Influencing Factors on the Approval Lag for Innovative Drugs in China: A Retrospective Study of Drugs Approved from 2021 to 2024

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Background and Objective

- China formally implemented accelerated registration pathways in 2020 to improve timely access to innovative medicines.

Breakthrough Therapy Designation	Conditional Approval	Priority Review	Special Approval Procedure
For serious diseases; preliminary evidence shows major clinical advantage.	Based on surrogate endpoints; requires confirmatory post-marketing trials.	For drugs with significant clinical benefit; shorter review timeline.	For public health emergencies; rapid access with limited data.

- "Acceleration" is the primary policy intention of these pathways and should be evaluated by comparing review and approval timelines between accelerated and non-accelerated drugs.
- These accelerated pathways differ in eligibility criteria, communication mechanisms, and allocation of review resources, which may lead to heterogeneous effects on time to approval.
- To examine the approval timelines of innovative drugs approved in China from 2021 to 2024 and identify **determinants** associated with shorter or longer time to approval after the implementation of accelerated registration pathways.

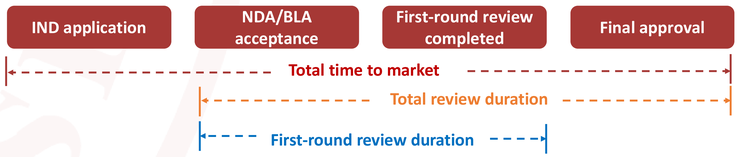
Methods

Data sources

- Collecting information on innovative drugs approved from 2021 to 2024 and their related characteristics from the National Medical Products Administration (NMPA, https://www.nmpa.gov.cn).

Inclusion criteria

1. Category 1 chemical drugs and biological products under China's drug registration classification;
2. Complete review timeline information and drug characteristics (drug classification, therapeutic area, clinical trial, and approval pathway).



IND: Investigational New Drug, NDA: New Drug Application, BLA: Biologics License Application.

Figure1 Timeline definition diagram

Exclusion criteria

- Drugs approved under the Special Approval Procedure, as this procedure is activated only during public health emergencies.

Statistical analysis

- Descriptive analysis: Characteristics and timelines were summarized using counts, percentages, and summary statistics.
- Group comparisons: Mann–Whitney U, Kruskal–Wallis, and Dunn's post-hoc tests were used for timeline comparisons.
- Regression analysis: Multiple linear regression identified factors associated with the three timeline outcomes; $P < 0.05$ was considered significant.

Results

Sample size and descriptive statistics:

- A total of 121 innovative drugs were included, with the highest number approved in 2024 (n=45). Among these, **47.93%** were anticancer drugs, and over half (**53.72%**) were included in at least one accelerated registration pathway.
- The median durations were **0.59** (interquartile range [IR]: 0.48-0.74) years for first-round review, **1.32** (IR: 1.07-1.64) years for total review, and **6.84** (IR: 4.92-9.08) years for total time to market.

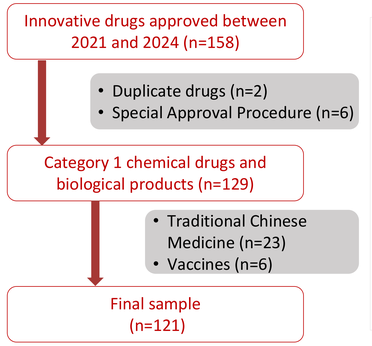


Figure2 Sample size diagram

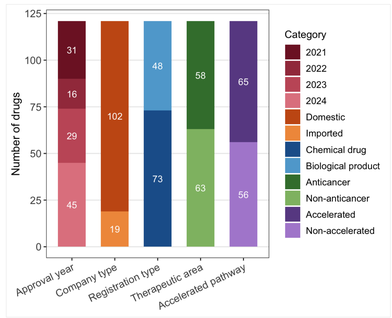


Figure3 Characteristics of included innovative drugs

Table1 Descriptive statistics of approval timelines for innovative drugs

Timelines	Mean (SD)	Median (Q1, Q3)	Range (Min, Max)
Total time to market	7.40 (3.60)	6.84 (4.92, 9.08)	1.93, 19.00
Total review duration	1.55 (1.18)	1.32 (1.07, 1.64)	0.54, 12.20
First-round review duration	0.64 (0.22)	0.59 (0.48, 0.74)	0.36, 1.59

