

Clinical Trials Trends of 2023 Year and Visionary to the Future

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ABSTRACT

Introduction: The importance of studying historical changes in the development of human activity is substantiated by the need to systematize such changes and the possibility of predicting them. Historical changes are extended in time and do not have clear boundaries, requiring greater involvement in their study and the prerequisites for their appearance. Clinical research is more than just the practical application of medical changes and discoveries. They make changes in medical practice but are subject to change. Changes in the clinical research industry are tendentious and develop gradually, requiring study and forecasting. According to the generally accepted temporal gradation of the forecast, there is an operational forecast of up to one month, a short-term forecast of up to one year, a medium-term forecast of up to five years, a long-term forecast of up to 20 years and a long-term forecast over long-term, and a short-term forecast is common in the clinical research industry. We analyzed publications in open sources from 1930 to 2023 by keywords in the Russian-language literature trends in the clinical trial industry and the English-language literature trends in the clinical trial industry.

Discussion and Conclusion: Trends in the development of clinical trials until the end of 2023 can be divided into two groups, those related to changes in the conduct of clinical trials and changes in the products of clinical trials in nosologies. If in the first group, the trends remain similar to 2022, the ongoing digitalization of operations, the shift of centralized research towards decentralization, and the shift in protocol design towards patient-centricity, then in the second group, the number of expected drugs has decreased, and there is a shift of drugs towards biologics and gene therapy drugs.

Keywords: Clinical Trials Tendencies • Real World Data • Decentralized Trials • Hybrid Clinical Trials • Artificial Intelligence in Clinical Trials

INTRODUCTION

For a complete consideration of the proposed topic, we considered it appropriate to review some historical facts related to such a specific area of human activity as clinical research. The prototypes of clinical research were found in 2000 BC [1]. For example, in Babylon, a sick person went to the square and waited for the most appropriate advice on treating his illness, which can be considered a prototype of the publicity of clinical research. For the first time, the term clinical trials appears in 1931 [2]. A. Koterov et al. (2021) cite a source in 1896 [3]. After 1946, prototypes of clinical trials appeared, consisting of a sponsor, a researcher, and a patient, which were then joined by an ethical component (the Nuremberg Code and the Declaration of Helsinki) [4]. Until the end of the 20th century, the scheme included a clinical center where patients were concentrated and conducted basic procedures; centralized clinical trials were formed [5]. With the development of technology, the need for centralization in research began to decrease. However, it indicates



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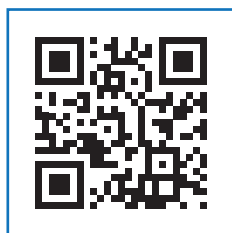
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that the role of the clinical center remains with a steady increase in trends [6]. With the established classical centralized scheme for conducting clinical trials, the changes concerned the nosology and indications of the studied new medical substances of chemical synthesis. Since 1975, with the discovery of hybridoma technologies [7], the era of clinical trials of biological preparations has begun. With the development of genomic and gene technologies since the early 1990s [8], it can be considered the beginning of the era of clinical trials of gene and cell therapy preparations. Changes began to appear in recent decades in the methods of conducting clinical trials. By the end of 2022, the classical scheme will have certain modifications associated with introducing new technologies, and we can talk about the following clinical trials [9-14]:

- Centralized Clinical Trials (CT) conventional or routine
- Decentralized CT
- Personalized CT
- Hybrid CT
- Virtual CT
- Clinical studies using Bayesian Statistics (Bayesian CT)
- Clinical studies using real clinical practice data or Real-World Data (RWD) and real evidence-based medicine data Real-World Evidence (RWE)
- Clinical trials based on Artificial Intelligence

Clinical research activity in one direction or another is also tendentious and is undoubtedly determined by the need to treat diseases. For example, the emergence of new infectious diseases like COVID-19, Ebola, and others has significantly increased the number of clinical trials in the field of infections, and the clinicaltrial.gov database now contains more than 18,000 clinical trials in the field of infectious diseases, compared with 590 in the last decade of the 20th century. Cancer clinical trials are by far the most common (clinicaltrial.gov contains over 43,000 CTs compared to 2,700 in the last decade of the 20th century).

