2022. Volume 3

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Drugs

The Annual Report on Progress of Clinical Trials for New Drug Registration in China (2021) Released (Excerpt)

I. Purpose and significance

In order to comprehensively master the current situation of clinical trials of new drug registration in China, promptly disclose the information on the progress of clinical trials, and provide reference for the R&D, resource allocation and drug review and approval of new drugs, Center for Drug Evaluation, NMPA (hereinafter referred to as CDE), based on the registration information of new drug clinical trials in the drug clinical trial registration and information publicity platform, comprehensively summarize and analyze the current situation of clinical trials of new drug registration in China in 2021, analyze the characteristics of trends in the past three years, and gradually use informatization means to help improve drug regulatory capacity.

II. Research method

In this annual report, based on the drug clinical trial information registered in 2021, the overall change trend, main characteristics and prominent problems of the clinical trial are summarized and analyzed from the perspectives of drug type, variety and target characteristics, indications, sponsor type, registration classification, trial classification, trial phase, trial in special populations, leading site of clinical trial, initiation time and completion status. Simultaneously, the clinical trial registration data of the past three years are compared, the trend characteristics in recent years are summarized and analyzed, and the *Annual Report on the Progress of Clinical Trials for New Drug Registration in China (2021)* is prepared.

III. Main research results

(I) Number of clinical trials for new drug registration

In 2021, the total number of registered clinical trials in the drug clinical trial registration and information publicity platform exceeded 3,000 for the first time, an increase of 29.1% compared with the total number of registered clinical trials in 2020. Among them, the number of clinical trials for new drugs (exploratory and confirmatory clinical trials registered with acceptance number) was 2033, an increase of 38.0% compared with the registration volume in 2020.

According to the statistics by drug type of traditional Chinese medicines, chemical drugs and biological products, in 2021, the drug clinical trials in China were still dominated by chemical drugs, accounting for 70.8%; followed by biological products, 26.7%; and traditional Chinese medicines were the least, 2.4%. Compared with the data in the past three years, the proportion of clinical trials of various drugs was similar, but the proportion of biological products showed an increasing trend year by year, and the proportion of chemical drugs and traditional Chinese medicines showed a decreasing trend year by year.

(II) Drug type and target characteristics

According to the classification of chemical drugs, biological products and traditional Chinese medicines, from the data analysis in the past three years, the clinical trials for new drugs of chemical drugs and biological products accounted for a relatively high proportion, with an average annual proportion of 54.6% and 40.4% respectively. In the past three years,

药品

《中国新药注册临床试验进展年度报告（2021年）》发布（节选）

一、目的及意义

为全面掌握中国新药注册临床试验现状，及时对外公开临床试验进展信息，为新药研发、资源配置和药品审评审批提供参考，国家药监局药审中心（以下简称药审中心）根据药物临床试验登记与信息公示平台的新药临床试验登记信息，对2021年中国新药注册临床试验现状进行全面汇总和分析，同时对近三年的变化趋势特点进行分析，逐步运用信息化手段助力提升药品监管能力。

二、研究方法

本次年度报告根据2021年度登记的药物临床试验信息，从药物类型、品种及靶点特征、适应症、申办者类型、注册分类、试验分类、试验分期、特殊人群试验、临床试验组长单位、启动耗时和完成情况等角度对临床试验的总体变化趋势、主要特点、突出问题等进行汇总分析。同时对比近三年临床试验登记数据，对近年来的趋势特征进行总结分析，编制了《中国新药注册临床试验进展年度报告（2021年）》。

三、主要研究结果

（一） 新药注册临床试验数量

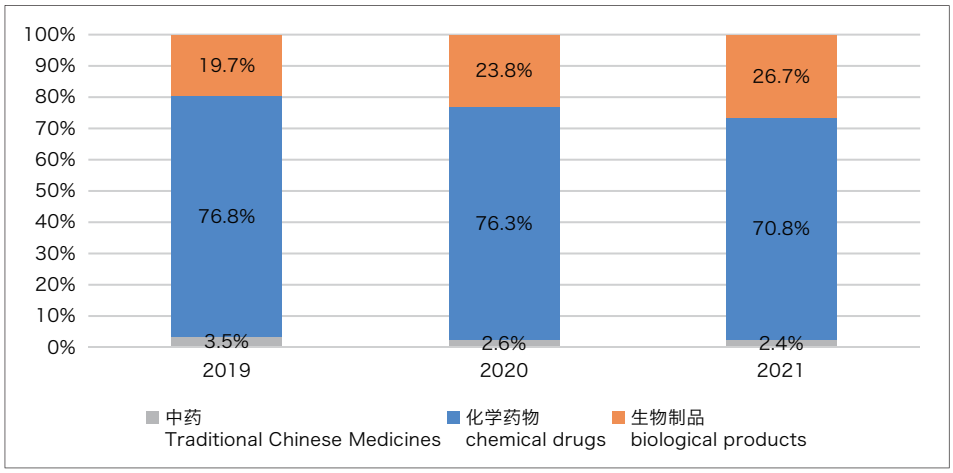
2021年，药物临床试验登记与信息公示平台登记临床试验总量首次突破3000余项，较2020年年度登记总量增加29.1%。其中新药临床试验（以受理号登记的探索性和确证性临床试验）数量为2033项，较2020年登记量增加38.0%。

按药物类型中药、化学药和生物制品统计，2021年中国药物临床试验仍以化学药为主，占比为70.8%；其次为生物制品，为26.7%；中药最少，仅为2.4%。对比近三年数据，各类药物临床试验数量占比类似，但生物制品占比呈逐年递增趋势，化学药和中药占比呈逐年递减趋势。

（二） 药物类型与靶点特征

Published by
China Center for Food and Drug International Exchange

图1 各药物类型总体占比变化（2019-2021）
Figure 1 Overall change in the proportion of each drug type (2019-2021)



the targets of the drugs were relatively concentrated, of which PD-1 and PD-L1 were particularly prominent, and the indications were also mainly concentrated in the anti-tumor field. Analyzed by trial phase, the proportion of phase III clinical trials of PD-1 and PD-L1 targets is also higher than that of other targets.

