White Paper

More Chinese biotech startups are testing their new drugs but slowly, CDE report reveals.

By Chang Jianqing
Vice President of Drug Regulatory Policy

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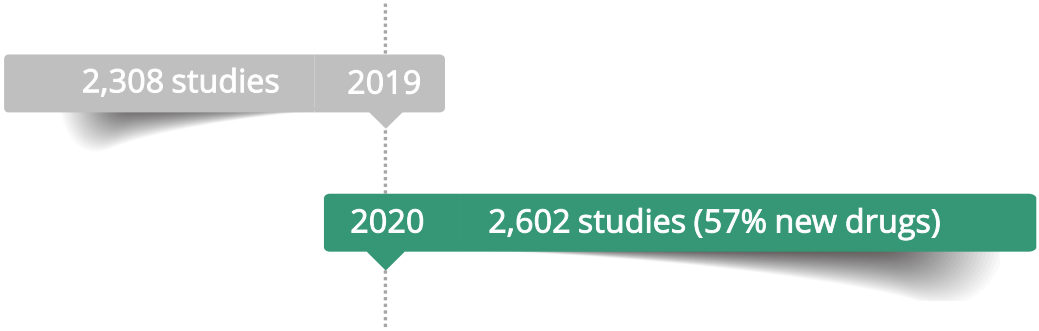
Chinese regulators are seeing more clinical studies of new drugs initiated by domestic startups, but they are concerned about slow clinical progress and inadequate care for young and old patients, a recent report revealed.

China's CDE said a total of 2,602 clinical trials were registered in China in 2020, up by 9.1% from 2,308 studies in 2019, including 57% contributed by new drugs. 1142 Chinese biotech startups made up over 70% of trial sponsors.

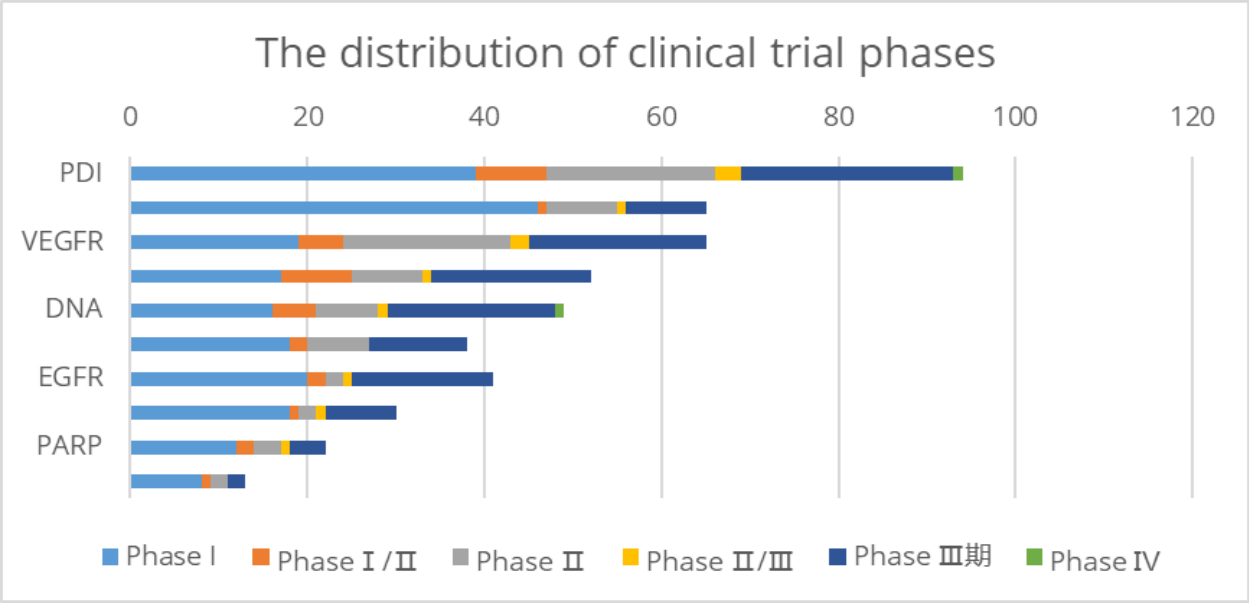


The data came from the CDE's first report on new drug clinical trials in China, which was published on Nov. 10 to detail the number and types of studies registered with the agency in 2020. It provided a rare glimpse into what Chinese drugmakers are interested in and how fast they are turning innovative.

