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Clinical trials in endocrine system diseases in Ukraine according to the ClinicalTrials.gov site database

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Abstract. Endocrine system diseases (ESD) occupy one of the leading places in the structure of the general morbidity of the population. Recent events have had a significant impact on the healthcare system in Ukraine, including the treatment of ESD and the conduct of clinical trials (CTs). **Aim**. Analysis of information about CTs of ESD in Ukraine. **Material and methods.** Descriptive analysis was conducted on the ClinicalTrials.gov website database using the keywords «Endocrine System Diseases» in the «Active, not recruiting» and «Recruiting» groups. **Results.** Information is presented on 17 CTs of ESD in Ukraine according to the ClinicalTrials.gov website database as of January 25, 2024, 13 of which had the current status of «Active, not recruiting» and 4 – «Recruiting». The average duration of these 17 CTs is 5 years and 6 months, with 2 of them running for more than 10 years. The total number of CT participants was 28 710 people (minimum – 48, maximum – 13 299, average – 1689). 14 CTs were interventional, 3 studies were observational prospective (2 case-control and 1 cohort). Allocation for 12 CTs was randomized. According to the type of intervention model, 12 CTs were assigned in parallel groups and 2 were assigned in single groups. No masking was used in 7 CTs, 2 CTs were double-blind, 1 CT was triple-blind and 4 CTs were quarter-blind. The main purpose of 14 CTs was treatment. Phase II of the study was indicated for 4 CTs, phase III – for 9 CTs. CTs were conducted in 58 countries, and the average number of medical facilities was 116. In Ukraine, 35 medical facilities were the bases for conducting CTs. The undisputed leader in terms of the number of CTs (10 out of 17 or 58.8%) is the State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine». 4 CTs are held exclusively in Ukraine. CT was sponsored by 8 commercial and 2 state organizations. **Conclusions.** As of January 25, 2024, the website www.ClinicalTrials.gov published information about 17 CTs of ESD in Ukraine («Active, not recruiting» – 13 and «Recruiting» – 4). In recent years, a negative trend has been observed in conducting CTs in Ukraine. The stability of the system in most specialized institutions of Ukraine and the rapid restoration of the level of providing high-quality special care indicate good prospects for restoring the status quo.

Keywords: endocrine system diseases, clinical trials, Ukraine.

ESD is a class of diseases that occur when the function of the endocrine glands is impaired. Recent events have had a significant impact on the healthcare system in Ukraine, including the treatment of ESD and implementation of CTs.

CTs are of paramount importance for the promotion and development of new treatment methods [1]. The ultimate goal of such trials and studies is to provide the best quality patient care with the highest and most favourable outcome, while reducing cost and suffering for the recipient.

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The largest database of CTs and information about their results is the ClinicalTrials.gov web resource, developed under the auspices of the U.S. Department of Health and Human Services in conjunction with the National Institute of Health and Food and Drug Administration [2].

As of January 25, 2024, the official website www.ClinicalTrials.gov contained information on 478 855 CTs conducted in over 200 countries, of which 258 285 CTs (54% of the total) were outside the United States, 145 825 (30%) – in the United States, 23 217 (5%) combined in the United States and other countries, and for 51 528 (11%) studies, study location information was not provided by the sponsor [3].

The number of CTs (368 021 records or 77% of the total number of registered studies) significantly exceeded the number of clinical observations (109 030 or 23%) and included 188 656 records of studies of drugs or biological effects, 129 608 records of behavioral reactions, 38 202 records of surgical procedures, and 49 687 records – medical instruments and devices [3]. 924 records of registered CTs had expanded access.

For many years Ukraine has been one of the largest markets for international CTs [4]. Ukraine was a sought-after location for international CT with nearly 2500 public medical facilities and a competent healthcare system.

The COVID-19 pandemic has unconditionally affected clinical researches in most regions of the world [1]. The focus on developing a vaccine for SARS-CoV-2 and treating COVID-19 has actually derailed many ongoing CTs for other diseases around the world.

Also, the Russian-Ukrainian war undoubtedly influenced world science and healthcare in Ukraine [5]. CTs in Ukraine were seriously damaged by the Russian invasion [6].

The subject of this review is information on CTs of ESD in Ukraine according to the ClinicalTrials.gov website database.

Material and methods

A descriptive analysis of the CTs of ESD was carried out using the ClinicalTrials.gov website database using the keywords «Endocrine System Diseases» [7]. Further analysis was carried out in the «Active, not recruiting» groups (the trial is ongoing, participants are undergoing examination and/or treatment, potential participants are not currently being recruited) and «Recruiting» (recruitment of trial participants are being continued) according to data: duration, number of participants, type, model and phase of the study, purpose and type of intervention, sampling method, masking, sponsors, countries and health care institutions, conducting CTs, etc. Statistical analysis was performed using standard methods. The results are presented as n, M±m or Me (min-max).

Results

As of January 25, 2024, a search on the official website www.ClinicalTrials.gov found information about 2466 CTs in Ukraine, of which 210 (8.5% of the total) were found using the keywords «Endocrine System Diseases» (**Table 1**).

Table 1. CTs in Ukraine according to the database ClinicalTrails.gov

Status	All studies	ESD
Not yet recruiting	0	0
Recruiting	152	6
Enrolling by invitation	13	1
Active, not recruiting	272	19
Suspended	0	0
Terminated	288	24
Completed	1683	153
Withdrawn	8	2
Unknown status	50	5
Total	2466	210

Note: all data are given as of January 25, 2024.

6 CTs with the status «Active, not recruiting» and 2 CTs with the status «Recruiting» were excluded from the analysis, since their groups were formed by patients with neoplasms of the breast, ovaries, fallopian tube and peritoneum, as well as thrombocytopenia caused by chemotherapy.

In the future, the publications will consider 13 CTs with the status «Active, not recruiting» and 4 CTs with the status «Recruiting» as of January 25, 2024 (**Table 2**).

