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ANALYSIS OF THE CURRENT SITUATION ON THE AVAILABILITY OF INFORMATION ON ONGOING CLINICAL TRIALS IN THE REPUBLIC OF KAZAKHSTAN

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Abstract

Availability of information about clinical trials (CTs) in the country is an important condition for sufficient transparency and quality of CTs. The purpose of this study was to analyze the availability of information about CTs in Kazakhstan. The main method was searching among publicly available sources on the internet. Data from four sources were found and analyzed: two Russian-language ones – the National Database of CTs of the National Center for Expertise of Medicines and Medical Devices and the Russian Federation Register "State Register of Medicines" with data on CTs in Kazakhstan; two English-language ones - the International Clinical Trials Database of the US National Library of Medicine ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP). Data from local ethical commissions were also taken into account. Based on the results of the analysis, the following main conclusions were made: English-language databases were more accessible and informative; the amount of information and its content was different in all four resources; all four resources had missing data. Based on this analysis, some recommendations were made to improve the availability of information about CTs in Kazakhstan.

Keywords: *clinical trial, Kazakhstan, clinical trial registration, data availability.*

Абстракт

АНАЛИЗ ТЕКУЩЕЙ СИТУАЦИИ ДОСТУПНОСТИ ИНФОРМАЦИИ О ПРОВОДИМЫХ КЛИНИЧЕСКИХ ИСПЫТАНИЯХ В РЕСПУБЛИКЕ КАЗАХСТАН

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Доступность информации о клинических исследованиях (КИ) в стране является важным условием достаточной прозрачности и качества проводимых КИ. Целью настоящего исследования стал анализ доступности информации о

КИ в Казахстане. Основным методом стал поиск информации о КИ среди общедоступных источников в сети интернет. Были найдены и проанализированы данные четырех ресурсов: двух русскоязычных – Национальная база КИ Национального центра экспертизы лекарственных средств и медицинских изделий, Российский регистр «Государственный реестр лекарственных средств» с данными о КИ в Казахстане; двух англоязычных - Международная база КИ национальной медицинской библиотеки США ClinicalTrials.gov и Международная платформы регистра клинических исследований ВОЗ International Clinical Trials Registry Platform (ICTRP). Также были учтены данные локальных этических комиссий. По результатам анализа были сделаны следующие основные выводы: англоязычные базы оказались более доступными и информативными; количество информации и ее содержание оказалось разным; на всех ресурсах наблюдались пропущенные данные. На основании данного анализа были даны некоторые рекомендации для повышения доступности информации о КИ в Казахстане.

Ключевые слова: *клинические исследования, Казахстан, регистрация клинических исследований, доступность данных.*

Түйіндеме

ҚАЗАҚСТАН РЕСПУБЛИКАСЫНДА ҚАЗІРГІ УАҚЫТТА ЖҮРГІЗІЛЕТІН КЛИНИКАЛЫҚ СЫНАҚТАР ТУРАЛЫ АҚПАРАТТЫҢ ҚОЛЖЕТІМДІЛІГІН АНЫҚТАЙТЫН ТАЛДАУ

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Елдегі клиникалық зерттеулер (КЗ) туралы ақпараттың қолжетімділігі жеткілікті ашықтықтың және жүргізілетін КЗ сапасының маңызды шарты болып табылады. Осы зерттеудің мақсаты Қазақстанда КЗ туралы ақпараттың қолжетімділігін талдау болды. Негізгі әдісті интернетте жалпыға қол жетімді дереккөздермен іздеу болып табылады. Төрт дереккөз бойынша мәліметтер табылып талданды: екі орыс тілді-дәрілік заттар мен медициналық бұйымдарды сараптау ұлттық орталығының КЗ ұлттық базасы, Қазақстандағы КЗ туралы деректермен бірге "дәрілік заттардың мемлекеттік тізілімі" ресейлік тіркелімі; екеуі ағылшын тілінде- ClinicalTrials.gov АҚШ Ұлттық медицина Кітапханасының халықаралық базасы және ДДҰ International Clinical Trials Registry Platform (ICTRP) клиникалық зерттеулер тізілімінің халықаралық платформасы. Сондай-ақ, жергілікті этикалық комиссиялардың деректері ескерілді. Талдау нәтижелері бойынша келесі негізгі тұжырымдар жасалды: ағылшын тіліндегі мәліметтер базасы қол жетімді және ақпараттар толық берілген; ақпарат мөлшері мен оның мазмұны әр түрлі; барлық ресурстарда мәліметтер аса жеткіліксіз. Осындай талдаулар негізінде Қазақстанда КЗ туралы ақпараттың қолжетімділігін арттыру үшін кейбір ұсыныстар берілді.

