

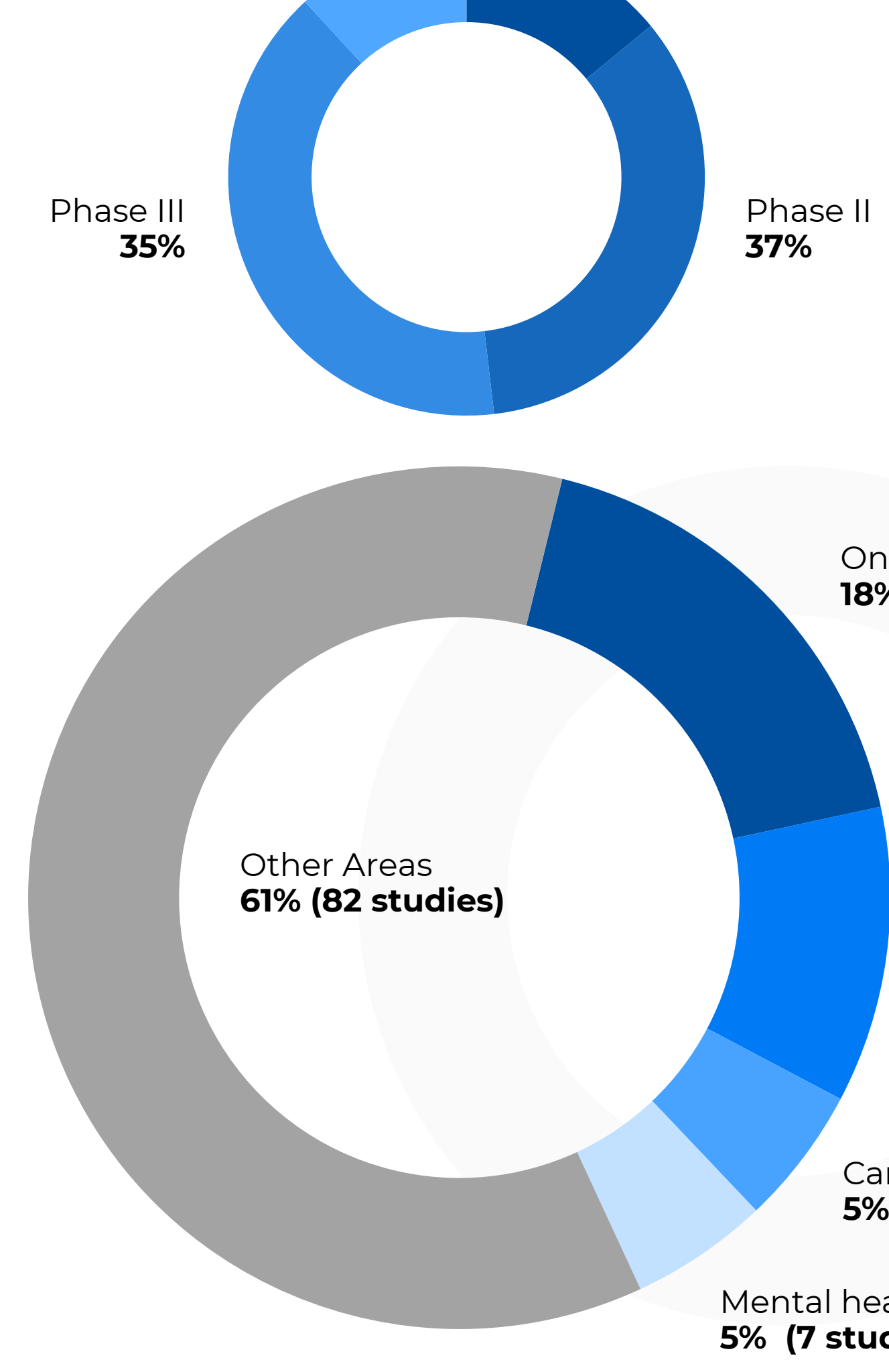
Clinical Trials in Canada

Q3 2021 Research report

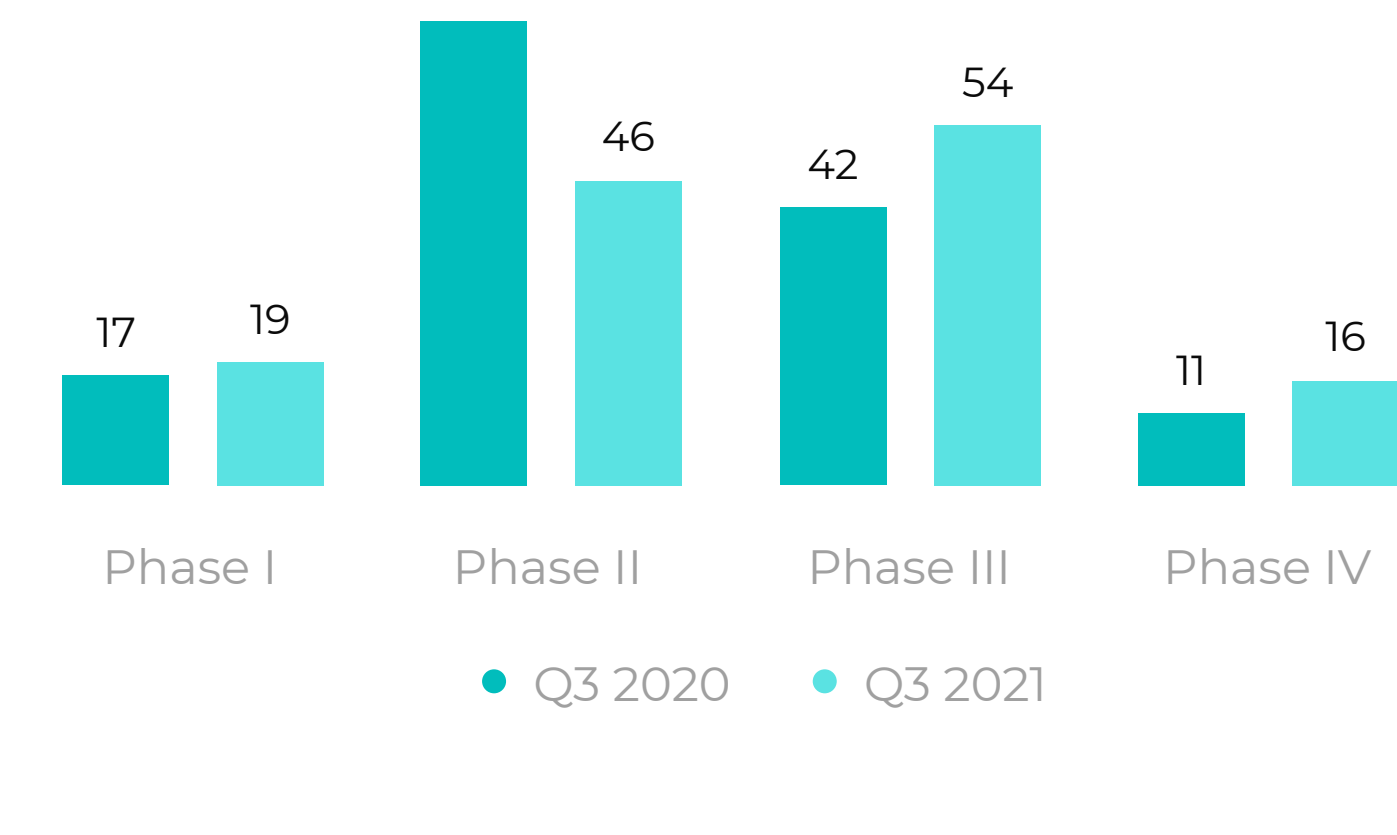
Trial Data

During Q3 2021 there were 327 clinical trials initiated in Canada including local and bioequivalence studies. That represents a 6% increase rate in comparison with the previous year when 308 studies were initiated. But if one excludes bioequivalence studies and studies without an FDA-defined Phase, there were only 135 clinical trials initiated during Q3 2021, compared to 140 studies initiated in previous year.

The majority of clinical trials conducted in Canada were interventional studies with a 86% 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 2021 were related to Oncology (24 studies), Infectious diseases (15 studies), Cardiology (7 studies) and Mental health (7 studies). Other prominent therapy areas included Gastroenterology, Rheumatology, Dermatology and Endocrinology.

Breakdown of Clinical Trials by Therapeutic Area

More than one therapeutic area may be assigned to a trial. Observational trials and trials without an FDA-defined phase (I-IV) were not included in this chart.

“Other Areas” includes: Gastroenterology, Rheumatology, Dermatology, Surgery, Endocrinology, Neurology, Geriatrics, Ophthalmology, Hematology, Urology.