Analysis of CTs start dates (dates when the first participant was enrolled in CTs) showed that the

Table 2. Characteristics of the CTs «Endocrine system diseases» in Ukraine according to the database ClinicalTrails.gov

End the table 2

Status	Active, not recruiting	Recruiting
Total	13	4
Duration, month		
M±m	72.8±8.5	45.3±15.3
Me (min-max)	70 (24-130)	45 (10-81)
Intervention/treatment		
drugs	11	2
medical devices	0	1
procedures	0	0
dietary supplement	0	1
other products	2	0
Enrollment, participants		
M±m	2138.6±1195.4	227.0±145.4
Me (min-max)	200 (48-13299)	96 (56-660)
phase II	66 (48-80)	0
phase III	1882 (200-13299)	94 (56-132)
Study type		
interventional	11	3
observational	2	1
Allocation		
randomized	9	3
N/A	2	0
ND	2	1
Intervention model		
parallel assignment	9	3
single group assignment	2	0
ND	2	1
Masking		
none (open label)	6	1
double (participant, investigator)	2	0
triple (participant, investigator, outcomes assessor)	0	1
quadruple (participant, care provider, investigator, outcomes assessor)	3	1
ND	2	1
Primary purpose		
treatment	11	3
ND	2	1
Phase of study		
II	4	0
III	7	2
not applicable	0	1
ND	2	1
Sponsor		
commercial	13	2
non-commercial	0	2
Location in countries		
M±m	17.3±3.0	8.5±5.0
Me (min-max)	20 (1-34)	5.5 (1-22)
Location in facility		
M±m	141.1±46.1	33.0±20.1
Me (min-max)	81 (1-467)	22 (1-87)
Location in Ukrainian city		
Kyiv	6	5
Kharkiv	5	1
Dnipro	3	1
Lviv	2	1
Odesa	2	1
Poltava	2	0
Vinnytsia	2	0
Zaporizhzhya	2	0
Cherkasy	1	0
Chernivtsi	1	0
Donetsk	1	0
Ivano-Frankivsk	1	0
Uzhhorod	1	0
Zhytomyr	1	0

Note: ND – no data, N/A – not applicable. All data are given as of January 25, 2024.

overwhelming majority of CTs (10 out of 17) were registered in 2019 and 2020. The date of completion of the overwhelming majority of CTs (the date when the last CT participant was examined or underwent intervention (i.e., the last visit of the last participant)) (11 of 17) were 2024 and 2025. The average duration of these studies is already 5 years and 6 months (from 10 months to 10 years and 10 months).

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The total number of CT participants was 28 710 people (minimum – 48, maximum – 13 299, average – 1689).

The type of study in 14 cases was interventional (the researcher, according to the protocol, assigned subjects to diagnostic, therapeutic or other types of intervention with follow-up and evaluation of biomedical results and/or health consequences) and in 3 cases it was observational (participants are defined as belonging to study groups and assessed based on the results of biomedical and medical research; participants may receive diagnostic, therapeutic, and other types of prescriptions, but the researcher does not prescribe specific interventions and/or treatments to participants).

By type of intervention (process or action that is the focus of the CT), trials were divided into the following groups: «drugs» – 13 (76.4% of the total), «devices» – 1 (5.9%), «food supplements» – 1 (5.9%) and «others» – 2 (11.8%).

According to the sampling method, of the 14 intervention CTs, 12 were random (the sample includes random selection, allowing statistical conclusions to be made about the entire group), and 2 were – not applicable.

By type of intervention model, 12 CTs were parallel group assignments (participants in two or more groups receive a different intervention/treatment) and 2 were single-group assignments (all participants receive the same intervention/treatment).

In 7 clinical studies (50.0% of the number of interventional trials), masking was not used, that is, all study participants knew about the essence of the assigned intervention, 2 studies (14.2%) were double blind (the participant and the researcher did not know about the assignment of the intervention), 1 study (7.1%) was triple-blind (the participant, researcher, and outcome assessor were unaware of the intervention assignment) and 4 studies (28.7%) were quarter-blind (the participant, physician, researcher and outcome assessor were not aware of the intervention assignment).

The primary goal of interventional CTs was treatment (evaluation of one or more interventions to treat a disease, syndrome, or condition).

For interventional CTs, the following study phases were specified: phase II (a research stage to evaluate the effectiveness of the drug and short-term side effects in patients with a specific condition or disease) – for 4 studies (28.7%) and phase III (research phase for a more in-depth assessment of the safety and effectiveness of a drug in different doses and combinations with other drugs in different groups with a large number of patients) – for 9 studies (64.2%); 1 study (7.1%) did not use phase definition.

According to the study design (model) (general scheme of the identification strategy and further work with participants during the study), the distribution among the 3 observational CTs was as follows: a case-control study (comparing a group of individuals with specific characteristics (for example, conditions or exposures compared with a group of individuals with different characteristics, but otherwise similar) – 2 CTs, cohort study (study of a group of individuals, initially identified and compiled, with common characteristics (for example, year of birth), which are considered or followed over a certain period of time) – 1 CT.

In terms of time perspective, all observational CTs were prospective (analysis of periodic observations obtained primarily after forming subject group).

The total number of countries in which CTs were conducted was 58 (median – 19, minimum – 1, maximum – 34, average – 15.2±2.7). The largest number of CTs was recorded in the USA (13), Israel (11), India and Russia (10 each), Great Britain (9), Poland (8), Australia, Spain, Italy, Canada, South Korea, Turkey, France and Japan (7 each).

The average number of medical institutions in which CTs were carried out was 115.6±44.2 (median – 58, minimum – 1, maximum – 467).