Түйін сөздер: *клиникалық зерттеу, Қазақстан, клиникалық зерттеуді тіркеу, деректердің қолжетімділігі.*

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Introduction

Clinical research (CT) is an important part of medical science. CTs are a key stage in the transition of theoretical knowledge into practice, so their importance is difficult to overestimate. Therefore, the quality of clinical trials, which depends on transparency, is ensured, among other things, by registration of clinical trials.

WHO calls for registration of all clinical trials for reasons such as

- "There is a need to ensure that decisions about health care are informed by all of the available evidence
- It is difficult to make informed decisions if publication bias and selective reporting are present
- The Declaration of Helsinki states, "Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject".
- Improving awareness of similar or identical trials will make it possible for researchers and funding agencies to avoid unnecessary duplication
- Describing clinical trials in progress can make it easier to identify gaps in clinical trials research
- Making researchers and potential participants aware of recruiting trials may facilitate recruitment
- Enabling researchers and health care practitioners to identify trials in which they may have an interest could result in more effective collaboration among researchers. The type of collaboration may include prospective meta-analysis
- Registries checking data as part of the registration process may lead to improvements in the quality of clinical trials by making it possible to identify potential problems (such as problematic randomization methods) early in the research process" [12].

CTs in Kazakhstan are carried out in relatively small numbers. Thus, according to WHO, only 243 CTs were registered in Kazakhstan, which is more than in other Central Asian regions (in Uzbekistan - 65, Kyrgyzstan - 68), but much less than in some other post-Soviet countries like Ukraine (5279 CTs), Belarus (773 CTs) or Georgia (1277 CTs) [11]. V. Koikov et al. discuss the reasons for the relatively small number of CTs in Kazakhstan, highlighting insufficient legislative regulation, bureaucratic barriers and low staff motivation. In addition, the authors of this publication mentioned unsatisfactory transparency or limited access to information about conducted CTs due to the lack of an open register [8].

In this study, we made an attempt to understand whether the situation with the transparency of data on CTs has changed and to analyze the current situation regarding the availability of information on ongoing studies in Kazakhstan.

Materials and methods

Internet data was used to search for information; using the Google search engine, several databases containing information about CTs registered in Kazakhstan were found in the public domain. The search was carried out in Kazakh, Russian and English using the queries: "clinical trials Kazakhstan", "registration of clinical trials". The following databases with data on Cts were found:

1. International CT database of the U.S. National Library of Medicine ClinicalTrials.gov (CT.gov) https://classic.clinicaltrials.gov/ct2/results?cond=&term=&country=KZ&state=&city=&dist=

2. International Clinical Trials Registry Platform (ICTRP) (WHO platform) https://www.who.int/clinical-trials-registry-platform

3. National CT database of the National Center for Expertise of Medicines and Medical Devices (NCEMMD register) https://www.ndda.kz/category/reestr_KI_LS

4. Russian Federation register "State Register of Medicines" with data on clinical trials in Kazakhstan (RF register) (https://grlsbase.ru/clinicaltrails/clintrailskz/)

Data from the clinical trial database were analyzed using descriptive statistics.

To fulfill the purpose of the study, the authors attempted to answer the following questions:

1. How easy it was to find this database;
2. In what language is the CT base;
3. When was the last update;
4. Is it possible to download CT data;
5. How many studies are included in it;
6. How many of them are active;
7. What date was the first and last CT entered;
8. How many CTs have published the results and is there information about this;
9. How many studies were registered prospectively (before the start of recruitment of trial participants);
10. Compare the available registries of CTs, whether there are any matches, and vice versa;
11. What data is collected in each of the databases.

Since in the Republic of Kazakhstan, coordination of the activities of local ethics commissions (LEC) and assessment of compliance of their activities with standards is carried out by the Central Commission on Bioethics (CCB), which is an independent expert body under the authorized body that conducts bioethical examination of documents related to biomedical research, at the planning stage, during execution and after completion in order to ensure the safety and protection of the rights of participants in biomedical research. [1] We searched for information about CTs on the official websites of the CCB and LEC, which received an opinion based on the results of an ethical review.

Results

When comparing the databases, it was discovered that the indicators used in the English-language databases are larger in number (23 indicators each) and, accordingly, can provide more information. Thus, the English-language CT.gov and the WHO platform reflect more information on the study design, include the CT identifier, and provide information about the results of the study, both interim and final. The indicators of the Russian-language databases (NCEMMD register- 12 indicators and the RF register - 10 indicators) are almost identical to each other and contain similar information (Table 1).

