Clinical Trial Sites
in Eastern Europe and Central Asia
HIV, Viral Hepatitis, Tuberculosis
Brief Landscape Review

March 2021
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List of Abbreviations

CAB – Community Advisory Board
CRO – Contract Research Organisation
CT – Clinical Trial
CTS – Clinical Trial Site
EATG – European AIDS Treatment Group
EC – Ethics Committee
EECA – Eastern Europe and Central Asia
EEU – Eurasian Economic Union
EU – European Union
GCP – Good Clinical Practice
GLI – Global Laboratory Initiative
GLP – Good Laboratory Practice
GMP – Good Manufacturing Practice
GVP – Good Pharmacovigilance Practice
HBV – Hepatitis B Virus
HCV – Hepatitis C Virus
HIV – Human Immunodeficiency Virus
ICH – International Conference on Harmonization
IUATLD – International Union Against Tuberculosis and Lung Disease
IMP – Investigational Medical Product
MDR-TB – Multi-drug resistant tuberculosis
NLN – Nordic Council on Medicines
SRLN – Supranational Reference Laboratory Network
TB – Tuberculosis
WHO – World Health Organisation
XDR-TB – extensively drug-resistant tuberculosis
Disclaimer

The information contained in this report has been taken from public sources or obtained through confidential interviews with country experts over the period of September-October 2020. This report represents an update of the first edition produced in 2015 and contains some of the data originally obtained over the period of November 2015.

The authors do not guarantee 100% accuracy of the data obtained from third parties and, likewise, might not share the opinions of third parties cited in this report. The authors do not carry any responsibility for the use or interpretation of data, conclusions and recommendations presented in this report by third parties. The conclusions and recommendations contained in this report express the points of view of the authors which might not coincide with views held by other interested parties. No mention of the clinical trial sites means that the authors of the report recommend these centres. The authors have made all possible efforts to provide up-to-date information about the laws and norms regulating the field of clinical trials, effective as of the date of the report. However, the lists of these norms and clinical trial sites may not be exhaustive; likewise, some of the norms may no longer have legal effect, and some of the sites might no longer function when this report is accessed.

The document can be subject to changes.

[The current draft was last reviewed on 17/3/2021]
Background

Access to new drugs for treating and preventing HIV, viral hepatitis and tuberculosis in Eastern Europe and Central Asia (EECA) remains limited. For some patients, clinical trials (CT) represent one of the few opportunities of getting access to life-saving treatment. The request to initiate clinical trials in EECA has been voiced by representatives of EECA countries at numerous meetings with pharmaceutical companies, including community advisory board meetings in Europe (ECAB) and EECA (Eurasian Community for Access to Treatment, ECAT). For some countries like Russia, conducting local clinical trials is a legal prerequisite for drug registration. Overall, there is limited information about CT centres in the region. To accumulate and analyse data about medical institutions potentially having capacity of conducting CTs of drugs for treating HIV, HCV, HBV and TB, EATG launched a pilot monitoring and analysis project. This report represents an update of the first edition produced in 2015.

The countries covered by this edition include Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Ukraine, and Uzbekistan. Estonia, Latvia, Lithuania, Poland were covered by the first edition; the second edition does not cover them as it has been decided to focus the project on countries outside the European Union.

Project Methodology

A review of publicly available sources has been carried out to analyse basic requirements and the regulatory framework for clinical trials in the respective countries. The literature review covered regional and national standards. References to national laws and norms regulating the field of clinical trials are given in the respective country chapters.

The authors have established contacts with representatives of national non-governmental organisations to collect information about CT centres (CTC) potentially conforming to the requirements. The lists of clinical trial centres obtained from public sources or from country representatives are given in the country sections. The https://clinicaltrials.gov/ website was also used to collect information about the CTCs currently involved in conducting clinical trials of drugs for treating or preventing HIV, viral hepatitis, and tuberculosis.

The CTC lists in the respective country chapters include:

a) centres having official approval to conduct clinical trials from the respective regulatory body (as accessed both at the time of the report preparation and as
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accessed in 2015 when the first report edition was prepared, unless evidence has been found that the centre no longer exists, has been re-named or restructured, or no longer has accreditation for conducting clinical trials);

b) centres identified by local experts as having capacity to conduct clinical trials in the field of HIV, viral hepatitis, and TB; and

c) centres referred to as currently involved in trials related to HIV, viral hepatitis, or TB on the clinicaltrials.gov website.

Whenever publicly available, references to websites containing these lists are given. The websites were last accessed over the period of September - October 2020.

The presence of a centre in the list does not mean the centre would actually conform to the requirements set by stakeholders such as pharmaceutical companies or regulatory bodies. It is also difficult to verify whether each centre currently meets the requirements by relying only the data publicly available. Such work should be performed by a team of experts, preferably through country visits. Alternatively, a large-scale qualitative survey using in-depth interviews with a range of national and international experts could be carried out.

Brief information about the requirements to clinical trial sites

According to the results of the literature review, general requirements for the clinical trial sites are set by the Good Laboratory Practice\(^1\) and Good Clinical Practice\(^2\) guidelines. Each country also sets its own standards regarding clinical trials. For most countries, the authors have been able to find this information; a brief review is presented in the respective country sections, following by a more detailed list of laws and regulations. These are normally available publicly in national languages.

The national requirements of most EECA countries stipulate that the sites should follow the GLP guidelines (for pre-clinical studies) and the GCP guidelines. For example, in Russia GCP is integrated as a standard through national regulatory norms (see the respective chapter in the report). According to national rules in most countries covered by the research, clinical trial sites must undergo a certification procedure to obtain an official approval for conducting clinical trials (notably, in Russia such certification shall no longer be applied starting from 2021, according to the updated information about regulatory norms). As stated above, the authors relied mostly on the lists of such centres available publicly.

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\(^1\) [http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm](http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm)

To gain a better understanding of the clinical trial field in EECA, interviews with representatives of international pharmaceutical companies producing drugs for preventing and treating HIV and viral hepatitis, as well as representatives of associations of clinical trial organisations were also conducted. According to the answers, all the work related to organising and conducting clinical trials is carried out through specialized contract research organisations (CRO), such as PRA Health Sciences\(^3\) and PPD\(^4\). These organisations provide recommendations to the companies regarding the choice of clinical trial sites.

Almost all the trials conducted in the countries of EECA are phase III (pre-registration) clinical trials, and neither CROs nor pharmaceutical companies are willing to take the risks of choosing unreliable centres. In most cases, preference is given to centres which the company has experience of working with. Basically, the centres must meet the two major criteria:

- Compliance with GLP (pre-clinical studies) and GCP guidelines;
- Capacity to recruit participants quickly.

Countries are chosen primarily on operational considerations such as the ability to recruit the required number of participants in the required timeline and access to suitable and representative patient populations (e.g. genotypes). For some indications, the standard of care must be considered as most studies are conducted globally and use of concomitant and background medication needs to be consistent.

Compliance with GCP is normally verified by means of monitoring activities carried out by CRO and pharmaceutical companies, as well as relevant government authorities. These can be national (in Russia, for instance, such inspections are carried out by Roszdravnadzor) or foreign (for multicentral trials, such inspections can be carried out by FDA or EMA). Over the course of clinical trials compliance with GCP is audited either by independent audit companies or by the pharmaceutical companies themselves. There are summary reports about violations identified in clinical trials; such reports are published, for instance, by the Association of Clinical Trials Organizations.

Overall, the region is considered equally friendly for the conduct of clinical trials when compared to other regions of the world (this is a perception of one of the interviewees). Trials in the region usually start up in line with other regions and the number of

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\(^3\) [http://prahs.com/](http://prahs.com/)

\(^4\) [http://www.ppidi.com/](http://www.ppidi.com/)
participants recruited can be higher. Extra work can be involved when setting up a trial in Russia in most cases – local depot required, full translations of IB and protocol, as well as custom clearance issues.

Based on the absolute number of trials in the EECA countries (in accordance with the data of clinicaltrials.gov), one can assume that the most attractive countries for CTs among the ones covered by the project are Russia, Ukraine, and Georgia, respectively, followed by Belarus and Moldova. This is confirmed by interviews with experts and information in the media. Some countries, such as Kyrgyzstan, are in the process of developing a detailed regulatory framework for clinical trials. Country experts in Kyrgyzstan have indicated a lack of norms regulating CT as one of the obstacles for expanding this area in the country.