The sponsors of CTs (the organization or person initiating the study and having the authority to supervise it) were 8 commercial organization («Novo Nordisk A/S» – 6 CTs, «Ukraine Association of Biobank» and «OPKO Health, Inc.» – 2 CTs each, «Amgen», «Ascendis Pharma Endocrinology Division A/S», «AstraZeneca», «Eli Lilly and Company» and «Lumos Pharma» – 1 CT each) and 2 state (Bogomolets National Medical University and State Institution «The Filatov Institute of Eye Diseases and Tissue Therapy of National Academy of Medical Sciences of Ukraine» – 1 CT each.

The bases for conducting the CTs were 35 medical organizations and scientific institutions in Ukraine («Active, not recruiting»/«Recruiting»):

- Cherkasy (Communal Non-Profit Enterprise «Cherkasy Regional Hospital of Cherkasy Regional Council», 1/0);
- Chernivtsi (Communal Non-Commercial Enterprise «Chernivtsi Regional Endocrinology Center», 2/0);

- Dnipro (State Institution «Ukrainian State Scientific Research Institute of Medical and Social Problems of Disabilities of the Ministry of Health of Ukraine», 2/0; Communal Enterprise «I.I. Mechnykov Dnipropetrovsk Regional Clinical Hospital»; Communal Non-Profit Enterprise «Dnipropetrovsk Children's Municipal Clinical Hospital No. 5» of Dnipro City Council, 1/0; Communal Non-Profit Enterprise «City Clinical Hospital No. 9 of Dnipro City Council», 2/1);
- Donetsk (Communal treatment and preventive institution «Regional Children's Clinical Hospital», 1/0);
- Ivano-Frankivsk (Municipal Non-Profit Enterprise «Regional Clinical Hospital of Ivano-Frankivsk Regional Council», 3/0);
- Kharkiv (State Institution «L.T. Malaya Therapy National Institute of the National Academy of Medical Sciences of Ukraine», 2/0; Municipal Non-Profit Enterprise «City Clinical Hospital No. 8» of Kharkiv City Council, 1/0; Communal Non-Profit Institution «City Clinical Hospital No. 27» of Kharkiv City Council, 1/0; Communal Non-Profit Enterprise «Kharkiv Regional Children Clinical Hospital» of Kharkiv Regional Council, 2/1; Institute of Bio-Stem Cell Rehabilitation, 2/0);
- Kyiv (State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine», 9/1; Ukrainian Scientific and Practical Center of Endocrine Surgery, Transplantation of Endocrine Organs and Tissues of the Ministry of Health of Ukraine, 3/0; Communal Non-Profit Enterprise «Kyiv City Clinical Endocrinology Center», 0/1; Bogomolets National Medical University, 0/1; State Scientific Institution «Center for Innovative Medical Technologies of the National Academy of Sciences of Ukraine», 1/1; National Children's Spezialized Hospital «Ohmatdyt» of the Ministry of Health of Ukraine, 0/1; Kyiv Railway Clinical Hospital No. 2 of Branch «Health Center» of the Joint Stock Company «Ukrainian Railway», 1/0; Center for Medical Service and Rehabilitation «Artem» State Holding Company, 1/0; Medical Center «Ok!Clinic+», 1/0);
- Lviv (Danylo Halytsky Lviv National Medical University, 0/1; Communal Non-Commercial Enterprise of Lviv Regional Council «Lviv Regional State Clinical Medical and Diagnostic Endocrinological Center», 2/0; Municipal Non-Profit Enterprise «Lviv City Clinical Hospital No. 4», 1/0);
- Odesa (State Institution «The Filatov Institute of Eye Diseases and Tissue Therapy of the National Academy of Medical Sciences of Ukraine», 0/1; Municipal Non-Profit Enterprise «Odesa Regional Clinical Hospital» of Odesa Regional Council, 2/0; Municipal Non-Profit Enterprise «Odesa Regional Clinical Children's Hospital» of Odesa Regional Council, 2/0);
- Poltava (Communal Institution «M.V. Sklifosovskyi Poltava Oblast Clinical Hospital of Poltava Regional Council», 1/0; Communal Institution «1st City Clinical Hospital of Poltava City Council», 2/0);
- Uzhhorod (Communal Non-Profit Enterprise «Andriy Novak Transcarpathian Regional Clinical Hospital» of Zakarpatska Regional Council, 1/0);
- Vinnytsia (Vinnytsia National Pyrohov Memorial Medical University, 1/0; Communal Non-Profit Enterprise «Vinnytsia Regional Clinical Highly Specialized Endocrinology Center Vinnytsia Regional Council», 5/0);
- Zaporizhzhya (Communal Non-Profit Institution «City Hospital No. 10» of Zaporizhzhya City Council, 1/0; Communal Non-Profit Institution «Zaporizhzhya Regional Clinical Child Hospital» of Zaporizhzhya Regional Council, 1/0);
- Zhytomyr (Communal Non-Profit Enterprise «O.F. Gerbachevsky Regional Clinical Hospital» of the Zhytomyr Regional Council, 1/0).

The undisputed leader in the number of CTs (10 out of 17 or 58.8%) is the State Institution «V.P. Komissarenko Institute of Endocrinology and Metabolism of National Academy of Medical Sciences of Ukraine» – a scientific, advisory and medical institution that provides assistance to adults and children with endocrine pathology [8]. The Institute is also Ukraine's leading research base for training graduate students, clinical residents, defending doctoral and candidate's theses in the specialty «endocrinology», training specialists in internship and information courses.

4 CTs are conducted exclusively in Ukraine, 2 of them – on the basis of LLC «Institute of Bio-Stem Cell Rehabilitation» in Kharkov with the support of the Ukrainian Association of Biobanks, 1 – based on Bogomolets National Medical University,

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Communal Non-Profit Enterprise «Kyiv City Clinical Endocrinology Center, State Scientific Institution «Center of Innovative Medical Technologies of the National Academy of Sciences of Ukraine» and Danylo Halytsky Lviv National Medical University and 1 – based on the State Institution «The Filatov Institute of Eye Diseases and Tissue Therapy of the National Academy of Medical Sciences of Ukraine» and State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine». Scientific institutions from the United States of America are participating in 13 CTs.

