Державний Експертний Центр МОЗ України

ФАРМАЦЕВТИЧНИЙ ФОРУМ

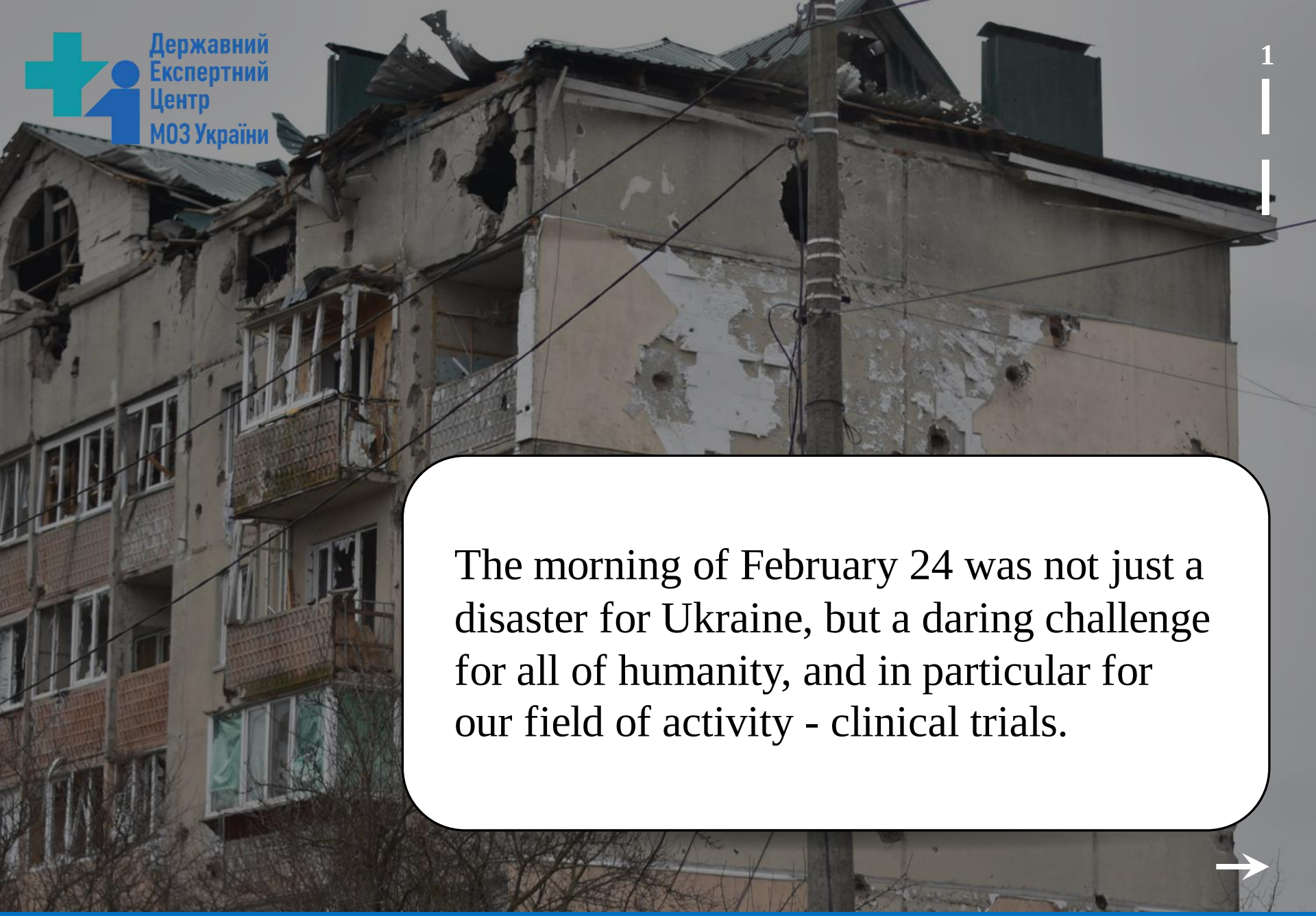
КЛІНІЧНІ ВИПРОБУВАННЯ В УКРАЇНІ. ЄВРОПЕЙСЬКА ІНТЕГРАЦІЯ

Clinical Trials Sector in Ukraine during the War. Expert analysis

Taisa Herasymchuk
Director of the Preclinical and Clinical Trials Materials Expert Evaluation Department of the SECMOH of Ukraine

Київ, 29.06.2023

UkrComXPO
Компанія УкрКомЕкспо



The morning of February 24 was not just a disaster for Ukraine, but a daring challenge for all of humanity, and in particular for our field of activity - clinical trials.

