

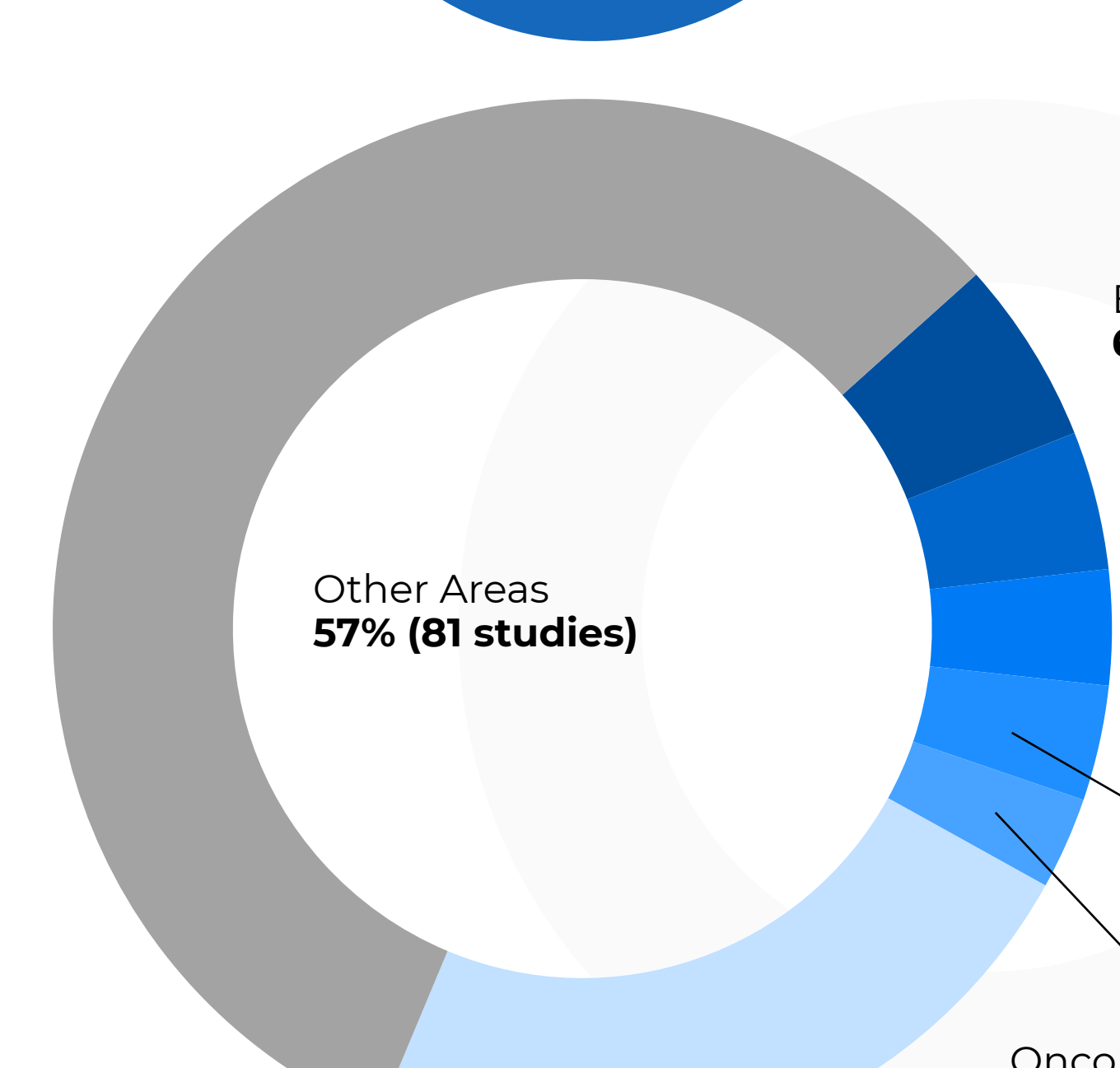
