

Original Article

Drug discovery and drug marketing with the critical roles of modern administration

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Abstract: Drug research and development is a long-term and complicated process with the involvement of multidisciplinary, multi-sector cooperation and regulations of the Food and Drug Administration (FDA). It is of high risk, high cost, high benefit and time-consuming. Therefore, the drug administration and management is extremely necessary and useful. We discussed the whole process including laboratory study, target determination, drug discovery and screening, leading compound and optimization, preclinical and clinical trials, FDA approval and marketing. Actively exploring and applying modern administration and innovative management technology, we can scientifically and effectively enhance the discovery of new drug research and development, and strengthen the supervision of drug market. In recent years, innovation such as artificial intelligence has been applied to drug discovery and drug administration. We further analyzed the possibility of applying management technology to reduce risks, generate profits and benefit patients in the whole process of new drug research and development. In conclusion, drug administration and management plays critical roles in modern drug research and development, and the new technology can be helpful for drug launching.

Keywords: Drug research and development, laboratory, preclinical and clinical trial, administration, management

Introduction

At present, drug research and development (R&D) is becoming more and more difficult, as it is more challenging to get potential leading compounds, and the process to bring a drug into market is increasingly becoming costlier and riskier [1]. Market-oriented drug R&D calls for not only more innovative ideas from scientists, but also more resource integration, multidisciplinary cooperation, and both remote and on-site collaboration [2]. On July 18, 2018, the European Medicines Agency (EMA) announced that carcinogenic impurity was found in the blood and heart drug valsartan supplied by Zhejiang Huahai Pharmaceuticals in China (https://getzpharma.com/articles/__valsartan). The raw material medicine Valsartan was recalled from the markets and immediately forbidden to import by EMA and FDA of United States. This case demonstrates that, with no doubt, the modern administration plays a sig-

nificant role in drug R&D and drug marketing. The modern administration needs to integrate multiple resources timely. Through improving efficiency and optimizing the use of modern science and technology and innovative ideas [3, 4], we shall endeavor to improve the benefit of patients by effectively enhancing the development of innovative drugs and the monitoring of drugs in market [5, 6]. In this article, we will discuss the details and the involvement of management science in each step of the whole process of drug discovery and drug marketing.

The general process of drug R&D and drug marketing

Drug discovery has a long and arduous process from the initial stage of laboratory bench to clinical trials and eventually to the entry of drugs into the market (**Figure 1**). Research and development are closely related, and the hallmarks of the two stages are the identification of candidate drugs. Via bench work, we can find

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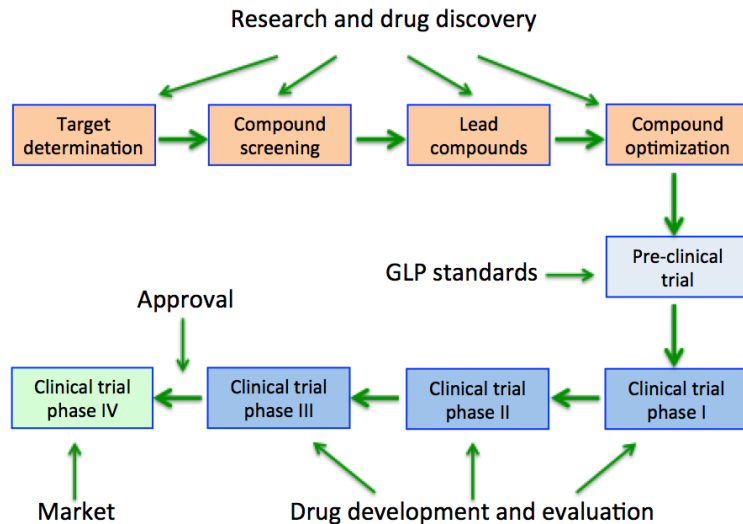


Figure 1. The process of drug research and development.

the leading compounds and then optimize them [7]. Via preclinical study and clinical trials, we can identify the safety and efficacy of the tested drugs. After drug approved for market, post-marketing surveillance trial or phase IV will possibly be conducted for drug safety (Figure 1).

