

Clinical Trials in Canada

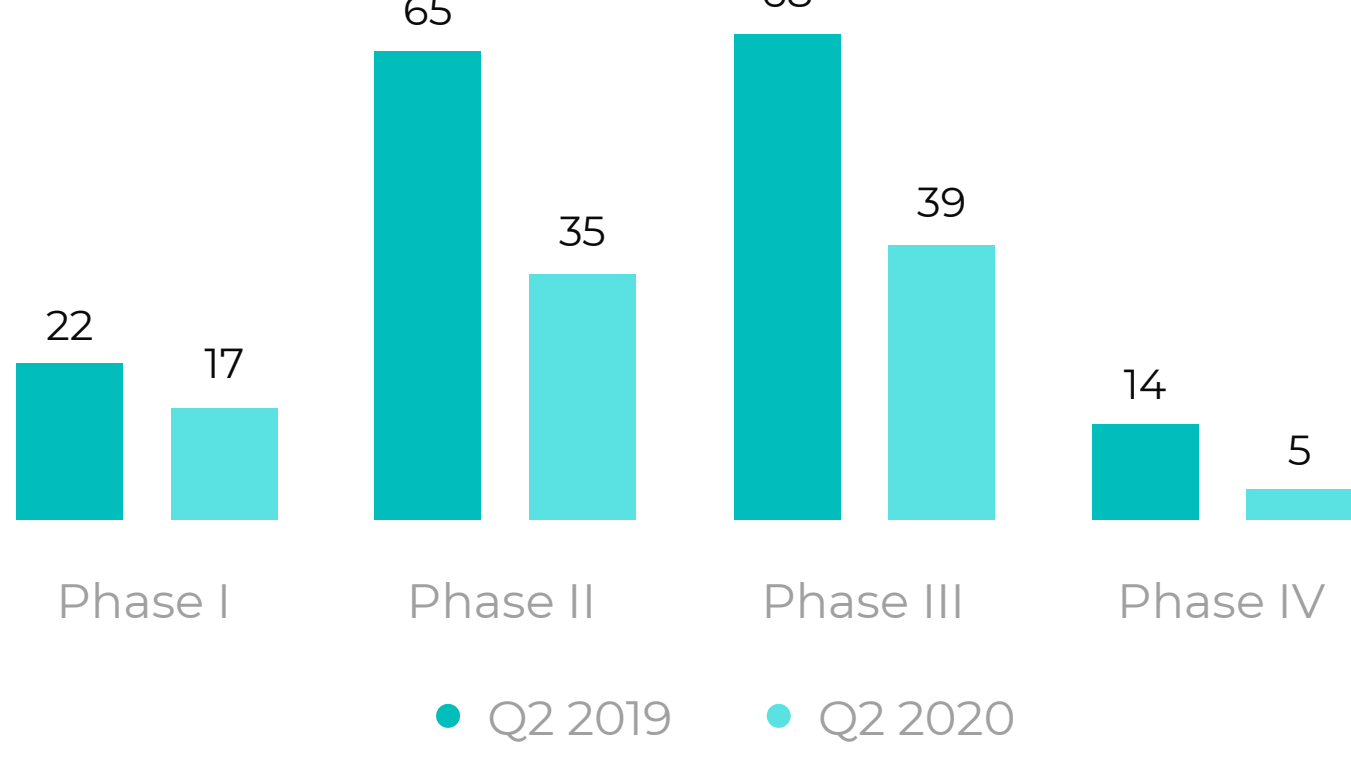
Q2 2020 Research report

Trial Data

During Q2 2020 there were 222 clinical trials initiated in Canada including local and bioequivalence studies. That represents a 39% collapse in comparison with the previous year when 362 studies were initiated. But if one excludes bioequivalence studies and studies without an FDA defined Phase there were only 96 clinical trials initiated during Q2 2020 compared to 169 studies initiated in previous year.

The majority of clinical trials conducted in Canada were interventional studies with a 82% market share.

