Reference Information on the Clinical Trial Status in Ukraine for the period from 01 January 2024 until 31 December 2024

The State Expert Center of the Ministry of Health of Ukraine (hereinafter referred to as the Center) during the year in question traditionally publishes analytical information on the status of clinical trials (hereinafter referred to as CT) in Ukraine, prepared by the Department for the Expert Review of Nonclinical and Clinical Trial Materials (hereinafter referred to as the Department).

The full-scale military aggression of the russian federation in Ukraine continues and has a significant impact on the processes of planning and conducting clinical trials of medicines in Ukraine, however the Center will continue to highlight on a **half-year term** basis dynamic processes in the field of clinical trials in the country.

We emphasize that the main and constant priority during the CT life cycle was and remains the observance of international ethical principles and ensuring that the rights, safety, and well-being of subjects is protected. The CT life cycle requires clear, coordinated actions from all participants within the process.

The data below reflect the recorded dynamic changes in CTs in Ukraine for four quarters of 2024.

The priorities of the Center regarding communication with stakeholders did not change in Q4 of 2024. 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 24 February 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.

In Q4 of 2024, the Center recommended that the Ministry of Health of Ukraine (hereinafter referred to as the MoH) approved the conduct of **27 CTs** in total, including **1 CT** protocols with domestic manufacturers, as well as **202 substantial amendments** (hereinafter referred to as SA) to the protocols of international/ domestic multicenter CTs, including **1 SA** for the protocol of domestic manufacturer.

In Q4 of 2024, the Department received and processed **816 incoming correspondences**, of which:

22 were referral letters from the Ministry of Health to Applications for Conducting a CT, **215** approvals of substantial amendments and **5** charity applications;

463 information Sheets, of which **111** were the responses of the applicants to the letters regarding the completeness of the CT materials; information sheets for applicants according to the stages of the CT included: answers to the comments of the Center on the results of a specialized examination (**145**); information sheets of applicants in accordance with the stages of CT; letters of request, consultation letters of request; letters about CT initiation; information on the safety of investigational medicinal products; and other CT-related correspondence, namely:

- **79** CT Periodic Reports;

- **54** CT Final Reports;

- **56** regarding the end of the CT, including 7 notification letters regarding early completion of the CT in Ukraine, of which 2 CT due to the war and 4 CT – due to low efficacy, 1 CT – others reason;

- **4** notification letters regarding the transfer of 7 patients enrolled in a CT from one approved study site to another study site in Ukraine (4 patients) or outside Ukraine (3 patients, to study sites in Switzerland, Poland and Italy). All incoming documentation was processed by the Department's employees properly and on time.

Of the positive trends according to the information received by the Center during the reporting period:

ANALYSIS OF CT STATUS AT VARIOUS STAGES OF CONDUCT

As of **01 January 2024**, the following information is current regarding the number of CTs that are being conducted in Ukraine at various stages: **400 CTs** in total, of which **309 CTs** have already been initiated and **91 CTs** were approved by the Ministry of Health for conduct.

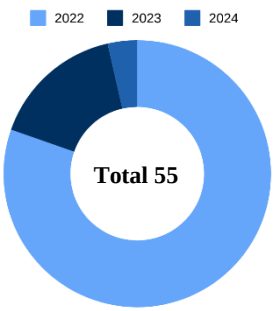
Picture. 1 Number of CTs as of 01.01.2024

As of **01 January 2025**, the following information is relevant 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.

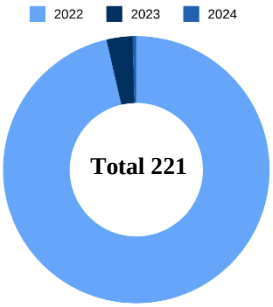
Picture. 2 Number of CTs as of 01.01.2025

INFORMATION ON THE ACTIONS OF CT SPONSORS

During the specified period (**01.01.2024 – 31.12.2024**), the Sponsor took the following actions regarding CTs approved by Orders of the Ministry of Health and initiated CTs:



1. **Temporary suspension of CT initiation due to the war in the country:** 2024 – 1 CT, 2023 – 9 CTs, 2022 – 45 CTs;



