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A comparison of the potential of Clinical Trials Centers within both public and commercial trial facilities

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ABSTRACT

Clinical trials are an integral part of the process of developing new drugs, diagnostic methods and medical devices. Clinical trials offer patients the chance to access alternative treatment methods, thereby improving their quality of life, and even achieving recovery. Additionally, clinical trials provide the opportunity for regular contact with a specialist doctor and easier access to diagnostics, ensuring a faster therapeutic path for the patient. One of the key aspects of conducting clinical trials is choosing the right investigator and research center so as to meet specific criteria and guarantee high quality of the conducted studies. Therefore, the aim of the current study was to evaluate the differences between conducting clinical trials in public and commercial centers. A diagnostic survey was used in the study and the research tool chosen was a proprietary questionnaire belonging to the research technique as survey questionnaire. Questionnaires were constructed for the appropriate stakeholders/respondents, namely: doctors and employees of pharmaceutical companies and CROs. The analysis showed that employees of pharmaceutical companies, given the choice, prefer to cooperate with commercial centers. They choose public centers only when they need a center for phase one trials or those requiring hospitalization. The research obtained shows that public centers should improve administrative processes in order to optimize tasks such as contracting or obtaining a study.

INTRODUCTION

Clinical Trials Centers represent places where researchers, doctors, nurses and other specialists collaborate on conducting research aimed at understanding, diagnosing, treating and preventing various diseases. Therefore, one of the key aspects of conducting clinical trials is choosing the right researcher and center that meets specific criteria and ensures high quality of the conducted research. Between 2009 and 2012, hospital-based clinical trial sites accounted for 51% of the total, while dedicated and other commercial sites accounted for only 26%. Analysis presented in "INFARMA's: Industry Clinical Trials in Poland Possibilities to increase number and scope of trials in Poland", showed that between 2017 and 2020, hospital-based centers accounted for 40%, while dedicated and other commercial centers accounted for only 30% [1].

In Poland, clinical trials are mainly conducted in public centers, such as public and/or clinical hospitals, outpatient healthcare entities and commercial centers, including facilities dedicated to clinical trials, clinical trials networks, as well as private practice offices. Since 2020, Poland has listed an additional type of clinical research center that supports public institutions in effectively managing clinical trials. This is the Clinical Trials Support (CTSC) financed by the Medical Research Agency (MRA). So far, there is a lack of literature data on comparative analyses of the types of centers and preferences in choosing them. Therefore, it is important to undertake research in the field of comparing the types of centers and the specifics of their work. It is important to undertake research in the field of comparing the types of centers and the specifics of their work.

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The aim of the current study was to conduct a survey based on the analysis of original questionnaires regarding the reasons for choosing commercial and public trials centers by pharmaceutical company/CRO employees. The preferences of doctors regarding cooperation with public centers were evaluated by analyzing the needs they indicated necessary for conducting clinical trials.

MATERIALS AND METHODS

Development of an original questionnaire

The research method used in the study is a diagnostic survey due to the possibility of collecting quantitative and qualitative data. Original survey questionnaires were developed as part of the research technique – survey questionnaires Before proceeding to construct the questionnaires, an assessment of the centers was made using a Key Success Factors Analysis, which is part of the set of methods for internal enterprise analysis, for example, a center. The aim of the analysis is to determine the strength and set the competitive position for a given type of center. The analysis included commercial trials centers (private physician's offices, dedicated clinical research centers of clinical research networks) and public trials centers, including public hospitals with additional clinical trials activity with a separate research department or without a dedicated department, outpatient healthcare entities with additional clinical trials activity, as well as CTSCs dedicated to supporting clinical trials. However, CTSCs as a type of center were not analyzed in the current paper (these were only listed for comparison). Using the Key Success Factors Assessment, differences in the activity profile of the centers were determined. Weights ranging from 1 to 3 were assigned to each of the mentioned factors on a scale from 1 point - indicating the least important, to 3 points – indicating the most important. The value of the criteria was expressed using a scale from 1 to 5, where 1 is an unfavorable value of a given criterion for the trials center, and 5 is a very favorable value. Due to the different importance of the factor for the assessment of a given center, additional weighted assessments were introduced. Assessments were assigned subjectively based on personal experience working in different types of centers. The strength of scoring was presented in color in the current analysis with green for the highest score obtained with 4-5 pts, orange for the score of 3 pts, and light red for the score of 1-2 pts (Table 1). The maximum assessment of key success factors was 255 pts.