LITERATURE REVIEW

It used retrospective observation of the open source and limited-access publications in the English-language part of the Internet for crucial queries “trends in clinical trials” in the Russian-language part “trends in clinical trials” and publications on the history of the development of clinical trials for the 1933-2023 year and earlier back before Christ Centuries to embrace the most beginning of the trends. The eligibility criteria for analysis of publications were the

chronological order of appearance of any trends or a new direction in the clinical trials industry and the correlation of findings with the 2023 year.

DISCUSSION

After studying the existing publications on the proposed topic, two main groups of trends can be distinguished:

- A group of trends in the organization and conduct of clinical trials and
- The second group, trends in the release of new drugs in a particular area after clinical trials

We have identified and listed below the following trends in clinical research until the end of 2023, shown in (Table 1 and Table 2).

The digitalization trend of clinical trials in 2023 will accelerate, and today most of the activities related to conducting clinical trials have received their virtual copy. In particular, introducing electronic informed consent will be accelerated, increasing patient awareness and the possibility of his participation in the study. The FDA 2016 issued a regulatory document on implementing electronic informed consent [18,19]. In addition to the advantage of maximizing the availability of research aspects, electronic consent may attract patients from remote regions. Paper originals and copies of study documents are also transferred to digital format, including primary documentation, and this is facilitated by the development of Electronic Medical Health Record (EMHR) technologies. Electronic signature technologies DocuSign and payments to researchers Popsipay [20,21] make it possible to solve the problem of payments in clinical trials. Directions of digitalization blockchain, cloud technologies, and cybersecurity are also among the trends in the digitalization of clinical research [22].

The tendency to centralize clinical trials is because the procedures [23,24] for performing clinical trials are becoming more complicated, which can only be performed in a clinical center. The trend towards decentralization of clinical research has been made possible by the advent of new wearable technologies and the improvement of remote data transmission capabilities [25]. M. Alsumidae et al. [26] point out that the driver for the development of decentralized research is the fact that 70% of patients live more than 2 hours away from the site. The same author considers the following decentralization options complete absence, that is, a centralized clinical trial when all procedures are carried out on the site; partial decentralization when only part of the clinical trial procedures are done remotely; completely decentralized and centralized virtually when

Table 1: Group of trends in conducting clinical trials.

Group of trends	Trends	The expectations of presence this trends until end of 2023 year
1. Trends related to the conduct of clinical trials	1.1 The trend of digitalization of clinical trials	Expected to be presented during the whole year
	a. Creation of digital copies of research documents	Expected to be presented during the whole year
	b. Development of Digital Informed Consent of the Patient	Expected to be presented during the whole year
	c. Remote access to verification of primary documentation	Expected to be presented during the whole year
	d. Electronic filing and other digital technologies	Expected to be presented during the whole year
	1.2 Centralization of clinical trials associated with the increasing complexity of clinical trial procedures.	Expected to be presented during the whole year
	1.3 Decentralization of clinical trials with out-of-center patient procedures	Expected to be presented during the whole year
	1.4 Trend of clinical research implementation based on real-world data and real-world evidence clinical data	Expected to be presented time to time
	1.5 Trends in risk-based approach in various aspects of clinical trial execution	Expected to be presented time to time
	1.6 The trend towards virtual pre-clinical and clinical trials, and the resulting next trend of connected trials.	Very rare presented
	1.7 Connected trail as a trend	Not presented as no yet developed enough
	1.8 Artificial intelligence adoption trend	Very rare presented
	1.9 The trend of personalization of clinical trials	Very rare presented
	1.10 The trend of introducing Bayesian statistics into clinical research	Expected to be presented time to time
	1.11 Tendency to maintain population diversity (diversity) in clinical trials	Expected to be presented time to time
	1.12 The trend of introducing game technologies into clinical research is the mixing of game technologies with CI [15]	Not presented as no yet developed enough
	1.13 The trend of global standardization of clinical trials [16]	Not presented as no yet developed enough
1.14 Trend in the introduction of telemedicine technologies into clinical trials	Expected to be presented during the whole year	
1.15 Trend in single ethics committee approval of clinical trials	Very rare presented	
1.16 Remote auditing trend	Expected to be presented during the whole year	
1.17 Trend in clinical trials by large pharmacy chains	Expected to be presented during the whole year	

Table 2: Group of trends in the research of new drugs.