Державний Експертний Центр МОЗ України

AT THE BEGINNING OF THE WAR

794 clinical trials were approved and conducted at various stages in Ukraine

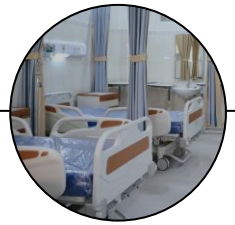
of which **584** were started

and **210** were approved by the Ministry of Health to be conducted in Ukraine

Scan me

Challenges to clinical research participants

Safety of trial subjects



Site visits

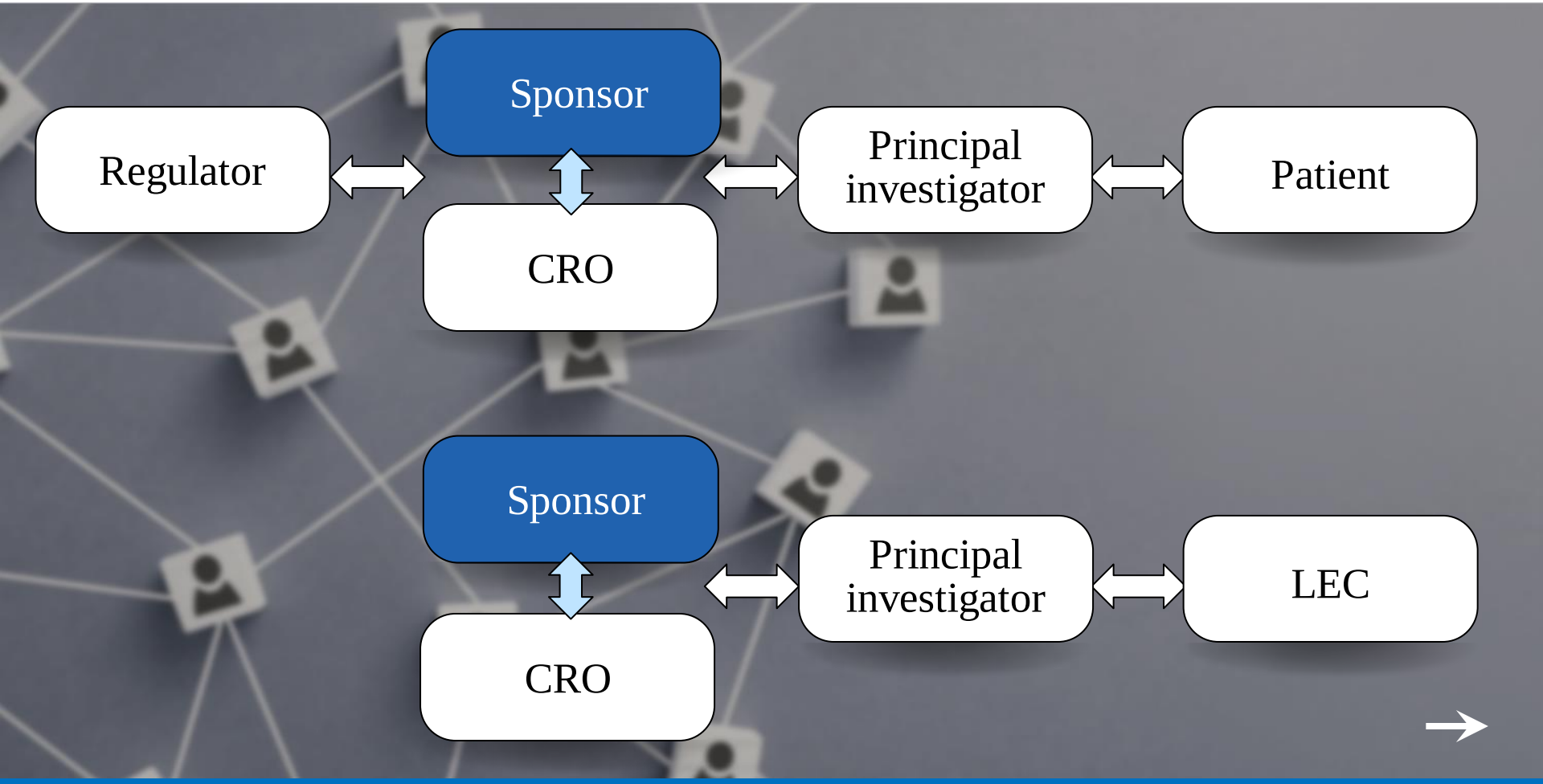
Provision of investigational medicinal product

Collection and transfer of samples to the specified laboratories

Patient observation

Recording the results obtained etc.

The communication chain has been defined to ensure full functioning:



Communication with the applicant

From 2022 to 31.05.2023

From 2022 to 31.05.2023, the Department received incoming correspondence (referrals for clinical trials, letters from applicants) – **6469** namely:

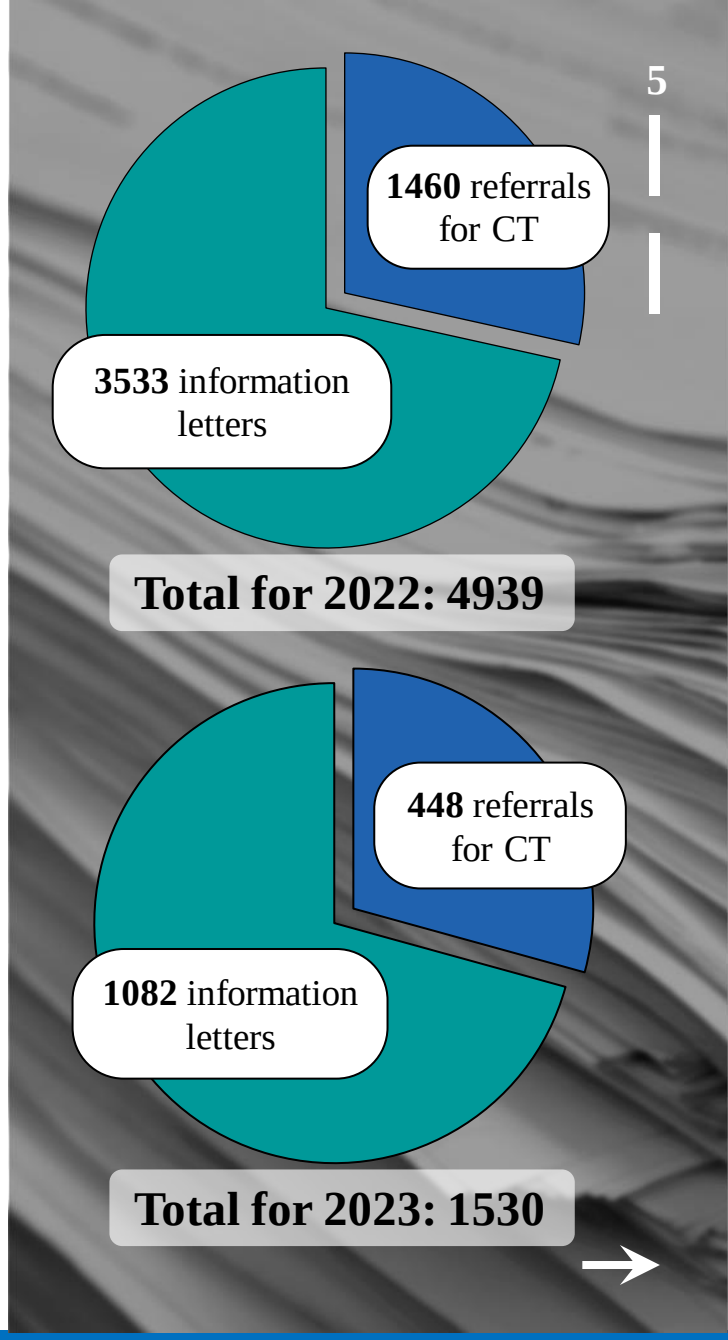
- 4939 in 2022;
- 1530 during the first five months of 2023

Of which **1854** – referrals for clinical trials:

- 1406 in 2022;
- 448 during the first five months of 2023.

Information letters from applicants, letters of inquiry, advisory letters, letters of notification of patient transfer, letters of initiation of clinical trials, letters of completion of clinical trials (including early completion of clinical trials), periodic reports, final reports, others – **4615**:

- 3533 in 2022;
- 1082 during the first five months of 2023



GCP Compliance

The priority is to continue ensuring the rights and safety of the subjects

> 2.3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society
>
> *ICH GCP (R2)*

Realizing that certain changes and deviations from a study protocol in the current situation are inevitable, the SECMOH has published recommendations for Sponsors, Investigators, Ethics Committees

SECMOH Recommendations for investigators, sponsors

Main topics

- assessing the possibility to start a new CT; screening, recruitment
- possibility of the patients' transfer to another trial site in Ukraine and/or in another country
- taking all possible measures to ensure the continuous provision of IMPs to patients at the trial site;
- reporting all protocol deviations related to patient safety and other trial aspects

In case of impossibility of patient visits to the site:

- telephone contacts
- remote patients informing and consenting (verbal/written)
- postponement of visits, transferring patients to another site
- delivery of the IMP to patients
- carrying out the visit (or its part) off-site (at home)
- switching from central labs to local ones to control patients safety parameters

Scan me

SECMOH Recommendations for investigators, sponsors (Continued)

- EMA recommendations «Advice to sponsors on managing the impact of the war in Ukraine on CT» **(QR-code)**
- EMA recommendations «Impact of the war in Ukraine on methodological aspects of ongoing clinical trials» **(QR-code)**
- Guideline 20. «Research in the context of natural disasters and disease outbreaks» recommendations: «International ethical guidelines for health-related research involving human subjects» developed by the Council of International Organizations of Medical Sciences (CIOMS) in cooperation with WHO

Sponsor is responsible for decision making and all actions taken in such force majeure circumstances, namely

- Maximum possible safety and security of all trial subjects
- Compliance with the trial protocol
- Recording all protocol deviations with justification
- Ensuring the impartiality, reliability, and validity of the trial results through the proper compliance with all items.

SECMOH Recommendation for Local Ethics Committees (LECs)

SOPs

- e-submission
- online meetings (using video and/or audio connections)
- members replacement if no quorum
- single opinion for multi-centre CT

(!!! exceptional cases which require urgent decisions !!!)

