

Clinical Trials in Canada

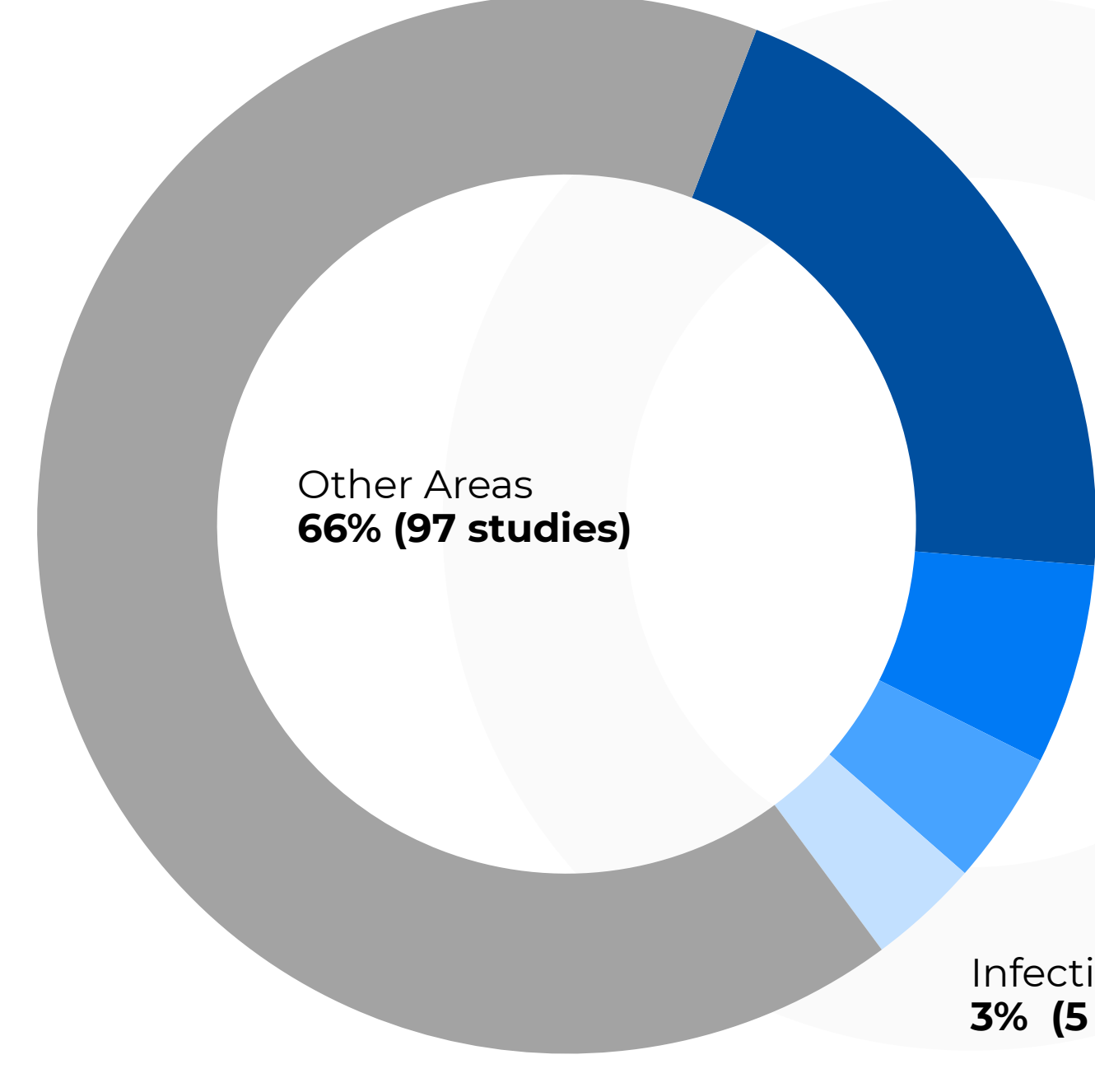
