State Expert Center MOH RA Ukraine

Informational Leaflet
Clinical trials in Ukraine for the period of 01.07.2024 - 30.09.2024

The State Expert Center of the Ministry of Health of Ukraine (hereinafter - the Center) traditionally during the current year publishes analytical information on the state of clinical trials (hereinafter - CT) in Ukraine, prepared by the Department of Examination of Materials for Preclinical and Clinical Trials.

The full-scale military aggression of the Russian Federation continues and has a significant impact on the processes of planning and conducting clinical trials of medicinal products in Ukraine. The State Expert Center opinion to highlight dynamic and metrics of processes in the clinical trials field of on a quarterly basis in comparison with the corresponding periods of 2022, 2023 as necessity.

We would like to emphasize that the main and constant priority of the life cycle of CT has been and remains - the oversight of international ethical principles, ensuring the protection of the rights, safety and well-being of the subjects. The life path of CT requires clear, coordinated actions from all stakeholders, facilitators and participants in CT processes.

Provided Q3 data - reflects the trends and tendencies of dynamic changes in the CT industry in Ukraine for the 3 quarters of 2024 and the 2022 - 2023, incl. showing changes for the Q3 of 2024.

The priorities of the Center regarding communications with all involved parties in the III quarter of 2024 have not changed and are supported by all available means, namely: by E-mail, requests through the electronic resource "On-line consultation" and of the official website of the Center, Also SEC responses to all written communication requests, various information letters, off-line consultations, Conducting webinars and seminars, etc.

Q3 2024

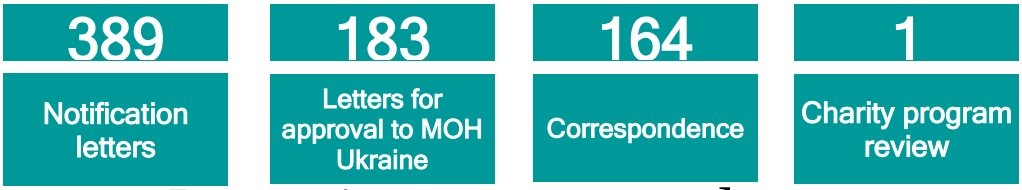
During III quarter of 2024, the Center approved to the Ministry of Health of Ukraine (hereinafter referred to as the Ministry of Health) for approval to be carried out in general **23 Clinical Trial Protocols** including **1** domestic/local Clinical trial protocols for pharmaceutical manufacturers in Ukraine; also **148 Substantial** Clinical Trial Amendments (hereinafter – sCTAm.) to the protocols of international multi-center CVs, in particular **5 Substantial CTAms** for the protocols of domestic pharmaceutical manufacturers.

During III quarter of 2024, the MoHRA processed **737 incoming** letters of correspondence, such as:

- **21 Letters** from the Ministry of Health granted permit to conduct CT,
- **162 granted** approval of Substantial CTAms,
- **1 Charity** statements;
- **164 Letters-replies** to letters regarding the completeness/not finalized CT materials

provided in CT application by applicants;

- **389 Information** letters from applicants regarding**:**
  - **69** Periodic reports (DSUR/PSURs);
  - **45** Final CT reports**;**
  - **40 notification letters** regarding the completion of the CT, including **5 notification letters** regarding the early completion of the CT in Ukraine (**4 CT due Sponsor's economy** challenges; 1 CT – due to results of efficacy);
  - **2 notification letters** regarding the transfer of 2 participants involved in CT;
    - 1 patient transferred within Ukraine - from approved CT Site to other approved CT Site.
    - 1 patient out of the Ukraine to Canadian CT site.



Incoming correspondence

Among the positive trends according to the information received by the Center during the period of Q3:

- 12 Start of new CTs;
- 2 CTs Re-Start of enrolment;
- 0 notification of Stop or Closure of the CT in Ukraine;
- 0 notification of Pause on screening of new participants and/or pause/stop/randomization.