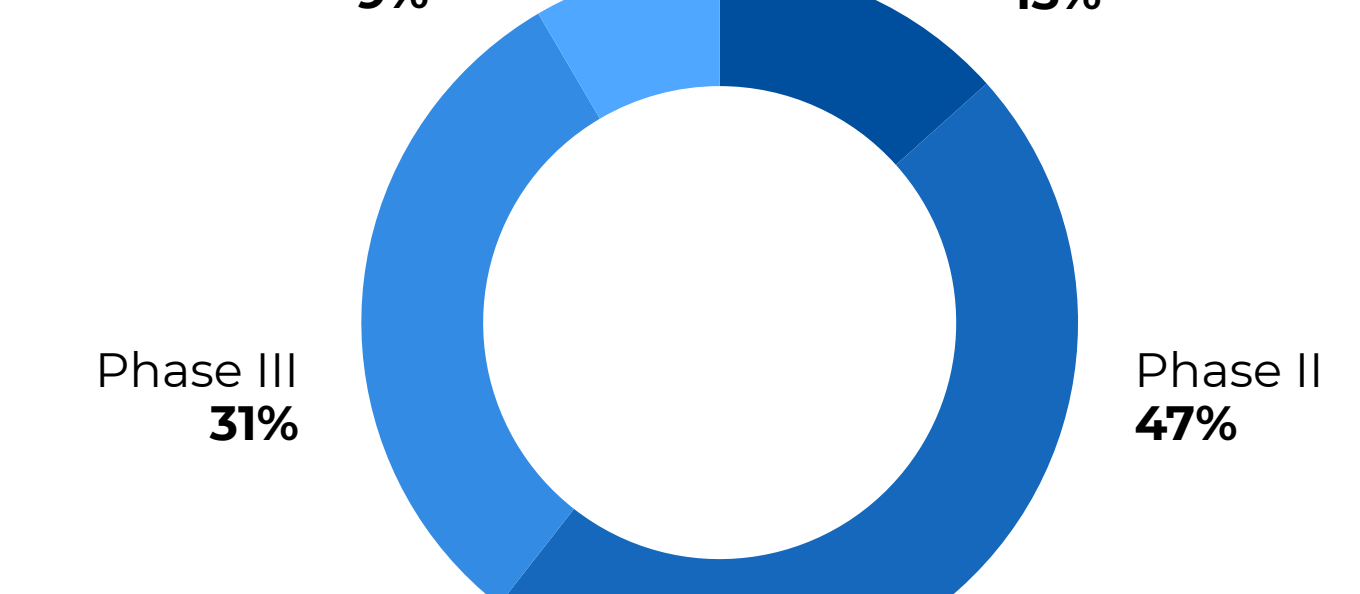
Clinical Trials in Canada