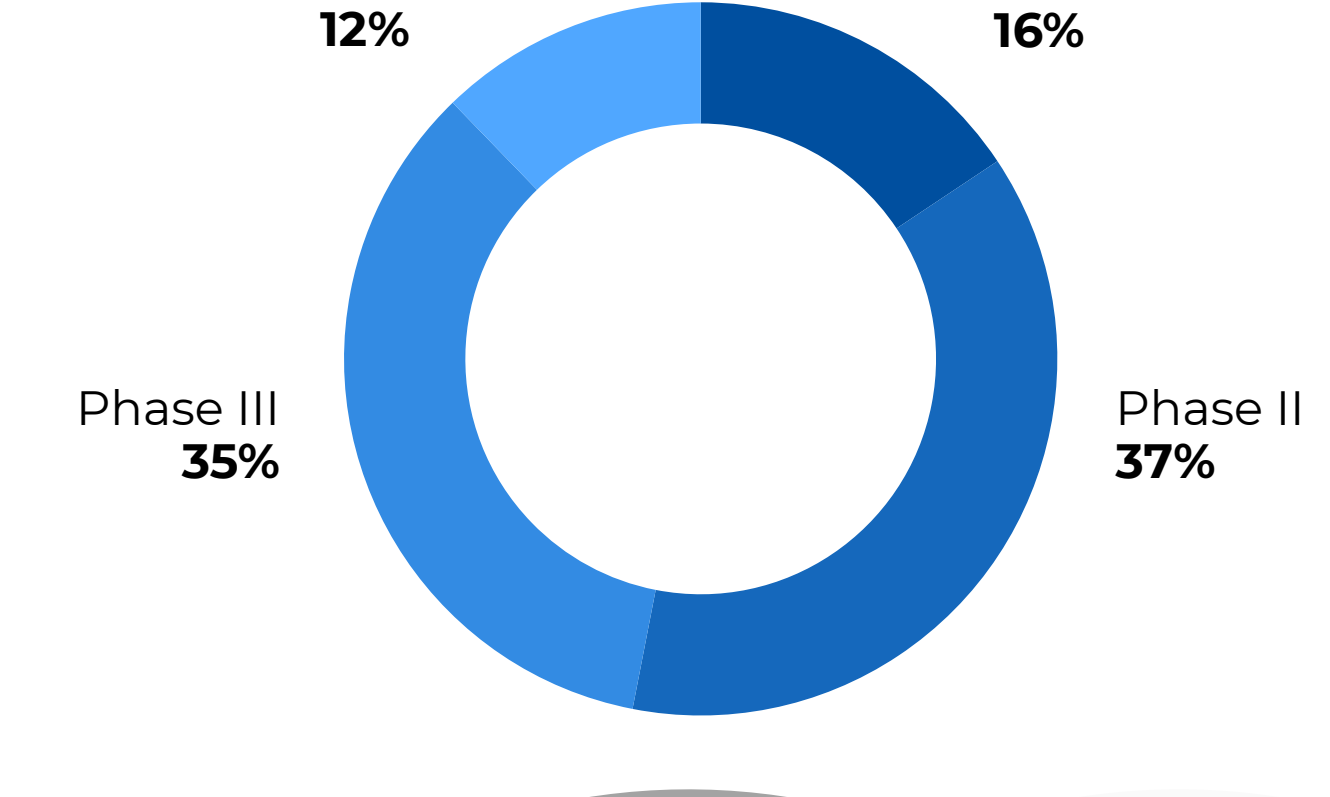
Q2 2021 Research report

