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EVOLVING TRENDS IN REGULATORY SCIENCE: A COMPREHENSIVE ANALYSIS OF FDA NOVEL DRUG APPROVALS (2021–2024)

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ABSTRACT

Background: The United States Food and Drug Administration (FDA) is internationally recognized for its pivotal role in protecting public health through the rigorous evaluation and approval of novel therapeutic agents. Over recent years, major legislative acts and policy initiatives—such as the Orphan Drug Act and PDUFA—have transformed the regulatory landscape by innovation, and predictability in drug development. Insightful, up-to-date analyses of regulatory trends are vital for understanding both scientific progress and policy impacts within modern drug approvals. **Objectives**: This study aims to systematically evaluate patterns and characteristics of FDA novel drug approvals from 2021 to 2024. The primary objectives are to quantify approval volumes, identify dominant therapeutic areas, classify drug types (small molecule vs. biologic), and assess reliance on expedited regulatory pathways such as First in Class, Orphan Drug, Fast Track, Breakthrough Therapy, and Priority Review designations. Further aims include analysis of approval predictability, access metrics, and visualization of sectoral trends to inform regulatory science, healthcare policy, and pharmaceutical innovation. **Methods & Results**: Using a curated dataset of 192 approvals, annual and therapeutic trends were mapped, with oncology, haematology, dermatology, and neurology accounting for a majority of new therapies. The use of expedited regulatory pathways remained consistently high, and biologics comprised a large share of novel approvals, illustrating the advancing shift to complex therapeutic technologies. **Conclusions**: The findings reinforce FDA's unique and dynamic role in facilitating innovative drug development and rapid patient access to new treatment options, while offering a robust framework for future regulatory evaluation and global benchmarking.

KEYWORDS: Regulatory Science, Biologics, Orphan Drugs, Drug Development, Pharmacovigilance.

INTRODUCTION

The United States Food and Drug Administration (FDA) serves as the global benchmark for pharmaceutical regulation, exercising profound influence over the trajectory of drug development and patient access to therapy. The agency's Centre for Drug Evaluation and Research (CDER) is tasked with a complex mandate: to expedite the availability of innovative medical products while rigorously enforcing standards of safety, efficacy, and manufacturing quality.[1] This regulatory ecosystem has undergone a dynamic transformation over the last three decades, shaped by a synergy of legislative reforms and paradigm shifts in molecular medicine. Foundational statutes, most notably the Prescription Drug User Fee Act (PDUFA) of 1992 and its subsequent reauthorizations, along with the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, have provided the resources and framework necessary to modernize the review process.[2]

Drug discovery is a complex process that involves target identification, formulation studies, preclinical and clinical evaluations, and regulatory submissions. The FDA's regulatory framework includes Investigational New Drug (IND) applications, NDAs and expedited pathways like Accelerated Approval and Breakthrough Therapy designations. The structured regulatory approval pathway facilitates scientifically driven decision-making, ensuring that approved therapies align with public health objectives while meeting evidence-based regulatory standards. To address the growing burden of unmet medical needs, the FDA has progressively implemented a

suite of expedited programs designed to streamline the clinical development and regulatory assessment of high-impact therapies. Beyond the financial incentives established by the Orphan Drug Act of 1983 for rare diseases—defined as conditions affecting fewer than 200,000 individuals in the U.S.—the agency has operationalized four distinct expedited pathways: Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review.[3] These mechanisms allow for greater regulatory flexibility, such as the use of surrogate endpoints and rolling reviews, reflecting a strategic pivot toward balancing risk with the imperative of timely access for life-threatening conditions.[4]

The rise in cancer drug therapies has advanced because of the global burden of developing cancer conditions and rapidly increasing cancer cases across different countries and regions. So, prioritizing the need for oncology treatments, the FDA has streamlined the process flow of cancer drug approval regardless of any ignorance of the effectiveness and stability of the drug product. Modern drug discovery utilizes innovative technologies such as combinatorial chemistry, high-throughput screening, and computational modelling to accelerate success rates. The process of approval includes distinctive steps, which are tailored to development phases. The phases are classified based on preclinical and clinical studies, which assess target conditions and guide drug development. The use of artificial intelligence has significantly improved study phases, including trial design, patient recruitment, and outcome assessment. The drug development process is facilitated by the advancements in artificial intelligence and advanced technologies developed.