More detailed information about CTs is presented in **Table 3** and **Table 4**.

Table 3. Characteristics of the clinical trials «Endocrine system diseases» with status «Active, not recruiting» in Ukraine according to the database ClinicalTrails.gov

NN	Characteristics
1	1. Safety and Dose Finding Study of Different MOD-4023 Dose Levels Compared to Daily R-human Growth Hormone (hGH) Therapy in Prepubertal Growth Hormone Deficient Children 2. NCT02500316 (CP-4-004-extension, EudraCT: 2011-004553-60) // 02.2013-12.2023 // 11.2023 3. OPKO Health, Inc. // 6 countries // Communal Treatment and Preventive Institution «Donetsk Regional Children Clinical Hospital» / State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine» / Ukrainian Scientific and Practical Center of Endocrine Surgery, Transplantation of Endocrine Organs and Tissues of the Ministry of Health of Ukraine / Municipal Non-Profit Enterprise «Odesa Regional Clinical Children's Hospital» of Odesa Regional Council 4. Interventional, N/A, single group assignment, none (open label), treatment, phase 2 // Growth hormone deficiency // Drug: Once weekly injection of long acting R-human Growth Hormone (MOD-4023) (48 participants)
2	1. A Randomised, Multinational, Active-controlled, (Open-labelled), Dose Finding, (Double-blinded), Parallel Group Trial Investigating Efficacy and Safety of Once-weekly NNC0195-0092 Treatment Compared to Daily Growth Hormone Treatment (Norditropin® FlexPro®) in Growth Hormone Treatment naïve Pre-pubertal Children With Growth Hormone Deficiency 2. NCT02616562 (NN8640-4172, EudraCT: 2015-000531-32, WHO: U1111-1166-7062) // 03.2016-09.2024 // 12.2023 3. Novo Nordisk A/S // 13 countries // Municipal Non-Profit Enterprise «Regional Clinical Hospital of Ivano-Frankivsk Regional Council», State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine» 4. Interventional, randomized, parallel assignment, quadruple (participant, care provider, investigator, outcomes assessor), treatment, phase 2 // Growth hormone disorder, growth hormone deficiency in children // Administered somapacitan (NNC0195-0092) subcutaneously once-weekly or administered Norditropin® subcutaneously once daily (74 participants)
3	1. A Phase 3, Open-label, Randomized, Multicenter, 12 Months, Efficacy and Safety Study of Weekly MOD-4023 Compared to Daily Genotropin - Therapy in Pre-pubertal Children With Growth Hormone Deficiency 2. NCT02968004 (CP-4-006) // 12.2016-12.2023 // 01.2023 3. OPKO Health, Inc. // 20 countries // Ukrainian Scientific and Practical Center of Endocrine Surgery, Transplantation of Endocrine Organs and Tissues of the Ministry of Health of Ukraine / State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine» / Municipal Non-Profit Enterprise «Odesa Regional Clinical Children's Hospital» of Odesa Regional Council / Communal Non-Commercial Enterprise «Vinnytsia Regional Clinical Highly Specialized Endocrinology Center Vinnitsa Regional Council» / Communal Non-Profit Institution «Zaporizhzhya Regional Clinical Child Hospital» of Zaporizhzhya Regional Council 4. Interventional, randomized, parallel assignment, none (open label), treatment, phase 3 // Pediatric growth hormone deficiency // Drug: Once weekly subcutaneous injection of MOD-4023 (Somatrogon) using pre-filled pen device or once daily subcutaneous injection of Somatropin (Genotropin) using pre-filled pen device (224 participants)
4	1. A 26 Week, Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase 3 Trial With a 26 Week Safety Extension Period Evaluating the Safety and Efficacy of Dapagliflozin 5 and 10 mg, and Saxagliptin 2.5 and 5 mg in Pediatric Patients With Type 2 Diabetes Mellitus Who Are Between 10 and Below 18 Years of Age 2. NCT03199053 (D1680C00019, EudraCT: 2015-005042-66) // 10.2017-01.2024 // 11.2023 3. AstraZeneca // 23 countries // Research Site: Communal Non-Profit Enterprise «Dnipro City Clinical Hospital No. 9 of Dnipro City Council», Ukrainian Scientific and Practical Center of Endocrine Surgery, Transplantation of Endocrine Organs and Tissues of the Ministry of Health of Ukraine, Communal Non-Commercial Enterprise «Vinnytsia Regional Clinical Highly Specialized Endocrinology Center Vinnitsa Regional Council» 4. Interventional, randomized, parallel assignment, double (participant, investigator), treatment, phase 3 // Diabetes mellitus, type 2 // Drug: dapagliflozin or saxagliptin administered once daily (256 par

Continuation of Table 3

NN	Characteristics
5	1. A Trial Comparing the Effect and Safety of Once Weekly Dosing of Somapacitan With Daily Norditropin® in Children With Growth Hormone Deficiency 2. NCT03811535 (NN8640-4263, WHO: U1111-1207-9691, EudraCT: 2018-000231-27, JAPIC: JapicCTI-194773) // 05.2019-09.2025 // 12.2023 3. Novo Nordisk A/S // 23 countries // Communal Non-Profit Enterprise «Kharkiv Regional Children Clinical Hospital» of Kharkiv Regional Council, State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine», Vinnytsia National Pyrohov Memorial Medical University, Communal Non-Commercial Enterprise «Vinnitsa Regional Clinical Highly Specialized Endocrinology Center Vinnitsa Regional Council» 4. Interventional, randomized, parallel assignment, none (open label), treatment, phase 3 // Growth hormone deficiency in children // Drug: receive either somapacitan once weekly or Norditropin® once daily for 52 weeks and next receive somapacitan weekly for 3 years (200 participants)
6	1. Effect of Semaglutide Versus Placebo on the Progression of Renal Impairment in Subjects With Type 2 Diabetes and Chronic Kidney Disease 2. NCT03819153 (NN9535-4321, WHO: U1111-1217-6259, EudraCT: 2018-002878-50, JAPIC: JapicCTI-194843) // 06.2019-08.2024 // 01.2024 3. Novo Nordisk A/S // 28 countries // State Institution «Ukrainian State Scientific Research Institute of Medical and Social Problems of Disabilities of the Ministry of Health of Ukraine», Municipal Non-Profit Enterprise «Regional Clinical Hospital of Ivano-Frankivsk Regional Council», State Institution «L.T. Malaya Therapy National Institute of the National Academy of Medical Sciences of Ukraine», Communal Non-Profit Institution «City Clinical Hospital No. 27» of Kharkiv City Council, State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine», Communal Institution «1st City Clinical Hospital of Poltava City Council», Communal Non-Profit Institution «City Hospital No. 10» of Zaporizhzhya City Council 4. Interventional, randomized, parallel assignment, quadruple (participant, care provider, investigator, outcomes assessor), treatment, phase 3 // Type 2 diabetes // Drug: use a pen to inject semaglutide 1 time a week under their skin (3508 participants)

