European AIDS Treatment Group

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

June 2016

European AIDS Treatment Group

Contents

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
EU – European Union
GCP – Good Clinical Practice
GLI – Global Laboratory Initiative
GLP – Good Laboratory Practice
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
NLN – Nordic Council on Medicines
SRLN – Supranational Reference Laboratory Network
TB – Tuberculosis
WHO – World Health Organisation

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 October 2015 – June 2016. 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 report's authors which might not coincide with views held by other interested parties. No mentioning 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 may not be exhaustive; likewise, some of these norms may no longer have legal effect when this report is accessed.

Background

Access to new drugs for treating HIV, HCV and TB in Eastern Europe and Central Asia (EECA) remains limited. For some patients, clinical trials (CT) represent one of the very few opportunities of getting access to life-saving treatment. The request to initiate CTs in EECA has been voiced by representatives of the region on numerous meetings with pharmaceutical companies, including community advisory board meetings in Europe (ECAB) and EECA (EECA CAB). For some countries like Russia, conducting local clinical trials is a legal prerequisite for drug registration. Overall, there is limited information of CT centres in the region. For the purpose of accumulating and analyzing data about the centres' potential of conducing CTs of drugs for treating HIV, HCV and TB, EATG launched a pilot monitoring and analysis project. The first results are summarized in this report.

The countries included in the project so far are: Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Poland, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan. The project can be extended to other countries as further information on CT centres is obtained.

Project Methodology

A literature review has been performed in order to analyze the landscape of the requirements for CTs in the respective countries. The literature review covered both international and national standards. References to national norms regulating the field of clinical trials are given in the respective chapters.

The authors of the report have established contacts with representatives of national non-governmental organisations to collect information about CTs with potential to conform to the requirements. The lists of CTs obtained from public sources or from country representatives are given in the country sections. In most cases, the lists contain centres having official approval to conduct clinical trials from the National Ministry of Health. Whenever publicly available, references to websites containing these lists are given. The websites were accessed in November 2015.

The presence of a CT centre in the list does not mean the centre would conform to the requirements set by stakeholders such as pharmaceutical companies or by the World Health Organisation (WHO). Also, it is difficult to verify whether each individual centre does actually meet the national requirements by using 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 clinical trial landscape in EECA

Based on the data available on the website clinicaltrials.gov, which accumulates information about clinical trials carried out globally, 11,453 clinical trials were registered in the 15 countries of EECA covered by the review. 19% of them (2139) were open at the date when the website was accessed (November 27, 2015). Clinical trials of drugs for treating HIV, HCV and TB account for 6% of the total number of trials conducted in the EECA region (both completed and currently open as of November 2015). The statistics reflected below indicates all the trials entered into the database of clinicaltrials.gov since the launch of the website.

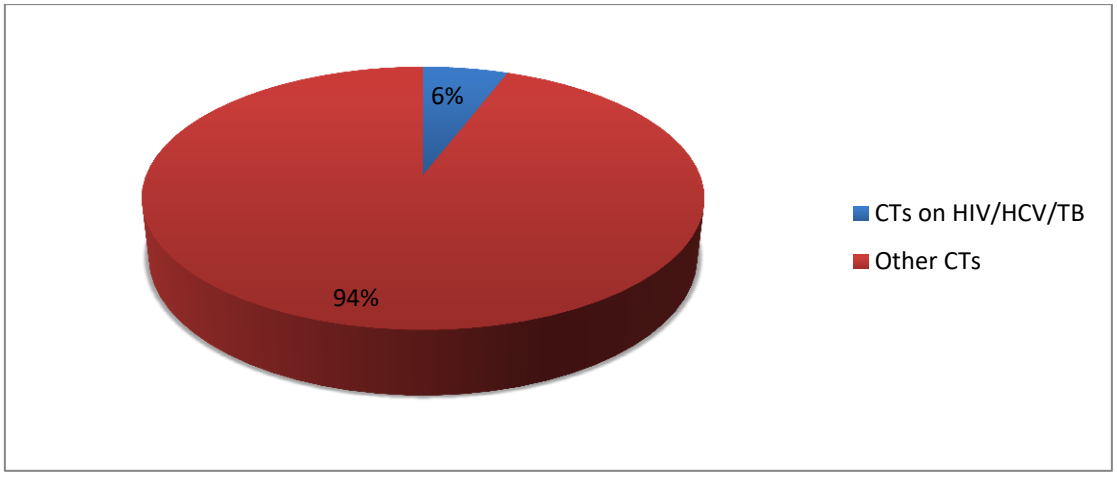

Figure 1. Proportion of clinical trials in the field of HIV/HCV/TB conducted in EECA as compared to other clinical trials

As of November 2015, 78% of all the trials[1] (not only HIV/HCV/TB) have been conducted in 3 countries, namely Poland, Russia, and Ukraine. Less than 1% of the trials have been conducted in the countries of Central Asia (Kazakhstan, Kyrgyzstan, Uzbekistan, and Tajikistan).

[1] This number refers to the total number of studies published on the website (by individual country using the search engine of the website)

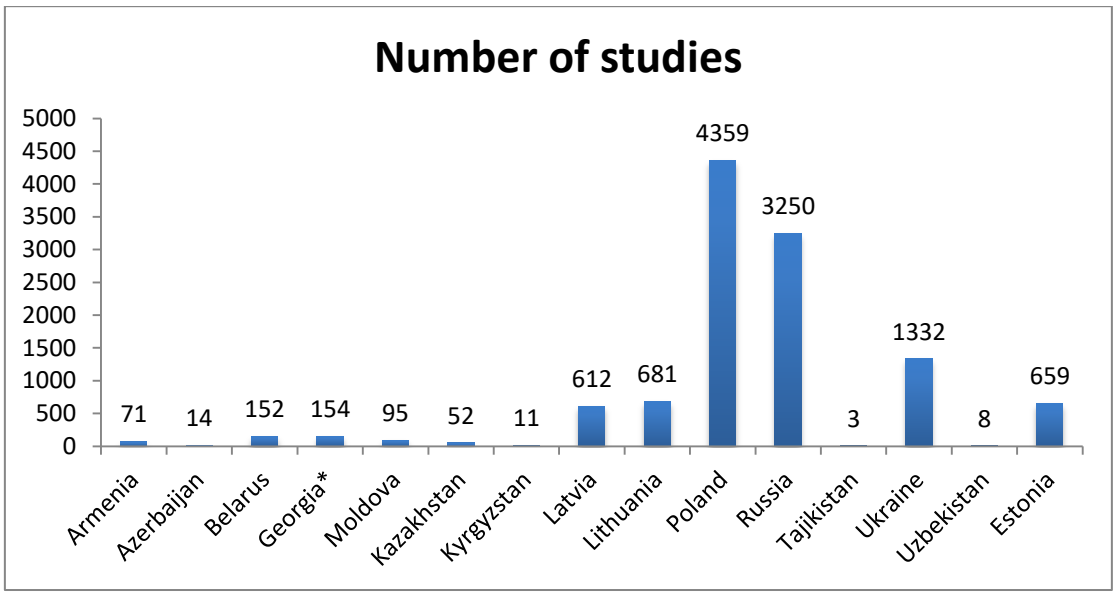

Figure 2. Number of trials in EECA countries

Brief information about the requirements to clinical trial sites

According to the results of the literature review, the general requirements for the clinical trial sites are set by the Good Laboratory Practice[2] and Good Clinical Practice[3] guidelines. Also, each country (for most countries the authors have been able to find this information) sets its own standards regarding clinical trials. The national requirements of most EECA countries stipulate that the sites should follow GLP (for pre-clinical studies) and GCP. 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 in order to obtain an official approval for conducting clinical trials. As stated above, the authors relied mostly on the lists of such centres available publicly.

