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ASSESSMENT OF THE RESEARCH POTENTIAL OF HEALTHCARE SPECIALISTS IN THE REPUBLIC OF KAZAKHSTAN IN THE IMPLEMENTATION OF CLINICAL RESEARCH: RESULTS OF ONLINE QUESTIONNAIRES AND SELF-ASSESSMENTS. GLOBAL CRISIS OF CLINICAL RESEARCHER SHORTAGE

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The study aimed to identify and analyze the potential of practical healthcare professionals in terms of skills and knowledge for conducting clinical research in Kazakhstan, as well as to identify obstacles that may arise and cause the low involvement of specialists in research activities.

Materials and methods. A specially developed questionnaire was conducted online. Various healthcare professionals (doctors, nurses, teachers of medical educational organizations) from all regions of Kazakhstan participated. By random sampling, 337 respondents answered the questions. Data was collected anonymously through Google Forms.

Results and discussion. 29,7% respondents had participated in clinical research. Most respondents do not have sufficient knowledge in conducting clinical research; on average, 35% of respondents answered correctly. On average, respondents' self-assessment of knowledge and skills in choosing a study design, forming groups of study objects, collecting, analyzing, and interpreting data obtained during clinical trials, and performing statistical processing of results was 3 points (max = 5 points). A majority expressed a need for further training in clinical research. The main barriers to conducting clinical research were identified as lack of working time (44%), insufficient knowledge in conducting clinical research (34%), inaccessibility of educational programs (28%), lack of personal interest (27%), non-compliance of clinical base infrastructure (23%), difficulties in patient recruitment (20%), and the risk of losing professional autonomy (13%).

Conclusions: The survey results show an unsatisfactory level of existing research potential of healthcare professionals in the organization and conduct of clinical research. The findings reveal a significant gap in the research potential of healthcare professionals in Kazakhstan. There is a lack of understanding of clinical research concepts, international standards, and local legislative requirements. The main obstacles are inadequate time for research, insufficient knowledge and experience, limited access to training, and low interest among professionals.

Keywords: specialist potential; clinical research; researchers; capacity building; research team

INTRODUCTION

Planning and conducting clinical research require skills and knowledge from healthcare professionals. A low level of such training may be one of the reasons for the slow development of medical science and clinical research. Strengthening the capacity of

healthcare professionals to conduct clinical research in the country is crucial for achieving access to high-quality medical services for the population.

At the Global Medical Research Forum in 2004, the importance of countries' efforts to strengthen research capacity was noted as a central role in the

process of selecting research needs, priorities, and clinical research strategies [1].

However, to this day, this issue remains acute and causes problems in many countries. Globally, the number of interested specialists willing to build a professional career in conducting clinical research is declining [2].

In Kazakhstan, this problem is also relevant, and the need for qualified research personnel is growing annually. The current situation is due to several factors, one of the main ones being the lack of professional training for clinical researchers and research teams, and the financing of medical science.

Professional researchers are one of the key resources for conducting clinical research. The group of clinical researchers typically includes doctors and nurses, and may also involve clinical and non-clinical managers, researchers (medical and non-medical staff), research coordinators (nurses, scientific staff), pharmacists, biostatisticians, and other healthcare professionals [7].

In Kazakhstan, there is no information system that accumulates data on specialists conducting clinical research or who are part of a research team. Additionally, there is no data on specialists who have received training in clinical research, international GCP certification, or clinical research project manager certification [2]. Globally, there are numerous training and education programs for specialists in the field of clinical research [1,3,9].

The aim of the study was to identify and analyze the situation regarding the potential of practical healthcare professionals in terms of skills and knowledge for conducting clinical research in Kazakhstan, as well as to identify obstacles that may arise and cause low involvement of specialists in research activities.

MATERIALS AND METHODS

To study the knowledge and skills of healthcare professionals in Kazakhstan regarding their readiness to conduct clinical trials, a descriptive study was conducted. The research tool was a developed questionnaire.