7	1. A Dose-finding Trial Evaluating the Effect and Safety of Once-weekly Treatment of Somapacitan Compared to Daily Norditropin® in Children With Short Stature Born Small for Gestational Age With no Catch-up Growth by 2 Years of Age or Older
	2. NCT03878446 (NN8640-4245, WHO: U1111-1207-9741, EudraCT: 2018-000232-10) // 07.2019-05.2025 // 01.2024
	3. Novo Nordisk A/S // 19 countries // Communal Non-Profit Enterprise «Kharkiv Regional Children Clinical Hospital» of Kharkiv Regional Council, State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine»
	4. Interventional, randomized, parallel assignment, none (open label), treatment, phase 2 // Short stature children born small for gestational age (SGA) // Drug: Somapacitan injected under the skin once a week or Norditropin® injected under the skin once a day for a total of 52 weeks (62 participants)

8	1. Semaglutide Cardiovascular Outcomes Trial in Patients With Type 2 Diabetes 2. NCT03914326 (EX9924-4473, EudraCT: 2018-003141-42, WHO: U1111-1218-5368) // 06.2019-07.2024 // 12.2023 3. Novo Nordisk A/S // 34 countries // Communal Non-Profit Enterprise «Cherkasy Regional Hospital of Cherkasy Regional Council», Communal Non-Commercial Enterprise «Chernivtsi Regional Endocrinology Center», Communal Enterprise «I.I. Mechnykov Dnipropetrovsk Regional Clinical Hospital», Kyiv Railway Clinical Hospital No. 2 of Branch «Health Center» of the Joint Stock Company «Ukrainian Railway», State Research Institution «Center of Innovative Medical Technologies of the National Academy of Sciences of Ukraine», Communal Non-Commercial Enterprise of Lviv Regional Council «Lviv Regional State Clinical Medical and Diagnostic Endocrinological Center», Municipal Non-Profit Enterprise «Odesa Regional Clinical Hospital» of Odesa Regional Council, Communal Institution «1st City Clinical Hospital of Poltava City Council», Communal Non-Profit Enterprise «Andrii Novak Transcarpathian Regional Clinical Hospital» of Transcarpathian Regional Council, Communal Non-Profit Enterprise «O.F. Gerbachevsky Regional Clinical Hospital» of the Zhytomyr Regional Council 4. Interventional, randomized, parallel assignment, quadruple (participant, care provider, investigator, outcomes assessor), treatment, phase 3 // Type 2 diabetes // Drug: one tablet daily for 3.5 to 5 years (9642 participants)
9	1. The Effect of Tirzepatide Versus Dulaglutide on Major Adverse Cardiovascular Events in Patients With Type 2 Diabetes (SURPASS-CVOT) 2. NCT04255433 (17073; Eli Lilly and Company: I8F-MC-GPGN; EudraCT: 2019-002735-28) // 05.2020-10.2024 // 10.2023 3. Eli Lilly and Company // 30 countries // Communal Non-Commercial Enterprise «Chernivtsi Regional Endocrinology Center»; Communal Non-Profit Enterprise «Dnipro City Clinical Hospital No. 9 of Dnipro City Council»; State Institution «L.T. Malaya Therapy National Institute of the National Academy of Medical Sciences of Ukraine»; Municipal Non-Profit Enterprise «City Clinical Hospital No. 8» of Kharkiv City Council; Center for Medical Services and Rehabilitation «Artem»; State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine»; Communal Non-Commercial Enterprise of Lviv Regional Council «Lviv Regional State Clinical Medical and Diagnostic Endocrinological Center»; Municipal Non-Profit Enterprise «Lviv City Clinical Hospital No. 4»; Municipal Non-Profit Enterprise «Odesa Regional Clinical Hospital» of Odesa Regional Council; Communal Institution «M.V. Sklifosovskyi Poltova Oblast Clinical Hospital of Poltava Regional Council»; Communal Non-Profit Enterprise «Vinnitsa Regional Clinical Highly Specialized Endocrinology Center Vinnitsa Regional Council»; State Institution «Ukrainian State Scientific Research Institute of Medical and Social Problems of Disabilities of the Ministry of Health of Ukraine»; Medical Center «Ok!Clinic+» 4. Interventional, randomized, parallel assignment, double (participant, investigator), treatment, phase 3 // Type 2 diabetes mellitus // Drug: Weekly subcutaneous injections of tirzepatide or dulaglutide (13 299 participants)