Q1 2021 Research report

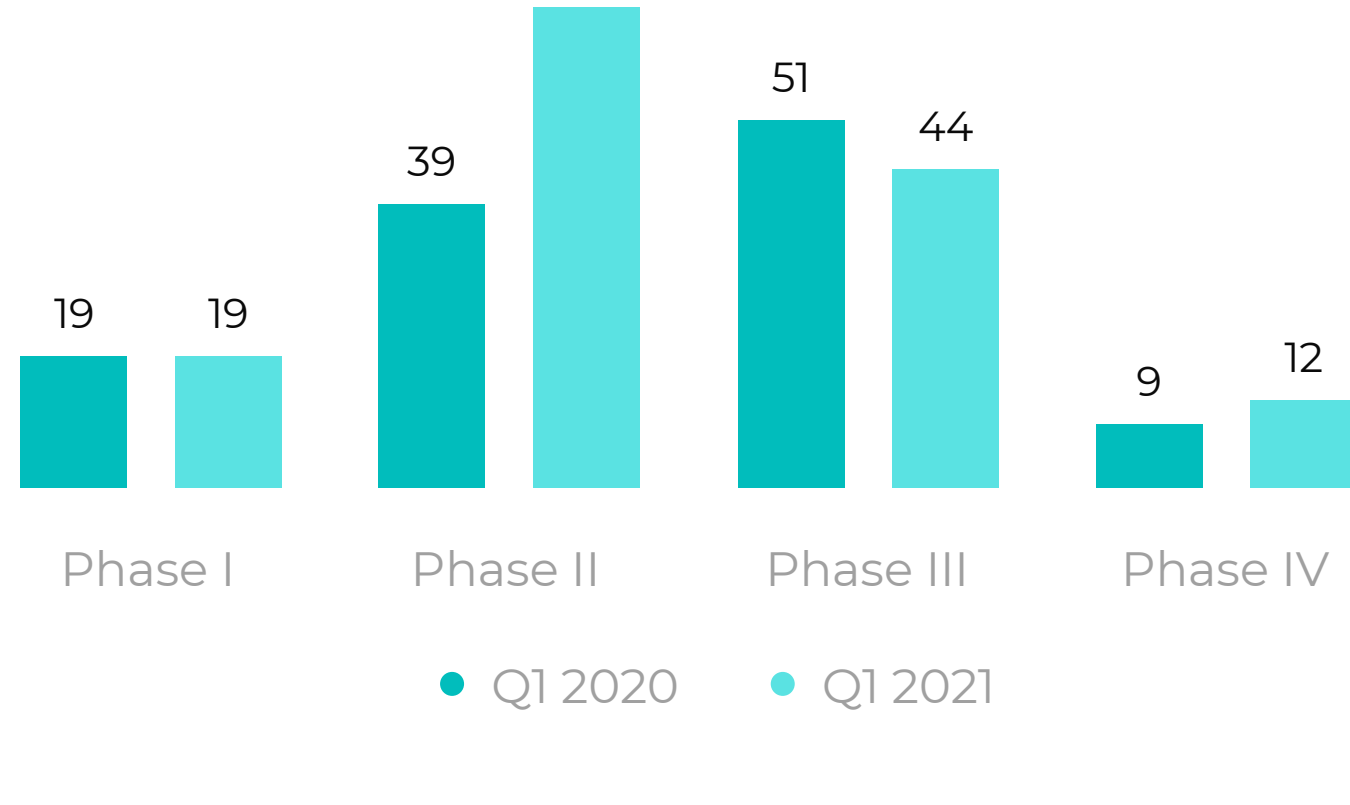
Trial Data

During Q1 2021 there were 350 clinical trials initiated in Canada including local and bioequivalence studies. That represents a 22% growth rate in comparison with the previous year when 287 studies were initiated. But if one excludes bioequivalence studies and studies without an FDA-defined Phase, there were only 142 clinical trials initiated during Q1 2021 compared to 118 studies initiated in previous year.

The majority of clinical trials conducted in Canada were interventional studies with a 87% 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 the Q1 2021 were related to Oncology (33 studies), Endocrinology (8 studies), Neurology (6 studies), Cardiology (5 studies) and Geriatrics (5 studies). Other prominent therapy areas included Mental health, Hematology and Dermatology.

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 Hematology, Dermatology, Gastroenterology, Infectious diseases, Rheumatology, Surgery, Urology, Immunology, Ophthalmology.

Sponsor Data

By country of origin, Europe/UK accounted for the largest number of pharmaceutical sponsored clinical trials in Q1 2021 in Canada. The headquarters of the sponsor companies conducting clinical trials in Q1 2021 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 Q1 2021