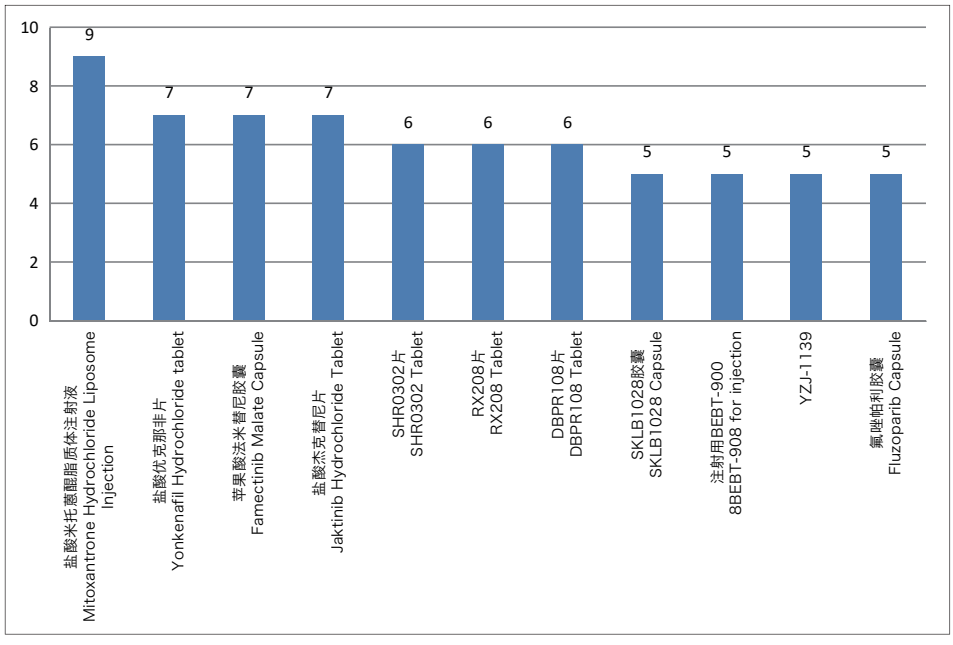
1. Varieties for new drug clinical trials

The number of varieties involved in 2033 new drug clinical trials in 2021 (by drug name in clinical trial license document) was statistically analyzed according to different drug types, and the data in the past three years were analyzed.

Traditional Chinese medicine: In 2021, only one clinical trial was carried out for about 90% of traditional Chinese medicine varieties, and the varieties carrying out two clinical trials included Qishen Yiqi Dropping Pills, Suzi Afu Tablets, Baofukang Suppositories and Artificial Bear Bile Powder. For Suzi Afu Tablets, one trial was suspended and the clinical trial was conducted again after the protocol was updated. The overall data trend was basically the same in the past three years, and only one trial was carried out in the same year for nearly 90% of the varieties.

Chemical drugs: A total of 68 trials were registered for the top 10 varieties of chemical drug clinical trials in 2021, with the most trials conducted for mitoxantrone hydrochloride liposome injection (9 trials). Compared with 2020, the similarity is that the top 10 varieties all contain the anti-

图2 2021年化学药临床试验数量前10位品种
Figure 2 Top 10 varieties in chemical drug clinical trials in 2021



按化学药、生物制品和中药分类，从近三年数据分析，化学药和生物制品的新药临床试验占比较高，年均分别为54.6%和40.4%。药物作用靶点在近三年中均相对集中，其中PD-1和PD-L1尤为突出，适应症也主要集中在抗肿瘤领域。从试验分期分析，PD-1和PD-L1靶点III期临床试验的比例亦高于其他靶点。

1. 新药临床试验品种

按照不同药物类型分别对2021年度2033项新药临床试验所涉及的品种（按临床试验许可文件药品名称）数量进行统计，并对近三年数据进行分析。

中药：2021年约90%的中药品种仅开展1项临床试验，开展2项临床试验的品种包括芪参益气滴丸、苏孜阿甫片、保妇康栓和人工熊胆粉，其中苏孜阿甫片涉及暂停试验1项，更新方案后重新开展临床试验。近三年数据总体趋势基本一致，接近九成品种同年仅开展了1项试验。

化学药：2021年化学药临床试验数量前10位品种共登记68项试验，以盐酸米托蒽醌脂质体注射液开展试验数量最多，为9项。与2020年相比，相同点是前10位品种中均包含抗肿瘤药物盐酸米托蒽醌脂质体注射液、苹果酸法米替尼胶囊、盐酸杰克替尼片和氟唑帕利胶囊，不同点是，前10位品种中包含4个非抗肿瘤药物，分别为盐酸优克那非片、SHR0302片、DBPR108片和YZJ-1139。从近三年数据分析，各年前10位品种中均有50%以上品种为抗肿瘤药物，其中氟唑帕利胶囊均为近三年前10位品种之一。