Laboratory research

Drug research mainly includes four important stages: (i) target determination, (ii) model establishment, (iii) discovery of lead compounds, and (iv) optimization of the lead compounds.

Target determination

This is the starting point of new drug R&D process and the basis of all kinds of operations for the further selection and determination of the targets of human diseases. Once drug targets are identified, the potential compounds or polypeptides are synthesized or modified, bioengineering products such as antibody/recombinant proteins are developed, and metadata analysis is applied to screen database for new druggable molecules [8, 9]. Drug candidates will be tested for drug effects, chemical safety, mechanism of action, etc.

Establishment of experimental models

After the target is selected, the experimental models such as *in vitro* assays, *in vivo* assays, unique cell lines, binding affinity, kinetics, gene knockout, transgene, are needed to screen and

evaluate the biological and pharmacological activity of the potential drug candidates [6, 7, 10]. These experimental models are developed or adapted according to the screening criteria and different tested compounds or other drug candidates [11], and used to determine whether these drug candidates meet the requirements of the action, and to ensure the specificity of the research process.

Discovery of lead compounds

The lead compound is the one with certain biological or pharmacological activity and is likely therapeutically druggable. To find a lead compound that possibly target a unique gene, a protein or a signaling pathway, thousands of small molecule compounds are usually tested in laboratories with many different strategies applied and a plenty of experimental methods and technologies used [7]. For instances, G Protein-Coupled Receptor (GPCR) family is of significance in drug R&D. GPCRs are transmembrane receptors that interact with their ligands which are generally thought to be potential drugs. The discovery of the GPCR-targeting lead compounds depends on the ligand-receptor interactions and the associated models. There are two main ways to obtain new lead compounds, which are extensive experimental screening and computer pre-screening based on previous known structures and models [12].

Optimization of lead compounds

The optimization of a lead compound is one of the most critical steps in drug R&D. Once an initial lead compound is identified, optimization will be applied to further test drug potency, selectivity, toxicity, safety, molecule mechanism and distribution [6]. The lead compound may have some defects or detrimental properties, such as low action intensity or specificity, inappropriate pharmacokinetic properties, strong toxic side effects or chemical or metabolic instability. As the compound cannot be used as a drug directly, it is necessary to optimize the lead compound. For instances, the chemical

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Table 1. The pre-clinical and clinical trials in drug development

Contents	Preclinical trials	Clinical trials			
		Phase I	Phase II	Phase III	Phase IV
Objects	Lab study	Human	Human	Human	Human
	<i>In vitro</i> assays	20-80 people	100-300 people	>1000 people	>1000 people
	<i>In vivo</i> animals				
Goal	Effects	Safety	Efficacy	Efficacy	Efficacy
	Safe	Side effects	Safety	Safety	Long-term safety
	Dose	Administration routes	Side effects	Side effects	Side effects
	Administration routes drug distribution etc	Dose escalation			Mortality rate
Time to last	1-3 years	Months to years	1-2 years	Several years	Long-term
Chance to pass	NA	70%	30%	25-30%	Rare withdrawal

structure of the compound can be modified in order to be more receptor-specific, more potent and less toxic. In brief, the goal of the optimization process is to prepare a series of compounds based on the principle of similarity, and to evaluate their comprehensive structure-activity relationship together with optimization of their physical, chemical and biochemical properties [6]. Afterward, the *in vitro* and *in vivo* activities are evaluated.

Preclinical studies and clinical trials

Preclinical studies: After a series of *in vitro* and *in vivo* experiments to determine the best drug candidate and before drug clinical trials, pre-clinical studies are conducted to evaluate preparation process, safety, dosage, acute and chronic toxicity, stability, formulation and components, pharmacokinetics, allergic reactions, efficacy, hemolytic and local irritation tests, mutagenicity, reproductive toxicity, carcinogenic toxicity, etc [1]. These evaluation experiments need to be conducted by the organizations or laboratories qualified with good laboratory practice (GLP) standards that refer to the management controls of non-clinical studies for assessing the efficacy and safety of drug candidates on animals prior before clinical studies in humans. Studies conducted under these GLP restrictions can be approved by FDA for new drug application.