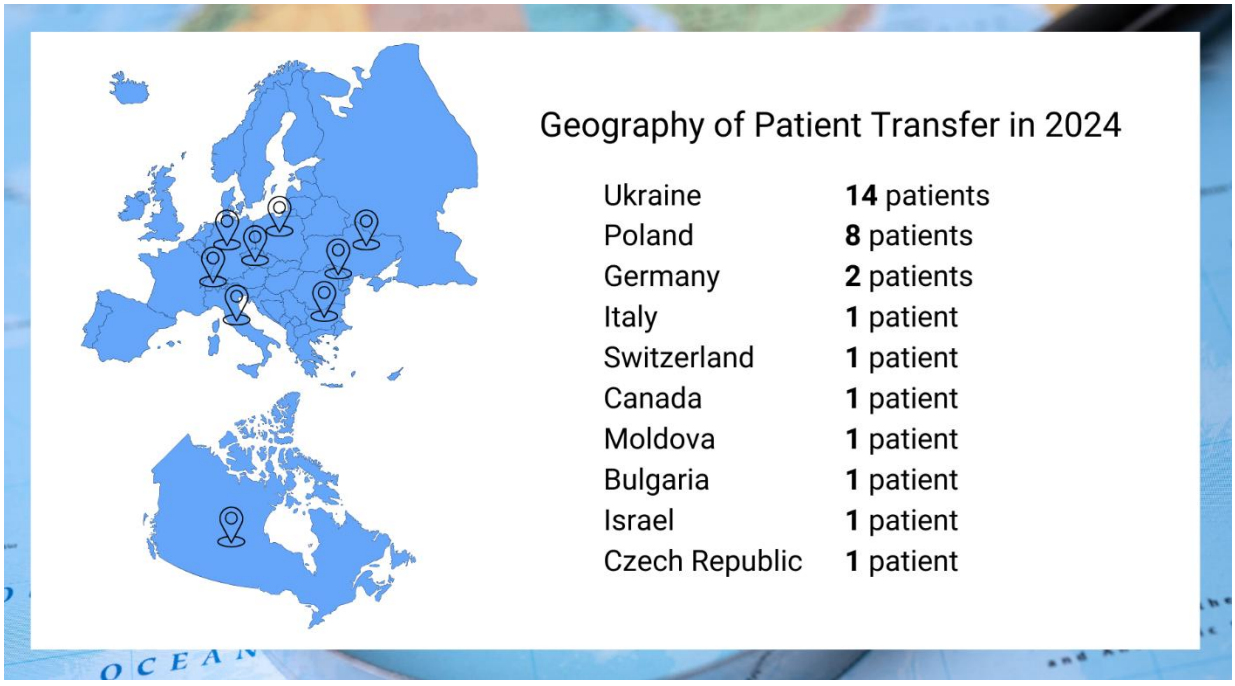
2. Suspension of patient recruitment (suspension of patient screening, suspension of patient randomization): 2024 – 0 CT, 2023 – 7 CTs, 2022 – 214 CTs.

3. Early termination of CTs: 2024 – 42 CTs, of which 12 CTs due to the war in Ukraine, and 30 CTs due to another reason (20 CTs – due to low efficacy, 10 CTs – economic reasons); 2023 – 128 CTs, of which 69 CTs due to the war in Ukraine, and 59 CTs due to other reason (18 CTs – due to financial issues, 37 CTs – due to low efficacy, 4 CTs – safety issues); 2022 – 132 CTs, of which 108 CTs due to the war, 24 KB CTs – other reason.

TRANSFER OF SUBJECTS TO OTHER STUDY SITES

In Q4 of 2024, the Department processed **4 letters** from Sponsors/CROs related to the transfer of study subjects to other study sites (hereinafter referred to as SS) (**7 patients** in total): in Ukraine (**4 patients** – therapeutic area of oncology) and abroad: Poland, Italy, Switzerland (**3 patients** – therapeutic area of neurology).

In 2024, the geography of Patient Transfer includes **10 countries** (**31 patients**), of which – **14 patients** (oncology) in Ukraine and 17 **patients** outside the borders of Ukraine (Poland – **8 patients**; Italy, Switzerland, Canada, Moldova, Bulgaria, Israel, Czech Republic – **1 patient each**, Germany – **2 patients**).