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End the table 3

NN	Characteristics
10	1. A Multicenter, 24-Month, Randomized, Open-Label, Active Control, Parallel Arm, Phase 2 Study of Daily Oral LUM-201 in Naïve-to-Treatment, Prepubertal Children With Idiopathic Growth Hormone Deficiency (GHD) 2. NCT04614337 (LUM-201-01) // 12.2020-04.2025 // 11.2023 3. Lumos Pharma // 6 countries // State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine» 4. Interventional, randomized, parallel assignment, none (open label), treatment, phase 2 // Growth hormone deficiency // Drug: receive one of three oral daily doses of LUM-201 or daily injections of recombinant human growth hormone Norditropin® pen up to 24 months (80 participants)
11	1. Longterm Follow-up of Subjects With Diabetes 2 Type Treatment With ex Vivo Gene Therapy Using Autologous Mesenchymal Stem Cell 2. NCT04642911 (UAB00171120-1) // 10.2020-10.2030 // 10.2021 3. Ukraine Association of Biobank // 1 country // Institute of Bio-Stem Cell Rehabilitation 4. Observational, case-only, prospective // Diabete type 2 // Other: ex vivo gene therapy using autologous mesenchymal stem cell (91 participants)
12	1. Long Term Follow up Patients With Premature Ovarian Failure ex Vivo Gene Therapy Using Autologous Mesenchymal Stem Cell and Mesenchymal Stem Cell Lyophilisate 2. NCT04675970 (UAB1220-2) // 09.2020-09.2022 // 05.2022 3. Ukraine Association of Biobank // 1 country // Institute of Bio-Stem Cell Rehabilitation 4. Observational, case-only, prospective // Primary ovarian insufficiency, premature ovarian failure // Other: ex vivo gene therapy using autologous mesenchymal stem cell and mesenchymal stem cell lyophilisate (86 participants)
13	1. A Multicenter, Open-Label, Extension Trial to Investigate Long Term Efficacy and Safety of Lonapegsomatropin in Adults With Growth Hormone Deficiency 2. NCT05171855 (TCH-306EXT) // 12.2021-01.2025 // 01.2024 3. Ascendis Pharma Endocrinology Division A/S // 21 countries // Municipal Non-Profit Enterprise «Regional Clinical Hospital of Ivano-Frankivsk Regional Council», State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine», Communal Non-Profit Enterprise «Vinnitsa Regional Clinical Highly Specialized Endocrinology Center Vinnitsa Regional Council» 4. Interventional, N/A, single group assignment, none (open label), treatment, phase 3 // Adult growth hormone deficiency, endocrine system diseases, hormone deficiency // Drug: subcutaneous injection of Lonapegsomatropin once-weekly for 52 weeks (232 participants)

Note: 1 – Study official title; 2 – ClinicalTrials.gov Identifier (other study ID numbers) // actual study start date & estimated study completion date // last verified; 3 – Responsible Party // the number of countries where the research is carried out //research implementers in Ukraine (study status); 4 – Study type, allocation, intervention model, masking, primary purpose, phase // condition or disease // intervention/treatment (estimated enrollment).
All data are given as of January 25, 2024.

Table 4. Characteristics of the clinical trials «Endocrine system diseases» with status «Recruiting» in Ukraine according to the database ClinicalTrails.gov

NN	Characteristics
1	1. Phase 3, Randomized, Open-label, Controlled, Multiple Dose, Efficacy, Safety, Pharmacokinetic, and Pharmacodynamic Study of Etelcalcetide in Pediatric Subjects 28 Days to < 18 Years of Age With Secondary Hyperparathyroidism and Chronic Kidney Disease Receiving Maintenance Hemodialysis 2. NCT03633708 (20140315, EudraCT: 2017-002411-34) // 04.2019-01.2026 // 12.2023 3. Amgen // 10 countries // National Children's Spezialized Hospital «Ohmatdyt» of the Ministry of Health of Ukraine 4. Interventional, randomized, parallel assignment, none (open label), treatment, phase 3 // Secondary hyperparathyroidism, chronic kidney disease // Receive etelcalcetide in addition to standard of care (56 participants)
2	1. Efficacy and Safety of Oral Semaglutide Versus Placebo Both in Combination With Metformin and/or Basal Insulin in Children and Adolescents With Type 2 Diabetes 2. NCT04596631 (NN9924-4437, WHO: U1111-1218-1527, EudraCT: 2018-002952-34) // 11.2020-08.2025 // 01.2024 3. Novo Nordisk A/S // 22 countries // Communal Non-Profit Enterprise «Dnipro City Clinical Hospital No. 9 of Dnipro City Council», Communal Non-Profit Enterprise «Kharkiv Regional Children Clinical Hospital» of Kharkiv Regional Council 4. Interventional, randomized, parallel assignment, quadruple (participant, care provider, investigator, outcomes assessor), treatment, phase 3 // Diabetes mellitus, type 2 // Drug: oral semaglutide treatment for 52 weeks (132 participants)

End the table 4

NN	Characteristics
3	1. Effect of Probiotic Lysate (Postbiotic and Metabiotic) Supplementation on Metabolic Parameters in Type 2 Diabetes Patients 2. NCT05770076 (DELI_Diab) // 02.2023-12.2023 // 03.2023 3. Nazarii Kobyliak, Bogomolets National Medical University // 1 country // Bogomolets National Medical University / Communal Non-Profit Enterprise «Kyiv City Clinical Endocrinology Center» / State Scientific Institution «Center of Innovative Medical Technologies of the National Academy of Sciences of Ukraine» / Danylo Halytsky Lviv National Medical University 4. Interventional, randomized, parallel assignment, triple (participant, investigator, outcomes assessor), treatment, phase not applicable // Obesity; obesity, abdominal; insulin resistance; insulin sensitivity; type 2 diabetes; type 2 Diabetes mellitus in obese // Dietary Supplement: Probiotic lysate (postbiotic and metabiotic) daily for 3 month treatment (60 participants)
4	1. USING ARTIFICIAL INTELLIGENCE FOR MASS SCREENING OF THE DIABETIC RETINOPATHY 2. NCT06112691 (24.01.2022) // 02.2022-11.2024 // 06.2023 3. Andrii Korol, MD, PhD, MD, PhD, DMedSc, The Filatov Institute of Eye Diseases and Tissue Therapy // 1 country // State Institution «The Filatov Institute of Eye Diseases and Tissue Therapy of the National Academy of Medical Sciences of Ukraine» / State Institution «V.P. Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine» 4. Observation, Cohort, Prospective // Diabetic retinopathy // Device: using artificial intelligence to identify diabetic retinopathy in the early stages using fundus photography (660 participants)

Note: 1 – Study official title; 2 – ClinicalTrials.gov Identifier (other study ID numbers) // actual study start date & estimated study completion date // last verified; 3 – Responsible Party // the number of countries where the research is carried out //research implementers in Ukraine (study status); 4 – Study type, allocation, intervention model, masking, primary purpose, phase // condition or disease // intervention/treatment (estimated enrollment).
All data are given as of January 25, 2024.