In 2020, some of the centres presented in this report have been involved in clinical trials of experimental drugs for treating COVID-19. For example, clinical trials of generic versions of favipiravir and remdesivir – drugs tested against COVID-19 – were performed in Russia to provide data for emergency registration of these drugs.
Armenia


The document states, among other things, that the list of sites eligible for conducting clinical trials must be approved by the Ministry of Health based on certain criteria, such as:

a) experience of conducting clinical trials of a given site;
b) technical capacity of a given site;
c) professional and research capacity of the staff.

The same decree states that to obtain an approval for conducting a clinical trial, the site should submit an application to the Ministry with a documentation package.

The following documents are required to conduct a clinical trial:
• authorisation to conduct a clinical trial (Ministry of Health)
• favourable opinion of the Ethics Committee for a clinical trial
• preclinical trials results demonstrating safety and efficiency of a drug product
• registration of a clinical trial with international / national / regional registers
• GCP, GMP
• inspection of a clinical trial
• accreditation of the clinical site
• authorisation for medicines import

Armenia has officially joined the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union (EEU), dated December 23, 2014. The EEU regulatory framework has specific norms dedicated to the Good Clinical Practice of the EEU (Decision No. 79 of Council of the Eurasian Economic Commission “On approval of the Rules of Good Clinical Practice of the Eurasian Economic Union”), Good Laboratory Practice of the EEU (Decision No. 81 of Council

5 https://ria.ru/20161020/1479636936.html
6 http://www.eurasiancommission.org/ru/act/txnreg/deptxreg/konsultComitet/Documents/Sogl_LS_Ito g.pdf
of the Eurasian Economic Commission), Rules for Conducting Clinical Trials of Biological Drugs (Decision No. 89 of Council of the Eurasian Economic Commission).

Other relevant Decisions and Recommendations on the level of the Eurasian Economic Union include:
- Decision No.78 of November 3, 2016 “On rules for registration and expertise of drug products for medical use”;
- Decision No 202 of November 26, 2019 “On approving guidelines for pre-clinical safety trials with the purpose of conducting clinical trials and registering drug products”;
- Decision No 87 of November 3, 2016 “On approving rules for good pharmacological vigilance practice of the Eurasian Economic Union”;
- Recommendation No 42 of December 17, 2019 “On guidelines for selecting not studied drug products with the purpose of conducting clinical trials”;
- Recommendation No 19 of November 3, 2020 “On applying principles of biostatistics in clinical trials of drug products”;
- Recommendation of the Commission No 11 of July 17, 2018 “On guidelines for general issues related to conducting clinical trials”;
- Recommendation No 25 of September 2, 2019 “Guidelines for pre-clinical and clinical studies of fixed-dose combinations of drug products”.

The full texts of these documents can be found online on the website of the Eurasian Commission. The national regulatory framework shall be ultimately brought in compliance with the requirements of the EEU.

The clinicaltrial.gov website contains 55 entries related to clinical trials in Armenia (accessed November 2020), with at least two trials related to TB and at least one related to HIV (behavioral study conducted by the Hope and Help NGO).

National Laws


Government Resolutions


Orders

3. Order of the Minister of Health of the Republic of Armenia dated May 17, 2011 No.05-H "On approval of the list of the documents required to obtain an authorization to conduct a clinical study and the Charter of the Ethics Committee."

List of Potential Clinical Trial Sites

Based on literature review and interviews with local experts, as well as analysis of the clinicaltrials.gov website, the following potential clinical trials centres and contract research organisations with a capacity of carrying out research in the field of HIV, viral hepatitis and TB have been identified:


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8 Here and hereinafter, the information about clinical trial centres is provided in the following format: city, name, address and contact details (if available)
3. **Yerevan**, Medical Research Centre of Dermatology and Sexually Transmitted Diseases.
4. **Yerevan**, Republican Medical Centre.
7. **Yerevan**, National Treatment Centre for Pulmonology [http://www.ntp.am/](http://www.ntp.am/)
8. **Yerevan**, School of Public Health, American University of Armenia Fund.
Azerbaijan

The rules for conducting clinical trials in the Republic of Azerbaijan are described in the last updated version of the Resolution of the Cabinet of Ministers of the Republic of Azerbaijan No.83 dated April 30, 2010 “On approval of the rules for conducting scientific research, preclinical studies and clinical trials of medical drug products” (dated March 13, 2019, the Resolution of the Cabinet of Ministers of the Republic of Azerbaijan No.89). No official Russian or English translations of the whole document have been found online. There is paucity of official and mass media information about the rules for conducting clinical trials. Below follows a list of national laws and norms that the authors were able to identify as a result of literature review.

National Laws


Government Resolutions


The clinicaltrials.gov website contains 15 entries related to clinical trials in Azerbaijan, either active or completed (website accessed November 2020). None of them are related to HIV, viral hepatitis or TB.

List of Potential Clinical Trial Sites

Based on literature review and interviews with local experts, as well as analysis of the clinicaltrials.gov website, the following potential clinical trials centres and contract research organisations with a capacity of carrying out research in the field of HIV, viral hepatitis and TB have been identified (all located in Baku):

1. Centre for Analytical Expertise of Medicines under the Ministry of Health of Azerbaijan
2. Republican Clinic named after Mirkasimov
3. Research Institute of Clinical Medicine named after academician M.A.Topchubashev
4. Central Clinical Hospital
6. Scientific Research Institute of Lung Diseases Baku, Sherifli str. 2514
7. Azerbaijan Gastroenterology and hepatology Association
9. Medicines Analytic Review Centre (MARC)
Belarus

According to the analysis of the regulatory framework, a CT in Belarus can be done only by State Institutions approved by the Ministry of Health after obtaining a specific approval from the Ministry of Health (in the case of the positive results of the pre-clinical studies). The list of the approved centers is updated at least once a year and published on the website of the Republican Centre of Expertise and Tests in Healthcare⁹. The Republican Center of Expertise and Trials in Healthcare was established in 1997. The centre is currently responsible for all stages of registration, CT, as well as other tests, import/export movements and circulation of drug products and medical devices, pharmacovigilance, inspections including GCP and GMP (within the country and abroad). Verifying compliance with Good Pharmacy Practice (including GCP, GMP) also falls within their responsibility. The Republican Centre is also authorised to audit and control clinical trial sites.

The application forms are available on the official website. The documents are first submitted to the Ministry of Health: notarised translation is required. A local ethical committee of the research institution should approve the CT¹⁰ before it is submitted to the Ministry of Health. The Ethics Committee, established in 2008, should also approve the CT as a part of the agreed procedure.

Belarus has officially joined the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union (EEU), dated December 23, 2014¹¹. The EEU regulatory framework has specific norms dedicated to the Good Clinical Practice of the EEU (Decision No. 79 of Council of the Eurasian Economic Commission “On approval of the Rules of Good Clinical Practice of the Eurasian Economic Union”), Good Laboratory Practice of the EEU (Decision No. 81 of Council of the Eurasian Economic Commission), Rules for Conducting Clinical Trials of Biological Drugs (Decision No. 89 of Council of the Eurasian Economic Commission).

Other relevant Decisions and Recommendations on the level of the Eurasian Economic Union include:

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⁹ https://www.rceth.by/
¹⁰ http://www.eurecnet.org/information/belarus.html
- Decision No.78 of November 3, 2016 “On rules for registration and expertise of drug products for medical use”;
- Decision No 202 of November 26, 2019 “On approving guidelines for pre-clinical safety trials with the purpose of conducting clinical trials and registering drug products”;
- Decision No 87 of November 3, 2016 “On approving rules for good pharmacological vigilance practice of the Eurasian Economic Union”;
- Recommendation No 42 of December 17, 2019 “On guidelines for selecting not studied drug products with the purpose of conducting clinical trials”; 
- Recommendation No 19 of November 3, 2020 “On applying principles of biostatistics in clinical trials of drug products”; 
- Recommendation of the Commission No 11 of July 17, 2018 “On guidelines for general issues related to conducting clinical trials”; 
- Recommendation No 25 of September 2, 2019 “Guidelines for pre-clinical and clinical studies of fixed-dose combinations of drug products”.