Table 2 shows the data obtained from a subsequent comparison of four databases of clinical trials conducted or currently being conducted in Kazakhstan. The number of studies at the time of analysis of the relevant databases (August 2023) is different: in CT.gov - 176 CTs, on the WHO platform – 280 CTs, in the NCEMMD register - 95, in the RF register - 96. At the same time, the WHO platform contains all studies registered in CT.gov. There are also 91 CTs in Russian-language databases, the data of which is present in both databases - the RF register and the NCEMMD register.

Table 1.

Indicators of the CT databases.

No	CT.gov	WHO platform	NCEMMD register	RF registry
1	Status	Primary Registry and Trial Identifying Number	Date	Date
2	States	Date of Registration in Primary Registry	Drug/ medical device	International non-propriety name
3	Interventions	Secondary Identifying Numbers	Name of the drug/medicine sample under study	A drug
4	Type of study	Source(s) of Monetary or Material Support	International non-propriety name	Drug form
5	Phase	Primary Sponsor	Drug form	Dosage
6	Sponsor / collaborators	Secondary Sponsor(s)	Dosage	Manufacturer
7	Type of financing	Contact for Public Queries	Manufacturer, country	Applicant
8	Study design	Contact for Scientific Queries	Applicant, country	Sponsor
9	Outcome/Outcome Measurements	Public Title	Sponsor, country	Phase
10	Number of participants	Scientific Title	Name of CT	Study title
11	Gender	Countries of Recruitment	CT phase	
12	Age	Health Condition(s) or Problem(s) Studied	Status	
13	Registration number (NCT Number)	Intervention(s)		
14	Other identifiers	Key Inclusion and Exclusion Criteria		
15	Name abbreviation	Study Type		
16	Beginning of CT	Date of First Enrollment		
17	Preliminary result	Sample Size		
18	Completion of the study	Recruitment Status		
19	First publication about CT	Primary Outcome(s)		
20	Latest published update	Key Secondary Outcomes		
21	Results published for the first time	Ethics Review		
22	Locations	Completion date		
23	Research documents	Summary Results		

Results on the ease of finding data on CT conducted in Kazakhstan showed that on the Internet, databases in English appear in the first lines of search results, while the register of drugs of the Russian Federation appears on the third page of the search. The NCEMMD database is not reflected when asked in the Google search engine, but on the NCEMMD website it is located in the "Register of Clinical Trials of the Republic of Kazakhstan" section and is reflected when you click "искать" in the Russian version of the site and "іздеу" in the Kazakh version of the site.

In Russian-language databases it is not indicated whether the results of the CTs are published; in the English-language databases this information is present in 22 (12.5%) of 176 CTs in the CT.gov database and in 32 (11.4%) of 280 CTs on the WHO platform.

Data on whether CTs were registered before the start of recruiting participants is available in English-language databases. There are 134 (76.1%) such studies in the CT.gov database, and 209 (74.6%) on the WHO platform.

Table 2.

Description of the main CT databases.

Indicators	CT.gov	WHO platform	NCEMMD register	RF register
1	2	3	4	5
Accessibility (ease of finding)	When requested in English it appears in the top lines	When requested in English it appears in the top lines	Does not appear as a search result in any of the three languages examined. It is located on the **NCEMMD** website in the section "Register of CTs of the Republic of Kazakhstan" and is reflected when you click "искать" in the Russian version of the site and "іздеу" in the Kazakh version of the site	Available on the third search page
Language of information	English	English	Russian	Russian

Continuation of Table 2.

1	2	3	4	5
Update information	Yes	Yes	No	No
Is it possible to download as a file?	Yes	Yes	No	Yes, only after using the filter
Number of CIs as of 08/02/2023	176	280	95	96
Start and end date of the first CI	August 2006 - March 2011	March 5, 1998 - November 18, 2016	07.28.2015 – no information	April 22, 2014 – no information
Start date of last CI	August 2023	2023-07-11	07/09/2021	May 15, 2023
Number of CTs matched	176 in English-language databases		91 Russian-language databases	
Number of unique CTs	0	104	4	5
Number of trials with published results	22 (12.5%) 19.3% (for completed 114 CTs)	32 (11.4%)	No data	No data
Number of CTs registered prospectively (before the start of recruitment of CT participants)	134 (76.1%)	209 (74.6%)	No data	No data
CT status	Active, not recruiting – 11 Completed – 114 Not yet recruiting) – 4 Recruiting – 23 Suspended – 1 Terminated – 4 Unknown – 17 Withdrawn - 2	Authorized – 14 Not recruiting – 214 Recruiting - 52 _	Completed – 45 Discontinued – 2 Suspended – 1 Ongoing – 31 No information – 16	Completed – 41 Discontinued – 2 Ongoing – 31 No information - 22

