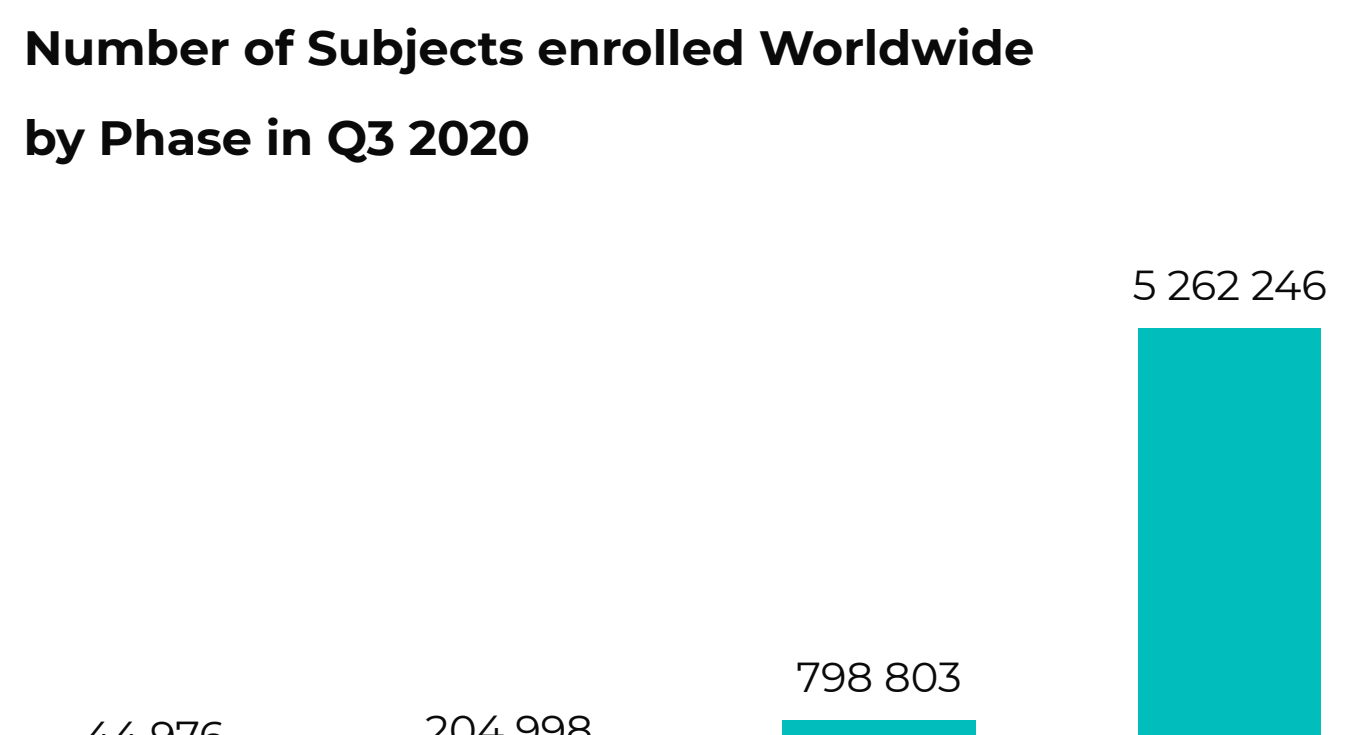
Here are the top-10 global sponsors by total number of studies initiated in Q3 2020.

Nº	Site Name	No. Studies	No. Subjects
1	Merck	56	11 854
2	AstraZeneca	52	40 561
3	Janssen	51	75 694
4	Pfizer	47	114 268
5	Novartis	38	7 429
6	Eli Lilly	35	8 368
7	Bristol-Myers Squibb	35	4 595
8	Hoffmann-La Roche	27	7 513
9	Jiangsu HengRui Medicine	27	4 071
10	GlaxoSmithKline	25	9 701
Combined market share of these companies		12%	5%

The total number of subjects enrolled in Clinical trials worldwide of all types in Q3 2020 reached 6,311,023 subjects. The majority of subjects were (or planned to be) enrolled in Phase III and Phase IV trials, and the largest proportion of the global subject population were from the U.S., Canada and European countries.

However, the share of subjects participating in clinical trials remains extremely low in comparison with overall size of the population – with approximately 0,08% Worldwide.

Number of Subjects enrolled Worldwide by Phase in Q3 2020



## About The Orange Paper

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: 01/10/2020

## About Synergy Research Group

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

We set up the highest level of world-class quality both for SOPs and for final study data in every clinical trial we conduct.

Synergy consistently ranks in the top-10 market leaders by number of conducted clinical studies and enrolled patients. 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 are continuously improving our SOPs, study risk management and IT infrastructure – and replacing outdated R&D strategies by novel, more efficient approaches to clinical research.