

Information Report Regarding the Status of the Clinical Audits of the Clinical Trials in Ukraine in the period from January 01, 2022 till March 31, 2023

Clinical audit (hereinafter - CA) of a clinical trial (hereinafter - CT) of a medicinal product is an important aspect of ensuring the quality of conducting a clinical trial of a medicinal product and protecting the rights, safety and well-being of trial subjects.

The SEC of MOH of Ukraine conducts CA CT of medicinal products. Clinical audits of a clinical trial is conducted free of charge.

The quarterly plans of the CA CT and their results are published on the official web-site of the SEC of MOH of Ukraine <https://www.dec.gov.ua/materials/aktualna-informacziya-audit-laboratornih-ta-klinichnih-praktik/> .

Year 2022, - the russian full-scale military aggression against Ukraine significantly affected the processes of planning and conducting clinical trials of medicinal products in Ukraine.

The introduction of martial law throughout Ukraine (Decrees of the President of Ukraine No.64/2022 dated 02/24/2022, No.133/2022 dated 03/14/2022, No.259/2022 dated 04/18/2022, No.341/2022 dated 05/17/2022, No.573/2022 dated 08/12/2022 and No.757/2022 dated 11/07/2022), scheduled CA of CT were suspended from February 24, 2022.

In order to check compliance with regulatory requirements for conducting CTs and respecting the rights of patients who were transferred to other sites of CT, the CAs have been renewed by the SEC of MOH of Ukraine since May 13, 2022.

For the reporting period from 01.01.2022 to 31.03.2023 36 CAs of CTs were conducted: 14 CAs of the corresponding CTs at the clinical trial sites (hereinafter referred to as the CTS),

8 CAs for the purpose of checking of the organizing the conduct of CTs in the CTSs,
12 CAs of CTs, the purpose of which was to verify compliance with regulatory requirements when transferring the clinical trial subjects in the CTs,
1 CA in the bioanalytical laboratory,
as well as 1 CA of CT at the applicant's office.

The list of places where the CAs of CTs were held for the period from 01.01.2022 to 31.03.2023 is given in Annex 1.

The remarks as to the 36 conducted clinical audits were made grading as followed:

- 12 CAs – no comments;
- 16 CAs – minor findings (the identified deficiencies did not affect the rights, safety and health of the subjects and the integrity of the CT data);

- 6 CAs – major findings (identified deficiencies that could adversely affect the rights, safety and health of the subjects and the integrity of the CT data);
 - 2 CAs – critical findings (identified deficiencies that adversely affect the rights, safety or health of the subjects and/or affect the quality and integrity of clinical trial data).
- The recruitment of subjects in this CT is suspended.

It is important to note that, despite the state of the war, the number of CAs of CTs conducted exceeded the number of CAs of CTs in 2020 during quarantine measures in response to the coronavirus disease pandemic.

Thus, the SEC of MOH of Ukraine emphasizes, despite the russian full-scale military aggression CAs in Ukraine are being conducted in compliance with the modern legal framework that meets world standards, international ethical principles, and planning and reporting are carried out in compliance with the requirements and principles of Good Clinical Practice (GCP).

We deeply believe that clear and coordinated actions of all participants in the process of CTs in Ukraine and help of the World, compliance with international ethical principles of protection of the rights, safety and well-being of the subjects will change the situation for the better in Ukraine.

**The list of places where the clinical audits of CTs were held
for the period from 01.01.2022 to 31.12.2022**

№	Name of the clinical trial site
1.	Kharkiv Laboratory of Pharmacokinetics SE "State expert center of the Ministry of Health of Ukraine» Responsible researcher: Libina V.V.
2.	Kharkiv Communal non-profit enterprise of Kharkiv Regional Council "Regional Clinical Hospital", neurology department Responsible researcher: Skripchenko I.R.
3.	Kharkiv State Institution "Institute of Medical Radiology and Oncology. S.P. Grigoriev National Academy of Medical Sciences of Ukraine", Department of Clinical Oncology and Hematology Responsible researcher: Golubeva L.V.
4.	Kharkiv Communal non-profit enterprise of Kharkiv Regional Council "Regional Clinical Hospital", neurology department Responsible researcher: Skripchenko I.R.
5.	Kyiv Medical Center of Limited Liability Company "Edelweiss Medix" Responsible researcher: Bilotkach O.U.
6.	Kyiv Medical Center of the Limited Liability Company "Center of Family Medicine Plus", medical and prophylactic unit Responsible researcher: Beiko G.V.
7.	Cherkasy Communal non-profit enterprise "Cherkasy Regional Hospital of Cherkasy Regional Council", cardiology department. Responsible researcher: head. department Kulik A.V.
8.	Ternopil Communal non-profit enterprise "Ternopil Regional Hospital" of Ternopil Regional Council, Regional Center of Clinical Immunology and Allergology, rheumatology department Responsible researcher: MD. N., prof. Hospodarskyi I.Ya.
9.	Lviv Lviv State Oncology Regional Medical and Diagnostic Center, Department of Chemotherapy Responsible researcher: Ph.D. n. Shparyk Ya.V.
10.	Ivano-Frankivsk Municipal non-profit enterprise "Regional Clinical Hospital of Ivano-Frankivsk Regional Council", Department of Surgery Responsible researcher: Zborak I.M.
11.	Krykhyvtsi village, Ivano-Frankivsk region NeuroGlobal Medical and Diagnostic Center of NeuroGlobal Limited Liability Company Responsible researcher: MD. N., prof. Hryb V.A.
12.	Rivne Communal Enterprise "Rivne Regional Clinical Hospital" of Rivne Regional Council, Regional Stroke Center Responsible researcher: Pogrebnyak O.O.