The questionnaire for doctors started with an informational section indicating the purpose of the research, how to respond to the questions asked, and the guarantee of anonymity of the responses given. Respondents first filled in the so-called "respondent's metric", which verified the length of professional experience and experience in research. Here, the initial set of questions referred to doctors' familiarity with clinical trials topics and their potential willingness to refer patients to clinical trials. The respondent then moved on to the main questions, which took the form of closed, open and semi-open questions. This section was dedicated only to those doctors who, in the past or currently, were/are members of research teams or acted as Principal Investigators. The questions related to their experience and feelings associated with conducting research, and any potential clinical and administrative problems related to the place of conducting the study.

In contrast to the aforementioned, the questionnaire intended for pharmaceutical companies and CROs was single-part. This began with an informational section indicating the purpose of the trials, how to respond to the questions asked, and a guarantee of anonymity of the responses given. The main questions related directly to the feelings of conducting research in public entities, as well as preferences when choosing a center for cooperation in clinical trials.

The current study received the approval of the bioethics committee (KE_0254_204_10_2022).

Table 1. Key success factors for different types of Clinical Trials Centers

Lp.	Key Success Factors (KSF)	Weight	Clinical Research Support Center		Public centers		Commercial centers	
		from 1 to 3	Rating from 1 to 5	Weighted value	Rating from 1 to 5	Weighted value	Rating from 1 to 5	Weighted value
1	Patient base (5 – large, 1 – none)	3	5	15	5	15	3	9
2	Availability of the Principal Investigator (5 – available, 1 – unavailable)	3	4	12	3	9	4	12
3	Space for receiving patients from a clinical trial (5 – dedicated, 1 – none)	3	5	15	3	9	5	15
4	Conducting studies that require hospitalization (5 – yes all, 1 – no)	3	5	15	5	15	1	3
5	Conducting phase I studies (5 – yes all, 1 – no)	3	5	15	3	9	1	3
6	Clinical research coordinators (5 – dedicated, 1 – none)	3	5	15	3	9	5	15
7	Feasibility process (acquisition of study) (5 – efficient, 1 – long)	2	5	10	2	4	5	10
8	Legal assistance (5 – dedicated, 1 – none)	3	4	12	2	6	4	12
9	Time to sign contracts (5 – short, 1 – long)	3	4	12	2	6	4	12
10	Space for monitors (5 – dedicated, 1 – none)	2	5	10	2	4	5	10
11	Center equipment (5 – dedicated to research, 1 – no adaptation)	3	5	15	3	9	5	15
12	Quality system e.g.: procedures, standards dedicated to clinical research (5 - dedicated, 1 - none)	3	5	15	1	3	5	15
13	Start-up department as the first contact regarding the study (5 – dedicated, 1 – none)	3	5	15	1	3	5	15
14	Quality of work and knowledge of ICH GCP principles 5 – high, 1 – low)	3	5	15	3	9	4	12
17	Database of potential Investigators (5 – good, 1 – low)	2	4	8	4	8	2	4
18	Administrative handling of the study (5 – good, 1 – poor)	2	4	8	3	6	4	8
19	Contact with the Research Team (5 – good, 1 – difficult)	3	4	12	3	9	4	12
20	Low start-up fees (5 – low, 1 – high)	2	4	8	2	4	4	8
21	IT system for managing clinical trials (5 – dedicated, 1 – none)	2	5	10	1	2	5	10
		255		237		1139		200