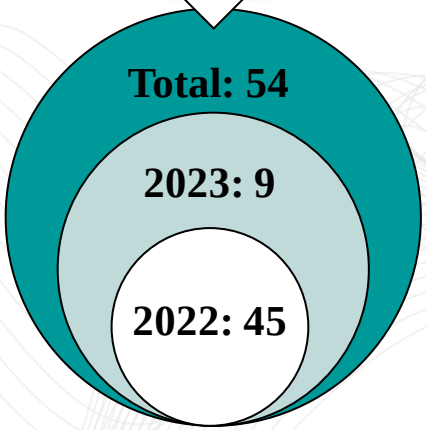
Scan me

Державний Експертний Центр МОЗ України

Sponsor’s actions (24.02.22 - 31.05.23)

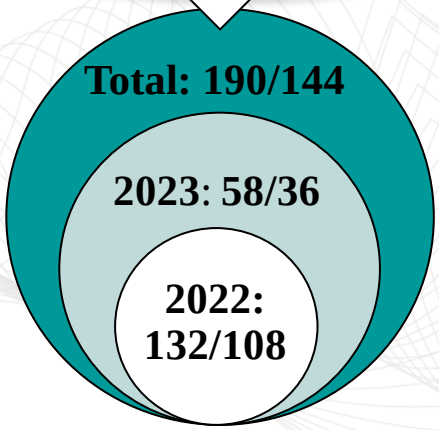
54

Suspension of the start of clinical trial



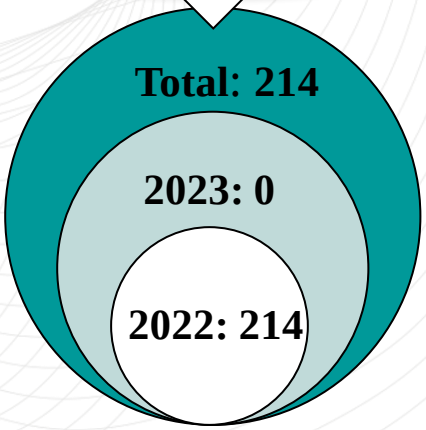
190

Premature termination of clinical trial



214

Suspension of patient recruitment



Державний Експертний Центр МОЗ України

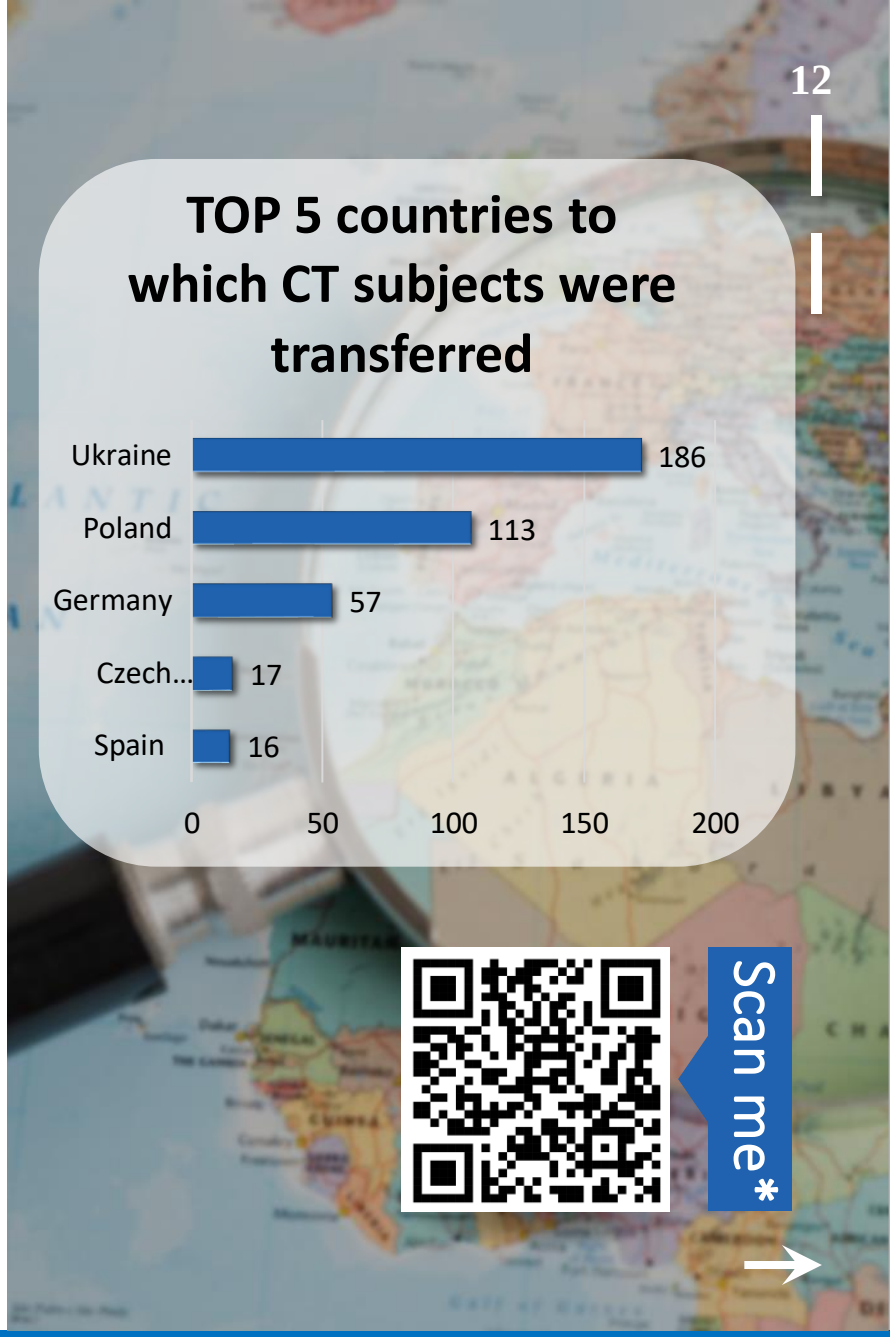
Four scenarios of Sponsor's actions related to patients participation in CT:

