Information Report Regarding the Status of Clinical Trials in Ukraine in the Period from January 01, 2022 to December 31, 2022

The State Expert Center of the Ministry of Health (the Center) traditionally publishes information on the status of clinical trials (CTs) in Ukraine prepared by the Department of Expert Evaluation of Preclinical and Clinical Trial Materials (the Department) and the Office for Laboratory and Clinical Practice (GLP, GCP) Audit.

In 2022, the full-scale military aggression of the russian federation significantly affected the processes of planning and conducting clinical trials of medicinal products in Ukraine. However, compliance with international ethical principles has always been and remains the main and constant priority throughout the CT life cycle to ensure the protection of the rights, safety and well-being of study subjects. The peculiarity of multi-national multicenter CTs is that a single CT protocol is prepared and submitted for review and approval in several countries, including Ukraine, which requires clear and coordinated actions from all stakeholders in the process.

In view of the full-scale military aggression of the russian federation against Ukraine and the imposition of martial law under the Decree of the President of Ukraine No. 64/2022 dated February 24, 2022, all CT stakeholders faced a number of problems and issues that had to be urgently resolved, and the Center did everything possible to support and resume the CTs.

Objectively, this Information Report on the Status of Clinical Trials in Ukraine differs from the traditional data presentation and mainly reflects the changes in the field of CTs in Ukraine for 2022, including 10 months during the war.

To ensure the uninterrupted conduct of the CTs in Ukraine during the war, the Department, within the framework of the Center's statutory tasks, has given priority to the communication chain: Regulator/(MoH SEC – competent authority) – Sponsor/CRO (Applicants) – Principal Investigator – Patient.

In connection with the above-mentioned information and in order to coordinate the Sponsor's actions, since February 24, 2022 special e-mail lines have been allocated for adequate communication between the Sponsor or his representative, CRO, and the Center, i.e. the work of the Department has practically been transferred to electronic communication with applicants, namely:

dec@dec.gov.ua – e-mail for all information letters related to clinical trials in Ukraine (e.g., letters regarding the start or end of a clinical trial, interim and final reports, etc.);

evikno@dec.gov.ua – e-mail for submitting applications for clinical trials of medicinal products, substantial amendments and relevant cover letters to the MoH;

kv@dec.gov.ua – e-mail for submitting materials pertinent to clinical trials and substantial amendments to clinical trials in accordance with the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Clinical Trial Materials approved by Order of the MoH of Ukraine No. 690 dated September 23, 2009; additional materials, responses to remarks on clinical trial and substantial amendment materials.

clinic@dec.gov.ua – e-mail for submitting safety reports (DSURs), ADR reports from clinical trials.

In 2022, the Department received and processed 4,939 incoming letters, of which 1,406 were referrals for CTs/SAs and 3,533 were information letters from applicants, letters of inquiry, letters of consultation, letters of notification of patient transfer, letters of CT commencement, letters of CT completion (including premature CT termination), and other CT-related letters, interim reports, final reports, including:

- 214 letters of notification regarding the suspension of new patient enrollment and/or screening and/or randomization of study subjects;
- 45 letters of notification regarding the CT temporary suspension;
- 132 letters of notification regarding the premature termination of the CT in Ukraine, incl. 108 due to the war and 24 - other reasons (financial, safety, efficacy);
- 223 letters of notification regarding the transfer of patients involved in the CTs from one approved clinical trial site (CTS) to other CTSs in Ukraine or outside of Ukraine (to trial sites in Poland, the UK, Canada, the Czech Republic, Moldova, Belgium, Switzerland, Georgia, Italy, Romania, Spain, Estonia, Slovakia, Latvia, Israel, the Netherlands, Portugal, France, Hungary, Germany, and the russian federation).

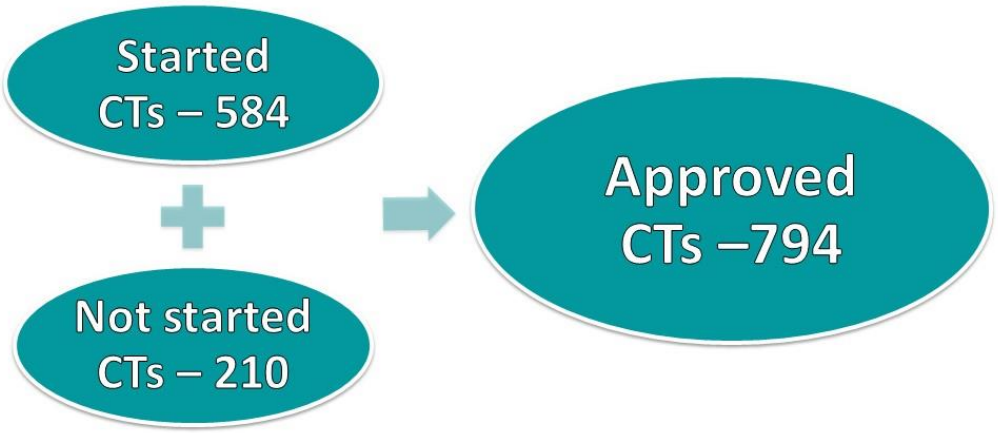
All the letters were duly processed by the Department's staff and answered by e-mail and/or in paper form via the Center's Service Center.

An analysis of the status of clinical trials that were at various stages as of the beginning of the war is provided below.

Review of actions taken by the Sponsor in relation to clinical trials approved by MoH orders and started since the beginning of the war in Ukraine.

At the beginning of the war in Ukraine, 794 clinical trials had been approved by the MoH Ukraine, of which 584 had started.

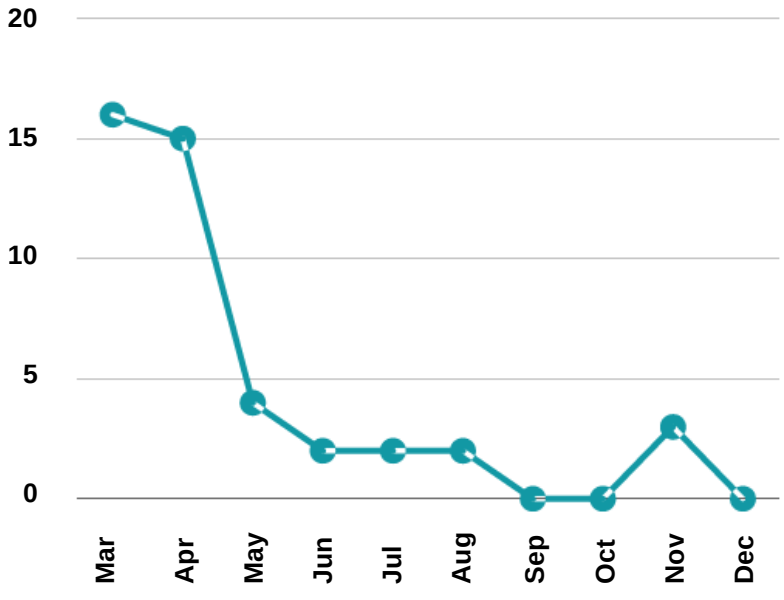
Number of CTs as of February 24, 2022



From March 01, 2022 to December 31, 2022 the Sponsor took the following actions related the MoH-approved and started clinical trials:

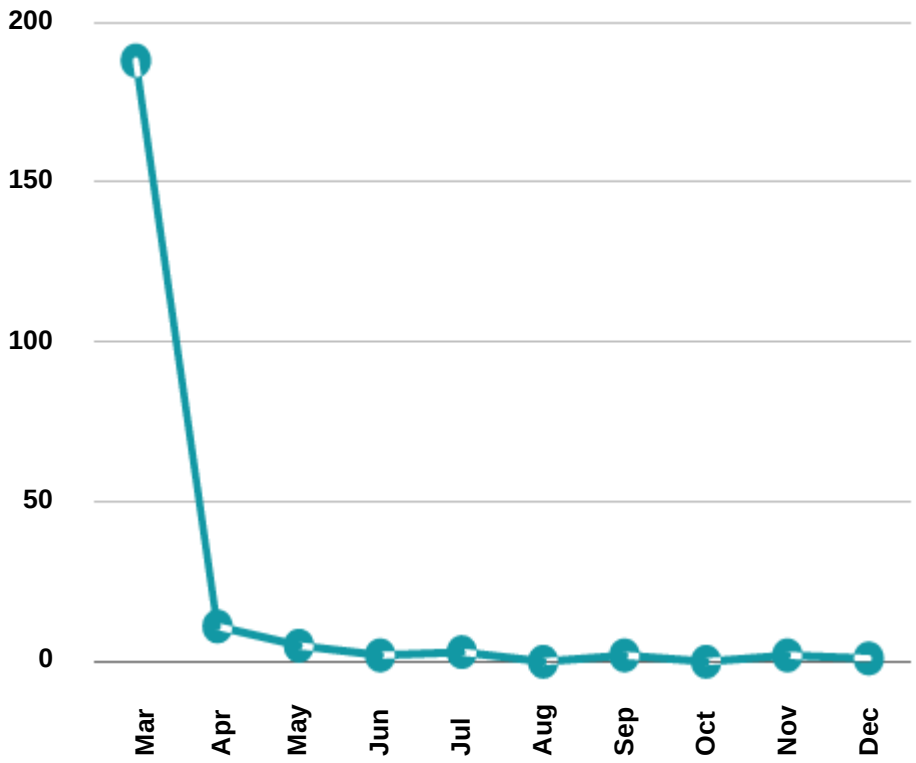
✓ **Suspension of the CT start – 45**

Month	CTs
March	16
April	15
May	4
June	2
July	2
August	2
September	0
October	0
November	3
December	0
Total	**45**



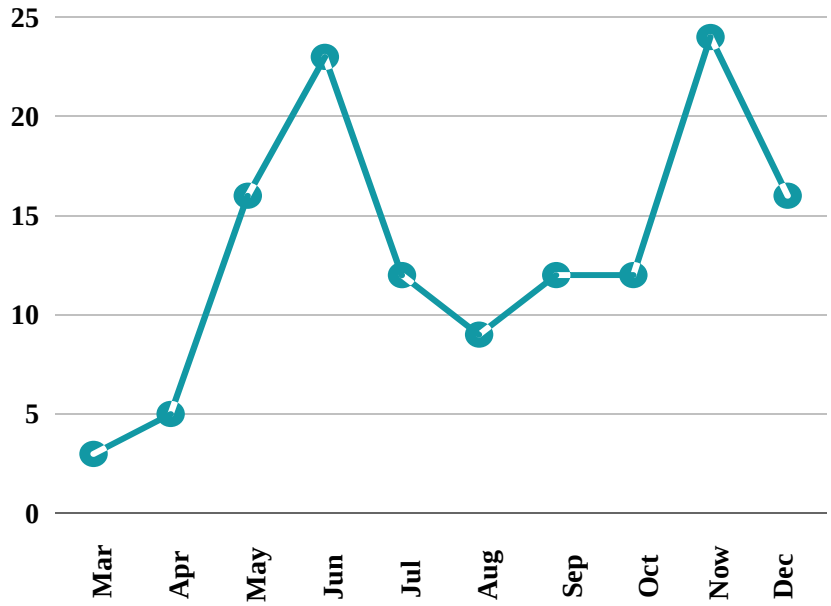
✓ **Suspension of patient recruitment (incl. patient screening and randomization) – 214**

Month	CTs
March	188
April	11
May	5
June	2
July	3
August	0
September	2
October	0
November	2
December	1
Total	**214**



✓ **Premature CT termination – 132, including 108 due to the war in Ukraine and 24 – other reasons (financial, safety, efficacy)**

Month	CTs
March	3
April	5
May	16
June	23
July	12
August	9
September	12
October	12
November	24
December	16
Total	**132**



The geography of the study subjects transfer

Patient transfer
Feb 24, 2022 – Dec 31, 2022

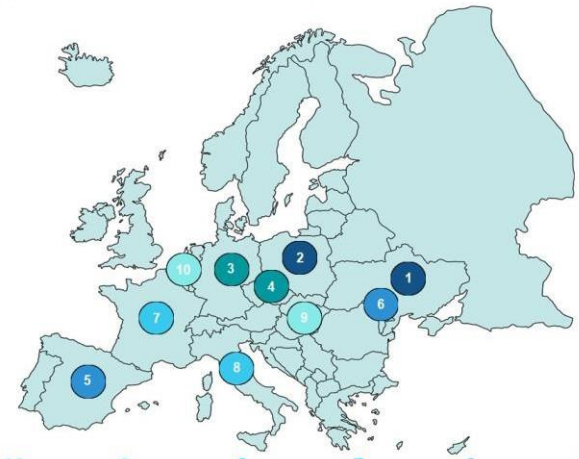
223 letters from Sponsors/CROs regarding the transfer of study subjects (451 patients in total) to other trial sites, namely:

- in Ukraine – 172 patients
- abroad – 279 patients

The geography of the study subjects transfer includes 24 countries, with Poland being the nearest one and the USA being the most remote one.

The Department has processed 223 letters from Sponsors/CROs regarding the transfer of study subjects to other clinical trial sites (451 patients in total): in Ukraine (172 patients) and abroad (279 patients).

Number of study subjects transferred in 2022



Other:

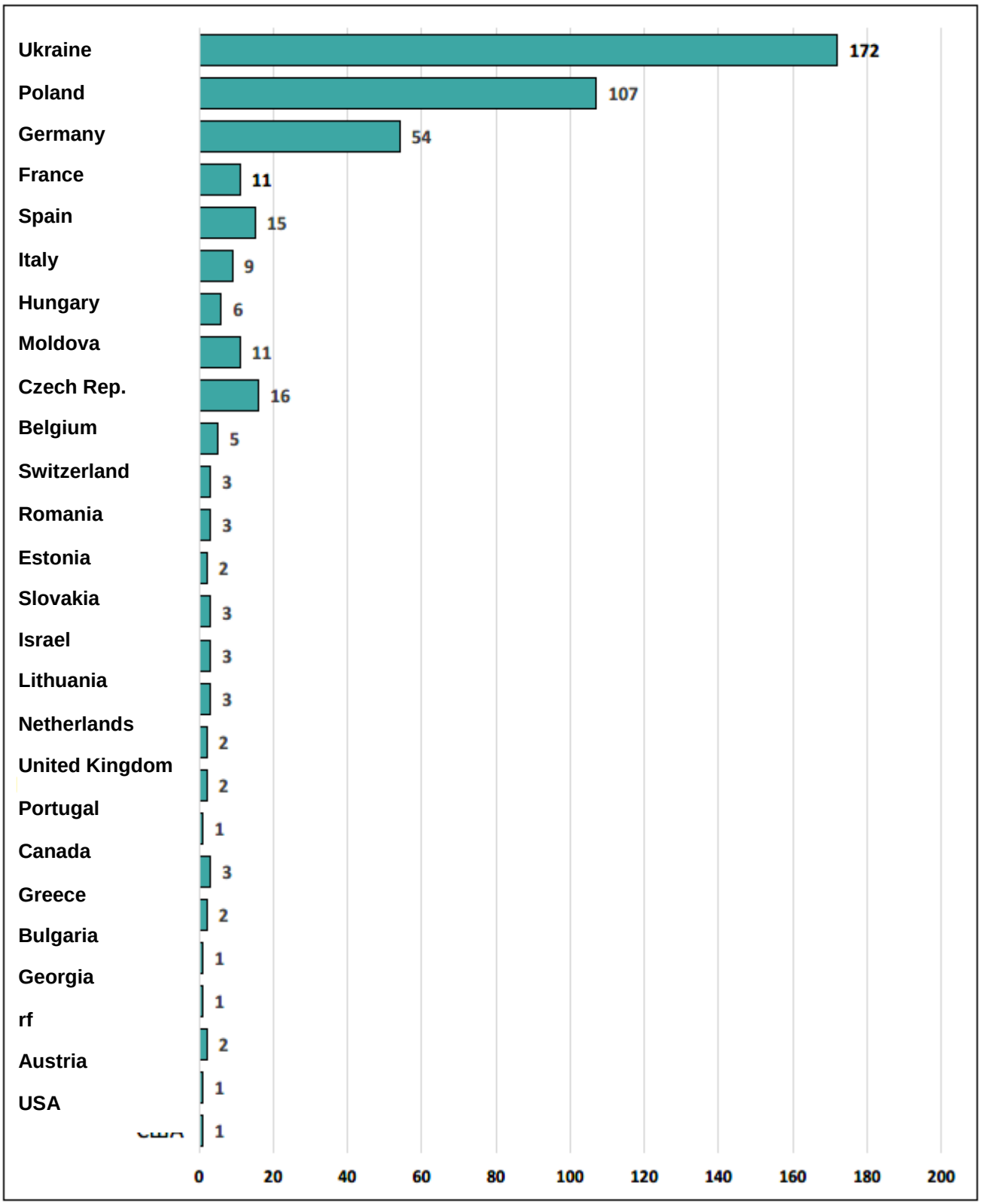
3 Switzerland
3 Romania
3 Slovakia
3 Israel
3 Lithuania
3 Canada
2 Estonia
2 Netherlands
2 United Kingdom
2 Greece
2 rf
1 Portugal
1 Bulgaria
1 Georgia
1 Austria
1 USA