The full texts of these documents can be found online on the website of the Eurasian Commission. The national regulatory framework shall be ultimately brought in compliance with the requirements of the EEU.

The clinicaltrials.gov website contains 287 entries related to clinical trials in Belarus, either active or completed (website accessed November 2020). At least several of them are related to HIV, viral hepatitis, or TB.

National Laws
Government Resolutions\(^1\)

1. The Resolution dated May 07, 2009 No.50 "On approval of the technical code of the established practice "Good Clinical Practice" (as amended by the Resolution of the Ministry of Health of 04.05.2012 No.44, as amended by the Resolution of the Ministry of Health of 06.06.2012 No.60)


3. The Resolution of the Ministry of Health of the Republic of Belarus dated 17.04.2015 No.46 "On approval of the Guidelines for the procedure and conditions for inspecting clinical trials of the medicines in terms of their compliance with the requirements of the Good Clinical Practice"


5. The Resolution of the Ministry of Health of the Republic of Belarus dated 13.10.2008 No.168 "On establishing time rates for the services on approbation of the methods of analysis of medicines, pharmaceutical substances, medicines quality control when ordering their clinical trials and inspection of the quality of the medicines authorized in the Republic of Belarus prior to circulation, as well as the medicines in circulation in the Republic of Belarus, provided by the state healthcare organizations" (as amended 15.12.2015 under No.122)

6. The procedure for organization and performance of the Ethics Committee. Methodological recommendations No.16 dated 01.01.2000

7. The Resolution of the Ministry of Health of the Republic of Belarus dated 28.03.2008 No.55 "On approval of the Regulations on the Ethics Committee" (as amended 17.04.2015)

8. The Resolution of the Ministry of Health of the Republic of Belarus dated 28.03.2008 No.56 "On approving the technical code of common practice"

Orders


2. The Order of the Ministry of Health of the Republic of Belarus No.251 dated 22.03.2016 “On Certain Aspects of Clinical Trials and on Repealing the Order of the Ministry of Health of the Republic of Belarus No 1338 dated December 16,

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\(^1\) A regularly updated list of laws and regulations in force in the Republic of Belarus is available at the website [https://www.rceth.by/ru/Documents/Drug](https://www.rceth.by/ru/Documents/Drug)
Comment: The Order which has been repealed stipulated the requirements for obtaining approval of the contracts for clinical trials by the Ministry of Health and set requirements as to the price of the CT contracts.

List of Potential Clinical Trial Sites

Based on the data of the official internet site of the Ministry of Health, 102 clinical trials centres based in Belarus have been identified (data as of October, 2020)\(^\text{14}\); below follows the list of clinical centres which can be related to infectious diseases and tuberculosis based on the extra information given in the detailed description of the centres. The list also includes centres mentioned at the clinicaltrials.gov website and those identified by local experts.

1. **Brest**: Brest Regional Clinical Hospital, [https://www.hospital.brest.by](https://www.hospital.brest.by)
2. **Homel**: Homel Regional Infectious Diseases Hospital, (Phase II-IV, profile “Diagnosis and treatment of infectious diseases”). [http://uzgoikb.by/](http://uzgoikb.by/), Gomel, ul. Feduninskogo, 18
3. **Homel**: Homel Regional Clinical Hospital [https://gokb.by/](https://gokb.by/)
4. **Homel**: Homel Regional Tuberculosis Clinical Hospital [http://www.gotkb.by/](http://www.gotkb.by/)
5. **Hrodna**: Hrodna Regional Infectious Diseases Hospital (Phase II-IV, profile “Diagnosis and treatment of infectious diseases”) [http://goicb.by/](http://goicb.by/), 230030, Grodno, blvd Leninskiy Komsomol, 57
7. **Mahiliou**: Mahiliou Regional Pediatric Clinical Hospital (infectious diseases) [https://uzmodb.by/](https://uzmodb.by/)
8. **Minsk**: City Clinical Hospital No. 9 (liver diseases).
11. **Minsk**: Minsk Clinical Centre for Phthisiopulmonology. [http://mkcpf.by](http://mkcpf.by)
12. **Minsk**: Central Military Clinical Medical Centre (infectious diseases) [https://www.mil.by/ru/health/medicine/950/](https://www.mil.by/ru/health/medicine/950/)

\(^{14}\)http://rceth.by/ru/Departments/Rcpl/Documents/2
14. **Minsk.** Minsk Scientific and Practical Centre of Surgery, Transplantology and Hematology State Institution. [https://msth.by/english](https://msth.by/english)


17. **Viciebsk.** Viciebsk Regional Tuberculosis Dispensary, [http://tubdispvitebsk.by/](http://tubdispvitebsk.by/)

18. **Viciebsk.** Viciebsk Regional Clinical Infectious Diseases Hospital [https://vokib.103.by](https://vokib.103.by)

19. **Republican Scientific and Practical Centre Mother and Child (infectious diseases in children).** [https://www.medcenter.by/](https://www.medcenter.by/)
Georgia

To perform a CT in Georgia, a specific approval must first be obtained from the Ministry of Health; then, the CT must be approved by the Ethics Committee. The centre should comply with the national GCP standards. The documents are first submitted to local ECs; notarised translation is required. The national EC is not involved, except for cases of Phase I trials or medical devices. Accreditation of CT centres is not required.

The legislation and system of organising clinical trials in Georgia makes it attractive for international clinical trials. According to public sources, it can take as little as one month from the document preparation to the actual study launch.

Georgia was among the first countries in the region of Eastern Europe and Central Asia to initiate a study of pre-exposure prevention of HIV as part of a demonstration project\(^\text{15}\), which is an indication of the country’s potential capacity to conduct clinical trials in this field.

The clinicaltrials.gov website contains 415 entries related to clinical trials in Georgia, either active or completed (website accessed November 2020). Georgia ranks third in terms of the absolute number of trials among the project countries, after Russia and Ukraine. At least several of the entries are related to HIV, viral hepatitis, or TB.

National Laws

1. Law No.1775 dated 24.06.2005 About License and Permissions, as updated December 09, 2005; May 25, 2006; June 23, 2006; July 24, 2006; July 25, 2006; December 29, 2006; March 28, 2007; May 08, 2007; December 14, 2007; March 14, 2008; March 19, 2008; November 21, 2008; December 05, 2008; March 27, 2009; June 12, 2009; August 10, 2009; September 24, 2009; November 03, 2009; December 01, 2009; April 08, 2010; July 02, 2010; July 21, 2010; October 15, 2010; November 12, 2010; February 22, 2011; April 08, 2011; May 17, 2011; June 21, 2011; June 24, 2011; October 11, 2011; October 13, 2001; November 08, 2011; December 09, 2011; December 20, 2011; December 27, 2011; March 16, 2012; March 20, 2012; March 27, 2012; April 24, 2012; May 25, 2012; June 22, 2012; September 06, 2013; November 29, 2013; February 05, 2014; February 20, 2014; May 14, 2014; May 29, 2014; September 18, 2014; March 20, 2015; June 12, 2015; April 13, 2016; March 22, 2017; April 21, 2017; May 17, 2017; June 01, 2017; June 28, 2017; December 07, 2017; May 04, 2018; June 27, 2018;

\(^{15}\) [https://aidscenter.ge/2018_05_05_eng.html](https://aidscenter.ge/2018_05_05_eng.html)
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July 20, 2018; July 21, 2018; October 31, 2018; December 22, 2018; December 26, 2018; April 19, 2019; November 01, 2019; December 20, 2019; February 19, 2020; March 17, 2020; May 22, 2020; June 12, 2020; June 26, 2020; June 25, 2020; July 15, 2020; July 17, 2020.

2. Law No.5069-вс dated 27.06.2007 About Public Health, as updated November 03, 2009; March 09, 2010; March 23, 2010; September 24, 2010; November 12, 2010; March 22, 2011; March 27, 2012; May 08, 2012; March 25, 2013; May 29, 2014; March 20, 2015; April 01, 2015; May 01, 2015; July 08, 2015; November 11, 2015; December 11, 2015; April 13, 2016; June 24, 2016; June 01, 2017; December 07, 2017; June 27, 2018; July 05, 2018; October 31, 2018; November 14, 2018; December 22, 2018; April 02, 2019; April 23, 2020; May 22, 2020; July 14, 2020; July 17, 2020.

