СОЦІАЛЬНИЙ МАРКЕТИНГ ТА ФАРМАКОЕКОНОМІЧНІ ДОСЛІДЖЕННЯ

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The study of awareness of Ukrainian clinical research professionals in GCP

Aim. To assess whether the self-assessment of Ukrainian clinical trial professionals corresponds to their actual (proven) GCP knowledge; to estimate the actual GCP knowledge in groups with different experience level, different roles in clinical trials, and the number of GCP trainings attended; to assess whether short-term GCP trainings are sufficient for proper professional development in the GCP domain.

Materials and methods. We developed a questionnaire that consisted of the following parts: demographic data, self-assessment of core competencies, tests on the basic issues of ICH GCP, and an assessment of the need for additional training. The data were analyzed using statistical methods of description and Kruskal-Wallis, Chi-square, Fisher exact test, and Mann-Whitney tests. The statistical analysis was performed using a Statistica StatSoft software, Version 8.0 (StatSoft Power Solution Inc.).

Results. We received 216 questionnaires with answers; some questionnaires were incomplete and did not contain answers to key questions of the study. Therefore, only 186 properly completed questionnaires were included in the analysis.

Conclusions. The respondents' self-assessment of their competence level in GCP corresponds to the test results. The level of experience did not significantly affect the GCP knowledge. Regardless of their experience level, the respondents showed a low level of knowledge on the questions "The aim of randomization according to ICH GCP" and "The aim of monitoring according to ICH GCP". Both groups with a high self-assessment of competence and with a low self-assessment of competence demonstrated the level of knowledge above 70 % for all other questions. Respondents of the group, which brought together representatives of the regulatory authority, research ethics committees and contract research organizations had slightly better results than other clinical research professionals. The number of trainings attended did not affect the quality of knowledge demonstrated by respondents. Thus, the in-depth long-term academic training for clinical research professionals has been substantiated and is a possible topic for future research.

***Key words*:** clinical research competence domains; good clinical practice; clinical research professionals; professional development; self-assessment; clinical trials.

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Дослідження обізнаності українських професіоналів клінічних досліджень в GCP

Мета – оцінити, чи відповідає самооцінка українських професіоналів клінічних досліджень їхнім фактичним (перевіреним) знанням GCP; оцінити фактичні знання GCP у групах з різним рівнем досвіду, різними ролями в клінічних випробуваннях і різною кількістю відвіданих тренінгів GCP; оцінити, чи є короткострокові тренінги з GCP достатніми для належного професійного рівня у сфері GCP.

Матеріали та методи. Ми розробили анкету, яка складалася з таких частин: демографічні дані, самооцінка основних компетенцій, тести з основних питань ICH GCP та оцінювання необхідності додаткового навчання. Дані було проаналізовано з використанням статистичних методів опису та тестів Крускала-Волліса, Хі-квадрата, точного критерію Фішера та критеріїв Манна-Вітні. Статистичний аналіз здійснювали за допомогою програмного забезпечення Statistica StatSoft, версія 8.0 (StatSoft Power Solution Inc.).

Результати дослідження. Було отримано 216 анкет з відповідями; деякі анкети було заповнено не повністю, вони не містили відповідей на ключові питання дослідження. Тому до аналізу було залучено лише 186 анкет, заповнених належним чином.

Висновки. Самооцінка респондентами рівня своєї компетентності з GCP відповідає результатам тестування. Рівень досвіду суттєво не впливав на знання GCP. Незалежно від рівня досвіду, респонденти продемонстрували низький рівень знань щодо питань «мета рандомізації відповідно до ICH GCP» та «цілі моніторингу згідно з ICH GCP». І група з високою самооцінкою компетентності, і група з низькою самооцінкою компетентності продемонстрували рівень знань вище 70 % для всіх інших питань. Респонденти групи, яка об'єднала представників регуляторного органу, комітетів з етики досліджень і контрактних дослідницьких організацій, продемонстрували трохи кращі результати, ніж інші фахівці з клінічних досліджень. Кількість відвіданих тренінгів не вплинула на якість продемонстрованих респондентами знань. Отже, поглиблена довгострокова академічна підготовка для фахівців з клінічних досліджень є виправданою, а тому постає можливою темою для майбутніх досліджень.

