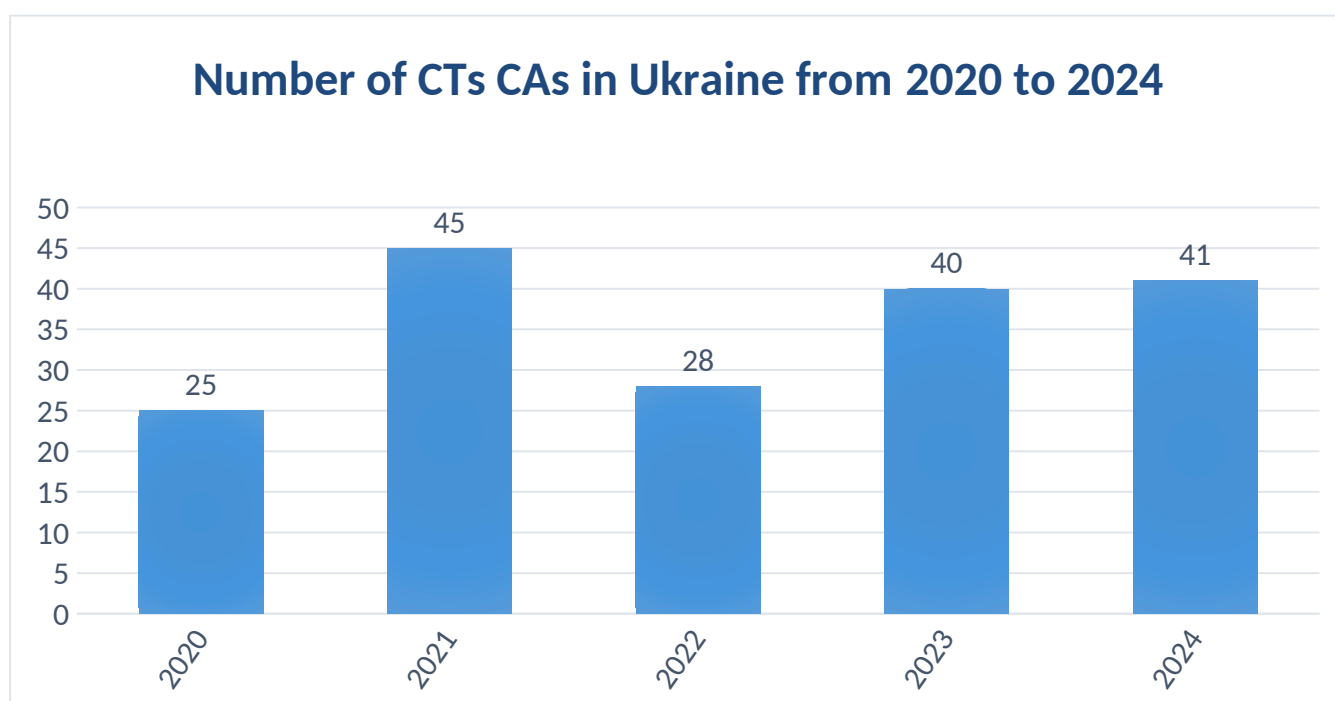


Results of the Clinical Audits of the Clinical Trials in 2024

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 01.01.2024 to 31.12.2024 41 planned CAs of CTs were conducted at the clinical trial sites (hereinafter referred to as the CTS) by the Audit Department of the State Expert Center of the Ministry of Health of Ukraine.



The remarks as to the 41 conducted CAs were made grading as followed:

- 3 CAs – no comments;
- 31 CAs – minor findings (the identified deficiencies did not affect the rights, safety and health of the subjects and the integrity of the CT data);
- 7 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 – 25 CAs;
- obtaining and documenting informed consent – 10 CAs;
- IRB/IEC activities – 29 CAs;
- maintenance of the investigator site file – 11 CAs;
- investigational MP labelling and handling – 4 CAs;
- completion of the case report forms – 2 CAs.

The list of places where the CAs of CTs were held for the period from 01.01.2024 to 31.12.2024 is given in Annex 1.