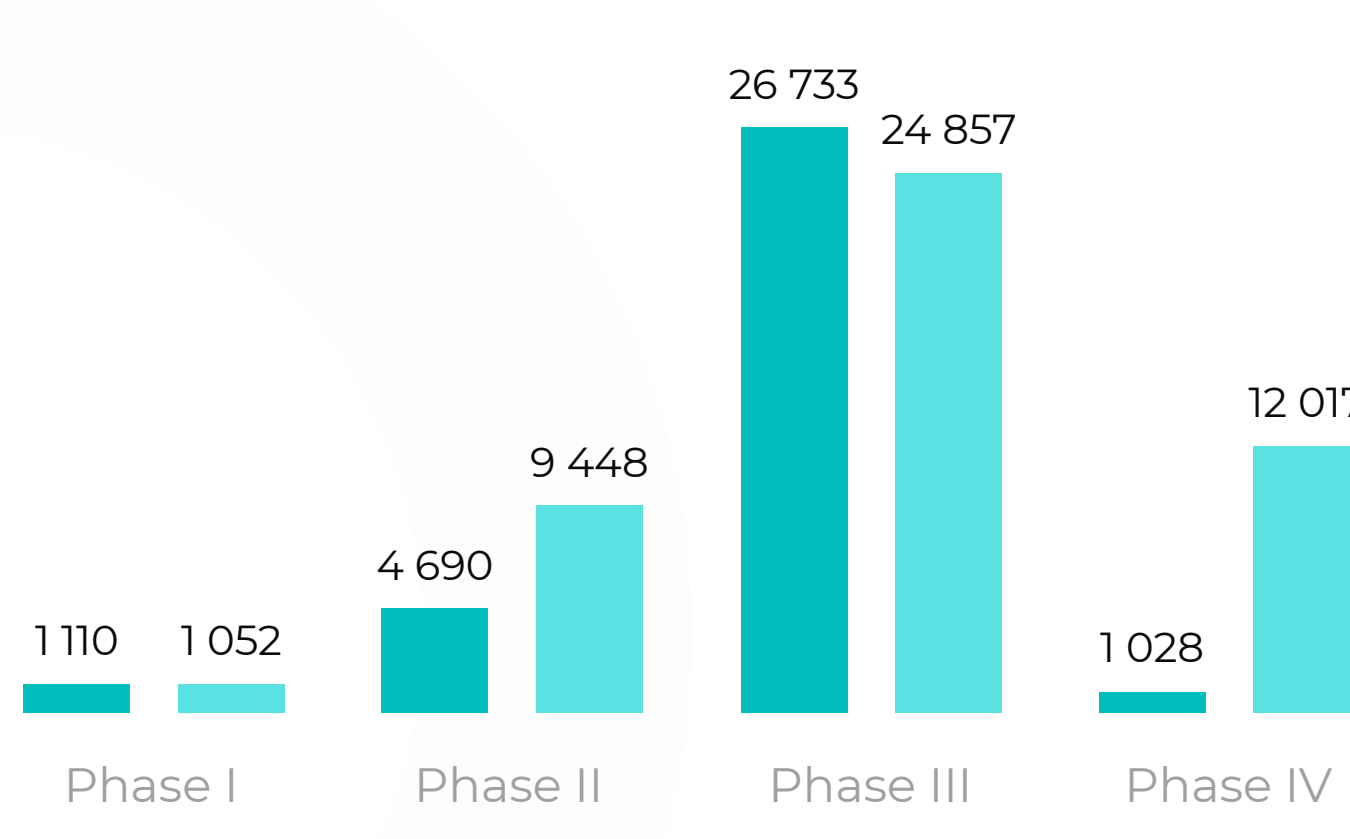
Nº	Company Name	Studies	Subjects
1	Hoffmann-La Roche	11	5 138
2	AstraZeneca	11	3 164
3	Janssen	6	1 180
4	Novo Nordisk	4	3 610
5	Bristol-Myers Squibb	3	254
6	Bayer	2	975
7	Allergan	2	970
8	AbbVie	2	433
9	Eli Lilly	2	370
10	Merck	2	340
Combined share		32%	35%

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in Q1 2021 (including multi-center international studies) jumped from 33,561 subjects in Q1 2020 to 47,374 subjects in Q1 2021 with year on year jump rate of 41%. 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