Ключові слова: сфери компетентності в клінічних дослідженнях; належна клінічна практика; спеціалісти з клінічних досліджень; професійний розвиток; самооцінка; клінічні випробування.

Today, Ukraine, as a dynamically developing country, needs highly qualified specialists who are responsible for the conduct of clinical trials – clinical research professionals. Since 2019, the National University of Pharmacy has been training specialists of this level to ensure the planning, conduct, organization, control and analysis of clinical trials in accordance with the principles of Good Clinical Practice (GCP), international regulatory requirements, state regulations and ethical principles. Clinical research education is expected to provide the society with graduates who are able to work independently, use evidence-based knowledge for making clinical research decisions, and have the necessary skills to make these decisions; are encouraged to lifelong learning; and committed to the GCP guidelines.

Previously published work has shown that it is important to promote the introduction of basic education in the field of clinical research in the form of professionally oriented academic programs with compulsory practical internship, which will provide the necessary experience [1].

Training specialists who understand various aspects of conducting clinical trials is more important today than ever before. The modern paradigm of clinical research education is based on competencies [2, 3].

The project of Spies R. with co-authors demonstrates the value of collaboration between clinicians and engineers to optimize their respective skill sets [4]. Research competencies in the field of emergency care for clinical research professionals are also of great importance [5]. Not all members of the clinical research team require the highest level of competency in all of the areas listed, but these harmonized core competencies can provide a basis for development of specific statements of knowledge, skills, and attitudes required by clinical research professionals in the environments specialized [6]. The level competencies defined as the fundamental, skilled, and advanced levels and the examples included are expected to provide clearer tools and resources to organizations that create educational and training programs, standardized role descriptions, or plan professional development for clinical research professionals [7]. Mogre V. et al. demonstrate that improving the skills, self-efficacy and attitudes of learners by adopting the appropriate teaching and learning strategies is critical to the success of nutrition education interventions [8]. The review by Sonstein S. et al. not only identifies potential needs, but also stimulates conversations about minimal education requirements, definition of roles, standardization of job titles by ascending levels of competence, policies for staff training, and potential new research on the application of these core competencies [9].

Clinical research coordinators assume critical responsibilities that are central to the success of the research team. The complexity of their role requires essential professional qualifications. Access to meaningful training and quality instruction has strengthened the integral role of the coordinator in research and supports the professionalization of clinical research coordinators. The experience of sharing direct knowledge has revealed the ability to transform and develop a sense of personal strengths and self-identification as a clinical research professional [10]. It is in the interest of all persons involved in clinical trials to meet the development needs of clinical research professionals since without their skills and expertise, high-quality clinical trials will not be conducted effectively [11].

Statement of the problem. Qualification of clinical research professionals is crucial for

achieving the highest quality of clinical trials. Nevertheless, we lack the structured approach for the assessment of the whole variety of skills needed to be a great clinical research professional.

Analysis of recent research and publications. A group of researchers named the Joint Task Force have designed such a structured approach and called it the Core Competency Framework. They defined 8 domains of competence for clinical research professionals with the corresponding knowledge, skills, and attitudes in each domain. The domains are as follows: 1. Scientific Concepts and Research Design; 2. Ethical and Participant Safety Considerations; 3. Drug Development and Regulation; 4. Clinical Trial Operations (GCP); 5. Study and Site Management; 6. Data Management and Informatics; 7. Leadership and Professionalism; and 8. Communication and Teamwork. Such framework bridges the gap in our understanding of the required competencies and provides a universally applicable and globally relevant framework [9, 12].

Identification of aspects of the problem unsolved previously. The Core Competency Framework has been studied and adopted by many institutions worldwide [6, 9, 12]. However, Ukraine has yet to make it a part of the national practice [1]. We aim to assess competencies of Ukrainian clinical research professionals in the domain of Clinical Trial Operations (GCP).

Objective statement of the article. The aim of our work was to assess whether the respondents' self-assessment of the Clinical Trial Operations (GCP) domain defining the competence as "knowledge and compliance with the requirements of GCP and conducting Clinical Trials (CTs) according to these Guidelines" corresponded to their actual of knowledge of the ICH GCP Guidelines. In addition, taking into account that six test questions dealt with various aspects of CTs, another purpose of the test was to identify those parts of the ICH GCP Guidelines for which respondents needed additional training. We assessed whether the number of short-term GCP trainings attended correlated with the level of the GCP knowledge tested by the test questions.