10	9	8	7	6	5	4	3	2	1
Belgium	Hungary	Italy	France	Moldova	Spain	Czech Rep.	Germany	Poland	Ukraine
5	6	9	11	11	15	16	54	107	172

Number of subjects transferred to other Clinical Trial Sites

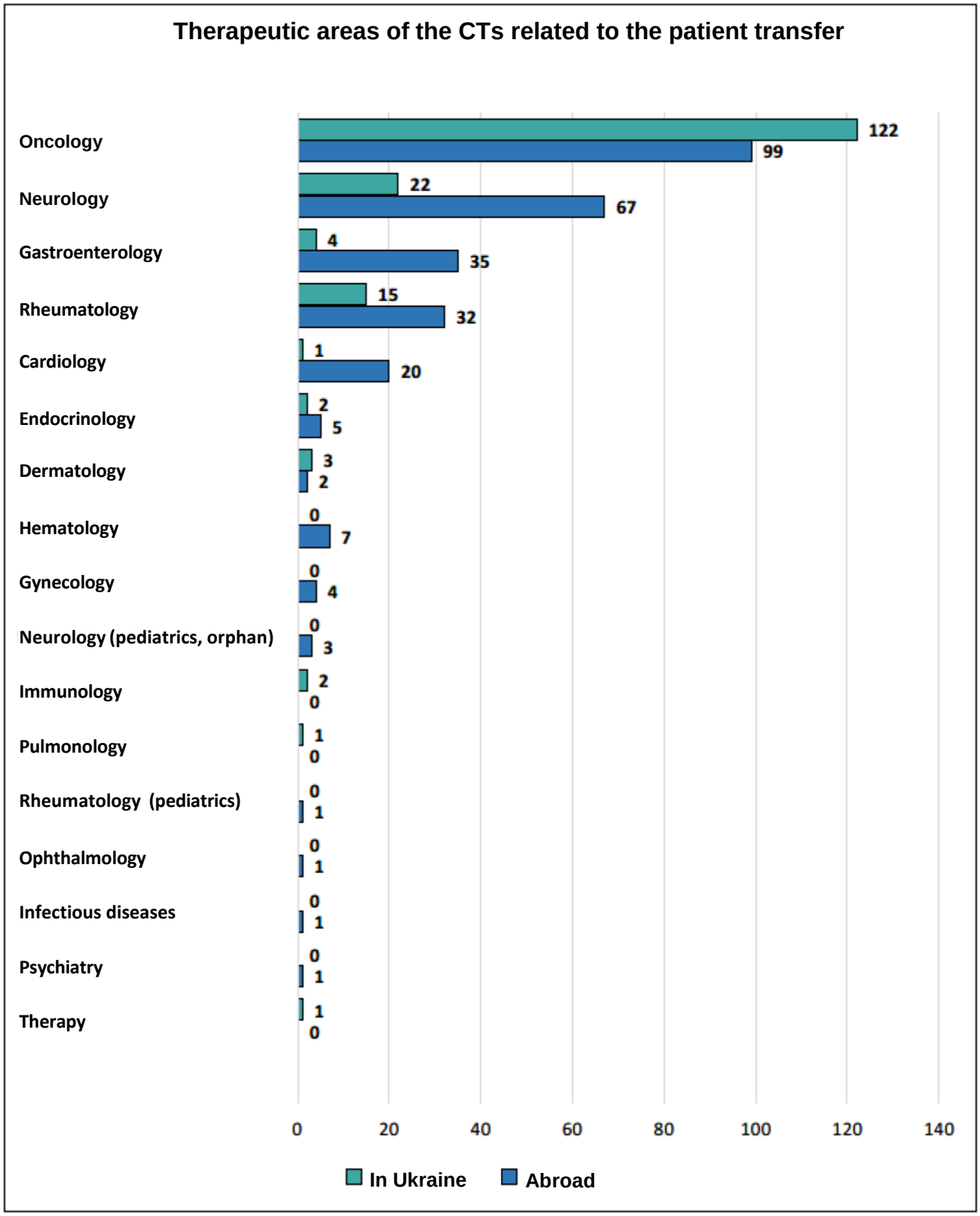
	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Ukraine	0	43	41	24	44	4	9	5	2	0	172
Poland	4	34	34	24	5	6	3	6	1	2	107
Germany	1	3	15	14	4	9	3	2	0	3	54
Czech Republic	0	3	3	6	2	2	0	0	0	0	16
Spain	0	6	2	3	1	2	0	0	0	1	15
France	0	1	3	2	1	0	1	1	0	2	11
Moldova	0	7	3	0	1	0	0	0	0	0	11
Italy	0	4	0	1	0	3	1	0	0	0	9
Hungary	0	5	0	0	0	0	0	1	0	0	6
Belgium	0	1	2	1	0	0	2	0	0	0	5
Canada	0	0	2	0	0	0	0	0	0	1	3
Switzerland	0	1	1	0	0	0	1	0	0	0	3
Romania	0	1	0	1	1	0	0	0	0	0	3
Slovakia	0	1	0	1	0	1	0	0	0	0	3
Israel	0	0	1	2	0	0	0	0	0	0	3
Lithuania	0	0	0	3	0	0	0	0	0	0	3
Estonia	0	2	0	0	0	0	0	0	0	0	2
Greece	0	0	2	0	0	0	0	0	0	0	2
Netherlands	0	1	0	0	0	0	0	1	0	0	2
United Kingdom	0	1	0	0	1	0	0	0	0	0	2
rf	0	0	0	1	0	1	0	0	0	0	2
Portugal	0	1	0	0	0	0	0	0	0	0	1
Bulgaria	0	0	1	0	0	0	0	0	0	0	1
Georgia	0	0	0	1	0	0	0	0	0	0	1
Austria	0	0	0	0	0	0	1	0	0	0	1
USA	0	0	0	0	0	0	1	0	0	0	1
Total:	**5**	**112**	**110**	**87**	**60**	**27**	**22**	**16**	**3**	**9**	**451**

Number of subjects transferred to other Clinical Trial Sites in 2022 (a histogram):



