

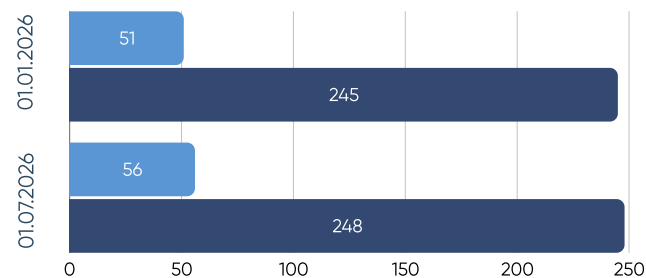
INFORMATION NOTE

CLINICAL TRIALS IN UKRAINE: FIRST HALF OF 2026

The State Expert Center of the Ministry of Health of Ukraine (SEC) provides an overview of the activities undertaken by the Department for the Evaluation of Preclinical and Clinical Trial Materials during the first six months of 2026.

Despite the challenges of martial law, the SEC has kept regulatory and scientific review running, continued to support national and international applicants, and maintained a strong focus on protecting clinical trial participants.

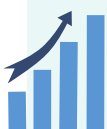
CONTINUED GROWTH IN CLINICAL TRIAL ACTIVITY



As of 1 January 2026, 245 clinical trials (CTs) had been initiated and were ongoing at clinical trial sites in Ukraine; in addition, 51 CTs were approved by MoH orders. As of 1 July 2026, the number of active CTs had increased to 248, and the number of CTs approved by MoH orders had risen to 56.

This indicates a sustained positive trend and continued sponsors' interest in conducting clinical trials in Ukraine, despite the challenges posed by wartime conditions.

DEPARTMENT ACTIVITY RESULTS



During the reporting period, the total number of CTAs and SMAs to approved CTs submitted to the SEC through the MOH Single Submission Portal increased by 15.8%, from 373 in 2025 to 432 in 2026.

The number of SEC recommendations issued for the review and approval of study documentation by the Scientific Expert Council (SExC) and the Technical Expert Council (TExC) increased by 18.6%, from 345 in 2025 to 409 in 2026, reflecting sustained activity in the clinical research sector.

Number of Clinical Trial Applications (CTAs) and Substantial Modification Applications (SMAs) received through the MoH Single Window Portal

	H1 2025	H1 2026
International Clinical Trial Protocols	33	46
Domestic Clinical Trial Protocols	5	2
Substantial amendments to international CTs	334	383
Substantial amendments to domestic CTs	1	1

Number of CTAs and SMAs reviewed and recommended for approval by the SEC Advisory Bodies (SExC, TExC):

	H1 2025	H1 2026
International CTs Protocols	24	49
Domestic CTs Protocols	6	3
SAs to international CTs	314	355
SAs to domestic CTs	1	2

PATIENT SAFETY AND SAFETY REPORTING

The Department carries out continuous and rigorous monitoring of the safety of CT participants through the following activities:



During the reporting period, the Department processed 5,818 SUSARs associated with CTs approved in Ukraine, representing a 17.9% increase compared to the corresponding period of the previous year.



49 adverse events (assessed sponsors as SUSARs) reported at CT sites in Ukraine (+48% vs. the previous reporting period)

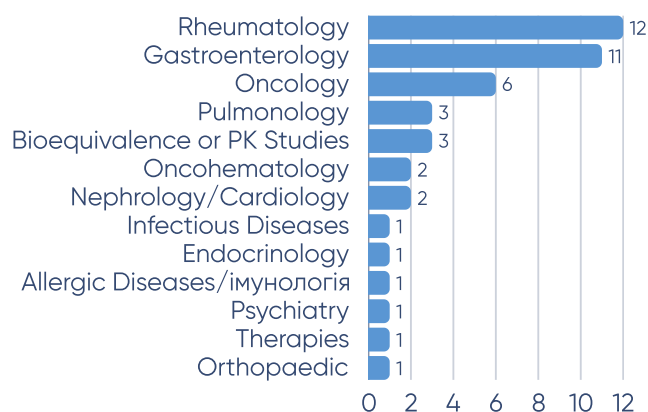


89 safety reports concerning investigational medicinal products (IMPs) used in CTs currently ongoing in Ukraine were reviewed and processed during the reporting period.



6 CT participants successfully relocated to other CT sites in Ukraine, the UK, and Spain, marking a significant decrease in patient transfers.

During H1 2026, 45 CT initiation notifications were received, representing a 28.5% increase compared to H1 2025, across the following therapeutic areas:



REGULATORY FRAMEWORK DEVELOPMENT AND EUROPEAN INTEGRATION

As part of Ukraine's commitments related to the screening of national legislation for compliance with EU law (Negotiation Chapter 28 "Consumer and Health Protection"), the Department made substantial progress in aligning the national regulatory framework with the EU acquis, including:

Legislative Harmonization:

Developed by SEC:

- Amendments to MoH Order №690 were approved by MoH Order №302 dated March 10, 2026.
- New "Procedure for Conducting Clinical Trials" was approved by MoH Order №184 dated February 16, 2026 and will enter into force on January 1, 2027

EU Regulatory Roadmaps:

Three key EU regulations in the field of CTs were assessed:

- Regulation (EU) № 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;
- Commission Implementing Regulation (EU) 2022/20 of 7 January 2022 laying down rules for the application of Regulation (EU) № 536/2014 of the European Parliament and of the Council as regards setting up the rules and procedures for the cooperation of Member States in safety assessment of clinical trials;
- Regulation (EC) № 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) № 726/2004 (Text with EEA relevance), insofar as it relates to clinical trials.
- Compliance tables reflecting the current implementation status of these regulations were prepared.