生物制品：2021年生物制品开展临床试验数量前10位品种共登记104项试验，仍以治疗用生物制品为主，共涉及10个品种75项试验（72.1%）；预防用生物制品涉及2个品种29项试验（27.9%），均为新型冠状病毒疫苗。从单一品种临床试验数量分析，新型冠状病毒灭活疫苗（Vero细胞）开展临床试验数量最多，为20项，其次分别为替雷利珠单抗注射液和阿替利珠单抗注射液，均为10项，二者同为2020年度前10位品种。对比近三年数据，前10位品种均以治疗用生物制品为主，其中2019年占比最高，为88.7%（94vs.106）。帕博利珠单抗注射液均为近三年前10位品种之一。

2、新药临床试验品种的作用靶点

按药物品种统计，2021年登记临床试验的前10位靶点分别为PD-1、PD-L1、VEGFR、HER2等，品种数量分别多达71个、59个、46个、43个（以“受理号”字段不重复计数），其中5个靶点（PD-1、PD-

tumor drugs mitoxantrone hydrochloride liposome injection, famectinib malate capsule, jaktinib hydrochloride tablet and fluzoparib capsule, and the difference is that the top 10 varieties contain 4 non-antitumor drugs, yonkenafil hydrochloride tablet, SHR0302 tablet, DBPR108 tablet and YZJ-1139 respectively. According to the data analysis in the past three years, each year more than 50% of the top 10 varieties were anti-tumor drugs, of which fluzoparib capsule was one of the top 10 varieties in the past three years.

Biological products: In 2021, a total of 104 trials were registered for the top 10 varieties in the number of clinical trials carried out for biological products, mainly therapeutic biological products, involving a total of 75 trials of 10 varieties (72.1%); prophylactic biological products involved 29 trials of 2 varieties (27.9%), all of which were COVID-19 vaccines. From the analysis of the number of clinical trials of a single variety, the number of clinical trials carried out for the inactivated COVID-19 vaccine (Vero cells) was the highest, 20, followed by tislelizumab injection and atezolizumab injection, 10 for both, and both of them were among the top 10 varieties in 2020. Compared with the data in the past three years, the top 10 varieties were mainly therapeutic biological products, with the highest proportion of 88.7% in 2019 (94vs.106). Pembrolizumab injection was one of the top 10 varieties in the past three years.

2. Targets of varieties in new drug clinical trials

According to the statistics by drug varieties, the top 10 targets of clinical trials registered in 2021 are PD-1, PD-L1, VEGFR, HER2, etc., and the number of varieties are as many as 71, 59, 46 and 43, respectively (not repeatedly counted by "acceptance number" field), of which more than 90% of the drug indications of 5 targets (PD-1, PD-L1, HER2, EGFR and CD3) are concentrated in the anti-tumor field, and all the drug indications of 4 targets (PD-1, PD-L1, HER2 and EGFR) are concentrated in the anti-tumor field.

According to the statistics by the number of clinical trials, the top 10 targets with the highest number of clinical trials in 2021 are PD-1, PD-L1, HER2, EGFR, etc., as many as 84, 68, 57 and 53 respectively; among them, there are 36 and 21 Phase III clinical trials for PD-1 and PD-L1 targets respectively. In addition, in the drug clinical trials of 4 targets (VEGFR, GLP-1/GLP-1R, JAK1 and CD3), phase I clinical trials account for more than 40%, and phase II clinical trials account for 8% ~ 37% of each target.

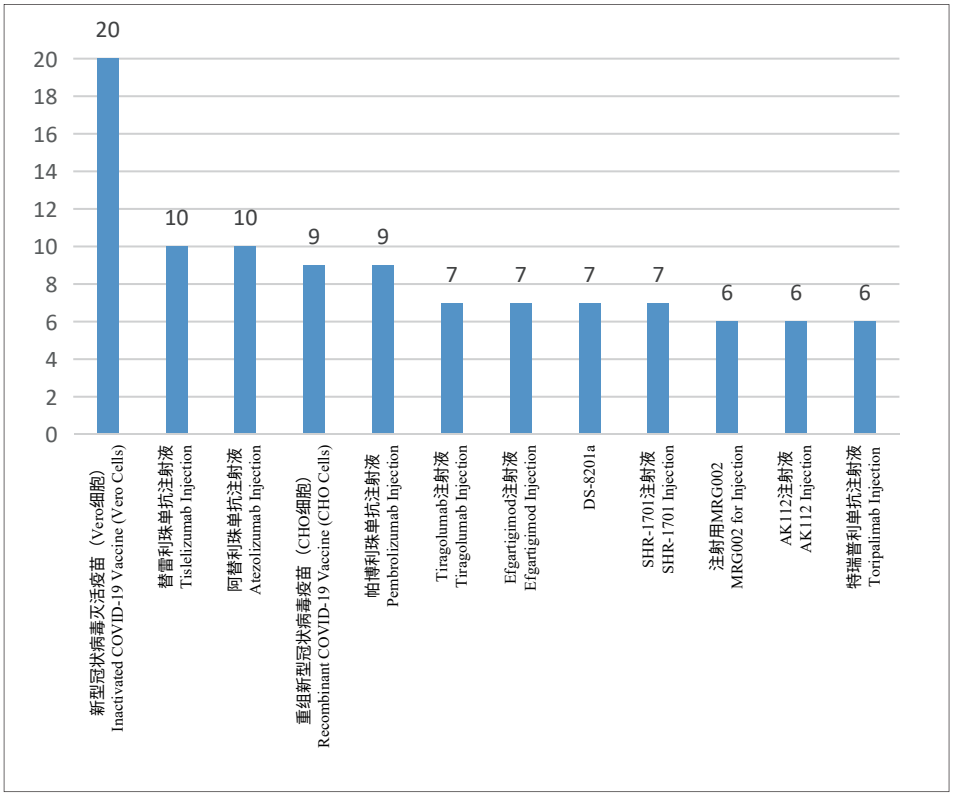
Compared with the data analysis in the past three years, no matter according to the number of drug varieties or clinical trial registrations, the drug targets are still relatively concentrated, of which PD-1 and PD-L1 were particularly prominent, and the indications were also mainly concentrated in the anti-tumor field. Analyzed by trial staging, the proportion of phase III clinical trials of PD-1 and PD-L1 targets is also higher than that of other targets; the trials for other targets are still mainly phase I clinical trials.