Also, in order to gain better understanding of the clinical trial field in EECA, interviews with representatives of international pharmaceutical companies producing drugs for treating HIV and HCV were conducted. According to the answers, all the work related to organizing and conducting clinical trials is carried out through specialized contract research

[2] http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm
[3] http://ec.europa.eu/health/files/eudralex/vol-10/3cc1aen_en.pdf

organisations (CRO), such as PRA Health Sciences[4] and PPD[5]. 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 the majority of 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 and 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 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.

Recently, there have emerged initiatives which could potentially enhance the research capacity of the EECA healthcare institutions; in the field of TB, for instance, the TB Supranational Reference Laboratory Network (SRLN) was created in 1994 to promote strong and tailored interventions to expand TB laboratory services and to address different

[4] http://prahs.com/
[5] http://www.ppdi.com/

tiers of laboratories with different levels of testing. More specifically, the RB SRLN is a sub-group of the WHO/Global Laboratory Initiative (GLI) in order to support the WHO/IUATLD Global Project on TB drug resistance surveillance and with the objectives to estimate the magnitude of drug resistance globally and provide data to inform WHO policy decisions. The SRLN can give an estimation of the burden of TB drug resistance across the EECA region which can guide the focus of local initiatives for new research.

Armenia

According to the interview carried out with the member of EECA CAB based in Armenia, there is a decree of the Government of Armenia stipulating the procedure for conducting clinical trials (Order 24.01.2002 N 63[6]). It 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 in order to obtain an approval to conduct clinical trials, the site should submit an application to the Ministry with a documentation package[7].

National Laws

1. The Law of the Republic of Armenia "On Medical Assistance and Healthcare" dated 04.03.1996
2. The Law of the Republic of Armenia "On Medicines" dated 27.10.1998

Government Resolutions

1. The Resolution of the Government of the Republic of Armenia No.63 dated January 24, 2002 on approval of the "Order of Conducting Clinical Trials of New Medicines in the Republic of Armenia"

Orders

1. 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."

The following documents are required to conduct a clinical trial:

- authorization to conduct a clinical trial (Ministry of Health)
- consent of the Ethics Committee for a clinical trial
- registration of a clinical trial with international / national / regional registers
- GCP, GMP
- inspection of a clinical trial
- accreditation of the clinical sites
- authorization for medicines import is required

Based on literature review and interviews with local experts, as well as analysis of the clinicaltrials.gov website, the following potential clinical trials centres/contract research organizations have been identified:

1. Yerevan. Crocus Medical B.V. (Contract Research Organization) http://crocusmedical.com/?q=en/node/106; **Telephone:** +374 10 20 20 42,

[6] http://www.arlis.am/DocumentView.aspx?docID=9154
[7] (http://www.arlis.am/DocumentView.aspx?docID=69580)

Mobile: +374 99 500741 **Address:** Adonts str. 2, 0014 Yerevan, Armenia, Business Centre "Eraz", corp. B, 2 floor[8]

2. Yerevan. Scientific Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan CJSC. Yerevan 0051 49/4 Komitas av. http://www.pharm.am/index.php/en/home
3. Yerevan. Izmirlyan Scientific Medical Centre. Yerevan 0014, Kanaker-Zeitun, ul. Gr. Nersisyana 19. http://www.stnerses.am/
4. Yerevan. Medical Research Centre of Dermatology and Sexually Transmitted Diseases.
5. Yerevan. Republican Medical Centre.
6. Yerevan. State Medical University. http://www.ysmu.am/en
7. Yerevan. National Centre for AIDS Prevention http://www.armaids.am/en/

Azerbaijan

National Laws

1. The Law of the Republic of Azerbaijan "On Medicines" dated 22.12.2006

Based on literature review and interviews with local experts, as well as analysis of the clinicaltrials.gov website, the following potential clinical trials centres/contract research organizations have been identified:

1. Medicines Analytic Review Centre (MARC)
2. Arterium corporation's representative office; http://www.arterium.ua/en/Contacts
3. Centre for Analytical Expertise of Medicines under the Ministry of Health of Azerbaijan
4. Republican Clinic named after Mirkasimov
5. Research Institute of Clinical Medicine named after academician M.A.Topchubashev
6. Central Clinical Hospital
7. National AIDS Centre http://aids.az/ru/
8. Scientific Research Institute of Lung Diseases Baku, Sherifli str. 2514

[8] Here and hereinafter, the information about clinical trial centres is provided in the following format: city, name, address and contact details (if available)

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 audit and monitoring in most of the cases are done by State Institute "Republican center of expertise and studies" that was crated for the purposes of the tests and import/export movements of the medical goods. Then, the CT must be approved by the Ethics Committee. The documents are first submitted to the Ministry of Health: notarized translation is required.

National Laws

- The Law of the Republic of Belarus "On Medicines" No.161-z dated 20.07.2006 (as amended by the laws of the Republic of Belarus dated 05.08.2008 No.428-3, dated 15.06.2009 No.27-3, dated 22.12.2011 No.326-3, and dated 17.11.2014 No.203-3)
- The Law of the Republic of Belarus dated 18.06.1993 No.2435-XII "On Healthcare" (as amended on 16.06.2014)

Government Resolutions

- The procedure for organization and performance of the Ethics Committee. Methodological recommendations No.16 dated 01.01.2000
- The Resolution of the Council of Ministers of the Republic of Belarus dated 16 October, 2002 No.1437 "On the State Program for Transition of the Pharmaceutical Industry of the Republic of Belarus to the Principles of Good Manufacturing Practices (GMP)"
- The procedure for development of the working guidelines and standard operation procedures for pharmacies of the Republic of Belarus No.050-0807 dated 18.09.2007
- 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 on 17.04.2015)
- 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 on 15.12.2015 under No.122)

- The Resolution dated May 07, 2009 No.50 "On approval of the technical code of the common 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)
- The Resolution of the Ministry of Health of the Republic of Belarus "On Technical Rating and Standardization" No.181 dated 29.12.2010
- 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"
- The Resolution of the Ministry of Health of the Republic of Belarus dated 23.04.2015 No.53 "On making amendments to the Resolution of the Ministry of Health of the Republic of Belarus dated May 07, 2009 No.50"
- Orders
- The Order of the Ministry of Health of the Republic of Belarus No.250 dated October 15, 1997 "On Establishing State Enterprise "The Republican Centre of Expertise and Trials in Healthcare"
- The Medicines Provision Concept of the Republic of Belarus, approved by the Resolution of the Council of Ministers of the Republic of Belarus dated August 13, 2001 No.1192
- Clarifications concerning conducting clinical trials of medicines, medicinal products, and medical devices. Letter No.03-3-11/841/387 dated 08.06.2011
- 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, 2010”. *Comment: The Order which has been repealed stipulated the requirement to obtain approval of the contracts for clinical trials by the Ministry of Health and set requirements as to the price of the CT contracts.*

Based on the data obtained at the website of the Republican Centre of Expertise and Trials in Healthcare under the Ministry of Health, 76 clinical trials centres based in Belarus have been identified (data as of September, 2016)[9]; 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:

[9] http://rceth.by/ru/Departments/Rcpl/Documents/2

1. Gomel: Gomel Regional Infectious Diseases Hospital, (Phase II-IV, profile "Diagnosis and treatment of infectious diseases"). http://uzgoikb.by/, Gomel, ul. Feduninskogo, 18
2. Gomel. Gomel Regional Clinical Hospital
3. Gomel: Gomel Regional Tuberculosis Clinical Hospital http://www.gotkb.by/
4. Grodno: Grodno Regional Infectious Diseases Hospital (Phase II-IV, profile "Diagnosis and treatment of infectious diseases") http://goicb.by/, 230030, Grodno, blvd Leninsky Komsomol, 57
5. Minsk. City Clinical Hospital No. 9 (liver diseases).
6. Minsk: Municipal Children's Infectious Diseases Hospital (Phase II-IV, profile "Diagnosis and treatment of childhood infectious diseases") http://www.gdikb.by/, Minsk, ul.Yakubowski, 53, +375172565509
7. Minsk: Clinical Infectious Diseases Hospital, (Phase II-IV, profile "Diagnosis and treatment of infectious diseases") http://www.gkib.by/, 220002, Minsk, ul. Kropotkina, 76
8. Minsk. City TB Dispensary No. 1
9. Minsk. City TB Dispensary No. 2
10. Minsk. Central Military Clinical Medical Centre (infectious diseases)
11. Minsk. Republican Scientific and Practical Centre of Pulmonology and Tuberculosis, http://www.rnpcpf.by/en/one-window.html
12. Mogilev. Mogilev Regional Tuberculosis Dispensary, http://www.moptd.by/
13. Mogilev. Mogilev Regional Pediatric Clinical Hospital (infectious diseases)
14. Vitebsk: Vitebsk regional children's clinical centre, (Phase II-IV, profile "Infectious Diseases"). http://www.vdokb.by/index.php, 210022, Vitebsk, st. Chkalov, 14
15. Vitebsk. Vitebsk Regional Clinical Hospital
16. Republican Scientific and Practical Centre Mother and Child (infectious diseases in children)

