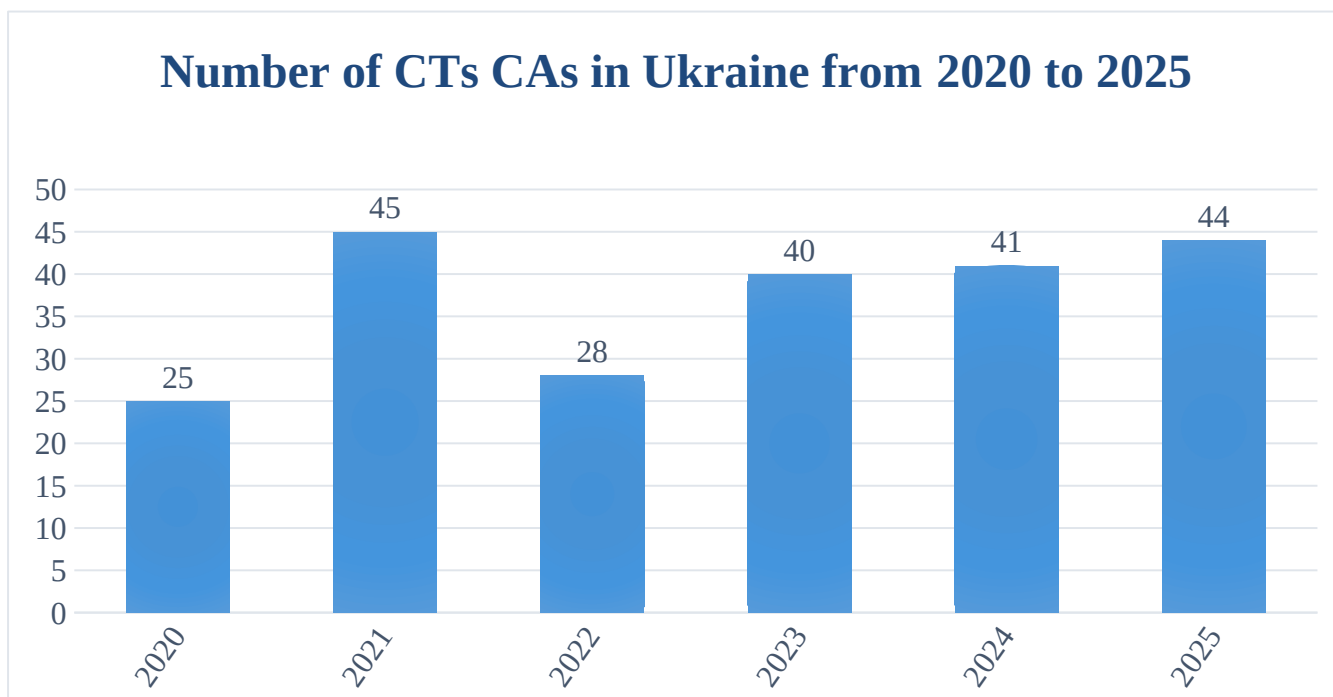


Results of the Clinical Audits of the Clinical Trials in 2025

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

In order to check compliance with regulatory requirements for conducting CTs and respecting the rights of patients for the reporting period from 01.01.2025 to 31.12.2025 43 planned CAs of CTs were conducted at the clinical trial sites (hereinafter referred to as the CTS) and 1 planned CA of CT was conducted at the CRO's office by the Audit and Post-Authorization Expertise Department of the State Expert Center of the Ministry of Health of Ukraine.



The remarks as to the 44 conducted CAs were made grading as followed:

- 34 CAs – minor findings (the identified deficiencies did not affect the rights, safety and health of the subjects and the integrity of the CT data);
- 10 CAs – major findings (identified deficiencies that could adversely affect the rights, safety and health of the subjects and the integrity of the CT data).

