

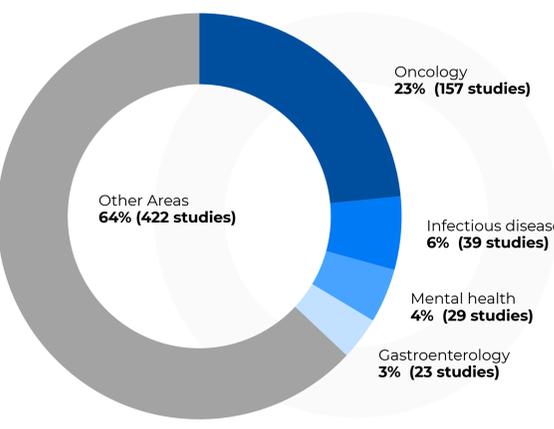
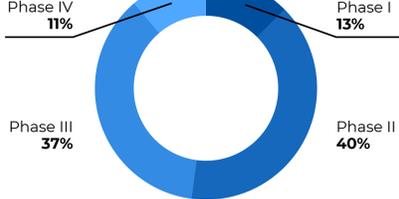
Clinical Trials in Canada

Y 2021 Research report

Trial Data

During the Year 2021 there were 1,466 clinical trials initiated in Canada, including local and bioequivalence studies. That represents a 23% growth rate in comparison with the previous year when 1,196 studies were initiated. But if one excludes bioequivalence studies and studies without an FDA-defined Phase, there were only 670 clinical trials initiated during 2021, compared to 540 studies initiated in the 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 Year 2021 were related to Oncology (157 studies), Infectious diseases (39 studies), Mental health (29 studies), Gastroenterology (23 studies). Other prominent therapy areas included Cardiology, Endocrinology, Neurology, Dermatology and Rheumatology.

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.

Sponsor Data

By country of origin, the Europe/UK accounted for the largest number of pharmaceutical sponsored clinical trials in the Year 2021 in Canada. The headquarters of the sponsor companies conducting clinical trials in the Year 2021 in Canada were split between the US (3 companies) and Europe/UK (7 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 Y 2021

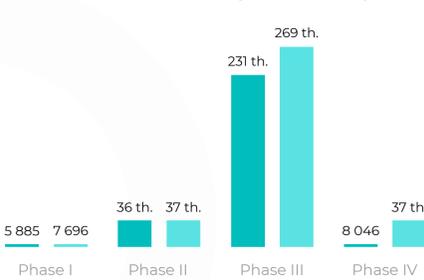
Nº	Company Name	Studies	Subjects
1	AstraZeneca	33	14 168
2	Hoffmann-La Roche	28	13 015
3	Merck	24	15 690
4	Novo Nordisk	19	19 120
5	Janssen	17	49 358
6	Novartis	16	18 863
7	GlaxoSmithKline	15	33 045
8	Bristol-Myers Squibb	13	3 543
9	AbbVie	12	2 566
10	Sanofi	11	2 535
Combined share		28%	49%

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in the Year 2021 (including multi-center international studies) jumped from 281,712 subjects in the Year 2020 to 352,587 subjects in the Year 2021 with year on year growth rate of 25%. 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 Q4 2021 the Health Products and Food Branch of Health Canada authority approved 13 new drug applications.

FDA inspections

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

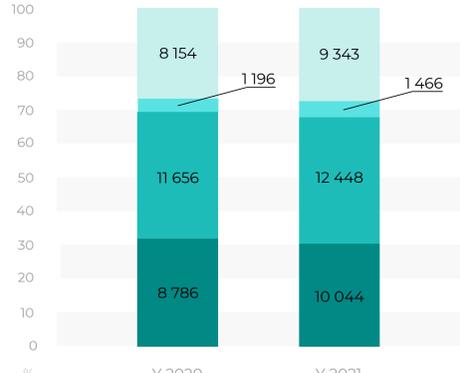
Appr.Date	Drug (Active Ingredient)	Company
21.12.2021	Ixifi (Infliximab)	Pfizer
30.11.2021	Saphnelo (Anifrolumab)	AstraZeneca
30.11.2021	Aybintio (Bevacizumab)	Samsung Bioepis
23.11.2021	COVID-19 Vaccine (AD26.COV2.S (Recombinant))	Janssen
23.11.2021	Wegovy (Semaglutide)	Novo Nordisk
19.11.2021	Vaxzevria (ChAdOx1-S (Recombinant))	AstraZeneca
16.11.2021	Vaxneuvance (Pneumococcal 15-Valent Conjugate Vaccine)	Merck
05.11.2021	Abevmy (Bevacizumab)	BGP Pharma
29.10.2021	Padcev (Enfortumab Vedotin)	Seagen
26.10.2021	Ngenla (Somatrogen)	Pfizer
13.10.2021	Adtralza (Tralokinumab)	Leo Pharma
12.10.2021	Kirsty (Insulin Aspart)	BGP Pharma
08.10.2021	Nypozi (Filgrastim)	Tanvex Biopharma

Worldwide Clinical Trials

During the Year 2021 the official FDA website showed approvals for initiation of 33,301 new clinical trials of all types worldwide, including local and bioequivalence studies with an overall year on year growth rate of 12%. At the same time according with the official FDA website there were only 12,811 studies with clearly defined study Phase I – IV.

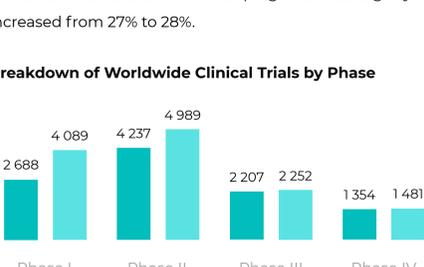
The combined market share of the U.S. and European countries by number of global initiated studies slightly dipped from 69% to 67%, with the U.S. having 30% and Europe having 37%.

77% of all global clinical trials initiated during the Year 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 the Year 2021 slightly changed in comparison to the Year 2020: the combined market share of developing countries slightly increased from 27% to 28%.

Breakdown of Worldwide Clinical Trials by Phase



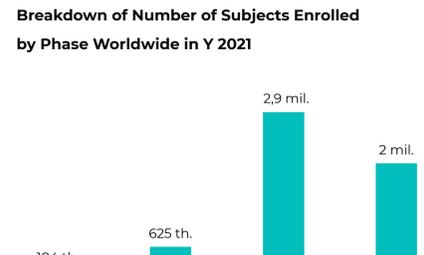
The Top-10 list of global Sponsors of Clinical Trials worldwide remained almost unchanged for the past 10 years – this fact may be explained by the significant and continuously increasing amount of investment required for research and development of new drugs.

However, it's remarkable that the combined market power of these leading pharmaceutical corporations accounts for just 9% of all interventional clinical trials worldwide where the study Phase has been identified, and just 25% of all enrolled subjects.

Nº	Site Name	No. Studies	No. Subjects
1	Merck	186	46 761
2	AstraZeneca	154	38 522
3	Novartis	137	40 641
4	Janssen	134	1 070 162
5	Pfizer	123	80 764
6	Bristol-Myers Squibb	107	14 498
7	Jiangsu HengRui Medicine	104	21 821
8	Eli Lilly	90	26 239
9	Hoffmann-La Roche	86	29 236
10	Sanofi	85	88 175
Combined market share of these companies		9%	25%

The total number of subjects enrolled in trials worldwide of all types in Y 2021 reached 5,8 million subjects.

Breakdown of Number of Subjects Enrolled by Phase Worldwide in Y 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 0,07% Worldwide

About The Orange Paper

The Orange Paper is a free publication produced by the 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: 10/01/2022

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.