Differences in approval timelines:

- Significant differences in **all three** timeline outcomes were observed across accelerated pathway types, including first-round review duration, total review duration, and total time to market.

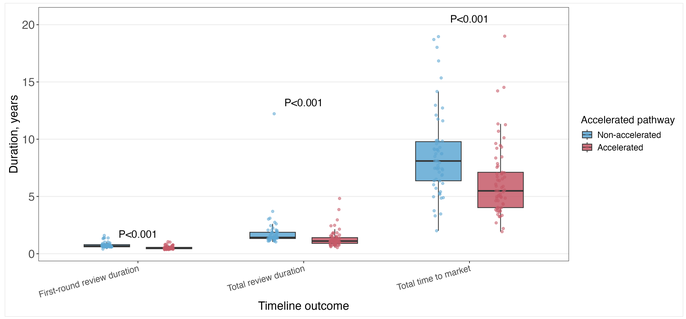


Figure4 Approval timelines by accelerated registration pathway

Results

- Post-hoc pairwise comparisons further suggested that the time-shortening effects varied across different accelerated pathway types, indicating heterogeneity in the effectiveness of these pathways.

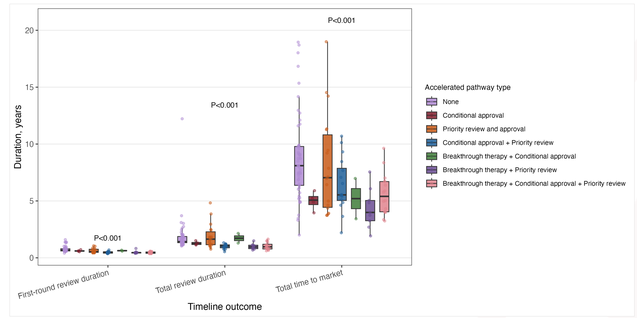


Figure5 Approval timelines by type of accelerated registration pathway

Factors associated with approval timelines for innovative drugs:

- Multiple linear regression showed that accelerated pathway status and anticancer indication were associated with shorter first-round review duration, while accelerated pathway status also shortened total review duration.
- **More supplementary material submissions** prolonged total review duration, and **review-based clinical pathway** was associated with longer total time to market.

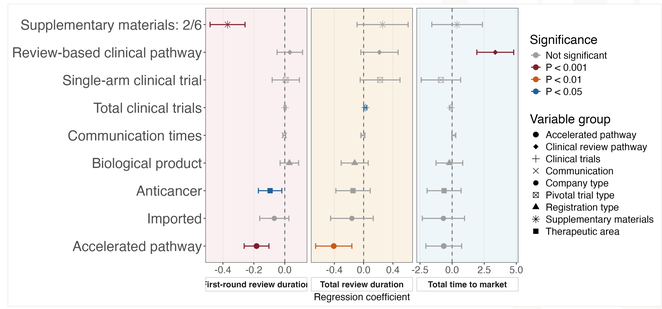


Figure6 Multiple linear regression analysis of factors associated with approval timelines

Conclusion

- Accelerated registration pathways were associated with shorter first-round review duration and total review duration for innovative drugs approved in China from 2021 to 2024.
- Anticancer drugs experienced shorter first-round review duration, suggesting possible prioritization in areas with high unmet clinical needs. Additional supplementary material submissions significantly prolonged total review duration.
- Streamlining clinical trial approval procedures and reducing avoidable supplementary submissions may further shorten the total time to market.

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