Sponsor Data

By country of origin, the European companies accounted for the largest number of pharmaceutical sponsored clinical trials in Q3 2021 in Canada. The headquarters of the sponsor companies conducting clinical trials in Q3 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 Q3 2021

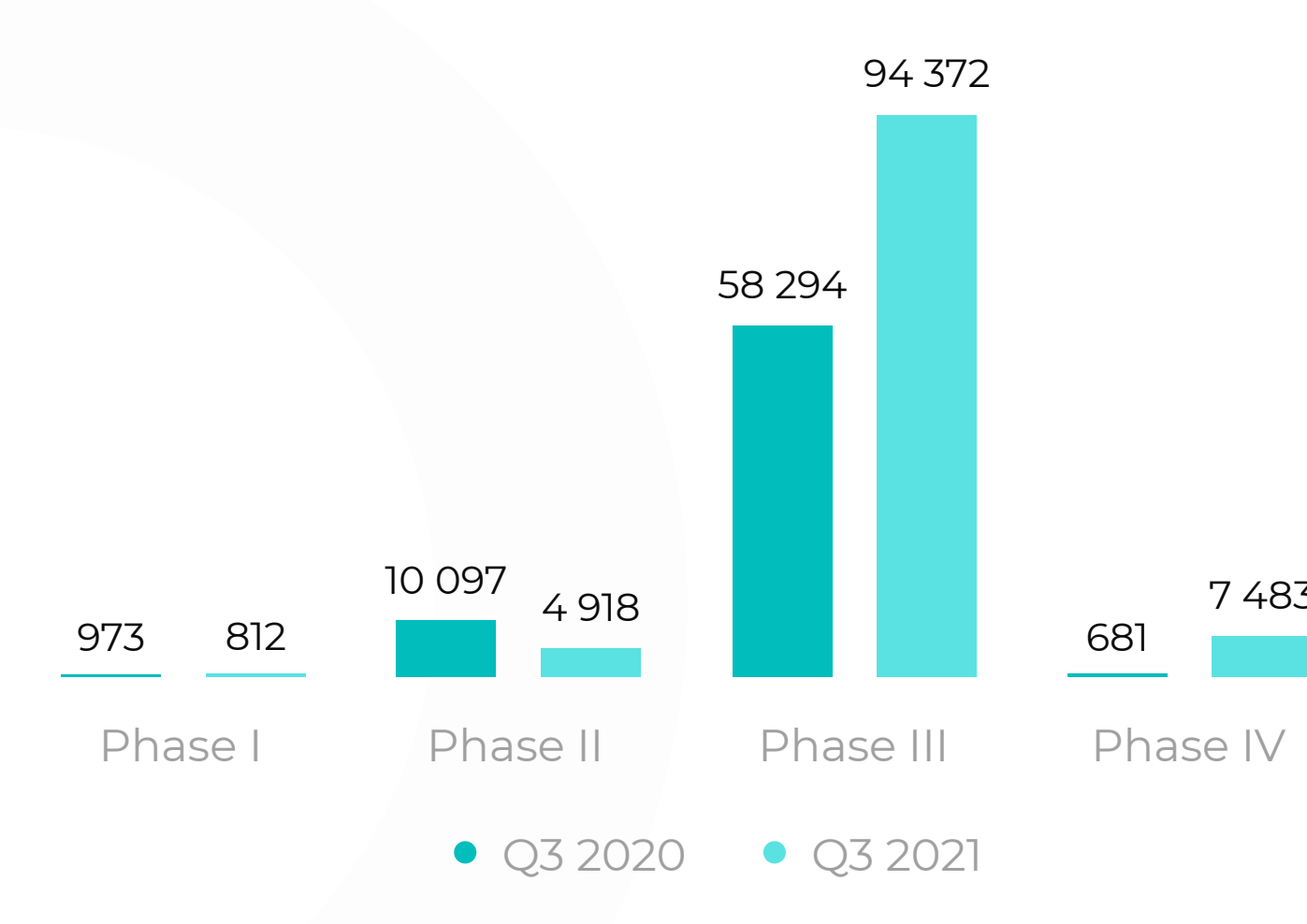
Nº	Company Name	Studies	Subjects
1	Hoffmann-La Roche	6	1 112
2	AstraZeneca	5	1 627
3	Novo Nordisk	4	7 159
4	Celgene	4	1 345
5	Pfizer	3	40 120
6	Janssen	3	23 830
7	Bristol-Myers Squibb	3	1 900
8	Allergan	3	1 577
9	Bayer	3	1 408
10	AbbVie	3	513
Combined share		27%	75%

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in Q3 2021 (including multi-center international studies) jumped from 70,045 subjects in Q3 2020 to 107,585 subjects in Q3 2021 with year on year jump rate of 54%. 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

Source: Health Canada

During Q3 2021 the Health Products and Food Branch of Health Canada authority approved 7 new drug applications.