Trial Data

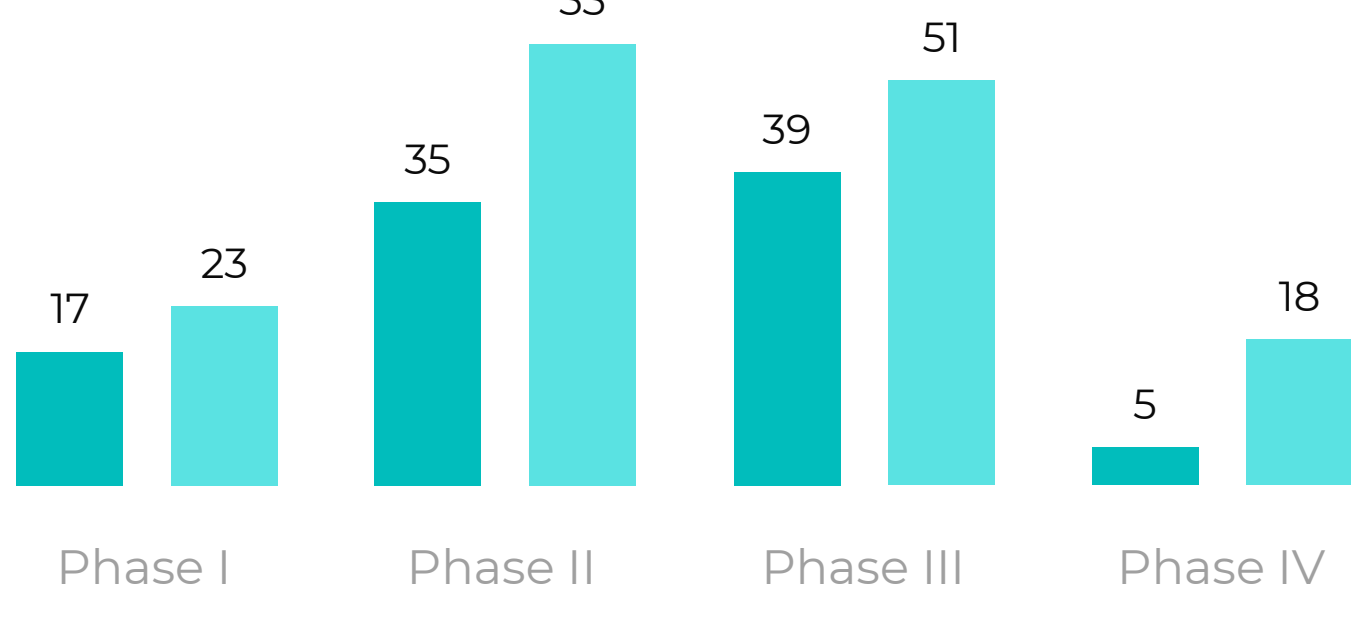
During Q2 2021 there were 350 clinical trials initiated in Canada including local and bioequivalence studies. That represents a 58% jump rate in comparison with the previous year when 222 studies were initiated.

But if one excludes bioequivalence studies and studies without an FDA-defined Phase, there were only 147 clinical trials initiated during Q2 2021 - compared to 96 studies initiated in the previous year.

The majority of clinical trials conducted in Canada were interventional studies with a 88% 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 Q2 2021 were related to Oncology (30 studies), Mental health (9 studies), Cardiology (6 studies) and Infectious diseases (5 studies). Other prominent therapy areas included Gastroenterology, Hematology, Dermatology and Neurology.

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" includes: Gastroenterology, Hematology, Dermatology, Neurology, Rheumatology, Geriatrics, Immunology, Endocrinology, Ophthalmology, Surgery.

Sponsor Data

By country of origin, the European companies accounted for the largest number of pharmaceutical sponsored clinical trials in Q2 2021 in Canada. The headquarters of the sponsor companies conducting clinical trials in Q2 2021 in Canada were almost evenly split between the U.S. (4 companies) and Europe/UK (6 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 2021

