

Creation of Favorable Conditions for the Development of the Clinical Trials Market

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OBJECTIVES: The number of clinical trials (CTs) conducted annually in Kazakhstan in recent years has been and is at a fairly low level, amounting to 1,8 CTs per 1 million population at the beginning of 2020 and 1,4 CTs per 1 million population on 11 September 2020, while in most OECD countries this indicator exceeds 30 CTs per 1 million people. In this regard, the State Health Development Program for 2020-2025 set the task of developing a set of measures to develop the CTs market in the country. The development of the CTs market at the national level has not only economic, but also high social significance.

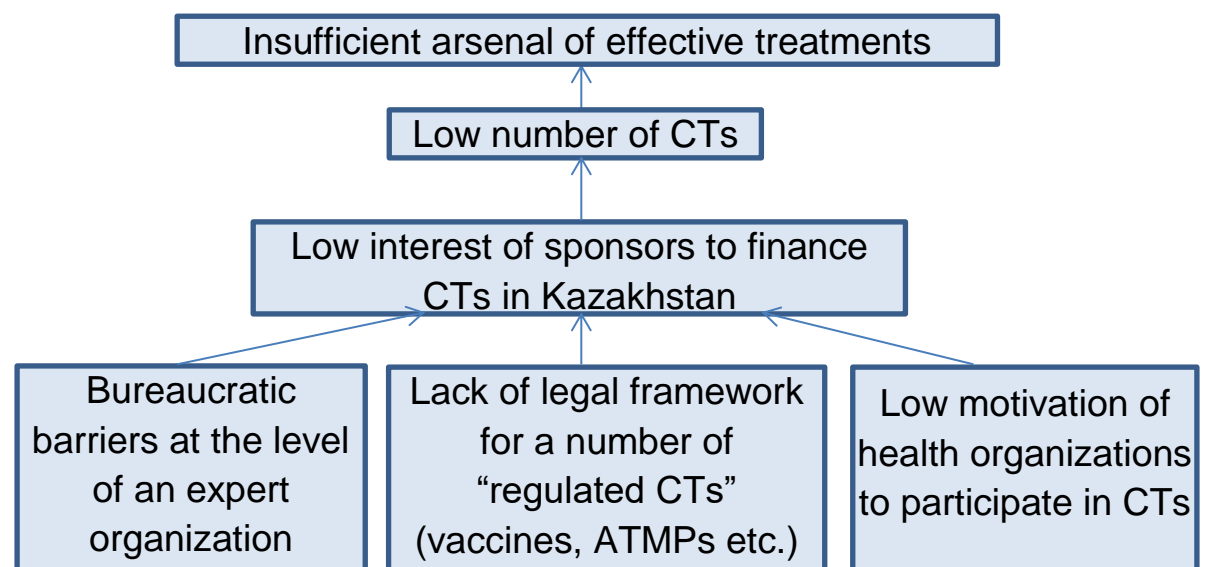
Number of active interventional clinical trials according to ClinicalTrials.gov* (11.09.2020)

	Number of active CTs	Number of CTs per million population **
United States	25,994	78,9
France	5,107	77,4
United Kingdom	3,486	52,1
Germany	3,246	39,8
Kazakhstan	26	1,4

*CTs in Status Recruiting, Enrolling by invitation, Active, not recruiting

**Population data source - <https://countrymeters.info>

METHODS: In order to determine the necessary measures for the development of the CTs market, we prepared a tree of problems with the identification of the causes and factors underlying the low level of CTs in the country. Then, publications (systematic analyzes, meta-analyzes and original studies) were examined on the best practices of organizing an appropriate environment for conducting CTs. Based on the analysis and taking into account the identified factors underlying the problem, policy options were selected.



RESULTS: Taking into account the analysis we selected the following policy options: Increasing the attractiveness of the CTs market for domestic and foreign sponsors; Creating conditions for the formation and development of the infrastructure necessary for conducting modern biomedical research and including in international CTs; Implementing effective mechanisms for involving physicians in CTs. These policy options were chosen because they are aimed at most of the factors and reasons for the underdevelopment of the CTs market in Kazakhstan.

CONCLUSIONS: Assessing the possibility of implementing the proposed policy options, taking into account the existing barriers and opportunities, we came to the conclusion that all three policy options complement each other. However more substantial achievement of the goal of development the CTs market, these policy options can give when they are combined.

Policy options

Option 1. Improving the attractiveness of the CT market in Kazakhstan for domestic and foreign investors

- Implementation of mechanisms obliging pharmaceutical companies to invest up to 10% of profits from the sale of pharmaceutical products in conducting multicenter CTs on the territory of the RK;
- Introduce mechanisms that motivate potential sponsors to fund biomedical research, including multicenter CT in the RK by reducing the tax burden for companies investing in CT;
- Creation of a favorable legal framework and conditions for biomedical research (BMR), including international multicenter CT in the RK on the basis of further harmonization with international standards and clear regulation of licensing procedures, conducting and subsequent monitoring of all types and directions of CT (including CT of advanced therapy medicinal products, CT of a combination of registered and unregistered drugs) and increasing the transparency of all stages of CT on the basis of digitalization.

Option 2. Creation of conditions for the formation and development in RK of the infrastructure necessary for conducting modern BMR and allowing inclusion in international research programs

- Adoption of a legal framework that defines the procedure for the creation and activities of biobanks;
- Creation Centers of personalized medicine (on the basis of medical universities, research institutes), functioning as "Excellence Centers", which play a key role in conducting BMR, including CTs, and transfer their results to clinical practice;
- Creation of an effective research environment in health organizations based on the improvement of resource provision, improvement of the logistics of medical services when conducting CT in health organizations, including by developing SOPs for conducting CT, a document establishing the procedure for working with confidential information, etc.
- Digitalization of the process of filing applications for conducting CT and creating a register of CTs conducted on the territory of the RK;
- Effective information support of CT in a professional medical environment in Kazakhstan and abroad.

Option 3. Implementation of effective mechanisms for the involvement of doctors in clinical trials

- Increasing the competence of doctors of the health organizations (first of all, the Republican, oblast and city-level hospitals) on the issues of the CT methodology and good clinical practice (GCP);
- Stabilization of the relationship "doctor-patient" on the basis of increasing communication skills and competencies in the field of medical ethics; introduction of preferences for patients in CT;
- Development of SOPs according to the competence and subordination of a doctor within the framework of CT;
- Taking organizational measures to involve doctors in CT based on effective time management in health organizations; redistribution of the functional of the doctor-researcher for the period of the CT; elimination of "routine" procedures due to the reorganization and restructuring of the health organizations through digitalization, the use of new technologies to support the doctor's functional in the health organizations