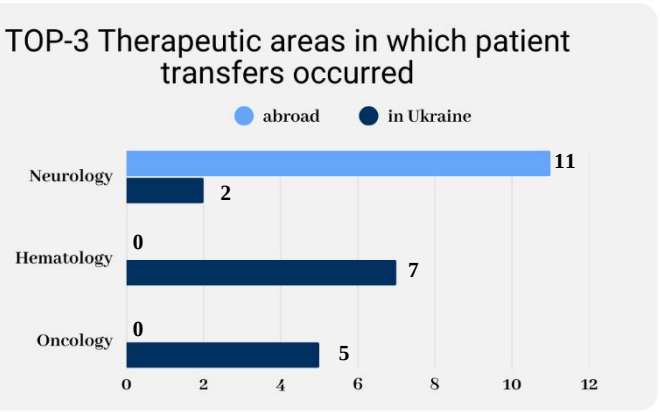
Number of study subjects transferred to other CT clinical study sites during 2024:

Contry	01	02	03	04	05	06	07	08	09	10	11	12	Total
Ukraine	2	1	5	0	0	1	0	1	0	1	3	0	**14**
Poland	1	2	2	0	2	0	0	0	0	1	0	0	**8**
Germany	0	1	0	0	0	1	0	0	0	0	0	0	**2**
Bulgaria	0	0	0	0	0	1	0	0	0	0	0	0	**1**
Moldova	0	0	0	0	1	0	0	0	0	0	0	0	**1**
Czech Republic	0	0	0	1	0	0	0	0	0	0	0	0	**1**
Israel	0	0	0	0	0	1	0	0	0	0	0	0	**1**
Canada	0	0	0	0	0	0	1	0	0	0	0	0	**1**
Italy	0	0	0	0	0	0	0	0	0	1	0	0	**1**
Switzerland	0	0	0	0	0	0	0	0	0	1	0	0	**1**
Total	**3**	**4**	**7**	**1**	**3**	**4**	**2**	**1**	**0**	**4**	**3**	**0**	**31**

The following table provides information regarding the CT therapeutic areas in which patient transfers occurred during 2024:

Therapeutic area	Month (abroad/in Ukraine)												
	01	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**	**11**	**12**	**Total**
Neurology	1/0	2/1	2/0	1/0	0	1/1	1	0	0	3/0	0	0	**11/2**
Hematology	0/2	0	0/5	0	0	0	0	0	0	0	0	0	**0/7**
Endocrinology/ Nephrology	0	1/0	0	0	2/0	2/0	0	0	0	0	0	0	**5/0**
Gastroenterology	0	0	0	0	1/0	0	0	0	0	0	0	0	**1/0**
Oncology	0	0	0	0	0	0	0	0/1	0	0/1	0/3	0	**0/5**
Total	**1/2**	**3/1**	**2/5**	**1/0**	**3/0**	**3/1**	**1/0**	**0/1**	**0**	**3/1**	**0/3**	**0**	**17/14**

The greatest number of transferred patients was in the therapeutic areas of neurology – 13, hematology – 7, oncology – 5, endocrinology – 5 and gastroenterology – 1.



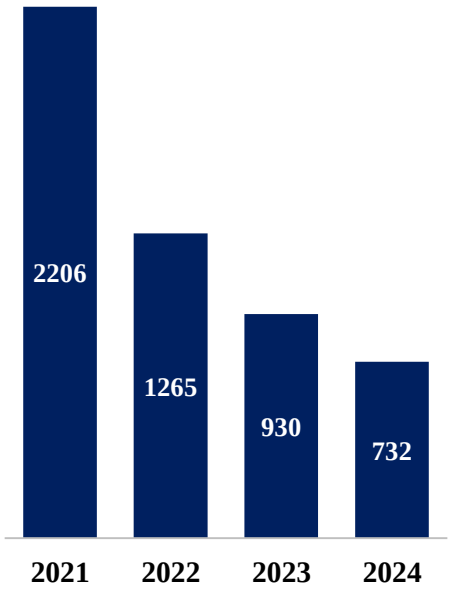
CT LIFE CYCLE

The life cycle of CTs conducted in Ukraine is supported by the incorporation of substantial amendments to CT protocols, information about which is presented on the histogram as monthly dynamics of 2022–2024 by the number of applications for substantial amendments received by the Center from the Ministry of Health, and by the number reviewed at the meetings of the Center's Scientific and Technical Councils (STC) and recommended for approval by the Ministry of Health.