Investigational new drug application

With the accomplishment of drug safety test, the pharmaceutical company will have to submit the appropriate investigational new drug application to FDA for approval of starting human clinical trials [13]. The proposed new drug application should include the following con-

tents: the preliminary experimental results, methods, location and the objects of further studies, the chemical structure of the compound, the mechanism of action *in vivo*, toxic side effects found in animal studies and the production process of the compounds. In addition, the new drug application must be reviewed and approved by the Institutional Review Board. Then, the pharmaceutical company can initiate human clinical trials beginning with phase I study. The subsequent clinical studies are required to submit at least one progress report to the FDA annually. The human clinical trials generally including Phase I, II and III (**Table 1**), are executed by contract research organizations (CROs) [1]. And sometimes, a post-marketing surveillance trial or phase IV trial may be continued to evaluate the safety and effects of the drug in market.

Clinical phase I

The phase I clinical study is to evaluate drug safety in humans with a small group (20-80 peoples) and identify the dose range and side effects. These participants will be divided into different groups and start cohort studies. The dose will be increased if the first cohort has no severe side effects on the given dose. The new cohort will be given higher dose until investigators figure out the optimal and safe dose for next phase II study. Additionally, clinical investigators need to evaluate the optimal administration aspects such as oral, intravenous and subcutaneous administration, and the frequency of the given drug [14]. Phase I study also needs to do some laboratory tests and determine the effects of the test drug on body system. The aim is to observe the degree of tolerance and pharmacokinetics of the new drug in human

body and to provide the basic and critical information for the formulation of a drug administration. Generally, the study lasts for months and about 70% of test drugs can pass phase I test (**Table 1**).

Clinical phase II

Based on understanding of the phase I clinical study, a phase II clinical trial will then be carried out. Several hundred patients (100-300) will participate in this study. Normally, the patients will be divided into a test group and a placebo group. Investigators will evaluate the efficacy of the test drug on the specific disease. Meanwhile, safety and side effects will continuously be monitored. Some side effects can be observed in some participants, not in others. Sometimes, side effects last for short term or long term. Phase I study may not identify all them. A large group of patients can help to confirm the side effects or to find the occurrence of new side effects. Generally, the study lasts for months or years. Some 30% of test drugs can pass phase II study [14]. The investigators collect more clinical information and evaluation for further phase III study (**Table 1**).

Clinical phase III

On the basis of the phase II clinical trials, the phase III clinical trial of the drug will be further tested with a large group of participants (1000-3000), and an expanded multicenter clinical trial will be conducted to evaluate the efficacy. Drug safety will continuously be monitored due to the patient test in phase II still not enough to identify drug safety. This study is for investigators to compare the test drug to the existing drug. To do this study, randomization strategy will be taken. The participants will be randomly separated into different groups to receive the test drug or existing drug. And a double-blind trial in which neither investigators nor patients will know what to be given is generally adapted. After this trial done, investigators will evaluate whether the test drug works better or worse than the existing drug. This trial is final confirmation of drug efficacy and safety before the drug is approved for marketing. Generally, the study is conducted in multiple clinical centers and lasts for several years. Some 25-30% of test drugs can pass phase III study (**Table 1**) [15].

New drug application and clinical phase IV

Through the clinical trial phase III, the company will collect and analyze all the trial data and decide to file a new drug application. FDA will carefully evaluate all data from phase III study and approve their application if the company can identify that their new drug is safe and more effective than the similar drug on market. Once approved, the new drug can be prescribed by physicians. The company must continue to submit periodic reports to FDA, including all adverse reaction reports and some quality control records. A phase IV study may be required to evaluate the long-term efficacy and side effects of the drug (**Table 1**) [16]. The phase IV clinical trial is participated with thousands of patients and lasts for years, but it is less common than phases I, II and III trials. Once severe side effects are confirmed, drug needs to be withdrawn from market [4]. In order to guarantee good and high quality, the drug used for all clinical trials has to be produced in the manufactory with Good Manufacturing Practice (GMP) standards. Good business management is accordingly very important from the beginning to the marketing.