Characteristics of the study group

The study was conducted from July 2023 to November 2023, and involved a total of 352 respondents from all over Poland. Of these, 147 received questionaires were complete and analyzed. The response rate for both groups of respondents was ≥42%. The questionnaires were completed electronically via the survio.pl portal, while the GCP.org.pl portal and CTSCs in Poland helped distribute the links to the questionnaires. The questionnaire for pharmaceutical company/CRO employees was filled out by 87 people, of which 54.02% work as clinical research monitors (CRAs) and 18.39% do so as clinical trial project managers throughout Poland (Figure 1). The questionnaire for doctors was filled out by 60 people. The respondents came from the Lublin, Masovian, Lower Silesian, Lubusz, Greater Poland and West Pomeranian voivodeships. In the study group, a total of 53.33% responders had experience in clinical trials as Principal Investigator or Co-Investigators, and 18.33% of all respondents declared the willingness to participate in clinical trials (Figure 2). The study group included physicians who participated in clinical trials conducted according to the responses given, the breakdown being 51.11% in clinical hospitals, and 11.11% in commercial facilities.

To clearly compare public and commercial trials centers, clinical hospitals, provincial and district hospitals were combined and designated as "public centers" (62.22% of the total, while commercial facilities, private practices and dedicated commercial centers were deemed "commercial centers" (24.44% of the total).

The process of selecting the number of respondents in the study group was based on the appropriate division of respondents by categorizing subtypes of hospitals and commercial trials centers into the category of "public centers", and the category of "commercial centers".

The characteristics used for grouping of the responders were carefully designated to preserve their meaning during statistical analysis. During data analysis, an exploratory data examination was conducted. The data were appropriately prepared, normalized, and correctly coded for categorical variables. The development of a data set was key to conducting statistical analysis.

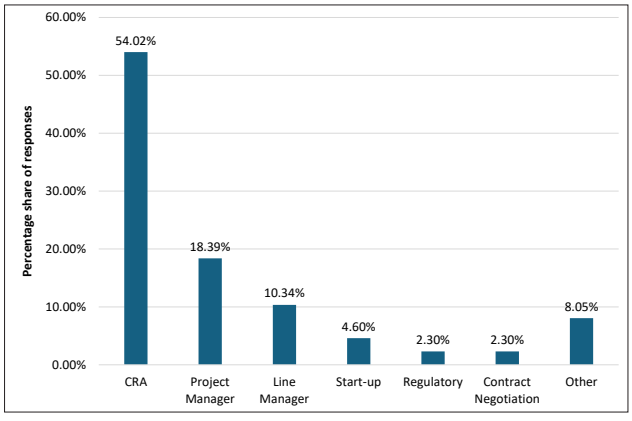

Figure 1. Percentage share of job positions in clinical trials among respondents from the group of pharmaceutical company/CRO employees

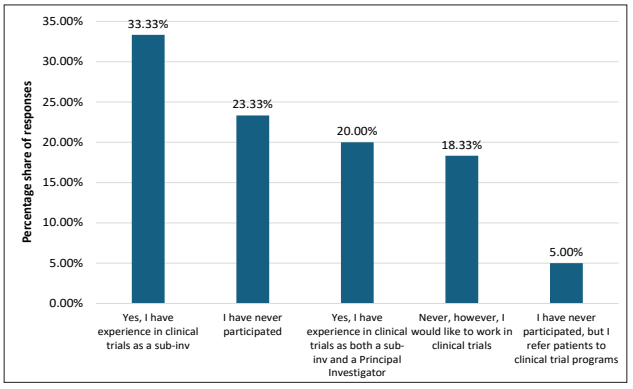

Figure 2. Percentage share of clinical trials experience among respondents from the doctors group

Statistical analysis

The responses gathered were examined for any missing indicators. Descriptive statistics were carried out, taking into account the count in groups and their percentage distribution, in line with the measurement scale. Percentage plots and tables were generated to pinpoint differences among different types of centers. To assess differences or correlations among the examined parameters, multi-way tables and the Chi^2 (χ^2) test were utilized to verify homogeneity or independence. For smaller sample sizes (less than 5) in the subgroups under study, Yates's correction was employed. An inference error of 5% and the corresponding $p < 0.05$ significance level were accepted, denoting statistically significant differences or correlations. Statistical analyses were conducted using STATISTICA v. 13.0 software (StatSoft, Poland) and Python programming language version 3.9, supplemented with numpy, pandas, matplotlib, seaborn and sklearn libraries. The coding involved identifying subtypes of commercial centers and hospital centers into categories of commercial centers, which include responses regarding commercial facilities, private medical offices, dedicated commercial research centers, and public centers such as clinical hospitals, provincial and district hospitals.