Number of Applications for Substantial Amendments to CT Protocols Received by the Center in 2021–2024

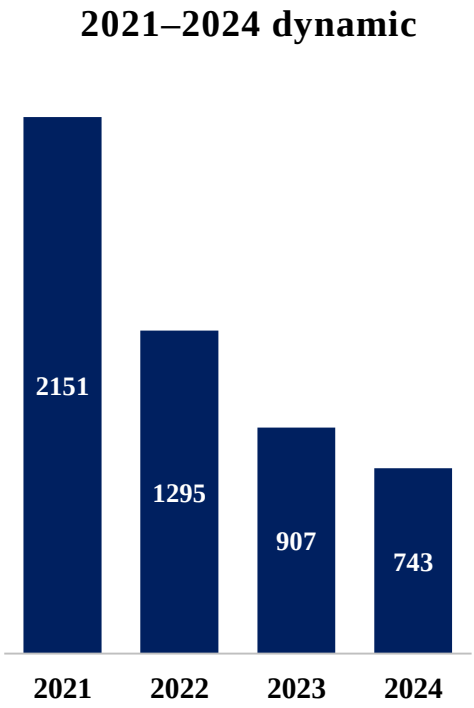
Month	2021	2022	2023	2024
January	127	119	79	67
February	153	149	99	67
March	194	9	112	73
April	219	116	70	47
May	173	121	71	43
June	176	110	81	59
July	181	141	72	58
August	176	129	65	54
September	186	113	48	51
October	207	79	92	78
November	206	95	60	71
December	208	84	81	64
Total	**2206**	**1265**	**930**	**732**
% of 2022/2023	**33.2%**	**57.8%**	**78.7%**	

2021–2024 dynamic



Number of Substantial Amendments to CT Protocols Reviewed at STC Meetings in 2021–2024

Month	2021	2022	2023	2024
January	113	155	92	67
February	157	124	84	94
March	169	68	79	64
April	213	87	121	65
May	177	113	53	53
June	168	136	99	50
July	212	82	71	38
August	138	71	76	62
September	254	154	50	48
October	145	119	62	61
November	193	74	87	63
December	212	112	33	78
Total	**2151**	**1295**	**907**	**743**
% of 2022/2023	**34.5%**	**57.3%**	**81.9%**	



The number of substantial amendments for 2024 period compared to the same period in previous years during the military aggression of the russian federation indicates the preservation of CT potential and their continuous monitoring during the life cycle and compliance with GCP requirements.

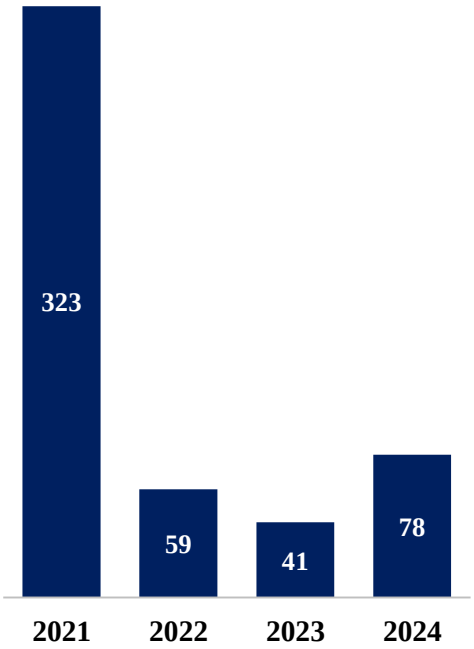
Number of Substantial Amendments to CT Protocols is decreasing due to the decrease in the number of Applications for Conducting a CT and the processes of termination the CT in accordance with the approved protocols.

The tables and histograms below provide comparative data on the receipt of Applications for Conducting a CT in Ukraine and the number of CT protocols with recommendations to the Ministry of Health regarding granting permission to conduct CT in Ukraine considered at meetings of the Scientific Expert Council Meetings in monthly dynamics for 2021 - 2024.

Number of CT Protocol Applications Received by the Center in 2021–2024

Month	2021	2022	2023	2024
January	14	22	3	6
February	18	12	1	6
March	27	0	2	1
April	33	1	4	7
May	21	3	3	11
June	39	0	6	4
July	33	4	3	10
August	24	0	1	3
September	24	3	3	6
October	30	2	4	11
November	24	9	7	2
December	23	3	4	9
Total	**323**	**59**	**41**	**78**
% of 2022/2023	**24.1%**	**132.2 %**	**190.2 %**	

