



## **Analysis of Clinical Trials Conducted in Oncology in the Greater Poland Voivodship against the Background of Poland**

**Mikołaj Bartoszkiewicz<sup>1</sup>**

<https://orcid.org/0000-0002-8728-5998>

<sup>1</sup>Department of Biology of Lipid Disorders, Poznan University of Medical Sciences,  
Poland

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### **Address for correspondence**

**Mikołaj Bartoszkiewicz**

Department of Biology of Lipid Disorders

Poznan University of Medical Sciences

7 Rokietnicka Str., 60-806 Poznan, Poland

e-mail: [m.bartoszkiewicz@ump.edu.pl](mailto:m.bartoszkiewicz@ump.edu.pl)

## Abstract

**Introduction:** *Clinical trials are an opportunity for healthcare systems to raise treatment standards, and for patients to be able to access innovative therapy. Conducting clinical research is a complex process that requires special involvement of research teams. Cancer comes second among the causes of death among Poles. The huge potential of clinical trials in oncology results in leading in the number of clinical trials by fields of medicine in Poland.*

**Aim:** *The aim of the study is to analyse the number and phases of clinical trials in oncology in the Greater Poland voivodship against the background of Poland.*

**Material and methods:** *Statistical data for work were collected from the National Cancer Registry in Poland, the European Statistical Office, the Central Statistical Office in Poland, the PwC report about clinical trials and the clinicaltrials.gov database. The clinicaltrials.gov database of clinical trials was used to analyse the individual number of studies and their phases, by type of cancer. It was also analysed in terms of the number of experiments carried out in individual cities in Greater Poland and against the background of Poland.*

**Results:** *In Poland there are 1523 clinical trials, of which as many as 575 are studies in oncology. The 503 clinical experiments are conducted in the Greater Poland voivodship. In Poznań 453 trials are conducted, in oncology – 225. In Poland, the majority of clinical trials (21%) are conducted in lung cancer. In the Greater Poland voivodship (31%) lung cancer trials are also dominant. The phase III clinical trial leads in both groups.*

**Conclusions:** *In Poland, the most clinical trials are conducted in oncology. The Greater Poland voivodship reflects the trend of clinical trials in Poland. Inhabitants of the Greater Poland voivodship have access to 39% of clinical trials in Poland in the field of oncology and 33% access to clinical trials without di-*

*vision into the therapeutic area as compared to the whole country. The implementation of phase I centres will allow for the increase of interest of potential clinical trial sponsors in Poland, which will be a positive impulse for the country's economy.*

**Key words:** *clinical trials, research phases, cancer, phase III, clinical research*

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## Introduction

Clinical trials are an indispensable element in the development of medicine, they are a chance for healthcare systems to raise treatment standards, and for patients the opportunity to access innovative therapy. Cancer in Poland is the second cause of Poles' mortality, only the cardiovascular diseases are ahead of it [1]. In the world in 2018 alone, 18.1 million new cancer cases were reported [2]. Clinical trials allow modern medicine to fight cancer better and better by introducing new drugs and treatment regimens. Unfortunately, the decreasing number of clinical trials in 2009-2014 limits the possibilities of Polish doctors to meet treatment standards in comparison with countries leading in the area of clinical trials [3]. Conducting medical experiments is a complex process, thus the analysis of ongoing clinical trials in oncology in Greater Poland voivodship against the nationwide trend allows to learn the trend in the number and phases of clinical trials for the given voivodship and Poland. The current situation of newly registered clinical trials in Poland shows a downward trend. In 2011, we recorded 495 new clinical experiments conducted in Poland, in 2014 there were only 396 of these studies [3].

## Aim

The purpose of this work is to analyse clinical trials in the Greater Poland voivodship against the nationwide trend in the field of oncology. The Greater Poland voivodship is the third largest voivodship in Poland in terms of population, which is why the analysis of the number of clinical trials conducted in the voivodship will allow to identify the types of malignant neoplasms in which the most research is conducted [4]. The analysis will also provide information on the phases and status of clinical trials in the Greater Poland voivodship and Poland.