Estonia

The regulation of clinical research is in full compliance with the respective EU legislation. In general terms, approval by one of the two Independent Ethics Committees and informed consent by the study participant, according to the international codes and Declaration of Helsinki, is mandatory. Clinical trial medications should be manufactured according to the GMP (Good Manufacturing Practice) and the trials should be performed and the data generated in compliance with the GCP (Good Clinical Practice) to ensure the ethical and scientific integrity of the trial (GCP code close to the nordic document by the Nordic Council on Medicines (NLN) was mandatory since 1991, later the International Conference on Harmonization (ICH) GCP was adopted and is currently directly referred to by the legislation).

Notification of the clinical trial needs to be submitted to the State Agency using the EudraCT format. The time taken by the Agency to assess the notification depends directly on the quality and completeness of the documentation submitted. Please note that together with the notification, a signed declaration by the head of the health-care institution (study centre) has to be submitted. An activity license holder (according to the Medicinal Product Act § 18) can import medicinal products intended for clinical trials after the clinical trial has been approved by the State Agency of Medicines. The State Agency of Medicines shall be duly notified of conveyance of medicinal products from the European Economic Area to Estonia.

European Normative documents:

1) Guideline for good clinical practice E6 (R1), 10.06.1996
2) WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, June 1964
3) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
4) Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)
5) Ethical considerations for clinical trials on medicinal products conducted with the paediatric population, Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use
6) Clinical safety data management: definitions and standards for expedited reporting e2a, 27.10.1994
7) Structure and content of clinical study reports E3, 30.11.1995

Estonia Normative documents

1) Conditions and Procedure for Conducting Clinical Trials of Medicinal Products, Regulation No.23 of the Minister of Social Affairs of 17 February 2005[10]
2) Procedure for reporting serious adverse events occurring in clinical trials, Minister of Social Affairs Regulation No.26 of 17 February 2005
3) Rules of procedure of medical ethics committee for clinical trials, a list of data to be submitted for obtaining approval, procedure for adoption of resolutions and format of application for obtaining approval, Minister of Social Affairs Regulation No.17 of 17 February 2005
4) Medicinal Products Act, Passed 16.12.2004

Based on literature review and interviews with local experts, the following clinical trials centres have been identified:

1) Kohtla-Järve. East-Viru Central Hospital
2) Narva AIDS Centre.
3) Tallinn. West-Tallinn Central Hospital, http://www.keskhaigla.ee/?lang=en#
4) Tallinn. The North Estonia Medical Centre http://www.regionaalhaigla.ee/en/about-us-0
5) Tallinn. CCBR (Centre for Clinical and Basic Research) https://ccbr.com Estonia - Tallinn Pärnu 4 10128 Tallinn Estonia P: +372 680 2000 ccbr.tallinn@ccbr.com
6) Tartu. Tartu University Hospital http://www.kliinikum.ee/eng/studies-and-research

[10] Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ No. L 121, 01.05.2001, pp. 34–44

Georgia

According to the analysis of the regulatory framework, 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 national GCP standards. The documents are first submitted to local ECs; notarized 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.

National Laws

1. Law No.1775 dated 24.06.2005 About license and permissions
2. Law No.5069-вс dated 27.06.2007 About public health
3. Law No.1586 dated 10.08.2009 About medicines and pharmaceutical activities

National Standard

1. Convention of Council Europe about human rights and biomedicine and its role in the legal coverage of a patient's rights and freedoms dated 24.012002.

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.arensia-em.com/phase-1-units/

HIV:

1. Batumi: Centre for Infectious Pathology, AIDS and tuberculosis, http://cloud.moh.gov.ge/Pages/SearchPage.aspx
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

Tuberculosis:

1. Abastumani: Tuberculosis Hospital, no web-site available.
2. Batumi: Centre for Infectious Pathology, AIDS and tuberculosis, http://cloud.moh.gov.ge/Pages/SearchPage.aspx

3. Kutaisi: Centre for Tuberculosis and Lung Disease in Western Georgia, no web-site available.
4. Poti: Tuberculosis Hospital, no web-site available.
5. Tbilisi, National Centre for Tuberculosis and Lung Disease, http://www.tbgeo.ge
4. Zugdidi: Regional Tuberculosis Clinical Hospital, no web-site available.

Hepatitis C:

1. Tbilisi: Clinic of Hepatology "Hepa", http://www.hepaclinic.com/
2. Tbilisi: Georgian Research Centre of AIDS and Clinical Immunology; http://www.aidscenter.ge/index_eng.html
3. Tbilisi: "Mrcheveli", LLC, http://mrcheveli.com/
4. Tbilisi: "High technology Medical Centre, University Clinic", http://www.htmclinic.com/en/about-clinic/history-of-the-clinic
5. Tbilisi: Arensia Exploratory Medicine GmbH, http://www.arensia-em.com
6. Tbilisi: "Cito" Medical Centre, http://www.cito.ge/
5. Tbilisi: "Medical Research Centre" LLC, no web-site available.
7. Tbilisi: "Anti-Sepsys Centre of Vakhtang Bochorishvili"

Kazakhstan

In Kazakhstan, an approval from the Ministry of Health is required in order to conduct a CT on the territory of the country. The trial should also be approved by the National Ethics Committee. The centre must comply with the national GCP. Accreditation of centres is required; also, a specific approval for importation of medicines must be obtained.

Prior to commencement of a clinical trial, a sponsor shall obtain a written authorization 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.

National Laws

- The Code of the Republic of Kazakhstan dated September 18, 2009 No.193-IV "On Population Health and Healthcare System"

Orders

- Order of the Minister of Health of the Republic of Kazakhstan dated November 12, 2009 No.697. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 26, 2009 under No.5932 "On approval of the Rules of conduct of the medical and biological experiments, pre-clinical (non-clinical) and clinical trials"
- Order of the Minister of Health of the Republic of Kazakhstan dated November 19, 2009 No.744 "On approval of the Rules of conduct of the clinical trials and/or tests of pharmaceuticals and medicines, medicinal products and medical devices" (registered in the Register of the State Registration of Laws and Regulations under No.5924, published in the Collection of the acts of the national executive and other national governmental agencies of the Republic of Kazakhstan for 2010, No.4)
- Order of the Minister of Health of the Republic of Kazakhstan dated November 19, 2009 No.744. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 26, 2009 under No.5924 "On approval of the Rules of conduct of the clinical trials and/or tests of pharmaceuticals and medicines, medicinal products and medical devices"
- Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 29, 2015 No.421. Registered with the Ministry of Justice of the Republic of Kazakhstan on June 30, 2015 under No.11485 "On approval of the

Rules of performing pharmacological vigilance of medicines and monitoring adverse effects of medicines, medicinal products and medical devices"