Discussion

As already mentioned above, Ukraine has been one of the largest markets for international CTs for many years, with almost 2500 public medical institutions and a competent healthcare system [4]. Several other factors contributed to Ukraine's success as a CT center:

- A large pool of potential study subjects (large treatment-naïve population);
- An experienced group of GCP-trained clinicians;
- High quality of obtained data;
- lower costs compared to other European countries.

Almost all Big-Pharma companies conduct trials in certain Ukrainian trial centers and patients receive treatment within these CTs [4].

COVID-19 pandemic has a potentially negative impact on the management of clinical trials, which may compromise the scientific integrity of data and may raise concerns for patient safety [1, 9-11]. To date, many institutions and organisations have already put their CTs on hold. There are several critical challenges in the current pandemic which include: (a) limited accessibility of clinics mainly for essential or critical visits, (b) there is difficulty in recruiting homebound patients, or others are also reluctant to visit clinics, (c) currently trial operations may expose the staff or patients to the risk of acquiring the infection, (d) continuation of the trial may lead to a high drop-out rate, (e) inability to meet logistical trial obligations by sponsors as well as contractors (i.e., delivery of investigational products, PPE or site monitoring), and (f) deviation from the study timelines may affect data integrity due to delayed assessment and monitoring.

As circumstances change and the COVID-19 restrictions have largely been lifted, researchers and research institutions have actively responded to the challenges posed by the pandemic embraced some guidelines and adapted methods to ensure the continuity of CTs. Notably, the US Food and Drug Administration issued the Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency guidance, which provided valuable insights into this matter [12]. Over time, there was hope that CT activities may soon recover to at least pre-COVID-19 levels [9]. However, the beginning of the Russian-Ukrainian war on February 24, 2022, crossed out these hopes for domestic researchers.

Already on June 1, 2022, the State Enterprise «State Expert Center of the Ministry of Health of Ukraine» recommended to the sponsors of the CTs/

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representatives of sponsors, researchers, heads of enterprises, institutions and organizations involved in conducting the CTs [13]:

- assess the expediency of starting new CTs or including them in current CTs;
- in case of prevention of the continuation of the CTs at the approved test site, carry out the procedure for removing subjects from the CTs or, if possible, transferring such subjects to other test sites approved in Ukraine or another country, in accordance with the legislation of that country, if one is involved in this CT;
- in case of restrictions on the movement of patients, consider the possibility of: a) replacing physical visits by patients to the test site with telephone contacts or through video visits (use of telemedicine methods), postponing or canceling visits if necessary; b) if it is impossible to obtain updated written informed consent (hereinafter referred to as IC) of the CT participant due to restrictions on movement, the study participant can give verbal consent (using tele/video communication); c) ake all possible measures to ensure the uninterrupted provision of medical treatment for patients at the trial sites; d) consider the possibility of using laboratories of healthcare institutions to examine research subjects if contracts have been concluded with the sponsor and the laboratories have the appropriate technical capabilities;
- report all cases of violation порушення of the terms of the CT protocol relating to patient safety and other aspects of CTs in accordance with the provisions of the Procedure for conducting CTs of medicinal products and examination of CT materials, approved by Order of the Ministry of Health of Ukraine dated September 23, 2009 No. 690 and, if necessary, submit an application for significant amendment.

In order to ensure the safety of research participants and the integrity of data obtained in CTs in Ukraine, in times of martial law, the sponsor can use the experience gained during the COVID-19 pandemic and introduce an approach and flexibility in accordance with the situation, in particular the possibility of using remote verification of primary data from using special technologies, when data from individual registration forms of study subjects are remotely verified with the corresponding primary medical documents [13].

Regarding other aspects of conducting clinical researches under martial law conditions, the State Enterprise «State Expert Center of the Ministry of Health» advises sponsors to use the additional recommendations of the European Medicines Agency regarding methodological aspects of data collection of CTs affected by the war in Ukraine [13, 14].

Most importantly, safety of study participants is the absolute priority and must be at the heart of every decision taken, regardless of any potential consequences for an ongoing trial (even if this may require disclosure of information at the individual patient level) and supported to continue the trial as long as there is no safety risk involved. Second, when possible and in the best interest of their continued treatment, patients should be encouraged to continue treatment (even if this may require disclosure of information at the individual patient level) and supported to continue the trial as long as there is no safety risk involved. Consequently, sponsors should give priority to the interests of patients already participating in the trial when considering the future conduct and continued appropriateness of the trial from an ethical, medical and methodological point of view [14]. Significant changes in trial design and conduct must be properly documented, comply with local regulations, and be approved by Ethics Committees and the appropriate competent authority as significant amendments under the Clinical Trials Directive.

Some authors suggest that [15]:

- stopping the recruitment of new patients in CTs under such extreme conditions is acceptable;
- research participants already receiving trial medication in such disruptive situations should be considered highly vulnerable due to their medical dependency on current treatment according to the approved CT protocol;
- based on the current experience in Ukraine and other countries, we conclude that completion of ongoing trial treatments in accordance with approved or modified protocols should be considered an ethical obligation of CT sponsors, regardless of whether trial failure is caused by war, economic sanctions, or natural disasters;
- it is important to pay more attention to the ethical challenges raised by such fundamentally disruptive situations for CTs generally in any region of the world.