All incoming documentation was processed by the Department staff in a proper and timely manner, answers were provided by e-mail and/or in paper form through the Service Center of the Center.

ANALYSIS OF THE STATE OF ONGOING CLINICAL TRIALS AT DIFFERENT STAGES OF CONDUCT

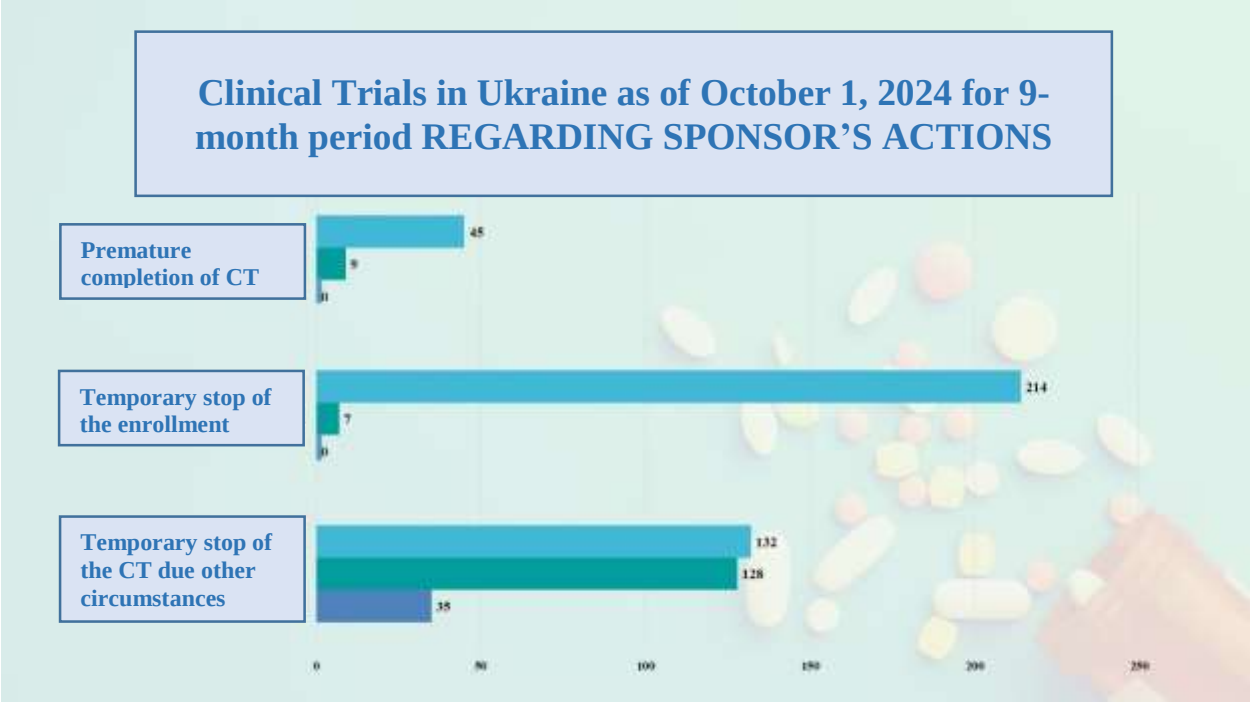
As of October 1, 2024, the following information is relevant regarding the number of CTs that are being conducted in Ukraine at various stages: **a total of 355 CTs,** of which **264 are initiated CTs**, of which **37 were started** during Q1-Q3 of 2024 **and for 91 CTs approvals has been granted** by the Ministry of Health of Ukraine.

INFORMATION REGARDING SPONSOR'S ACTIONS

During the period Q3 of 01/07/2024 – 30/09/2024, the following actions were taken by the sponsor regarding the approved by the Center and Ministry of Health initiated CTs:

- **Premature completion of CT:** I-III quarter 2024 - 35 CTs, including following:
- **9 CTs** due to war in Ukraine,
- **22 CTs** – regarding insufficient efficacy of IMP;
- **4 CTs** – economic/financial challenges

There were no any stop of the screening or enrolment of the subjects in ongoing CTs – these are indicators of positive trends and stabilization in clinical trial industry and Ukraine.