- Order of the Minister of Health of the Republic of Kazakhstan dated July 30, 2008 No.425 "On Establishing Central Commission for Ethical Issues"
- Order of the Minister of Health of the Republic of Kazakhstan dated July 25, 2007 No.442 (State registration No.4894 as of August 27, 2007) "On approval of the Rules of conduct of pre-clinical trials, medical and biological experiments and clinical trials in the Republic of Kazakhstan"
- Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 29, 2015 No.432. Registered with the Ministry of Justice of the Republic of Kazakhstan on June 30, 2015 under No.11494 "On approval of the List of the Orphan Products"
- Order of the Minister of Health of the Republic of Kazakhstan dated November 12, 2009 No.697. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 26, 2009 under No.5932 "On approval of the Rules of conduct of the medical and biological experiments, pre-clinical (non-clinical) and clinical trials"
- Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 15, 2015 No.348. Registered with the Ministry of Justice of the Republic of Kazakhstan on June 17, 2015 under No.11371 "On Making Amendments to Order of the Minister of Health of the Republic of Kazakhstan dated November 12, 2009 No.697 "On approval of the Rules of conduct of the medical and biological experiments, pre-clinical (non-clinical) and clinical trials"
- Order of the Minister of Health of the Republic of Kazakhstan dated November 19, 2009 No.744. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 26, 2009 under No.5924 "On approval of the Rules of conduct of the clinical trials and/or tests of pharmaceuticals and medicines, medicinal products and medical devices"
- Resolution of the Customs Union Commission dated March 02, 2011 No.565 "On Draft Rules of the Customs Union Good Clinical Practice"
- Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 22, 2015 No.369. Registered with the Ministry of Justice of the Republic of Kazakhstan on June 24, 2015 under No.11429 "On Approval of the Rules of Development and Approval of the Kazakhstan National Medicines Formulary"
- Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated March 10, 2015 No.127. Registered with the Ministry of Justice of the Republic of Kazakhstan on April 15, 2015 under No.10735 "On approval of the Rules of Accreditation in the Sphere of Healthcare"

National Standard

- The State Standard of the Republic of Kazakhstan. Good Clinical Practice. "GSP", CT РК 1616-2006
- The State Standard of the Republic of Kazakhstan. Medicines Manufacture. Good Manufacturing Practice. CT РК 1617-2006

Based on the data published on the website of the Republican State-Owned Enterprise "Дәрідәрмек Centre for Drug Products" under the Ministry of Health[11], 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.

1. Aktobe. West-Kazakhstan State Medical Academy
2. Almaty. National Centre for Tuberculosis Problems, http://www.ncpt.kz/, 050010, Almaty, ul. K. Bekhozhina, 5
3. Almaty. Dermatology Research Centre. Raiymbek prospect, 60, www.dsnikvi.kz, tel: (727) 230-48-75, (727) 230-16-39, (727) 230-40-85
4. Almaty. City Hospital No.7 of Almaty, 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
8. Astana. National Medical Research Centre, http://nnmc.kz/, Astana, pr. Abylaikhana, 42, e-mail: national_clinic@nnmc.kz
9. Astana. Kazakh State Medical Academy, http://www.kazgma.kz/, Sary-Arka street, 33, Astana
10. Astana. Astana Medical University, http://www.amu.kz, Astana, ul. Beibitshilik, 49A

[11] http://www.dari.kz/pages/351

11. Astana. National Centre of Biotechnology, http://www.biocenter.kz, 13/5, Kurgalzhynskoye road, Astana, 010000, tel: +7 (7172) 70-75-65
12. Karaganda. Karaganda State Medical Academy, http://www.kgmu.kz, Karaganda, ul. Gogol, 40
13. Semipalatinsk. Semipalatinsk State Medical Academy
14. Shymkent. South-Kazakhstan State Medical Academy

Kyrgyzstan

Conducting clinical trials requires an authorisation from the Department of the medicines and medicinal devices provision of the Ministry of Health of the Republic of Kyrgyzstan.

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"
2) Order of the Ministry of Health of the Republic of Kyrgyzstan dated June 09, 2011 No.2850 on implementation of Resolution of the Government of the Republic of Kyrgyzstan dated April 06, 2011 No.137 "On approval of the Technical Regulations "On Safety of Medicines for Human Use"

Government Resolutions

1) The Resolution of the Government of the Republic of Kyrgyzstan "On approval of the Technical Regulations "On Safety of Medicines for Human Use" dated April 06, 2011 No.137
2) The Resolution of the Government of the Republic of Kyrgyzstan "On the procedure for import into the Republic of Kyrgyzstan of the products subject to compulsory confirmation of conformity in form of a compulsory certification and on recognition of the results of compulsory confirmation of conformity, received outside the Republic of Kyrgyzstan dated 11.01.2006 No.8

Federal Laws

1) The Law of the Republic of Kyrgyzstan "On Medicines" No.91 dated 30.04.2003, as amended

National Standard

1) The Standard of the Republic of Kyrgyzstan "Medicinal Products. Rules for Conducting Clinical Trials" dated 16.09.2010

Below follows the list of clinical trial sites which could carry out trials in the field of infectious diseases as per the Order of the Ministry of Health of Kyrgyzstan "On Clinical Trials of Drug Products" (full list is available in the text of the order)[12]:

1) Bishkek. Kyrgyz National Research Centre for Tuberculosis, Bishkek, ul. Akhtunbaeva, 90-A, tel: +996 (312)470924, +996 (312)470925
2) Bishkek. National Centre under the Ministry of Health of Kyrgyzstan

[12] Law on Medicines of the Republic of Kyrgyzstan as of October 11, 2012.

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. Dzhantosheva, 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) Osh. Osh Clinical Hospital, incl. Osh Pediatric Clinical Hospital, Osh, ul. Verkhne-Uvamskaya, 10, tel: +996 (3222) 55852.
9) Osh. Osh Oblast Tuberculosis Hospital.

Latvia

For obtaining clinical trial authorisation from the competent authority in Latvia, the sponsor should submit an application both to the ethics committee and to competent authority (State Agency of Medicines). A clinical trial cannot be started without a positive decision from an ethics committee and without authorization from the State Agency of Medicines. There are 5 ethics committees, one central and four other independent committees. Members of those committees are proposed by the chairperson of committee and accepted by the Ministry of Health.

The State Agency of Medicines, whose website is at http://www.vza.gov.lv, is responsible for issuing guidelines on all aspects of clinical research involving investigational medicinal products.

European Normative documents:

1) Guideline for good clinical practice E6(R1), 10.06.1996
2) WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, June 1964
3) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
4) Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)
5) Ethical considerations for clinical trials on medicinal products conducted with the paediatric population, Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use
6) Clinical safety data management: definitions and standards for expedited reporting e2a, 27.10.1994
7) Structure and content of clinical study reports E3, 30.11.1995

Latvia Normative documents:

1) The Pharmaceutical Law of 24 April 1997, amended on 19 March 1998, 17 December 1998, 1 June 2000, 14 June 2001, 16 April 2003, 9 September 2003 and 15 June 2004.
2) Regulation of the Cabinet of Ministers 289 dated 23.03.2010 “Regulations Regarding the Conduct of Clinical Trials and Non-interventional Trials, the Procedures for the

Labelling of Investigational Medicinal Products and the Procedures for Inspection of Conformity with the Requirements of Good Clinical Practice".

3) The law on Human Genome Research: Regulation of the Cabinet of Ministers "Procedures for Genetic Research" came into force August 2004.

