

COST AND REVENUE DYNAMICS OF CLINICAL TRIALS IN STATE-OWNED HOSPITALS (2019-2022)

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Abstract

Objective: The object of the article is to overview the cost and revenue dynamics of clinical trials conducted in state-owned hospitals. **Material and methods:** We have created a unique database of clinical trials from public registers of competent authorities. Our overview is based on the protocol content of 550 clinical trials conducted in 62 Bulgarian state-owned hospitals (a total 1,297 medical sites) in the period from 2019 to 2022. **Results:** In the new reality, reduced budget and declined state funding, the attitudes of state-owned hospitals are shifted to the benefits of clinical trials. The primary motive for state-owned hospitals to conduct clinical trials is not revenue, but rather access to new pharmaceutical products and treatment methods.

Keywords: Bulgaria; trial sites; cost-benefit analysis; health care market

JEL Codes: D61; H51; I11

Introduction

There is no universally correct answer to how much it cost to research and develop a new pharmaceutical product (Schlander et al., 2021, p. 1243). Yuleva's opinion is that innovations are a guaranteed positive change for society, especially when we talk about novelties in pharmaceuticals and pharmaceutical products (Yuleva, 2019a). Most of the reachable research is the product of a trade-off between the transparency and public accessibility of data and their specificity. Despite these challenges, fresh data reveals the value of the global clinical trials market at USD 80.7 billion (Kanhere, 2023) and forecasts world revenue for the clinical trial market to exceed USD 4.10 billion.

Clinical trials add social and fiscal values through access to new therapeutic treatments and investment in new pharmaceutical products (Rickwood, Pereira, and Gómez, 2022). Regardless of the declared goal of adding social value to public goods, the

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data indicate that the healthcare sector's priority is mainly on financial performance. According to Yuleva, this can be explained as a process - evident that the first step in the process is to establish the possibilities of the pre-order, the second step is to choose a strategy for the use of the opportunities already established, and the third is to manage the results of their use (Yuleva, 2019b). While social value receives due academic attention (Filipova, 2023, p. 58), there is a deficit of research on fiscal value due to its specific interdisciplinary nature (Kyurova, 2022, p. 7). We will try to add value to the healthcare sector by providing an overview of cost and revenue dynamics in conducting clinical trials.

The aim of our paper is carrying out an evidence-informed overview by systematically and scientifically collecting, combining and evaluating multiple reliable sources of information, including the best available and most relevant evidence from research and/or data, as a step towards improving policy and practice in clinical trials. Therefore, the term 'evidence-informed' better describes our overview than the term 'evidence-based'.

Objective

Hospitals in Bulgaria are located in accordance with the administrative division of the country, as well as with the distribution of natural resources. At the end of 2022, 341 hospitals with 54,707 hospital beds were reported. The number of hospitals remains unchanged and a slight increase in hospital beds is reported (less than one percent per year, according to the new reality of hospitalization due to the COVID-19 pandemic).

The number of state-owned hospitals in Bulgaria is 62 enterprises (112 entities, including subsidiaries and medical centers). Their number has not changed, with the exception of two cases – the re-registration of Lozenets University Hospital as a state-owned hospital (2019) and Sveta Sofia Pulmonary Hospital is acquired by Sveti Ivan Rilski University Hospital (2022). One state-owned hospital, Specialized Hospitals for Rehabilitation-National Complex, is a special case as it is a holding group of 13 rehabilitation subsidiaries located in localities with natural resources (mineral springs, healing mud and healthy climate).