Based on the results of a study of information on the CCB website, there is data on registered 29 LEC of scientific organizations and educational organizations, as well as 5 LEC of medical colleges and other organizations. Information about the bioethical examinations carried out for conducting CTs and biomedical research was collected from the official websites of the organizations (Supplementary Table 1). There is no information on the examinations carried out on the official page of the CCB. Of the 29 LEC of scientific and educational organizations, only 8 have annual reports on the examinations carried out in the public domain with the data on the name of the study, source of funding, name of the organization, status of approval and disapproval of the study. But there is no such information on the websites of LEC medical colleges and other organizations.

There is publicly available information about the examinations carried out at the LEC from 2013 to 2022 for 300 CTs. Thus, information on permission to conduct CTs based on the results of examinations of the LEC coincides with the NCEMMD register in only 5 applications (5.3%). There were 9 matches out of 176 CTs (5.11%) with the CT.gov register and the WHO platform. In the RF registry, 5 applications out of 96 registered coincided (5.2%).

Table 3.

The studies according to LEC data.

Type of study	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
CT	3	4	3	1	8	14	2	2	3	2
Biomedical research		11	14	11	5	6	36	2	17	
Biomedical research using biospecimens					1	3	10	19	3	
Research involving humans					9		1	1		
Research involving animals			4	8	29		12	37		6
Research using biospecimens and research involving animals							2	5		1
Biomedical research involving people and animals					5					
TOTAL	**3**	**15**	**21**	**20**	**57**	**23**	**63**	**66**	**23**	**9**

Discussion

The main conclusions of this study were the following:

1. Availability of English-language databases and limitations of Russian-language databases

2. Discrepancy between the amount of information and its content in the four databases

3. Incomplete data

Each of these findings has been discussed below.

1. Availability of English-language databases and limitations of Russian-language databases

To find information about CTs in English, the least amount of effort was spent; the data was obtained by requesting registered CTs; both platforms (CT.gov and the WHO platform) showed results for Kazakhstan immediately when applying the appropriate filter. Data from both resources can be downloaded as a file that can be easily converted to Excel format. However, it is worth noting that the prevalence of English proficiency in Kazakhstan is unknown to the authors. There is a report from the Education First organization, which conducts annual tests of English language proficiency in more than a hundred countries around the world, and according to their data, Kazakhstan has Very Low Proficiency of the English language. [5] Low English language proficiency likely poses some limitations in the availability of these data to the general public.

Data from Russian-language sources are reflected much later, as in the case of the RF Register, which was found only on the third page of Google results, or are located on the NCEMMD website in the section with the CT register in which it is logical to enter search parameters, but in order to see the data of all available CTs you need to click on the “search / izdeu” icon without entering any search parameters, which seems to the authors not the most obvious way to search. In addition, the data could not be downloaded as a single file, which requires additional manipulations to save the data as a file. Thus, to find aggregated information about CTs conducted in Kazakhstan, it is better to search in English, as well as directly on the NCEMMD website.

2. **Discrepancy between the amount of information and its content in the four databases**

At this point, we also see differences in Russian-language sources and English-language ones. Both English-language sites provide preliminary information about how their CT databases were formed, based on what requirements, what reasons are behind the collection of CT data, etc. Thus, the WHO platform accepts data on CTs from other primary registries and, accordingly, sets a number of requirements for them, such as a list of indicators that must be included in the register, accessibility, clear identification of CTs, data management etc. (https://www.who.int/ clinical-trials-registry-platform/network/registry-criteria). In total, the WHO platform has 17 primary data sources, which include both international and national CT registries (https://www.who.int/clinical-trials-registry-platform/network/primary-registries), including the CT.gov, which explains the presence of all CT register data on the WHO platform, as well as their uniformity in content.