(24.02.22 – 31.05.23)

When patients are enrolled in a clinical trial and receive a treatment:

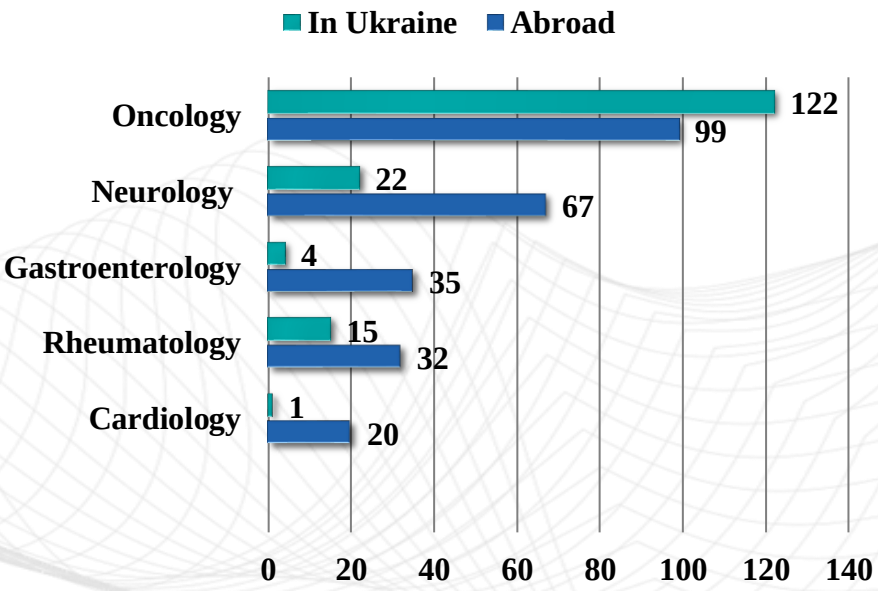
- Continuation of a treatment at the trial site
- Exit from CT due to its early termination **190 CT**, including early termination due to war **144 CT**, other reasons **46 CT**
- Transfer of the patient to another trial site in Ukraine approved by MoH – **186**
- Transfer of the patient to a trial site in other countries – **295**

*Information Report Regarding the Status of CT in Ukraine (01/01/2023 – 01/03/2023)

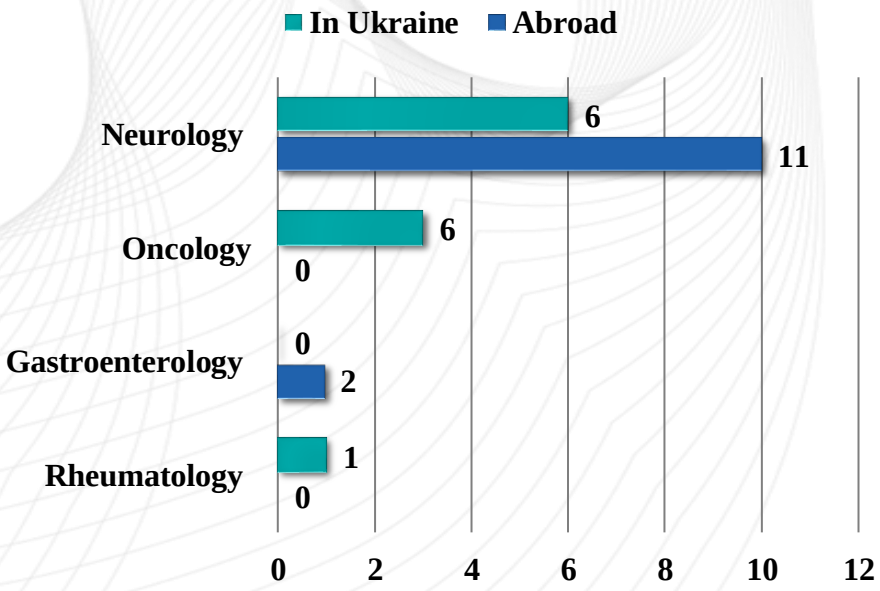


Number of patients transferred to other trial sites in Ukraine/abroad:

TOP therapeutic areas related to the patient transfer **(2022)**



TOP therapeutic areas related to the patient transfer **(2023)**



Державний Експертний Центр МОЗ України

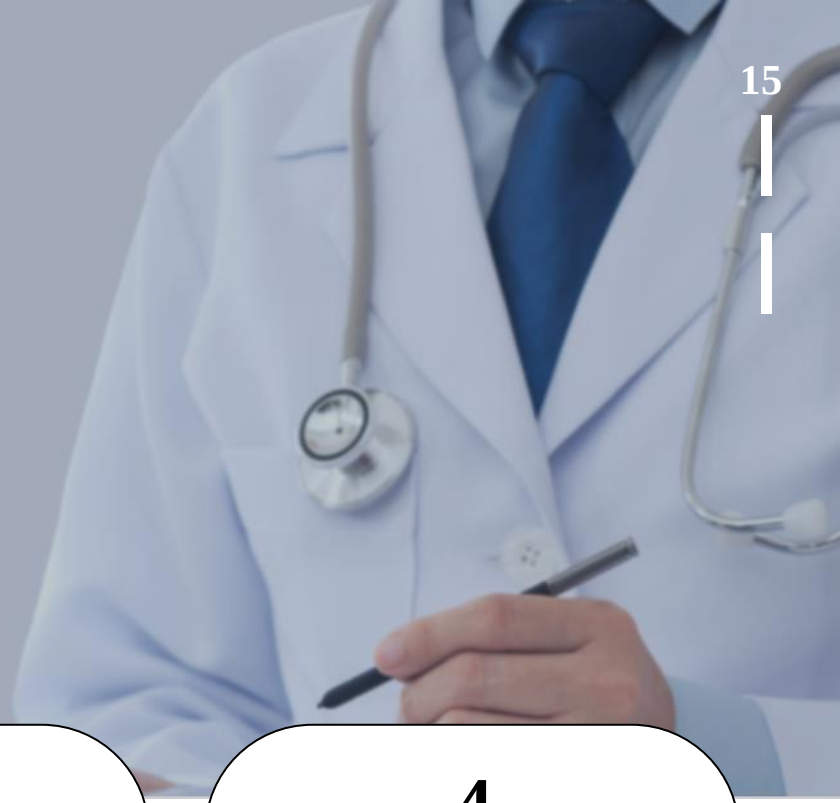
A positive tendency toward

In 5 months of 2023, **13** clinical trials were started

Resumption of clinical trials – **11** protocols

Resumption of patient recruitment – **20** protocols

Return of **32** patients to trial sites in Ukraine



10	8	4
Oncology	Neurology	Hematology and gastroenterology

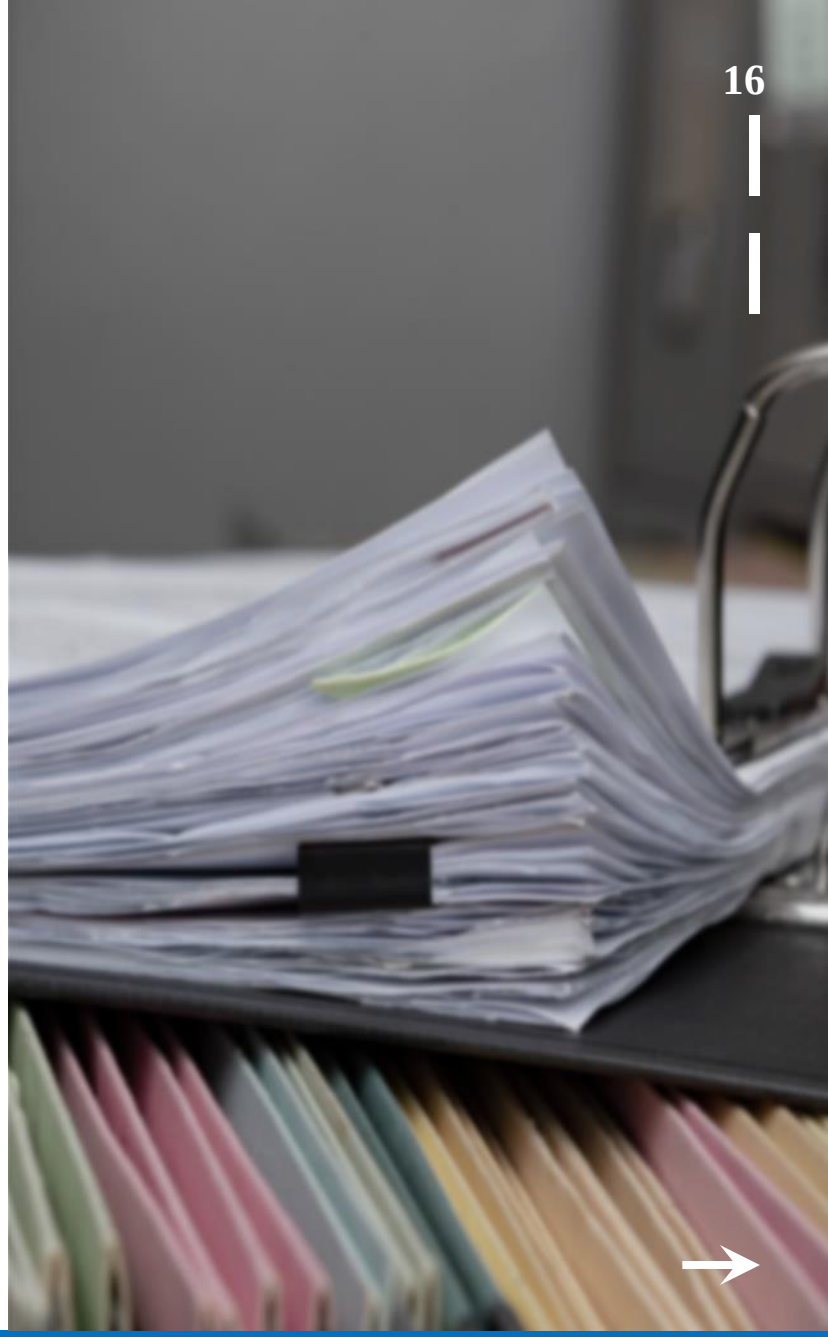
During this period (from 01.01.22 to 31.05.23), 36 clinical trials were launched in Ukraine