Material and Methods

We have selected sources that are publicly available and regularly updated. First, we have formed a set of clinical trials that are authorized to be conducted in Bulgaria by the competent authority – the Bulgarian Drug Agency. Second, we have extracted the protocol items for each clinical trial according to the structure of the European Union Clinical Trials Register. Third, we have calculated financial data from the annual reports of state-owned hospitals provided by the Public Enterprises and Control Agency. Fourth, we have

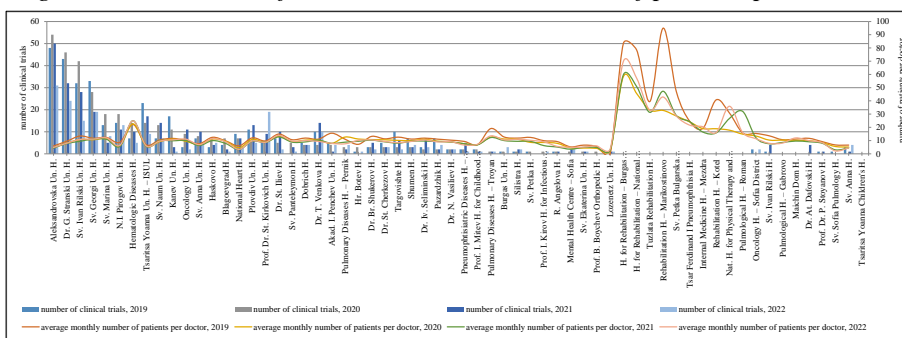
supplemented the medical and statistical data of state-owned hospitals from the Ministry of Health. Fifth, we have used aggregated data on the macroeconomic development of Bulgaria for the period of 2019-2022 of the National Statistical Institute.

Based on these criteria, we have created database of clinical trial protocols conducted in state-owned hospitals – 550 clinical trials at 1,297 medical sites in 62 state-owned hospitals. The database is unique, universal and pioneering. The collected information is systematised for sponsors and investigators, competent authorities and entities in the development of a competitive strategy at the micro and macro level. Our data are suitable for studying the future trend of clinical trials as well as for comparative analysis for other countries.

Results

Over a third to a half of all clinical trials are conducted in state-owned hospitals and their medical sites. The decline in both the number of clinical trials and the participation of state-owned hospitals in clinical trials applies to general state-owned hospitals (Figure 1). Clinical trials in four state-owned hospitals (Aleksandrovska University Hospital, Dr. G. Stranski University Hospital, Sveti Ivan Rilski University Hospital, and Sveti Georgi University Hospital) represent 40% of the number of all clinical trials.

Figure no. 1 Number of clinical trials* and number of patients per doctor**



Source: * – Register of Authorised Clinical Trials by Bulgarian Drug Agency, ** – Ministry of Health

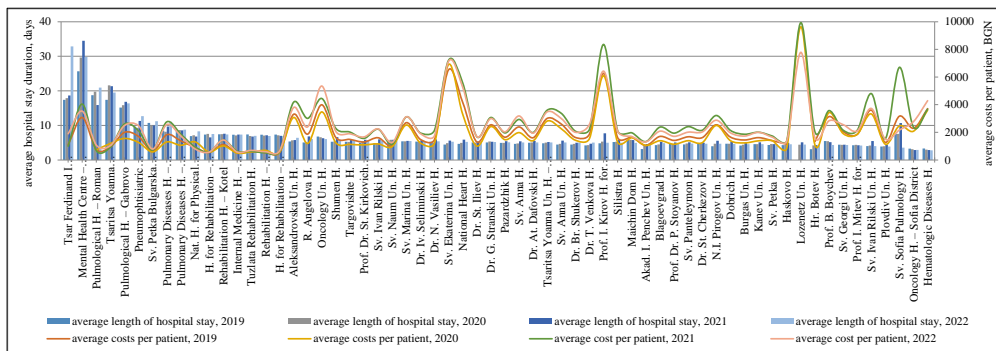
At the head of the number of clinical trials are general hospitals with 100% state ownership, followed by general hospitals with minority shareholders and speciality hospitals, finally – rehabilitation hospitals with zero clinical trials. The hospitals are arranged in reverse order when presenting the average monthly number of patients per

doctor – the leading ones are rehabilitation hospitals, followed by the speciality ones, and finally, the general hospitals.