3. Law No.659 dated 17.04.1997 About Medicines and Pharmaceutical Activities, as updated December 09, 1999; July 13, 2000; December 28, 2000; December 18, 2001; April 10, 2002; December 25, 2002; May 08, 2003; August 13, 2004; June 08, 2005; October 11, 2005; March 21, 2008, June 18, 2008; August 10, 2009; September 24, 2009; February 12, 2010; July 21, 2010; November 12, 2010; December 17, 2010; March 27, 2012; July 30, 2013; December 25, 2013; June 27, 2015; December 23, 2017; July 05, 2018; September 10, 2018; September 02, 2020.

National Standard

List of Potential Clinical Trial Sites
Based on literature review and interviews with local experts, the following clinical trials centres have been identified:

1. Tbilisi. Arensia (phase I Clinical Trial Unit) [http://www.arenzia-em.com/phase-1-units/]
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Treatment and Prevention of HIV:
2. **Kutaisi**, Centre for Infectious Pathology, AIDS and tuberculosis, no website available.
3. **Tbilisi**: Georgian Research Centre of AIDS and Clinical Immunology; [http://www.aidscenter.ge/index_eng.html](http://www.aidscenter.ge/index_eng.html)
4. **Tbilisi**: Tbilisi Infectious Diseases Hospital or Tbilisi Centre for Infectious Pathology, AIDS and Clinical Immunology

Tuberculosis:
1. **Abastumani**: Tuberculosis Hospital
3. **Kutaisi**: Centre for Tuberculosis and Lung Disease in Western Georgia
4. **Poti**: Tuberculosis Hospital
5. **Tbilisi**, National Centre for Tuberculosis and Lung Disease, [http://www.tbgeo.ge](http://www.tbgeo.ge)
6. **Zugdidi**: Regional Tuberculosis Clinical Hospital

Viral Hepatitis:
2. **Tbilisi**: Georgian Research Centre of AIDS and Clinical Immunology; [http://www.aidscenter.ge/index_eng.html](http://www.aidscenter.ge/index_eng.html)
6. **Tbilisi**: “Cito” Medical Centre, [http://www.cito.ge/](http://www.cito.ge/)
7. **Tbilisi**: “Medical Research Centre” LLC
8. **Tbilisi**: “Anti-Sepsys Centre of Vakhtang Bochorishvili”
Kazakhstan

In Kazakhstan, an approval from the Ministry of Health is required to conduct a CT on the territory of the country. The trial should also be approved by the so-called Commission on Bioethics (in accordance with the new edition of the code, see below). The centre must comply with the national GCP. All the standards (GCP, GMP, GLP, GVP etc) were approved on May 27, 2015 by the Order of the Minister of Health and Social Development of the Republic of Kazakhstan No.392 and updated May 08, 2019 by Order No.KP ΔСМ-71. Licensing of centres is required; a specific approval for importation of medicines must be obtained.

Prior to commencement of a clinical trial, a sponsor shall obtain a written authorisation of all the parties involved in the clinical trial for providing direct access to all the clinical databases involved in the trial, to all primary data/documents and reports for their monitoring and audits by the sponsor as well as the inspections of the clinical trials. During the clinical trials, the sponsor may order an audit of the clinical trials in order to control and ensure quality of the clinical trial, systematic and independent check of the documentation and activities of the parties involved in the trial; this is a desirable, but not a compulsory procedure.

Clinical trials in humans can be conducted in Kazakhstan only for domestic drug products. Foreign drug products can be registered with already completed 3 phases of clinical trials; in their case, only non-interventional, post-marketing studies can be conducted.

Kazakhstan has officially joined the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union (EEU), dated December 23, 2014. The EEU regulatory framework has specific norms dedicated to the Good Clinical Practice of the EEU (Decision No. 79 of Council of the Eurasian Economic Commission “On approval of the Rules of Good Clinical Practice of the Eurasian Economic Union”), Good Laboratory Practice of the EEU (Decision No. 81 of Council of the Eurasian Economic Commission), Rules for Conducting Clinical Trials of Biological Drugs (Decision No. 89 of Council of the Eurasian Economic Commission).

Other relevant Decisions and Recommendations on the level of the Eurasian Economic Union include:

- Decision No.78 of November 3, 2016 “On rules for registration and expertise of drug products for medical use”;
- Decision No 202 of November 26, 2019 “On approving guidelines for pre-clinical safety trials with the purpose of conducting clinical trials and registering drug products”;
- Decision No 87 of November 3, 2016 “On approving rules for good pharmacological vigilance practice of the Eurasian Economic Union”;
- Recommendation No 42 of December 17, 2019 “On guidelines for selecting not studied drug products with the purpose of conducting clinical trials”;
- Recommendation No 19 of November 3, 2020 “On applying principles of biostatistics in clinical trials of drug products”;
- Recommendation of the Commission No 11 of July 17, 2018 “On guidelines for general issues related to conducting clinical trials”;
- Recommendation No 25 of September 2, 2019 “Guidelines for pre-clinical and clinical studies of fixed-dose combinations of drug products”.

The full texts of these documents can be found online on the website of the Eurasian Commission\(^\text{17}\). The national regulatory framework shall be ultimately brought in compliance with the requirements of the EEU.

The clinicaltrials.gov website contains 110 entries related to clinical trials in Kazakhstan, either active or completed (website accessed November 2020). At least several of them are related to HIV, viral hepatitis, or TB.

**National Laws**


**Orders**


\(^{18}\) [https://online.zakon.kz/Document/?doc_id=34464437](https://online.zakon.kz/Document/?doc_id=34464437)
1. Order of the Ministry of Health of the Republic of Kazakhstan dated April 2, 2018, No. 142 on Approval of the rules for conducting pre-clinical (non-clinical) trials, clinical trials, clinical and laboratory trials, medical devices for in-vitro diagnostics, and issuing approvals for conducting clinical trials and (or) tests of medicines and medical devices (with amendments and additions as of 01.06.2020)\(^{19}\)


3. Order of the Minister of Health of the Republic of Kazakhstan dated July 18, 2018 No.432 "On the approval of the composition and the Regulation on the Central Ethics Commission"


**National Standard**

1. The State Standard of the Republic of Kazakhstan. Good Clinical Practice. (Attachment 2 to Order No.392 dated May 27, 2015, updated May 08, 2019

2. The State Standard of the Republic of Kazakhstan. Medicines Manufacture. Good Manufacturing Practice. (Attachment 3 to Order No.392 dated May 27, 2015, as updated May 08, 2019

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\(^{20}\) [https://online.zakon.kz/Document/?doc_id=39119765#pos=0:0](https://online.zakon.kz/Document/?doc_id=39119765#pos=0:0)
List of Potential Clinical Trial Sites

Based on the data published on the website of the National Centre for Expertise of Drug Products and Medical Devices\(^\text{21}\) under the Ministry of Health, over 30 clinical trials centres based in Kazakhstan have been identified. Below follows a list of CT cites which can be related to the field of infectious diseases based on the textual analysis of the titles. The full list is available in Russian on the website\(^\text{22}\). The list also contains sites identified through the clinicaltrials.gov website.