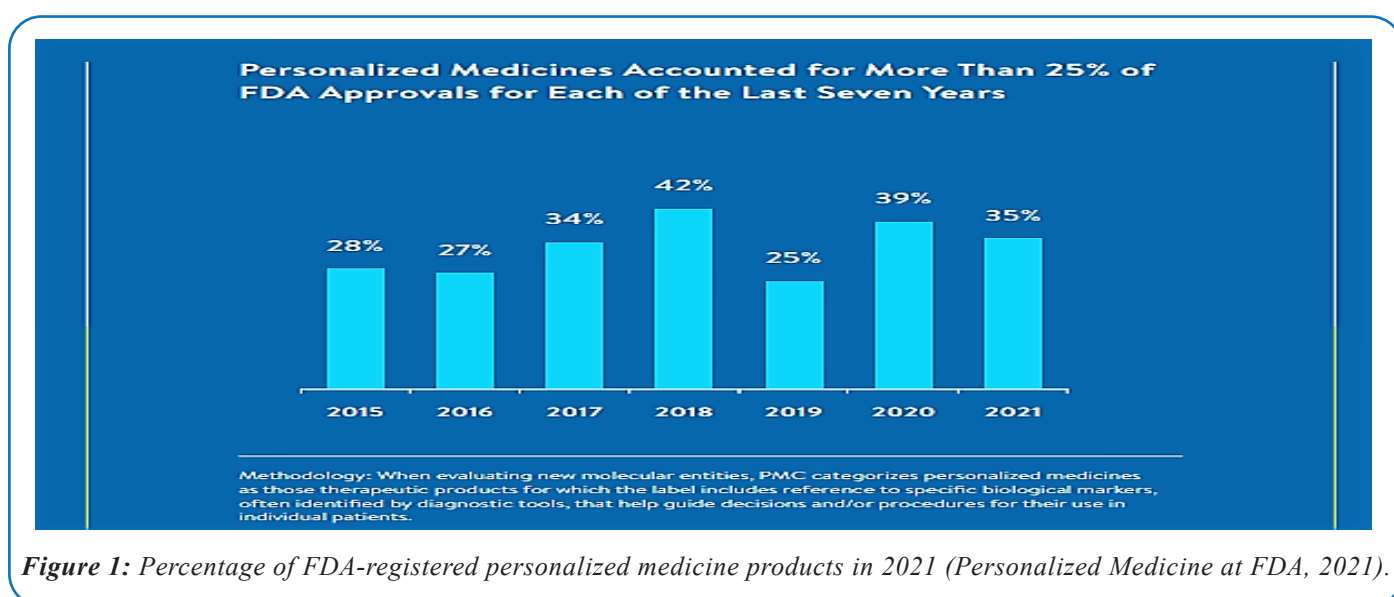
Group of trends	Trends	The expectations of presence these trends until end of 2023 year
2. The second group: trends in the research of new drugs (by nosology, by methods of treatment, etc.) in which there is a shift from the study of small molecules towards biological drugs and cell therapy, as well as the study of known finished substances for medical reasons:	2.1 Biologic research trend	Expected to be presented during the whole year
	2.2 The trend of research into therapies mainly for oncological, orphan and auto-immune diseases	Expected to be presented during the whole year
	2.3 Trends in Gene Therapy Development	Expected to be presented during the whole year
	2.4 Clinical studies of known substances for new indications-cannabinoids [17]	