Unfortunately, the authors were unable to find information on how the data gets into the CT registers of the Republic of Kazakhstan and the Russian Federation. However, it is logical to assume that since NCEMMD (on which website the register of CT of the Republic of Kazakhstan is posted) is responsible for conducting the examination of CTs of drugs, which is a mandatory step in obtaining permission to conduct CTs from the authorized body of the Committee for Medical and Pharmaceutical Control of the Ministry of Health, it has information about all submitted applications for conducting CTs in Kazakhstan and, accordingly, has the opportunity to create a register of CTs in the Republic of Kazakhstan. However, the final decision on permission is issued by the authorized body on the basis, inter alia, of the examination of materials from CTs of medicinal products, carried out by the National Center for Drug Control, and the ethical examination carried out by the CCB, in accordance with the current legislation of the Republic of Kazakhstan. [2]

3. Incomplete data

In addition, the registers of the Republic of Kazakhstan and the Russian Federation do not contain such important information as study results, contact person, the study design, inclusion/exclusion criteria, number of planned participants, etc. All this information is critical for transparency and improving the quality of CTs. According to many international requirements, registration of a CT must be carried out before the first participant in a CT is recruited, which is a prerequisite for publishing the results of a CT in many peer-reviewed journals. However, such information is not available in the registers of the Republic of Kazakhstan and the Russian Federation. According to the WHO platform and CT.gov registry, about three quarters of all CTs conducted in the Republic of Kazakhstan were registered before the start of recruitment of study participants. These results are consistent with data obtained from the register by the CT.gov study team Lamberink HJ et al., which demonstrates that 72.6% (69 of 95) in 2016 were registered before the start of recruitment of study participants [9]. Slightly different data were obtained by Mustafa Al-Durra et al, namely, 71.2% of published articles on the results of CT indicated the identifier of the registered CT and only 41.7% registered the CT prospectively. [3]

Also, only 12.5% (19.3%) and 11.4% of Kazakhstani CTs have data on published results according to the CT.gov registry and the WHO platform, respectively. This is much less compared to publications in other countries. For example, according to a study conducted in New Zealand, 88.6% of the results of CTs performed from 1999 to 2017 were disseminated [7], in Hungary 24.1% of studies did not have published results [11], in the Netherlands 77% of CTs had published results [6], which makes the share of CT with published results in Kazakhstan very small. All of the above studies stipulate that publication as an article in a scientific journal takes some time, however the primary registries of the WHO platform allow preliminary and final results to be published directly on these platforms so that the interested public can have access to information about what was studied and what the results were received.

Many international and academic requirements (https://classic.clinicaltrials.gov/ct2/manage-recs/background) require that investigators, authors, sponsors, editors, and publishers have ethical obligations regarding the publication and dissemination of research

results. [4] Researchers are obliged to publish the results of their studies on people and are responsible for the completeness and accuracy of their reports to the CCB and/or LEC, but based on the results of searching for information about obtaining a positive decision from the ethical commission, it suggests that in only 23.5 % of websites of officially registered LEC contain information about applications that have received approval. Thus, the availability of information about CTs in the Republic of Kazakhstan on the websites of the LEC and the CCB is limited. In the vast majority of cases, the general public does not know which applications have been approved by ethical commissions, whether the implementation of the principles of safety, justice and benefit for research participants is monitored by ethical commissions; theoretically, such information could be useful for potential participants in CTs, other ethical commissions and clinics as potential bases for CTs. However, given the voluntary nature of the work of ethical commissions, probably the best solution would be to introduce reporting on the results of the examination and monitoring of ethical commissions into the CT register, as is done on the resources of the WHO platform (https://www.who.int/clinical- trials-registry-platform/network/registry-criteria) without obliging liability to LEC.

Conclusion

The analysis of the current situation on the availability of information on CTs in Kazakhstan demonstrated that the Kazakhstani Russian-language register exists, but finding it requires knowledge of the procedures for obtaining permission to conduct CT, and therefore the existence of the NCEMMD website. More accessible sources of information are the English-language WHO platform and the CT.gov registry. However, all the sources found by the authors have a significant proportion of incomplete or missing data on important indicators such as the presence of published results, prospective registration of CTs, details of the study design and the planned number of participants in Russian-language registers.

Thus, to improve the quality of data on CTs conducted in Kazakhstan, to increase the transparency and quality of CTs, to increase the availability of information about CTs both for potential participants and their close ones, for researchers, for potential sponsors, we offer the following:

1. Make the Kazakhstan register available when searching on Google
2. Make register data available in Kazakh and English languages
3. Add indicators as standard ones for primary registers of the WHO platform
4. Strive for the Kazakh registry to become the primary registry of the WHO platform and/or register Kazakhstani CTs in the primary WHO registries
5. Oblige research teams to register CTs in the Kazakhstan registry with regular updates of information as the research progresses
6. Creation of a legal basis for ensuring the operation of the register, that is, ensuring that measures are taken, if necessary, based on the register data or lack of it.
7. Ensure openness and accessibility on the websites of the LEC and the CCB about the passage of ethical examination to ensure biosafety for conducting CTs, as well as the results of ongoing and final monitoring of CTs carried out by LEC.

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