Presentation of the main material of the research. *Survey Tool and Participant Recruitment.* We developed a questionnaire that consisted of the following parts: demographic data, self-assessment of core competencies, tests on the basic issues of ICH GCP, and an assessment of the need for additional training. Demographic data included general characteristics of respondents, namely basic education, the functional role in CTs, the experience level in CTs, namely the number of years working in CTs, and the number of CTs held with the respondent.

Responders were introduced to the concept of 8 Clinical Trial Competency Domains for the self-assessment of their core competencies levels. For each domain, responders were asked their competency level (from level 1 – "basic awareness" to level 5 – "expert") [9].

To determine the level of competence based on the respondents' self-assessment, it was decided to apply the approach proposed by Sonstein S. et al. [9]. Detailed results of the self-assessment of competence were published in our previous article [1].

The survey further tested the respondents' basic knowledge of the ICH GCP guidelines. They were given 6 closed-ended test questions on the basic concepts of GCP. These questions are as follows: 1) Define the "Master File of the Trial" according to ICH GCP; 2) Which of the following terms corresponds to the definition "a document describing the objectives, design, methodology, statistical aspects and organization of the trial" according to ICH GCP; 3) Determine what the aim of randomization is according to ICH GCP; 4) Who is responsible for reporting on the research at the research site according to ICH GCP; 5) Which of the following is not the aim of monitoring according to ICH GCP; and 6) What is the aim of audit according to ICH GCP. All questions had only one correct answer out of the 4 suggested options. If the respondent gave the correct answer, he received 1 point, if not – 0 points. The maximum number of points that a respondent could receive was 6, and the minimum number was 0. We decided to group the results as follows: respondents who gave 2 or less correct answers to the tests should be considered as a subgroup with a low level of the GCP knowledge, the group with 3-4 correct answers were an intermediate level, and the group with 5 - 6 correct answers belonged to a high level. The data were analyzed using statistical methods of description and Kruskal-Wallis, Chi-square, Fisher exact

test, and Mann-Whitney tests. The statistical analysis was performed using a Statistica StatSoft software, Version 8.0 (StatSoft Power Solution Inc.).

We received 216 questionnaires with answers; some questionnaires were incomplete and did not contain answers to key questions of the study. Therefore, only 186 properly completed questionnaires were included in the analysis.

Test of the basic ICH GCP knowledge

The assessment of the ICH GCP knowledge by testing showed that only 34 % of the total number of respondents provided correct answers to 5 or 6 questions, i.e., demonstrated a high level of the GCP knowledge. The largest number of respondents (62 %) had an intermediate level (3 or 4 correct answers were given), while 4 % had a low level of GCP knowledge (2 or less correct answers were given) (Fig. 1).

Then the analysis of the distribution of the GCP knowledge in the groups with high and low competence relative to their previous self-assessment in the "Clinical Trial Operations (GCP)" domain was conducted. It was found that low levels of the GCP knowledge were demonstrated by the same percentage of respondents, namely 4 % in each competence group (Fig. 1). The tendency of respondents in these groups towards intermediate and high levels of the GCP knowledge according to their correct answers to test questions was also similar. The highest percentage of respondents in both groups showed an intermediate level of knowledge. However, in the low-competence group in the GCP domain, 76 % of respondents demonstrated an intermediate level of GCP knowledge, and only 20 % showed a high level. At the same time, in the high-competence group, relatively twice as many respondents showed a high level of the GCP knowledge, namely 39 %, and the percentage of respondents with an intermediate level of knowledge decreased (57 %) according to their correct answers to the test questions.