№	Name of the clinical trial site
13.	Uzhgorod Communal non-profit enterprise "Central City Clinical Hospital" of Uzhhorod City Council, therapeutic department, State Higher Educational Institution "Uzhhorod National University", Department of Oncology and Radiology of the Faculty of Postgraduate Education and Pre-University Training Responsible researcher: MD. N., prof. Gotko E.S.
14.	Uzhgorod. Communal non-profit enterprise "Regional Clinical Center for Neurosurgery and Neurology", Zakarpattia Regional Council, Department of Neurosurgery No2; Uzhhorod National University, School of Medicine, Department of Neurology, Neurosurgery and Psychiatry Responsible researcher: Ph.D. n. Chomolyak Yu.Yu.
15.	Lviv Communal non-profit enterprise of Lviv Regional Council "Western Ukrainian Specialized Children's Medical Center", pediatric department. Responsible researcher: MD, prof. Kostyuchenko L.V.
16.	Kyiv State Institution "Institute of Endocrinology and Metabolism. V.P. Komisarenko National Academy of Medical Sciences of Ukraine", Department of Pediatric Endocrine Pathology, Department of Pediatric Endocrine Pathology Responsible researcher: Vishnevskaya O.A.
17.	Kyiv State Institution "Institute of Endocrinology and Metabolism. V.P. Komisarenko National Academy of Medical Sciences of Ukraine", Department of Pediatric Endocrine Pathology, Department of Pediatric Endocrine Pathology Responsible researcher: Vishnevskaya O.A.
18.	Ivano-Frankivsk Carpathian Research Group LLC, Ukraine Applicant's Office
19.	Ivano-Frankivsk Municipal non-profit enterprise "Ivano-Frankivsk Regional Clinical Infectious Diseases Hospital of Ivano-Frankivsk Regional Council", intensive care unit Responsible researcher: MD. N., prof. Pryshliak O.Ya.
20.	Chernivtsi Municipal Institution "Chernivtsi Regional Clinical Oncology Dispensary", day hospital department Responsible researcher: Semegen Yu.V.
21.	Chernivtsi Municipal non-profit enterprise "City Clinical Hospital No3" of Chernivtsi City Council, neurological department, Chernivtsi. Responsible researcher: MD, Ph.D., prof. Pashkovsky V.M.
22.	Kyiv Communal non-profit enterprise "Kyiv City Clinical Hospital No. 4" of the Executive Body of the Kyiv City Council (Kyiv City State Administration), Department of Demyelinating Diseases of the Nervous System, Kyiv. Responsible researcher: MD. n. Kobys T.O.
23.	Ivano-Frankivsk Communal non-profit enterprise "Regional Clinical Hospital of Ivano-Frankivsk Regional Council", Department of Urology, Ivano-Frankivsk. Responsible researcher: Gotsuliak Ya.V.

№	Name of the clinical trial site
24.	Ivano-Frankivsk Communal non-profit enterprise "Precarpathian Clinical Oncology Center of Ivano-Frankivsk Regional Council", Ivano-Frankivsk National Medical University, Department of Oncology. Responsible researcher: MD, Ph.D., prof. Kryzhanivska A.E.
25.	Lviv Communal non-profit enterprise of Lviv Regional Council "Lviv Regional Clinical Hospital", neurological department. Responsible researcher: MD. N., prof. Negrich T.I.
26.	Lviv Communal non-profit enterprise of Lviv Regional Council "Lviv Regional Clinical Hospital", neurological department. Responsible researcher: head. from. Sanotskyi Ya.E.
27.	Uzhgorod Communal non-profit enterprise "Zakarpattia Regional Clinical Center of Cardiology and Cardiac Surgery" of the Transcarpathian Regional Council, infarction department, State Higher Educational Institution "Uzhhorod National University", Department of Hospital Therapy. Responsible researcher: MD. N., prof. Rishko M.V.
28.	Uzhgorod Medical Center "Diamed" of the Limited Liability Company "Medical Center "Diamed", Uzhgorod. Responsible researcher: Ph.D. n. Chomolyak Yu.Yu.