# Clinical Trials in Canada

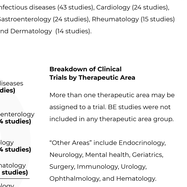
Y 2020 Research report

## Trial Data

During the Year 2020 there were 1,196 clinical trials initiated in Canada including local and bioequivalence studies. That represents an 11% decline in comparison with the previous year when 1,343 studies were initiated. But if one exclude bioequivalence studies and studies without FDA-defined Phase there were only 540 clinical trials initiated during the Year 2020 compared to 594 studies initiated in previous year.

The majority of clinical trials conducted in Canada were interventional studies with a 83% market share.

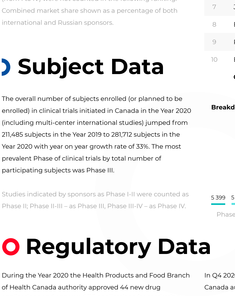
**Breakdown of Clinical Trials by Phase (Canada)**





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

The largest number of clinical trials initiated in Canada during the Year 2020 were related to Oncology (156 studies), Infectious diseases (43 studies), Cardiology (24 studies), Gastroenterology (24 studies), Rheumatology (15 studies) and Dermatology (14 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 Endocrinology, Neurology, Mental health, Geriatrics, Surgery, Immunology, Urology, Ophthalmology, and Hematology.

## Sponsor Data

By country of origin, the U.S. accounted for the largest number of pharmaceutical sponsored clinical trials in the Year 2020 in Canada. The headquarters of the sponsor companies conducting clinical trials in the Year 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 Y 2020**

| № | Company Name | Studies | Subjects |
|---|---|---|---|
| 1 | AstraZeneca | 28 | 15 714 |
| 2 | Hoffmann-La Roche | 27 | 11 238 |
| 3 | Merck | 26 | 13 252 |
| 4 | AbbVie | 16 | 6 283 |
| 5 | Eli Lilly | 15 | 19 380 |
| 6 | Sanofi | 14 | 6 696 |
| 7 | Janssen | 14 | 6 084 |
| 8 | Bayer | 13 | 16 298 |
| 9 | Pfizer | 11 | 10 620 |
| 10 | Bristol-Myers Squibb | 10 | 4 033 |
| | **Combined share** | **32%** | **39%** |

## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Canada in the Year 2020 (including multi-center international studies) jumped from 211,485 subjects in the Year 2019 to 281,712 subjects in the Year 2020 with year on year growth rate of 33%. 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 the Year 2020 the Health Products and Food Branch of Health Canada authority approved 44 new drug applications and approved 115 applications for marketing authorization for new medical devices.

In Q4 2020 the Health Products and Food Branch of Health Canada authority approved 8 new drug applications.

**Source: Health Canada**

| Appr.Date | Drug (Active Ingredient) | Company |
|---|---|---|
| 02/10/2020 | Zeposia (Ozanimod Hydrochloride) | Celgene |
| 13/10/2020 | Luxturna (Voretigene Neparvovec) | Novartis |
| 15/10/2020 | Trurapi (Insulin Aspart) | NovoRapid |
| 28/10/2020 | Nyvepria (Pegfilgrastim) | Pfizer |
| 29/10/2020 | Menquadfi (Meningococcal Polysaccharide Tetanus Toxoid Conjugate) | Sanofi |
| 30/10/2020 | Idacio (Adalimumab) | Fresenius Kabi |
| 04/11/2020 | Amgevita (Adalimumab) | Amgen |
| 25/11/2020 | Hulio (Adalimumab) | BGP Pharma |

**FDA inspections**

According to U.S. FDA data, there were 3 FDA inspections conducted in the Canadian investigative sites during 2020, wherein two inspections ended with No Action Indicated (NAI) outcomes, and one inspection ended with Voluntary Action Indicated (VAI) outcome.

| City | Company / Investigator Site Firm | Outcome |
|---|---|---|
| Scarborough | Pharma Medica Research | NAI |
| Halifax | Agada Biosciences | VAI |
| Mississauga | Pharma Medica Research | NAI |

# Worldwide Clinical Trials

During the Year 2020 the official FDA website showed approvals for initiation of 29,792 new clinical trials of all types worldwide, including local and BE studies with an overall year on year growth rate of 9% 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 10,486 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 72% to 69%, with the U.S. having 30% and Europe having 39%.

74% of all global clinical trials initiated during the Year 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 the Year 2020 slightly changed in comparison to the Year 2019: the combined market share of developing countries increased from 28% to 31%.

**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. But in the Year 2020 the new Chinese challenger – Jiangsu HengRui Medicine Company – appeared in this ranking for the first time.

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 13% of all enrolled subjects.

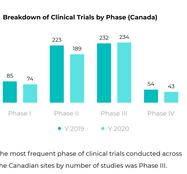
Here are the top-10 global sponsors by total number of studies initiated in the Year 2020.

| № | Site Name | No. Studies | No. Subjects |
|---|---|---|---|
| 1 | Merck | 175 | 44 741 |
| 2 | AstraZeneca | 165 | 75 508 |
| 3 | Pfizer | 130 | 187 495 |
| 4 | Janssen | 128 | 116 695 |
| 5 | Eli Lilly | 105 | 50 907 |
| 6 | Jiangsu HengRui Medicine | 102 | 12 239 |
| 7 | Novartis | 97 | 18 200 |
| 8 | Bristol-Myers Squibb | 97 | 10 745 |
| 9 | Hoffmann-La Roche | 76 | 19 214 |
| 10 | Sanofi | 71 | 42 779 |
| | **Combined market share of these companies** | **11%** | **13%** |

The total number of subjects enrolled in Clinical trials worldwide of all types in the Year 2020 reached 4,577,865 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 0,06% Worldwide

**Number of Subjects Enrolled Worldwide by Phase in Y 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: 20/01/2021

## About Synergy Research Group

Synergy Research Group is a contract research organization successfully operating in Russia, Kazakhstan, Ukraine and Canada since 2002.

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 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.