Therapeutic areas of the CTs related to the patient transfer

Therapeutic area	**Month (abroad/in Ukraine)**										
	III	IV	V	VI	VII	VIII	IX	X	XI	XII	Total
Oncology	4/-	34/37	24/19	14/10	7/43	2/3	4/5	4/3	1/2	5/0	**99/122**
Neurology	-/-	-/-	17/10	25/6	1/-	14/-	8/3	2/3	0/0	0/0	**67/22**
Gastroenterology (or proctology)	-/-	9/-	15/1	8/3	1/-	-/-	-/-	2/0	-/-	-/-	**35/4**
Rheumatology	-/-	17/2	7/7	4/4	-/1	3/1	1/0	0/0	0/0	0/0	**32/15**
Cardiology	-/-	1/-	-/-	9/1	3/-	2/-	-/-	1/0	-/-	4/0	**20/1**
Hematology	-/-	3/-	1/-	1/-	1/-	-/-	-/-	1/0	-/-	-/-	**7/-**
Endocrinology	-/-	-/-	1/ 2	-/-	3/	-/-	-/-	1/0	-/-	-/-	**5/2**
Dermatology	-/-	1/2	-/1	-/-	-/-	1/-	-/-	-/-	-/-	-/-	**2/3**
Gynecology	-/-	-/-	4/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	**4/-**
Neurology (pediatrics, orphan)	-/-	3/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	**3/-**
Immunology	-/-	/1	-/-	-/-	-/-	-/-	0/1	-/-	-/-	-/-	**-/2**
Therapy	-/-	/1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	**-/1**
Pulmonology	-/-	-/-	-/1	-/-	-/-	-/-	-/-	-/-	-/-	-/-	**-/1**
Ophthalmology	-/-	-/-	-/-	1/-	-/-	-/-	-/-	-/-	-/-	-/-	**1/-**
Rheumatology (pediatrics)	-/-	1/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	**1/-**
Infectious diseases	-/-	-/-	-/-	1/-	-/-	-/-	-/-	-/-	-/-	-/-	**1/-**
Psychiatry	-/-	-/-	-/-	-/-	-/-	1/-	-/-	-/-	-/-	-/-	**1/-**
Other	1/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	**1/-**
Total	**5/-**	**69/43**	**69/41**	**63/24**	**16/44**	**23/4**	**13/9**	**11/5**	**1/2**	**9/0**	**279/172**

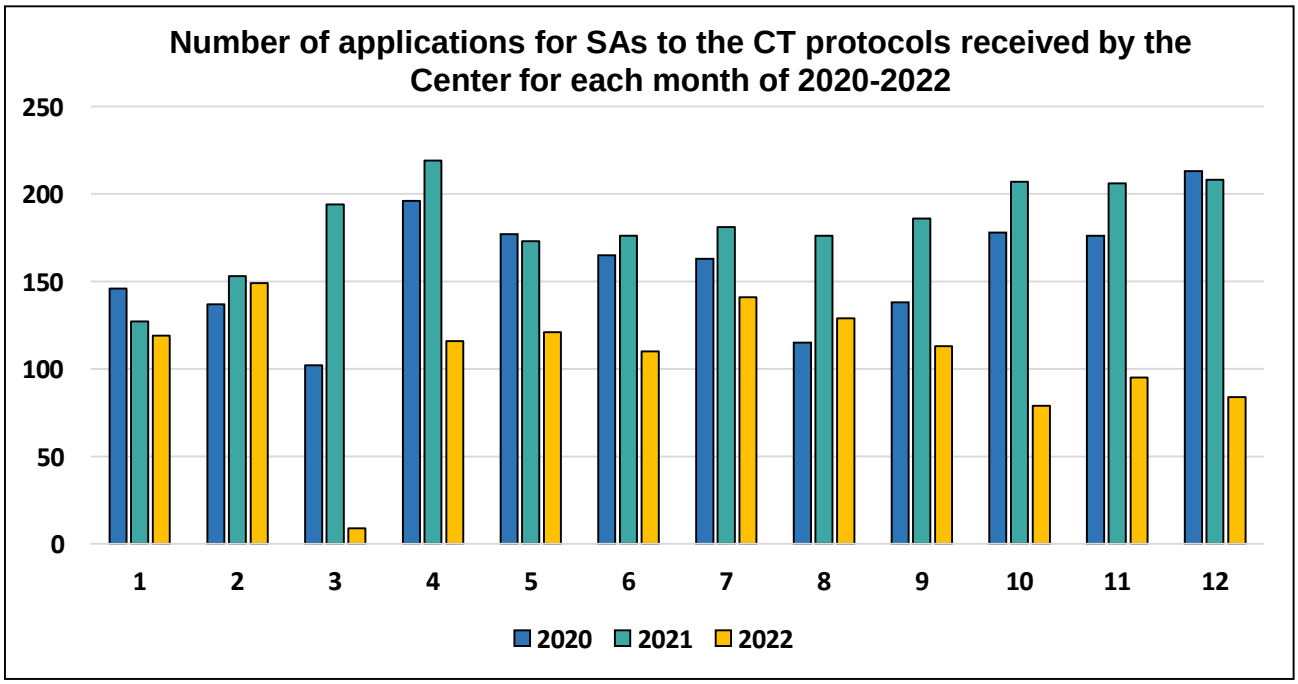


Most transferred patients were in the therapeutic areas of oncology (221), neurology (89), rheumatology (47), gastroenterology (39), cardiology (21).

The lifecycle of CTs conducted in Ukraine is supported by substantial amendments to the CT protocols, information of which is presented as a histogram showing the number of applications for SAs received by the Center from the MoH and the number of applications reviewed at the meetings of Scientific and Technical Councils (STC) of the Center and recommended for approval by the MoH for each month of 2020-2022.

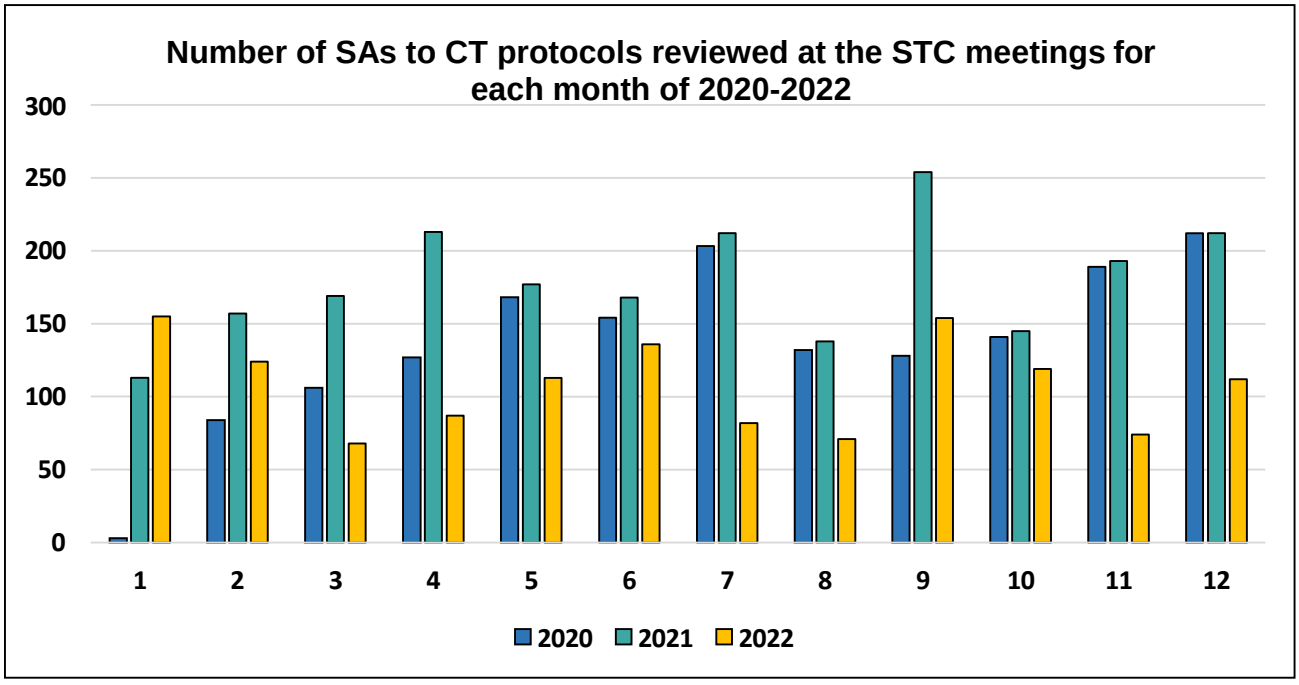
Number of applications for SAs to CT protocols received by the Center (as table and histogram)