Questionnaire Components. The questionnaire consisted of 45 questions grouped into 4 sections. The first section of the questionnaire (questions 1-9) was used to collect the socio-demographic characteristics of the respondents (gender, age, region, education level, academic degree/title, place of work, position, and work experience). The second section of the questionnaire (questions 10-15) aimed to identify attitudes towards participating in clinical trials, as well as their role and experience in conducting clinical trials in the organization where the respondent works. The third section of the questionnaire (questions

16-21) included questions characterizing publication activity and the implementation of research results into practice by the healthcare professional. The fourth section of the questionnaire (questions 22-39) focused on the general level of knowledge and self-assessment of skills in the field of clinical trials. The final section of the questionnaire (questions 40-45) addressed questions regarding the motivation created by organizations and the barriers encountered in conducting clinical trials.

The questionnaire form included open-ended questions for qualitative analysis of responses and closed-ended questions for both qualitative and quantitative processing of the obtained data, as well as scales for respondents to self-assess their skills (5-point scale).

Respondent Selection and Confidentiality.

A total of 337 healthcare professionals participated in the survey. The survey was conducted without emphasizing a specific role within the research team and included all potential participants: researchers, clinical trial coordinators, data managers, biostatisticians, regulatory managers, and others involved in the implementation of clinical trials.

Respondents were selected randomly. The survey was conducted online in both Russian and Kazakh languages using Google Forms. To distribute the questionnaire, convenient tools such as WhatsApp messengers, social networks, and email were used. The survey was anonymous, and each respondent could participate only once.

Statistical Analysis. The survey results were analyzed using the statistical package Microsoft Excel. Considering that the questionnaire did not require mandatory responses to all questions, the analysis of the results was conducted based on the number of responses received.

RESULTS

Gender, Age, and Professional Data. Out of the 337 survey participants, the majority were women, most of whom were in the age group of 20 to 45 years. The average age of the respondents was 39 years.

A total of 75 respondents (22,3%) indicated that they hold an academic or scientific degree. The average age of these degree-holding specialists was 43 years. A total of 22 respondents (6,5%) hold an academic title. The majority of respondents (44%) with an academic or scientific degree have more than 20 years of work experience (Table 1).

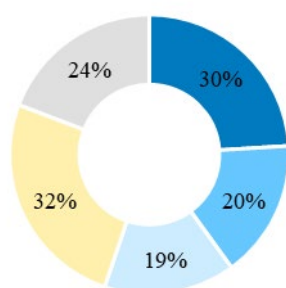
The survey covered 15 regions of Kazakhstan, including 12 regions and 3 cities (Almaty, Astana, and Shymkent). The predominant share of survey participants (79,8%) came from 5 regions: Almaty Region (33,5%), East Kazakhstan Region (14,2%),

Организация и экономика здравоохранения

Table 1 – Basic gender, age and professional components (%)

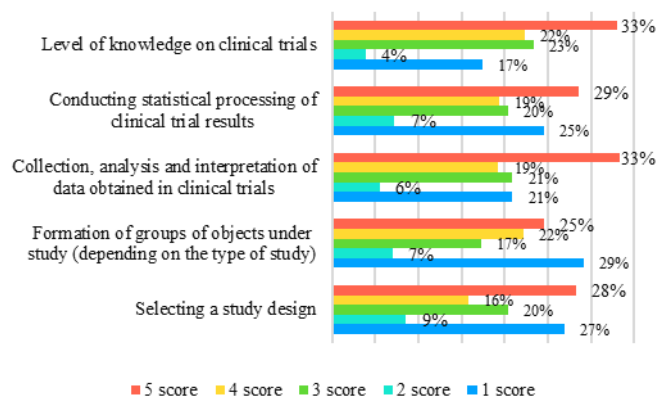
Education		Age		
higher medical or pharmaceutical	54	20-25 years	11,6	
secondary specialized medical and pharmaceutical	42	26-30 years	15,7	
other	4	31-35 years	17,5	
Experience (years)		36-40 years	13,9	
1-5 years	26	41-45 years	6,2	
6-10 years	21	46-50 years	12,5	
11-15 years	13	51-55 years	10,4	
16-20 years	10	56-60 years	8	
Over 20 years	31	61-65 years	3	
		>65 years	1	
Academic degree		Gender		
Doctor of Medical Sciences	4,2	Female	75,4	
Candidate of Medical Sciences	7,1	Male	24,6	
PhD	2,1	Job		
MD	5,0	Medical organization (including private)	80	
MBA	3,0	organization of medical education and science	9	
DBA	0,3	scientific center/research institute	0,08	
		Other	3	
Experience in clinical trials*		29,7	The role of participation in a clinical trial	
1-2 clinical trials	62,5	principal investigator	11,2	
3-6 clinical trials	27,2	co-researchers	57	
10 and more	10,2	Coordinator	15,3	
		pharmacist	2	
		nurse	8	
		Other	6	