1. **Aktobe.** West-Kazakhstan Marat Ospanov State Medical University [https://www.zkgmu.kz/ru/](https://www.zkgmu.kz/ru/)
4. **Almaty.** City Hospital No.7 of Almaty, [http://www.gkb7.kz/](http://www.gkb7.kz/), tel: +7 (727) 270-86-06, 270-86-31, 270-56-33, +7 (727) 270-86-16, e-mail: info@gkb7.kz
5. **Almaty.** Almaty State Institute of Vocational Training in the field of Healthcare
6. **Almaty.** Central Clinical Hospital of the Medical Centre under the Administrative Department of the President of Kazakhstan
7. **Almaty.** City Tuberculosis Clinic under the Healthcare Department of Almaty
11. **Almaty.** Crocus Medical B.V. (Contract Research Organization) [http://crocusmedical.com/?q=en/node/106](http://crocusmedical.com/?q=en/node/106); Telephone: +7 (727) 272 63 99, +7 778 974 09 44, +7 778 974 09 43 Address: 308-531 Seyfullina St. (Saryaka-Aluan business center), Almalinsky District
12. **Almaty.** MedExpert [https://medexpert.group/](https://medexpert.group/) Address: st. Karasay Batyra, b. 152/1, of. 500, Telephone: +7 727 250 0011, +7 776 250 00 11, E-mail: info@medexpert.group
8. **Karaganda.** Karaganda State Medical Academy, [http://www.kgmu.kz](http://www.kgmu.kz), Karaganda, ul. Gogol, 40
9. **Nur-Sultan.** National Medical Research Centre, [http://nnmc.kz/](http://nnmc.kz/), Astana, pr. Abylaikhana, 42, e-mail: national_clinic@nnmc.kz

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\(^{21}\) [https://www.ndda.kz/category/mainpage](https://www.ndda.kz/category/mainpage)

\(^{22}\) [https://www.ndda.kz/category/mi_prechen_klin_issled](https://www.ndda.kz/category/mi_prechen_klin_issled)
11. **Nur-Sultan.** Astana Medical University, http://www.amu.kz, Astana, ul. Beibitshilik, 49A


14. **Semey.** Semipalatinsk State Medical University. [https://semeymedicaluniversity.kz/](https://semeymedicaluniversity.kz/)

15. **Shymkent.** South-Kazakhstan State Medical Academy
Kyrgyzstan

Conducting clinical trials on the territory of Kyrgyzstan requires an authorisation from the Department of Medicines and Medicinal Devices Provision of the Ministry of Health of the Republic of Kyrgyzstan.

There are several articles in the local media stating that in real-life settings clinical trials are not conducted due to a lacking regulatory framework. In 2018-2019 there were announcements about planned renewal of the laws regulating CTs; however, no additional data regarding it was found in the public domain.23 The new procedure, according to the media, has been developed based on the rules set by the Eurasian Economic Committee, dated February 12, 2016 (No. 29)24 and November 3, 2016 (No. 79)25. It is likely that in the future Kyrgyzstan will follow the procedures in accordance with the rules of the common market of the Eurasian Economic Union (EEU).

Kyrgyzstan has officially joined the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union (EEU), dated December 23, 2014.26 The EEU regulatory framework has specific norms dedicated to the Good Clinical Practice of the EEU (Decision No. 79 of Council of the Eurasian Economic Commission “On approval of the Rules of Good Clinical Practice of the Eurasian Economic Union”), Good Laboratory Practice of the EEU (Decision No. 81 of Council of the Eurasian Economic Commission), Rules for Conducting Clinical Trials of Biological Drugs (Decision No. 89 of Council of the Eurasian Economic Commission).

Other relevant Decisions and Recommendations on the level of the Eurasian Economic Union include:
- Decision No.78 of November 3, 2016 “On rules for registration and expertise of drug products for medical use”;

24 http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/MD/Pages/medical_devices.aspx
25 http://base.garant.ru/71546282/
26 http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/konsultComitet/Documents/Sogl_LS_Ito g.pdf
- Decision No 202 of November 26, 2019 “On approving guidelines for pre-clinical safety trials with the purpose of conducting clinical trials and registering drug products”;
- Decision No 87 of November 3, 2016 “On approving rules for good pharmacological vigilance practice of the Eurasian Economic Union”;
- Recommendation No 42 of December 17, 2019 “On guidelines for selecting not studied drug products with the purpose of conducting clinical trials”;
- Recommendation No 19 of November 3, 2020 “On applying principles of biostatistics in clinical trials of drug products”;
- Recommendation of the Commission No 11 of July 17, 2018 “On guidelines for general issues related to conducting clinical trials”;
- Recommendation No 25 of September 2, 2019 “Guidelines for pre-clinical and clinical studies of fixed-dose combinations of drug products”.

The full texts of these documents can be found online on the website of the Eurasian Commission. The national regulatory framework shall be ultimately brought in compliance with the requirements of the EEU.

The clinicaltrials.gov website contains 39 entries (accessed November 2020) related to clinical trials in Kyrgyzstan (either active or completed), of which at least two are related to TB (one conducted in Bishkek, the other one in Kara-Suu, Osh Region).

**National Laws**


**Orders**

1. Order of the Ministry of Health of the Republic of Kyrgyzstan dated July 25, 2008 No.386 "On Converting the Bioethics Committee under the Pharmacological Committee of the Department of the Medicines and Medicinal Devices Provision into the Bioethics Committee under the Ministry of Health of the Republic of Kyrgyzstan"

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Government Resolutions

National Standard

List of Potential Clinical Trial Sites

Based on literature review and interviews with local experts, as well as analysis of the clinicaltrials.gov website, the following potential clinical trials centres and contract research organisations with a capacity of carrying out research in the field of HIV, viral hepatitis and TB have been identified:

2. **Bishkek. National Centre under the Ministry of Health of Kyrgyzstan**
3. **Bishkek. Republican Dermatology Clinic**
4. **Bishkek. Republican Infectious Disease Clinic, Bishkek, ul.Tolstogo, 70, rki1961@ktnet.kg tel: +996 312 59 00 53**
5. **Bishkek. Republican Pediatric Clinic, Bishkek, Akhtunbaeva, 190, tel: +996 (312) 48-42-33**
6. **Bishkek. City Clinical Hospital #6, Bishkek, ul. Dzhantsosheva, 117, tel: +996 (312) 57-09-76, +996 (312) 57-09-75**
7. **Bishkek. City Clinical Hospital #1, Bishkek, ul. Fuchika, 15, tel: +996 (312) 64-45-09**
8. **Bishkek. MedExpert [https://medexpert.group/](https://medexpert.group/) Address: st. Turusbekova, b. 109/3, of. 302, Telephone: +996 777 25 00 11, E-mail: info@medexpert.group**
9. **Kara Suu (Osh Region). Kara Suu District Tuberculosis Hospital.**
10. **Osh.** Osh Clinical Hospital, incl. Osh Pediatric Clinical Hospital, Osh, ul. Verkhne-Uvamskaya, 10, tel: +996 (3222) 55852.

11. **Osh.** Osh Oblast Tuberculosis Hospital.
**Moldova**

To perform a CT in Moldova, a specific approval must first be obtained from the Ministry of Health. The body responsible for granting these approvals is the Medicines and Medical Devices Agency\(^28\), that was established in 2005 and is responsible for regulating the clinical trial field. All the CTs must also be approved by the Ethics Committee established in 2016.

The centre should comply with national GCP standards. Accreditation of CT centres is required; also, a specific approval for importation of medicines must be obtained. It is not obligatory to include the CT into the national list of CTs.

All the documentation related to regulating the field of clinical trials, including templates for applications, is available at the website of the Medicines and Medical Devices Agency.

As of November 2020, the list of CTs in Moldova (also available at the website of the Medicines and Medical Devices Agency\(^29\)) included 126 CTs at different phases. These include at least several trials of drugs for treating HCV, HBV and MDR and XDR-TB.

The clinicaltrials.gov website contains 213 entries related to clinical trials in Moldova, either active or completed (website accessed November 2020). At least several of them are related to HIV, viral hepatitis, or TB.

Moldova was among the first countries in the region of Eastern Europe and Central Asia to initiate a study of pre-exposure prevention of HIV as part of a demonstration project\(^30\), which is an indication of the country’s potential capacity to conduct clinical trials in this field.

**National Laws**


Clinical Trial Sites in Eastern Europe and Central Asia
HIV, Viral Hepatitis, Tuberculosis
Brief Landscape Review

April 06, 2017; July 20, 2017; July 21, 2017; September 21, 2017; December 15, 2017; February 23, 2018; May 24, 2018; July 05, 2018; July 7, 2018; November 30, 2018.