	Month	2020	2021	2022
1	January	146	127	119
2	February	137	153	149
3	March	102	194	9
4	April	196	219	116
5	May	177	173	121
6	June	165	176	110
7	July	163	181	141
8	August	115	176	129
9	September	138	186	113
10	October	178	207	79
11	November	176	206	95
12	December	213	208	84
	Total	**1,906**	**2,206**	**1,265**



Number of SAs to CT protocols reviewed at the STC meetings (as table and histogram)

	Month	2020	2021	2022
1	January	3	113	155
2	February	84	157	124
3	March	106	169	68
4	April	127	213	87
5	May	168	177	113
6	June	154	168	136
7	July	203	212	82
8	August	132	138	71
9	September	128	254	154
10	October	141	145	119
11	November	189	193	74
12	December	212	212	112
Total		**1,647**	**2,151**	**1,295**
	2022 % of 2020/2021	**79**	**60**	



✓ **The increase in the number of SAs shows the continuous monitoring of CT during its life cycle and CT compliance with GCP requirements.**

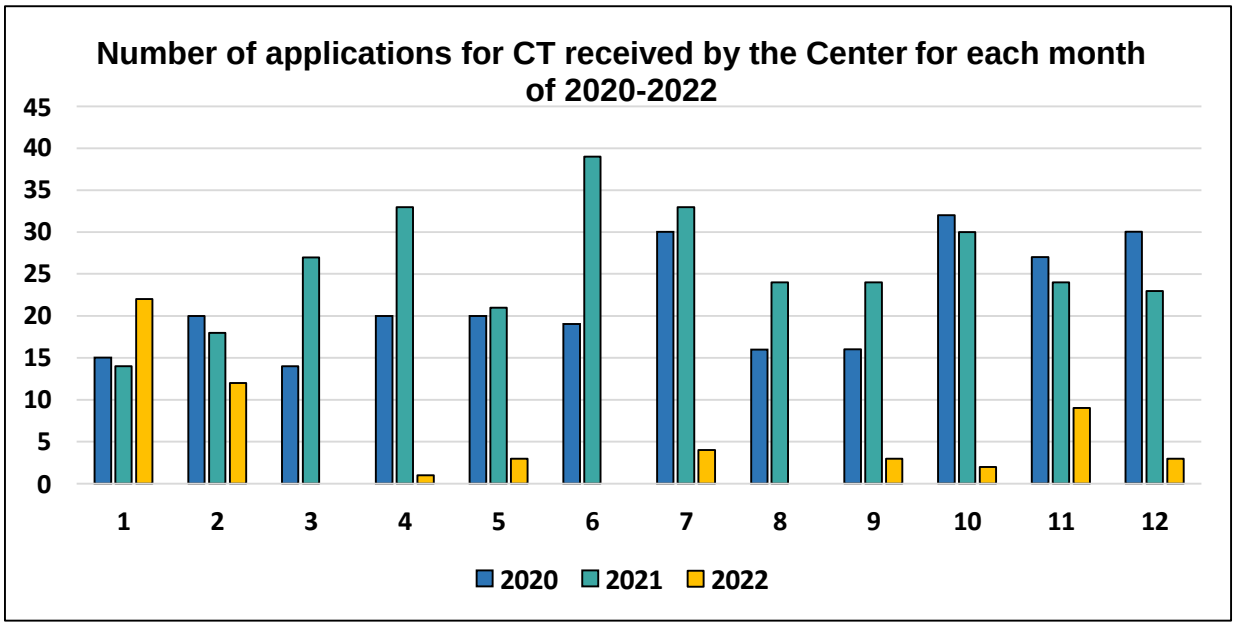
As to the number of applications for CTs in 2022, comparative analytical information in the usual format is not relevant under conditions of the war, since, in addition to reviewing and approving the CT materials, the CT participants – subjects, investigators, sponsors, and their representatives – are involved in its conduct. The Sponsors evaluate the situation and the

possibility of conducting the CTs in Ukraine.

The following tables and histograms provide comparative data on the number of applications for CTs in Ukraine and the number of CT protocols reviewed at the meetings of the Center's Scientific Expert Councils (SEC) with recommendations for the MoH to approve the conduct of CTs in Ukraine for each month of 2020-2022.

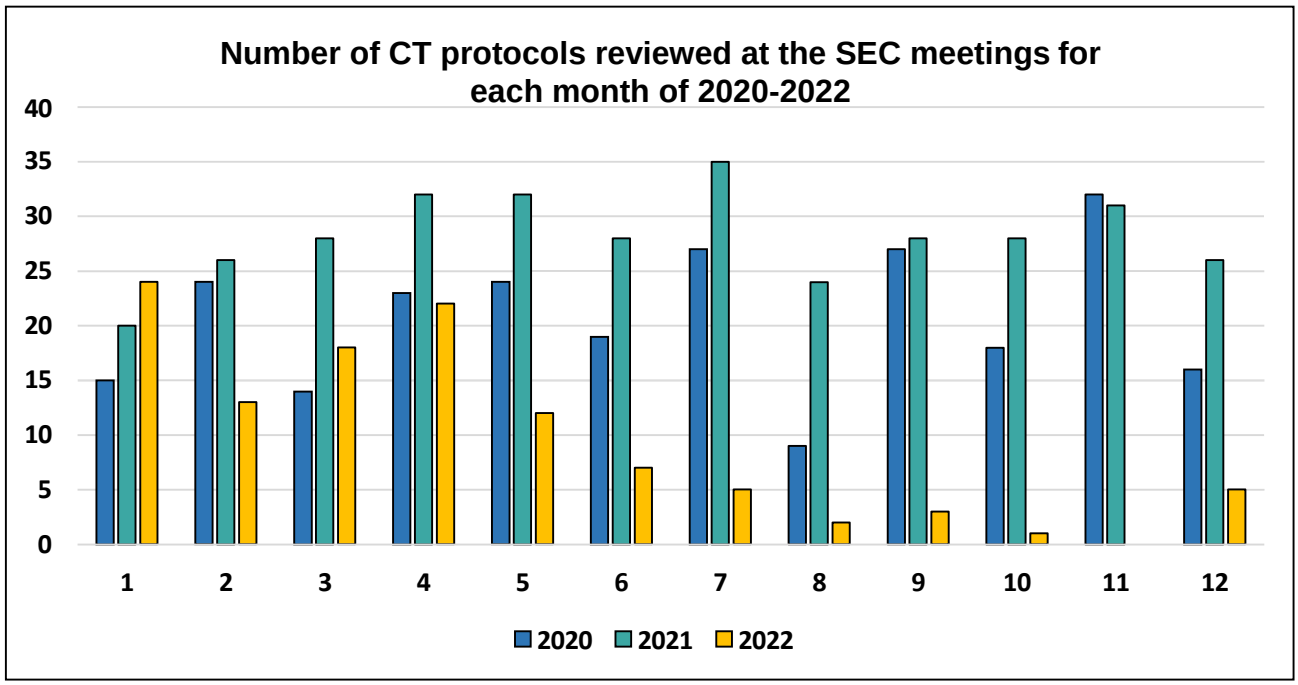
Number of applications for CT received by the Center