Whether or not to develop a drug requires expected success possibilities, commercial attractiveness, market competitiveness, and identification of comparative advantages, as well as assessment of success risk, litigation risk, cost risk and other overall considerations. Much of this is precisely the duty of management and related personnel, and not the work of R&D scientists.

Current situation of drug development and development trends of the pharmaceutical industry

Successful R&D of a new drug can take considerable effort. Besides the expensive and time-consuming laboratory research, all three clinical trials (Phase I, II, III) normally take about 15-18 years [17]. Therefore, modern administration and management plays a critical role in drug R&D (**Figure 2**).

High risk of drug R&D

New drug R&D is actually a project, and it must have its own attributes. There are risks involved in doing any research project or investment

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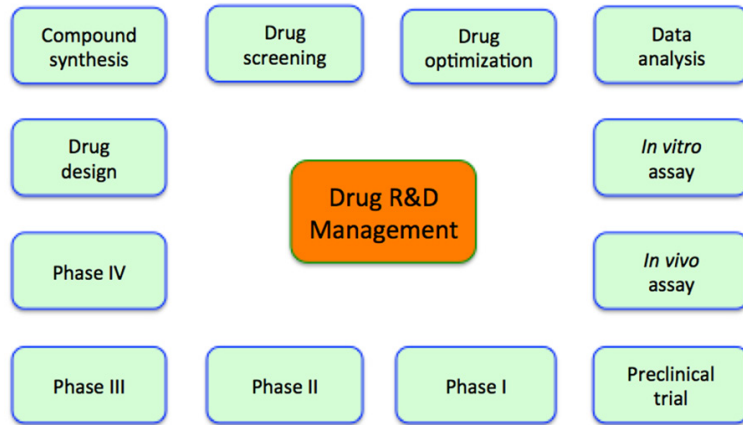


Figure 2. Management is involved in many fields of drug research and development.

project [1]. Without complete assurance, it is necessary to invest a large amount of manpower, material resources in such projects and accordingly bear high stakes. Therefore, the project manager needs to make efforts at the management level to reduce the risks in the project as much as possible [18].

The Asian financial crisis broke out in 1997, and the world financial industry began to experience turbulences. Various fields around the world began to further consider risk prevention and management issues [19]. Both pharmaceutical companies and other operators should know that a single form of risk is often interlinked with others. Risk management is not only the management of a single risk of a single company as which was in the past, but also the integrated management of all risks from the perspective of the whole system. The core idea of overall risk management is: business units at all levels across the organization, all kinds of risk management. The high risk of drug R&D is inevitable, but the risks existing in these projects can be reduced by integrated application of mature management mechanisms in the relevant fields [18, 19].

Strengthening drug safety supervision

Drug safety and side effects have become an issue of great concern to the whole society [4]. The use of antibiotics has been reported to result in the greater drug resistance. Therefore, the supervision of drug safety has been greatly strengthened by the relevant regulatory authorities. Pharmaceutical enterprises must st-

rengthen their internal management systems in order to avoid being defeated by the changes of the times and to get more resources and development. The interpretation of the revised draft of the “Standards for Quality Management of Drug Clinical Trials” [20] implemented in China clearly points out that the mechanism of drug safety management has been further improved. Not only has it strengthened the supervision of clinical research on generic drugs and electronic clinical trial data, but the evaluation and supervision

of third-party organizations becomes stricter. At the same time, more attention is paid to information disclosure and conflict of interest management.

In drug management, the relevant regulatory bodies have strengthened and improved the operational mechanism. This shows that their clients, the regulated pharmaceutical enterprises, need to improve innovation in the way of pharmaceutical production and the gold content of its management, and correspondingly operation mechanism has also become more important [20].

