Clinical Trials in Ukraine

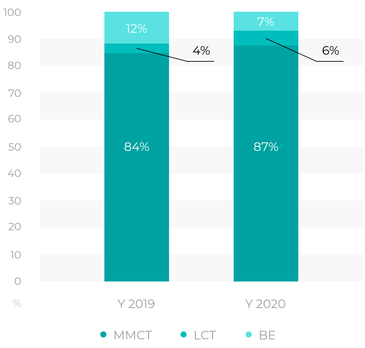
Y 2020 Research report

Trial Data

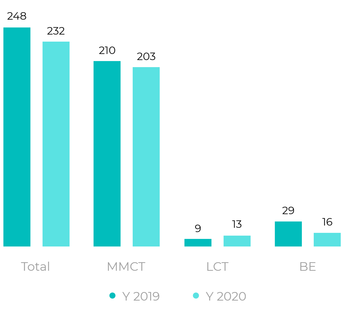
The MoH of Ukraine approved 232 new clinical trials of all types including MMCTs, LCTs and Bioequivalence (BE) studies during 2020, demonstrating a 7% decline in comparison to the previous year.

The main contribution to the total number of studies was made by multinational multi-center clinical trials (MMCTs), with the number of these studies decreasing from 210 studies in 2019 to 203 in 2020. The number of local clinical trials (LCT) increased from 9 in 2019 to 13 clinical trials in 2020. The number of bioequivalence studies (BE) decreased from 29 in 2019 to 16 clinical trials in 2020, a decrease of 45% over last year's figure.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials in Ukraine in Y 2020 by Phase



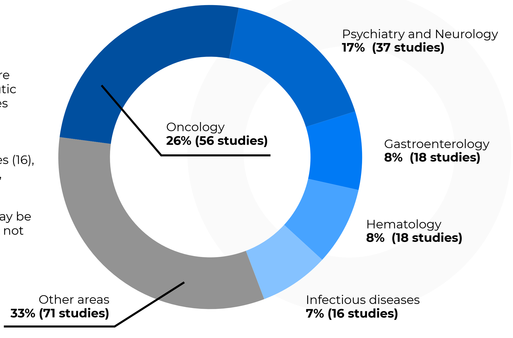
The share of BE studies decreased from 12% in 2019 to 7% of the total number of clinical trials approved in 2020. Of the total number of trials approved during 2020, the share of the LCTs increased from 4% in 2019 to 6% in 2020 and the share of MMCTs increased from 84% in 2019 to 87% in 2020.

During the course of a clinical trial, an applicant may submit to the State Expert Center of MoH of Ukraine (Center) for significant amendments to the clinical trial protocol (additions or changes of existing information) which are reviewed according to current local legislation. During 2020, the Center issued 1828 positive conclusions for MMCT amendments, representing approximately a 6 % growth compared to 2019 (with 1731 positive conclusions).

Breakdown of Clinical Trials by Therapeutic Area

In 2020, the majority of MMCTs were initiated in seven leading therapeutic areas: the largest number of studies were initiated in Oncology (56), Psychiatry and Neurology (37), followed by Gastroenterology (18), Hematology (18), Infectious diseases (16), Rheumatology (10), Cardiology (10), and Endocrinology (4).

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

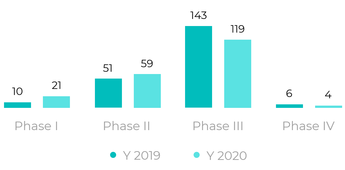


MMCTs in Pediatrics in Ukraine

During 2020, the State Expert Center of the MoH of Ukraine granted 10 positive permissions for MMCTs to be conducted in pediatrics, eight studies less than in 2019 when 18 studies were approved.

No phase I trial in pediatric patients approved in 2020. The number of pediatric Phase II trials decreased from six studies in 2019 to no study in 2020. Phase III pediatric trials decreased from 12 (2019) to 10 (2020) respectively. Phase III trials in pediatric patients accounted for 100% of pediatric trials in 2020 compared with 67% in 2019.