Parallel to these policy evolutions, the pharmacological landscape has shifted from a predominance of small-molecule chemical entities to a diverse array of complex biologicals and precision medicines. The modern drug pipeline is increasingly characterized by monoclonal antibodies, antibody-drug conjugates (ADCs), bispecific T-cell engagers, and gene-based therapies.[5] This transition towards "precision medicine" targets distinct molecular phenotypes, necessitating adaptive regulatory approaches that can accommodate smaller patient populations and novel trial designs.[6] Consequently, the FDA's ability to evaluate these sophisticated modalities without compromising scientific predictability remains a critical determinant of global pharmaceutical innovation.

Historical analyses of FDA approvals over the past decade have documented consistent trends, including a surge in oncology and immunology agents, a higher proportion of first-in-class designations, and the routine utilization of expedited pathways.[7, 8] However, the period spanning 2021 to 2024 represents a unique epoch in regulatory history. This timeframe captures the industry's calibration following the acute phase of the COVID-19 pandemic, a resurgence in diverse therapeutic areas beyond infectious diseases, and the maturation of cell and gene therapy frameworks.[9] Despite the significance of this period, there remains a paucity of comprehensive literature synthesizing the specific regulatory and therapeutic patterns of the last four years. Continuous monitoring of approval trends is essential for benchmarking regulatory efficiency and informing the strategic decisions of pharmaceutical developers, investors, and policymakers.

To address this gap, the present study offers a systematic evaluation of FDA novel drug approvals from January 1, 2021, through December 31, 2024. Analysing a curated dataset of 192 novel therapeutics, this research dissects temporal trends, therapeutic class distributions, and the utilization of specific regulatory designations. By providing a granular quantitative analysis and rich graphical visualization of this data, this study elucidates the contemporary dynamics of the U.S. drug approval landscape, offering actionable insights into the future of drug development and regulatory science.

Furthermore, the utilization of expedited pathways—Fast Track, Breakthrough Therapy, Priority Review, and Accelerated Approval—has solidified into a standard operating procedure rather than an exception. In recent years, over 60% of novel drugs utilized at least one of these expedited mechanisms, reflecting an agency-wide commitment to accelerating access for life-threatening conditions.[10]

Yet, this rapid acceleration brings new challenges. The "dangling" status of accelerated approvals—where confirmatory trials are delayed or fail to verify clinical benefit—has prompted the FDA to rigorously reassess its withdrawal procedures and post-marketing requirements during this specific four-year window.[11]

While historical reviews of FDA approvals exist[12], there is a paucity of literature comprehensively analysing the post-pandemic epoch (2021–2024). Current research often lacks a granular breakdown of how recent legislative shifts (like the Cures Act) and scientific breakthroughs (like CRISPR-based therapies) have materialized in approval data.

To meet serious unmet needs, FDA employs four principal mechanisms to expedite drug development. These are Fast Track designation, Breakthrough Therapy designation, Accelerated Approval, and Priority Review. Although each expedited program is intended to target novel drugs for serious conditions, each program has its qualifying criteria and advantages.

To overcome the stagnation in the number of novel drug approvals and to foster an environment to promote novel drug approvals FDA regulations for drug approval are continuously evolving in the form of revisions of PDUFA and the introduction of new acts.

Previous studies examining FDA approval patterns have reported increasing numbers of oncology therapies,

orphan-designated products, and first-in-class drugs over the last decade.[5,6] Therefore, the present study was conducted to evaluate trends in FDA novel drug approvals during this period, with emphasis on therapeutic distribution, biologic expansion, and utilization of expedited regulatory pathways.

METHODS

This retrospective descriptive study analysed FDA approval novel drug approvals between January 1, 2021 and December 31, 2024.

Data were collected from official U.S. Food and Drug Administration (FDA) resources, mainly the Center for Drug Evaluation and Research (CDER) databases, in order to examine the trends in FDA drug approvals from 2021 to 2024. The study included New Molecular Entities (NMEs) and Biologics License Applications (BLAs).

Information regarding year of approval, therapeutic indication, drug type, and regulatory designations was collected for each approved therapeutic agent. Regulatory pathways evaluated included Priority Review, Orphan Drug designation, Fast Track, Breakthrough Therapy, Accelerated Approval, and First-in-Class status.