The average monthly number of patients per doctor decreased by 25% in 2020 and remained unchanged, with an increase in the number of autonomous medical centres and private hospitals, as well as a decrease in patient admissions due to the COVID-19 pandemic. With the largest number of patients per doctor are rehabilitation hospitals that do not conduct clinical trials. Some speciality hospitals belong to this group, a large number of patients per doctor and a relatively small number of clinical trials (Maichin Dom Hospital, Sveta Sofia Pulmonary Hospital, Oncology Hospital – Sofia District, Mental Health Centre – Sofia, Professor I. Kirov Hospital for Infectious and Parasitic Diseases, Professor I. Mitev Hospital for Childhood Diseases).

The decrease in the number of clinical trials has been accompanied by an increase in the average length of stay (Figure 2). Speciality hospitals and rehabilitation hospitals have the longest length of stay (7-34 days). In pulmonary hospitals, the length of stay is 12-15 days, and in only one hospital the length of stay is doubled from 17 days to 33 days (Tsar Ferdinand I Pneumophthisia Hospital). In general hospitals, the average length of stay of one patient is 4-6 days, regardless of the pandemic reality.

Figure no. 2 Cost per patient and hospital length of stay



Source: Ministry of Health

Average length of stay is inversely related to average cost per patient. In addition to longer length of stay, speciality hospitals are also characterized by lower average cost per patient (Table 1). In three state-owned hospitals, the average cost per patient for a hospital stay of 4-5 days exceeds the annual cost for a person (Sveta Ekaterina University Hospital, Prof. I. Kirov Hospital for Infectious and Parasitic Diseases, and Lozenetz University Hospital). The amount of hospital stay exceeds the cost per capita on health – BGN 2,564 (Mitkova and Petrova, 2021, 9).

Table no. 1 - Cost per patient for a hospital stay and annual cost for a person, BGN

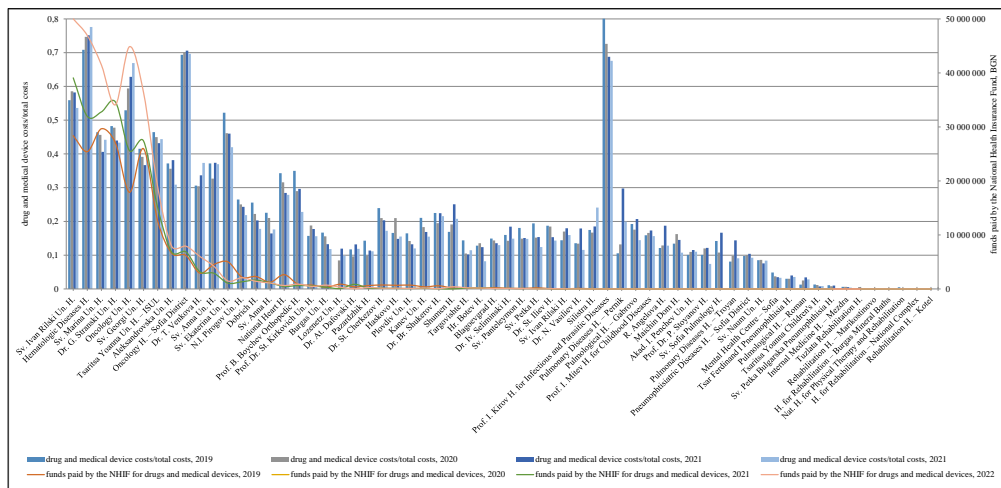
Cost	2019	2020	2021	2022
cost per patient for a hospital stay of 4-5 days*	6 397	8 273	8 502	8 574
annual cost for a person**	6 214	6 220	7 042	8 389

Source: * - annual reports of state-owned hospitals, Public Enterprises and Control Agency and ** - National Statistical Institute

Three hospitals with the highest number of clinical trials had a consistent average length of stay of 5 days, with average costs per patient increasing by 15%.

Average length of stay and average cost per patient reflect other medico-statistics data of state-owned hospitals. For example, in three hospitals, the cost of pharmaceutical products and medical devices exceeded 50% of all costs (Figure 3). The specialization of these hospitals in oncology and haematology explains both the high percentage of cost on pharmaceutical products and medical devices, as well as the large amounts paid for pharmaceutical products and medical devices by the core source of funding – the National Health Insurance Fund.