**The list of places where the CAs of CTs were held
for the period from 01.01.2024 to 31.12.2024**

No	Name of the clinical trial site	Date of CA
1	Ternopil Municipal Non-profit Enterprise “Ternopil University Hospital” of Ternopil Regional Council, Rheumatology Department, I. Horbachevsky Ternopil National Medical University of the Ministry of Health of Ukraine, Department of Internal Medicine #2 Principal investigator: Smiian S. I.	07.02.2024 - 08.02.2024
2	Boiiany village, Chernivtsi region Medical Center of the Limited Liability Company “INNOFAR Clinic – Ukraine Innovative Pharma Research” Principal investigator: Artysh B. I.	19.02.2024 - 21.02.2024
3	Kyiv State Institution "Shalimov National Institute of Surgery and Transplantology of the National Academy of Medical Sciences of Ukraine", Oncology Department Principal investigator: Zubkov O. O.	01.03.2024, 15.03.2024
4	Rivne Municipal Non-profit Enterprise “City hospital #2” of Kharkiv Regional Council "Regional Clinical Hospital" of Rivne Regional Council, Department of Clinical Neurology and Neurorehabilitation Principal investigator: Brozhyk I. V.	04.03.2024 - 05.03.2024
5	Kyiv Municipal Facility of Kyiv Regional Council “Kyiv Regional Clinical Hospital”, Highly specialized Therapeutic Department Principal investigator: Khimion L. V.	13.03.2024, 19.03.2024
6	Ivano-Frankivsk Medical and Diagnostic Center of the Limited Liability Company "Medex Plus", Polyclinic Department Principal investigator: Aleksandruk O. D.	18.03.2024 - 19.03.2024
7	Vinnytsia Municipal Non-profit Enterprise " Vinnytsia City Clinical Hospital #1", Gastroenterology Department. National Pirogov Memorial Medical University, Vinnytsia, Department of Internal Medicine #3. Principal investigator: Ivanov V. P.	20.03.2024 - 21.03.2024
8	Krykhyivtsi village, Ivano-Frankivsk region Medical and Diagnostic Center “NeuroGlobal” of the Limited Liability Company “NeuroGlobal”. Principal investigator: Doroshenko O. O.	20.03.2024 - 21.03.2024

9	Hlevakha rural settlement, Kyiv region Municipal Non-profit Enterprise “Kyiv City Psychoneurological Hospital #3” of the Executive Body of the Kyiv City Council (Kyiv City State Administration). Principal investigator: Vrublevska I. V.	27.03.2024, 29.03.2024
10	Chernivtsi Regional Municipal Non-profit Enterprise “Bukovyna Clinical Oncology Centre”, Structural Unit of Clinical Oncology. Principal investigator: Semehen I. V.	08.04.2024 - 09.04.2024
11	Chernivtsi Regional Municipal Non-profit Enterprise “Bukovyna Clinical Oncology Centre”, Structural Unit of Clinical Oncology. Principal investigator: Pidverbetska A. V.	10.04.2024 - 11.04.2024
12	Lviv Municipal Non-profit Enterprise of Lviv Regional Council "Lviv Regional Clinical Hospital", Urology Department with Lithotripsy Room, Danylo Halytsky Lviv National Medical University, Urology Department. Principal investigator: Lychkovskyi O. E.	16.04.2024 - 17.04.2024
13	Lviv Municipal Non-profit Enterprise of Lviv Regional Council "Lviv Regional Clinical Hospital", Urology Department with Lithotripsy Room, Danylo Halytsky Lviv National Medical University, Urology Department. Principal investigator: Lychkovskyi O. E.	18.04.2024
14	Kyiv Limited Liability Company “Medical Center “Concilium Medical”, Clinical and Consultative Department. Principal investigator: Herasymenko O. M.	23.04.2024 - 24.04.2024
15	Kyiv Medical Center of the Limited Liability Company "Medical Clinic “Blagomed”. Principal investigator: Pugach M. M.	30.04.2024 - 01.05.2024
16	Kyiv Medical Center "University Clinic “Oberih” of the Limited Liability Company "Capital”, Clinical and Consultative Department. Principal investigator: Babanina T. V.	06.05.2024 - 07.05.2024
17	Vinnytsia Municipal Non-profit Enterprise "Vinnytsia Regional Pediatric Clinical Hospital of the Vinnytsia Regional Council”, Pediatric Department #1, National Pirogov Memorial Medical University, Vinnytsia, Pediatric Department #2. Principal investigator: Zvenihorodska H. I.	29.05.2024 - 30.05.2024

18	Uzhhorod Municipal Non-profit Enterprise "Andrii Novak Zakarpattia Regional Clinical Hospital" of Transcarpathian Regional Council, Hematology Department. Principal investigator: Popovych I. I.	25.06.2024 - 26.05.2024
19	Uzhhorod Municipal Non-profit Enterprise "Regional Clinical Center of Neurosurgery and Neurology", Department #2, State Higher Education Establishment "Uzhhorod National University", Department of Neurology, Neurosurgery and Psychiatry. Principal investigator: Smolanka V. I.	27.06.2024 - 28.05.2024
20	Kyiv Medical Center of the Limited Liability Company "Smart Medical Center". Principal investigator: Halych L. F.	19.06.2024, 02.07.2024
21	Kyiv Municipal Non-profit Enterprise "Clinical Hospital #15 of Podil District of Kyiv" of the Executive Body of the Kyiv City Council (Kyiv City State Administration), Department of Vertebroneurology, Cerebrovascular Pathology, Pathology of the Peripheral Nervous System and Treatment of Chronic Pain with Stroke Block. Principal investigator: Kovalenko O. I.	09.07.2024 - 10.07.2024
22	Kyiv Medical Center of the Limited Liability Company "Dopomoha Plus". Principal investigator: Seliuk O. V.	21.08.2024 - 22.08.2024
23	Kyiv Limited Liability Company "CITY DOCTOR", Outpatient Department. Principal investigator: Klymenko S. V.	23.08.2024
24	Vinnytsia Limited Liability Company "Medical Center Health Clinic", Medical Clinical Investigational Center. Principal investigator: Holovchenko O. I.	27.08.2024 - 28.08.2024
25	Ternopil Limited Liability Company "Medical Center "Hospodarski Clinic", Therapeutic Department. Principal investigator: Hospodarskyi I. I.	05.09.2024 - 06.09.2024
26	Kyiv Medical Center of the Limited Liability Company "CLINIC VERUM EXPERT". Principal investigator: Trukhin D. V.	14.08.2024, 11.09.2024