Державний Експертний Центр МОЗ України

A positive tendency toward (Continued)

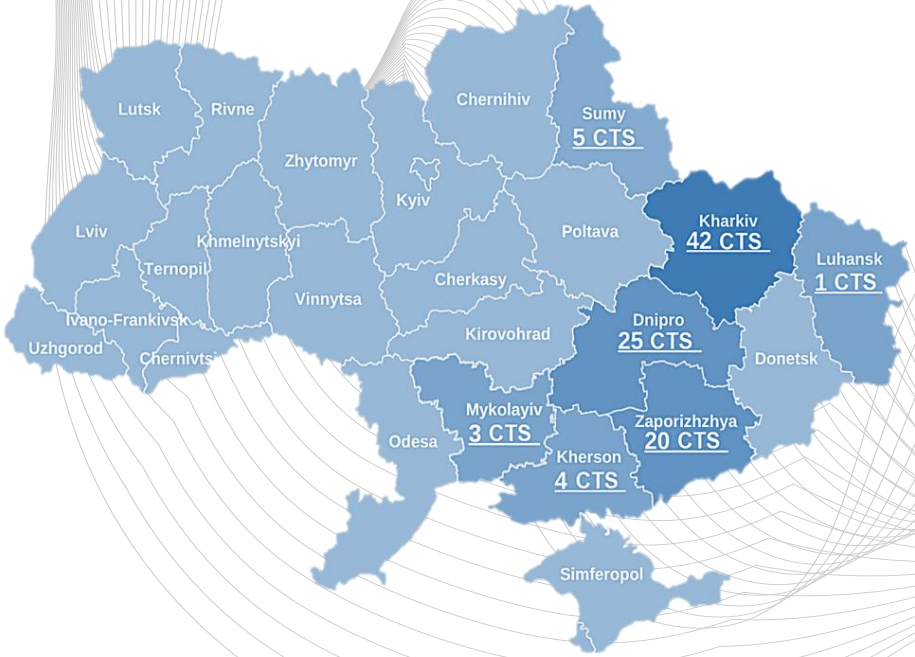
1. The logistics of delivery of the investigational drugs and materials has been restored;
2. Samples collection and transfer to the laboratories selected by replacement/ involvement of local laboratories.
3. Sponsors implement innovative approaches to conducting trials, such as:

    - introduction of decentralized elements in the CT;
    - remote monitoring of primary data in the CT materials.

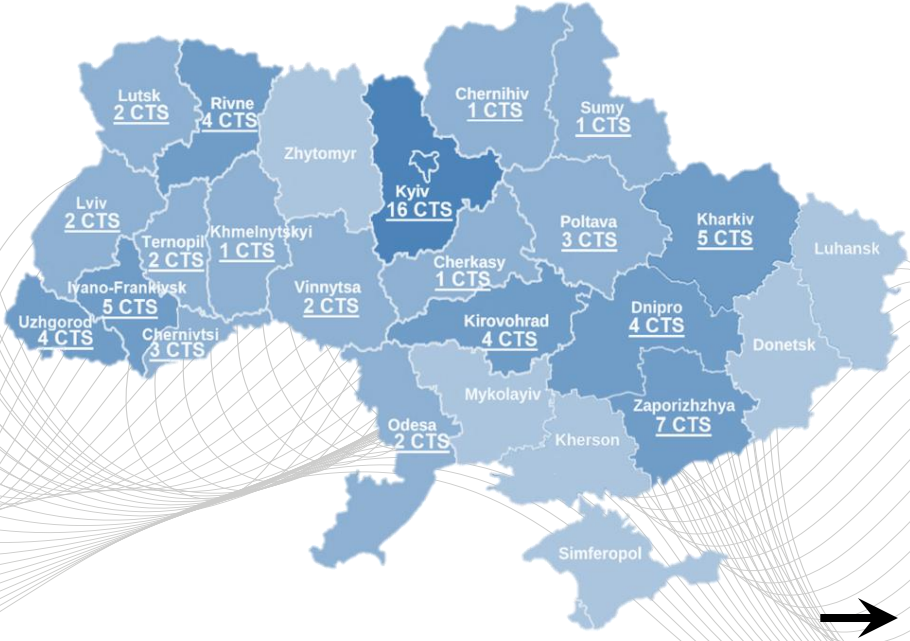


Clinical trial sites

Out of **383** sites (according to the list of ethics committees), **100** are located in the frontline areas:



72 new clinical trial sites have been approved, of which 4 sites have started CT:



The lifecycle of the clinical trials

The lifecycle of clinical trials in Ukraine is supported by introducing significant amendments to the protocols of clinical trials.