*Participation in the clinical trial was described based on the responses of 88 respondents, these data were obtained after cleaning all responses and excluding erroneous «non-logical lines»



■ 5 score ■ 4 score ■ 3 score ■ 2 score ■ 1 score

Figure 1 – Level of self-esteem of respondents on 5 questions, 5-point scale (%)



■ 5 score ■ 4 score ■ 3 score ■ 2 score ■ 1 score

Figure 2 – Results of self-assessment of respondents on knowledge and skills in implementing clinical trials (%)

West Kazakhstan Region (12,8%), Karaganda Region (9,8%), and the city of Almaty (9,5%).

Participation of Respondents in Clinical Trials and Their Roles. A total of 100 respondents (29,7% of the total cohort surveyed) participated in a clinical trial. Of this number, half of the specialists (54%) hold an academic or scientific degree. The survey also revealed that 20 specialists with a degree are not engaged in scientific activities or conducting clinical trials, despite having more than 20 years of work experience (9%).

For the analysis of the results of the next section of the questionnaire, responses from 88 respondents were used. Among them, 62% participated in 1-2 clinical trials, 27% in 3-6 trials, and 10% conducted 10 or more clinical trials. Members of the research team often combined multiple roles simultaneously during clinical trials, mainly as principal investigators and co-investigators. The roles chosen by the respondents were: principal investigator (12,5%), co-investigator (63,6%), coordinator (17%), and other roles such as pharmacist, nurse, or research assistant (18%).

Most respondents noted that clinical trials are not conducted in the organizations where they work (45%) or they are not aware of them (28%). However, some indicated that clinical trials are conducted in their organizations (26,8%), and among them, 39% do not participate in these trials.

Implementation of Results into Practice and Publication Activity of Respondents. Respondents who participated in clinical trials reported having scientific publications based on clinical trial results in national scientific journals (57,9%) and international journals (51%). Twenty-seven respondents noted a Hirsch index ranging from 1 to 9. The average Hirsch index among respondents who reported having one was 2,4. Based on clinical trial results, 26% of respondents have authorship certificates and 18% have patents.

Self-Assessment of Knowledge and Skills. Based on self-assessment, 30% of respondents rated their knowledge and skills in conducting clinical trials highly, scoring themselves 5 points on the defined list of knowledge and skills (Figure 1). Among all respondents, 24% rated their skills low (1 point).

Self-Assessment of Knowledge and Skills in Conducting Clinical Trials. The self-assessment of knowledge and skills in conducting clinical trials was carried out in 5 areas (Figure 2), with an average score of 3 points for each question: 1) skills in determining the research design sample, with 27% of respondents rating themselves the maximum 5 points, 28% of whom previously noted that they had not participated in research. 2) Skills in forming study groups depending on the type of research, with 24% rating themselves the maximum (5 points). 3) Skills in collecting, analyzing, and interpreting data obtained

during clinical trials, with 1/3 of respondents (33%) rating themselves 5 points. 4) Conducting statistical analysis of clinical trial results, with an equal share of respondents rating themselves the maximum (5 points) (29%) and the minimum (1 point) (25%). 5) Overall, 55% of respondents rated their knowledge of clinical trials as good or excellent.

Assessment of Respondents' Potential in Conducting Clinical Trials. To assess the potential of respondents, 11 questions were defined in the field of organizing and conducting clinical trials. The average score of correctly answered questions was 35% (Table 2).

The need for training in conducting clinical trials. All respondents expressed a need for training in conducting clinical trials in the following priority areas: «evidence-based medicine» (34%), «clinical trial methodology (protocol design and clinical trial process, data management, etc.)» (26%), «regulatory and standardizing documents for clinical trials (GCP, GMP, GLP)» (15%), «epidemiology and statistics» (12,5%), «ethical issues in biomedical research» (8%), and «principles of ICH GCP» (4%).