TRANSFER OF THE CT PARTICIPANTS TO OTHER INVESTIGATIONAL SITES

During Q3 of 2024 MoH RA has reviewed an 2 letters from **applicants Sponsors/CROs**, regarding participant transfers to other Clinical Trial sites (onwards -CT Sites)

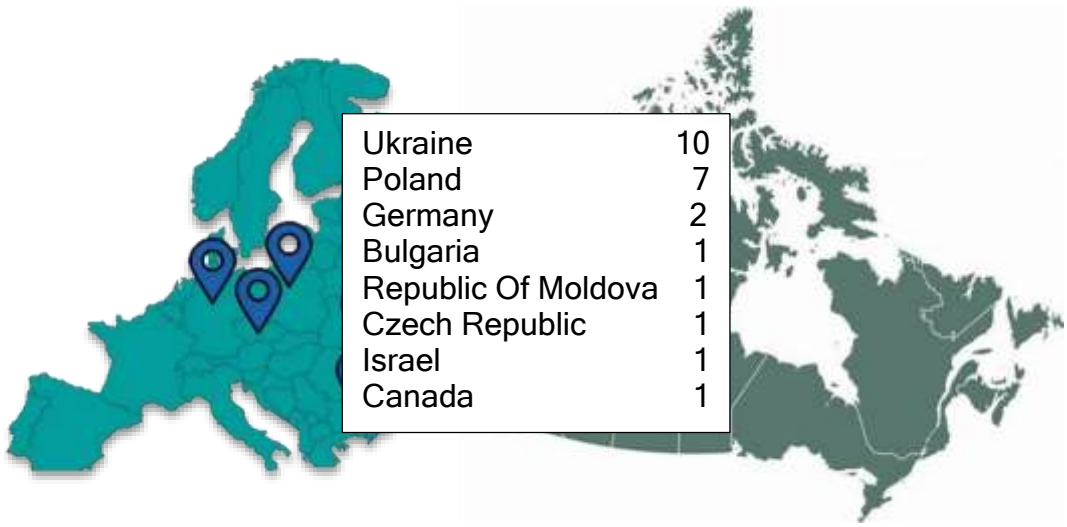
Total 2 participants:

Within Ukraine – 1 patient, 1 Oncology)

Abroad/Canada – 1 patient, 1 Neurology)

The number of subjects transferred to other CT Sites during Q1-Q3 2024 around the world:

Subject's geography of relocation:



	Calendar Month									
Country	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**Total**
Ukraine	2	1	5	0	0	1	0	1	0	**10**
Poland	1	2	2	0	2	0	0	0	0	**7**
Germany	0	1	0	0	0	1	0	0	0	**2**
Bulgaria	0	0	0	0	0	1	0	0	0	**1**
Republic Of Moldova	0	0	0	0	1	0	0	0	0	**1**
Czech Republic	0	0	0	1	0	0	0	0	0	**1**
Israel	0	0	0	0	0	1	0	0	0	**1**
Canada	0	0	0	0	0	0	1	0	0	**1**
Total	**3**	**4**	**7**	**1**	**3**	**4**	**2**	**1**	**0**	**24**

The following table provides information on therapeutics areas of the CT in which patients were transferred:

	Calendar Month (Abroad/Domestic)									
Therapeutic areas	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**Total**
Neurology	1/0	2/1	2/0	1/0	0	1/1	1	0	**0**	**8/2**
Hematology	0/2	0/0	0/5	0	0	0	0	0	**0**	**0/7**
Endocrinology/ Nephrology	0/0	1/0	0/0	0	2/0	2/0	0	0	**0**	**5/0**
Gastroenterology	0	0	0	0	1/0	0	0	0	**0**	**1/0**
Oncology	0	0	0	0	0	0	0	0/1	**0**	**0/1**
Total	**1/2**	**3/1**	**2/5**	**1/0**	**3/0**	**3/1**	**1/0**	**0/1**	**0**	**14/10**

During 9-month period of 2024 - 24 subjects has been transferred. Majority were in the therapeutic area of neurology – 10, hematology – 7, endocrinology – 5.