Pre-clinical and clinical trials with the importance of administration

Laboratory management: There are cases when the laws in the course of drug development are not followed, which provide a major safety risk for the drug launching. Laboratory works including drug design, drug screening, drug optimization are necessary for developing and researching a drug, and laboratory management plays an irreplaceable role in drug development (Figure 2) [21]. There are many types of drug R&D institutions in China, mainly in the forms of R&D institutions and universities, research institutes and other drug research institutions. Among them, national research institutions and institutions of higher learning have obvious advantages of capital and policy, and their theoretical research and technical levels are in the leading position in China. However, because of the system and mechanism limitation, good research achieve-

ment cannot be commercialized in time, and a large amount of national capital input have been transformed into academic papers rather than actual drug products [21].

Most of the drug research institutions in China have not established a perfect quality management system. They lack effective and normative control of the research process and the supervision measures are imperfect, so that the research methods are not scientific and the results are not true or reliable. At present, international laboratories rely on a laboratory accreditation method as an independent evaluation of laboratory capacity. The evaluation criteria used are based on the international standard ISO/IEC17025, and the professional and technical assessor evaluates all the factors that affect the data in an organization on the basis of the standard. But until now, only a few of the laboratories in the field of drug research in China have been accredited, and the main laboratory is a pharmacological research laboratory [21].

Therefore, it is suggested to make reference to the international standard ISO/IEC17025 and IS 9000 series quality management system, to formulate the criteria for assessing the ability of the pre-clinical research laboratories in our country, and to evaluate the ability of the laboratories by the third party organizations. We should give some preferential policies in the relevant administrative examination and approval processes, such as speeding up the evaluation process in order to promote the active management of pre-clinical research laboratories (**Figure 2**) and give full play to their main role as the main responsibility [4, 21].

Drug-testing management

Drug testing involves the use of a drug, or a placebo used as a trial or control in a clinical trial. Because of the uncertainty in the safety and efficacy of the test drugs, it is very important to strengthen the management of the test drugs in order to protect the rights and interests of the subjects [4]. Establishing a complete drug management system and strengthening the whole process management of drug research is the basis for ensuring the true and reliable data of clinical trials (**Figure 2**) [22]. At present, the drug management patterns of clinical research are mainly divided into three categories: the

management model of the professional group (which has been rarely used at present), the joint management model of the organization and the professional group, and the management mode of the pharmacy of clinical research center. The traditional drug management adopts the mode of professional custody and institutional supervision. The drug administrators of the professional group are responsible for the receiving, storage, distribution and recovery of drugs. There are many problems in the management mode, such as the lack of timely temperature and humidity records in the professional group, and the lack of special locking cabinets for maintenance and safekeeping of management records and documents. It is easier to control drug storage temperature and humidity, or to control the opportunity that non-test subjects have the research drugs, and it is impossible to completely ensure the safety of the subjects. Therefore, the centralized management of experimental drugs will become the trend of the future [22, 23].

The management of drug use mainly includes receiving confirmation, registration, storage and protection, use, recovery and destruction of drugs and records, and so on. Only by following these steps and practicing strict management according to relevant professional regulations, quality of the test drugs and the efficient use of the drug in clinical trials can be ensured. As a quality management department of clinical trials, the office of clinical trials of drugs should establish a management system which conforms to the actual situation of the agency so as to ensure the scientific, reliability and authenticity of the test results, thus to improve the overall level in the clinical trials of our country [4, 22].

Experimental drug management is tedious and meticulous work. Every link should strictly abide by GCP, relevant systems and test plans. In the course of drug clinical trials, any unstandardized link in drug management may lead to unscientific results for the trials and even endanger the safety of the subjects and the safety of the patients after the drug launching (**Figure 2**). All parties involved in clinical trials, including the applicant, the researcher and the contract research organization (CRO), should attach great importance to the management of experimental drugs to ensure that the manage-