Motivation System and Challenges in conducting clinical trials. Respondents were asked to assess the motivation system for scientific activities and the conditions for conducting research in the organizations where they work. Respondents were divided into those who rated the motivation system in their organizations low, scoring it from 1 to 3 points (55%), and those who rated it high, scoring it from 4 to 5 points (45%).

In conducting clinical research, respondents encounter a number of difficulties (42%): resource barriers (low funding for scientific activities, lack of proper infrastructure, shortage of research materials/equipment), administrative barriers (lack of adequate support from the administrative system), patient-related barriers (difficulties in recruiting patients), communicative barriers, and others.

Respondents also indicated a desire (56%) and pointed to the privileges of potentially participating in clinical research: additional financial incentives (13%), interest in the research topic (24%), the opportunity to enhance professional potential (12%), and the chance to expand their experience in clinical research (48%). A total of 43% of respondents showed no interest or desire to conduct or participate in clinical research.

Barriers and Solutions for implementing clinical trials. Respondents identified the main barriers to conducting clinical trials: a lack of working time (44%), insufficient knowledge in the field of clinical research (34%), unavailability of educational programs focused on clinical research (28%), lack of personal interest (27%), inadequate infrastructure of clinical bases (23%), difficulties in patient recruitment (20%), and the risk of losing professional autonomy (13%).

Table 2 – Results of testing respondents for knowledge in the field of clinical research

Question	Proportion of correct answers (%)	Number of responses
Awareness of respondents regarding regulatory documents in the field of clinical research	35	280
Knowledge of permitting documents necessary for the implementation of clinical trials	32	296
Knowledge of factors when conducting clinical trials according to ICH GCP principles	29	304
Knowledge of studies that are carried out after state registration of medicines or medical devices and are prescribed within the framework of medical practice	38	295
Awareness of the research phase, which aims to evaluate the effectiveness and short-term safety of drugs in a patient with a specific disease	29	290
Awareness of those responsible for conducting clinical trials at the trial site	39	301
Knowledge of the concept of «undesirable/adverse event» – any malfunction and (or) deterioration of characteristics or disruption of the functioning of a medical device, or insufficiency or incorrectness of accompanying information (documentation) for a medical device, side effects or undesirable reaction not specified in the instructions for use or manual exploitation that directly or indirectly leads to...»	35	296
Awareness of a document that describes the objectives/design/methodology/statistical aspects and organization of the study	70	300
Knowledge of the timing and person to whom the investigator must report serious adverse events from the time the information is first received	34	298
Knowledge of responsibility for reporting serious adverse events to the ethics committee	12	
Awareness of the person who has the right to obtain patient consent to participate in clinical trials	44	301

Several solutions were proposed to address these barriers. Respondents highlighted the need for the following changes to successfully conduct clinical research: increasing financial subsidies (39%), creating an information system for clinical research (26%), establishing a system for training clinical researchers (26.5%), expanding the range of educational programs on clinical research (23.5%), revising regulatory legal acts (25%), and forming a unified provider/coordinator for clinical research (19%).

DISCUSSION

This study was conducted in response to a crisis in Kazakhstan regarding the development of a clinical research base, as well as identifying the reasons for the stagnation and lack of growth in the number of clinical trials conducted in Kazakhstan, both by national researchers and international companies. In recent years, Kazakhstan has implemented a number of reforms aimed at creating a favorable environment for conducting clinical trials, including optimizing the

registration time for clinical trials (the examination for issuing a conclusion is carried out within 30 days) [8] and establishing infrastructure to support the development and coordination of clinical trials. The National research center for healthcare development named after S. Kairbekova has been designated as the center for clinical research development [4], and it is also working on the creation of a National Information System for Biomedical Research.

One of the important issues that arise is the potential level of clinical researchers in Kazakhstan. The medical education system lacks specific training programs for researchers and career development mechanisms in this field. Currently, there is no accessible information on researchers who have received professional training as investigators. There are no training programs on regulatory requirements for clinical trials in Kazakhstan and GCP standards, which are fundamental for the competence of clinical researchers. Training is needed in clinical trial methods, specific knowledge in study design,

epidemiology, and biostatistics, among other areas. The workforce crisis among researchers may be one of the limiting factors for the development of clinical trials in Kazakhstan.