Breakdown of Clinical Trials by Type and Phase



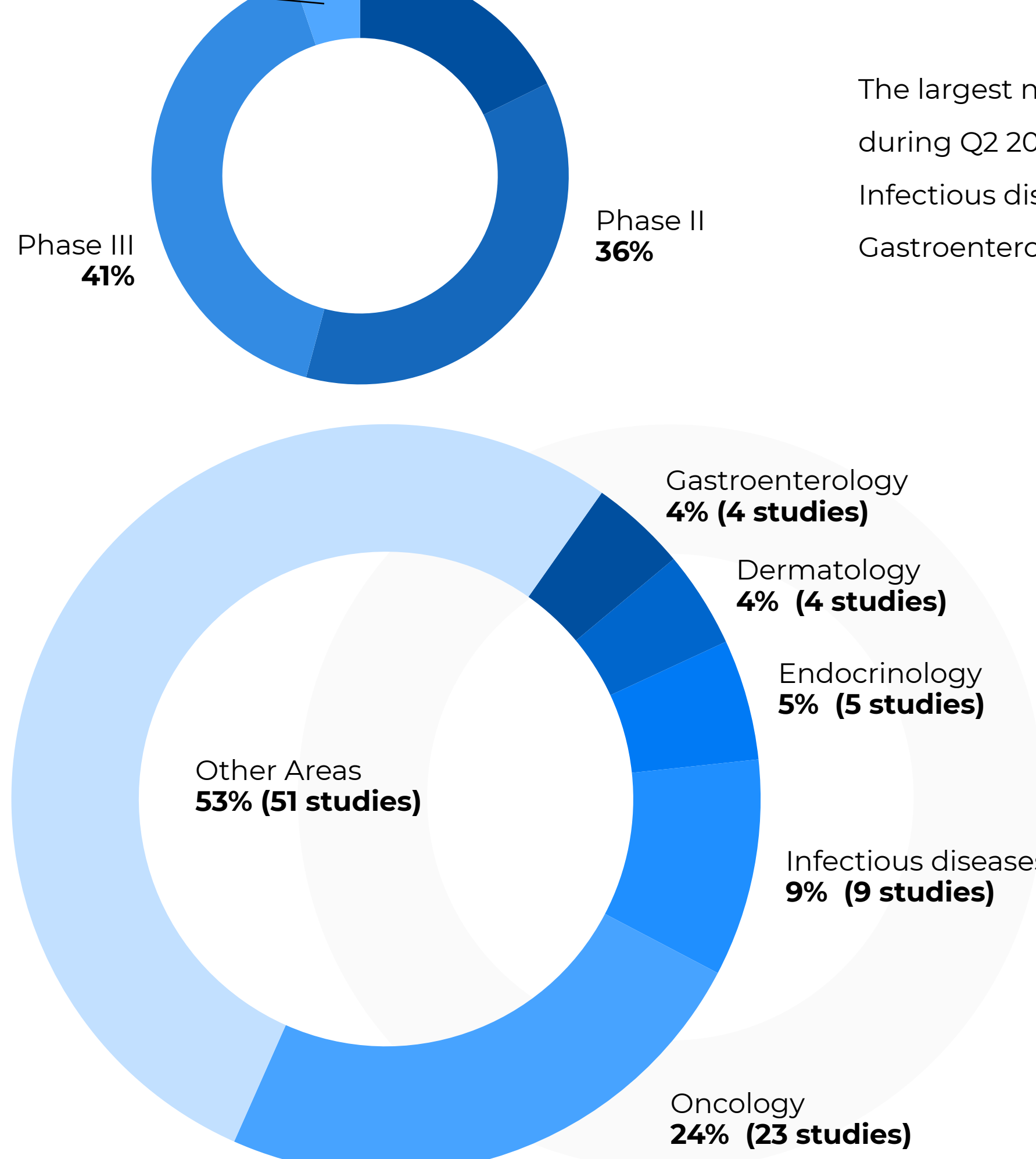
The most frequent phase of clinical trials conducted across the Canadian sites by number of studies was Phase III.

The largest number of clinical trials initiated in Canada during Q2 2020 were related to Oncology (23 studies), Infectious diseases (9 studies), Endocrinology (5 studies), Gastroenterology (4 studies) and Dermatology (4 studies).