A comparative assessment of the statistical significance of the distribution of test results between two groups with different previous self-assessments in the GCP domain confirmed that the above-mentioned general trend of the difference in the knowledge distribution between groups was not accidental (the Mann-Whitney test = 0.025 < 0.05). Thus, the percentages of respondents demonstrating a high and medium proficiency on the test questions in the group with high GCP domain competence scores differ significantly from those in the group with low self-assessed competence

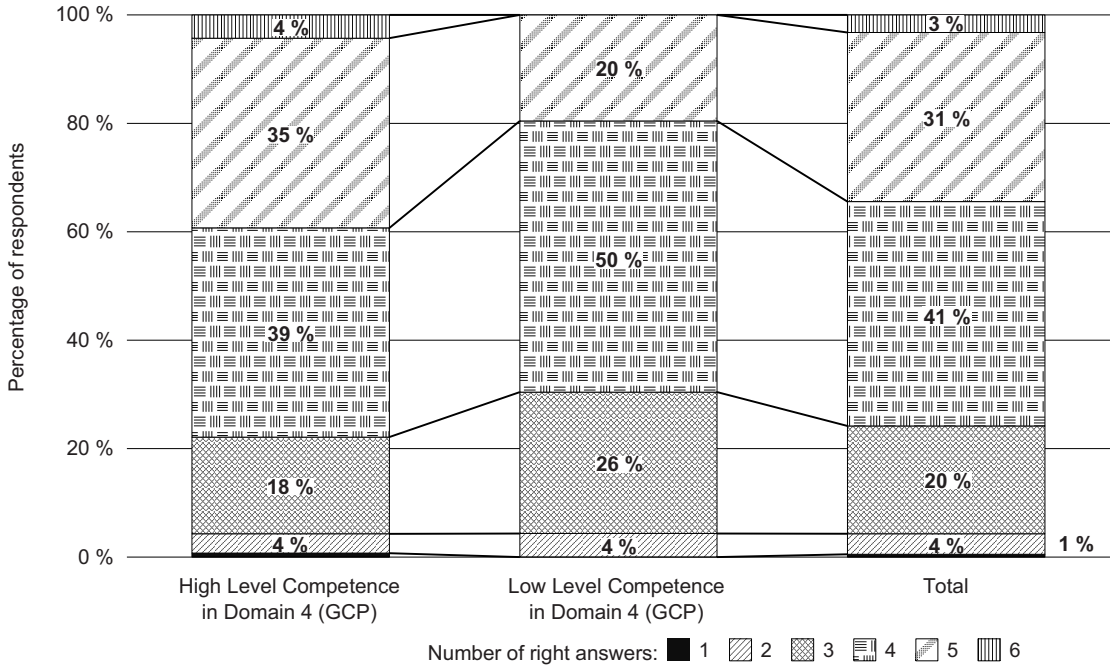

Fig. 1. Distribution of correct answers to the test questions on the basic concepts of ICH GCP (Clinical Trial Operations (GCP) domain)

in this domain. This shows that the level of self-assessment of the respondents' competence in the GCP domain is appropriately corresponds to their knowledge of the ICH GCP Guidelines defined by the tests.

The assessment of the impact of the level of competence in the GCP domain on respondents' answers to each of the six test questions is presented in Table. The vast majority (over 70 %) of respondents in both groups gave correct answers to the test questions asking for definitions of the "Master File" (test 1), "Protocol" (test 2) and demonstrated the knowledge of procedures of supplying and handling the products under study (test 4), and audit procedures (test 6). At the same time, a comparison between groups with different levels of competence in the GCP domain did not show a statistically significant difference in the number of correct answers to these questions (Table). The equally high level of knowledge in both groups on these issues is shown.

Responding to tests 3 and 5 (definitions of randomization and monitoring aims), respondents in both groups of the GCP domain competence showed a low level of knowledge below 30 % of correct answers. However, the number of correct answers to the question regarding the aim of randomization in both groups did not differ in statistical significance. It can be assumed that the level of competence in the GCP domain did not affect the depth of the respondents' understanding of the aim of randomization. At the same time, the number of correct answers to the question about the monitoring aims provided in the group with a high level of competence in this domain (23.6 %) was almost three times higher than the corresponding indicator in the group with a low level of competence (8.7 %). This difference was statistically significant, indicating a higher level of knowledge about the aim of clinical trial monitoring in the group with a high GCP domain competence.