After analysis of the comments most of the findings are related to:

- maintenance of the primary medical records – 36 CAs;
- IRB/IEC activities – 35 CAs;
- maintenance of the investigator site file – 20 CAs;
- obtaining and documenting informed consent – 18 CAs;
- completion of the case report forms – 9 CAs;
- investigational MP labelling and handling – 6 CAs;
- storage of clinical trial materials – 1 CAs.

The list of places where the CAs of CTs were held for the period from 01.01.2025 to 31.12.2025 is given in Annex 1.

**The list of places where the CAs of CTs were held
for the period from 01.01.2025 to 31.12.2025**

No	Name of the clinical trial site	Date of CA
1	Chernihiv Municipal Non-profit Enterprise "Chernihiv Medical Center of Modern Oncology" of Chernihiv Regional Council, Mammology Department with Reconstructive and Plastic Surgery Principal investigator: S. Polenkov	16.01.2025 - 17.01.2025
2	Khmelnyskyi Municipal Non-profit Enterprise "Khmelnyskyi Regional Cardiovascular Center" of Khmelnytskyi Regional Council. Principal investigator: A. Klantsa	05.02.2025 - 06.02.2025
3	Kyiv Medical Center of the Limited Liability Company "Medical Center "ARTES MEDICUM", Treatment and Diagnostic Department. Principal investigator: M. Puhach	05.02.2025 - 07.02.2025.
4	Kyiv State Institution "D. F. Chebotaryov Institute of Gerontology of the National Academy of Medical Sciences of Ukraine", Department of Clinical Physiology and Pathology of Internal Organs, General Therapeutic Department. Principal investigator: E. Asanov	14.02.2025 - 17.02.2025
5	Kyiv State Institution "National Scientific Center of Phthiology, Pulmonology and Allergology named after F. G. Yanovsky of the National Academy of Medical Sciences of Ukraine, Department of Pulmonology. Principal investigator: N. Prymushko	25.02.2025 - 26.02.2025
6	Kyiv Municipal Non-profit Enterprise "St. Michael's Clinical Hospital" of Kyiv, of Executive Body of Kyiv City Council (Kyiv City State Administration), Department of Otolaryngology for Adults and Children. Principal investigator: J. Deyeva	27.02.2025 - 28.02.2025
7	Kyiv Medical Center of the Limited Liability Company "Arensia Exploratory Medicine", Department of Clinical Trials. Principal investigator: M. Doronina	13.03.2025 - 14.03.2025
8	Chernivtsi Regional Municipal Non-Profit Enterprise "Chernivtsi Regional Clinical Hospital", Department of Pulmonology. Principal investigator: S. Kovalenko	18.03.2025 - 19.03.2025

9	Chernivtsi Regional Municipal Non-Profit Enterprise "Chernivtsi Emergency Hospital", Center of Emergency Neurology. Principal investigator: O. Ilnitska	20.03.2025 - 21.03.2025
10	Lviv Medical Center of the Limited Liability Company "Kalyna. Center of Modern Medicine". Principal investigator: U. Abrahamovych	25.03.2025 -26.03.2025
11	Vinnytsia Medical Center of the Limited Liability Company "Medical Center "Salutem", Treatment and Diagnostic Department. Principal investigator: S. Moskovko	09.04.2025, 10.04.2025
12	Lutsk Municipal Enterprise "Volyn Regional Territorial Medical Association for the Protection of Motherhood and Childhood" of Volyn Regional Council, Outpatient Department. Principal investigator: N. Shchuruk	22.04.2025, 23.04.2025
13	Vinnytsia Municipal Non-profit Enterprise "Podilskyi Regional Oncology Center of Vinnytsia Regional Council", Thoracic Department. Principal investigator: S. Prytuliak	30.04.2025, 01.05.2025
14	Lviv Separate subdivision "4th Hospital" of the Municipal Non-profit Enterprise "Lviv Territorial Medical Association "Clinical Hospital of Planned Treatment, Rehabilitation and Palliative Care", Rheumatology Department, Danylo Halytskyi Lviv National Medical University, Department of Family Medicine. Principal investigator: O. Nadashkevych	08.05.2025, 09.05.2025
15	Kyiv Municipal Non-profit Enterprise of Kyiv Regional Council "Kyiv Regional Oncological Dispensary", Department of Abdominal Surgery. Principal investigator: Y. Holovko.	14.05.2025, 15.05.2025
16	Kyiv State Institution "National Research Center for Radiation Medicine, Hematology and Oncology of the National Academy of Medical Sciences of Ukraine", Department of Radiation Psychoneurology of the Institute of Clinical Radiology based on the Department of Radiation Psychoneurology of the Clinic. Principal investigator: I. Perchuk	19.05.2025, 20.05.2025
17	Kyiv Kyiv Clinical Hospital on Railway Transport No. 2 of the "Health Care Center" Branch of the Joint-Stock Company "Ukrainian Railways", Day Hospital Department. Principal investigator: T. Zalievska	21.05.2025, 22.05.2025