## Method

To analyse the number of ongoing clinical trials in Greater Poland against the nationwide trend, the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website was used, which is the database of private and publicly funded clinical trials conducted worldwide. Information is provided by the US National Library of Medicine. Each diagram analysis used in the paper is based on the results from [www.clinicaltrials.gov](http://www.clinicaltrials.gov). 10 largest cities in terms of population of the Greater Poland voivodship were included in the analysis, i.e. Poznań, Kalisz, Konin, Piła, Ostrów Wielkopolski, Gniezno, Leszno, Luboń, Swarzędz, and Września. To assess the number of clinical trials in the field of oncology, the focus was on the most common incidence of malignancies in Poland. The phases of clinical trials have been divided into four main ones, i.e. I, II, III, IV. The analysis of individual types of malignant tumours included cancers with the most frequent incidence in Poland in 2013, without sex division i.e. lung cancer, lymphoma, breast cancer, leukaemia, prostate cancer, ovarian cancer, stomach cancer, colorectal cancer, bladder cancer, renal cell carcinoma, hepatocellular carcinoma, brain tumour, pancreatic cancer, cervical cancer [5]. All results from the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website are from analysis period between 01.07.2019 to 30.07.2019. Data access day is mentioned with each analysis.

## Results

There are 1523 clinical trials in Poland, of which 876 (57.5%) are in the patient recruitment phase and 647 (42.5%) are in the active phase after the recruitment process.

The largest number of clinical trials by therapeutic field is conducted in oncology – 575, which is 37% of all clinical trials in the country. The second field in which the most clinical experiments are conducted is neurology – 174, that is about 10% of market share (Figure 1). The difference in the market share of clinical trials between the first and second fields is 27%, therefore, the position of oncology as the leading field in which

clinical trials are conducted in Poland is not expected to change in the coming years, which is also closely related to forecasts of the increase in the incidence of malignant neoplasms in Poland [6].

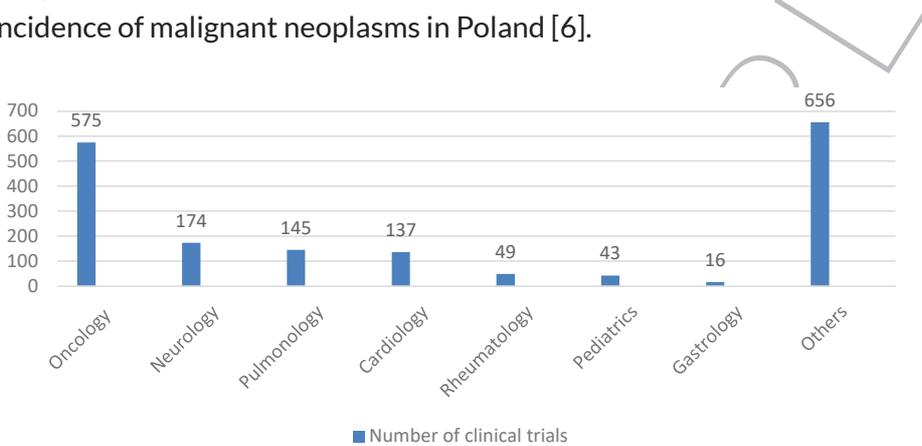


Figure 1. The number of clinical trials in Poland divided into therapeutic areas (active + recruitment)

Source: clinicaltrials.gov [cited 10.07.2019].

503 clinical trials are conducted in the Greater Poland voivodship, there are 250 (49%) in the recruitment phase, and 253 (51%) in the active phase (after the recruitment is completed). The 10 largest cities in the voivodship have been included in the analysis. 10 largest cities in terms of population of the Greater Poland voivodship were included in the analysis, i.e. Poznań, Kalisz, Konin, Piła, Ostrów Wielkopolski, Gniezno, Leszno, Luboń, Swarzędz, Września [7]. The most clinical experiments are conducted in Poznań – 453, due to the location of university clinics in the city and several times higher number of inhabitants compared to other cities. In the field of oncology 225 (44.7%) clinical trials are being conducted in Greater Poland voivodship. Most research is conducted in Poznań in the post-recruitment phase – 103 (45.7%), in the recruitment phase – 94 (41.7%). The second city in terms of the number of medicinal product trials is Konin, which carries out 21 (9.3%) trials after closing recruitment and 7 (3.1%) in recruitment to the trial. Eight out of ten cities included in the analysis in Greater Poland do not conduct clinical research in the

field of oncology, i.e. Kalisz, Piła, Ostrów Wielkopolski, Gniezno, Leszno, Luboń, Swarzędz, Września.