Drugs were categorized according to therapeutic area, including oncology, haematology, dermatology, neurology, endocrinology, cardiology, and infectious diseases. Drug types were classified as small molecules or biologics.

Data analysis was descriptive in nature. Therapeutic categories, drug types, and regulatory designations were calculated and summarized using tables and graphical representations.

Inclusion and Exclusion Criteria

Inclusion criteria encompassed all novel drug approvals by the FDA from January 1, 2021, through December 31, 2024. Specifically, this included.

- New Molecular Entities (NMEs) and Biologic License Applications (BLAs) receiving first-time FDA approval.
- Drugs classified as New Chemical Entities (NCEs) or biological products with unique active ingredients.
- Approvals covering all therapeutic areas and all regulatory designations, including accelerated or expedited approval categories.

Exclusion criteria comprised

- Supplemental approvals or new indications for previously approved drugs.
- Generic drug approvals, biosimilars, or over-the-counter medications.
- Withdrawn or disapproved applications during the study period.
- Approvals not officially listed within FDA's public novel drug approval databases during the specified timeframe.

RESULTS

Year-wise Approval Trends

A total number of drugs approved by the FDA between 2021 and 2024 were 192. 50 drugs were approved in 2021, followed by 37 approvals in 2022 and then number increased to 55 approvals in 2023 and remained stable with 50 approvals in 2024.

Year	Number of Approvals
2021	50
2022	37
2023	55
2024	50
Total	**192**

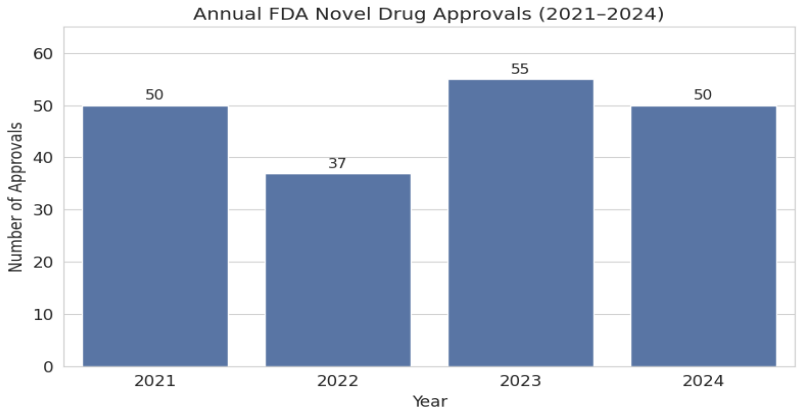

Fig.1.

Therapeutic Area Distribution

The highest number of approvals during the study period is oncology and Haematology. Oncology represented 31 approvals, while haematology had 30 approvals. Dermatology, neurology, and metabolic diseases were also among the commonly represented therapeutic areas.

Therapeutic Area	Number of Approvals
Oncology	31
Haematology	30
Dermatology	21
Neurology	18
Metabolic	12
Endocrinology	11
Gastroenterology	10
Immunology	8
Cardiology	7
Psychiatry	7
Nephrology	6
Paediatrics	6
Radiology	6
Respiratory Medicine	6
Ophthalmology	5
Infectious Disease	4
Urology	3
Gynaecology	1

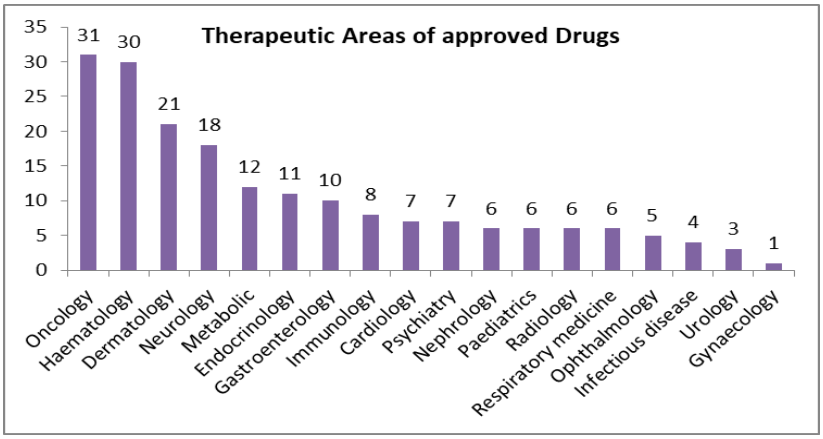

Fig. 2.