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 Q2 2020 in Canada. The headquarters of the sponsor companies conducting clinical trials in Q2 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 Q2 2020

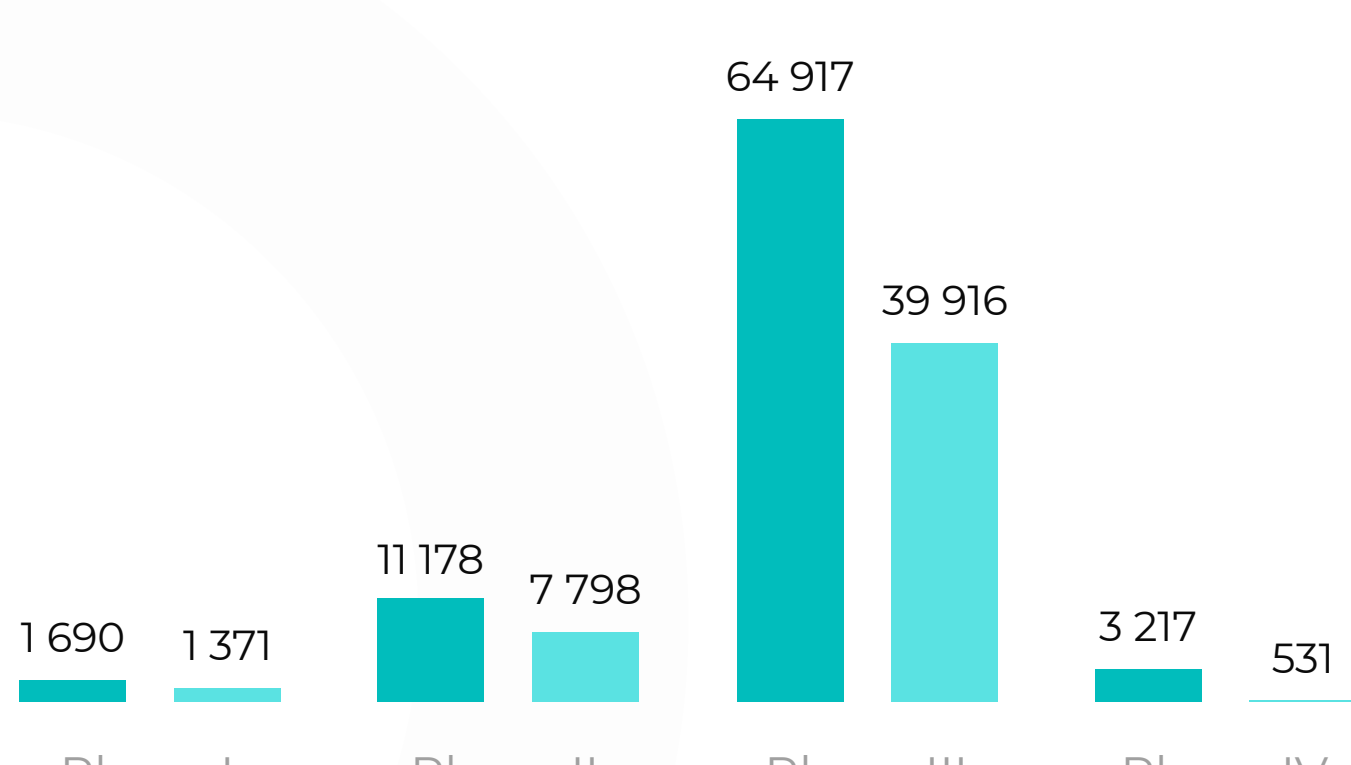
Nº	Company Name	Studies	Subjects
1	Eli Lilly	7	16 425
2	AstraZeneca	6	2 588
3	Hoffmann-La Roche	5	1 423
4	Pfizer	4	1 351
5	AbbVie	4	301
6	Bayer	3	5 236
7	Actelion	2	1 044
8	Novartis	2	840
9	Celgene	2	116
10	Regeneron	1	960
Combined share		38%	61%

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in Q2 2020 (including multi-center international studies) plunged from 81,002 subjects in Q2 2019 to 49,616 subjects in Q2 2020 with year on year decline of 39%. 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