Figure no. 3 Pharmaceutical products and medical device cost/total cost* and funds paid by the National Health Insurance Fund for pharmaceutical products and medical devices**



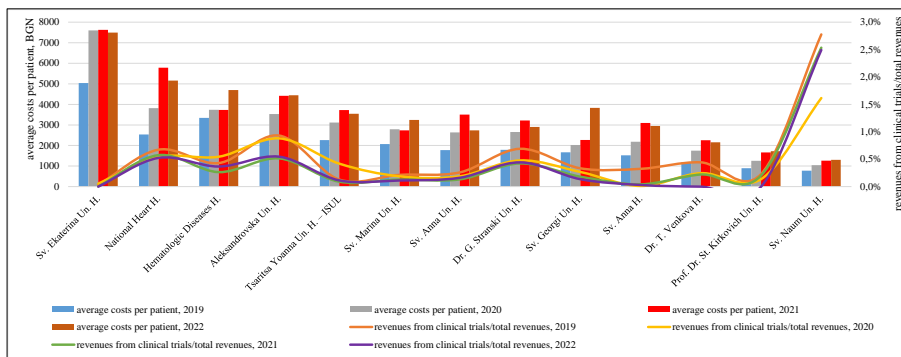
Source: * – annual reports of state-owned hospitals, Public Enterprises and Control Agency.
 ** – Ministry of Health

Hospitals with the highest number of clinical trials have an average of 40% pharmaceutical products and medical device cost/total cost. These hospitals received

disproportionately high funds paid by the National Health Insurance Fund for pharmaceutical products and medical devices – funds received increased by 75% during the COVID-19 pandemic.

The financial performance of state-owned hospitals is on a downward trend – cost per patient is increasing and revenue from clinical trials is decreasing. General state-owned hospitals report better results for cost per patient than specialty state-owned hospitals (Figure 4). Clinical trial revenue is higher for specialty state-owned hospitals, where trial and pharmaceutical product cost are higher, than in general state-owned hospitals.

Figure no. 4 Cost per patient and revenue from clinical trials



Source: annual reports of state-owned hospitals, Public Enterprises and Control Agency

Our overview found a higher level of disclosure of clinical trial revenue from hospitals that are wholly state-owned (specialty hospitals) compared to hospitals with minority shareholders (general hospitals). Different practices have been established in the reporting of clinical trial revenue. For example, revenue from clinical trials is reported as an additional fee – ‘ethics commission and clinical trial fees’ (Tsaritsa Yoanna University Hospital – ISUL EAD, 2023), as well as other revenue ‘payment for documentation review, incl. for clinical trials’ (Dr. Georgi Stranski University Hospital EAD, 2020). In another case, revenue from clinical trials is reported as combined fees: ‘clinical trials and related fees for administrative document review’ (Sv. Anna University Hospital EAD, 2021).

Conclusion

General state-owned hospitals have a higher number of clinical trials than speciality hospitals. Speciality state-owned hospitals report higher cost per patient and revenue from clinical trials. There is no evidence that revenue is the primary motive for state-owned hospitals to conduct clinical trials. The motive is rather intangible – access to innovative

pharmaceutical products and treatment methods in search of safety and efficacy (preferences to health, not wealth).

The number of clinical trials, the cost of pharmaceutical products and medical devices/total cost, the average cost per patient, as well as the funds paid by the National Health Insurance Fund for pharmaceutical products and medical devices do not affect the revenue from clinical trials/total revenue. A lack of correlation between medical and financial data may mean that an individual doctor or team is conducting the clinical trial but not on behalf of the hospital itself, or that the clinical trial is not being reported as a part of the hospital's R&D.

The conclusion is drawn that the leading factor for the number of clinical trials and for the revenue from clinical trials is the hospital's specialization in certain diseases, as well as the provision of the hospital with doctors and medical devices for conducting clinical trials. The COVID-19 pandemic has shifted the dynamics of clinical trials, shifting the burden of health care to hospitals and diseases that are not subject to restrictions on both visitor accesses policy and doctor-patient contacts.

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