Breakdown of MMCTs in Ukraine by Phase (2019 - 2020)



2020 saw the approval of 21 new Phase I MMCTs, an increase of 10 studies compared to 2019. Phase IV trials decreased from six studies in 2019 to four new studies in 2020.

Sponsor Data

International Applicants of MMCTs in Ukraine in 2020

№	Company Name	Market Share
1	IQVIA RDS Ukraine	12%
2	Arensia Exploratory Medicine	8%
3	CRO InnoFarm Ukraine	7%
4	MSD Ukraine	7%
5	Parexel Ukraine	6%
6	IHC Research	5%
7	Janssen Pharm. NV	5%
8	Sanofi Ukraine	5%
	Remaining Applicants	45%

Applicants of Local Clinical Trials in Ukraine in 2020

№	Company Name	Market Share
1	RPF "Microkhim" LTD	17%
2	PJSC SIC "Borshchahivskiy CPP"	14%
3	LLC "Biopharma plasma"	10%
4	JSC "Kyiv Vitamin Plant"	10%
5	PJSC "Farmak"	7%
6	LLC "Arterium LTD"	7%
7	PrJSC Pharmaceutical Firm Darnitsa"	7%
	Remaining Applicants	28%

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Regulatory Data

The Center for Drug Evaluation and Research (CDER) of the US-FDA approved 124 new drugs during 2020; fourty-one of these were new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Nineteen of the 124 new drugs were (or are being) studied in clinical trials conducted (or being conducted) in Ukraine.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
18.12.2020	Orgovyxnda (Relugolix)	MyovantSciences
20.11.2020	Zokinvynda (Lonafarnib)	Eiger Biopharms
25.09.2020	Xeljanzndа (Tofacitinib)	Pfizer
28.08.2020	Sogroyabla (Somapacitan)	Novo Nordisk
26.08.2020	Winlevinda (Clascoterone)	Cassiopea
23.07.2020	Breztri Aerosphrenda (Budesonide; Formoterol Fumarate; Glycopyrrolate)	AstraZeneca
06.07.2020	Huliobla (Adalimumab)	Mylan Pharms
12.06.2020	Tivicay (Dolutegravir Sodium)	ViiV Healthcare
26.05.2020	Vesicare (Solifenacin Succinate)	Astellas
08.05.2020	Retevmonda (Selpercatinib)	Loxo Oncology
17.04.2020	Pemazyrenda (Pemigatinib)	Incyte
10.04.2020	Koselugonda (Selumetinib Sulfate)	AstraZeneca
27.03.2020	Trifericnda (Ferric Oyrophosphate Citrate)	Rockwell Medical
25.03.2020	Zeposianda (Ozanimod Hydrochloride)	Celgene
02.03.2020	Sarclisabla (Isatuximab)	Sanofi Aventis
21.02.2020	Nexletolnda (Bempedoic Acid)	Esperion Therapeutics
27.01.2020	Trijardy (Empagliflozin; Linagliptin; Metformin Hydrochloride)	Boehringer Ingelheim
23.01.2020	Rybelsusnda (Semaglutide)	Novo Nordisk
16.01.2020	Tazverikndа (Tazemetostat Hydrobromide)	Epizyme

During the course of 2020, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) gave positive recommendations on 104 new drugs.