The respondents' answers to the questions "The number of years working in clinical trials" and "The number of clinical trials conducted with the respondent" were grouped into three clusters of experience levels: Cluster 1 – "the low experience of participation in clinical trials" – specialists who had less than 5 years of experience in clinical trials and were involved in fewer than 5 clinical trials; Cluster 2 – "the moderate experience of participation in clinical trials" – specialists who had less than 5 years of experience in clinical trials, but were involved in 5 or more clinical trials, or had 5 or more years of experience in clinical trials, but were involved in less than 5 clinical trials; Cluster 3 – "the extensive experience in clinical trials" – specialists who had 5 years or more of experience in clinical trials and were involved in 5 or more clinical trials. The first cluster included 60 respondents, or 32 %; the second one had 33 respondents, or 18 %; and the third cluster had 93 respondents, or 50 %. These three clusters further defined the indicator of "the experience level in clinical trials".

Table

THE PERCENTAGE OF CORRECT ANSWERS TO THE TEST QUESTIONS WITH REGARD TO THE COMPETENCE LEVEL IN THE "CLINICAL TRIAL OPERATIONS (GCP)" DOMAIN

Test question	Competence level in the "Clinical Trial Operations (GCP)" domain	
	Low (n = 46)	High (n = 140)
1. Define "Master File of the Trial" according to ICH GCP	93.5 %	97.0 %
2. Define the notion "protocol" according to ICH GCP *	74.0 %	82.0 %
3. Define what the aim of randomization is according to ICH GCP	19.6 %	28.6 %
4. Who is responsible for reporting on-site research according to ICH GCP?	100 %	98.6 %
5. What is the aim of monitoring according to ICH GCP?	**8.7 %**	**23.6 %**
6. What is the aim of audit according to ICH GCP?	89.0 %	87.0 %

Note: The Fisher exact test was used for all questions, except marked with *; * – the c^2 (Chi-square test) was used; a bold font – statistically significant difference between groups ($p < 0.05$ across the level of competence in the "Clinical Trial Operations (GCP)" domain).

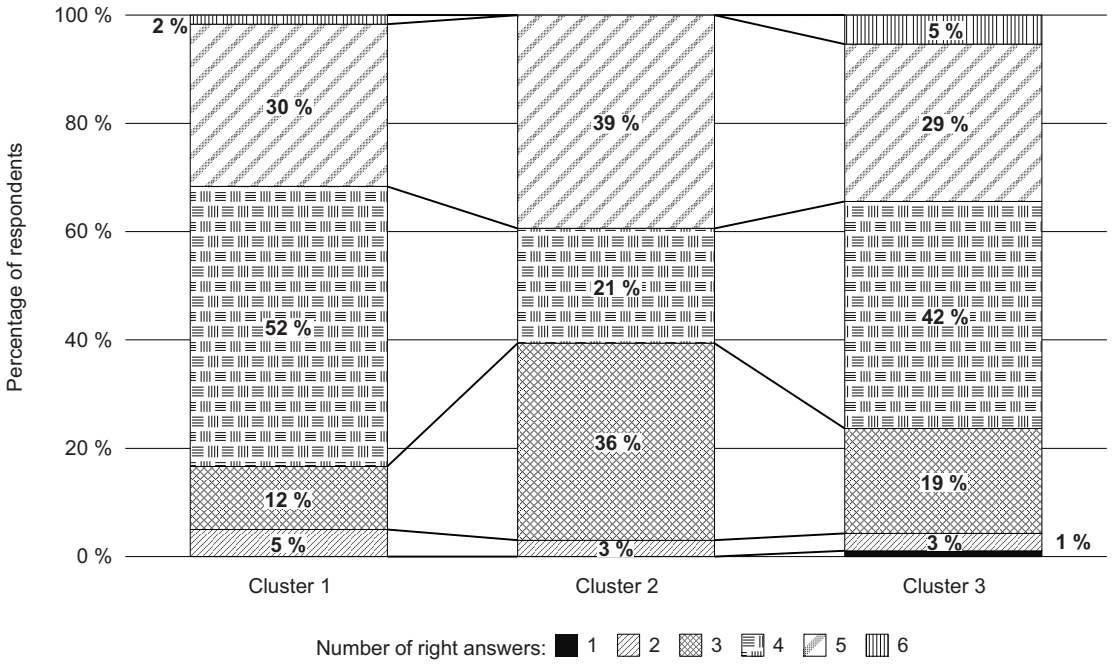

Fig. 2. Distribution of correct answers to the test questions on the basic concepts of ICH GCP according to the clusters of experience levels

The GCP knowledge levels according to the clusters of experience levels and the role in the clinical research were also analyzed (Fig. 2 and 3).