CTs can be adapted for refugees [16]. Recommendations for facilitating Ukrainian refugees to continue CTs are proposed. This commentary outlines policy recommendations regarding participants' re-enrollment, the handover of participants and data to new principal investigators, and the consent process as well as the sponsor's obligations related to translation, data transfer, and support for Ukrainian investigators [17]. The safety of study participants should be the main priority and guide every decision, regardless of any potential consequences for an ongoing trial.

This case study investigates the strategy and best practices for ensuring business stability through contingency, resilience, and recovery actions analysis, and the SWOT analysis of the study findings [18]. In particular, the organisational continuity framework features financial policy, human resources management, organisational behaviour practices, internal communication, and diversification. The main areas that ensured the sustainability in the face of recurring crises were diversification, the use of tools for financial stability, clear management of human capital and operation design.

It should be noted that the system is stable in most specialized institutions in Ukraine, as well as quickly restore the level of provision of high-quality special assistance in the center and areas close to the combat zone [19].

At the same time, an assessment of the impact of the war in Ukraine on 10 key risk indicators commonly used as an important component of central monitoring in drug development, covering several study risk categories (compliance, timeliness of data reporting, registration and storage, and safety), showed that the overall the significant results rate for Ukraine increased from 1.2% in 2021 to 3.9% in 2022 and 5.7% in 2023, while the rate across all countries remained stable at around 2.8% over the same period of time [20].

The top five key risk indicators with the highest rate of significant p-values in Ukraine since 2022 (Ukraine vs. all countries): visit to electronic case report form entry cycle time (9.6% vs. 3.4%), query response cycle time (8.1% vs. 3.9%), missed assessment rate (7.6% vs. 2.8%), off-schedule visit rate (5.5% vs. 3.1%) and protocol deviation rate (4.2% vs. 2.5%) [20]. According to the authors, this is clear evidence of the significant disruption of CTs in Ukraine during the current crisis.

Results of this study suggest that war-related changes in trial conduct in Ukraine may not be completely visible in the largest public trial registry, which is expected to present accurate and timely information on CTs [6]. These conclusions raise questions about the updating practices for registration information, which should be mandatory, especially in times of crises, to ensure the safety and the rights of trial participants in a war zone.

Our study shows that there has been a significant number of publications on the Russia-Ukraine war and only a small portion of first authors, co-authors, and last authors of these publications are affiliated to an institution in Ukraine [5]. Therefore, despite the relatively high number of publications, most publications do not arise from the perspective of Ukrainian authors.

5 CTs have published results, although it has previously been shown that 25-50% of CTs have not published their results, and the average time to publication is approximately 2 years [21].

Conclusions

1. As of January 25, 2024, the website www.ClinicalTrials.gov posted information about 17 CTs of ESD in Ukraine («Active, not recruiting» – 13 and «Recruiting» – 4).
2. In recent years, there has been a negative trend in conducting CTs in Ukraine.
3. The stability of the system in most specialized institutions in Ukraine and the rapid restoration of the level of providing high-quality special assistance indicate good prospects for restoring the status quo.

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Abbreviation:

ESD – endocrine system diseases
CT – clinical trials

Клінічні випробування при захворюваннях ендокринної системи в Україні згідно бази даних сайту ClinicalTrials.gov

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Резюме. Захворювання ендокринної системи (ЗЕС) посідають одне з провідних місць у структурі загальної захворюваності населення. Події останнього часу суттєво вплинули на систему охорони здоров'я в Україні, включаючи лікування ЗЕС і проведення клінічних випробувань (КВ). **Мета.** Аналіз інформації про КВ ЗЕС в Україні. **Матеріал і методи.** Дескриптивний аналіз проведено по базі даних сайту ClinicalTrials.gov за ключовими словами «Endocrine System Diseases» в групах «Active, not recruiting» і «Recruiting». **Результати.** Представлена інформація про 17 КВ ЗЕС в Україні станом на 25 січня 2024 р., 13 з яких мали поточний статус «активний, без набору» і 4 – «набір». Середня тривалість КВ становить 5 років і 6 місяців, а 2 з них виконуються ≥10 років. Загальна кількість учасників КВ становила 28 710 осіб (мінімальна – 48, максимальна – 13 299, середня – 1689). 14 КВ були інтервенційними, 3 КВ – обсерваційними проспективними (2 – «випадок-контроль» і 1 – когортне). Розподіл для 12 КВ був рандомізованим. За типом інтервенційної моделі 12 КВ були призначеннями в паралельних групах і 2 – призначеннями в одинарних групах. У 7 КВ маскування не застосовувалося, 2 КВ були подвійними сліпими, 1 КВ – потрійним сліпим і 4 КВ – четвертним сліпим. Основною метою 14 КВ було лікування. Для 4 КВ була вказана II фаза дослідження, для 9 КВ – III фаза. КВ проводилися в 58 країнах, а середня кількість медичних закладів становила 116. В Україні базами проведення КВ були 35 медичних закладів. Беззаперечним лідером за кількістю КВ (10 із 17 або 58,8%) є Державна установа «Інститут ендокринології та обміну речовин ім. В.П. Комісаренка НАМН України». 4 КВ проводяться виключно в Україні. Спонсорами КВ були 8 комерційних і 2 державні організації. **Висновки.** Станом на 25 січня 2024 р. на сайті www.ClinicalTrials.gov була розміщена інформація про 17 КВ ЗЕС в Україні («активні, без набору» – 13 і «набір» – 4). Протягом останніх років спостерігається негативна тенденція в проведенні КВ в Україні. Стійкість системи в більшості спеціалізованих закладів України та швидке відновлення рівня надання якісної спеціальної допомоги свідчать про хороші перспективи на відновлення status quo.

Ключові слова: захворювання ендокринної системи, клінічні випробування, Україна.

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