When comparing Greater Poland voivodship to the whole country, individual cancer diseases must be taken into account. To compare the number of clinical trials in oncology in the Greater Poland voivodship with the whole country, malignant neoplasms with the most frequent incidence in Poland were included in the analysis, i.e. lung cancer, lymphoma, breast cancer, leukaemia, prostate cancer, ovarian cancer, stomach cancer, colorectal cancer, head and neck cancer, bladder cancer, kidney cancer, liver cancer, brain cancer, pancreatic cancer, cervical cancer [8].

In Figure 2 and Figure 3 we can see that in nationwide trend in cancer diseases a lung cancer dominates. In this diagnosis 96 clinical trials are carried out, which is 21% of the total. The second cancer with 81 clinical trials (18%) is a group of cancers of the lymphatic system. Third place is breast cancer with 67 medical experiments (15%). The next one is leukaemia with 59 trials and is the last group of cancers that exceeds 10% of therapeutic experiments in Poland. Next are prostate cancer – 27 trials (6%), ovarian cancer – 24 trials (5%), stomach cancer – 17 (4%), colorectal cancer – 16 (4%), bladder cancer – 14 (3%), renal cell carcinoma – 14 (3%), hepatocellular carcinoma – 9 (2%), brain tumour – 7 (2%), pancreatic cancer – 7 (2%), cervical cancer – 7 (2%). Analysing Figure 4 in terms of the number of clinical trials in oncology in the Greater Poland voivodship, lung cancer with 50 trials (31%) is leading, breast cancer with 30 trials (16%) is in the second place and third is ovarian cancer – 16 trials (9%). Further groups of cancers in which clinical trials are conducted in the Greater Poland voivodship are: lymphoma – 14 (8%), renal cell carcinoma – 12 (6%), stomach cancer – 8 (4%), head and neck cancer – 11 (6%) prostate cancer – 6 (3%), bladder cancer – 6 (3%), pancreatic cancer – 5 (3%), leukaemia – 4 (2%), brain tumours – 3 (2%), hepatocellular carcinoma – 2 (1%), cervical cancer – 2 (1%).

Comparing the Greater Poland voivodship to the situation of clinical trials in cancer in Poland, we can see that the largest group in which the most clinical trials are conducted is lung cancer in both study groups – 21% (Poland) to 31% (Greater Poland). In Greater Poland voivodship,

breast cancer is in the second place with 16% of trials, in the nationwide group breast cancer ranks third (15%). The group of lymphatic neoplasms in Poland covers as much as 18% of trials, this percentage in Greater Poland is a 9% share of the total number of trials.

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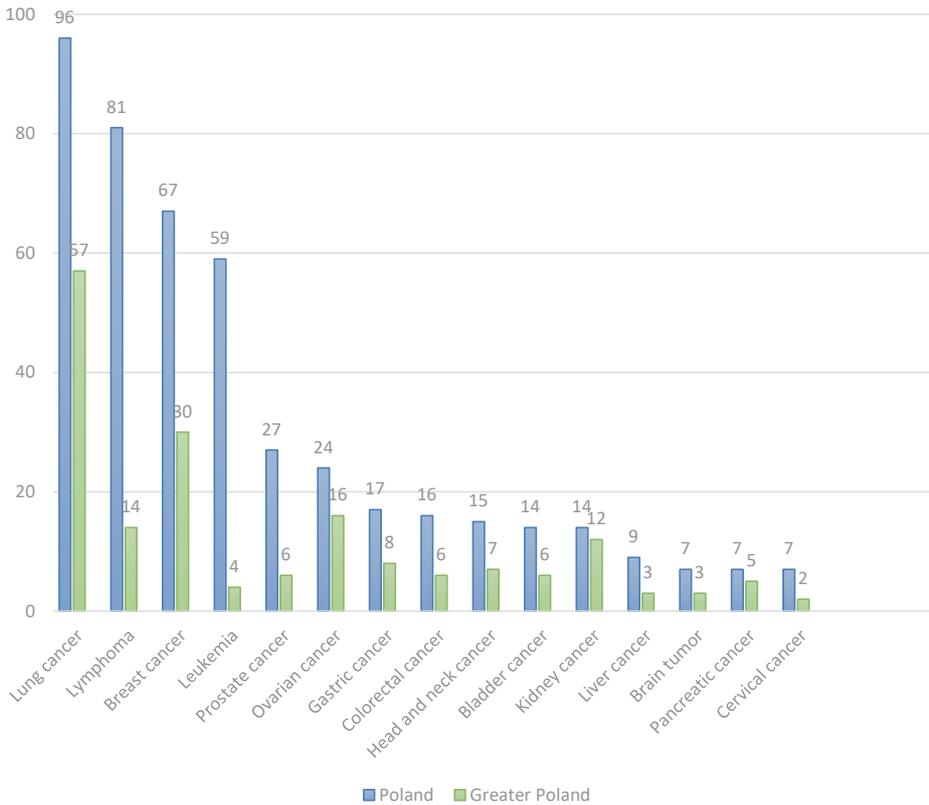