Based on literature review and interviews with local experts, the following clinical trials centres have been identified:

1. Riga. Pauls Stradins Clinical University Hospital (abbreviation in Latvian PSKUS)
2. Riga. University of Latvia (abbreviation in Latvian LU), http://www.lu.lv/eng
3. Riga. Latvian Institute of Organic Synthesis (abbreviation in Latvian LOSI), http://www.osi.lv/en/
4. Riga. Infectology Centre of Latvia (abbreviation in Latvian LIC), www.aslimnica.lv
5. Riga. Riga Stradins University (abbreviation in Latvian RSU), http://www.rsu.lv/eng/
6. Riga. Latvian Biomedical Research and Study Centre (abbreviation in Latvian BMC), http://biomed.lu.lv/en/
7. Riga. Riga East Clinical University Hospital (abbreviation in Latvian RAKUS)

Lithuania

After joining the European Union (2004), Lithuania has harmonised the legislation on clinical trials with the EU, has implemented Directives 2001/20/EC and 2005/28/ EC in local regulations, and also follows the applicable EU guidelines. The function of competent authority was given to the State Medicines Control Agency (SMCA) and the function of single opinion adoption was given to the Lithuanian Bioethics Committee (LBC). Clinical trial documents can be submitted simultaneously to both institutions, which makes the approval process faster. The assessment of the application usually takes no longer than 60 days. The other advantage that makes the setup of the clinical trial faster is that permission to conduct a CT received from the SMCA allows to import Investigational Medical Products (IMP) and trial-related material from other EU countries (no separate approval is needed). The major principles relating to the conduct of clinical trials are covered by the Law on Pharmacy of Lithuania No.X-709 (22-Jun-2006) and the Law on Ethics of Biomedical Research NovIII-1679 (11-May-2000). These regulatory documents are available on the homepage of Seimas (Parliament) of the Republic of Lithuania.[13]

European Normative documents:

1) Guideline for good clinical practice E6(R1), 10.06.1996
2) WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, June 1964
3) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
4) Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)
5) Ethical considerations for clinical trials on medicinal products conducted with the paediatric population, Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use
6) Clinical safety data management: definitions and standards for expedited reporting e2a, 27.10.1994
7) Structure and content of clinical study reports E3, 30.11.1995

[13] http://www.olainfarm.lv/

Lithuania Normative documents:

1) Law on Pharmacy of Lithuania No.X-709 (22-Jun-2006)
2) Law on Ethics of Biomedical Research NovIII-1679 (11-May-2000).
3) The Decree No.23 of the Ministry of Health on the Procedure for the Estimation and Covering of Expenses Incurred by Research Subjects, November, 2000.
4) The Decree No.745 of the Ministry of Health on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor, dated: 20 December 2000.
5) The Decree Nov-1078 of the Ministry of Health on the Territories Assigned to the Jurisdiction of the Regional Biomedical Research Ethics Committees, dated: 29 December 2007.
6) Decree Nov-405 of the Ministry of Health on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage and Providing Information on Biomedical Research, dated: 6 May 2010.
7) The Decree Nov-14 of the Chairman of the Lithuanian Bioethics Committee on the Requirements for the Biomedical Research Protocol, Patient Information Sheet and Informed Consent Form and for the CV of Investigator, dated: 5 November 2010.
8) The Decree No.435 of the Ministry of Health on the Procedure for Issuing Favourable Opinion to Conduct Clinical Trial on Medicinal Product, Approval for Clinical Trial on Medicinal Product, Conducting and Controlling Clinical Trials, dated: 31 May 2006 (updated on 19 April 2009 and 7 September 2010).
9) The Decree No.320 of the Ministry of Health on the Rules of Good Clinical Practice, dated: 12 June 1998 (updated in 2006).
10) The Decree Nov-11 of the Chairman of the Lithuanian Bioethics Committee on the Documents Required by the Lithuanian Bioethics Committee to be Presented by the Sponsor of Biomedical Research and (or) by the Principal Investigator in Order to be Authorized to Conduct a Clinical Trial on Medicinal Products, and on the Procedure on the Submission of the Documents to be presented to the Lithuanian Bioethics Committee, dated: 30 June 2004.
11) The Decree Nov-10 of the Chairman of the Lithuanian Bioethics Committee, on the Procedure for Issuing a Favourable Opinion for Substantial Amendment, dated: 14 October 2008.
12) Guidelines to advertise clinical trials, adopted by the Group of Experts on Biomedical Research of the LBEC on 15 May 2007.
13) Guidelines for Patient Information Sheet and Informed Consent Form, adopted by the Group of Experts on Biomedical Research of the LBEC on 28 September 2010.

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:

1. Siauliai. Public Institution Republican Siauliai Hospital Subsidiary Hospital of Tuberculosis and Lung Diseases.
2. Vilnius. Lithuanian AIDS Centre. http://www.ulac.lt/en
3. Vilnius. Infectious Diseases and Tuberculosis Hospital affiliate of Public institution Vilnius University Hospital.
4. Vilnius. Vilnius University Hospital Santariskiu Klinikos http://www.santa.lt/index.php?option=com_content&view=article&id=107&Itemid=379
5. Vilnius. CCBR (Centre for Clinical and Basic Research), https://ccbr.com; ccbr.vilnius@ccbr.com ; Smélio str. 20 LT 10323 Vilnius Lithuania
6. Vilnius. Biotechpharma (Lithuania), http://www.biotechpharma.lt/; info@biotechpharma.lt ; Mokslininku str. 4 LT-08412 Vilnius, Lithuania
7. Lithuanian Good Clinical and Regulatory Practice Association, http://www.gkrp.lt/about-association/association/, currently consisting of the following 5 members:
    a. JSC "Biomapas", http://www.biomapas.lt/
    b. JSC "Quintiles", http://www.quintiles.com/,
    c. JSC "Parexel International", https://www.parexel.com/,
    d. ICON public limited company representative office, http://www.iconplc.com/,
    e. JSC "Crown CRO", http://www.crowncro.com/.

Annual data on clinical trials in the country is available here: http://www.vvkt.lt/Metines-suvestines

Moldova

To perform a CT in Moldova, 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 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.

National Laws

- The Law of the Republic of Moldova "On Pharmaceutical Activities" No.1456-XII dated May 25, 1993.
- The Law of the Republic of Moldova "On Medicines" No.1409-XIII dated December 17, 1997
- The Law of the Republic of Moldova dated October 27, 2005 No.263-XVI "On Patients Rights and Responsibilities" (as amended by the Laws of the Republic of Moldova dated 14.02.2008 No.13-XVI, 14.12.2007 No.280-XVI, 16.05.2008 No.107-XVI, and 31.07.2015 No.166)

Government Resolutions

- 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"
- The Resolution of the Government of the Republic of Moldova No.5 dated January 18, 2016 "On National Committee for Clinical Trials Ethic Expertise"
- The Resolution of the Government of the Republic of Moldova dated January 23, 2013 No.71 "On approval of the Regulations on organization, functioning, framework and limit headcount of the staff of the Agency for medicines and medicinal products"
- The Resolution of the Government of the Republic of Moldova No.71 dated 23.01.2013 on approval of the "Regulations on organization, functioning, framework and limit headcount of the staff of the Agency for medicines and medicinal products"

Orders

- 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"

- 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"
- The Order of the Ministry of Health and Social Development of the Republic of Moldova No.22 dated 12.01.2006 "On amendments to Order of the Ministry of Health of the Republic of Moldova No.10 dated 14.01.2001 "On the procedure for conducting medicines clinical trials in the Republic of Moldova"
- The Order of the Ministry of Health and Social Development of the Republic of Moldova No.382 dated February 18, 2005 "On approval of the Guidelines for the medicines registration procedure in the Republic of Moldova"
- The Order of the Ministry of Health and Social Development of the Republic of Moldova No.739 dated 23.07.2012 "On authorization of the medicines for human use and approval of the post-marketing changes"

The list of potential CT centres is based on the data of the website of the Moldova Medicines Agency[14] and on information from the website clinicaltrials.gov:

1) Chisinau. Republican Clinical Hospital, http://scr.md/page/ro-contacte-38
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
5) Chisinau. Public Medical Sanitary Institution Institute of Phtysiopneumology "Chiril Draganiuc" , MDR TB dept No.1 http://www.ifp.asm.md/en
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
9) Chisinau. Institute of Neurology and Neurosurgery, http://inn.md/
10) Chisinau. Scientific Research Institute of Mother and Child, http://www.asm.md/?go=membrii-colectivi&list=1&n=2&m=15&new_language=1
11) Chisinau. Psychiatric Hospital, Municipal Clinical Hospital No.1
12) Chisinau. "Trinity", Municipal Clinical Hospital No.3
13) Chisinau. "Medpark", International Hospital, http://www.medpark.md/en/contact

[14] http://www.amed.md/ru/node/746

Poland

Regulatory Agency/Competent Authority (RA) and Ethics Committee (EC) approval is required prior to any new drug or non-CE marked medical device clinical trial initiation in Poland. The Clinical Trial Application (CTA) should be submitted to the RA by the clinical trial sponsor or its authorised representative. Before the CTA is submitted to the RA and EC, all non-EU sponsors must appoint a so-called 'Legal Representative' that has to be legally established in the European Union. Application for drug studies can be made to RA and EC in parallel, however, the CTA for medical devices must be made to the RA after EC approval has been obtained.