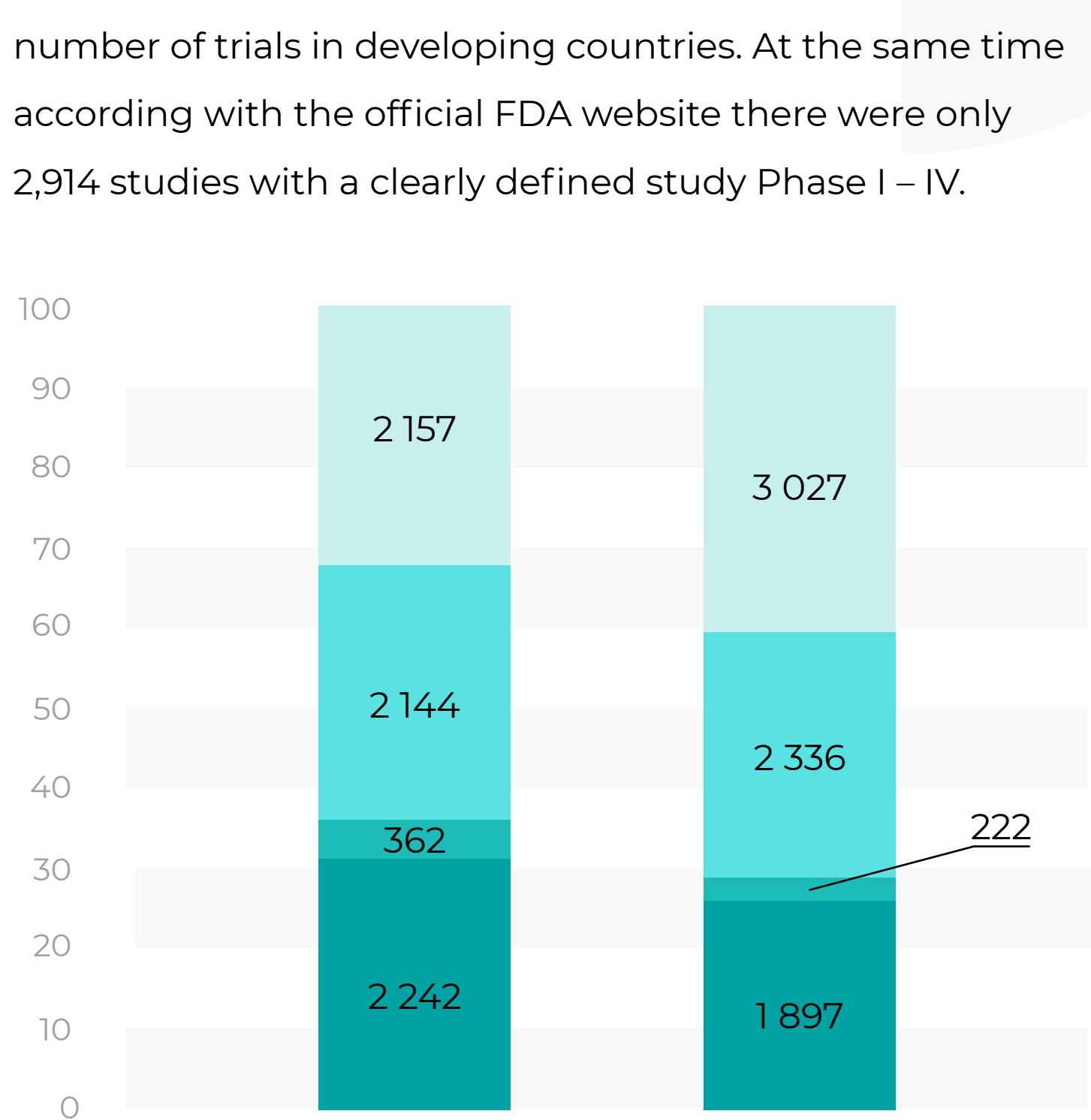
During Q2 2020 the Health Products and Food Branch of Health Canada authority approved 7 new drug applications.

Source: Health Canada

Appr.Date	Drug (Active Ingredient)	Company
09/04/2020	Ajovy (Fremanezumab)	Teva
15/04/2020	Itulatek (standardized Allergen Extract, White Birch)	ALK-Abellø
16/04/2020	Nivestym (Filgrastim)	Pfizer
28/04/2020	Riximyo (Rituximab)	Sandoz
29/04/2020	Sarclisa (Isatuximab)	Sanofi
04/05/2020	Ruxience (Rituximab)	Pfizer
01/06/2020	Enspryng (Satralizumab)	Hoffmann-La Roche

Worldwide Clinical Trials

During Q2 2020 the official FDA website showed approvals for initiation of 7,482 new clinical trials of all types, 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 2,914 studies with a 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 Q2 2019 to 56% in Q2 2020, with the U.S. having 25% and Europe having 31%. 74% of all global clinical trials initiated during Q2 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 Q2 2020 changed in comparison to Q2 2019. The share of U.S. dipped from 32% to 25% whilst the Rest of the World countries share increased from 31% to 41%.

Breakdown of Worldwide Clinical Trials by Phase



The Top-10 list of global Sponsors of Clinical Trials worldwide remained almost unchanged for the past 8 years – this fact may be explained by the significant and continuously increasing amount of investment required for research and development of new drugs. During Q2 2020 two new Chinese challengers appeared in this ranking for the first time: Jiangsu HengRui Medicine and Chia Tai Tianqing Pharmaceutical Group.