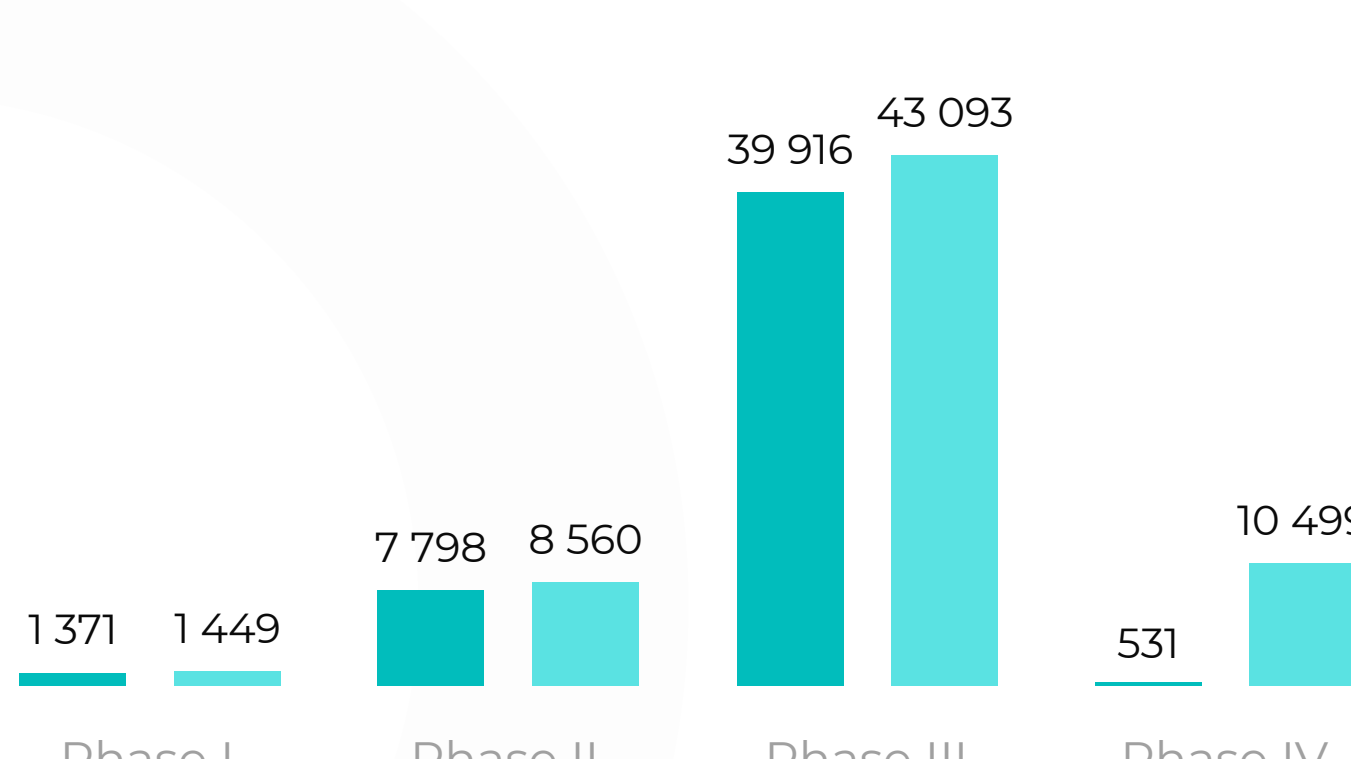
Nº	Company Name	Studies	Subjects
1	Hoffmann-La Roche	10	3 472
2	AstraZeneca	7	5 369
3	Novo Nordisk	5	6 070
4	AbbVie	4	1 035
5	Merck	4	607
6	Janssen	3	19 706
7	Sanofi	3	298
8	LEO Pharma	2	900
9	Amgen	2	670
10	Bristol-Myers Squibb	2	584
Combined share		29%	61%

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in Q2 2021 (including multi-center international studies) jumped from 49,616 subjects in Q2 2020 to 63,601 subjects in Q2 2021 with year on year growth rate of 28%. 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 2021 the Health Products and Food Branch of Health Canada authority approved 7 new drug applications.