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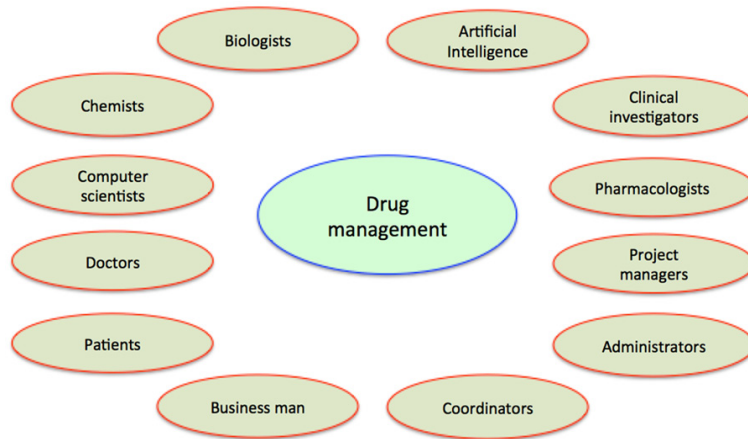


Figure 3. People from different fields are involved in drug administration and management.

ment of each link is standardized to obtain scientific and reliable and experimental data and to protect the safety of the subjects [24].

Clinical trial project management

Drug R&D managements are involved with experts, patients, businessman, administrators, coordinators and other participants from different fields (**Figure 3**). Project management is applicable to one-time tasks with huge investment, complex relationships, limited time and resources. New drug research and development processes also need project management. The research and development of new drugs is a complex and strict process. From laboratory research to new drug launching, it is necessary to undergo a series of procedures, such as synthetic extraction, biological screening, pharmacology, toxicology and other preclinical studies, formulation and stability experiments, bioavailability tests and amplification experiments, and the need for human clinical trials. There are many complicated links such as registration, launching and after-sales supervision. In such complex and huge system engineering, effective project management plays a key role in the success of a project. However, project management has not been systematical and mature in the research and development of new drugs in China, especially in the process of clinical trials involving the safety of human drugs. The project management concern and awareness of the researchers is not strong. Therefore, strengthening the application of project management in the pro-

cess of new drug clinical trials is of great significance [4, 25].

In recent years, project risk management has gotten more and more attention from relevant personnel, especially because of the product particularity of new drug clinical trial projects, which makes the risk factors of the project complicated and changeable. Therefore, in the process of project management, it is necessary to emphasize the awareness of risk management, establish risk assessment and decision response to minimize

or reduce the impact of risk. In addition, as the new drug clinical trials involve a large number of stakeholders, the establishment of an effective performance evaluation system and the strengthening of the human resource management of the project stakeholders are also a basic guarantee for the success of the project management [25].

Project management is widely applied in an attempt to make a project as perfect as possible, and its value is greatly recognized by technicians and managers. The practice has proved that strengthening the application of project management in the process of new drug clinical trials is of great significance for improving the efficiency of R&D and the ability of the new drug research and development of the enterprises [26]. In the system of project management, the formulation of plans, the determination of "milestone events", the control of the process, the termination of the project and the management of the project team are of great guiding significance for the new drug developers. In addition, many project process control chart tools in project management knowledge systems have more direct and practical significance for new drug research and development [25, 26].

Data management

The safety monitoring of experimental data is one of the most important aspects of protecting the rights and safety of participants in clinical trials. Ensuring the accuracy, completeness

and traceability of test data is also the basic work of GCP institutions to comply with CFDA policies and regulations. Those responsible for monitoring involve GCP institution managers, researchers, applicants, quality monitors, auditors, etc (**Figures 2 and 3**). In the course of drug development, strengthening data management can not only improve the quality of drug development, but also integrate data quickly, discover problems and improve the development data of more scientific systems at the stage of drug certification. Therefore, good data management is essential [12, 26]. In recent years, the application of electronic data management systems has become the trend. The application of electronic data capture (EDC) is an important measure to ensure the quality of new drug clinical trials. It can improve the accuracy of data collection, shorten the time of data acquisition and management, enhance the monitoring of the research by the applicant, and improve the R&D efficiency [12, 25, 27] as a whole. Drug research and development program often invests 2-3 electronic data management systems to create greater economic benefits.