Figure 2. The number of clinical trials for specific malignancies in Greater Poland and Poland

Source: clinicaltrials.gov [cited 15.07.2019].

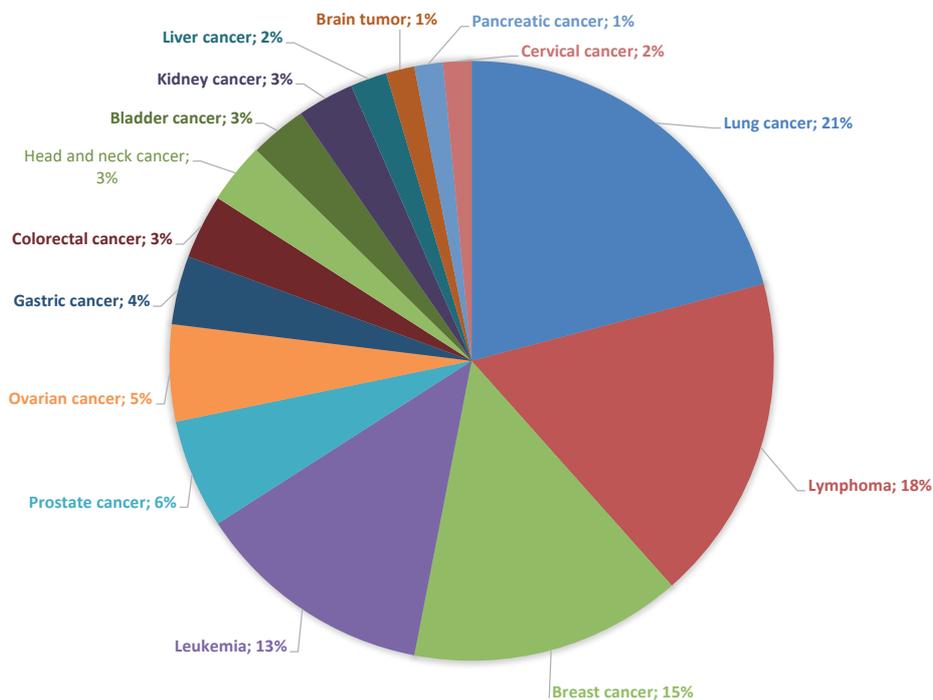


Figure 3. The number of clinical trials for specific cancer in Poland

Source: [clinicaltrials.gov](http://clinicaltrials.gov) [cited 15.07.2019].

Analysing Figure 5, in Poland in the field of oncology, the most phase III clinical trials are conducted – 357 trials, which represents 63% of the total. The second place is phase II with 151 tests (26%), the third is phase I – 45 tests (8%), the last is phase IV – 16 tests (3%).

In the Greater Poland voivodship in the field of oncology, the most research is conducted in phase III – 130 trials, which represents 65% against all phases. Phase II is 48 studies (24%), which puts it in the second place. Phase I is 16 studies (8%), which gives it the third place. In the last place is phase IV – 6 tests (3%).