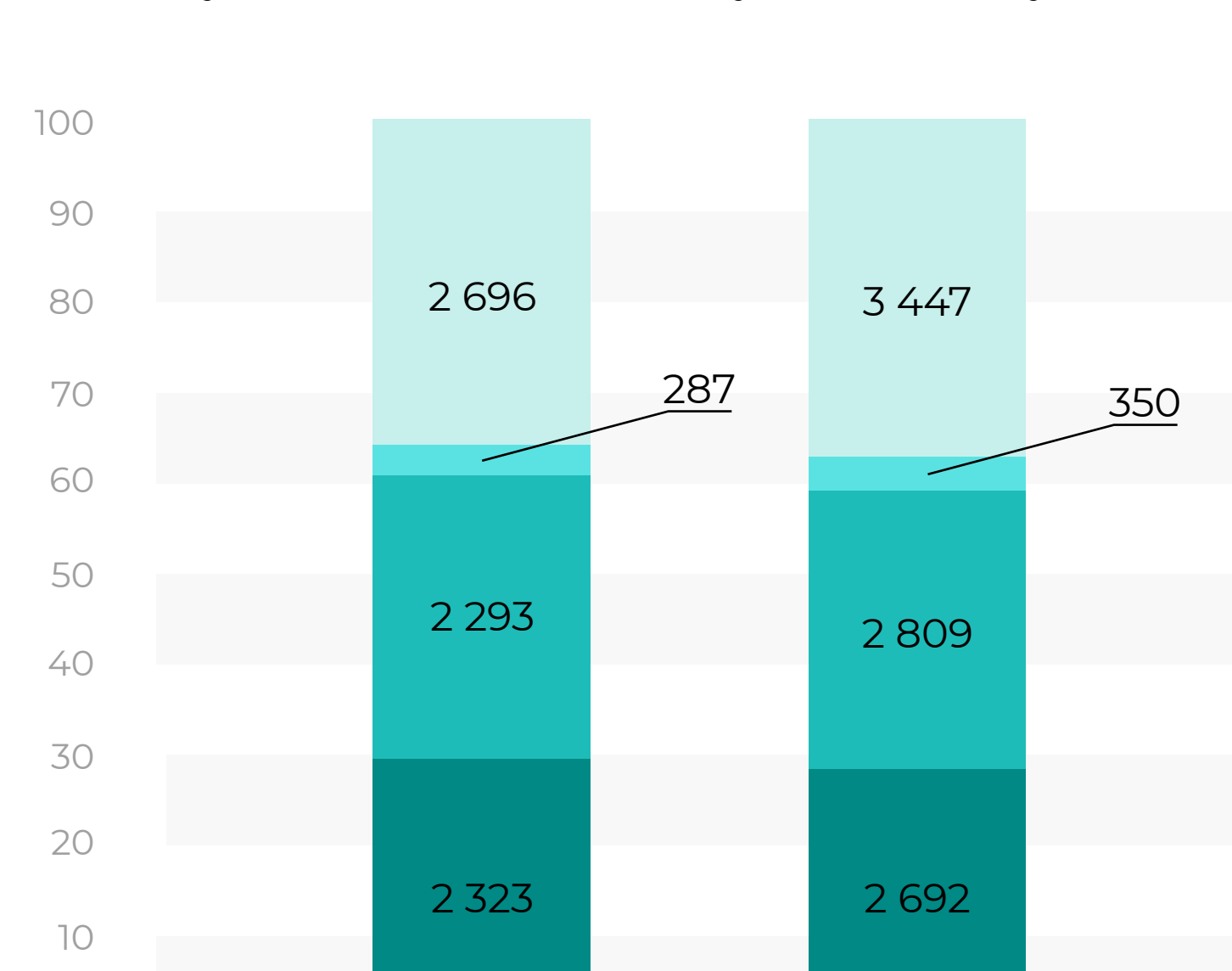
During Q1 2021 the Health Products and Food Branch of Health Canada authority approved 8 new drug applications.

Source: Health Canada

Appr.Date	Drug (Active Ingredient)	Company
07.01.2021	Foclivia (Pandemic Influenza Vaccine)	Seqirus
11.01.2021	Vyepti (Eptinezumab)	Lundbeck
14.01.2021	Supemtek (Quadrivalent Recombinant Influenza Vaccine)	Sanofi
14.01.2021	Adalimumab Injection (Adalimumab Injection)	Pfizer
22.01.2021	Kesimpta (Ofatumumab)	Novartis
11.02.2021	Reblozyl (Luspatercept)	Celgene
16.02.2021	Cequa (Cyclosporine)	Sun Pharma
01.03.2021	Phesgo (Pertuzumab and Trastuzumab Injection)	Hoffmann-La Roche

Worldwide Clinical Trials

During Q1 2021 the official FDA website showed approvals for initiation of 9,298 new clinical trials of all types worldwide, including local and BE studies with an overall year on year growth rate of 22% 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 3,191 studies with a clearly defined study Phase.