FDA requirement for drug production management

When the registration of the new drug's DMF document has been completed with the application of the drug in the United States, an FDA official carries out an onsite GMP conformity inspection of the manufacturer and the whole drug production chain to ensure the quality of the produced drugs [26]. The FDA makes the decision of launching approval of the raw materials in the US market on the basis of on-site inspection. One of the characteristics of GMP in the United States is timeliness and dynamics. The current GMP is emphasized and the whole process of production, quality control and logistics and facilities and equipment must be verified [26, 28]. The GMP procedure is also traceable and explanatory, and its regulations in the United States are generally considered to be the most stringent in the world. In contrast, FDA's requirements for Chinese API manufacturers are very strict and FDA officials are very serious about on-site inspections. Many domestic manufacturers have passed the FDA approval.

The FDA inspection of the production process from the raw material to the finished products

is both comprehensive and important, and the results of the operation conditions, methods and equipment of some key steps in the process are usually paid close attention. FDA considers that the validation of the production process is the basic condition for ensuring the quality of the products. For a new product, a complete verification system should be established from the pilot stage until the scale is enlarged to full industrial scale. A retrospective verification should be made for the production process that has been adopted for many years. The production process verification is generally not permanent, and any change should be recognized. In addition, there are standard operating procedures (SOP) for each process and operation of the production, including the warehousing, inspection and distribution of the raw materials, the quality control and the operation management [26, 29].

The importance of clinical trial phase IV management

Phase IV clinical trial is a process with high technical and managerial requirements. To ensure the objectivity and impartiality of the outcome of this stage, there must be a professional technology and management team [30] qualified with proficiency in post-market drug evaluation. Strengthening the management of drug clinical trial institutions is effective to ensure the standardization of the clinical trial process and scientific and reliable results, to protect the rights and interests of the subjects and to ensure the safety of the drug (**Figure 2**). It is also an important measure to ensure the quality of the clinical study [4, 31]. Drug development is a complex process with a series of processes, such as synthetic extraction, biological screening (refining), pharmacology, toxicology and other preclinical trials, formulation and stability testing, bioavailability testing and amplification testing. Such a systemic project may be the responsibility of an R&D enterprise, project undertaking unit and a number of agencies (also known as the contract research organization, CRO) [26, 32, 33]. Therefore, effective project management plays a key role in the success of a project [32].

Application of big data and artificial intelligence (AI) in drug discovery

Artificial intelligence (AI): In the era of big data, artificial intelligence (AI) has been applied to

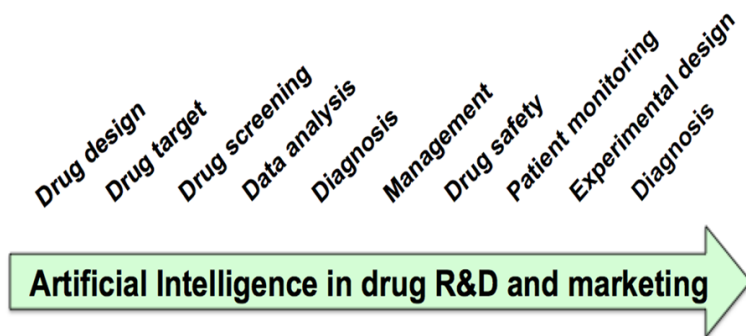


Figure 4. Artificial intelligence (AI) has been widely applied in different fields of drug R&D.

support the new breakthroughs and innovations. AI is a branch of computer-based science, which produces intelligent machines similar to human intelligence and is widely used in the medical field at home and abroad [27, 34]. Big data and AI can perform high intensity computations, designs, and forecast which humans themselves cannot achieve, and can be applied to the discovery of drug candidates which are resistant to unique diseases, and to promote drug R&D (**Figure 4**) [9, 35, 36]. How to better apply AI technology to serve the medical field is also a management concern.