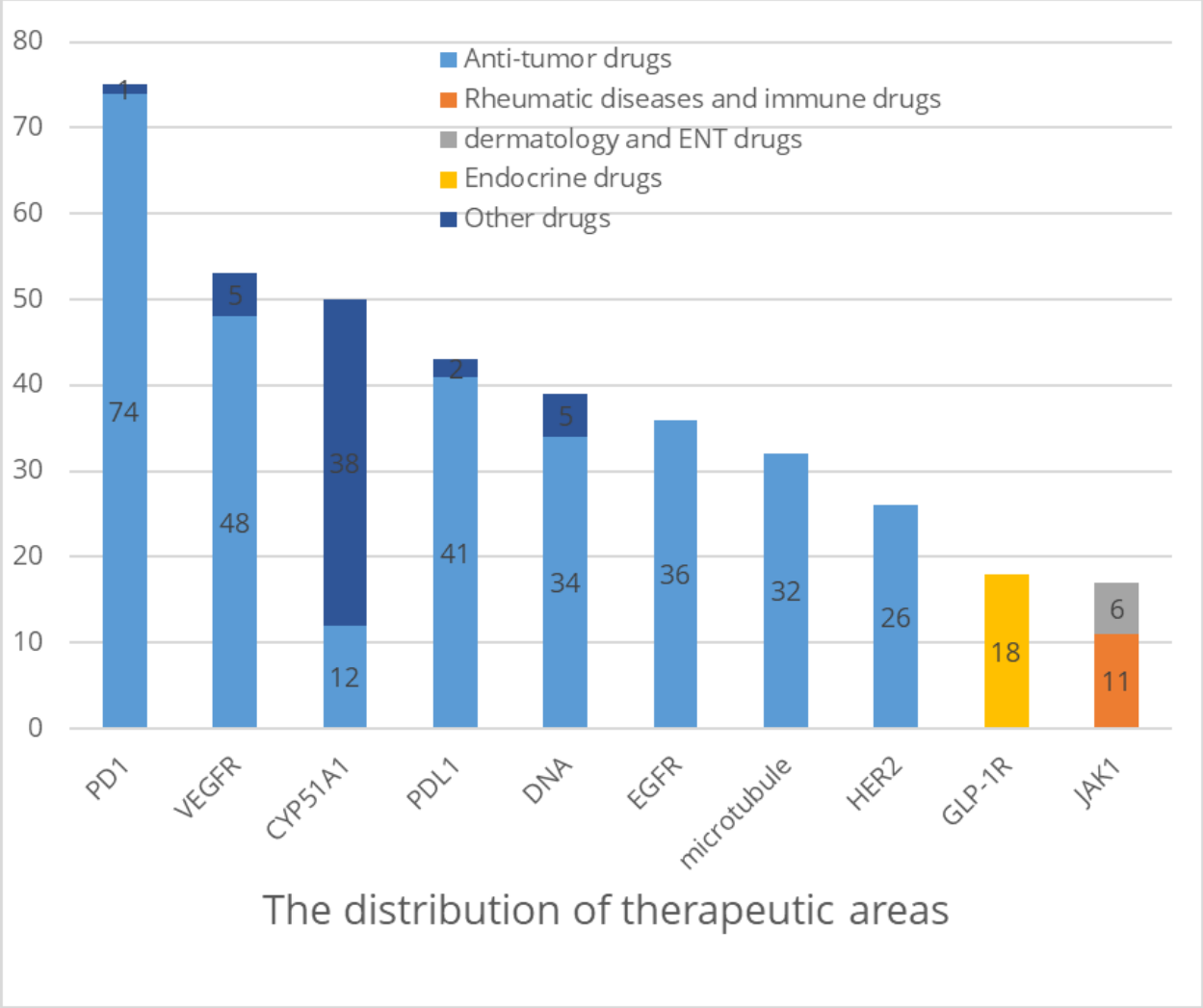
According to the report, for new drug clinical trials, new chemical drug trials registered a total of 801 trials (54.4%), followed by biological products and traditional Chinese medicines, with 605 items (41.1%) and 67 items (4.5%) respectively. Most of the registered clinical trials were phase I studies of class 1 new drugs, in total 643 (43.7%), which are defined as innovative drugs that have not been marketed in China or overseas. Followed by Phase III and Phase II, accounted for 24.4% (359 trials) and 19.9% (293 trials) respectively. 4 of the 39 phase IV clinical trials were real world studies.

Indications were mainly concentrated in oncology, endocrine and cardiovascular diseases. Non-small cell carcinoma, a top killer in China, was the most common type of lung cancer that Chinese drugmakers want to tackle.

Since immuno-oncology and precision medicine have opened a new front in cancer treatment, more drugmakers are eyeing biological drugs, which accounted for 24% of the clinical trials registered in 2020. Most common targets included PD-1, VEGFR, and PD-L1.



Source: The CDE's 2020 annual report on new drug clinical trials in China



Source: The CDE's 2020 annual report on new drug clinical trials in China

The findings are in line with the tremendous regulatory progress the CDE has made since the reforms in 2015. CDE directors said publicly in recent conferences that approvals for oncology drugs are granted faster than ever, and Chinese drugmakers have won more NDA approvals than their foreign peers for the first time.

However, the report also pointed to slow clinical progress and inadequate care for younger and older patients in China.

Among clinical trials registered in 2020, only 45.4% of them initiated patient recruitment within one year after IND clearance was granted. Only 14% of phase I trials were completed in the same year.

And among 2,602 studies, only 3 and 33 of them targeted elderly and pediatric patients, respectively.

For this report, the CDE collected data from the Registration and Information Disclosure Platform for Drug Clinical Trials that was launched in 2013 to improve transparency.

Planning to publish a report every year in future, the CDE hopes to enhance communications with the industry to promote the healthy development of high-quality clinical trials by highlighting regulatory progress and capabilities.

In July, for seeking public comments, CDE published the draft Guideline for Clinical Research and Development of Oncology Drugs Oriented by Clinical Value. The objective is to implement the clinical value-oriented and patient centric R&D, promote the development of oncology drugs in scientific and orderly way. Reviewer warned that drug development in China is over heat in oncology and certain targets such as PD-1. To date, 71 Chinese drugmakers have filed 424 NDAs for their PD-1/PD-L1 candidates.

About the **Author**:

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is the Vice President of Drug Regulatory Policy at Tigermed. She joined Tigermed in 2013, following working with PDPAC for 5 years as Director Drug Regulatory and Science where she devoted in the drug regulatory policy advocacy. She had 15 years experience in the area of drug registration and clinical trial with the local subsidiaries of Schering AG, SmithKline Beecham and Schering-Plough.

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