3. Varieties in BE trials

According to the information of the top 10 varieties in BE trials (including the registration with acceptance number) in 2021, the number of clinical trials

图3 2021年生物制品临床试验数量前10位品种

Figure 3 Top 10 varieties in the biological product clinical trials in 2021



L1、HER2、EGFR和CD3）的药物适应症超过90%集中在抗肿瘤领域，4个靶点（PD-1、PD-L1、HER2和EGFR）的药物适应症全部集中在抗肿瘤领域。

按临床试验数量统计，2021年临床试验数量最多的前10位靶点分别为PD-1、PD-L1、HER2、EGFR等，分别多达84项、68项、57项和53项；其中PD-1和PD-L1靶点III期临床试验分别高达36项和21项。另外，4个靶点（VEGFR、GLP-1/GLP-1R、JAK1和CD3）的药物临床试验中Ⅰ期临床试验占比均超过40%，Ⅱ期临床试验在各靶点中的占比在8%~37%之间。

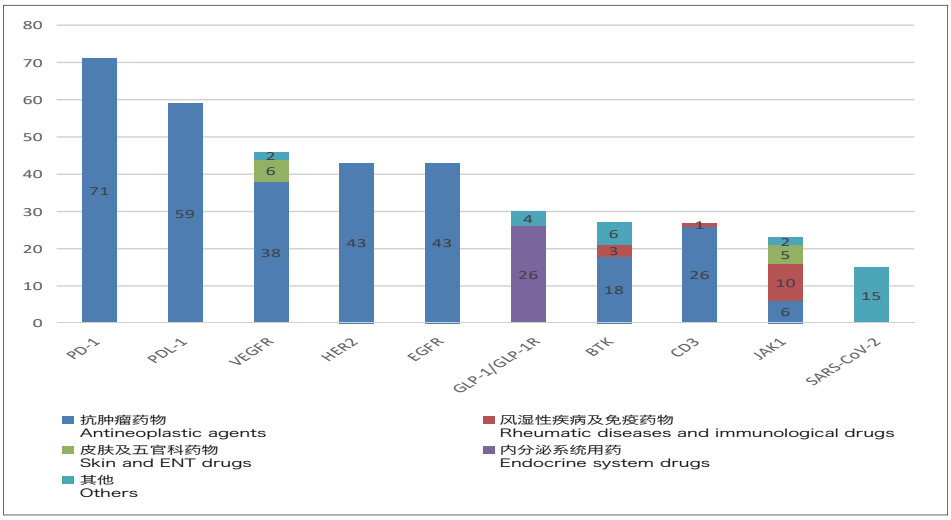
对比近三年数据分析，无论是按药物品种还是临床试验登记数量统计，药物作用靶点仍相对集中，其中PD-1和PD-L1尤为突出，适应症也主要集中在抗肿瘤领域。从试验分期分析，PD-1和PD-L1靶点III期临床试验的比例亦高于其他靶点；其他靶点仍主要以Ⅰ期临床试验为主。

3、生物等效性试验品种

2021年度BE试验（含受理号登记）数量前10位品种信息，其中磷酸奥司他韦干混悬剂登记试验数量最多，为18项，具体如图6。

与2020年数据对比，前10位品种中相同品种有4个，分别为磷酸奥司他韦胶囊、利伐沙班片、他达拉非片和富马酸丙酚替诺福

图4 2021年前10位靶点品种数量及适应症分布
Figure 4 Number of varieties and indication distribution of top 10 targets in 2021



registered of oseltamivir phosphate dry suspension is the largest (18 trials). See Figure 6 for details.

Compared with the data in 2020, there are four of the same varieties in the top 10 varieties, namely oseltamivir phosphate capsules, rivaroxaban tablets, tadalafil tablets and propofol tenofovir fumarate tablets. From the analysis of the data in the last three years, rivaroxaban tablets were among the top 3 varieties over the years.

(III) Trial classification and sponsor

According to the classification of drug clinical trials by new drug clinical trials and bioequivalence trials (BE trials), new drug clinical trials accounted for 60.5% and BE trials accounted for 39.5% in 2021. According to the data in the past three years, the proportion of new drug clinical trials showed an increasing trend year by year, while the proportion of BE trials showed a decreasing trend year by year, from 47.3% in 2019 to 39.5% in 2021. Domestic sponsors still accounted for the majority, for about 80% in the past three years.