European Normative documents:

1) Guideline for good clinical practice E6(R1), 10.06.1996
2) WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, June 1964
3) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
4) Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)
5) Ethical considerations for clinical trials on medicinal products conducted with the paediatric population, Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use
6) Clinical safety data management: definitions and standards for expedited reporting e2a, 27.10.1994
7) Structure and content of clinical study reports E3, 30.11.1995

Based on the interview conducted with the member of EECA CAB based in Poland, the following centres have been identified:

1. Bialystok: University Hospital, Marii Skłodowskiej-Curie 24a, 15-276 Bialyst, tel. +48 85 746 83 35, e-mail: uskwb@umb.edu.pl
2. Bydgoszcz: Hospital of Infectious Diseases of Browicz, 12 Saint Florian 12 St, 85-030 Bydgoszcz, Poland, phone: +48 52 325 56 16,
3. Chorzow: Specialized Hospital
4. Gdansk: Centre of Infectious Diseases and Tuberculosis, http://www.pcchz.pl/, ul. Smoluchowskiego 18, 80-214 Gdansk
5. Krakow: University Hospital in Krakow, https://en.su.krakow.pl/addresses-phone-numbers, Kraków, 5 Śniadeckich Street
6. Lancut: Medical Centre in Lancut
7. Lodz: Provincial Specialized Hospital
8. Lublin: Independent Public Clinical Hospital N1, https://www.umlub.pl , Racławickie 1 Street, 20-059 Lublin
9. Lublin: Independent Public Provincial Hospital
10. Opole: Regional Hospital
11. Ostroda: Specialized Hospital
12. Poznan: Specialized Municipal Hospital of J. Strusia
13. Poznan: Clinical Hospital. of Karol Jonscher
14. Szczecin: Independent Public Provincial Hospital
15. Torun: Regional Hospital
16. Warsaw: Provincial Hospital of Infectious Diseases, 37 Wolska st, 01-201 Warsaw, Poland, tel: 0048 22 33 55 351-355, e-mail: info@zakazny.pl
17. Warsaw: Institute of Mother and Child,
18. Warsaw: Health Centre of Women and Newborn of Medical University in Warsaw
19. Wroclaw: Provincial Specialized Hospital of J. Gromkowski
20. Wroclaw: Clinical Hospital No.1
21. Wroclaw: Health Centre in Wroclaw
22. Zielona Gora: Regional Hospital Unit of Karol Marcinkowski

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 December 29, 2015[15]); 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.266 as of June 19, 2003 stipulates the rules for performing clinical trials based on good clinical practice[16]. According to Federal Law No.61, the clinical trial sites 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[17]. 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

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. Recently, this organization has been criticized 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.

Below follows a list of laws and norms regulating the field of clinical trials in Russia (database accessed June 2016):

Federal Laws

- Federal Law as of 12.04.2010 No.61-FZ "On Circulation of Medicines"
- Tax Code of the Russian Federation (certain provisions), stipulating the sum of duties to be paid
- Federal Law dated November 21, 2011 N 323-FZ "On the basics of Healthcare in Russia" (certain provisions)
-

Government Resolutions

- The Resolution of the Russian Federation Government of September 29, 2010 N 771 "On the order of medicines import into the Russian Federation."
- The Resolution of the Russian Federation Government of September 13, 2010 N 714 (edited of October 15, 2014) "On approval of standard rules of mandatory life and health insurance of a person participating in clinical studies of a drug product."

[15] https://www.consultant.ru/document/cons_doc_LAW_99350/ (Russian Language only)
[16] https://www.consultant.ru/document/cons_doc_LAW_43346/#dst100011
[17] https://www.consultant.ru/document/cons_doc_LAW_104459/#dst100009

- The Resolution of the Russian Federation Government of September 3, 2010 N 673 “On approval of Rules of import into the Russian Federation and export out of the Russian Federation of biological materials obtained during clinical studies of a medical drug product.”
- The Resolution of the Russian Federation Government of September 3, 2010 N 683 "On approval of Rules of medical institutions accreditation to carry out clinical studies of medical drug products.”
- The Government Decree of September 15, 2008 N 688 “On approval of lists of codes of medical goods liable to the value added tax on the tax rate of 10 percent.”
- The Russian Federation Ministry of Health Order N266 of June 19, 2003 “On approval of rules of clinical practice in the Russian Federation.”
- Ministry of Health and Social Development of Russia Order N703н of August 23, 2010 “On approval of a form of the message of completion, suspension or termination of a clinical study of a medical drug product.”
- Ministry of Health and Social Development of Russia Order N748 of August 26, 2010 “On approval of the issuance of authorization to conduct a clinical study of a medical drug product” (in the wording of the Russian Federation Ministry of Health Order March 13, 2015 N111н).
- Ministry of Health and Social Development of Russia Order N750 of August 26, 2010 “On approval of the rules of medical drug products examination and forms of conclusion of the experts committee” (in the wording of the Russian Federation Ministry of Health Order of December 13, 2012 N1041н and of April 03, 2014 N152н)
- Ministry of Health and Social Development of Russia Order N753н of August 26, 2010 “On approval of the procedure for organizing and conducting an ethical review of the possibility of a clinical study of a medical drug product and form of conclusion of the Board of Ethics”
- Ministry of Health and Social Development of Russia Order N775н of August 31, 2010 “On approval of the procedure to consider a report of the need for changes in the medical drug product clinical studies protocol”
- Ministry of Health and Social Development of Russia Order N774н of August 31, 2010 “On the Board of Ethics”
- 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”
- Ministry of Health and Social Development of Russia Order of December 3, 2010 N1073н “On approval of an application form to provide a certificate of accreditation of a medical organization to conduct clinical studies of medical drug products”
- Ministry of Health and Social Development of Russia Order N1091н of September 29, 2011 “On approval of the Administrative Regulations of the Federal Service on Surveillance in Healthcare and Social Development on execution of a State function to

monitor the conduct of pre-clinical studies of medicines and clinical studies of medical drug products."

- The Russian Federation Ministry of Health Order of August 2, 2012 N 61н "On approval of the Administrative Regulations of the Russian Federation Ministry of Health to provide a State service to issue permits to import into the Russian Federation and export from the Russian Federation of biological materials obtained from clinical studies of medical drug products" (in the wording of the Russian Federation Ministry of Health Order of October 07, 2013 N 704н).
- The Russian Federation Ministry of Health Order of August 29, 2012 N 1106-Пр/12 on the annulment of the order of the Federal Service on Surveillance in Healthcare and Social Development of August 17, 2007 N 2314-ПР/07 "On the Board of Ethics."
- The Russian Federation Ministry of Health Order N986н of November 29, 2012 "On approval of the Regulations of the Board of Ethics."
- The Russian Federation Ministry of Health Order N1359н of December 24, 2012 "On annulment of the Order of the RSFSR Ministry of Health of August 25, 1992 "On organization of departments of clinical tests of drug products with healthy volunteers."
- The Russian Federation Ministry of Health Order N 1570 of December 27, 2012 "On the Board of Ethics Composition."
- Attachment 13 to the Order of the Russian Industry and Trade Ministry of June 14, 2013 N916 (edited of December 18, 2015) "On approval of the Rules of good manufacturing practice, medical drug products for clinical studies."
- The Russian Federation Ministry of Health Order of March 24, 2015 N137 "On the Board of Ethics Composition."
- The Russian Federation Ministry of Health Order of April 1, 2016 No.200н "On Approval of Good Clinical Practice Rules"

National Standard

The Russian Federation National Standard GOST R 52379-2005 "Good Clinical Practice"

The full list of institutions currently having accreditation for carrying out clinical trials is available at grls.rosminzdrav.ru (http://grls.rosminzdrav.ru/Ree_orgCI2.aspx). The full list contains over 1100 sites.