Additionally, there is a need to develop a document that regulates the functions and competencies of specialists in the field of clinical research, defining the roles of clinical research specialists based on their competencies. Several issues identified in the survey also revealed a lack of awareness among specialists about what clinical trials are, the processes involved in conducting them, and their regulation. The lack of information about the necessity, methods, and opportunities for conducting clinical trials is one of the barriers to their growth.

In conclusion, the survey revealed a number of pressing human resource issues in the field of clinical research. Healthcare organization specialists, given the current realities and lack of specific knowledge and skills, are limited in their ability to raise their level to meet the high requirements and expectations regarding the quality, efficiency, and complexity of clinical trials.

CONCLUSION

Despite the low results of the self-assessment of knowledge and skills, and the results of the knowledge test in the field of clinical research, it is worth noting the presence of motivation and desire among healthcare professionals to conduct clinical trials. To build potential, the main issue becomes the creation of specialized training programs for specialists in the field of clinical research, including topics on clinical research in the training cycles of master's and doctoral students, which should comply with international standards and evidence-based medicine.

Authors' contributions:

G. U. Kulkayeva – concept, research design and editing.

V. M. Tarassova – collection and processing of material, statistical processing and writing of text.

M. A. Graf – writing and editing.

A. B. Tabarov – editing.

Conflict-of-interest statement. The authors have no conflicts of interest to declare.

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ОЦЕНКА ИССЛЕДОВАТЕЛЬСКОГО ПОТЕНЦИАЛА СПЕЦИАЛИСТОВ ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ КАЗАХСТАН В ОБЛАСТИ РЕАЛИЗАЦИИ КЛИНИЧЕСКИХ ИССЛЕДОВАНИЙ: РЕЗУЛЬТАТЫ ОНЛАЙН-АНКЕТИРОВАНИЯ И САМООЦЕНКИ. ГЛОБАЛЬНЫЙ КРИЗИС ДЕФИЦИТА КЛИНИЧЕСКИХ ИССЛЕДОВАТЕЛЕЙ

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Целью данного исследования являлось выявление и анализ ситуации по наличию потенциала у специалистов практического здравоохранения, навыков и знаний для реализации клинических исследований. Определение препятствий и причин низкой вовлеченности в исследовательскую деятельность.

Материалы и методы. Проведен онлайн опрос по специально разработанной анкете. Участвовали специалисты здравоохранения различных специальностей и уровней подготовки (врачи, медицинские сестры, преподаватели) со всех регионов Казахстана. Методом случайно выборки, на вопросы ответили 337 респондентов. Опрос проводился анонимно, через Google Forms.

Результаты и обсуждение. 29,7% от общей когорты опрошенных учувствовали в клиническом исследовании. Большая часть респондентов не обладает достаточными знаниями по проведению клинических исследований, в среднем по каждому вопросу 35% дали правильные ответы. В среднем самооценка знаний и навыков респондентов по выбору дизайна исследования, формированию групп исследуемых объектов, сбору, анализу и интерпретации данных, полученных в ходе клинических исследований, проведение статистической обработки результатов, составила 3 балла (max= 5 баллов). Все респонденты выразили потребность в обучении по клиническим исследованиям по различным приоритетным направлениям. Основными барьерами для проведения клинических исследований определены нехватка рабочего времени (44%), недостаточный уровень знаний (34%), недоступность образовательных программ (28%), отсутствие личного интереса (27%), несоответствие инфраструктуры клинических баз (23%), трудности с набором пациентов (20%) и риск потери профессиональной автономии (13%).

Выводы. Результаты анкетирования показывают не удовлетворительный уровень исследовательского потенциала по вопросам организации и проведения клинических исследований. Выявлены проблемы в понимании определения клинического исследования, знании международных стандартов и требований законодательства Казахстана в области клинических исследований, на всех этапах реализации клинических исследований от выбора дизайна, формирования исследовательской команды до проведения самого клинического исследования.