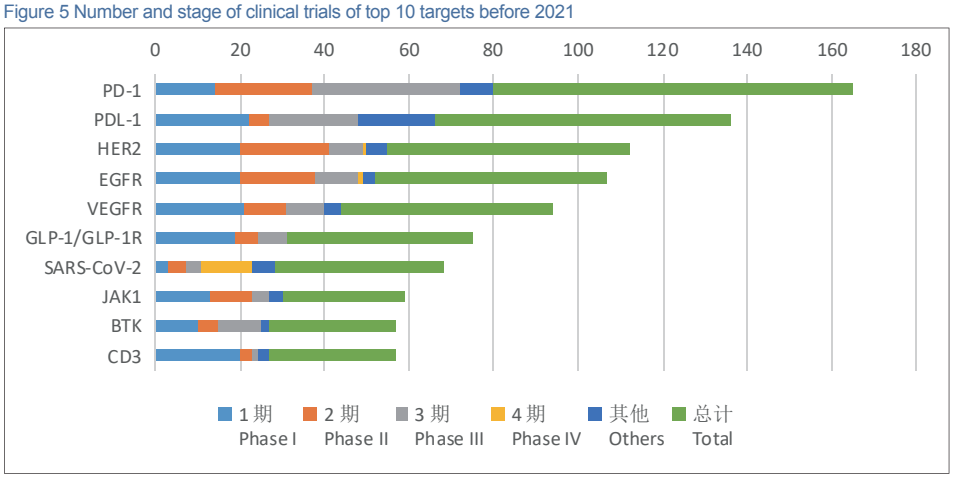
(IV) Target indications and clinical trial phase

The target indications for clinical trials of chemical and biological products mainly focus on the fields of anti-tumor and prophylactic vaccines. Due to the influence of COVID-19, the number of clinical trials of inactivated COVID-19 vaccines ranked first in prophylactic vaccine trials in 2021 (20 trials). In the past three years, traditional Chinese medicine mainly focused on four indications: respiratory, digestive, cardiovascular and psychoneurotic diseases.

The proportion trend of clinical trial stages remained consistent in the past three years, with phase I clinical trials accounting for the highest proportion, and the overall phase I clinical trials account for 42.9% in 2021; clinical trials conducted in specific populations in the past three years were relatively few, and the clinical trials only conducted in the elderly and pediatric populations did not exceed 0.2% and 3% of the overall proportion of trials over the years, respectively. Drugs for rare diseases mainly focus on the treatment of nervous system diseases and hematological diseases, and the number of clinical trials and indication fields are increasing year by year.

(V) Analysis of geographical distribution of clinical trials

图5 2021年前10位靶点临床试验数量及试验分期
Figure 5 Number and stage of clinical trials of top 10 targets before 2021



韦片。从近三年数据分析，利伐沙班片均为历年前3位品种之一。

（三）试验分类与申办者

将药物临床试验按新药临床试验和生物等效性试验（BE试验）分类，2021年新药临床试验占比60.5%，BE试验占比39.5%。从近三年数据分析，新药临床试验占比呈逐年增长趋势，而BE试验占比呈逐年下降趋势，从2019年的47.3%下降至2021年的39.5%。境内申办者仍占主体，近三年占比均约为80%左右。

（四）目标适应症与临床试验分期

化学药和生物制品临床试验的目标适应症主要集中在抗肿瘤和预防性疫苗等领域。受新冠疫情因素影响，2021年新型冠状病毒灭活疫苗临床试验数量位居预防性疫苗类试验首位（20项）。中药近三年均集中在呼吸、消化、心血管和精神神经4个适应症。

近三年临床试验分期占比趋势保持一致，均为Ⅰ期临床试验占比最高，2021年总体Ⅰ期临床试验占比为42.9%；近三年在特定人群中开展的临床试验均相对较少，仅在老年人群和儿童人群中开展的临床试验，分别不超过历年试验总体比例的0.2%和3%。罕见疾病药物主要以治疗神经系统疾病和血液系统疾病为主，临床试验数量和适应症领域均呈现逐年增加趋势。

（五）临床试验地域分布分析

临床试验组长单位和参加单位仍以北京市、上海市、江苏省、广东省等为主。

（六）临床试验实施效率分析

对首次登记的新药临床试验进行分析，结果显示，2021年超半数试验（51.4%）可在6个月内启动受试者招募，且化学药和生物制品的比例明显超过中药，分别为51.2%和58.1%，而中药近九成（89.1%）临床试验启动受试者招募超过1年。结合临床试验机构所在地分析，提示临床试验组长单位较多

The leading site and participating site of clinical trials are still mainly in Beijing, Shanghai, Jiangsu and Guangdong.

(VI) Analysis of the implementation efficiency of clinical trials

Analysis of the new drug clinical trials registered for the first time show that more than half of the trials (51.4%) in 2021 may initiate subject recruitment within 6 months, and the proportion of chemical drugs and biological products significantly exceeded that of traditional Chinese medicines (51.2% and 58.1%, respectively), while nearly nine-tenths (89.1%) of the clinical trials of traditional Chinese medicines initiated subject recruitment for more than 1 year. Combined with the analysis of the location of clinical trial institutions, it is suggested that the initiation of clinical trials in provinces, autonomous regions and municipalities with more leading sites of clinical trials takes more time; while the initiation of clinical trials in provinces, autonomous regions and municipalities with fewer leading sites of clinical trials takes less time.