	Month	2020	2021	2022
1	January	**15**	**14**	**22**
2	February	**20**	**18**	**12**
3	March	**14**	**27**	**0**
4	April	**20**	**33**	**1**
5	May	**20**	**21**	**3**
6	June	**19**	**39**	**0**
7	July	**30**	**33**	**4**
8	August	**16**	**24**	**0**
9	September	**16**	**24**	**3**
10	October	**32**	**30**	**2**
11	November	**27**	**24**	**9**
12	December	**30**	**23**	**3**
	Total	**280**	**323**	**59**
	2022 % of 2020/2021	**21**	**18**	



Number of CT protocols reviewed at the SEC meetings

	Month	2020	2021	2022
1	January	**15**	**20**	**24**
2	February	**24**	**26**	**13**
3	March	**14**	**28**	**18**
4	April	**23**	**32**	**22**
5	May	**24**	**32**	**12**
6	June	**19**	**28**	**7**
7	July	**27**	**35**	**5**
8	August	**9**	**24**	**2**
9	September	**27**	**28**	**3**
10	October	**18**	**28**	**1**
11	November	**32**	**31**	**0**
12	December	**16**	**26**	**5**
	Total	**280**	**323**	**112**
	2022 % of 2020/2021	**40**	**35**	



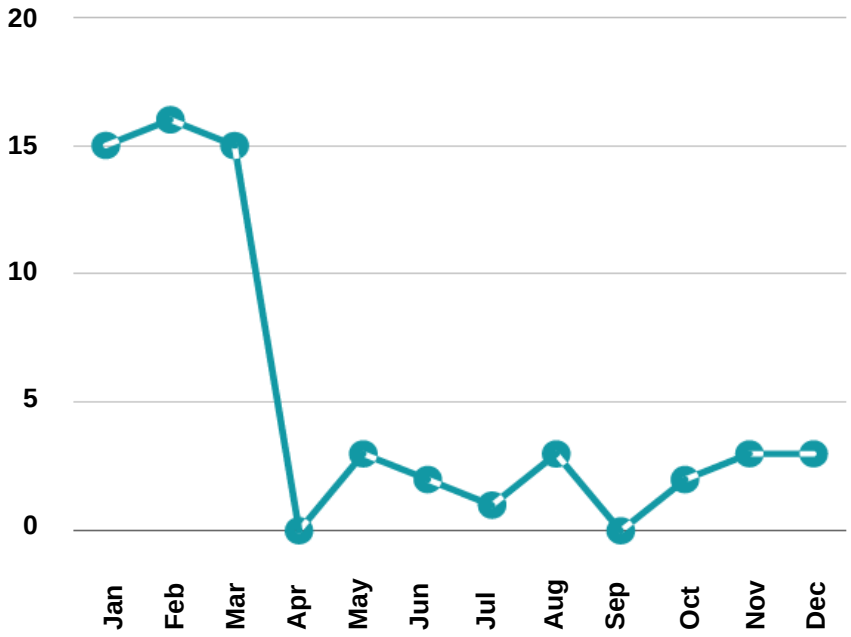
In the reporting period, 3 applications for a CT of medicinal product from a domestic manufacturer were received; 11 protocols of a domestic manufacturer were reviewed at the Center SEC meetings, 6 of which were the bioequivalence study protocols for investigational medicinal products (IMPs) (preregistration CTs of generics). For the treatment and/or prevention of COVID-19 acute respiratory infection, 11 CT protocols were reviewed at the SEC meetings with a recommendation for approval; in addition, 49 SAs to the CT protocols for the specific treatment and prevention profile were reviewed at the STC meetings.

As of January 01, 2023, the number of CTs approved by MoH orders is 662, of which 487 CTs started (https://clinicaltrials.dec.gov.ua).

Current positive trends in CTs in Ukraine

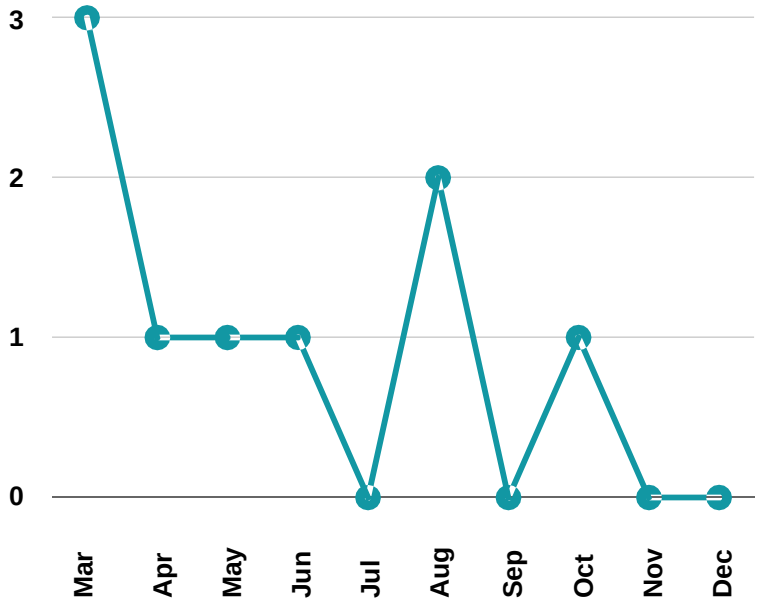
✓ **Start of CT – 63**

Month	CTs
January	**15**
February	**16**
March	**15**
April	**0**
May	**3**
June	**2**
July	**1**
August	**3**
September	**0**
October	**2**
November	**3**
December	**3**
Total	**63**



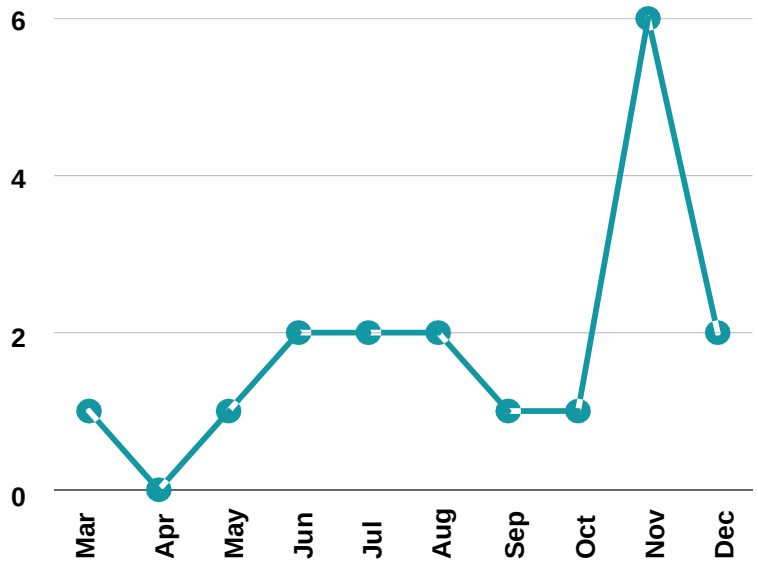
✓ **Resumption of CT – 9**

Month	CTs
March	**3**
April	**1**
May	**1**
June	**1**
July	**0**
August	**2**
September	**0**
October	**1**
November	**0**
December	**0**
Total	**9**



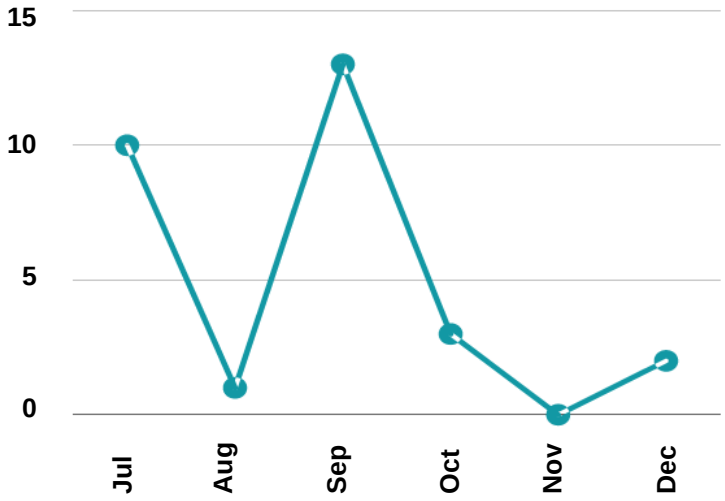
✓ **Resumption of patient enrollment in CT – 18**

