Reference Information on the Clinical Trial Status in Ukraine for the first half of 2025

State Expert Center MoH Ukraine

The State Expert Center of the Ministry of Health of Ukraine (hereinafter referred to as the Center) during the first half of 2025 traditionally publishes analytical information on the status of clinical trials (hereinafter referred to as CT) in Ukraine, prepared by the Department of Examination of Preclinical and Clinical Trials Materials (hereinafter referred to as the Department).

The data below reflects the current situation in the field of CTs in Ukraine for the first half of 2025.

In order to support and resume the conduct of the CT in Ukraine, the Center continues to focus on interaction through all available means, namely: by e-mail, receiving requests through the electronic resource «Online Consultation» on the Center's official website, responding to written requests, reviewing various formats of Information Sheets, offline consultations, holding seminars and forums, continuous professional development of stakeholders etc.

In connection with the above, dedicated e-mail addresses have been put in place for the coordination of Sponsor activity, starting from February 24, 2022 and to date, for proper communication between the Sponsor or Sponsor's representative, CRO and Center, namely:

dec@dec.gov.ua – e-mail for all Information Sheets related to the conduct of clinical trials in Ukraine (for example, letters regarding the start and end of a clinical trial, Periodic and Final Reports, etc.);

evikno@dec.gov.ua – e-mail for the submission of Applications for conducting a clinical trial of a medicinal product, substantial amendments, and corresponding cover letters to the Ministry of Health;

kv@dec.gov.ua – e-mail for the submission of clinical trial materials and substantial amendment clinical trial materials in accordance with the Procedure for the Conduct of Clinical Trials of Medicinal Products and the Expert Review of Clinical Trial Materials, approved by Order No. 690 of the Ministry of Health of Ukraine dated 23 September 2009; Additional materials, responses to remarks on clinical trial materials and substantial amendments;

clinic@dec.gov.ua – e-mail for the submission of Safety Reports (DSURs) and notifications of adverse reactions during the conduct of clinical trials.

Analysis of CT status at various stages of conduction

As of **01 January 2025**, the following information is current regarding the number of CTs that are being conducted in Ukraine at various stages: **324 CTs** in total, of which **248 CTs** have already been initiated and **76 CTs** were approved by the Ministry of Health for conduct.

As of **01 July 2025**, the following information is relevant regarding the number of CTs that are being conducted in Ukraine at various stages: **295 CTs** in total, of which **249 CTs** have already been initiated and **46 CTs** were approved by the Ministry of Health for conduct.

Activities of the Department of Examination of Preclinical and Clinical Trials Materials

During participation in a bilateral meeting between Ukraine and the European Commission on the official screening of the compliance of Ukrainian legislation with EU law under Negotiating Chapter 28: «Consumer protection and health» was demonstrated a presentation on the level of implementation of EU regulations on clinical trials in Ukraine. Brussels, Kingdom of Belgium, 8 – 14 February 2025.

In accordance with the letter of the Ministry of Health of Ukraine dated 10.06.2025 No. 23-04/18693/2-25, the Director of the Department – Taisa Herasymchuk took part in the visit of the Ukrainian delegation to the Danish Medicines Agency to participate in a meeting within the framework of the initial stage of strategic sectoral cooperation in the field of healthcare between Denmark and Ukraine, which took place on June 18-20, 2025.

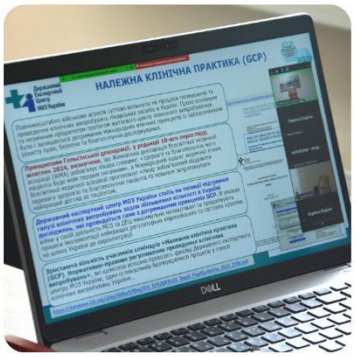


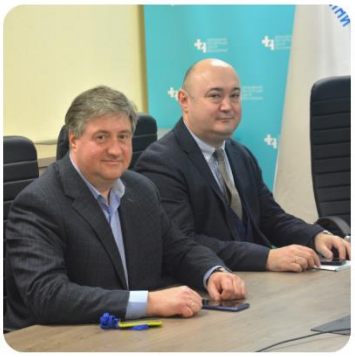
The Department's experts prepared and conducted 3 on-line consultations and 12 off-line consultations on preclinical and clinical drug development programs, informed consent, regulatory pathways for the study and use of biophages, recombinant drugs, psychedelic research, and others.