RESULTS

Subjective assessment of centers based on Key Success Factors compared with the assessment of data obtained from questionnaires for pharmaceutical company/CRO employees

The analysis of the subjective assessment of centers based on key success factors conducted by the author is presented in Table 1. According to the analysis, public centers conducting clinical trials scored 139/255 points. Public centers received the highest rating for factors such as patient and researcher base, and conducting studies with hospitalization. Private trials centers scored 200/255 points, with the highest score of 5 points for factors such as: having center equipment dedicated to conducting research, along with a place for receiving patients and a place for monitoring, having dedicated coordinators, employing efficient feasibility processes (acquisition of study), along with possessing a dedicated start-up department and an IT system dedicated towards managing clinical trials.

Based on the data obtained and listed in Table 1, respondents belonging to the group of pharmaceutical company/CRO employees were asked the question, "Which statement, in your opinion, is a strong point of conducting clinical trials in hospital facilities?" The percentage results of the respondents were classified into rating values according to the key: 100-80% – rating 5, 79-60% – rating 4, 59-40% – rating 3, 39-20% – rating 2, 19-0% – rating 1 and the results are presented in Table 2, with the ratings of factors assigned by the author in Table 1 (the weights of the ratings were applied the same as in the assessment in Table 1). The respondents assigned public trials centers 97/255 pts. The rating given by the author is 139 pts.

Table 2. Comparison of key success factors for public trials centers with the result of questionnaires for pharmaceutical companies/CRO employees

Lp.	Key Success Factors (KSF)	Weight	Public centers		Public hospitals in the assessment of Pharmacists/CROs		
		from 1 to 3	Rating from 1 to 5	Weighted value	% of responses given as a strong point	Rating obtained from respondents' votes from 1 to 5	Weighted value
1	Patient base (5 – large, 1 – none)	3	5	15	62.16	4	12
2	Availability of the Principal Investigator (5 – available, 1 1 – unavailable)	3	3	9	6.76	1	3
3	Space for receiving patients from a clinical trial (5 – dedicated, 1 – none)	3	3	9	17.57	1	3
4	Conducting studies that require hospitalization (5 – yes all, 1 – no)	3	5	15	85.14	5	15
5	Conducting phase I studies (5 – yes all, 1 – no)	3	3	9	40.54	3	9
6	Clinical research coordinators (5 – dedicated, 1 - none)	3	3	9	86.49	5	15
7	Feasibility process (acquisition of study) (5 –efficient, 1 - long).	2	2	4	1.35	1	2
8	Legal assistance (5 – dedicated, 1 – none)	3	2	6	5.41	1	3
9	Time to sign contracts (5 – short, 1 – long)	3	2	6	5.41	1	3
10	Space for monitors (5 – dedicated, 1 – none)	2	2	4	12.16	1	2
11	Center equipment (5 – dedicated to research, 1 – no adaptation)	3	3	9	20.27	2	6
12	Quality system e.g.: procedures, standards dedicated to clinical research (5 – dedicated, 1 – none)	3	1	3	6.76	1	3
13	Start-up department as the first contact regarding the study (5 – dedicated, 1 – none)	3	1	3	9.46	1	3
14	Quality of work and knowledge of ICH GCP principles (5 – high, 1 – low)	3	3	9	0.00	1	3
17	Database of potential Investigators (5 – good, 1 – low)	2	4	8	58.11	3	6
18	Administrative handling of the study (5 – good, 1 – poor)	2	3	6	2.70	1	2
19	Contact with the Research Team (5 – good, 1 – difficult)	3	3	9	8.11	1	3
20	Low start-up fees (5 – low, 1 – high)	2	2	4	10.81	1	2
21	IT system for managing clinical trials (5 – dedicated, 1 – none)	2	1	2	1.35	1	2
		255		139			97