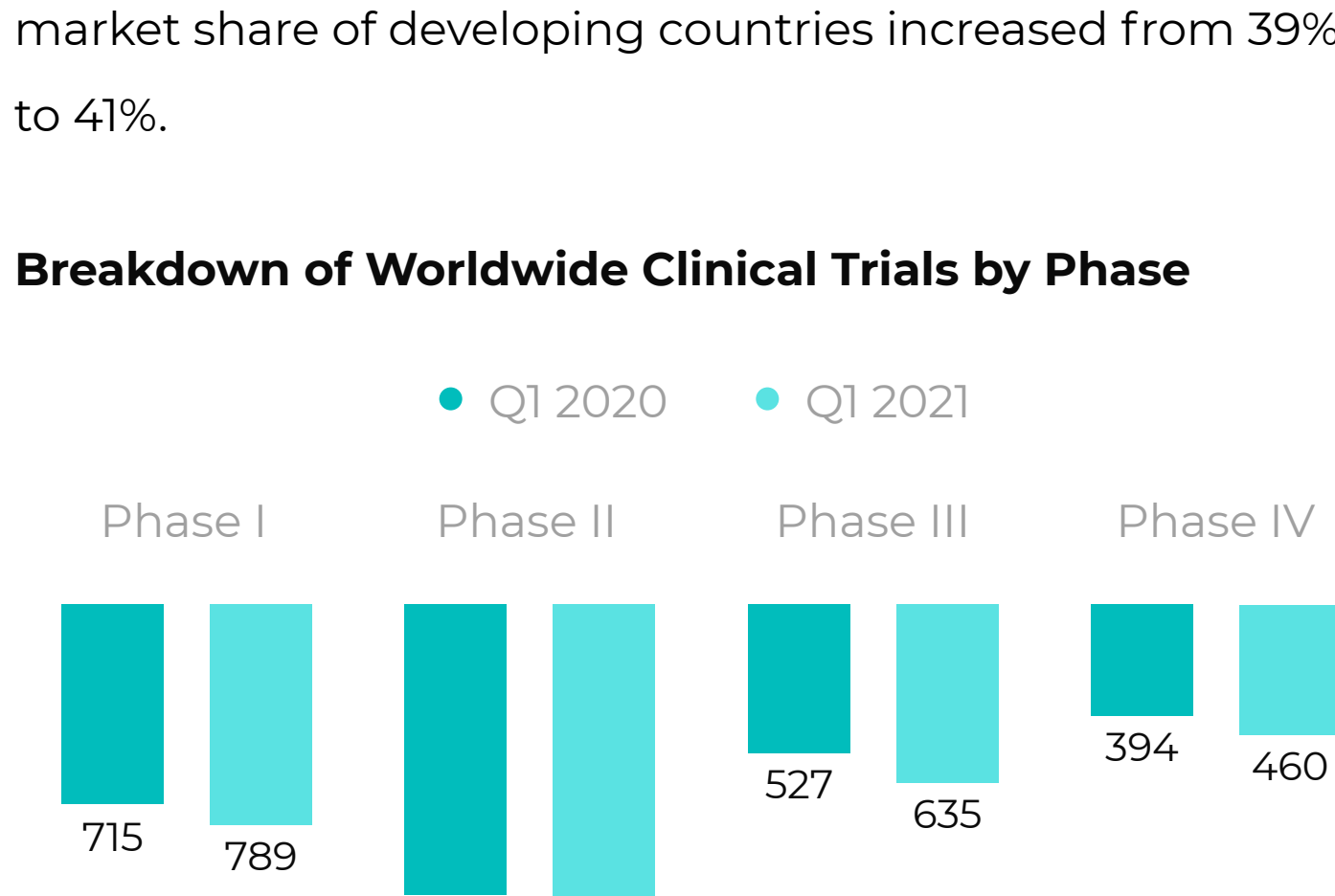


The combined market share of the U.S. and European countries by number of global initiated studies dropped from 61% to 59%, with the U.S. having 29% and Europe having 30%.

79% of all global clinical trials initiated during Q1 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 Q1 2021 slightly changed in comparison to Q1 2020: the combined market share of developing countries increased from 39% 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 10 years – this fact may be explained by the significant and continuously increasing amount of investment required for research and development of new drugs.