FDA inspections

According to U.S. FDA data, there were no FDA inspections conducted in Canadian investigative sites during Q3 2021

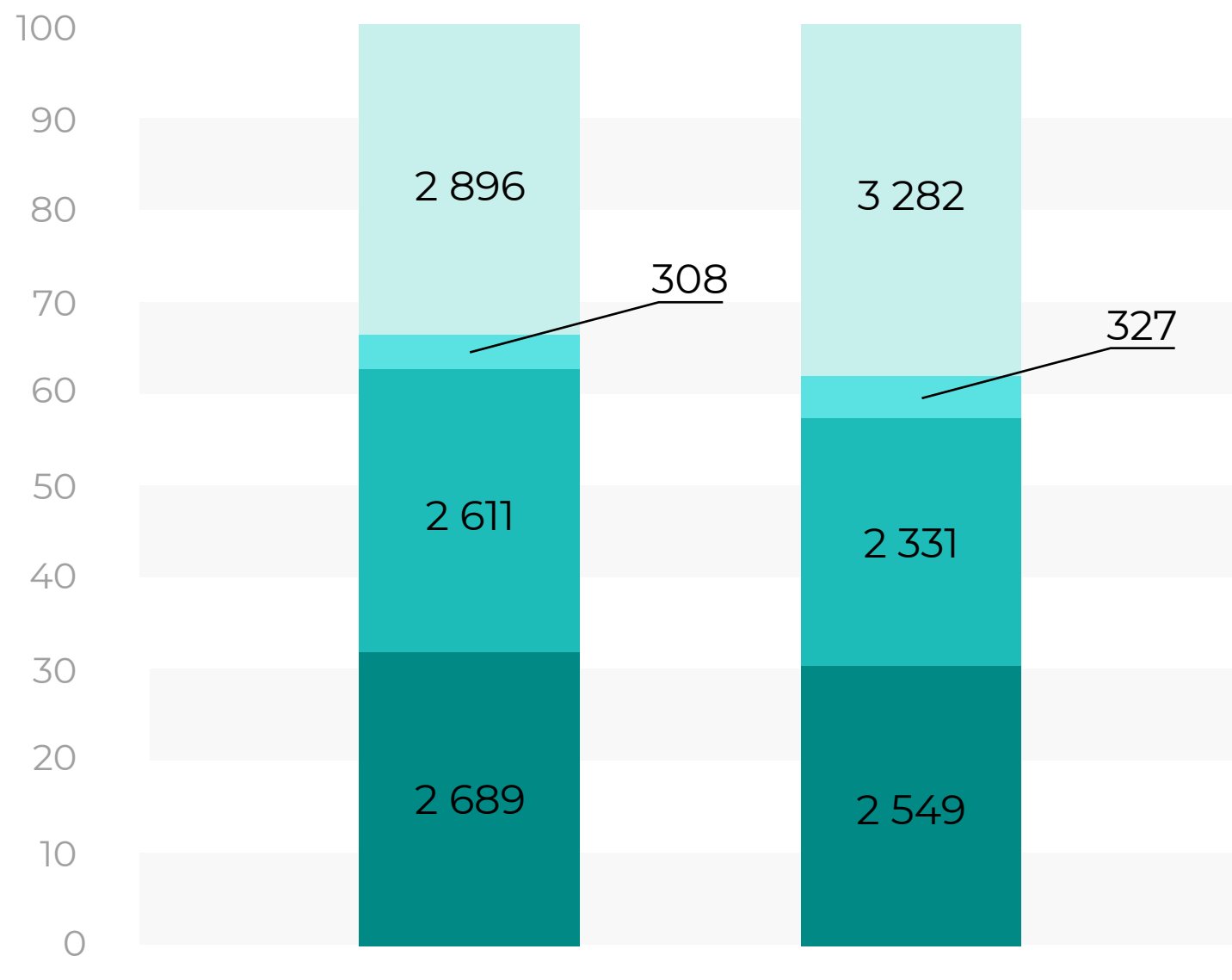
Appr.Date	Drug (Active Ingredient)	Company
08.07.2021	Arazlo (Tazarotene)	Bausch Health
28.07.2021	Vablys (Dequalinium Chloride)	Duchesnay
19.08.2021	Minjuvi (Tafasitamab)	Incyte
14.09.2021	Lyumjev (Insulin Lispro)	Eli Lilly
16.09.2021	Spikevax (Elasomeran)	Moderna
16.09.2021	Comirnaty (Tozinameran)	BioNTech - Pfizer
23.09.2021	Bambevi (Bevacizumab)	Apotex