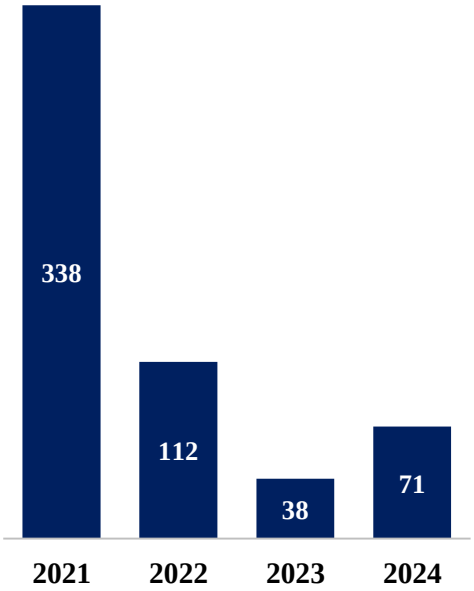
2021–2024 dynamic



Number of CT Protocols Reviewed at Scientific Expert Council Meetings in 2021–2024

Month	2021	2022	2023	2024
January	20	24	0	3
February	26	13	2	5
March	28	18	2	2
April	28	22	3	7
May	32	12	5	3
June	32	7	7	1
July	35	5	3	5
August	24	2	2	11
September	28	3	3	7
October	28	1	0	6
November	31	0	5	9
December	26	5	6	12
Total	**338**	**112**	**38**	**71**
% of 2022/2023	**21.0%**	**63.3%**	**186.8 %**	

2021–2024 dynamic



In 2024, **10** domestic manufacturer CT applications were received. And Reviewed at Scientific Expert Council Meetings – **8 CTs** of which **5** bioequivalence protocols.

During the reporting period **2 CTs** Protocols Reviewed at Scientific Expert Council Meetings therapeutic area of the treatment and/or prevention of acute respiratory infection COVID-19; and **9** Substantial Amendments to CT Protocols Reviewed at STC according to the specified treatment and prevention profile.

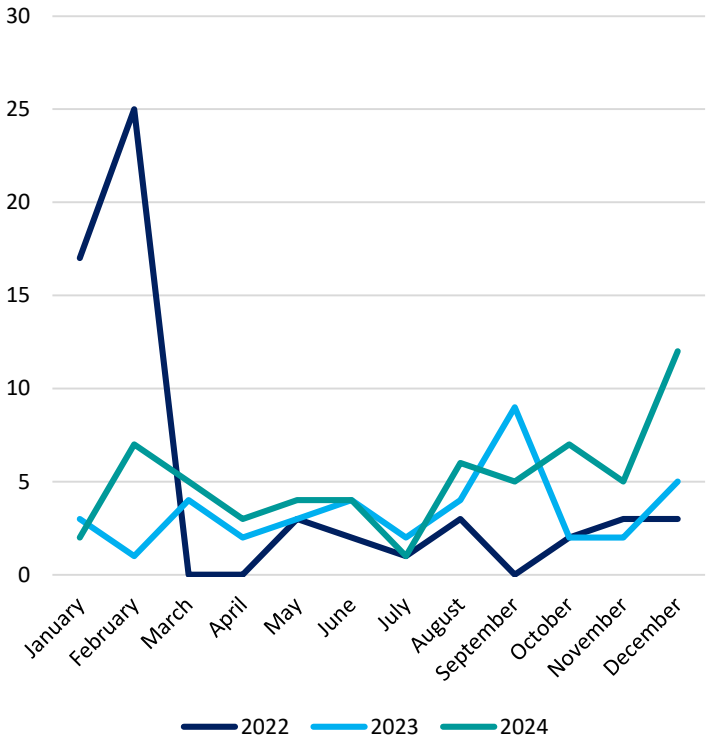
The number of applications for the conduct of a CT increased in of 2024 compared to the number of 2022 (01.03.2022 - 31.12.2022) – 25 CTs Protocol Applications; and 2023 – 78 CTs Protocol Applications.

As of 01.01.2025, the number of current CTs that are being conducted in Ukraine – **324 CTs** (approved by orders of the Ministry of Health – 76 clinical trials and initiated clinical trials – 248). More details at the **link** – https://clinicaltrials.dec.gov.ua

POSITIVE TRENDS IN THE RESUMPTION OF CTs IN UKRAINE

CT initiation – 61 CTs

Month	2022	2023	2024
January	17	3	2
February	25	1	7
March	0	4	5
April	0	2	3
May	3	3	4
June	2	4	4
July	1	2	1
August	3	4	6
September	0	9	5
October	2	2	7
November	3	2	5
December	3	5	12
Total	**59**	**32**	**61**



In particular, in 2024 CT initiation under the following therapeutic profiles: gastroenterology/proctology – **11 CTs**, neurology – **6 CTs**, oncohematology – **7 CTs**, oncology – **9 CTs**, bioequivalence – **5 CTs**, pulmonology – **8 CTs**, infectious

diseases – **4 CTs**, rheumatology – **5 CTs**, oncourology – **2 CTs**, allergology – **2 CTs**, otolaryngology – **2 CTs**.