Government Resolutions
1. The Resolution of the Government of the Republic of Moldova No.424, dated June 09, 2014 "On the draft law on making amendments and supplements to certain legislative acts"


Orders
1. The Order of the Ministry of Health and Social Development of the Republic of Moldova No.309 dated 26.03.2013 "On approval of the Rules of the Food Manufacturing Practice (GMP) for medicines intended for human use"

2. The Order of the Ministry of Health and Social Development of the Republic of Moldova No.10 dated 14.01.2001 "On the procedure for conducting medicines clinical trials in the Republic of Moldova"


6. The Order of the Ministry of Health and Social Development of the Republic of Moldova No.358 dated May 12, 2017 On the approval of the Regulation on the pharmacovigilance activities implementation

List of Potential Clinical Trial Sites

Based on literature review and interviews with local experts, the following clinical trials centres or organisations which can have information about such centres have been identified:

2. Chisinau, Arensia (phase I Clinical Trial Unit) http://www.arensia-em.md/
3. Chisinau, Infectious Clinical Hospital (n.a. Toma Ciorba)
4. Chisinau, Testemitanu State University of Medicine and Pharmacy, Chisinau, Republic of Moldova
6. Chisinau, Ministry of Health Hospital
7. Chisinau, Institute of Cardiology, http://www.asm.md/?go=membrii-colectivi&list=1&n=2&m=14&new_language=1
8. Chisinau, National Scientific and Practical Centre in Emergency Medicine
11. Chisinau, Psychiatric Hospital, Municipal Clinical Hospital No.1
12. Chisinau, “Trinity”, Municipal Clinical Hospital No.3
Russia

In order to register a drug in Russia, clinical trials to demonstrate safety and efficacy of that drug must be performed on the territory of the Russian Federation (Article 18 of the Federal Law No.61 “On Circulation of Medicines” as amended July 13, 2015\(^{31}\)); in case of orphan diseases (direct translation), results of clinical trials performed outside Russia can also be considered as a basis for registration. Order No.200н of April 01, 2016 stipulates the rules for performing clinical trials based on good clinical practice\(^{32}\). According to Federal Law No.61, it used to be mandatory for clinical trial sites to get accredited by the respective federal institution based on the rules set by the Government of Russia in Decree No.683 of September 3, 2010\(^{33}\). It is important to note, however, that starting from January 1, 2020, it will no longer be obligatory, and Decree No.683 shall no longer be applied\(^{34}\).

In 2012, a comparative analysis of differences between the EU and RF legislation was conducted; the results are available online: [http://ec.europa.eu/health/files/international/report_clinical-trials_sept2012.pdf](http://ec.europa.eu/health/files/international/report_clinical-trials_sept2012.pdf)

According to the Russian legislation currently in force, a report on the clinical trial results should be submitted to the Ministry of Health within three months after the completion of the study (part 11 of article 40 of the Federal Law of 12.04.2010 N 61-FZ " On Circulation of Medicines "). When it comes to studies applied for starting from September 4, 2016, these should meet comprehensive requirements for the final report. These requirements correspond to the international standards as set by ICH E3 (art. 9 of Good Clinical Practice Rules, approved by the Ministry of Health, Order of April 1, 2016 No.200н). However, it has been argued that such report meeting the ICH E3 requirements cannot be prepared within three months; another critical point is that this report cannot be based on the conclusions of medical organisations\(^{35}\).

In order to initiate a CT in Russia, a special approval must be obtained from the Ministry of Health; more specifically, this approval is issued on the basis of the assessment carried out by the National Centre for Expertise of Products for Medicinal Use. This organisation

\(^{31}\) https://roszdravnadzor.gov.ru/spec/drugs/controllsip/documents/12400 (Russian Language only)
\(^{33}\) http://base.garant.ru/12178533/#ixzz6bSCXK8mR
\(^{34}\) http://www.consultant.ru/document/cons_doc_LAW_355035/4b7a61067ade0e0a15734d6c5fc943f7ef3610170c/
\(^{35}\) http://acto-russia.org/index.php?option=com_content&task=view&id=379
has on several occasions been criticised by the Association of Clinical Trial Organizations due to the fact that several multinational CTs, including those in the field of HIV and HCV, did not receive the needed approval on unclear grounds.

Russia is part of the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union (EEU), dated December 23, 2014\textsuperscript{36}. The EEU regulatory framework has specific norms dedicated to the Good Clinical Practice of the EEU (Decision No. 79 of Council of the Eurasian Economic Commission “On approval of the Rules of Good Clinical Practice of the Eurasian Economic Union”), Good Laboratory Practice of the EEU (Decision No. 81 of Council of the Eurasian Economic Commission), Rules for Conducting Clinical Trials of Biological Drugs (Decision No. 89 of Council of the Eurasian Economic Commission).

Other relevant Decisions and Recommendations on the level of the Eurasian Economic Union include:
- Decision No.78 of November 3, 2016 “On rules for registration and expertise of drug products for medical use”;
- Decision No 202 of November 26, 2019 “On approving guidelines for pre-clinical safety trials with the purpose of conducting clinical trials and registering drug products”;
- Decision No 87 of November 3, 2016 “On approving rules for good pharmacological vigilance practice of the Eurasian Economic Union”;
- Recommendation No 42 of December 17, 2019 “On guidelines for selecting not studied drug products with the purpose of conducting clinical trials”;
- Recommendation No 19 of November 3, 2020 “On applying principles of biostatistics in clinical trials of drug products”;
- Recommendation of the Commission No 11 of July 17, 2018 “On guidelines for general issues related to conducting clinical trials”;
- Recommendation No 25 of September 2, 2019 “Guidelines for pre-clinical and clinical studies of fixed-dose combinations of drug products”.

\textsuperscript{36} \url{http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/konsultComitet/Documents/Sogl_LS_ltor.pdf}
Clinical Trial Sites in Eastern Europe and Central Asia
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The full texts of these documents can be found online on the website of the Eurasian Commission. The national regulatory framework shall be ultimately brought in compliance with the requirements of the EEU.

The clinicaltrials.gov website contains 5201 entries related to clinical trials in Russia, either active or completed (website accessed November 2020). Russia ranks first in terms of the absolute number of trials among the project countries. At least several of the entries are related to HIV, viral hepatitis, or TB.

Below follows a list of laws and norms regulating the field of clinical trials in Russia (database accessed October 2020):

Federal Laws
   http://base.garant.ru/12174909/
2. Tax Code of the Russian Federation (certain provisions), stipulating the sum of duties to be paid http://base.garant.ru/10900200/

Government Resolutions


10. Ministry of Health and Social Development of Russia Order N951н of November 02, 2010 “On approval of the register of permits issued (decisions to refuse to issue permits) to import into the Russian Federation and export from the Russian Federation of the biological materials (samples of biological fluids, tissues, secretions and excreta, physiological and pathological secretions, swabs, scrapings, microorganisms, biopsies) obtained from clinical studies of medical drugs” http://base.garant.ru/12180854/


15. Letter of the Federal Service for Surveillance in Healthcare and Social Development No. 04I-34/11 dated 27.01.2011


Clinical Trial Sites in Eastern Europe and Central Asia
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25. The Russian Federation Ministry of Health Order of August 24, 2017 No. 558п “On approval of the Rules for the examination of human medicinal products and the specificity of the examination of certain types of human medicinal products (reference medical drugs, generics, biological medicinal products, biosimilar medicinal products (similar biological medicinal products), homeopathic medicinal products, herbal medicinal products, medicinal products combinations), forms of expert commission conclusions”;
http://base.garant.ru/71835268/#ixzz6bSFwxY3l


28. The Russian Federation Ministry of Health Order of January 19, 2018 No. 20п “On approval of the Administrative Regulations of the Russian Federation Ministry of Health for the provision of state services for a trial permit issuing to conduct a clinical trial of a human medicinal product”
http://base.garant.ru/71918656/

29. The Russian Federation Ministry of Health Order of October 24, 2019 No. 880п “On amendments to the Administrative Regulations of the Russian Federation Ministry of Health for the provision of state services for a trial permit issuing to


National Standard
1. The Russian Federation National Standard GOST R 52379-2005 “Good Clinical Practice”

List of Potential Clinical Trial Sites

The full list of medical institutions currently having accreditation by the Ministry of Health is available at grls.rosminzdrav.ru (http://grls.rosminzdrav.ru/Ree_orgCI2.aspx). The full list contains over 1500 sites (database last accessed November 2020).