To sum up, no significant differences in Greater Poland occur in comparison to the whole country when it comes to participation in the phases of clinical research in the field of oncology. Phase III strongly dominates in Greater Poland – 65% to 63% in Poland in both groups. Phase

II trials take up 24% share in Greater Poland and 26% in Poland. Phase I, however, is at the same low level of 8% in both study groups. The marginal number of studies in phase IV is at the level of 3% in Greater Poland and Poland.

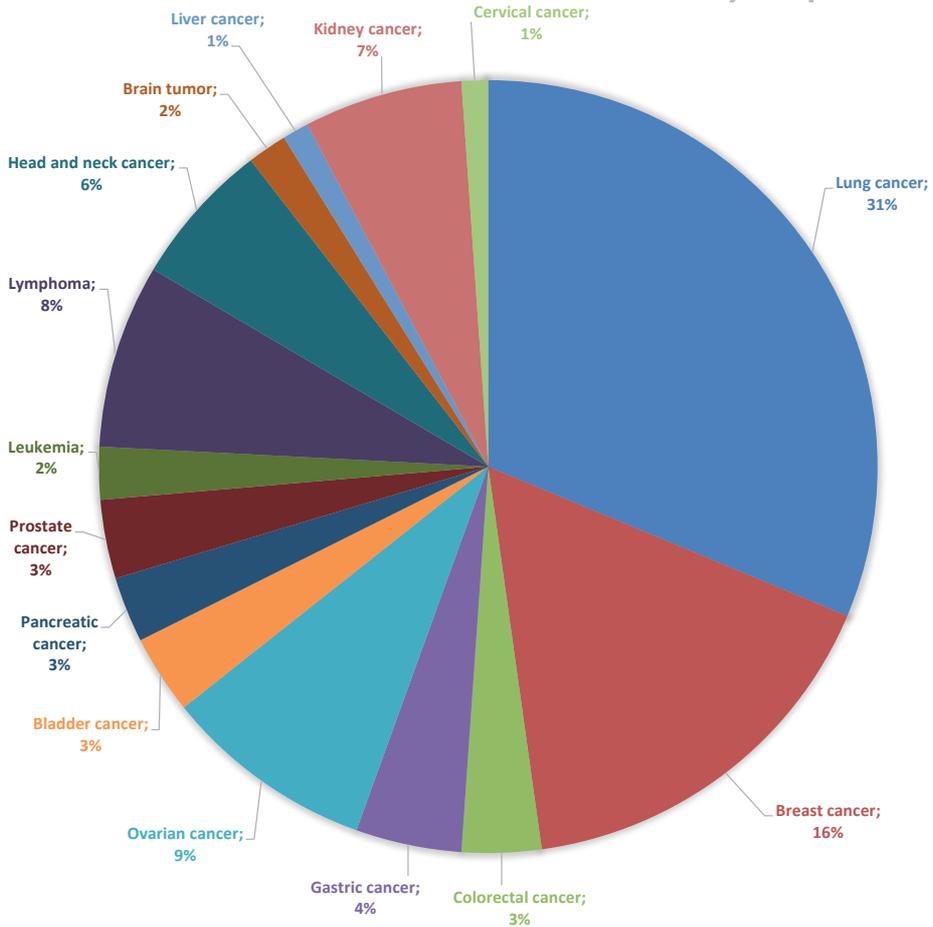


Figure 4. The number of clinical trials for specific cancer diseases in Greater Poland

Source: clinicaltrials.gov [cited 15.07.2019].