69 e-mail inquiries from applicants were processed – written responses were provided;

52 letters were prepared following consideration of messages from applicants during lifecycle of the clinical trials.

Department employees participated in the 5 on-line training seminars on international requirements for good clinical practice and legal regulations on conducting clinical trials in Ukraine on the subject «Good Clinical Practice (GCP). Legal Regulation of Clinical Trials», which were attended by 312 participants with the subsequent issuance of certificates.



Department employees also participated in the following:

- in meetings at the Ministry of Health of Ukraine with representatives of national authorities of Poland, Croatia, France, Denmark, and Norway;
- in 55 external seminars/webinars/meetings and 15 internal presentation webinars between structural units of the Department;
- in holding of online meeting with local ethics committees (65 participants) in order to properly organize methodological coordination of their work. The topic of the webinar was «Providing knowledge of ethical expertise, preventing possible risk for subjects and monitoring

compliance with ethical and moral and legal principles during clinical trials». Information about which is posted on the Center's website in the category EXPERTISE OF NONCLINICAL AND CLINICAL TRIALS MATERIALS;

- in holding of another online meeting as part of continuous professional development on the topic «Features of conducting clinical trials of medicinal products in Ukraine», 30.05.2025;
- involved in the preparation of the draft of The Order of the Ministry of Health of Ukraine ST-N MOZU 42-9.2-2025 «Medicinal Products. Requirements for quality documentation concerning biological investigational medicinal products in clinical trials»;
- furthermore, the Department is working on developing regulatory documents for the work of the unified state control body for medicines in Ukraine.

Generalized results of the main directions of work of the Department

	First half of 2024	First half of 2025
1. Number of applications received by the Center through the Single Window of the Ministry of Health		
Applications for international Clinical Trial Protocols	28	33
Applications for Substantial Amendments to international CT Protocols	352	334
Applications for Local Clinical Trial Protocols	7	5
Applications for Substantial Amendments to Local CT Protocols	4	1
Total	391	373
2. Number considered at the meetings of the Center's Scientific and Technical Councils (CSTC/CSEC or NTR/NER)		
International Clinical Trial Protocols	21	24
Substantial Amendments to International CT Protocols	393	314
Local Clinical Trial Protocols (including bioequivalence studies)	6	6
Substantial Amendments to Local CT Protocols	2	1
Total	414	345

During the reporting period, the Department processed **1213** incoming letters of correspondence, such as:

- **377** referrals from the Ministry of Health namely: granted permit to conduct CT (**40**), granted approval of Substantial CTAms (**333**) and Charity statements (**4**);
- **836** information letters;
- **214** Letters-replies to Form 4-5.

Letters regarding the life cycle of clinical trials included:

- **35** notification letters about the start of the clinical trial;
- **75** notification letters about the completion of the clinical trial, including 5 premature termination of the clinical trial (of which 2 due to war);
- **139** periodic reports (DSUR/PSURs) and **58** Final CT reports;
- **529** information letters, which related in particular to the safety reports of Investigational Medicinal Product Dossier (IMPD) – **97**, notification letters about IMPD – **45**, suspension of the patient recruitment – **2** (gastroenterology and COVID-19 disease) and **2** information letters regarding the transfer of 2 subjects (patients) to other investigator sites outside Ukraine (to Israel and Poland).

Development of «Program» of extended access for research subjects to provide the investigational medical product/drug after the completion of the clinical trial (hereinafter referred to as «expanded access program»)

Expanded access program access to unregistered medicinal products that are authorized for use under the specific indications or for which at least Phase II clinical trials (studies) have been initiated in the USA, European Economic Area countries, Australia, Canada, Japan, the United Kingdom, Israel or the Swiss Confederation and for which safety and efficacy data are available to assess the benefit/risk balance.