Drug Type Breakdown

Analysis of drug types indicated that small molecules accounted for 113 approvals (59%), whereas biologics represented 79 approvals (41%).

Small Molecule	113
Biological	79

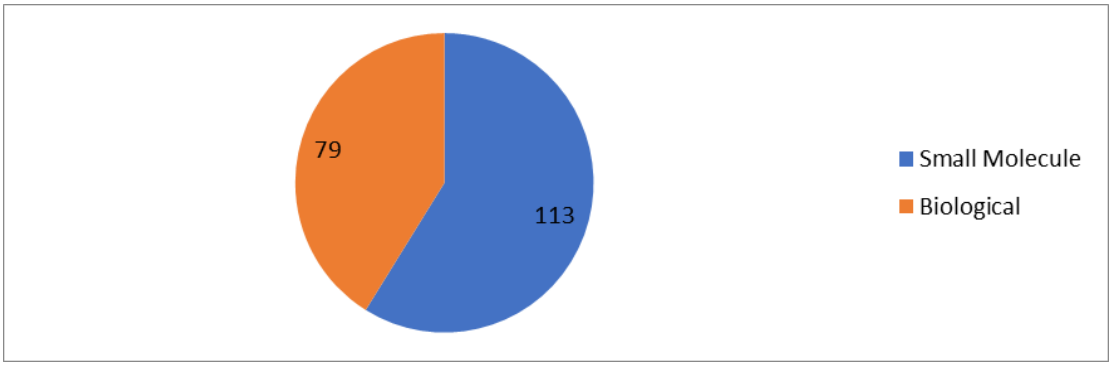

Fig.3.

Expedited Pathway Utilization by Year

A stacked bar chart illustrates annual proportions of expedited approval designations (First in Class, Orphan Drug, Fast Track, Breakthrough Therapy, Priority Review, Accelerated Approval). Use of such pathways

remains consistently high, especially for Priority Review and Orphan status.

Expedited pathway utilization remained consistently high throughout the study period. On average, 46% of approved drugs were designated as First in Class, indicating innovation with novel mechanisms of action. Approximately 52% of drugs received Orphan Drug status, reaffirming the FDA's commitment to rare disease therapeutics. Fast Track and Breakthrough Therapy designations were present in 39% and 29% of approvals respectively, while Priority Review designation was utilized in 59% of cases (Figure 2). Accelerated Approval comprised roughly 19% of approvals, reflecting reliance on surrogate endpoints for critical conditions.

Regulatory Designations and Expedited Pathways - The FDA continued to utilize expedited pathways extensively to facilitate the development of drugs for serious conditions.

- **Priority Review:** This was the most frequently granted designation, applied to 114 drugs (59% of all approvals) over the four-year period.
- **Orphan Drug Designation:** Highlighting the focus on rare diseases, 100 novel drugs (52%) received Orphan status.
- **First-in-Class:** An indicator of mechanism-of-action novelty, 91 drugs (47%) were designated as First-in-Class, with the highest annual proportion observed in 2021 (54%) and 2024 (48%).
- **Accelerated Approval:** This pathway was utilized for 36 drugs (19%), with usage peaking in 2021 (14 approvals) and declining to 7 approvals by 2024.

Regulatory Designation	Total Number (2021-2024)
Priority Review	114
Orphan Drug	100
First-in-Class	91
Fast Track	75
Breakthrough Therapy	56
Accelerated Approval	36