Assessment of the potential for conducting clinical research in public (hospital) centers by respondents from the doctors group

Respondents from the doctors group were asked the question, "Which statement, in your opinion, characterizes conducting clinical trials in public centers?" The question was multiple choice. Respondents were asked to indicate a minimum of 8 answers, which are placed in Table 3, along with the quantitative results.

Table 3. Quantitative compilation of responses from the doctors group to the question, "Which statement, in your opinion, characterizes conducting clinical trials in hospital facilities?"

Possible answers to the question, "Which statement, in your opinion, characterizes conducting clinical trials in public trials centers?"	n	%
Possibility of conducting studies that require hospitalization	25	41.67
Possibility of conducting the study during "working hours"	19	31.67
Possibility of conducting phase I studies	14	23.33
Dedicated clinical trials coordinators	14	23.33
Unlimited patient base	13	21.67
Compensation proportional to engagement	11	18.33
Lack of space for conducting a patient visit in a clinical trial	10	16.67
Dedicated legal assistance	10	16.67
Long time for signing contracts by hospital management	10	16.67
Physician in charge of the department is the Principal Investigator on all projects	10	16.67
Dedicated space for receiving patients from a clinical trial	9	15.00
Lack of dedicated legal assistance	9	15.00
The center is equipped in a way dedicated to clinical trials	9	15.00
Defined quality system e.g. procedures, standards dedicated to clinical research	9	15.00
Dedicated clinical research department supporting Investigators	9	15.00
Limited patient data base	8	13.33
Compensation not proportional to engagement	8	13.33
Fast feasibility process	7	11.67
Principal Investigators are selected based on the number of projects	7	11.67
No possibility of conducting the study during "working hours"	6	10.00
Long feasibility process	6	10.00
Lack of dedicated clinical trials departments supporting Investigators	6	10.00
Short time for signing contracts by hospital management	5	8.33
Lack of a defined quality system e.g. procedures, standards dedicated to clinical research	5	8.33
Lack of dedicated coordinators	4	6.67
Dedicated space for monitors	4	6.67
The center is not equipped in a way dedicated to clinical trials	4	6.67
No possibility of conducting phase I studies	3	5.00
Problem with potential hospitalization	2	3.33

As shown in Table 3, 41.67% of all respondents from the doctors group indicated "Possibility of conducting studies that require hospitalization" as a statement that characterizes conducting clinical trials in public centers. The response is consistent with the position of pharmaceutical company/CRO employees rated as 5 points for "conducting studies requiring hospitalization" (Table 2). For 31.67% of the respondents,

the fact of working in a public hospital and simultaneously conducting clinical trials during working hours is important.

Predispositions of pharmaceutical company/CRO employees to choose a clinical trials center

Pharmaceutical company/CRO employees decide on the choice of a specific investigator, as well as the center that will carry out the study. Therefore, when there is no chosen investigator, the proposal is directed to the center. Respondents were asked in the questionnaire for pharmaceutical company/CRO employees: "What are your general experiences with Clinical Trials Centers located in public centers?" and "What are your general experiences with Clinical Trials Centers located in commercial centers?". The role of the respondent that they perform while working in a pharmaceutical company/CRO was compared with the choice of rating that is.: "poor", "satisfactory", "good", "very good", "excellent" for commercial centers (Table 4a) and public centers (Table 4b). The statistical analysis showed significance at p=0.05 level. The characteristics to compare were the role in clinical trials and the general experiences with Clinical Trials Centers located in private centers.