Worldwide Clinical Trials

During Q3 2021 the official FDA website showed approvals for initiation of 8,489 new clinical trials of all types worldwide, including local and bioequivalence studies – almost the same number as in the previous year when 8,504 studies were initiated. At the same time according with the official FDA website there were only 3,076 studies with a clearly defined study Phase I – IV.

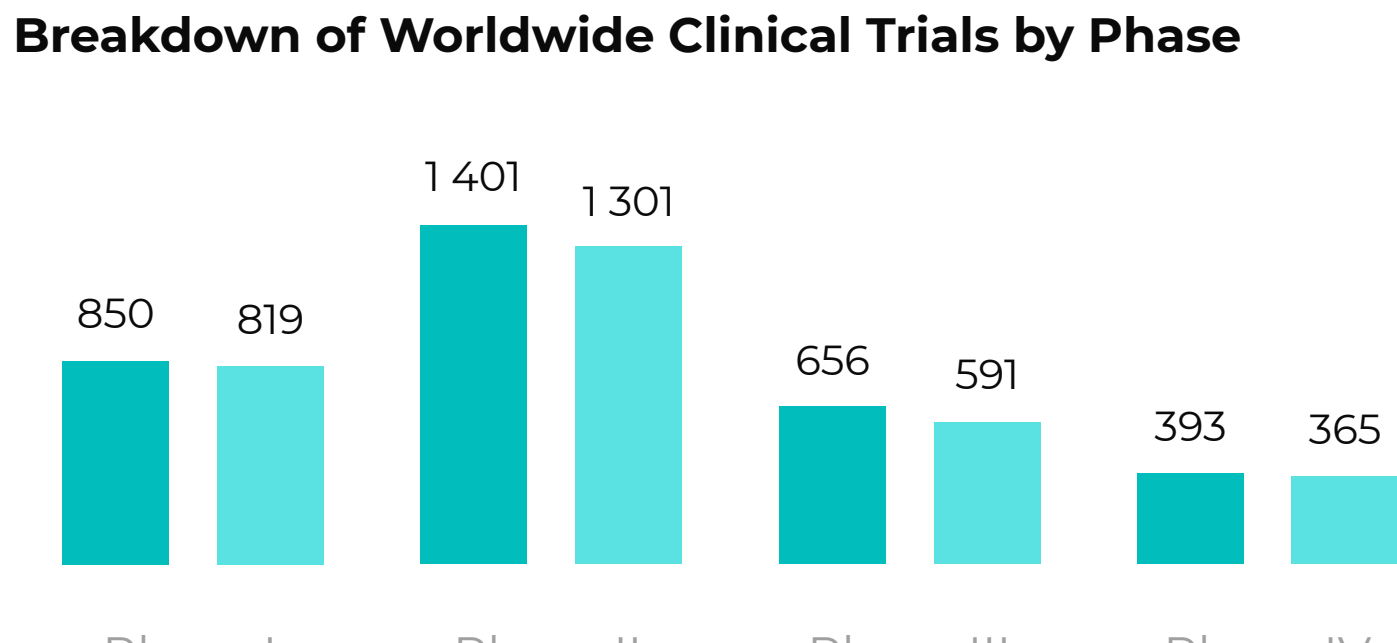
The combined market share of the U.S. and European countries by number of global initiated studies dropped from 62% to 57%, with the U.S. having 30% and Europe having 27%.

80% of all global clinical trials initiated during Q3 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 Q3 2021 slightly changed in comparison to the previous year: the combined market share of developing countries increased from 34% to 39%.