Compared to 2022 (from 01.03.2022 to 31.12.2022), **17** notifications about CT initiation were received, in 2023 – 32 notifications, and in 2024 – 61 such notifications.

- In 2024, the Sponsor resumed patient recruitment within **8 CTs** (6 – neurology, 2 psychiatry). In 2023 – **11 CTs** and in 2022 – **27 CTs**.
- In 2024, **3 patients within the neurology therapeutic group returned** from abroad to the approved study site in Ukraine.

Department staff are constantly in contact with Applicants in order to properly conduct the CT under martial law in Ukraine.

For 2024, **3** new study sites were approved with significant amendments which corresponds to **3** new Local Independent Ethic Committees at Medical institutions (hereinafter referred to as LIEC), Contacts for **37** LIECs have been updated, totaling **390** LIECs in operation. Information about CTs study sites in the temporarily occupied and frontline territories of Ukraine as of 01.01.2025 has not changed – 102 study sites.

CTs study sites in the temporarily occupied and frontline territories

At the beginning of the war, there were 308 LIECs, which in principle corresponded to over 1,200 clinical trial sites approved by orders of the Ministry of Health. As of 01.01.2025, there were **390 ethics commissions**, which corresponded to over **800 clinical trial sites**.

METHODOLOGICAL WORK AND REGULATORY SUPPORT OF THE CENTER FOR THE PROCESSES OF CREATING MEDICINAL PRODUCTS, INCLUDING THEIR PRECLINICAL STUDY AND CLINICAL TRIALS CONDUCTED BY THE DEPARTMENT

The successful development of scientific and research activities in the field of medicinal products development is based on a long-term global strategy, which requires significant financial investments, the involvement of the latest technologies and highly qualified specialists. The process of developing a medicinal product is complex and lengthy, as it includes several key stages. One of the most important among them are nonclinical studies and clinical trials, which allow assessing the effectiveness, safety and feasibility of using a new drug.

Nonclinical studies of medicinal products are an integral part of the process of their creation and preparation for CTs. They make it possible to establish a safe initial dose for humans, identify possible side effects and assess the potential efficacy of the drug. Clinical trials, in turn, allow to confirm the safety and therapeutic value of the medicinal product in real conditions of use. Modern scientific approaches to the development of medicines require strict adherence to international standards, in particular, such as GLP (Good Laboratory Practice) for preclinical studies and GCP (Good Clinical Practice) for clinical trials.

One of the most promising areas of modern pharmaceuticals is the development of Advanced therapy medicinal products (hereinafter referred to as ATMPs). These include gene-cell and tissue-engineered drugs that use the latest biotechnologies. Such drugs have enormous potential in the treatment of complex, previously incurable diseases, including oncological pathologies, hereditary diseases, autoimmune disorders and severe tissue damage. Innovative approaches to the creation of ATMPs open up new opportunities in personalized medicine, providing patients with more effective and safe treatment methods.

One of the key innovations was the introduction of a new category of investigational medicinal products – Advanced Therapy Medicinal Products. This decision is aimed at attracting international and domestic ATMPs in the field of gene, cell and tissue engineering therapy to Ukraine. This innovation allowed expanding access of Ukrainian patients to innovative treatment methods, in particular for cancer patients, people with rare and hereditary diseases, and harmonizing Ukrainian regulation with European standards.

In 2024, the Center initiated and developed a number of important changes to the Procedure for Conducting Clinical Trials of Medicinal Products and Expertise of Clinical Trial Materials, approved by the Order of the Ministry of Health of September 23, 2009 (Order of the Ministry of Health No. 138 dated January 26, 2024 and Order of the Ministry of Health No. 894 dated May 24, 2024).