The distribution of the GCP knowledge by levels (low, intermediate and high) did not differ depending on the cluster of the CT experience (Fig. 2) (Kruskal-Wallis ANOVA by Ranks, $p > 0.05$ for both factors examined). Respondents of the group, which brought together representatives of RA, members of RECs, monitors from contract research organizations (CRA), provided 3 or more correct answers to test questions and showed only a high (42 %) and intermediate (58 %) level of the GCP knowledge (Fig. 3).

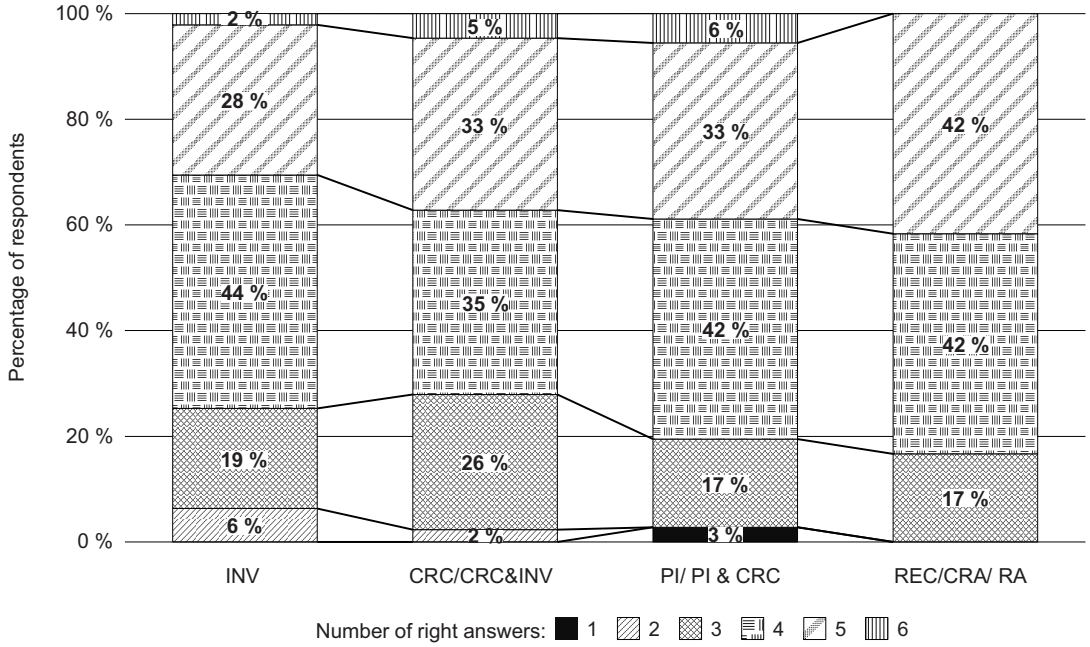

Fig. 3. Distribution of correct answers to the test questions on the basic concepts of ICH GCP according to the functional role in CT: INV – investigators; CRC – clinical research coordinators; PI – principal investigators; REC – research ethics committee members; CRA – contract research associates; RA – regulatory authority representatives