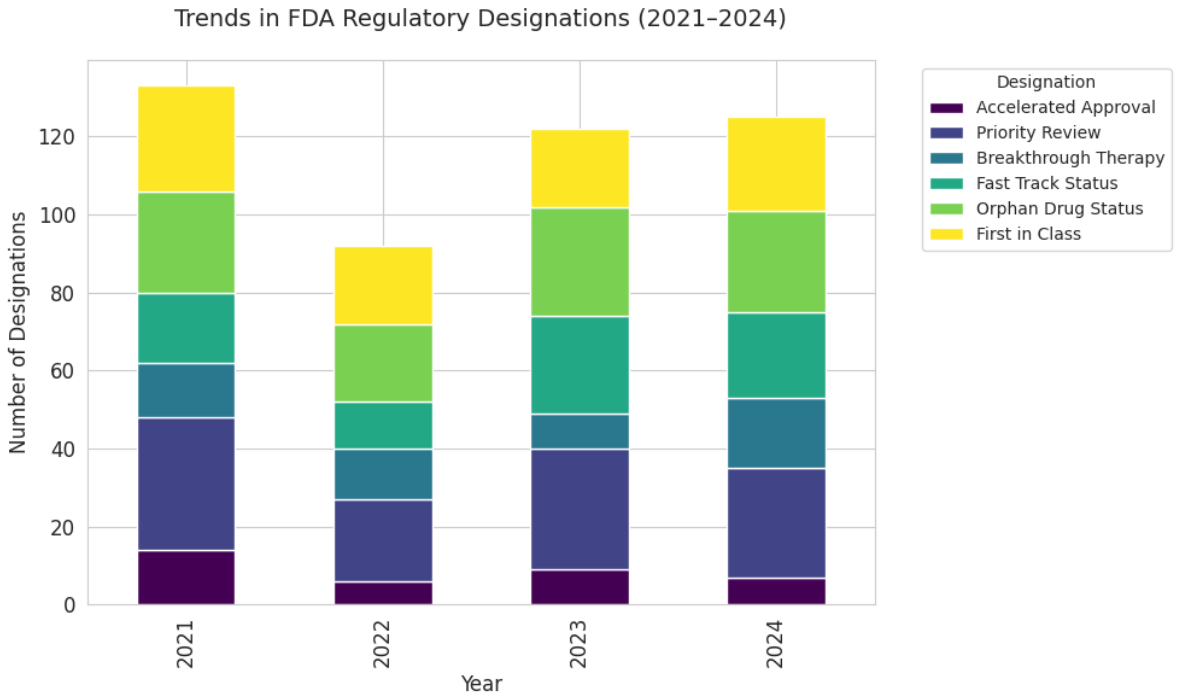

Fig.4.

This balance highlights the ongoing expansion of biological therapeutics alongside traditional chemical entities, aligned with shifts observed in 5-year rolling averages.

Predictability metrics reinforced FDA review efficiency, with first-cycle approval rates exceeding 80% and over 95% of applications meeting PDUFA goal dates. Such robust regulatory performance underscores effective communication and high-quality application submissions.

Overall, this comprehensive dataset illustrates sustained innovation, efficient regulatory pathways, and focused therapeutic development from 2021 through 2024, supporting progressive trends in drug availability and patient access in the US healthcare system.

Oncology and haematology continue to represent the largest share of new approvals, reflecting the high level of investment and clinical need in these areas. Biologics comprise a significant and growing fraction of approvals, indicative of a shift toward targeted therapies and advanced biologics platforms. Expedited regulatory paths—such as orphan drug designation, fast track, and priority review—remain widely used, particularly for treatments addressing unmet medical needs.

DISCUSSION

During the period of CY 2021-2024, there were total 192 novel drug approvals and 48 new drugs on average per year were approved.

The present study identified several important developments in the current pharmaceutical regulatory Pathways.

These therapies were heavily focused on oncology, haematology, and neurology, with a significant number utilizing expedited review or orphan drug pathways. cancer drug approvals have risen significantly, driven by advancements in targeted therapies and immunotherapy. Oncology remains a leading area for FDA approvals, driven by advancements in targeted therapies and immunotherapies. Recent advancements in oncology drug discovery have significantly influenced patient care, pharmaceutical research, and the development of new treatments.

Large majority of approvals each year (often over 50%) were classified as orphan drugs designed to treat rare diseases or specific genetic markers in cancer. orphan disease has a genetic origin, and due to their complex pathophysiology, the development of targeted therapies remains a challenge. Rare diseases, often called orphan diseases, affect fewer than 200,000 people in the United States and include 7000 to 10,000 conditions worldwide, Although annual approval numbers fluctuated during the study period, overall approval activity remained high. Oncology and haematology continued to account for the largest proportion of approvals, consistent with previous reports showing increasing investment in targeted cancer therapies and immunological treatments.

A substantial proportion of approved products were biologics, reflecting the growing importance of monoclonal antibodies, gene therapies, and other advanced therapeutic approaches in modern medicine. However, small molecules still represented the majority of approved therapies during the study period.