Month	CTs
March	**1**
April	**0**
May	**1**
June	**2**
July	**2**
August	**2**
September	**1**
October	**1**
November	**6**
December	**2**
Total	**18**



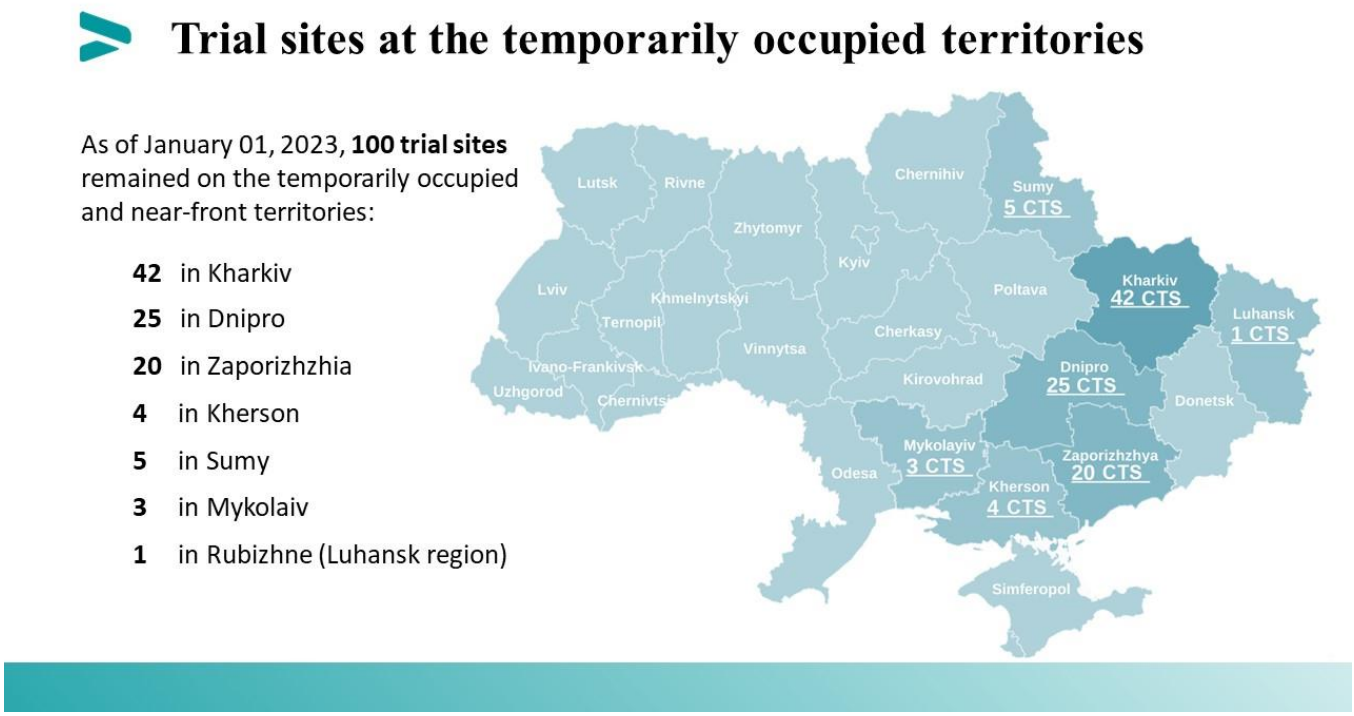
✓ **Return of subjects from abroad to the approved clinical trial sites in Ukraine (starting from July 2022) - 29**

Month	Subjects
July	10
August	1
September	13
October	3
November	0
December	2
Total	**29**



The Department's employees are in regular contact with applicants in order to properly conduct the CTs under the conditions of martial law in Ukraine.

By the start of the war, 308 ethics commissions had been functioning at healthcare settings that corresponded to more than 308 clinical trial sites approved by orders of the MoH of Ukraine. In 2022, 68 new clinical trial sites (CTSs) were approved via substantial amendments that corresponded to 68 new ethics commissions at healthcare settings.



As of January 01, 2023, 100 CTSs remained on the temporarily occupied and frontline areas (42 in Kharkiv, 25 in Dnipro, 20 in Zaporizhzhia, 4 in Kherson, 5 in Sumy, 3 in Mykolaiv, and 1 in Rubizhne, Luhansk region), which are currently practically not involved in the CTs.

Information work carried out by the Department

On March 01, 2022, the following information and recommendations were published on the Center's website in order to ensure uninterrupted operations:

"For the attention of clinical trial sponsors/representatives of sponsors, investigators, heads of companies, institutions and organizations involved in clinical trials!" (updated: 14.12.2022) https://www.dec.gov.ua/announcement/do-uvagy-Sponsoriv-klinichnyh-vyprobuvan-predstavnykiv-Sponsoriv-doslidnykiv-kerivnykiv-pidpryyemstv-ustanov-ta-organizaczij-zadiyanyh-u-provedenni-klinichnyh-vyprobuvan-2/.

"For the attention of ethics commissions, heads of enterprises, institutions and organizations involved in clinical trials" were prepared and published: https://www.dec.gov.ua/announcement/do-uvagy-komisij-z-pytan-etyky-kerivnykiv-pidpryyemstv-ustanov-ta-organizaczij-zadiyanyh-u-provedenni-klinichnyh-vyprobuvan/ (updated: 21.04.2022).

An online meeting was held between managers and specialists of the Center, and representatives of the European Business Association (EBA), where various issues related to the submission of CT and SA materials, conclusion of contracts, and execution of powers of attorney were discussed and agreed with stakeholders, which contributed to the resumption and support of CTs in Ukraine. Answers to written EBA requests were provided.

In addition, the current situation with the CTs in Ukraine was covered by the Department at a series of international online meetings "The Ukrainian Initiative to Support Clinical Trials During the War in Ukraine" and at the webinar "DIA Direct Webinar: Regulatory Considerations for Clinical Trials Responding to the War in Ukraine".

In 2022, the employees of the Department and the Office for Laboratory and Clinical Practice (GLP, GCP) Audit held 6 online workshops on international GCP requirements and

clinical trials regulations in Ukraine, which were attended by 337 investigators and representatives of local ethics commissions.

During the year, the Department reviewed and updated the documentation on the quality assurance system within the framework of the WHO benchmarking project, in particular, updated SOPs, Instructions for the processing and expert evaluation of clinical trial materials in order to prepare a conclusion on the conduct of a clinical trial and a conclusion on a substantial amendment at the State Expert Center of MoH of Ukraine, regulations on structural units, and job descriptions).

Employees of the Department took part:

- in the workshop on the COVID-19 Omicron variant organized by the International Coalition of Medicines Regulatory Authorities on January 12, 2022;
- in the WHO online meeting on the WHO research and development plan “Organizing a consultation to discuss emerging evidence towards the establishment of correlates of protection for COVID-19 vaccines, research and development plans”, February 23, 2022;
- in the workshop of the International Coalition of Medicines Regulatory Authorities (ICMRA) – ICMRA Workshop on Real-World Evidence (RWE). The event highlighted the use of real-world data and real-world evidence to share experiences and identify opportunities for regulatory cooperation in this area;
- in the Certification of graduates under the Clinical Trials Master Degree Program and, in a working meeting (held on 03.02.2022) to discuss the development of the Clinical Trials educational program at the Department of Clinical Pharmacology and Clinical Pharmacy of the National Pharmaceutical University (NPU) at the invitation of Mrs. Alla KOTVYTSKA, the NPU Rector;
- The Department has elaborated the draft guidance “WHO approach towards the development of a global regulatory framework for cell and gene therapy products”. The WHO Guidance WHO/BS/2022.2424 proposes a regulatory framework based on the risk category and classification of human cells and tissues (HCTs) and advanced therapy medicinal products (ATMPs). Global harmonization of regulatory requirements for HCTs and ATMPs is critical to facilitate their efficient development and timely approval in different jurisdictions, and ensure more equitable access in all regions of the world.
- The Department provided responses to the WHO online survey “Assessing barriers, enablers, and priority actions for improving access to morphine for medical use – Stakeholder survey”.