Analysis of subject recruitment after the initiation of clinical trials in the past three years show that the average initiation time decreased from 6.4 months to 3.8 months from 2019 to 2021, and the proportion of clinical trials initiated within 6 months increased year by year, reaching 85.7% in 2021.

IV. Conclusion

In 2021, the annual total number of registrations on the drug clinical trial registration and information publicity platform exceeded 3,000 for the first time, totaling 3,358. The proportion of new drug clinical trials has been increasing year by year, with phase I clinical trials accounting for the highest proportion over the years, and the trials are mainly domestic trials initiated by domestic sponsors. The proportion of BE trials showed a gradual decrease in the past three years.

In the past three years, the clinical trials of chemical drugs and biological products are still mainly for oncology indications, and the drug targets are relatively concentrated, especially PD-1 and PD-L1, and the number of phase III clinical trials is relatively high. Due to the influence of COVID-19, the number of clinical trials of inactivated COVID-19 vaccines was the largest among biological products of prophylactic vaccines in 2021. The number of clinical trials of traditional Chinese medicine has been the lowest over the years, mainly focusing on four indications: respiratory, digestive, cardiovascular and psychoneurotic diseases.

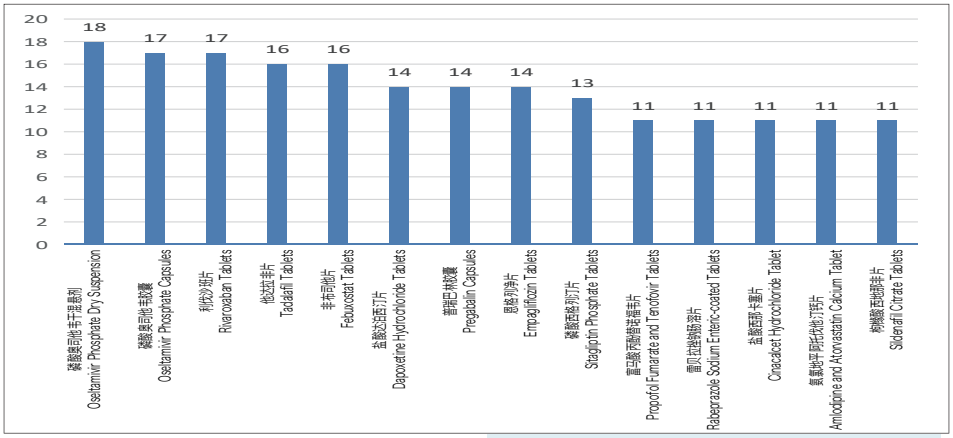
The proportion of clinical trials conducted in the elderly population and pediatric population (except prophylactic vaccines) is still low, and the types of diseases involved in drug clinical trials for rare diseases are still low. According to the 2021 registration information, the proportion of subject recruitment initiated within 6 months is significantly increased (51.4%).

In conclusion, the number of new drug clinical trials in China is increasing, and most of them are new drug clinical trials initiated and implemented by domestic sponsors. With the increasing number of phase III new drug clinical trials, it is expected that the number of new drug applications for marketing in China will increase and the process will accelerate to meet the demands for new drug for Chinese patients, including the demand for clinical medication for pediatric population and rare diseases.

(June 7, 2022)

图6 2021年BE试验数量前10位品种

Figure 6 Top 10 varieties in BE trials in 2021



的省、区、市,其临床试验的启动耗时较长；而临床试验组长单位较少的省、区、市，其临床试验的启动耗时较短。

对近三年当年临床试验获批后启动受试者招募情况进行分析，2019年至2021年平均启动耗时由6.4个月下降至3.8个月，6个月内启动招募的临床试验比例逐年提高，2021年达85.7%。

四、结论

2021年药物临床试验登记与信息公示平台年度登记总量首次突破3000项，共计3358项。新药临床试验数量占比逐年增加，历年均以Ⅰ期临床试验占比最高，且均以境内申办者发起的国内试验为主。BE试验数量占比近三年呈逐步下降趋势。

近三年化学药和生物制品临床试验仍主要针对肿瘤适应症，药物作用靶点相对集中，PD-1和PD-L1尤为突出，其开展III期临床试验的数量亦相对较多。受新冠疫情因素影响，2021年预防性疫苗类生物制品以新型冠状病毒灭活疫苗临床试验数量最多。中药临床试验数量历年均最少，主要集中在呼吸、消化、心血管和精神神经4个适应症。

在老年人群和儿童人群（预防性疫苗除外）中开展的临床试验占比仍较低,罕见疾病药物临床试验涉及的疾病种类仍较少。2021年登记信息中，6个月内启动受试者招募比例明显提高（51.4%）。

综上，中国新药临床试验数量不断增加，且多为由境内申办者启动实施的新药临床试验。随着新药III期临床试验数量不断增加，预期中国新药上市申请数量会增加，进程会加快，满足中国患者的新药治疗需求，包括儿科人群和罕见病的临床用药需求。

（2022-06-07）

Announcement of the Center for Drug Evaluation of NMPA on Issuing Technical Guidelines for Pharmaceutical Study and Evaluation of Biosimilars of Insulin Products

In order to standardize and guide the R&D, manufacturing and registration of biosimilars of insulin products and further clarify the technical evaluation criteria, the Center for Drug Evaluation organized to formulate the Technical Guidelines for Pharmaceutical Study and Evaluation of Biosimilars of Insulin Products under the deployment of NMPA, which is issued and shall come into force on March 10, 2022.