Below follows a list of accredited clinical trial sites related to the field of HIV, hepatitis C and TB (based on the textual analysis of titles, analysis of several currently open trials of HIV, HCV and TB drugs and interviews with experts, the list is not exhaustive):
1. Arkhangelsk. Arkhangelsk region State Budgetary Healthcare Institution “Arkhangelsk Regional Clinic TB Dispensary”
8. Irkutsk. State Budgetary Healthcare Institution “Irkutsk Regional Centre for Prevention and Control of AIDS and Infectious Diseases”; http://aids38.ru/
18. Magadan. State Budgetary Healthcare Institution “Magadan Regional Centre for Prevention and Control of AIDS and Infectious Diseases”
19. **Moscow.** Joint Stock Company “Rosch - Moscow”,
   [http://www.roche.ru/home/about/contacts.html](http://www.roche.ru/home/about/contacts.html)

20. **Moscow.** Technological company *Infectex*, Skolkovo

21. **Moscow.** Moscow Region State Public Healthcare Institution “Centre for Prevention and Control of AIDS and Infectious Diseases”,


23. **Moscow.** Moscow Clinical Hospital for Infectious Diseases No.1, [http://www.mosgorzdrav.ru/ikb1](http://www.mosgorzdrav.ru/ikb1)

24. Moscow Clinical Hospital for Infectious Diseases No.2 [http://xn--2-6kcd9arog9evc.xn--p1ai/](http://xn--2-6kcd9arog9evc.xn--p1ai/)

25. **Moscow.** Central Research Institute for Epidemiology, [http://www.nkkdc.ru/](http://www.nkkdc.ru/)


29. **Moscow.** Moscow Clinical Research Centre, [http://mknc.ru/mknts/](http://mknc.ru/mknts/)

30. **Moscow.** Central Clinical Hospital of the Russian Academy of Medical Sciences, [http://www.ckbran.ru/](http://www.ckbran.ru/)

31. **Moscow.** Federal State Budgetary Institution “Russian Academy of Medical Sciences Central Scientific Research Institute of TB”;

32. **Moscow.** MedExpert [https://medexpert.group/](https://medexpert.group/)
    Address: st. Avtozavodskaya, h. 23a, b. 2, of. 302, Telephone: +7 499 550 30 11, +7 968 550 31 11, E-mail:
    info@medexpert.group

33. Moscow H-Clinic Infections Diseases Clinic. [https://h-clinic.ru/services/](https://h-clinic.ru/services/)


36. **Novosibirsk region.** “Centre for Infectious Diseases” Limited Liability Company


38. **Petropavlovsk-Kamchatskiy.** State Budgetary Healthcare Institution “Kamchatka Territorial Centre for Prevention and Control of AIDS and Infectious Diseases”

40. Samara, Samara Regional Centre for Prevention and Control of AIDS, [http://samaraspidcenter.ru/](http://samaraspidcenter.ru/)
43. Smolensk, Smolensk Centre for Prevention and Control of AIDS, [http://www.spidsm.net/](http://www.spidsm.net/)
48. St. Petersburg, North-Western State Medical University named after I.I. Mechnikov
52. St. Petersburg, Republican Clinical Hospital for Infectious Diseases, [http://childhiv.ru/](http://childhiv.ru/)
55. Togliatti, Togliatti City Clinical Hospital No. 5.
56. Tyumen, ENDOS Consultancy and Diagnostics Centre, [http://www.kdctmn.ru/](http://www.kdctmn.ru/)
57. Vladimir, Vladimir Region State Budgetary Healthcare Institution “Centre of Specialized Phthisiopulmonological Help”
60. Voronezh. Voronezh Region Public Healthcare Institution “Voronezh Regional TB dispensary named after N.S. Pohvisneva
61. Yaroslavl. Yaroslavl Region State Budgetary Healthcare Institution “Regional Clinical TB Hospital”
Tajikistan

Tajikistan has a law on medicines and pharmaceutical activity (latest revision May 17, 2018 Order No.1531). The law states that the Ministry of Health of Tajikistan is responsible for controlling the field of clinical trials; organisations conducting clinical trials are accountable to the Ministry of Health.

To initiate a clinical trial, the researcher must obtain a special approval from the Ministry. Federal Service for Surveillance of Health Care and Social Protection of the Population of the Republic of Tajikistan is responsible for inspecting the documents.

The list of centres accredited for conducting CTs has not been found in the public domain; however, this list should be available at the Ministry of Health upon request.

The clinicaltrials.gov website contains 3 entries related to clinical trials in Tajikistan, either active or completed (website accessed November 2020). None of the studies are related to HIV, viral hepatitis, or tuberculosis.

Federal Laws

List of Potential Clinical Trial Sites

Based on literature review and interviews with experts, the following CT centres have been identified:
2. Dushanbe. Ibn-Sino International Clinic
3. Dushanbe. Infectious Disease Clinic for Children
Ukraine

The laws of Ukraine contain specific requirements for performing clinical trials in accordance with the principles of good clinical practice that Ukraine accepted in 1996. This is regulated by the “Medical Drug Products. Good Clinical Practice. ST-N Ukraine Ministry of Health 42-7.0: 2008” Guidelines. The latest revision of the regulatory framework in the field of clinical trials dates back to January 17, 2018 (On Conducting Clinical Trials of Medicines and Approving the Amendments).

All the clinical trials should be registered by the State Expert Center of the Ministry of Health of Ukraine38 and can be conducted only in centres authorised by the State Expert Center. A clinical trial can be conducted in Ukraine only upon obtaining an approval of the Ethics Commission39.

Starting from 2006, the list of the approved clinical trial centres has been published on the official website of the State Expert Centre. However, in November 2020, this list could not be found in the public domain.

Ukraine was among the first countries in the region of Eastern Europe and Central Asia to initiate a study of pre-exposure prevention of HIV as part of a demonstration project40, which is an indication of the country’s potential capacity to conduct clinical trials in this field.

The clinicaltrials.gov website contains 2089 entries related to clinical trials in Ukraine, either active or completed (website accessed November 2020); Ukraine ranks second in terms of the absolute number of trials among the project countries. At least several of the entries are related to HIV, viral hepatitis, or TB.

National Laws
3. Law of Ukraine of May 12, 2011 N 3323-VI “On amendments to certain legislative acts of Ukraine regarding clinical studies of medicines” which

38 https://www.dec.gov.ua/
39 https://crupp.org/ru/komissii-po-voprosam-etiki-v-ukraine/

Government Resolutions

1. The procedure for conducting clinical studies of medical drug products and examination of materials of the clinical studies (Ukraine Ministry of Health Order dated January 17, 2018 N 84)

Orders

2. Ukraine Ministry of Health Order dated August 15, 2016 N 835 On conducting of clinical trials of medical drug products and approving the amendments.
3. Ukraine Ministry of Health Order dated January 17, 2018 N 84 On conducting of clinical trials of medical drug products and approving the amendments.
5. Ukraine Ministry of Health Order dated December 27, 2006 N 898 On approval of the Procedure for supervision of adverse reactions of approved medical drug products, as updated September 26, 2016
6. Ukraine Ministry of Health Order dated September 26, 2016 N 996 On approval of the procedure for the implementation of pharmacovigilance.
7. Ukraine Ministry of Health Order N560 of August 11, 2006 with changes of February 20, 2007 “On approval of the list of medical and preventive facilities where medicines can be clinically tested”
9. Ukraine Ministry of Health Order of April 11, 2012 N 255 “On regulating the ethical aspects of clinical studies of medicines”

National standards

List of Potential Clinical Trial Sites

Below follows a list of CT centres identified through interviews with local experts and analysing the list of CT centres available during the previous search.