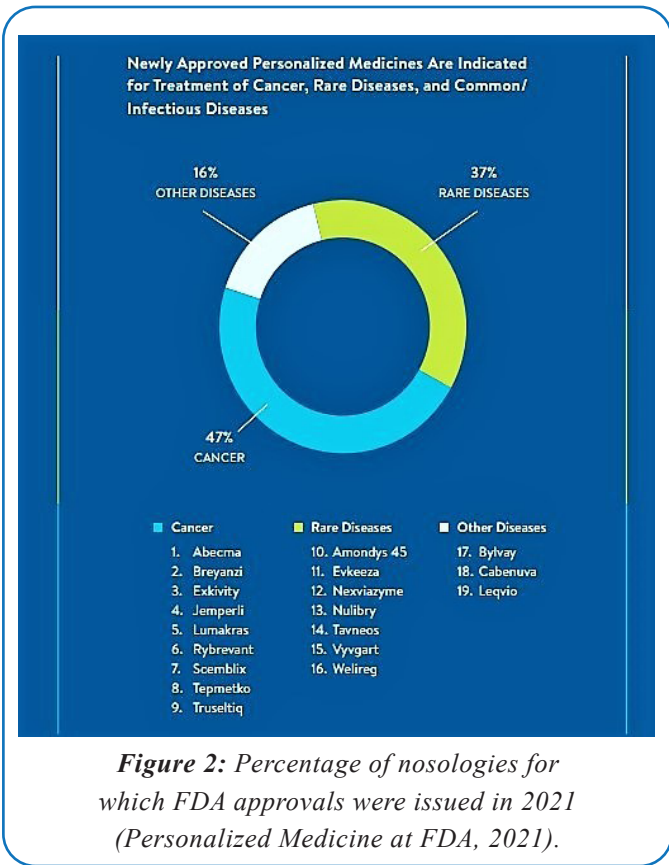
part of the elements of a clinical trial done remotely and part centrally. The following technologies also contribute to developing mobile decentralization sites and smartphone applications. Decentralization has impeded the development of nursing care in contract organizations [27,28]. The trend to implement clinical research based on real clinical data (RWD: real World Data/Real World Evidence Data) means that the data generated by the body of the patients and the patients themselves are immediately recorded and transferred to the data center. This trend is being developed [29], and currently, in particular, a HARPER protocol template is being developed for such a study [30].

The trend of a risk-based approach which means that it was calculated all risks could rise while conducting particular clinical trials, continues to be relevant for 2023. As part of this approach, finding effective ways to recruit patients remains relevant [23,31]. In some cases, the trend toward introducing virtual CT and preclinical studies is based on the rejection of preclinical studies. Regulatory approval for conducting clinical trials without preclinical trials was

released at the end of 2022 [32]. A unified platform for preclinical and clinical studies is being considered, and a trend of connected studies is emerging [33]. The trend of introducing artificial intelligence into clinical trials has already borne fruit, and in 2023 the first drug discovered by artificial intelligence passed phase 1 clinical trials [34]. Work is underway to improve the use of artificial intelligence in medicine [35]. The artificial intelligence technologies available in the public domain chatGPT and Google Bard are still in the initial stage. There are even suggestions that such developments will stop [36].

The trend of conducting personalized clinical trials is also traced. Another name for such studies is patient-centric CT in such studies, the patient actively participates in the design of the protocol and other activities [14]. This trend is closely intertwined with patient pool diversity, real-world data, telemedicine, and personalized medicine when medicines are used based on the patient's gene profile [37]. If there is an indication of an association with a gene marker when a new product is approved, then the approved product is considered personalized (Figure 1, and Figure 2).





The trend of introducing Bayesian statistics allows you to “rearrange the cause and effect” based on the known fact of the event, calculate the probability that this cause, and allows to speed up the results in clinical trials [38]. The trend of conducting clinical trials with the maximum diversity of involved patients (diversity) by sex, race, age, and ethnicity is in the most demand, as it allows for obtaining comprehensive data on efficacy and safety [19]. Diversity in clinical trials is a pressing issue, as it allows results to be applied to study groups. The more diverse the patient populations in clinical trials, the more indications for using an approved drug.

The trend of introducing game technologies into clinical trials was expressed by B. Birkhead et al., [39] and repeated by Sinha Abhishek [15]. International working groups have been created to introduce Augmented Reality (AR), Mixed Reality (MR), Virtual Reality (VR) [40], and Extended Reality (XR) game technologies into clinical research. The trend of standardization of clinical trials has been developed through standard operating procedures. However, the trend of standardization of all clinical centers in the world proposed by G. Koski et al. continues to be implemented [16]. The trend of introducing telemedicine into clinical research is related to the trend of personalized clinical research and the trend of decentralized clinical research.