Medicinal products within the expanded patients' access programs to unregistered medicines and trial subjects' (patients') access programs to the investigational medicinal product after the end of clinical trial are provided free of charge, exclusively for ethical and humane reasons.

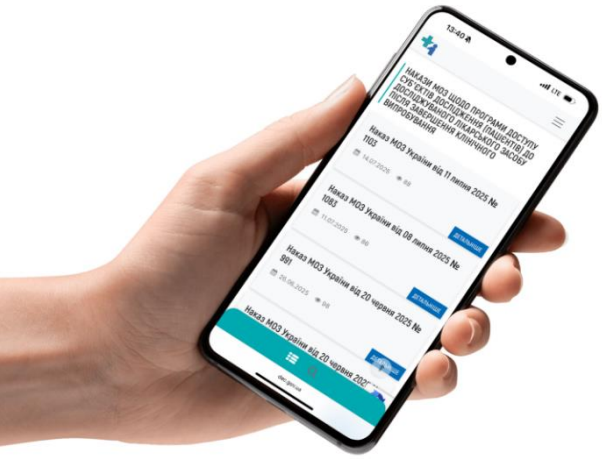
More detailed information about the program, as well as the procedure for approving these programs, can be found in the Order of the Ministry of Health No. 1525 dated August 24, 2022 «Procedure for approval and implementation of the program of expanded access of patients to unregistered medicinal products and the program of early access of trial subjects (patients) to the medicinal product after the completion of the clinical trial and Amendments to the Procedure for importing unregistered medicinal products, standard samples, and reagents into the territory of Ukraine» at the link: https://zakon.rada.gov.ua/laws/show/z1269-22#n2

In the first half of 2025, the Department considered 3 expanded access program:

1. Expanded Access Program Code: 67896062PAH4002 access of trial subjects (patients) to the medicinal product Macitentan after the completion of the clinical trial AC-055-312;
2. Expanded Access Program Code: B8011007 access of trial subjects (patients) to the medicinal product Sasanlimab (PF-06801591) after the completion of the clinical trial B8011007;

3. Expanded Access Program Code: AG46053 access of trial subjects (patients) to the medicinal product Crizotinib (Xalkori®) after the completion of the clinical trial VO28984.

In addition, during the specified period, were made **6 Amendments** to the approved programs.



«Orders of the Ministry of Health regarding the program of expanded access of trial subjects' (patients') to the investigational medicinal product after the completion of the clinical trial» are published on the Center's website in the section Examination of materials of preclinical and clinical trials at the link:

https://www.dec.gov.ua/applicant/nakazy-moz-shhodo-programy-dostupu-subyektiv-doslidzhennya-pacziyentiv-do-doslidzhuvanogo-likarskogo-zasobu-pislya-zavershennya-klinichnogo-vyprobuvannya/?role=applicant

Analysis of information about safety events during clinical trials of an investigational medicinal product

In the first half of 2025, **4935 reports of Suspected Unexpected Serious Adverse Reaction** (hereinafter referred to as SUSARs) were received, which occurred in Ukraine and abroad. During the reporting period, **100 reports** were received from Ukrainian investigator sites and **4,835 reports** were received from various countries under the CT protocols that were approved in Ukraine

Also, during the reporting period, the Center received and processed **97 reports** that provide a complete picture of the safety of investigational medicinal product drug over a certain period in clinical trials currently ongoing in Ukraine.

Department employees constantly maintains feedback with applicants in order to properly conduct CTs in Ukraine. During the reporting period, was translated into Ukrainian and published an information review «International Guidelines on good governance practice for research institutions, Geneva, Switzerland: CIOMS Working Group report, 2023». More details are available on the Center's website in the section Examination of preclinical and clinical trial materials at the link: https://www.dec.gov.ua/materials/aktualna-informacziya/?role=applicant