27	Kyiv Limited Liability Company “Medical Center “Consilium Medical”, Clinical and Consultative Department. Principal investigator: Husak O. S.	10.09.2024 - 11.09.2024
28	Lviv Municipal Non-profit Enterprise of Lviv Regional Council "Lviv Regional Clinical Hospital", Surgery Department #1. Principal investigator: Zborivskyi I. M.	17.09.2024 - 18.09.2024
29	Lviv “University Hospital” branch of Danylo Halytsky Lviv National Medical University, Therapy Department. Principal investigator: Ivanishyn O. B.	19.09.2024 - 20.09.2024
30	Ruzhychanka village, Khmelnytskyi region Municipal Non-profit Enterprise "Khmelnytskyi Regional Hospital for War Veterans" of the Khmelnytskyi Regional Council, Neurology Department. Principal investigator: Kovalchuk I. V.	20.09.2024
31	Kyiv Limited Liability Company “Center of Family Medicine Plus”, Medicine Center, Therapeutic and Prophylactic Unit. Principal investigator: Chupryna L. O.	07.11.2024, 14.11.2024
32	Kropyvnytsyi Medical and Diagnostic Center of the Private Enterprise of the Private Production Company "Acinus", Clinical Trials Department. Principal investigator: Zupanets I. A.	12.11.2024 -13.11.2024
33	Kyiv Municipal Non-profit Enterprise “Consultative and Diagnostic Center” of Pecherskyi District of Kyiv, Therapeutic Department. Principal investigator: Bondarchuk O. M.	13.11.2024, 21.11.2024
34	Kyiv Medical Center of the Limited Liability Company “Medbud-Clinic”, Therapeutic and Prophylactic Unit. Principal investigator: Sokolova L. I.	18.11.2024 - 19.11.2024
35	Kyiv Medical Center “Ok! Clinic+” of the Limited Liability Company “International Institute of Clinical Trials”, Department of Gastroenterology and Hepatology, Inpatient Department. Principal investigator: Skybalo S. A.	28.11.2024 - 29.11.2024

36	Ivano-Frankivsk Municipal Non-profit Enterprise " Ivano-Frankivsk Regional Pediatric Clinical Hospital of Ivano-Frankivsk Regional Council ", Surgery Department, State Higher Educational Institution "Ivano-Frankivsk National Medical University", Department of Pediatric Surgery with a course in clinical anatomy and operative surgery. Principal investigator: Fofanov O. D.	09.12.2024 - 10.12.2024
37	Ivano-Frankivsk Municipal Non-profit Enterprise " Ivano-Frankivsk Clinical Hospital of Ivano-Frankivsk Regional Council", Neurology Department with a Multiple Sclerosis Center. Principal investigator: Chmyr H. S.	11.12.2024 - 12.12.2024
38	Rivne Municipal Enterprise “Rivne Regional Specialized Dispensary for Radiation Protection of the Population” of the Rivne Regional Council, Center of Clinical Neurology and Multiple Sclerosis. Principal investigator: Lehka M. V.	16.12.2024 -17.12.2024
39	Rivne Municipal Enterprise “Iurii Semeniuk Rivne Regional Clinical Hospital” of the Rivne Regional Council, Regional Cardiothoracic Surgery Center. Principal investigator: Kobziev O. I.	18.12.2024 - 19.12.2024
40	Vinnytsia Municipal Non-profit Enterprise " Pirogov Vinnytsia Regional Clinical Hospital of the Vinnytsia Regional Council”, Regional Specialized Clinical Gastroenterology Center. Principal investigator: Kizlova N. M.	17.12.2024 - 18.12.2024
41	Vinnytsia Municipal Non-profit Enterprise "Iushchenko Vinnytsia Regional Clinical Psychoneurological Hospital of the Vinnytsia Regional Council”, Regional Pediatric Center of Mental Health. Principal investigator: Kyrychenko V. D.	19.12.2024