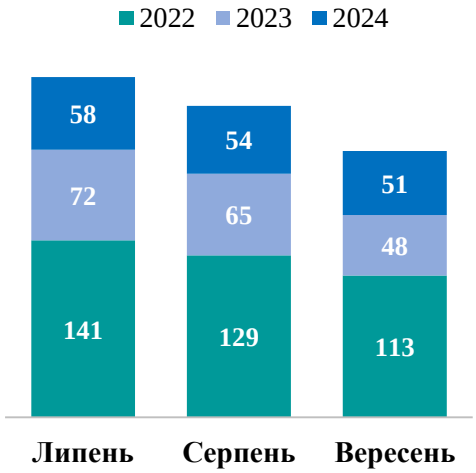
LIFECYCLE OF THE CLINICAL TRIAL

Lifecycle of clinical trials, which are conducted in Ukraine, are amended by approval of

Substantial Amendments to Clinical Trial Protocol, information about which is presented on the histogram as dynamics for the second quarter of 2022 - 2024 according to the number of CT applications received by the Center from the Ministry of Health, and the number considered at the meetings of the Center's Scientific and Technical Councils (CSTC/CSEC or NTR/NER) and recommended for approval by the Ministry of Health.

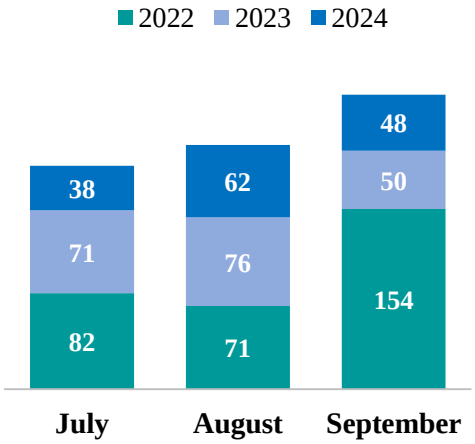
The number of applications for Substantial CTAms received by the Center for the Q3 2022-2024 years

Month to month	2022	2023	2024
July	141	72	58
August	129	65	54
September	113	48	51
Total	383	185	163
%2022 2023	43%	88%	



The number of applications for Substantial CTAms reviewed by the Center's CSTC/NTR committee for the Q3 2022-2024 years

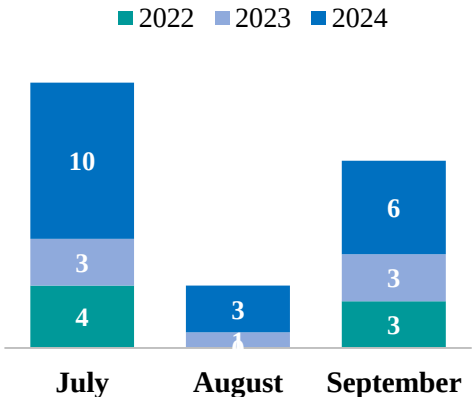
Month to month	2022	2023	2024
July	82	71	38
August	71	76	62
September	154	50	48
Total	307	197	148
%2022 2023	48%	75%	



The number of Substantial CTAms for the specified period in comparison with the same period (month-to-month) in previous years during the military aggression of the russian federation indicates the preservation of the same trend and their continuous control during the life cycle and compliance with the requirements of the **ICH-GCP E6(r2).**