In order to implement modern international recommended standards for conducting preclinical studies and CTs, in 2024, the following standards were developed by the employees of the Department and the Center, based on the relevant EMA Guidelines:

• The Order of the Ministry of Health of Ukraine No. 480 dated 20 March 2024, Guideline ST-N of the Ministry of Health of Ukraine 42-9.0:2024 «Medicinal Products. Classification of Advanced Therapy Drugs»;

• The Order of the Ministry of Health of Ukraine No. 1028 dated 14 June 2024, Guideline ST-N of the Ministry of Health of Ukraine 42-7.13:2024 «Medicinal Products. Requirements for documentation on the chemical and pharmaceutical quality of medicinal products within the framework of clinical trials»;

• The Order of the Ministry of Health of Ukraine No. 1895 dated 12 November 2024, Guideline ST-N of the Ministry of Health of Ukraine 42-9.1:2024 «Medicinal Products. Requirements for dossiers of investigational advanced therapy medicinal products in clinical trials».

The purpose of these documents is to provide guidance on the structure and requirements for the dossier submitted with the application for conducting a clinical trial for the approval of research and confirmatory clinical trials in Ukraine with ATMPs and drugs of chemical origin.

These standards are multidisciplinary and address the specifics of the development, production and quality control of ATMPs and chemical origin drugs, the specifics of preclinical and clinical development of ATMP and chemical origin drugs; determination of ATMP efficacy; benefit-risk assessment during the development and use of these drugs in humans; requirements for research trials (including First in Human studies) and confirmatory trials.

The changes introduced into the legislation and the developed Guidelines mentioned above contributed to the receipt of applications to the Center for conducting CTs using ATMPs. In 2024, 4 applications were received for Phase I clinical trials, the object of study of which is the ADI-001 medical product, created using genetic engineering - allogeneic gamma-delta (γδ) CAR-T cells, developed for the treatment of pathological conditions of rheumatological and oncological profile: systemic sclerosis, lupus nephritis, recurrent or refractory (R/R) clear cell renal cell carcinoma (ccRCC), idiopathic inflammatory myopathies. Two clinical trial protocols have already been launched in Ukraine on 14.10.2024 («A Phase 1 Study of ADI-001 Anti-CD20 CAR-engineered Allogeneic Gamma-Delta (γδ) T Cells in Adults With Lupus Nephritis») and 04.12.2024 («A phase 1/2 Study of ADI-270 (modified γδ chimeric receptor CAR Vδ T cells targeting CD70)».

In 2024, the Center continued, within its powers, methodological support, consulting and review procedures for programs for expanded patient access to unregistered medicines and programs for access of research subjects (patients) to investigational medical products after the completion of a CT, respectively in Order No. 1525 of the Ministry of Health of Ukraine dated 24 August 2022 «On the Approval of the Procedure for the Approval and Conduct of the Extended Patient Access Program to Unapproved Medicinal Products, and the Study Subject (Patient) Access Program to the Investigational Medicinal Product after Completion of the Clinical Trial, and Amendments to the Procedure for the Importation of Unapproved Medicinal Products, Standard Samples, and Reagents

into the Territory of Ukraine».

Certain unregistered innovative Medicinal Products have become available to patients who need them and do not have alternative therapies. Thus, in 2024, 2 expanded access programs for investigational medicinal products were considered and approved after the completion of the CT:

- Program for access of study subjects (patients) to the investigational medicinal product Enspring (satralizumab) after completion of the clinical trial (program code - AG45056) (CT code: WN42349);
- Program for access of study subjects (patients) to the investigational medicinal product Copanlisib and rituximab (CT code No. BAY 80-6946 / 17067) after completion of clinical trials.

In 2024, the Center considered 7 changes to the Program for Access of Research Subjects (Patients) to Investigational Medicinal Products after the Completion of a Clinical Trial and 1 minor change.

The Center developed a draft of amendments to the Order of the Ministry of Health No. 1525, which were approved by the Order of the Ministry of Health No. 1835 dated 01.11.2024.

In order to harmonize national legislation in the field of clinical trials, the Department prepared a presentation «Clinical Trials» for the purpose of conducting an official screening of the compliance of Ukrainian legislation with European Union law under negotiating chapter 28 «Consumer and health protection» for participation in a bilateral meeting between Ukraine and the European Commission in the field of health.

Department employees participated in the following:

- 9 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 651 participants with the subsequent issuance of certificates;
- 2 off-line seminars within the framework of the Scientific and Practical Conference «Innovative Technologies in Clinical Research» in Kropyvnytskyi;
- International scientific and practical conference «Immunology, allergology, rheumatology in the world and Ukraine: modern realities and challenges» (Christmas readings in Lviv) on the topic «Good Clinical Practice (GCP). Legal Regulation of Clinical Trials» for 651 participants (researchers, members of the LIECs, experts of advisory and expert groups) in Lviv.