Breakdown of Worldwide Clinical Trials by Phase



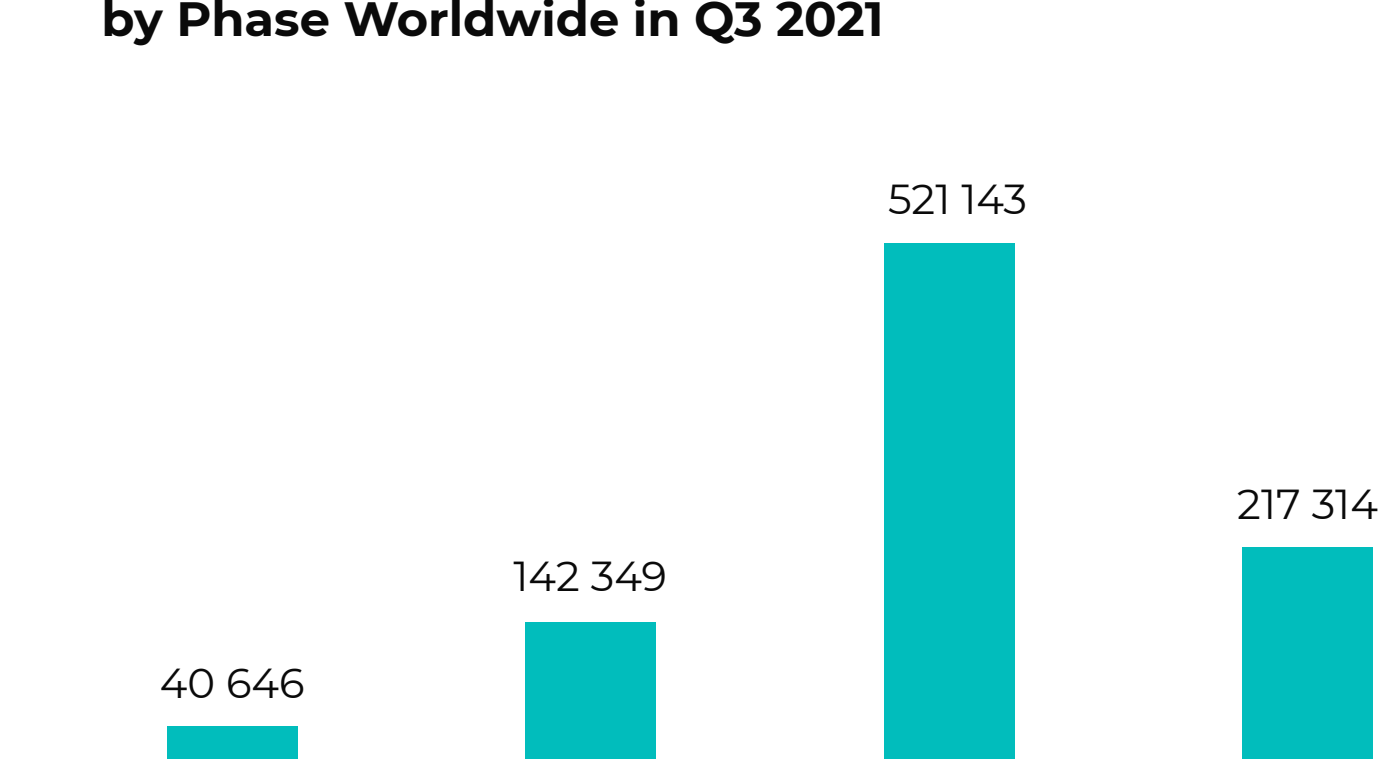
The Top-10 list of global Sponsors of Clinical Trials worldwide remained almost unchanged for the past 10 years – this fact may be explained by the significant and continuously increasing amount of investment required for research and development of new drugs.

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 15% of all enrolled subjects.

Nº	Site Name	No. Studies	No. Subjects
1	Novartis	47	6 908
2	AstraZeneca	43	8 589
3	Pfizer	41	52 884
4	Merck	40	8 971
5	Janssen	34	33 552
6	Bristol-Myers Squibb	34	5 930
7	Sanofi	24	3 615
8	Jiangsu HengRui Medicine	24	3 454
9	GlaxoSmithKline	22	10 293
10	Eli Lilly	22	6 982
Combined market share of these companies		11%	15%

The total number of subjects enrolled in Clinical trials worldwide of all types in Q3 2021 reached 921,452 subjects.

Breakdown of Number of Subjects Enrolled by Phase Worldwide in Q3 2021



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.

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: 08/10/2021

About Synergy Research Group

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 TOP-10 of market leaders by the numbers of conducted clinical studies and enrolled patients.

For all of clinical studies conducted by our company we've set up the highest level of world-class quality both for SOPs and for final study data.

We're continuously working on improvements of our SOPs, study risk management and IT infrastructure – and replacing an outdated R&D strategies by novel, more efficient approaches to clinical research.

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