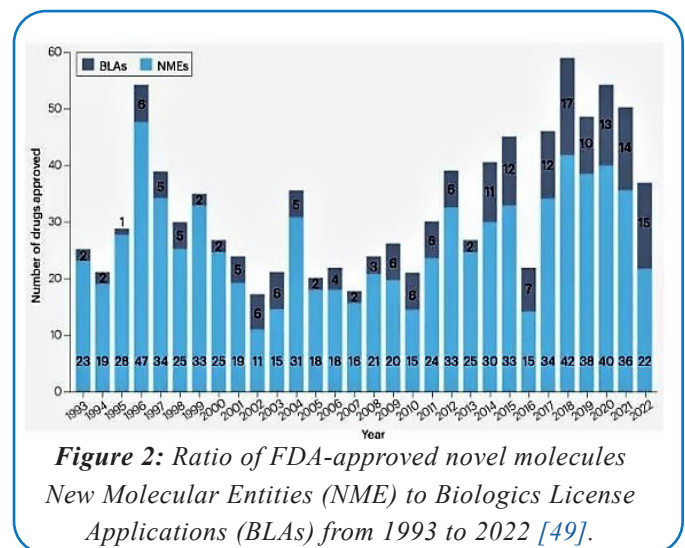
Single Ethics Committee Approval Trend: This trend refers to the approval of a clinical trial by a single Ethics Committee for all clinical sites in the study, and regulatory authorities have supported this trend [41]. The trend of remote auditing in clinical trials is similar to remote monitoring and was actively used during the COVID-19 pandemic [42]. However, the trend continues.

The trend of conducting clinical trials by large pharmacy chains is a rapidly growing trend that allows fulfilling the diversity of the population involved. Walgreens and CVS for 2022 launched their clinical trials using the decentralization trend [43]. The second trend pool is in research on medical end products by nosology, type of therapy, and other purposes.

In 2023, the continuing trend of research into mainly biological drugs for the treatment of oncological diseases and orphan diseases will be supplemented by the trend of research into gene therapy drugs and the ten most anticipated approvals of new drugs, from which 10% are gene therapy drugs (Roctavirin) and 20% monoclonal antibodies [44,45].

The new trend is clinical trials of cannabinoid drugs which means that new lives inspire the existing ready substances. This trend is expected to extend to other similar products [17]. For the drug approval trend, almost all expected drugs in 2023 compared to the previous year will be personalized medicine drugs [46-48], either gene-based or marker-based [45,50]. The development of personalized clinical research is closely related to the development of data from actual clinical practice, telemedicine, and patient pool diversity.

Changes in the number of approved new drugs in the biologics and new molecules ratio are shown below (Figure 3).



B. Bantz provides data on 25 expected drug approvals where the relative number of biological and personalized medicine drugs prevails over molecules [51]. The exact number of new products remains in development at stage 1 of phase-6147 new products [52]. An implicit trend in clinical trials to change quantity and quality correlates with the development of IT technologies [53].

In the second group of trends, personalized medicine preparations (marker preparations of gene and biological therapy) came to the fore for the first time. However, in developing drugs, it is also necessary to focus on developing new antimicrobial drugs, quite possibly biological ones [54]. We can also anticipate several new trends in the coming years. Also, an implicit trend is a search for ways to successfully recruit patients [55], which can be traced as the basis of some trends, a risk-based approach, and decentralized research that requires clear algorithms. The outcome of the successful recruitment of patients may be the success or failure of a clinical trial, which may be the

trend in subsequent years [56].

The Mergers and Acquisitions (M&A) market will remain a constant trend in 2023 [57]. Perhaps a new trend is emerging, Private clinical trials-compiling patient-centered studies and new technological approaches and implying unconditional and investigator-initiated clinical trials [58,59].

CONCLUSION

As we studied the article's topic, we grouped the trends in clinical trials into two large groups, detailed above, presented in the literature for the first time. In the first group of trends, most of the trends persist from previous years, and a new trend of conducting clinical trials in large pharmacy chains has reappeared.

CONFLICT OF INTEREST

The author declares no conflict of interest.

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