*The growing number of participants in the seminars «Good Clinical Practice (GCP). Legal Regulation of Clinical Trials», which are successfully conducted monthly by specialists of the State Expert Center of the Ministry of Health of Ukraine, is one of the indicators of the continuity of processes in the field of clinical trials in Ukraine.

Also:

• in the scientific and practical Internet-conference with international participation «Current issues of clinical pharmacology and clinical pharmacy» in Kharkiv, Ukraine. The Center presented a report «Key indicators of the state of clinical trials of medicinal products in Ukraine through the eyes of the regulatory body».

• On August 22, 2024, the Department's employees took part in a meeting with the Head of the Ukrainian Association for Clinical Trials (UACT) – I.I. Vyshnyvetsky. The meeting discussed topical issues of the state of clinical trials of medicinal products in Ukraine. Following the results of the meeting, the UACT, together with the State Expert Center, organized a webinar for sponsors «Ukrainian Clinical Trials - Sustainability, Efficiency and Strategic Opportunities», with the participation of more than 150 participants – sponsors and their representatives. The Department of Clinical Trials prepared a presentation on the topic «Key indicators of the field of clinical trials in Ukraine through the eyes of an expert body» (T. Gerasymchuk). The specified activities of the Department were covered on the official website of the Center in the «Latest News» section at https://www.dec.gov.ua/news and on Facebook.

• Department employees participated in a meeting with representatives of the clinical research sponsor, AstraZeneca LLC, and representatives of the Ukrainian Association for Clinical Trials (UACT) regarding current working situations when reviewing clinical trial materials and the specifics of the approach to determining criteria for the principal (responsible) investigator and research team, and the possibility of revising the requirements for them in the current order of the Ministry of Health dated 23.09.09 No. 690.

• Employees of the Center (including the Department) participated in an online meeting and 1 offline meeting with the participation of representatives of the Ministry of Health of Ukraine, the State Service for Medicines and Drug Control, and the National Children's Specialized Hospital of the Ministry of Health of Ukraine «Okhmatdyt» on the issue of introducing advanced therapy drugs based on CAR-T therapy in the National Children's Specialized Hospital «Okhmatdyt».

• in a meeting with representatives of medical institutions, clinics, organizations, manufacturers, associations, cell and tissue banks, to discuss amendments to the Ministry of Health Order No. 690 of September 23, 2009 on clinical trials of advanced therapy drugs (amendments approved by the Ministry of Health Order No. 138 of January 26, 2024).

• In on-line meetings with representatives of the Polish national authority.

The Department held 2 on-line meetings with local ethics committees (123 participants) in order to properly organize methodological coordination of their work. The topics of the webinars were «Conducting clinical trials involving vulnerable groups of subjects», «Meeting with Ethics Committee Members: Protecting the Rights of Study Subjects Participating in Trials of Medicinal Products». Information about which is posted on the Center’s website in the category EXPERTISE OF NONCLINICAL AND CLINICAL TRIALS MATERIALS, in the section «Methodological support for ethics committees».

1 message was also posted on the necessity and scope of reporting on the work of local ethics committees. Ethics issues are published on the official website and Facebook page of the Center.

The Department's support for external stakeholder feedback:

Provided by Department staff:

• 19 on-line (7) and off-line (12) consultations for foreign and domestic Applicants/ Sponsors;

• 124 consultative electronic requests from Applicants were processed and written electronic responses were prepared and provided

• 58 response letters were prepared for Applicants (CT Sponsors) after processing external correspondence (letters related to the conduct of CTs, Periodic Reports, Investigator's Brochures, Final Reports).

The Department has initiated meetings of experts of specialized expertise for their effective communication, which will contribute to improving the quality of professional assessment of clinical trial materials, consistent scientific opinion, and correct substantiated expert conclusions. Such meetings are introduced by the Department as necessary for all clinical trials of advanced therapy medicinal products and other clinical trials regarding, in particular, complex clinical trial design, the use of decentralized elements for conducting clinical trials, etc. The notification of the working meeting of experts to discuss the results of the review of clinical trial materials of advanced therapy medicinal products was published on the official website of the Center in the «Latest News» section at https://www.dec.gov.ua/news and on Facebook.

The Department’s employees attended 66 external seminars/webinars/meetings and 24 internal presentation webinars between the structural units of the Department and the Center.

Director of the Department **Taisa Herasymchuk**