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"
2) Arkhangelsk. State Budgetary Healthcare Institution "Centre for Prevention and Control of AIDS and Infectious Diseases"; http://spid29.ru/

3) Barnaul. Limited Liability Company Multidisciplinary clinic *Anturium* (LLC MDC *Anturium*)
4) Barnaul. State Healthcare Institution "Altai Territorial Centre for Prevention and Control of AIDS and Infectious Diseases", http://www.altaids.alt.ru/
5) Blagoveshchensk. Federal State Budgetary Scientific Institution "Far Eastern Scientific Centre of Physiology and Pathology of the Breath"; http://cfpd.amursu.ru/
6) Chelyabinsk. Chelyabinsk region State Budgetary Healthcare Institution "Regional Centre for Prevention and Control of AIDS and Infectious Diseases"; http://xn--d1achwgkbn7a.xn--p1ai/index.php/kontakty
7) Gorno-Altaisk. Republic of Altai Budgetary Healthcare Institution "Centre for Prevention and Control of AIDS and Infectious Diseases",
8) Irkutsk. State Budgetary Healthcare Institution "Irkutsk Regional Centre for Prevention and Control of AIDS and Infectious Diseases"; http://aids38.ru/
9) Izhevsk. Udmurt Republic Budgetary Healthcare Institution "Udmurt Republic Centre for Prevention and Control of AIDS and Infectious Diseases"; http://spid18.ru/
10) Kaluga. Kaluga Region State Autonomous Institution "Kaluga Regional Centre for Prevention and Control of AIDS and Infectious Diseases"; http://aids-kaluga.ru/
11) Kazan. State Budgetary Healthcare Institution Republican Clinical TB dispensary. http://rkpd.tatarstan.ru/
12) Kemerovo. Kemerovo Region State Budgetary Healthcare Institution "Kemerovo Regional Centre for Prevention and Control of AIDS and Infectious Diseases"; http://www.kemspid.ru/
13) Khabarovsk. Khabarovsk Territorial State Budgetary Healthcare Institution "Centre for Prevention and Control of AIDS and Infectious Diseases" http://xn--27-6kcqta7arri.xn--p1ai/
14) Kirov. Kirov Region State Budgetary Healthcare Institution "Kirov Regional Centre for Prevention and Control of AIDS and Infectious Diseases", http://www.aids43.ru/
15) Krasnodar. Clinical Centre for Prevention and Control of AIDS. http://www.hivkuban.ru/
16) Krasnoyarsk Krai Centre for Prevention and Control of AIDS, http://aids.krsn.ru/
17) Lipetsk. State Healthcare Institution "Lipetsk Regional Centre for Prevention and Control of AIDS and Infectious Diseases". http://www.aids48.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
20) Moscow. Technological company *Infectex*, Skolkovo

21) Moscow. Moscow Region State Public Healthcare Institution “Centre for Prevention and Control of AIDS and Infectious Diseases”, http://www.monikiweb.ru/
22) Moscow. City Clinical Hospital No 24, http://www.gkb-24.ru/
23) *Moscow.* Moscow Clinical Hospital for Infectious Diseases No.1, *http://www.mosgorzdrav.ru/ikb1*
24) Moscow Clinical Hospital for Infectious Diseases No.2 http://xn---2-6kcd9arog9evc.xn--p1ai/
25) Moscow. Central Research Institute for Epidemiology, *http://www.nkkdc.ru/*
26) Moscow. First Moscow State Medical University named after I.M. Sechenov, http://www.mma.ru/en/
27) Moscow. Ambulance Research Institute named after N.V. Sklifosovskiy, http://www.sklifos.ru/
28) Moscow. Federal Research Centre of Nutrition, Biotechnology and Food Safety, http://www.ion.ru/
29) Moscow. Moscow Clinical Research Centre, http://mknc.ru/mknts/
30) Moscow. Central Clinical Hospital of the Russian Academy of Medical Sciences, http://www.ckbran.ru/
31) Moscow. Federal State Budgetary Institution "Russian Academy of Medical Sciences Central Scientific Research Institute of TB”; http://critub.ru/contacts/
32) Nizhniy Novgorod. Nizhniy Novgorod Region State Budgetary Healthcare Institution “Nizhniy Novgorod Regional Centre for Prevention and Control of AIDS and Infectious Diseases”; http://antispidnn.ru/
33) Novosibirsk. Novosibirsk Region State Budgetary Healthcare Institution “Centre for Prevention and Control of AIDS”. http://spidnso.ru/
34) Novosibirsk region. “Centre for Infectious Diseases” Limited Liability Company
35) Orel. Orel Region Budgetary Healthcare Institution “Orel Regional Centre for Prevention and Control of AIDS and Infectious Diseases”. http://aids-orel.ru/
36) Petropavlovsk-Kamchatskiy. State Budgetary Healthcare Institution “Kamchatka Territorial Centre for Prevention and Control of AIDS and Infectious Diseases”
37) Petrozavodsk. Republic of Karelia State Budgetary Healthcare Institution “Republican Centre for Prevention and Control of AIDS and Infectious Diseases”. http://karelia-spid.ru/Kontakty/
38) Samara. Samara Regional Centre for Prevention and Control of AIDS, http://samaraspidcenter.ru/
39) Samara. Medical Company “Hepatologist”, http://www.hepatologi.ru/
40) Saratov. State Healthcare Institution “Saratov Regional Centre for Prevention and Control of AIDS and Infectious Diseases”; http://spid.medportal.saratov.gov.ru/about/

41) Smolensk. Smolensk Centre for Prevention and Control of AIDS. http://www.spidsm.net/
42) Stavropol. Stavropol State Medical University. http://stgmu.ru/
43) St. Petersburg. Clinical Hospital for Infectious Diseases named after S.P. Botkin. http://botkinhosp.org/
44) St. Petersburg. Saint-Petersburg State Budgetary Scientific Institution "Centre for Prevention and Control of AIDS and Infectious Diseases", http://www.hiv-spb.ru/
45) St. Petersburg. Military Medical Academy named after S.M.Kirov, http://www.vmeda.org/
46) St. Petersburg. North-Western State Medical University named after I.I. Mechnikov
47) St. Petersburg. Private research institution Biomedical Centre http://www.biomed.spb.ru/
48) St. Petersburg. Federal State Budgetary Scientific Institution "Scientific Research Institute of Influenza" Ministry of Health of the Russian, http://www.influenza.spb.ru/en/
49) St. Petersburg. Federal State Budgetary Institution "Federal Bio-Medical Agency Scientific Research Institute of Paediatric Infections"
50) St. Petersburg. Republican Clinical Hospital for Infectious Diseases, http://childhiv.ru/
51) St. Petersburg. Federal State Budgetary Institution "Saint-Petersburg Scientific Research Institute of Phthisiopulmonology" Ministry of Health of the Russian Federation. http://www.spbniif.ru/
52) Sverdlovsk Region. Sverdlovsk Region Clinical Hospital No. 1 http://www.okb1.ru/
53) Togliatti. Togliatti City Clinical Hospital No. 5.
54) Tyumen. ENDOS Consultancy and Diagnostics Centre. http://www.kdctmn.ru/
55) Vladimir. Vladimir Region State Budgetary Healthcare Institution "Centre of Specialized Phthisiopulmonological Help"
56) Volgograd. State Public Healthcare Institution "Volgograd regional Centre for Prevention and Control of AIDS and Infectious Diseases". http://aidsvolgograd.ru/
57) Voronezh. Voronezh Region Budgetary Healthcare Institution "Voronezh Regional Centre for Prevention and Control of AIDS". http://voronezh-aids.ru/
58) Voronezh. Voronezh Region Public Healthcare Institution "Voronezh Regional TB dispensary named after N.S. Pohvisneva
59) Yaroslavl. Yaroslavl Region State Budgetary Healthcare Institution "Regional Clinical TB Hospital"
60) Yekaterinburg. Sverdlovsk Regional Centre for Prevention and Control of AIDS. http://livehiv.ru/

Tajikistan

Tajikistan has a law on medicines and pharmaceutical activity (latest revision June 18, 2008, Order No.409). 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. In order to initiate a clinical trial, the research must obtain a special approval from the Ministry. 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.