Nº	Site Name	No. Studies	No. Subjects
1	AstraZeneca	42	9 981
2	Merck	39	21 705
3	Pfizer	37	35 268
4	Jiangsu HengRui Medicine	34	6 087
5	Novartis	31	7 242
6	Janssen	29	3013
7	Sanofi	22	5 992
8	Bristol-Myers Squibb	22	1 562
9	Eli Lilly	21	18 589
10	Chia Tai Tianqing Pharmaceutical Group	20	3 451

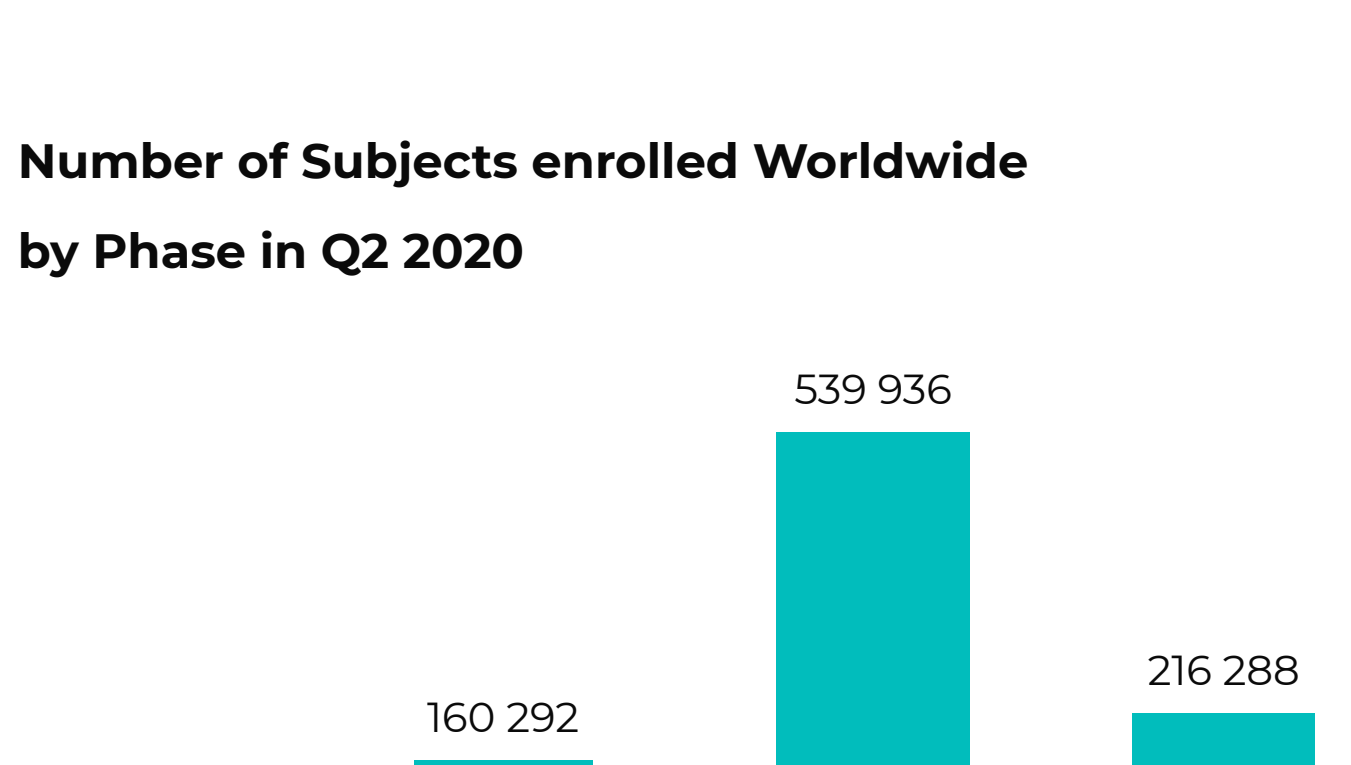
Combined market share of these companies

10% 12%

The total number of subjects enrolled in Clinical trials worldwide of all types in Q2 2020 reached 948,193 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 0,01% Worldwide.

Number of Subjects enrolled Worldwide by Phase in Q2 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: 01/07/2020

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.

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.

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.