18	Lutsk Municipal Enterprise "Volyn Regional Clinical Hospital" of the Volyn Regional Council, Surgical Department (Abdominal, Coloproctological, Endocrine Pathology) with Plastic Surgery and Hand Surgery Beds. Principal investigator: D. Shulga	21.05.2025, 22.05.2025
19	Kyiv Municipal Non-Profit Enterprise "Kyiv City Clinical Oncology Center" of Executive Body of Kyiv City Council (Kyiv City State Administration), Department of Urology; State Institution "Institute of Urology named after Academician O. F. Vozianov of the National Academy of Medical Sciences of Ukraine", Department of Oncourology. Principal investigator: V. Sakalo	28.05.2025, 29.05.2025
20	Lviv Municipal Non-profit Enterprise "Lviv Territorial Medical Association "Clinical Hospital of Planned Treatment, Rehabilitation and Palliative Care", Therapeutic Day Hospital of the Separate subdivision "4th Hospital". Principal investigator: V. Berenfus	05.06.2025, 06.06.2025
21	Zhytomyr Municipal Non-profit Enterprise "Regional Clinical Hospital named after O. F. Herbachevsky" of Zhytomyr Regional Council, Hematology Department with Intensive Care Beds. Principal investigator: T. Lysa	18.06.2025
22	Zhytomyr Municipal Non-Profit Enterprise "Zhytomyr Regional Oncological Dispensary" of Zhytomyr Regional Council, Department of Clinical Oncology. Principal investigator: O. Lipetska.	18.06.2025
23	Khmelnyskyi Municipal Non-Profit Enterprise "Khmelnyskyi Regional Hospital" of Khmelnyskyi Regional Council, Department of Proctology. Principal investigator: V. Balytskyi	25.06.2025, 26.06.2025
24	Kyiv Municipal Non-profit Enterprise "Kyiv City Clinical Hospital No. 18" of Executive Body of Kyiv City Council (Kyiv City State Administration), Department of Proctology. Principal investigator: V. Dubovyi	18.08.2025, 19.08.2025