The management of AI in drug R&D

The development of drugs is a difficult process that requires technological innovation, and scientists should actively apply AI technology in the field of medicine [9, 34]. The traditional scientific method is, for example, that scientists first come up with the hypothesis that a particular abnormal protein is the cause of some type of cancer, and then the drug companies test the hypothesis by sifting through hundreds of thousands of compounds that might react with the protein to become potential anticancer drugs [11, 35, 37]. These potential anticancer drugs are also subject to multiple rounds of screening and lengthy three-stage clinical trials. Even in clinical trials, less than 1% of the FDA's approval is available. Generally, the cost of a new drug can averagely be as high as \$1 billion, and it is also time-consuming, only with clinical trials taking over one decade. Many pharmaceutical companies, such as the scientists at Berg in Boston, have tried to design new drugs using artificial intelligence. They collected a large number of biological samples, such as blood, urine, tumors and tissue samples

from patients with cancer, and collected detailed clinical information of the patients, who were then tested for samples of genes, proteins, metabolites and fats. The results of the tests and the clinical manifestations of the patients will be input into an artificial intelligence system which will involve big data nodes to identify diseases and health tissue differences in the molecules [9, 36, 38]. Changing or replacing these molecules is the basis for

new drug development. In this way, Berg will only need 9-12 months to develop a new drug. Clinical phase II new drug BPM31510 combined with gemcitabine in the treatment of pancreatic cancer is a successful example of the outcome of this methodology.

Cooperative management mechanism of pharmaceutical companies

Applying computational chemistry technology, foreign pharmaceutical companies involve in the drug discovery and development process in the aspects of metabolism, cancer and immunology in various areas of disease, and small molecular drugs. The Nimbus Therapeutics Company cooperates deeply with the Schrödinger Company in the field of computer-assisted drug development to develop specific procedures (**Figure 4**) [34]. The joint teams of the two companies design, iterate, optimize and support the rapid iteration and refinement of new methods, so that there is a deep integration between computer technology and drug discovery [11]. Combining with computational chemistry, the latest advances in human genetics and biology are closely related to the selection of drug targets that focuses on unmet clinical needs. At the same time, the company with good cooperation of academia and the industry have created an efficient management system and jointly promoted new drug project progress. In the field of drug development, the company focuses on three overlapped physiological mechanisms: metabolic disorders, tumors and immune disorders, and the links between these three diseases are now being clarified [37, 39]. If the immune system is too active, it can cause a variety of metabolic system diseases such as nonalcoholic steatohepatitis, and type I diabe-

tes. It has become a major medical breakthrough for tumor immunotherapy using the immune system to fight and remove tumor cells in recent years. Tumor cells and normal cells through identifying physiological metabolic pathway differences can also be found in targeted tumor cell drug molecules.

Open data management system

Two elements of AI are technology (algorithms) and data. At present, the greatest challenge faced by the field of medicine industry AI is the insufficiency of data. Most of the international artificial intelligence algorithms are open source software; a new algorithm will soon be converted into a convenient module, so that the AI technology is not a bottleneck, but the data is [11, 39]. In the field of AI research in medicine, the main difficulty is the lack of high quality and clean clinical tagging of key data. To solve this problem, government agencies such as the Food and Drug Administration (FDA), the Institute of Health, large hospitals, and medical technology companies can make effects of collecting a large amount of high-quality data, which will greatly promote the AI in the field of medical applications [34, 36, 37]. For example, the gene screening testing company and sequencing instrument major manufacturer Illumina collect the genetic and clinical characterization data of 20,000 tumors, which are of great help to the application of artificial intelligence in precision tumor treatment.

Summary

As drug R&D moves forward and the development mechanism becomes innovative, drugs trends more diversified and effective. At the same time, the management and administration for drug R&D is becoming more challengeable. Therefore, the research and development of new drugs should be combined with an innovative management system, optimized management structure and integrated innovation of management modes into scientific research to promote the development of the pharmaceutical industry and to avoid the risk of enterprise development. With all these measurements, the economical value of drug R&D and benefits of human health will be enhanced.

Disclosure of conflict of interest

None.

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