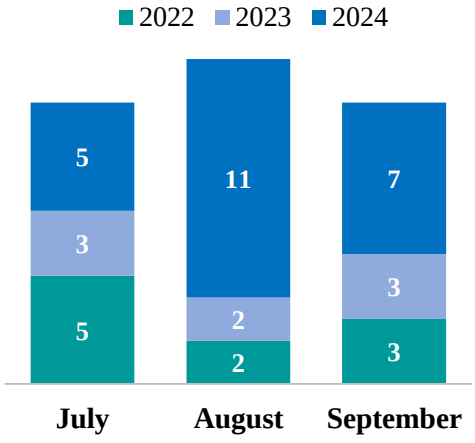
The number of applications for new Clinical Trial Protocols received by the Center for the Q3 2022-2024 years

Month to month	2022	2023	2024
July	4	3	10
August	0	1	3
September	3	3	6
Total	7	7	21
% 2022/2023	300%	300%	



The number of applications for new Clinical Trial Protocols reviewed by the Center's CSEC/NER committee for the Q3 2022-2024 years.

Month to month	2022	2023	2024
July	5	3	5
August	2	2	11
September	3	3	7
Total	10	8	23
% 2022/2023	230%	287%	



During the reporting period, 2 applications were received for conducting the new CT from the domestic pharmaceutical manufacturers.

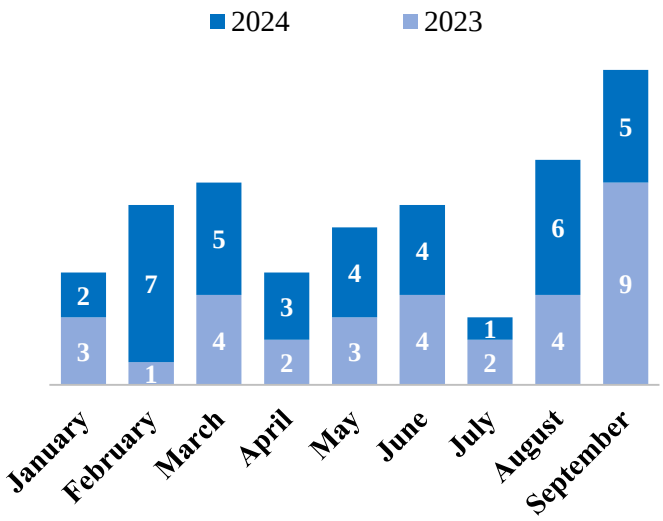
The number of applications for the implementation of CT in the 3rd Quarter 2024 has risen in 3 times. Compared to the numbers of same period of 3rd Quarter 2023.

POSITIVE TRENDS AND TENDENCIES REGARDING RECOVERY OF CLINICAL TRIALS AND INDUSTRY AT UKRAINE

Correspondence submitted by Applicants are:

- Clinical Trials - **37 new applications 9 months**, including **12 CTs for Q3 2024.**

Month/Year	2023	2024
January	3	2
February	1	7
March	4	5
April	2	3
May	3	4
June	4	4
July	2	1
August	4	6
September	9	5
Total	**32**	**37**



- To be precise, during Q3, 12 notifications has been received before the start date of CT for the following nosologies:

  Neurology - 1 trial,
  Oncology - 3 trials,
  Bioequivalence - 2 trials,
  Gastroenterology/proctology - 3 trials,
  Hematology - 1 trial,
  Infectious diseases - 2 trials,

- During **Q3 2024 has re-started recruitment** 2 clinical trials (**neurology, psychiatric disorders)** sponsor re-evaluated situation in Ukraine and re-started recruitment.

Associates of the State expert Center MoH RA has constant contact with applicants

(sponsors and/or CROs) in order to properly conduct the CT in lieu with ICH-GCP under the conditions of martial law in Ukraine.

List of Local independent Ethic Committees at Medical institutions, hospitals and private medical facilities in Ukraine.

During Q3 the reporting period, measures were taken to maintain correct information in the List of Local independent ethic committees at medical institutions, hospitals and private medical facilities in Ukraine (hereinafter - the List) in the conditions of the martial law regime on the territory of Ukraine. Currently, the updated List contains 390 contacts.