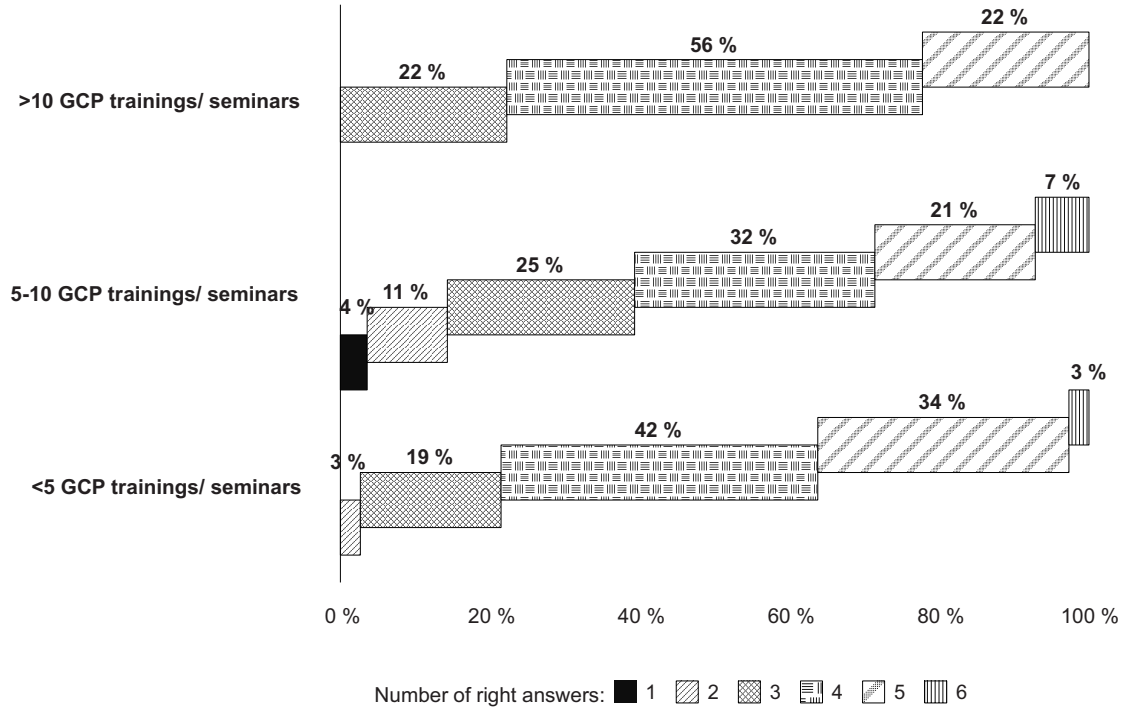

Fig. 4. Distribution of correct answers to the test questions on the basic concepts of ICH GCP according to the number of trainings attended

In the INV group, the GCP knowledge was also predominantly at an intermediate level (63 %), while the smallest number of respondents compared to all other groups were at a high level (31 %), and the largest number of respondents were at a low level (6 %) according to the answers to the test. Two groups of research coordinators (CRC, CRC&INV) and principal investigators (PI, PI & CRC) had almost the same distribution of the GCP knowledge, mainly of an intermediate level (58 %) and a high level (37.2 % for CRC, CRC&INV and 39 % for PI, PI&CRC, respectively).

The influence of the number of trainings attended by respondents on the results of testing their knowledge on GCP issues was also studied (Fig. 4). The largest number of respondents had an average level of knowledge on GCP issues, 60 % each in groups that attended less than 5 trainings and from 5 to 10 trainings, and 78 % in the group that attended more than 10 trainings. The increase in the number of trainings attended did not affect the quality of the GCP knowledge demonstrated by respondents during our testing (Kruskal-Wallis ANOVA by Ranks, $p > 0.05$).

The limitation of this research was that most participants of the survey were members of clinical trial sites (investigators). For these clinical research professionals, the GCP knowledge is the main prerequisite for participation in clinical trials. Therefore, this circumstance could provoke some bias in the self-assessment of respondents.

Conclusions and prospects for further research. It has been found that the respondents' self-assessment of their competence level in the domain of "Clinical Trial Operations (GCP)" corresponds to the test results.

The assessment of the impact of the level of competence in "Clinical Trial Operations (GCP)" on GCP knowledge for each of six test questions showed that both groups demonstrated a low level of knowledge on the questions "The aim of randomization according to ICH GCP" and "The aim of monitoring according to ICH GCP". Both groups with a high self-assessment of competence and with a low self-assessment of competence demonstrated the level of knowledge above 70 % for all other questions in the domain "Clinical Trial Operations (GCP)".

Although GCP questions are typical for the CRP training structure, the number of trainings attended did not affect the quality of knowledge demonstrated by respondents.

Thus, the in-depth long-term academic training for clinical research professionals has been substantiated and is a possible topic for future research.

Conflict of interests: authors have no conflict of interests to declare.

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