International Trainings:

SEC experts completed professional training and visits at:

- Danish Fellowship Centre (Copenhagen)
- Swedish Medical Products Agency (Uppsala)
- Danish Medicines Agency (Copenhagen)

Experts were also enrolled in the EMA training platform (EU Portal and EU NTC).

PATIENT ENGAGEMENT

Throughout H1 2026, the Department maintained active cooperation with patient organizations, healthcare professionals, and the public on issues related to access to innovative treatments and participation in clinical trials.

- Working meetings were held with the Rare Diseases of Ukraine Union to discuss opportunities for expanding patients' access to modern treatment options, as well as with specialists from the National Children's Specialized Hospital "Okhmatdyt" on the development and regulatory support of CAR-T cell therapies.
- Six citizen inquiries were processed regarding access to treatment, participation in CTs, and the use of innovative medicinal products. Following their review, comprehensive information and guidance were provided to patients within the scope of the SEC remit.



PROGRAMS PROVIDING POST-TRIAL ACCESS TO INVESTIGATIONAL MEDICINAL PRODUCTS (IMP)

During the first half of 2026, three amendments were introduced to previously approved Expanded Access Programs.

In addition, two new post-trial access programs for investigational medicinal products were reviewed:

- Crovalimab Post-Trial Access Program (AG44916)
- Ocrevus® (ocrelizumab) Post-Trial Access Program (AG41814)

COOPERATION WITH ETHICS COMMITTEES:

During the reporting period, activities were carried out to maintain and update information within the Register of Ethics Committees at Ukrainian healthcare institutions under martial law conditions.



The register includes administrative information and contains 390 contacts.

Following an online meeting held on March 6, 2026, entitled *"Self-Assessment of Ethics Committee Performance: Tools and Approaches for Evaluating Effectiveness and Improving Ethical Review Processes"*, the Department developed a package of methodological materials to support ethics committees.

Three assessment checklists were developed for Ethics Committees to use as practical tools to conduct internal reviews of their activities, improve internal procedures, and enhance the quality of ethical review. The package included:



Ethics Committee Self-Assessment Checklist



Ethics Committee Meeting Checklist



Ethics Committee Annual Report Preparation Checklist

These documents are advisory and methodological in nature, do not establish new regulatory requirements, and may be used according to the specific activities and internal procedures of individual committees.



The checklists are prepared as voluntary quality-support tools for Ethics Committee operations rather than compliance-monitoring instruments.

[Link via QR code](#)

EDUCATION AND QUALITY ASSURANCE UNDER GCP STANDARDS

Department staff participated in online and on-site seminars entitled:

"Good Clinical Practice (GCP). Regulatory Framework for Clinical Trials in Ukraine."

During the reporting period:



5 GCP training seminars were conducted;



311 participants attended;



4 comprehensive consultations were provided regarding preclinical and clinical drug development programs.

DIGITALIZATION OF CTA PROCESSING

Another important activity initiated during the first half of the year was the digitalization of SEC internal processes for CTAs processing.

The revised version of MoH Order № 690 places significantly greater emphasis on electronic document management, electronic interaction among stakeholders, and the use of modern information systems.

This approach aligns with the national digital transformation agenda and brings Ukrainian clinical trial procedures closer to practices already implemented within the European Union.

The State Expert Center continues to develop the Applicant Electronic Portal, which enables electronic submission of documents, tracking of application review status, and efficient communication with experts.

The portal simplifies and expedites document submission, ensures transparency of review procedures, and marks the launch of modern digital services for applicants.

ENHANCEMENT OF THE ELECTRONIC CLINICAL TRIALS REGISTER OF UKRAINE

The ongoing modernization of the Electronic Clinical Trials Register of Ukraine aims to improve access to clinical trial information and further strengthen the transparency of the clinical research environment.

To this end, the SEC has developed a new user interface for the platform and continues to improve its search capabilities and information display features.



The portal is currently available in beta version. If you experience any technical difficulties or have suggestions for improving the service, please let us know at: dec@dec.gov.ua

To support and restore the conduct of clinical trials in Ukraine, the SEC remains committed to maintaining communication through all available channels, including email, inquiries submitted via the Online Consultation service on the SEC official website, responses to written requests, review of information letters on various regulatory matters, in-person consultations, seminars, continuing professional development (CPD) activities, forums, and other engagement events.

The SEC continues to foster a favorable and transparent regulatory environment, ensuring the protection of the rights, safety, and well-being of clinical trial participants, as well as the quality, integrity, and reliability of data generated in clinical trials.

COMMUNICATION CHANNELS WITH THE STATE EXPERT CENTER (SEC)

To support the proper conduct of CTs in Ukraine, the Department maintains continuous communication with applicants.

To facilitate communication with sponsors, contract research organizations (CROs), investigators, and other stakeholders involved in clinical trials, the State Expert Center (SEC) maintains dedicated email channels for specific types of submissions, including:

dec@dec.gov.ua – for general notifications and correspondence related to the conduct of clinical trials (CTs) in Ukraine, including notifications of trial initiation and completion, periodic and final reports, and other CT-related communications;

evikno@dec.gov.ua – for the submission of CT applications, substantial amendments and supporting documentation to the Ministry of Health of Ukraine through the established electronic submission process;

kv@dec.gov.ua – for the submission of clinical trial documentation and documentation related to substantial amendments;

clinic@dec.gov.ua – for the submission of safety reports, including Development Safety Update Reports (DSURs) and reports of adverse reactions occurring during the conduct of CTs.