(April 1, 2022)

国家药监局药审中心关于发布《胰岛素类产品生物类似药药学研究与评价技术指导原则》的通告

为规范和指导胰岛素类产品生物类似药的研发、生产和注册，进一步明确技术评价标准，在国家药品监督管理局的部署下，药审中心组织制定了《胰岛素类产品生物类似药药学研究与评价技术指导原则》，于2022年3月10日起发布并施行。

（2022-04-01）

NMPA Notice on Printing and Issuing the Provisions on the Administration of Annual Reports of Drugs

In order to implement relevant requirements in the *Drug Administration Law*, the *Provisions for Drug Registration* and the *Provisions for the Supervision of Drug Manufacturing* and further guide the marketing authorization holders (hereinafter referred to as the MAHs) to establish the annual report system, NMPA organized to formulate the *Provisions for the Administration of Annual Report of Drugs* and the *Template for Annual Report of Drugs*, which were issued on April 11, 2022. At the same time, in order to ensure the implementation of the annual report system for drugs, NMPA has built a drug annual report collection module, which has been launched in the same period. Relevant matters are notified as follows:

I. To urge MAHs to fulfill their principal responsibilities for drug annual reports

The annual report system of drugs is a new system proposed in the *Drug Administration Law*. It is clearly specified in the *Drug Administration Law* that MAHs shall establish the annual report system to report the drug manufacturing and sales, post-marketing study, risk management and other information to the drug regulatory departments of the people's governments of provinces, autonomous regions and municipalities directly under the central government in accordance with the provisions each year. The principal for filling and submitting the annual report is the MAH; Where the MAH is an overseas enterprise, the enterprise legal person designated by the MAH according to law who assumes joint liabilities within the territory of China shall perform the obligation of annual report.

All provincial drug regulatory departments shall strengthen policy publicity, supervision and guidance, and further urge MAHs to implement the principal responsibilities for whole-process quality management by regulating the annual report of MAHs. MAHs shall take the annual report as a grasp, enhance the sense of principal responsibilities, give play to subjective initiative, and further improve its own management level. MAHs shall designate a special person to be responsible for the annual report, improve the internal report

国家药监局关于印发《药品年度报告管理规定》的通知

为贯彻落实《药品管理法》及《药品注册管理办法》《药品生产监督管理办法》有关要求，进一步指导药品上市许可持有人（以下简称持有人）建立年度报告制度，国家药监局组织制定了《药品年度报告管理规定》和《药品年度报告模板》，于2022年4月11日印发。同时，为保障药品年度报告制度的落地实施，国家药监局建设了药品年度报告采集模块，同期启用。有关事项通知如下：

一、督促持有人落实药品年度报告的主体责任

药品年度报告制度是《药品管理法》提出的一项新制度。《药品管理法》明确规定，药品上市许可持有人应当建立年度报告制度，每年将药品生产销售、上市后研究、风险管理等情况按照规定向省、自治区、直辖市人民政府药品监督管理部门报告。年度报告填报主体为持有人；持有人为境外企业的，由其依法指定的、在中国境内承担连带责任的企业法人履行年度报告义务。

各省级药品监管部门要加强政策宣传和监督指导，通过规范持有人的年度报告行为，进一步督促持有人落实全过程质量管理主体责任。持有人应当以年度报告为抓手，增强主体责任意识，发挥主观能动性，进

management system, strictly review and check the content of annual reports, and ensure that the information filled and submitted is true, accurate, complete and traceable.

II. To earnestly do a good job in data sharing and information application

NMPA has built an annual report collection module for drugs. In order to facilitate the MAHs to fill in and submit, this module directly connects with the drug registration, drug manufacturing license and other relevant information of the drug regulatory data sharing platform, realizes the automatic prompt of key basic information, and helps to improve the accuracy of information filled and submitted. Subsequently, it will give full play to the advantages of national drug regulatory data sharing platform, gradually collect the information of annual reports into drug variety archives and drug safety credit archives, respectively, and consolidate the information basis for smart regulation.

All provincial drug regulatory department shall take the annual report information as the reference material and deliberation basis for supervision and inspection, risk assessment, credit supervision and other work, gradually realize precise supervision and scientific supervision and improve the regulatory efficiency of the whole life cycle of drugs. At the same time, combined with supervision and inspection arrangements, the contents of MAHs' annual reports will be reviewed. MAHs who fail to make annual reports according to regulations will be investigated and handled in accordance with the law, and will be included in drug safety credit archives.

III. To make every effort to ensure the operation and maintenance of the annual report collection module

The annual report collection module for drugs is divided into enterprise end and regulator end. The information collected at the enterprise end includes two aspects: public part and product part. Among them, the public part includes six aspects: MAH information, the overall situation of the products held, quality management overview, the construction and operation of pharmacovigilance system, the acceptance of overseas entrusted processing, and the acceptance of inspection by overseas drug regulatory authorities; the product part includes four aspects: basic information of the product, manufacture and sales, post-marketing study and change management, and risk management. After the MAHs complete the filling and submission of the annual report of drugs, the provincial drug regulatory departments may view the annual report information of MAHs within their respective administrative regions through the regulator end.