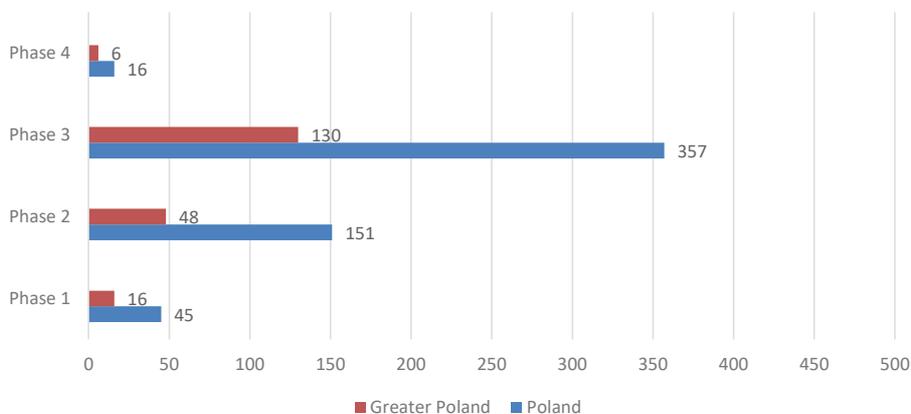


Figure 5. The number of studies divided into phases in which clinical trials in oncology is conducted Source: clinicaltrials.gov [cited 20.07.2019].

Groups of cancers with the most frequent incidence in Poland (Figure 6), i.e. lung cancer, breast cancer, and colorectal cancer were included in the analysis of the phases of clinical trials in individual cancer diseases. Analysing Figure 6, most trials are conducted in phase III. Respectively, lung cancer in Poland: phase I – 16 trials (16%), phase II – 27 (26%), phase III – 57 (56%), phase IV – 2 (2%), in Greater Poland phase I – 7 trials (12%), phase II – 18 (30%), phase III – 34 (56%), phase IV – 1 (2%). Breast cancer in Poland: phase I – 4 trials (2%), phase II – 17 (26%), phase III – 43 (66%), phase IV – no trials, in Greater Poland – phase I – 3 trials (10%), phase II – 9 (30%), phase III – 18 (60%), phase IV no trials. Colorectal cancer in Poland: phase I – 2 trials (17%), phase II – 4 (33%), phase III – 5 (42%), phase IV – 1 (8%), in Greater Poland phase I 1 trial (20%), phase II – 1 (20%), phase III – 3 (60%), phase IV no trials.

Summing up, in both examined groups (Poland and Greater Poland) in all neoplastic diseases (lung cancer, breast cancer, colorectal cancer) the largest number of clinical trials is conducted in phase III, followed by phase II, phase I, phase IV. There are no significant differences between the two research groups. Greater Poland reflects the trends of clinical trials

in oncology in Phase III against the background of the whole country, as the phase in which the most clinical experiments are conducted.

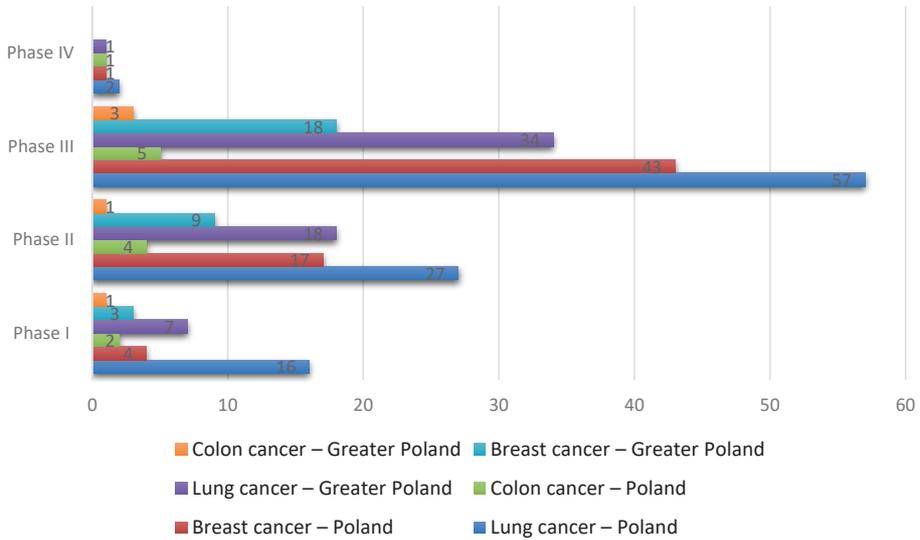


Figure 6. Individual malignancies by phases of clinical trials

Source: clinicaltrials.gov [cited 25.07.2019].