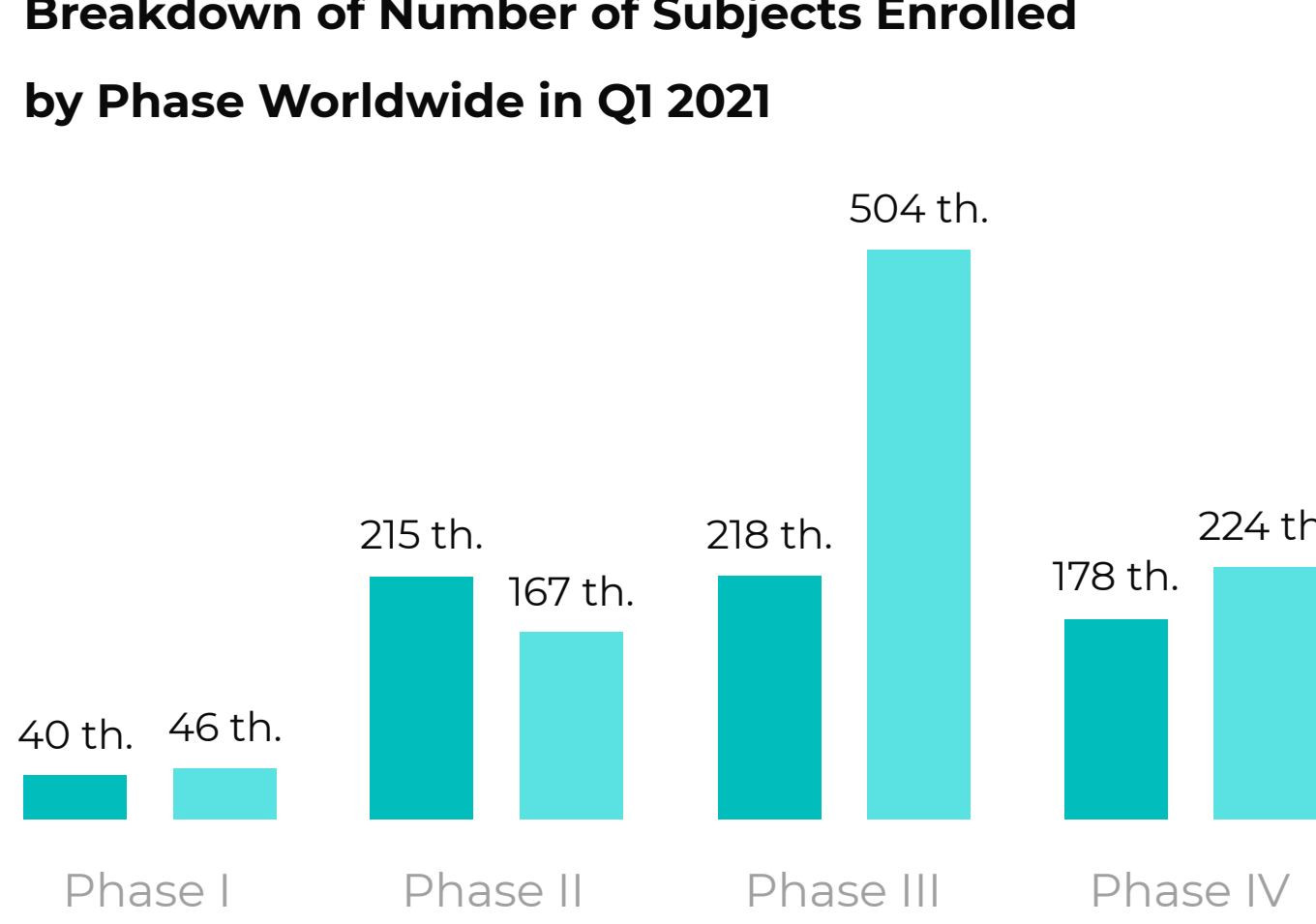
However, it's remarkable that the combined market power of these leading pharmaceutical corporations accounts for just 11% of all interventional clinical trials worldwide where the study Phase has been identified, and just 11% of all enrolled subjects.

Nº	Site Name	No. Studies	No. Subjects
1	Merck	63	27 710
2	AstraZeneca	46	12 492
3	Janssen	42	3 852
4	Pfizer	33	15 182
5	GlaxoSmithKline	32	9 802
6	Novartis	32	5 404
7	Bristol-Myers Squibb	32	2 614
8	Hoffmann-La Roche	30	10 114
9	Eli Lilly	25	11 429
10	Jiangsu HengRui Medicine Co	25	5 139
Combined market share of these companies		11%	11%

The total number of subjects enrolled in Clinical trials worldwide of all types in Q1 2021 reached 940,168 subjects with an annual jump rate of 45%. 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 – approximately 0,01% Worldwide.

Breakdown of Number of Subjects Enrolled by Phase Worldwide in Q1 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: 01/04/2021

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.