Source: Health Canada

Appr.Date	Drug (Active Ingredient)	Company
15.04.2021	Enhertu (Trastuzumab Deruxtecan)	AstraZeneca
05.05.2021	Pfizer-BioNTech COVID-19 Vaccine (Tozinameran)	BioNTech - Pfizer
19.05.2021	Ilumya (Tildrakizumab)	Sun Pharma
26.05.2021	Abecma (Idecabtagene Vicleucel)	Celgene
08.06.2021	Tecartus (Brexucabtagene Autoleucel)	Gilead Sciences
09.06.2021	Casirivimab and Imdevimab (Casirivimab and Imdevimab)	Hoffmann-La Roche
24.06.2021	Ruzurgi (Amifampridine)	Medunik

FDA inspections

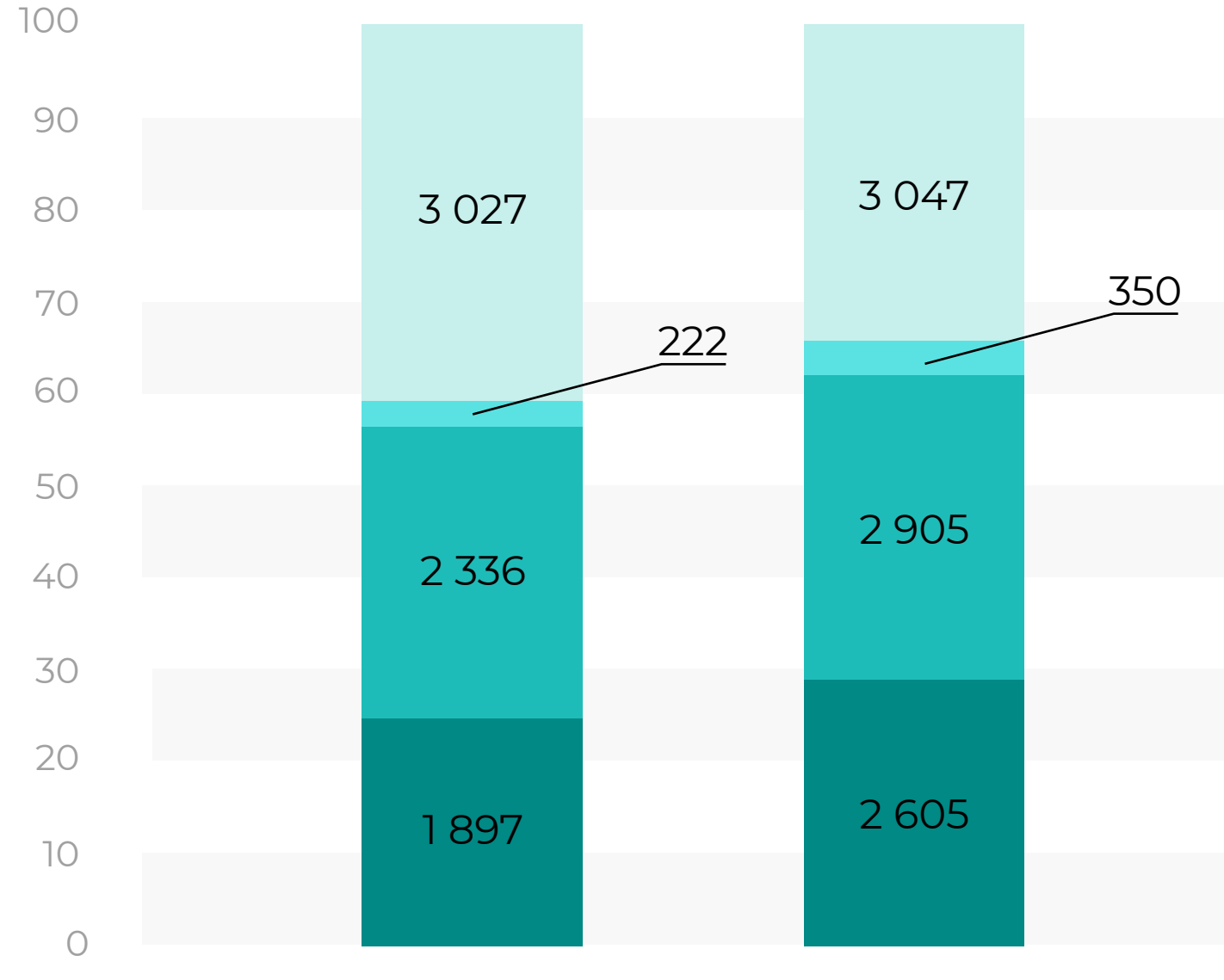
According to U.S. FDA data, there were no FDA inspections conducted in the Canadian investigative sites during Q2 2021