The Information Center of NMPA shall carry out the technical support after the module is launched. For the permission authorization and operation process of the enterprise end and regulator end, refer to the operation manual. The latest electronic operation manual can be downloaded from the system.

IV. Other matters

1. These Provisions shall come into force on the date of issuance, and the annual report collection module for drugs shall be enabled at the same time.

2. Since the drug annual report system is implemented for the first time in China, the drug annual report collection module is still in the trial operation stage, and the deadline for filling in and submitting the 2021 annual report is as of August 31, 2022; from next year, the information of the annual report for the previous year shall be filled in and submitted before April 30 each year.

(April 12, 2022)

一步提升自身管理水平。持有人应当指定专人负责年度报告工作，完善内部报告管理制度，对年度报告的内容严格审核把关，确保填报信息真实、准确、完整和可追溯。

二、切实做好数据共享和信息应用

国家药监局已经建设了药品年度报告采集模块。为方便持有人填报，该模块直接对接药品监管数据共享平台的药品注册、药品生产许可等有关信息，实现了关键基础信息自动带出，有助于提高填报信息的准确性。后续，还将充分发挥国家药品监管数据共享平台优势，逐步将年度报告信息分别归集纳入药品品种档案、药品安全信用档案，夯实药品智慧监管的信息基础。

各省级药品监管部门要将年度报告信息作为监督检查、风险评估、信用监管等工作的参考材料和研判依据，逐步实现精准监管、科学监管，提升药品全生命周期监管效能。同时，结合监督检查等工作安排，对持有人年度报告内容进行审核，对不按规定进行年度报告的持有人依法查处，并纳入药品安全信用档案。

三、全力做好年度报告采集模块的运行维护

药品年度报告采集模块分为企业端和监管端。企业端采集信息包括公共部分和产品部分两方面内容。其中，公共部分包括持有人信息、持有产品总体情况、质量管理概述、药物警戒体系建设及运行情况、接受境外委托加工情况、接受境外药品监管机构检查情况等六个方面内容；产品部分包括产品基础信息、生产销售情况、上市后研究及变更管理情况、风险管理情况等四个方面内容。持有人完成药品年度报告的填报并提交后，省级药品监管部门可以通过监管端查看本行政区域内持有人的药品年度报告信息。

国家药监局信息中心要做好模块上线后的技术支持工作。企业端和监管端的权限开通及操作流程可参考操作手册。最新电子版操作手册可从系统中下载。

四、其他事项

1.本规定自发布之日起施行，药品年度报告采集模块同时启用。

2.鉴于我国首次实施药品年度报告制度，药品年度报告采集模块尚处于试运行阶段，2021年度报告信息填报时间截止为2022年8月31日；从明年开始，每年4月30日之前填报上一年度报告信息。 （2022-04-12）

Announcement of Center for Drug Evaluation of NMPA on Issuing Guidelines for Summary of Adverse Reaction Data in the Package Inserts of Anti-tumor Drugs ([2022] No. 23)

With the progress in the research and development of anti-tumor drugs, more and more studies have shown that a drug can be applied to different tumors, different stages or populations of the same tumor, and can also be combined with drugs with different mechanisms of action. The package insert is the most important carrier of drug safety information and an important statutory document to guide the safe and rational use of drugs. Since a large amount of safety data can be accumulated for one drug for both monotherapy and combination therapy, it has become an urgent issue for regulatory authorities and industry to address how to scientifically, comprehensively, clearly, simply and easily present drug safety characteristics under different usage scenarios in the package insert in order to ensure patient safety. Under the deployment of NMPA, CDE organized experts to formulate the *Guidelines for Summary of Adverse Reaction Data in the Package Inserts of Anti-tumor Drugs*, which is issued and shall issued and shall come into force on Tuesday, April 19, 2022.

(April 21, 2022)

国家药监局药审中心关于发布《抗肿瘤药物说明书不良反应数据汇总指导原则》的通告（2022年第23号）

随着抗肿瘤药物研发的进展，越来越多的研究表明，一种药物可以应用于不同瘤种、同一瘤种的不同阶段或人群，还可以与不同作用机制的药物联合。药品说明书是药品安全性信息最主要的载体，是指导安全、合理使用药品的重要法定文件。在一种药物单药以及联合用药积累了大量的安全性数据的情况下，面对不同的使用者，如何科学、全面、清晰、简洁、易读的在说明书中呈现药物在不同使用场景下的安全性特征，切实保障患者用药安全，是目前监管方及业界亟需解决的问题。在国家药品监督管理局的部署下，药审中心组织制定了《抗肿瘤药物说明书不良反应数据汇总指导原则》，于2022年4月19日起发布并施行。

（2022-04-21）

Medical devices

NMPA Announcement on Approving the Registration of 181 Medical Devices (March 2022) ([2022] No. 33)

In March 2022, NMPA approved a total of 181 medical devices for registration. Among them, there were 138 domestic Class III medical devices, 23 imported Class III medical devices, 18 imported Class II medical devices and 2 medical devices from Hong Kong, Macao and Taiwan. (April 8, 2022)

医疗器械

国家药监局关于批准注册181个医疗器械产品公告(2022年3月)(2022年第33号)

2022年3月，国家药品监督管理局共批准注册医疗器械产品181个。其中，境内第三类医疗器械产品138个，进口第三类医疗器械产品23个，进口第二类医疗器械产品18个，港澳台医疗器械产品2个。

（2022-04-08）

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.

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备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。如有出入，以中文为准。

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