Clinical trials in the paediatric group <18 years of age are characterised by a special way of obtaining informed consent from study participants – both a written consent of a parent and a child is needed if they understand and can give such consent [9]. There are 51 such studies in Poland, and 7 in the Greater Poland voivodship (13.7%). Most trials are conducted in phase III – 24 (47%) Poland, Greater Poland – 4 (7.8%), then in phase II – 15 (29.4%) Poland, Greater Poland – 3 (5.8%), phase I and IV – 1 (1.9%) clinical trial in Poland. Also studies in the paediatric group correspond to the phase III trend, as the phase in which the most clinical trials are conducted compared to medical experiments in the group of adults >18 years of age.

Non-commercial trials (financed from own or public funds) are also carried out in Greater Poland, there are 2 such trials in colorectal cancer. Then, after 1 examination, the following tests are carried out: prostate

cancer, lung cancer, head and neck cancer, ovarian cancer, multiple myeloma, leukaemia, neuroblastoma.

## Discussion

In Poland, in 2018 there were 185,630 new cases of cancer, and there were 113,388 deaths caused by cancer [10]. There are only 575 clinical trials in the field of oncology with well-defined criteria for inclusion in the trial. The increasing number of new cancer cases should increase the number of clinical trials in Poland, which would allow access to more innovative therapies for patients. There are more clinical trials being conducted in the recruitment phase in the assessed period than after its completion, which may suggest increasing interest of potential clinical trial sponsors in Poland. Raising patients' awareness of clinical trials is a key challenge for healthcare systems and pharmaceutical companies. According to a study by Bhardwaj P. et al., a strong initiative to transform clinical trials through the European Patient Academy in the field of therapeutic innovations will increase patients' awareness and responsibility [11]. The majority of phase III studies, and the small number of phase I studies indicate the need to create phase I centres that could realise the potential of Polish specialists and attract sponsors of clinical trials and challenge the leader in conducting such trials. Creating coherent recruitment strategies allows to increase the recruitment of patients [12].

One of the strategies that can increase patient knowledge is educational videos on clinical trials [13]. Clinical research is not only the development of science and innovative treatment methods for patients, but also a positive impulse for the country's economy, through the income from VAT paid by pharmaceutical companies. According to the PwC report, a rational increase in the number of clinical trials is possible in Poland, with administrative barriers being lifted, and the precise application of the requirements of Regulation of the European Parliament and of the EU Council No. 536/2014 of April 16, 2014 on clinical trials of medicinal products for human use [3,14]. The Greater Poland voivodship can beco-

me an indicator for the rest of the voivodships in terms of the number of clinical trials conducted, if they encourage sponsors to invest in research centres not only in Poznań, but also in other cities of the voivodship.

## Conclusions

503 clinical trials are conducted in the Greater Poland voivodship, 453 of which in Poznań. Most research in Greater Poland is carried out in Poznań due to the presence of university clinics and a large concentration of specialists. Other cities in Greater Poland that conduct clinical trials are Konin, Ostrów Wielkopolski, Luboń and Leszno. In the field of oncology in Greater Poland, clinical trials are conducted in Poznań and Konin. Research after recruitment in cancer predominates over research at the recruitment stage in Poznań and Konin. Comparing the types of cancers in which clinical trials are conducted in Poland, lung cancer predominates (21%), followed by lymphatic system cancers (18%) and breast cancer (15%). In Greater Poland also lung cancer trials prevail (31%), breast cancer (16%) holds the second place, and ovarian cancer (9%) is third. Comparing both groups of respondents in Greater Poland, less research is carried out on the lymphatic and circulatory system cancers. In both groups lung cancer and breast cancer as an area of clinical research strongly dominate. The division into clinical trial phases in Poland and Greater Poland suggests the overwhelming number of clinical trials in phase III: 63% (Poland), 65% (Greater Poland) in the field of oncology. Considering the types of cancers with the most frequent incidence: lung cancer, breast cancer, colorectal cancer, phase III also prevails in both groups. The number of clinical trials on the paediatric group in Poland is 51, in the Greater Poland voivodship there are 7 such trials conducted. Also here phase III dominates. Non-commercial research is also carried out in Greater Poland – 9 studies.

Inhabitants of the Greater Poland voivodship have access to 39% of clinical trials in Poland in the field of oncology and 33% of clinical trials without division into the therapeutic area as compared to the whole country.

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