It can be assumed that positive opinions are the result of perceived high quality of clinical trials conducted in private units. This high quality may result from the use of advanced technologies, the employment of qualified personnel, and strict adherence to ethical standards and research protocols. The results presented in Table 4a show that 63.2% of all respondents from the group of pharmaceutical company/CRO employees have "very good" feelings about conducting research in commercial centers, while 10.34% of the respondents indicated the answer "excellent". In the same question referring to public centers (Table 4b), the answer "very good" was given by 11.49% and the answer "excellent" was not recorded. 36.78% of all respondents describe their experience with centers in public hospitals as "good".

The statistical analysis showed a significant relationship between the studied features with a p=0.05. Positive opinions may stem from the perceived high quality of clinical trials conducted in private units. This could include advanced technologies, skilled staff and strict adherence to ethical standards and research protocols.

Table 4a. Comparison of the role of the respondent from the group of pharmaceutical company/CRO employees in clinical trials with the answer to the assessment of "What are your general experiences with Clinical Trials Centers located in commercial centers?"

Role in clinical trials of respondents from the group of pharmaceutical company/CRO employees	Answer to the question: What are your general experiences with Clinical Trials Centers located in commercial centers?				
	Satisfactory	Good	Very good	Excellent	Total
CRA	1	8	37	2	48
CRA responses in percentage terms	2.08	16.67	77.08	4.17	
Manager/Director (Project Manager, Line Manager, Medical Director, Project Director/Portfolio Oversight Director, Remote site Monitor)	2	8	14	4	28
Manager/Director (Project Manager, Line Manager, Medical Director, Project Director/Portfolio Oversight Director, Remote site Monitor) responses in percentage terms.	7.14	28.57	50.00	14.29	
Another (Contract Negotiation, Start-up, Project Director/Portfolio Oversight Director, SC)	0	4	4	3	11
Another (Contract Negotiation, Start-up, Project Director/Portfolio Oversight Director, SC) %	0.00	36.36	36.36	27.27	
Total number of responses given, regardless of the indicated role	3	20	55	9	87
Total % of responses from respondents, regardless of the indicated role	3.46%	22.99	63.2%	10.35	

Table 4b. Comparison of the role of the respondent from the group of pharmaceutical company/CRO employees in clinical trials with the answer to the assessment of "What are your general experiences with Clinical Trials Centers located in public centers?"

Role in clinical trials of respondents from the group of pharmaceutical company/CRO employees	Answer to the question: What are your general experiences with Clinical Trials Centers located in public centers?				
	Unsatisfactory	Satisfactory	Good	Very Good	Łącznie
CRA	14	10	16	8	48
% of row	29.17	20.83	33.33	16.67	
Manager/Director (Project Manager, Line Manager, Medical Director, Project Director/Portfolio Oversight Director, Remote site Monitor)	7	7	13	1	28
% of row	25.00	25.00	46.43	3.57	
Another	5	2	3	1	11
% of row	45.45	18.18	27.27	9.09	
Total number of responses given, regardless of the indicated role	26	19	32	10	87
Total % of responses from respondents, regardless of the indicated role	29.89	21.84	36.78	11.49	

Respondents from the group of pharmaceutical company/CRO employees were asked, "Given the choice of a Center for a clinical trial, would you choose: 1) a commercial center specializing in conducting clinical trials; 2) a network of private Centers specializing in conducting clinical trials; 3) a small clinic of specialist doctors, where clinical trials are just an additional activity; 4) the Center does not matter, the experience of the Principal Investigator counts; 5) a large clinic of specialist doctors, where clinical trials are just an additional activity; 6) a public hospital; 7) a Clinical Trials Center; or 8) an individual private medical practice, where the doctor also conducts clinical trials". The results are presented in Table 5 (Table 5). Given the choice, pharmaceutical company/CRO employees choose "a commercial center specializing in conducting clinical trials" in 55.17% of all cases and "a network of private Centers specializing in conducting clinical trials" in 20.69% of all cases, giving a total result of 76.58% for commercial centers. A public hospital as a public center was chosen by 2.30% of the respondents.