In **2022:**

- 1265 applications for substantial amendments
- 1295 substantial amendments approved

For 5 months of **2023**:

- 431 applications for substantial amendments
- 429 substantial amendments approved

Державний Експертний Центр МОЗ України

Scan me*

Scan me**

Applications for new clinical trials

Applications that were received:

- In 2022 – **59 applications**
- During 5 months of 2023 – **13 applications**

Approved by orders of the Ministry of Health:

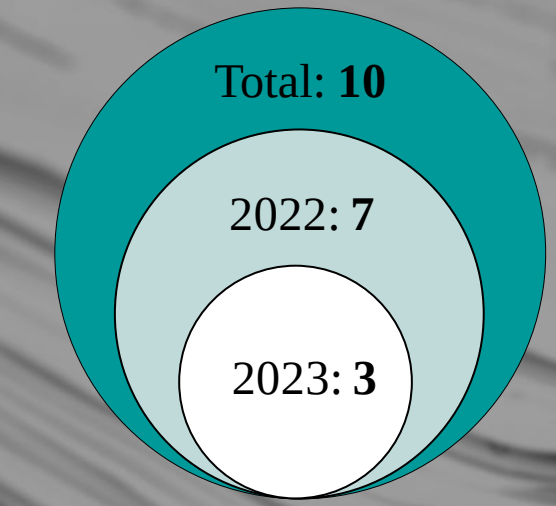
- In 2022 – **112 clinical protocols**
- During 5 months of 2023 – **11 protocols** of clinical trials

*Information Report Regarding the Status of CT in Ukraine (01/01/2023 – 01/03/2023)

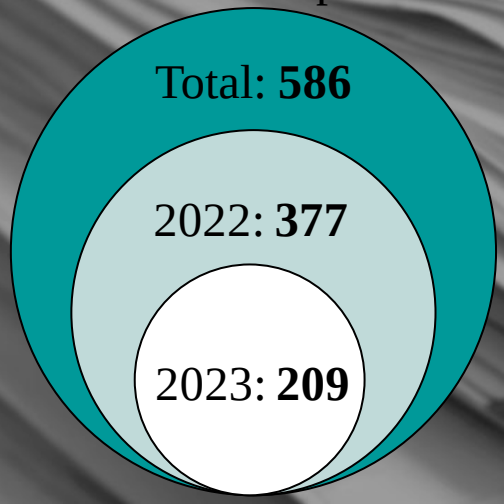
**Information Report Regarding the Status of CT in Ukraine (01/01/2022 – 01/12/2022)

Training workshops «The requirements and principles of Good Clinical Practice (GCP)»

SECMOH conducts workshops for researchers, representatives of local ethics committees, because the high-quality CT data and appropriate protection for patients can be provided only by adequately staffed, experienced team of researchers. Thus, in 2022, 7 workshops were held for 377 participants, in the current year 3 - 209 participants.



Total number of workshops



Total number of participants

Regulatory actions

Flexibility in decision-making by the regulator

Reduction of the terms of examination of clinical trial materials from 47* to 30 days

Digitalization of processes

Communication between stakeholders 24/7 facilitates the resumption of CT in Ukraine

Order of the Ministry of Health of Ukraine No. 190 dated 31.01.2023 – amendments to the Order of the Ministry of Health of Ukraine No. 690 dated 23.09.2009

Державний Експертний Центр МОЗ України

DIA Global & The Ukraine Clinical Research Support Initiative (UCRSI) A Global Webinar (6 Webinars)

- Series on Clinical Trials During the War in Ukraine in cooperation with The State Expert Center, Ministry of Health, Ukraine
- European Medicines Agency (EMA)
- Ethics and Research Integrity Sector, DG Research & Innovation, European Commission
- United States Food & Drug Administration (FDA)
- World Health Organization (WHO)
- Council for International Organizations of Medical Sciences (CIOMS)
- World Medical Association (WMA)
- Dnipropetrovsk Medical Academy, Dnipro, Ukraine
- International Federation of Associations of Pharmaceutical Physicians (IFAPP)
- Association for Good Clinical Practice in Poland (GCPpl)
- ECO-ASCO Special Network: Impact of the War in Ukraine on Cancer EURORDIS Ukraine Response, Rare Diseases

DIA FDA WHO CIOMS IFAPP WMA WORLD MEDICAL ASSOCIATION GCPpl

Державний
Експертний
Центр
МОЗ України

Thank You for the attention!

ДЯКУЮ ЗА УВАГУ!

Електронна пошта

dec@dec.gov.ua

amsw@dec.gov.ua

Веб-сайт

www.dec.gov.ua