Participation of the Department in the development of draft legislative and regulatory documents

- some comments and suggestions/remarks to the draft Law of Ukraine “On Medicines” have been elaborated and prepared;
- a draft Procedure for the Approval and Implementation of the Program for the Study Subjects’ (Patients’) Access to the Investigational Medicinal Product after Completion of a Clinical Trial has been developed in accordance with Article 44 of the Fundamentals of Healthcare Legislation and Article 8^{-1} of the Law of Ukraine “On Medicines”, taking into account ICH GCP requirements, WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.
- draft amendments to the Procedure for Conducting Clinical Trials of Medicinal Products

and Expert Evaluation of Clinical Trial Materials have been developed. They concern the emergency procedure for the expert evaluation of materials of the clinical trials for the treatment of non-infectious and infectious diseases identified as priority areas for the development of the healthcare sector during the period of martial law.

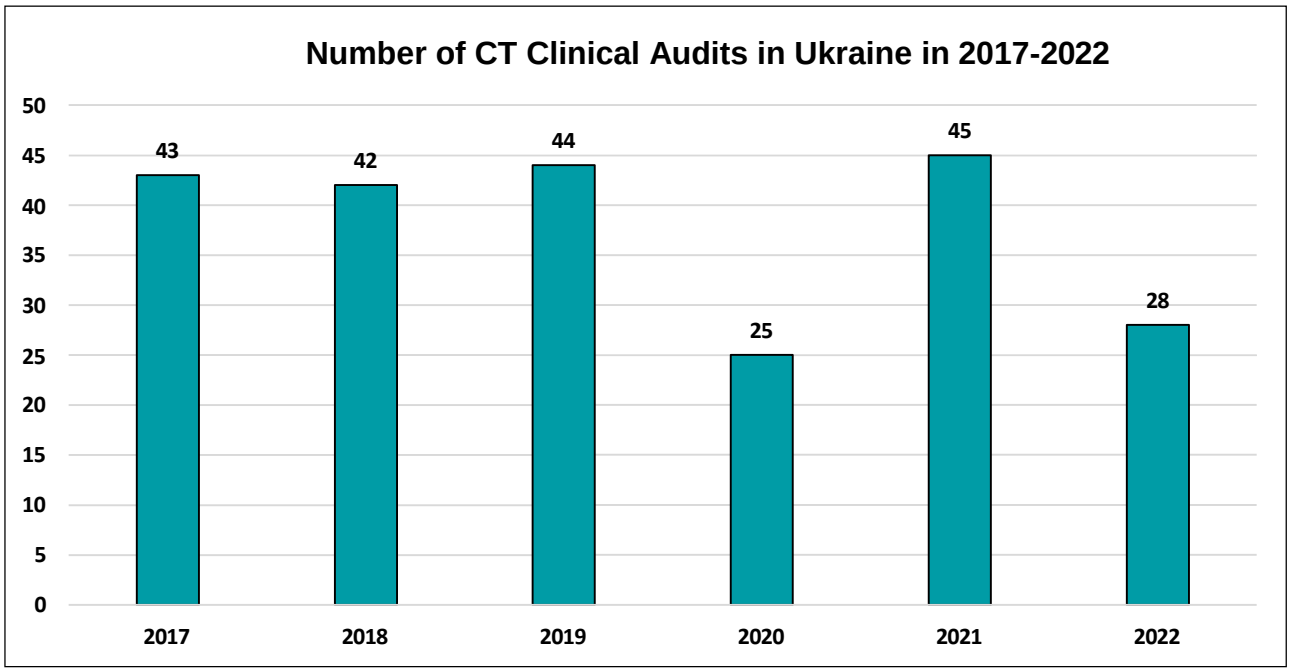
Clinical audit of clinical trials during the war in Ukraine

The clinical audit (CA) of a clinical trial (CT) of a medicinal product (MP) is an important aspect of the MP CT quality assurance and protection of the rights, safety and well-being of study subjects.

Due to the full-scale military aggression of the russian federation against Ukraine and the imposition of martial law in Ukraine, the scheduled CAs of CTs were suspended from February 24, 2022.

However, since May 13, 2022, the Center has resumed CAs of CTs in order to verify compliance with regulatory requirements for conducting CTs and observance of the rights of patients who were transferred to other CT sites.

Despite the martial law, the number of CAs of CTs conducted in 2022, exceeded the number of CAs of CTs during the quarantine measures in response to the coronavirus disease pandemic in 2020.



In 2022, 28 CAs were conducted, including 11 CAs on compliance with regulatory requirements during the transfer of study subjects in clinical trials.

Among the 28 CAs:

- 12 CAs (10 CAs regarding compliance with regulatory requirements during the transfer of subjects in clinical trials) – no remarks;
- 10 CAs (1 CA regarding compliance with regulatory requirements during the transfer of study subjects in a clinical trial) – minor remarks (the identified deficiencies did not affect the rights, safety, or health of the study subjects and the integrity of the CT data);
- 4 CAs – significant remarks (the identified deficiencies may adversely affect the rights, safety, or health of the study subjects and the integrity of the CT data);
- 2 CAs – critical remarks (the identified deficiencies adversely affect the rights, safety, or health of study subjects and/or affect the quality or integrity of clinical trial data), recruitment of subjects in the CT has been suspended.

Thus, only 1 case of minor deficiencies was identified during the CA regarding compliance with regulatory requirements during the transfer of study subjects in clinical trials. The other 10 CAs revealed no violations of regulatory requirements.

Therefore, despite the full-scale aggression of the russian federation, the clinical trials in Ukraine are conducted in compliance with the current regulatory framework that meets international standards, international ethical principles, and the planning and reporting are carried out in accordance with the requirements and principles of Good Clinical Practice (GCP). The coordinated actions of all stakeholders in the process and adherence to international ethical principles of protecting the rights, safety and well-being of study subjects change the situation for the better.

Preclinical studies of medicinal products

The success of scientific and research activities for the development of a new medicinal product is a result of a global long-term strategy that requires significant investment in the discovery of new technologies and the high qualification of many specialists. The process of developing a new medicinal product is long and complex, and includes a number of stages. Preclinical studies and clinical trials are the most important stages in developing a new medicinal product.

Preclinical studies of medicinal products lay the groundwork for further clinical trials. They are required to establish a safe starting (initial) dose and a safe dose range for human use, determine the parameters for clinical monitoring of potential adverse reactions, and solve other important tasks in accordance with the purposes of planned clinical trials.

The focus on safe use of medicinal products establishes strict requirements for the quality of preclinical studies, which is ensured by close adherence to the Good Laboratory Practice (GLP) rules to the maximum extent possible. The GLP rules provide recommended standards for conducting a wide range of toxicology studies and safety pharmacology studies and are intended to regulate them at a high level, control and record all stages of the study. Compliance with GLP requirements in preclinical studies ensures the quality, reproducibility and reliability of the results obtained, and contributes to the successful development of an MP.

In order to implement up-to-date internationally recommended standards for conducting preclinical studies and clinical trials, the Center’s staff developed the following Guidelines based on the relevant EMA Guidelines in 2022:

Guideline ST-N MOZU 42-7.10:2022 “Strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products” approved by the Order of MoH of Ukraine No. 143 dated January 21, 2022;

Guideline ST-N MOZU 42-7.11:2022 “General principles of non-clinical and clinical studies

of similar biological medicinal products containing biotechnology-derived proteins as active substance” approved by the Order of MoH of Ukraine No 2340 dated December 27, 2022 (updated version).