Организация и экономика здравоохранения

Главными барьерами являются отсутствие времени на занятие исследовательской деятельностью, низкий уровень знаний и опыта в этой области, недоступность программ подготовки, ориентированных на клинические исследования, и низкая заинтересованность специалистов.

Ключевые слова: потенциал специалистов; клинические исследования; исследователи; повышение потенциала

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КЛИНИКАЛЫҚ ЗЕРТТЕУЛЕРДІ ІСКЕ АСЫРУ САЛАСЫНДАҒЫ ҚАЗАҚСТАН РЕСПУБЛИКАСЫ ДЕНСАУЛЫҚ САҚТАУ МАМАНДАРЫНЫҢ ЗЕРТТЕУ ӘЛЕУЕТІН БАҒАЛАУ: ОНЛАЙН САУАЛНАМА ЖӘНЕ ӨЗІН-ӨЗІ БАҒАЛАУ НӘТИЖЕЛЕРІ. КЛИНИКАЛЫҚ ЗЕРТТЕУШІЛЕР ТАПШЫЛЫҒЫНЫҢ ЖАҢАНДЫҚ ДАҒДАРЫСЫ

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Бұл зерттеудің мақсаты – практикалық денсаулық сақтау мамандарының клиникалық зерттеулерді жүзеге асыру үшін потенциалын, дағдылары мен білімін анықтау және талдау болды. Сонымен қатар, зерттеушілік қызметке төмен қатысу себептерін анықтау.

Материалдар және әдістер. Арнайы әзірленген сауалнама арқылы онлайн сұрау жүргізілді. Қазақстанның барлық өңірлерінен әртүрлі мамандықтар мен білім деңгейлері бар денсаулық сақтау мамандары (дәрігерлер, медбикелер, медициналық білім беру ұйымдарының оқытушылары) қатысты. Кездейсоқ таңдау әдісімен 337 респондент сауалдарға жауап берді. Сауалнама анонимді түрде Google Forms арқылы жүргізілді.

Нәтижелер және талқылау. Респонденттердің 29,7% клиникалық зерттеулерге қатысқан. Респонденттердің басым көпшілігі клиникалық зерттеулерді жүргізу бойынша жеткілікті білімге ие емес, орташа алғанда әр сұраққа 35% дұрыс жауап берген. Респонденттердің зерттеу дизайнын таңдау, зерттеу объектілерінің топтарын құру, деректерді жинау, талдау және интерпретациялау, статистикалық өңдеу бойынша білімдері мен дағдыларын өзін-өзі бағалауы орташа 3 баллды (max = 5 балл) құрады. Барлық респонденттер клиникалық зерттеулер бойынша әртүрлі басымдықтағы оқытуды қажет ететінін білдірді. Клиникалық зерттеулерді жүргізудегі негізгі кедергілер ретінде жұмыс уақытының жетіспеушілігі (44%), білім деңгейінің төмендігі (34%), білім беру бағдарламаларының қолжетімсіздігі (28%), жеке қызығушылықтың болмауы (27%), клиникалық базалардың инфрақұрылымының сәйкес келмеуі (23%), пациенттерді жинаудағы қиындықтар (20%) және кәсіби автономияны жоғалту қаупі (13%) анықталды.

Қорытынды. Сауалнама нәтижелері клиникалық зерттеулерді ұйымдастыру мен жүргізу бойынша зерттеу потенциалының қанағаттанарлықсыз деңгейін көрсетеді. Респонденттер арасында клиникалық зерттеу анықтамасын түсіну, халықаралық стандарттар мен Қазақстан Республикасының клиникалық зерттеулер бойынша заңнамалық талаптарын білу бойынша олқылықтар анықталды, зерттеулерді жоспарлау, зерттеу командасын құру және зерттеуді жүргізуге дейінгі барлық кезеңдерде. Негізгі кедергілер – зерттеушілік қызметпен айналысуға уақыттың жетіспеушілігі, осы саладағы білім мен тәжірибенің төмендігі, клиникалық зерттеулерге бағытталған даярлық бағдарламаларының қолжетімсіздігі және мамандардың төмен қызығушылығы болып табылады.

Кілт сөздер: мамандардың әлеуеті; клиникалық зерттеулер; зерттеушілер; әлеуетті арттыру; зерттеу тобы