The widespread use of expedited review pathways observed in this analysis demonstrates the FDA's continued focus on improving access to therapies for serious and rare diseases. Priority Review and Orphan Drug designation were particularly common among approved products. The high proportion of First-in-Class therapies also suggests ongoing innovation in drug development and therapeutic mechanisms.

High first-cycle approval rates and adherence to PDUFA review timelines indicate efficient regulatory performance and improved coordination between pharmaceutical sponsors and regulatory authorities. Timely approvals remain important for patients with limited treatment options.

Despite these advances, therapies approved through accelerated pathways require continued post-marketing surveillance to ensure long-term safety and clinical benefit. Therefore, pharmacovigilance and confirmatory studies remain essential components of modern regulatory science.

CONCLUSION

FDA novel drug approvals between 2021 and 2024 demonstrated continued expansion in biologic therapies, increasing use of expedited review mechanisms, and sustained focus on oncology and rare diseases. The findings suggest that the FDA continues to support pharmaceutical innovation while maintaining regulatory efficiency and timely patient access to new therapies.

The widespread use of expedited regulatory pathways such as Fast Track, Breakthrough Therapy, and Priority Review illustrates how regulatory mechanisms have adapted to facilitate faster patient access to promising therapies without compromising the rigor of safety and efficacy assessments. The notable share of biologics among approvals further demonstrates the shift towards advanced therapeutic modalities including monoclonal antibodies and gene therapies.

Regulatory predictability, as demonstrated by high first-cycle approval rates and consistent achievement of PDUFA goal dates, confirms the FDA's efficiency and constructive collaboration with the pharmaceutical industry. However, vigilance remains essential in balancing speed with safety, particularly for accelerated approvals reliant on surrogate endpoints.

Overall, these findings confirm that the FDA's evolving regulatory framework successfully fosters pharmaceutical innovation and clinical translation, thus enhancing patient care while maintaining high standards of evaluation. This study provides insight into recent trends in drug approvals and may help researchers, policymakers, clinicians, and pharmaceutical developers better understand the evolving direction of regulatory science and therapeutic development.

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No external funding was received for this study.

Conflict of Interest
The authors declare no conflict of interest.

Ethical Approval
As this study was based entirely on publicly available FDA approval databases and did not involve human participants or patient-level data, institutional ethical approval was not required.

Consent to Participate
Not applicable.

Patient Consent
Not applicable.

REFERENCES

1. Darrow JJ, Avorn J, Kesselheim AS. FDA Approval and Regulation of Pharmaceuticals, 1983-2018. JAMA, 2020 Jan 14; 323(2): 164-76.
2. Galson S. The Prescription Drug User Fee Act (PDUFA) and its Impact on the FDA Review Process. Pharmacoepidemiol Drug Saf, 2012 May; 21 Suppl 1: 1-6.
3. Mullard A, 2023 FDA approvals. Nat Rev Drug Discov, 2024 Feb; 23(2): 78-82.
4. Jarow JP, LaVange L, Woodcock J. Multidimensional Evidence Generation and FDA Regulatory Decision Making: Defining and Using "Real-World" Data. JAMA, 2017 Aug 22; 318(8): 703-4.
5. Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. JAMA, 2020 Mar 3; 323(9): 844-53.
6. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ, 2016 May; 47: 20-33.
7. Senior M. Fresh from the biotech pipeline: fewer approvals, but biologics gain share. Nat Biotechnol, 2023 Feb; 41(2): 174-82.
8. Dugger SA, Platt A, Goldstein DB. Drug development in the era of precision medicine. Nat Rev Drug Discov, 2018 Mar; 17(3): 183-96.
9. Gottlieb S. The future of drug safety and innovation in a post-pandemic world. Health Aff (Millwood), 2021 Feb; 40(2): 1-5.
10. Hwang TJ, Darrow JJ, Kesselheim AS. The FDA's Expedited Programs and Clinical Development Times for Novel Therapeutics, 2012-2016. JAMA, 2017 Dec 5; 318(21): 2137-8.
11. Beaver JA, Pazdur R. "Dangling" Accelerated Approvals in Oncology. N Engl J Med, 2021 Apr 22; 384(16): 68.
12. Devenage M, Dong K, Plottel CS. Trends in FDA Approvals of Novel Therapeutics: 2011–2021. Ther Innov Regul Sci, 2022 Nov; 56(6): 931-42.