Clinical Trials in Ukraine

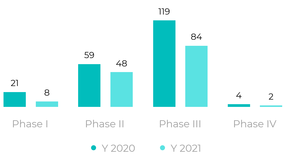
Y 2021 Research report

Trial Data

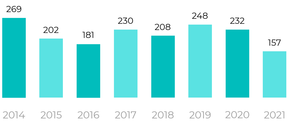
During the Year 2021 there were 157 MMCT (Multinational Multi-center Clinical Trials) studies initiated in Ukraine (we have to exclude both the local and bioequivalence studies for now). That represents a 23% decline rate in comparison with the previous year when 232 studies of all types and 203 MMCT studies were initiated.

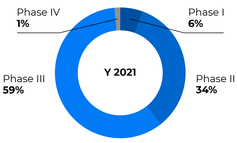
The most frequent phase of clinical trials conducted across the Ukrainian sites by number of studies was Phase III.

Breakdown of Clinical Trials in Ukraine by Phase



Clinical Trials in Ukraine (Y 2014 - Y 2021)

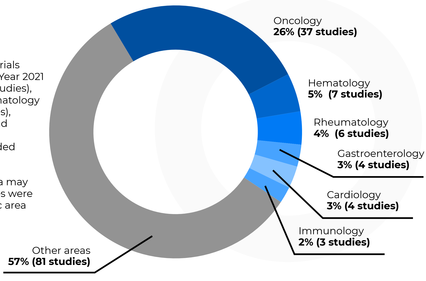




Breakdown of Clinical Trials by Therapeutic Area

The largest number of clinical trials initiated in Ukraine during the Year 2021 were related to Oncology (37 studies), Hematology (7 studies), Rheumatology (6 studies), Cardiology (4 studies), Gastroenterology (4 studies) and Immunology (3 studies). Other prominent therapy areas included Mental health and Urology.

More than one therapeutic area may be assigned to a trial. BE studies were not included in any therapeutic area group.



Sponsor Data

By country of origin, the Europe and the UK accounted for the largest number of pharmaceutical sponsored clinical trials in the Year 2021 in Ukraine.

The headquarters of the sponsor companies conducting clinical trials in the Year 2021 in Ukraine were split between the US (3 companies), Asia (2 companies) and Europe/UK (5 companies).

Observational clinical trials and clinical trials without an FDA-defined phases (from I to IV) were not counted in this ranking.

More than one Sponsor company may be involved into a Clinical trial.

International Applicants of MMCTs in Ukraine in 2020

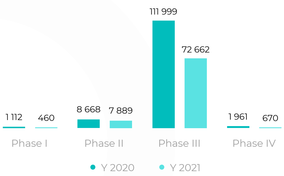
N°	Company Name	No. Studies	No. Subjects
1	Merck	17	15 459
2	Hoffmann-La Roche	11	10 114
3	AstraZeneca	11	8 145
4	Janssen	10	2 496
5	Pfizer	5	7 816
6	Novo Nordisk	4	10 406
7	Sanofi	4	525
8	BeiGene	3	1 486
9	Takeda	3	496
10	Adagio Therapeutics	2	7 496
	Combined market share	**49%**	**79%**

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Ukraine in the Year 2021 (including multi-center international studies) dropped from 123,740 subjects in the Year 2020 to 81,681 subjects in the Year 2021 with year on year drop rate of 34%. 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 & Inpection Data

According to the U.S. FDA data, there were 5 FDA inspections were conducted in the Ukrainian investigative sites during Y 2021; all of these 5 inspections were ended with NAI results.

We have to exclude the Regulatory Data section from the current Orange Paper Ukraine Y 2021 issue due to the complete lack of an appropriate source data from the Ukraine official web sources.

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: 08/08/2022

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.