Worldwide Clinical Trials

During Q2 2021 the official FDA website showed approvals for initiation of 8,907 new clinical trials of all types worldwide, including local and BE studies with an overall year on year growth rate of 19% driven in large by an increasing number of trials in developed countries. At the same time according with the official FDA website there were only 3,205 studies with a clearly defined study Phase.

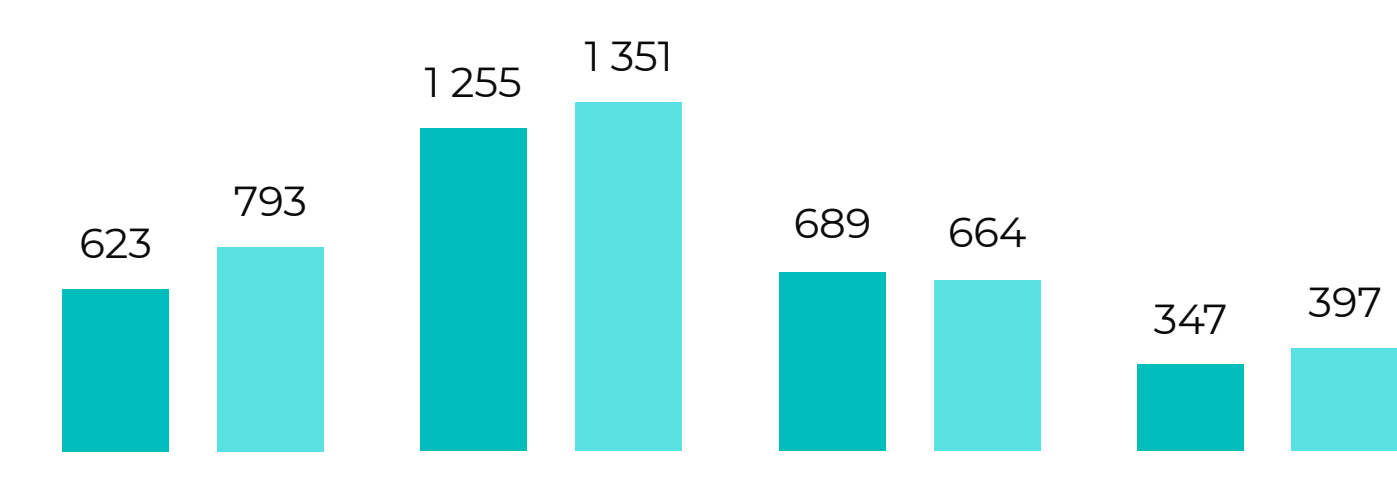
The combined market share of the U.S. and European countries by number of global initiated studies increased from 56% to 62%, with the U.S. having 29% and Europe having 33%.

78% of all global clinical trials initiated during Q2 2021 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 2021 slightly changed in comparison to the previous year: the combined market share of developing countries dipped from 41% to 34%.

Breakdown of Worldwide Clinical Trials by Phase



The Top-10 list of global Sponsors of Clinical Trials worldwide remained almost unchanged for the past 10 years - this fact may be explained by the significant and continuously increasing amount of investment required for research and development of new drugs.