During Q3 2024, 150 CT sites has been recommended for approval, and Substantial amendments were approved to the CT, which already has been started, as such:

64 CT sites in the Kyiv city and Kyiv region,
19 CT sites - in the city of Vinnytsia,
11 CT sites - in the city of Lviv,
10 CT sites - the city of Ivano-Frankivsk,
7 CT sites in the city Cherkasy,
6 CT sites - the city of Uzhgorod, the city of Dnipro,
5 CT sites - the city of Ternopil, Lutsk,
4 CT sites - in the city of Chernivtsi,
3 CT sites - the city Zhytomyr, Poltava,
2 CT sites – The city of Odesa, Kropyvnytskiy,
1 CT site each - in the cities of Rivne, Kharkiv, Khmelnytskyi.

Locations of the new CT in Ukraine's geographic map Q3 2024.

INFORAMATION REGARDING METHODOLOGIES AND DEPARTMENT OF EVALUATION CT AT STATE EXPERT CENTER, DURING Q3 2024

Participation of the Department in the development of the process on harmonization with EU for the development of projects regulatory documents.

In order to improve the qualifications of experts, the Department held 5 internal webinars and 20 external training events (seminars, webinars).

During the 3rd quarter of 2024, employees of the Department participated in the preparation and holding of 1 educational online seminar on the international requirements of good clinical practice and legal acts on the conduct of clinical trials in Ukraine on the topic "Good Clinical Practice (GCP). Normative and legal regulation of conducting clinical trials" which was attended by 77 researchers, representatives of local ethics commissions.

At the webinar "Ukrainian clinical trials - sustainability, efficiency and strategic opportunities", for sponsors (more than 150 participants), organized by the Ukrainian Clinical Research Association (UACR) together with the Center, a presentation on the topic of - **«Key indicators of the field of clinical trials in Ukraine through the eyes of an expert body» -** was presented.

Client support and collaboration with sponsors and CROs:

Associates of the state expert center helped with:

- 3 online consultations and 1 offline consultations for foreign and domestic applicants/sponsors/CROs;
- 22 consultations and/or electronic requests from applicants were processed - written responses has been prepared and provided to applicants;
- 18 letters of response were prepared for applicants (sponsors of CT) after processing external correspondence related to the life cycle of CT.

State expert Center reviewed: One “Program” of extended access for research subjects to provide the investigational medical product/drug (IMPD) after the completion of the clinical trial.

Performance and most recent information you may find in Section “Latest News” are available on-demand at https://www.dec.gov.ua/news and at our Facebook page.

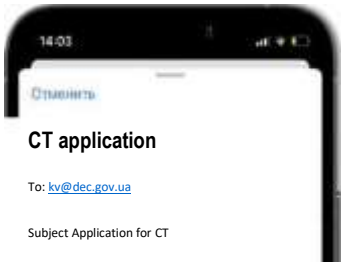
Contact Us

We would like to remind You that in order to coordinate the actions taken by the sponsor, starting from 24.02.2022 till today, for proper communication between the sponsor or their representative - CRO and the State Expert Center MoH RA, dedicated email for contact are e-Mail:

dec@dec.gov.ua – electronic mail address for all information letters 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 - electronic mail address for submission of applications for conducting a clinical trial of a medicinal product, significant amendments, and relevant cover letters to the Ministry of Health;

kv@dec.gov.ua - electronic mail address for providing materials of clinical trials and materials of significant amendments of clinical trials in accordance with the Procedure for conducting clinical trials of medicinal products and examination of clinical trial materials, approved by the order of the Ministry of Health Ukraine d.a.: 23.09.2009 № 690;



Additional materials, responses to comments on materials of clinical trials and substantial amendments.

clinic@dec.gov.ua - e-mail for submission of safety reports (**DSURs)**, reports of adverse reactions (**SUSARs)** occurring during clinical trials.