Comparing the data obtained in Table 5 with Table 4a, we see that the very good experience indicated by 63.22% of all respondents translates into a potential choice of a commercial center specializing in conducting clinical trials by 55.17% of all respondents and 20.69% for private centers specializing in conducting clinical trials, giving a total result of 75.86% for private centers (Table 5). Public hospitals received a score of 2.30%, which also matches the level of satisfaction.

Table 5. Results of pharmaceutical company and CRO respondents to the question, "Given the choice of a Center for a clinical trial, would you choose: a commercial center specializing in conducting clinical trials; a network of private Centers specializing in conducting clinical trials; a small clinic of specialist doctors, where clinical trials are just an additional activity; the Center does not matter, the experience of the Principal Investigator counts; a large clinic of specialist doctors, where clinical trials are just an additional activity; a public hospital; a Clinical Trials Center; or an individual private medical practice, where the doctor also conducts clinical trials"

Type of Center	n	%
A commercial center specializing in conducting clinical trials	48	55.17%
A network of private Centers specializing in conducting clinical trials	18	20.69%
A small clinic of specialist doctors, where clinical trials are just an additional activity	6	6.90%
The Center does not matter, the experience of the Principal Investigator counts	6	6.90%
A large clinic of specialist doctors, where clinical trials are just an additional activity	5	5.75%
Public Hospital	2	2.30%
Clinical Trials Support Center	1	1.15%
An individual private medical practice, where the doctor also conducts clinical trials	1	1.15%

DISCUSSION

Over the past few years, scientific publications and media reports about fraud, abuse, harmful research practices, lack of transparency, poor and selective reporting, insufficient data sharing and insufficient data sharing have left the public and researchers confused about trust in clinical trials [2]. Additionally, changes caused by the introduction of Directive 536 require researchers to provide higher quality and accuracy. Both commercial and hospital centers are aware that to ensure the quality of clinical trials, participant safety and data integrity must be ensured, which requires careful management throughout the study life cycle [3]. That is why it is so important for public facilities to be able to use the unquestionable advantage of safety by improving administrative processes.

The conducted research confirmed the hypothesis that pharmaceutical companies prefer to conduct clinical trials in commercial centers rather than public hospitals. So far, there is no literature data on comparative analyses regarding types of centers and preferences in their selection. Miyazaki et al. [4] referred to the specifics of the clinical trial market in Japan, where the sponsor signs a contract with the hospital director (not individual researchers) or in a tripartite form (hospital, researcher and sponsor), to conduct clinical trials. Therefore, researchers do not benefit financially from participation in a clinical trial. For this reason, most studies are conducted in Site Management Organizations (SMO), and only 47% in public and university hospitals.

The more frequent choice of commercial centers was confirmed in our studies, which showed that only 2.30% of all respondents chose a hospital center, and the vast majority (55.17%) – a commercial center specializing in conducting clinical trials or a network of private centers specializing in conducting clinical trials (20.69%). This trend is also confirmed by the decreasing number of hospital centers in Poland that are chosen, in favor of the development of commercial centers. Interestingly, in 2009-2012, hospital Clinical Trials Centers accounted for 51% of all research, and dedicated and commercial centers – only 26%. Analyses presented in the INFARMA Commercial Clinical Trials Report showed that in 2017-2020, hospital centers accounted for 40% of all research, while dedicated and other commercial centers – only 30% [1]. However, it should be borne in mind that hospital centers mainly conduct phase I and II trials and exceptionally difficult assessments requiring hospitalization, including oncology trials. The fact of choosing hospital centers to conduct phase I trials and those with hospitalization was confirmed in the analysis of questionnaires of pharmaceutical company/CRI employees and the current research. This is undoubtedly a strong point of public centers. This factor, due to the profile of activity, will always be difficult to achieve for commercial centers. Invariably, a public hospital can provide the patients as participants in a clinical trial, with greater safety in phase I trials than can a commercial center. This may also be the reason why, in the results of the author's research (Figure 3), researchers indicated a hospital rather than a commercial center as the preferred place to conduct a clinical trial. The ability to conduct clinical trials in hospitals rather than commercial centers could give the physician opportunity to work in one place and the awareness of taking care of the patient in a comprehensive way.