1. Cherkasy Regional Clinic, Pulmonology
2. Chernigov Regional AIDS Clinic
3. Chernivtsy Regional Clinic No 3, Pulmonology
4. Chernivtsy Regional Clinic, Bukovina National Medical University of the Ministry of Health of Ukraine, Gastroenterology
6. Dnipropetrovsk. Dnipropetrovsk City Clinic No.21 named after Professor Popkova, Dnepr, ul. Kanatnaya, 17, +380567706849
7. Dnipropetrovsk. Dnipropetrovsk Medical Academy under the Ministry of Health of Ukraine, Infectious Diseases, http://www.dpsmu.com/, 9, Dzerzhinskiy Street, Dnipropetrovsk, Ukraine
8. Ivano-Frankivsk Regional Pthisiopulmonology Centre, Ivano-Frankivsk National Medical University
9. Kharkiv National Institute of Therapy named after L.T. Malaya of the National Academy of Medical Sciences of Ukraine, liver diseases
10. Kharkiv Institute of Dermatology and Venereology of the National Academy of Medical Sciences of Ukraine
11. Kremunychug, City Clinic No 1 named after Bogaevskiy, Pulmonology
12. Kyiv, Republican Clinic under the Ministry of Health, National Medical University named after O.O. Bogomolets, Gastroenterology
16. Kyiv. City Tuberculosis Clinic No 1, Kyiv Medical University of the Kyiv Association of Complementary Medicine
17. Kyiv. National Institute of Phthisiology and Pulmonology named after F.G. Yanovskiy of the National Academy of Medical Sciences
19. Kyiv. Arensia (phase I Clinical Trial Centre) http://www.arenzia-em.com(phase-1-units/)
20. Kyiv OCT  
[https://oct-clinicaltrials.com/rus/contacts/ukr](https://oct-clinicaltrials.com/rus/contacts/ukr)  
Address: bul. Lesy Ukrainki, b. 34 of. 207  
Telephone: +38 (044) 281 02 01, +38 (044) 285 96 10  
E-mail: ukraine@oct-clinicaltrials.com

Address: st. M. Grushevskogo, h. 28/2, of. 15.  
Telephone: +38 (044) 228 78 19  
E-mail: info@regulatory.com.ua

22. Lutsk, Volyn' Regional Clinic, Pulmonology

23. Lviv, Regional Clinical Centre of Pthisiopulmonology

24. Lviv, City Public Clinic No 5, Pulmonology

25. Odesa, Regional AIDS Clinic

26. Sumy, Sumy Regional Clinic, Sumy Medical Institute of the Sumy National University, Pulmonology

27. Ternopyl, University Clinic, Ternopyl National Medical Academy named after I.Y. Gorbachevskiy

28. Vinnitsa, Vinnitsa Central District Clinic, Vinnitsa National Medical University named after M.I.Pirogov, 21000, Vinnitsa Region, Vinnitsa, Pirogov str, 46,  
+380675037465, +380936827384, +380432353273

29. Vinnitsa, Vinnitsa City Clinic No 1, Vinnitsa National Medical University named after M.I.Pirogov, infectious diseases, 21100, Vinnitsa Region, Vinnitsa, Khmelnitskoe Shosse, 92, +380432446531, +380432511233, +380432511231

30. Vinnitsa, Vinnitsa Regional Clinic named after M.I. Pirogov, gastroenterology

31. Vinnitsa, Interregional Clinical and Diagnostics Centre “Health Clinic”, liver diseases

32. Zaporizhzhya, City Clinic No 6, Gastroenterology

33. Zaporizhzhya, Regional Clinic, Pulmonology

34. Zaporizhzhya, Regional AIDS Clinic, Zapirozhzhya Medical Academy of Postgraduate Education under the Ministry of Health
Uzbekistan

Summary

The rules for conducting clinical trials in the Republic of Uzbekistan are defined in Appendix No. 1 to the Order of the Ministry of Health of the Republic of Uzbekistan dated 25.07.2001 No.334: Instructions for Clinical Trials of Medical Drug Products and Examination of Test Materials (its full text is available on the official internet site of the Ministry of Health of the Republic of Uzbekistan41). No information about whether this document has been revised has been found in the public domain.

It is stated that the document is developed in accordance with Articles 10 and 11 of the Law of the Republic of Uzbekistan “On Medicines and Pharmaceutical Activities” and taking into account the norms applied in the international practice, such as the ICH / GCP rules, the Declaration of Helsinki (1964), and EU clinical trial regulation.

The clinicaltrials.gov website contains 26 entries related to clinical trials in Uzbekistan, either active or completed (website accessed November 2020). At least four of them are related to MDR-TB or XDR-TB.

National Laws


Orders

2. Order of the Ministry of Health of the Republic of Uzbekistan dated 08.05.2009 No.26 "On the procedures for ordering trials to assess efficiency and clinical trials of biologically active food additives", with updates.

3. Order of the Ministry of Health of the Republic of Uzbekistan dated 03.08.1998 "The procedure for expertise, clinical trials, registration, and re-registration of medicines and substances manufactured in CIS and other foreign countries", with updates.

41 https://nrm.uz/contentf?doc=411273_prikaz_ministra_zdravoohraneniya_ot_25_07_2001_g_n_334_ob_usovershenstvovanii_provedeniya_klinicheskikh_ispytaniy_lekarstvennyh_sredstv

Government Resolutions
1. Resolution of cabinet of ministers of the Republic of Uzbekistan dated March 23, 2018 No.213 On approval of the regulations on the order of state registration of drugs, medical devices and medical equipment and issuance of the registration certificate.
2. Resolution of the President of the Republic of Uzbekistan dated February 14, 2018 No. ПП-3532 About additional measures for accelerated development of the pharmaceutical industry
3. Resolution of the President of the Republic of Uzbekistan dated August 2, 2018 No. ПП-3894 On measures for implementing an innovative model of healthcare management in the Republic of Uzbekistan
4. Resolution of the President of the Republic of Uzbekistan dated December 07, 2018 No. ПП-4055 On measures to organize the activities of the Ministry of Health of the Republic of Uzbekistan
5. Resolution of cabinet of ministers of the Republic of Uzbekistan dated October 27, 2018 No. 365 On approval of the general technical regulation on the safety of Medical drug products
6. Presidential decree of the Republic of Uzbekistan dated April 10, 2019 No. УП-5707 On further measures for accelerated development of the pharmaceutical industry of the republic in 2019 – 2021, with updates.
7. Resolution of cabinet of ministers of the Republic of Uzbekistan dated September 18, 2019 No. 788 About additional measures for implementing good practice (GXP) in the pharmaceutical industry

List of Potential Clinical Trial Sites

According to the public sources available\(^4^2\) and interviews with experts, the following potential clinical trial sites are based in the country:


\(^4^2\)http://www.uzpharmsanoat.uz/ru/concern/%D0%BE-%D0%BA%D0%BE%D0%BD%D1%86%D0%B5%D1%80%D0%BD%D0%B5

3. **Tashkent**: Republican Specialized Scientific and Practical Medical Centre of Therapy and Rehabilitation, no website available, 4, Osiyo street, Yunusabad district, 100084, tel: +998 (71) 234-33-21/+998 (71)234-69-14

4. **Tashkent**: Republican Specialized Scientific and Practical Medical Centre of Phthisiology and Pulmonology, no website available, 1, Alimov street, Shaykhantaur district, 100086, tel: +998 (71) 278-04-70 / +998 (71) 278-15-28, email: info.rsnpmc_fip@minzdrav.uz

5. **Tashkent**: Republican Specialized Scientific and Practical Medical Centre of Endocrinology, no website available, 56, Mirzo-Ulugbek avenue, Mirzo-Ulugbek district, 100125, tel: +998 (71) 262-27-02 / +998 (71) 262-25-53 / +998 (71) 262-23-68


7. **Tashkent**, Republican Tuberculosis Hospital No. 2, Mirzo-Ulugbek District.

8. **Tashkent**, MedExpert https://medexpert.group/ Address: st. T. Malika, b. 146, business center “Techno Plaza”, of. 217, Telephone: +998 93 550 30 11, E-mail: info@medexpert.group

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**About the European AIDS Treatment Group:**

The European AIDS Treatment Group (EATG) is a patient-led NGO that advocates for the rights and interests of people living with or affected by HIV/ AIDS and related co-infections within the WHO Europe region. Founded in 1992, the EATG is a network of more than 170 members from 47 countries in Europe. Our members are PLHIV and representatives of different communities affected by HIV/AIDS and co-infections. EATG represents the diversity of more than 2.3 million people living with HIV (PLHIV) in Europe as well as those affected by HIV/AIDS and co-infections. For more information, please visit www.eatg.org