Federal Laws

1) The Law of the Republic of Tajikistan dated 06.08.2001 No.39 "On Medicines and Pharmaceutical Activity"

Based on literature review and interviews with experts, the following CT centres have been identified:

1) Dushanbe. Republican Centre for Prevention and Control of AIDS, http://www.nc-aids.tj/
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 (Order No.523 issued by the Ukrainian Ministry of Health dated July 12, 2012).

National Laws

- Law of Ukraine "On Medicines" of May 7, 1996 N 123/96-BP (with changes).
- Law of Ukraine (3611-17) of July 07, 2011 N 3611-VI which amended the Law of Ukraine "Fundamentals of Healthcare Legislation."
- Law of Ukraine of May 12, 2011 N 3323-VI "On amendments to certain legislative acts of Ukraine regarding clinical studies of medicines" which amended Art. 281 of the Administrative Code of Ukraine and the Law of Ukraine "On Medicines".

Government Resolutions

- The procedure for conducting clinical studies of medical drug products and examination of materials of the clinical studies (Ukraine Ministry of Health Order of September 23, 2009 N 690)
- **Orders**
- Ukraine Ministry of Health Order of November 01, 2000 N 281 Instructions on the conduct of clinical tests of medicines and expert evaluation of the clinical tests materials. Model Regulations for the Board of Ethics.
- Ukraine Ministry of Health Order of December 19, 2000 N 347 Instructions on the surveillance over side effects/reactions of medicines.
- 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."
- Ukraine Ministry of Health Order N66 of February 13, 2006 "On approval of clinical tests of medicines and expert evaluation of the clinical tests materials and Model Regulations for the Board of Ethics."
- Ukraine Ministry of Health Order N245 of May 17, 2007 "On approval of the Procedure for definition of specialized healthcare facilities where medical drugs can be clinically tested."
- Ukraine Ministry of Health Order of September 23, 2009 N 690 "On approval of the Procedure for conducting clinical studies of medicines and examination of the studies materials and Model Regulations for the Board of Ethics."
- Ukraine Ministry of Health Order N 523 of July 12, 2012 "On amendments to the order of Ukraine Ministry of Health of September 23, 2009 N690."

- Ukraine Ministry of Health Order N 304 of May 06, 2014 "On amendments to the order of Ukraine Ministry of Health of September 23, 2009. N 690."
- Ukraine Ministry of Health Order N 639 of October 01, 2015 «On amendments to the order of Ukraine Ministry of Health of September 23 сентября, 2009 N 690."
- Ukraine Ministry of Health Order N 690 of September 23, 2009 "On approval of the conduct of clinical studies and examination of the materials of the clinical studies and Model Regulations for the Board of Ethics."
- Ukraine Ministry of Health Order of January 17, 2002 N 13 The procedure of import of unregistered medicines into the customs territory of Ukraine for the purpose of pre-clinical and clinical tests and State registration.
- Ukraine Ministry of Health Order N 355 of September 25, 2002 "On amendments and additions to the instructions on the conduct of clinical studies of medicines and examination of the materials of the clinical studies."
- Ukraine Ministry of Health Order of April 11, 2012 N 255 "On regulating the ethical aspects of clinical studies of medicines."

National standard

- "Guidelines for clinical tests of medicines in Ukraine" (1999)

There is a national register of accredited clinical trial sites available publicly at the website of the Laboratory for Quality Control of Medical Immunobiological Products (the name in English is taken from the official website of the organisation)[18]. As of December 2015, the register contains over 510 accredited clinical trial sites based in the country. Below follows a list of CT centres which based on the textual analysis of the titles are involved in research in the field of infectious diseases.

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
5) Dnipropetrovsk. Dnipropetrovsk Regional Clinic named after Mechnikov, Pulmonology, Infectious Diseases, http://www.mechnikova.com/, +380562473616

[18] http://www.dec.gov.ua/index.php/ua/responsive/2013-12-12-17-11-38

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) Kremunchug, 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
13) Kyiv, Red Star Central Military Clinic, Gastroenterology, http://healthyfuture.com.ua/news/glavnyy-voyenno-meditsinskiy-klinicheskiy-gospital-ordena-krasnoy-zvezdy.html
14) Kyiv. Kyiv City Clinic No 5, Infectious Diseases, http://kmkl5.org.ua
15) Kyiv. South-West Railway Clinic No 2, KYIV, Pulmonology, http://www.dkl2.kiev.ua/en
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
18) Kyiv City AIDS Clinic, http://www.kmcs.org.ua/
19) Kyiv. Arensia (phase I Clinical Trial Centre) http://www.arensia-em.com/phase-1-units/
20) Lutsk, Volyn' Regional Clinic, Pulmonology
21) Lviv Regional Clinical Centre of Pthisiopulmonology
22) Lviv, City Public Clinic No 5, Pulmonology
23) Odesa Regional AIDS Clinic
24) Sumy. Sumy Regional Clinic, Sumy Medical Institute of the Sumy National University, Pulmonology
25) Ternopyl University Clinic, Ternopyl National Medical Academy named after I.Y. Gorbachevskiy
26) Vinnitsa. Vinnitsa Central District Clinic, Vinnitsa National Medical University named after M.I.Pirogov, 21000, Vinnitsa Region, Vinnitsa, Pirogov str, 46, +380675037465, +380936827384, +380432353273

27) 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
28) Vinnitsa. Vinnitsa Regional Clinic named after M.I. Pirogov, gastroenterology
29) Vinnitsa, Interregional Clinical and Diagnostics Centre "Health Clinic", liver diseases
30) Zaporizhzhya City Clinic No 6, Gastroenterology
31) Zaporizhzhya Regional Clinic, Pulmonology
32) Zaporizhzhya Regional AIDS Clinic, Zapirozhzhya Medical Academy of Postgraduate Education under the Ministry of Health

Uzbekistan

National Laws

The Law of the Republic of Uzbekistan dated 25.04.1997 No.415-I "On Medicines and Pharmaceutical Activity"

Orders

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"

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"

Order of the Ministry of Health of the Republic of Uzbekistan dated 25.07.2001 No.334 "The Guidelines for conducting medicines clinical trials and trials materials expertise."

Guidelines

The Guidelines of the Ministry of Health of the Republic of Uzbekistan "Guidelines for pre-clinical testing pharmacological products safety" dated 22.12.2000.

According to the public sources available[19] and interviews with experts, the following potential clinical trial sites are based in the country:

1) Tashkent: Republican Specialized Scientific and Practical Medical Centre of Obstetrics and Gynecology, http://www.akusherstvo.uz, 132-a, Mirzo-Ulugbek street, Mirzo-Ulugbek district, Tashkent
2) Tashkent: Republican Specialized Scientific and Practical Medical Centre of Pediatrics, http://pediatriya.uz/?lang=en, 100179,Chimbay str. 2, Talant-3, Almazar district, Tashkent.
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 web site 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
6) Tashkent. Republican Centre for AIDS Control, http://www.spid.uz/

[19] http://www.uzpharmsanoat.uz/ru/concern/%D0%BE-%D0%BA%D0%BE%D0%BD%D1%86%D0%B5%D1%80%D0%BD%D0%B5