25	Ivano-Frankivsk Enterprise "Treatment and Diagnostic Center "St. Luke's Clinic" of the Ivano-Frankivsk Archdiocesan Administration of the Ukrainian Greek Catholic Church", consultative and treatment department "Research Center". Principal investigator: O. Varunkiv	21.08.2025, 22.08.2025
26	Chernihiv Municipal Non-profit Enterprise "Chernihiv Regional Hospital" of Chernihiv Regional Council, Neurological Department for Patients with Cerebral Circulation Disorders. Principal investigator: S. Kareta	26.08.2025, 27.08.2025
27	Kyiv State Institution "National Scientific Center "Institute of Cardiology, Clinical and Regenerative Medicine named after Academician M. D. Strazhesko of the National Academy of Medical Sciences of Ukraine", Department of Non-Coronary Heart Diseases and Rheumatology. Principal investigator: H. Khokhlova	28.08.2025, 29.08.2025
28	Kyiv Medical Center of the Private Enterprise "Sigma". Principal investigator: T. Kravchenko	04.09.2025, 05.09.2025
29	Chernihiv Municipal Non-profit Enterprise "Chernihiv City Hospital No. 4" of Chernihiv City Council, Neurological Department with Physical Rehabilitation. Principal investigator: L. Kadina	08.09.2025, 09.09.2025
30	Ivano-Frankivsk Municipal Non-profit Enterprise "Regional Clinical Hospital of Ivano-Frankivsk Regional Council", Department of ENT Microsurgery. Principal investigator: N. Komashko	17.09.2025, 18.09.2025
31	Kyiv LLC "SYNERGY GLOBAL UKRAINE".	24.09.2025, 30.09.2025
32	Uzhhorod Municipal Non-profit Enterprise "Andriy Novak Transcarpathian Regional Clinical Hospital" of Transcarpathian Regional Council, Department of Nephrology and Program Hemodialysis. Principal investigator: V. Stryzhak	15.10.2025, 16.10.2025

33	Kyiv National Children's Specialized Hospital "Okhmatdyt" of the Ministry of Health of Ukraine, Center of Pathology of Hemostasis. Principal investigator: K. Vilchevska	20.10.2025, 21.10.2025
34	Poltava Municipal Enterprise "Poltava Regional Clinical Hospital named after M. V. Sklifosovskyi of Poltava Regional Council", Regional Medical and Diagnostic Rheumatological Center. Principal investigator: O. Gordiienko.	27.10.2025, 28.10.2025
35	Poltava Medical and Diagnostic Center of the Limited Liability Company "Medical and Diagnostic Center "Medion", Outpatient Department. Principal investigator: I. Kryvoruchko	29.10.2025, 30.10.2025
36	Vinnytsia Municipal Non-Profit Enterprise "Vinnytsia City Clinical Hospital No. 1", Clinical Therapeutic Department No. 1, Vinnytsia National Medical University named after M. I. Pirogov, Department of Propaedeutics of Internal Medicine. Principal investigator: N. Pentiuk	05.11.2025, 06.11.2025
37	Dnipro Municipal Non-Profit Enterprise "City Clinical Hospital No. 4" of Dnipro City Council, Chemotherapeutic Department with Day Patient Facility, Dnipro State Medical University, Department of Oncology and Medical Radiology. Principal investigator: I. Bondarenko	13.11.2025
38	Dnipro Limited Liability Company "RDP UKRAINE", Medical Department. Principal investigator: I. Bondarenko	14.11.2025
39	Kyiv Medical Center of the Limited Liability Company "Edelweiss Medics", Medical and Preventive Unit. Principal investigator: K. Vasylenko	17.11.2025, 18.11.2025
40	Kyiv Limited Liability Company "MEDFIELD" Principal investigator: O. Romanova	19.11.2025, 20.11.2025
41	Lviv Municipal Non-profit Enterprise of the Lviv Regional Council "Lviv Oncological Regional Treatment and Diagnostic Center", Urology Department. Principal investigator: M. Sabadash	09.12.2025, 10.12.2025

42	Vinnytsia Municipal Non-profit Enterprise "Vinnytsia Regional Clinical Endocrinological Center of Vinnytsia Regional Council", Therapeutic Department of the Consultative Polyclinic. Principal investigator: M. Vlasenko	11.12.2025, 12.12.2025
43	Lviv Municipal Non-profit Enterprise of Lviv Regional Council "Lviv Regional Clinical Hospital", Cardiosurgery Department. Principal investigator: M. Konyk	11.12.2025, 12.12.2025
44	Kyiv Medical Center "Universal Clinic "Oberig" of the Limited Liability Company "Kapytal", Clinical and Advisory Department. Principal investigator: N. Kozak	23.12.2025, 24.12.2025