However, it should be emphasized that Poland's participation in global phase I trials is still low in relative values compared to other developed markets, for example, in 2019, 8% of all active phase I trials were conducted in Germany, 11% in the UK, and 10% in Spain, compared to less than 3% in Poland [1]. E. Tańska [5] emphasizes that the clinical trial market in Poland in 2014 reached an estimated value of about PLN 950 million, and oncology is the dominant field covered by clinical trials (29% in 2018). The Office for Registration of Medicinal Products (URPL) receives the most applications for the initiation of third (approx. 57%) and second phase trials (approx. 32%). As can be seen from the conducted research presented in Table 5, pharmaceutical companies prefer to choose commercial centers for trials that do not require hospitalization.

Researchers are increasingly referring to the fact of improving healthcare, which is a link in clinical trials. There should be a shift from viewing the efficiency and quality of healthcare organizations as ensuring the quality and patient experience of clinical trial participation to administrative improvements [6]. Administration support data were highlighted in our results presented in Table 2 as the opinion of pharmaceutical companies and Table 3 as the voice of doctors. During the surveys conducted, a group of respondents of pharmaceutical company representatives/CROs) gave the lowest ratings to such factors as the time to carry out the feasibility process, administrative handling and the time to sign contracts. Contracting in such entities as public center involves entering into a tripartite agreement where the parties to the contract are the sponsor, researcher, and center, i.e. the public hospital. Each party benefits from the implementation of the study. The complex decision-making process and lack of administrative support provided by hospitals, extends the contract negotiation process.

According to the "Industry Clinical Trials in Poland Possibilities to increase number and scope of trials in Poland" report, the average time of contracting studies in Poland is 434 days from the activation of the first center, whereas in the USA it is 313 days [1].Therefore, focusing on improving administrative actions using typically commercial mechanisms is very important to maintain the upward trend of clinical trials in Poland. It should be underlined that in the support of clinical trials, coordinators play a significant role in streamlining processes. The demand for clinical trials is growing worldwide, and clinical trials coordinators (CTCs) play an important role in participant recruitment and study quality. Although the role of CTC varies by country, they are involved in all aspects of clinical trials, including data management, contacting study participants, and assisting the principal investigator [7]. Interestingly, in the current research, the issue of cooperation with the coordinator was perceived differently by the author and pharmaceutical company/CRO employees. Despite the lack of questioning of their usefulness, pharmaceutical companies rated the number of coordinators in public hospitals very optimistically.

CONCLUSIONS

To conclude, in this research project, the availability of the researcher, the quality system procedure and standards dedicated to clinical trials (Table 2) were evaluated. These features can be classified as the quality of the research services provided. The research conducted in the article shows that public hospitals have good facilities for conducting difficult clinical trials and a virtually unlimited patient base. However, they have great administrative difficulties, which were confirmed in the studies conducted. The study showed that strong competition from commercial centers hinders the development of public centers because commercial centers are still more likely to be chosen for research by pharmaceutical companies. This is why it is so important for public facilities to be able to use the unquestionable advantage of safety by improving administrative processes.

The role of the CTSC created by the Medical Research Agency in Poland seems to be important in changing this trend. The role of this initiative is to streamline administrative processes to encourage pharmaceutical companies to conduct research in public hospitals managed by CTSCs. Their goal is to use the potential of existing hospital research centers by providing favorable conditions for initiating non-commercial and commercial clinical trials. It is worth noting that when designing standards for Clinical Trials Support Centers and creating the Polish Clinical Trials Network, Polish experts were inspired not only by domestic experiences, but also by the achievements of leading research centers in other countries. Inspiration was drawn from the experiences of the Danish, Israeli, Swiss and German clinical trial sectors.

ABBREVIATIONS

CTSC – Clinical Trials Support Centers
MRA – Medical Research Agency
INFARMA – Association of Employers of Innovative Pharmaceutical Companies
CRO – Chief Risk Officer
GCP – Polish Association for Good Clinical Practice

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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