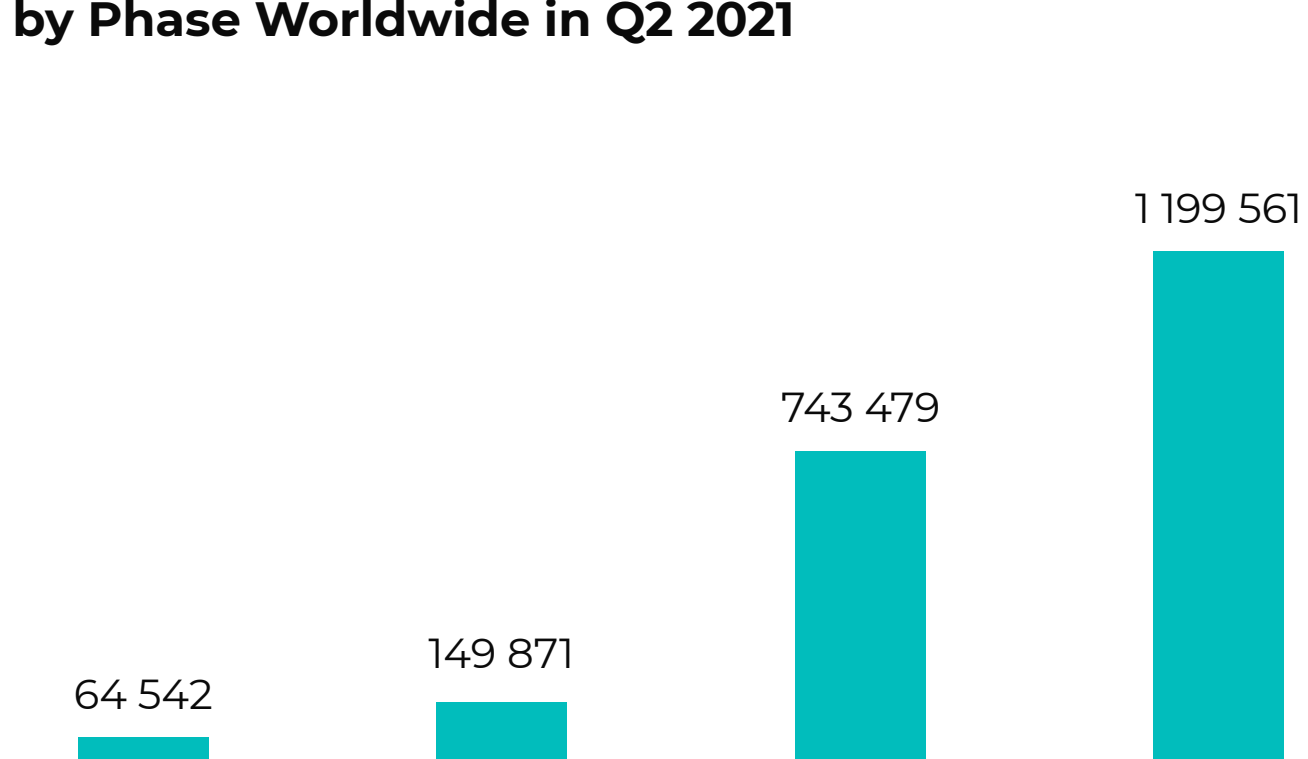
However, it's remarkable that the combined market power of these leading pharmaceutical corporations accounts for just 11% of all interventional clinical trials worldwide where the study Phase has been identified, and just 5% of all enrolled subjects.

Nº	Site Name	No. Studies	No. Subjects
1	Merck	51	11 618
2	AstraZeneca	47	11 153
3	Novartis	45	11 771
4	Janssen	38	23 939
5	Pfizer	38	15 711
6	Jiangsu HengRui Medicine	31	9 650
7	Bristol-Myers Squibb	30	3 372
8	Hoffmann-La Roche	27	10 283
9	Eli Lilly	27	6 541
10	Boehringer Ingelheim	24	5 857
Combined market share of these companies		11%	5%

The total number of subjects enrolled in Clinical trials worldwide of all types in Q2 2021 reached 2,157,453 subjects. The majority of subjects were (or were 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 - approximately 0,03% Worldwide.

Breakdown of Number of Subjects Enrolled by Phase Worldwide in Q2 2021



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: 12/07/2021

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.