Twenty-seven new drugs which received positive opinions were tested in clinical trials in Ukraine.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
10.12.2020	Yuflyma (Adalimumab)	Celltrion
10.12.2020	Retsevmo (Selpercatinib)	Eli Lilly
12.11.2020	Onbevzi (Bevacizumab)	Samsung Bioepis
12.11.2020	Xofluza (Baloxavir Marboxil)	Roche Holding
12.11.2020	Phesgo (Pertuzumab, Trastuzumab)	Roche Holding
15.10.2020	Trixeo Aerosphere (Budesonide, Glycopyrronium, Formoterol Fumarate Dihydrate)	AstraZeneca
15.10.2020	Leqvio (Inclisiran)	Novartis
17.09.2020	Yervoy (Ipilimumab)	Bristol-Myers Squibb
17.09.2020	Lynparza (Olaparib)	AstraZeneca
17.09.2020	Tecentriq (Atezolizumab)	Roche Holding
17.09.2020	Flucelvax Tetra (Influenza Virus Surface Antigens)	Seqirus
17.09.2020	Fycompa (Perampanel)	Eisai
23.07.2020	Equidacent (Bevacizumab)	Centus Biotherapeutics
23.07.2020	Calquence (Acalabrutinib)	AstraZeneca
25.06.2020	Aybintio (Bevacizumab)	Samsung Bioepis
28.05.2020	Xenleta (Lefamulin Acetate)	Nabriva Therapeutics
30.04.2020	Zimbus Breezhaler (Glycopyrronium Bromide, Indacaterol, Mometasone Furoate)	Novartis
30.04.2020	Rebloyl (Luspatercept)	Celgene
30.04.2020	Paliperidone (Paliperidone Palmitate)	Janssen
26.03.2020	Atectura Breezhaler (Indacaterol Acetate, Mometasone Furoate)	Novartis
26.03.2020	Zeposia (Ozanimod Hydrochloride)	Celgene
26.03.2020	Fluad Tetra (H1N1 Virus Surface Antigens)	Seqirus
26.03.2020	Sarclisa (Isatuximab)	Sanofi
27.02.2020	Fetcroja (Cefiderocol Sulfate Tosilate)	Shionogi
31.01.2020	Ruxience (Rituximab)	Pfizer
30.01.2020	Liumjev (Insulin Lispro)	Eli Lilly
30.01.2020	Rybelsus (Semaglutide)	Novo Nordisk

FDA inspections

In the period from 2012 to 2019 there were six US-FDA inspections conducted in Ukraine together with representatives of the State Expert Center of Ministry of Health of Ukraine; four inspections from the EMA, one from the Japanese PMDA (Pharmaceuticals and Medical Devices Agency) and one from State Medicines Control Agency of Lithuania.

In 2020 there were three the U.S. FDA inspections conducted in Ukraine sites (Odesa, Vinnytsia, and Ivano-Frankivsk) with participation of the State Expert Center of Ministry of Health of Ukraine representatives; all of these inspections were ended with NAI results.

Ukraine Regulatory Update

Clinical Trials in Ukraine are conducted in accordance with Order #690 MoH of Ukraine dated 23.09.2009 with changes stated in Orders issued by MoH of Ukraine #523 dated 12.07.2012, #304 dated 06.05.2014, #966 dated 18.12.2014 and #639 dated 01.10.2015.

In view of the quarantine imposed because of the COVID-19 pandemic, changes were made to the legislation, namely the Law of Ukraine "On Amendments to Some Legislative Acts of Ukraine on Provision of Treatment of Coronavirus Disease (COVID-19)" of 20.03.2020 № 539-IX) according to which the expert evaluation of materials of clinical trials of medicinal products for treating coronavirus disease

State Expert Center Clinical Audits (Inspections)

One of the main components of quality assurance in clinical trials is the conduct of clinical audits, which are regularly held by inspectors from the State Expert Center.

25 clinical audits were conducted in 2020, compared to 44 clinical audits in 2019, thus representing approximately 43% less clinical audits than in 2019. The decline of clinical audits is related to COVID-19.

Summary

According to the opinion of some clinical trials market experts Ukraine has only reached 10-15% of its total clinical trial capacity and an increase in the number of clinical trials to be conducted in the Ukraine is expected as a result of the step by step movement and harmonization of the Ukrainian health system with EU standards.

The current situation in Ukraine is favourable to conduct clinical trials. Contributing factors to this favourable environment include a country population of more than 41.6 million inhabitants, a well-developed and structured system of healthcare, highly qualified staff and a growing number of experienced investigative sites that contribute to the rapid recruitment of patients.

Compliance with regulatory requirements and GCP standards, the availability of local ethics committees, as well as a system for pharmacovigilance and control, ensure the quality of the data received from studies conducted in Ukraine.

We would like to express special gratitude to the employees of the State Expert Center of the MoH of Ukraine, for providing full and detailed data on the statistics of clinical trials in Ukraine.

The 2021 Annual Summary of Clinical Trials in Ukraine Orange Paper is scheduled for April 2022

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: 04/01/2021

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.