Figure 1. Return on Investment Sensitivity Analysis for Fexinidazole (Source: Authors' calculations)

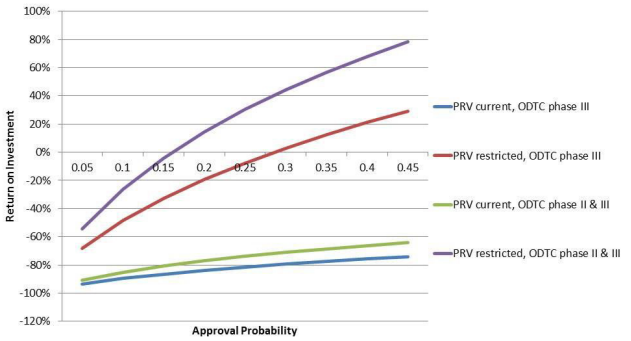
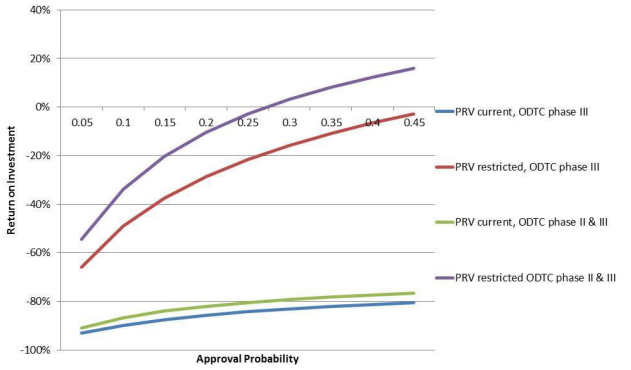


Figure 2. Return on Investment Sensitivity Analysis for Acoziborole (Source: Authors' calculations)



Conclusion. We find support for NTD drug development within the private sector, but no novel R&D without nonprofit stewardship. Our findings intend to foster PPPs that stimulate this pipeline from very low current levels.

Disclosures. **All Authors**: No reported disclosures

1235. On the Edge of Tomorrow: Expedited Regulatory Pathways for Anti-Infective Therapies

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Session: P-56. New Drug Development

Background. The FDA has developed expedited review programs and pathways to increase drug development for products that have a major clinical benefit. These programs include: Fast Track, Orphan Drug Status, Accelerated Approval, Priority Review, Breakthrough Therapy (BTD) and Qualified Infectious Disease Products (QIPD).

Given the heightened awareness of infectious diseases--and emerging global threats, such as resistant bacteria and Ebola—academia and industry have developed and received approval for 88 new infectious disease agents. The objective of this study was to assess the use of expedited review pathways for the 88 anti-infective agents that were approved between 2001-2020.

FDA Expedited Drug Development Programs

FDA Expedited Drug Development Programs

Program Type	Explanation
Fast Track Designation	Fast track designation is available for drugs that are intended to treat serious conditions and show data addressing an unmet need.
Priority Review	Priority review ensures a new drug application will be reviewed within a 6 month window instead of the conventional 10 months.
Accelerated Approval	Accelerated approval is considered when a drug provides a meaningful advantage over current therapies through a surrogate endpoint that is likely correlated to a clinical benefit; the "conditional" approval is contingent upon verification of the benefit in future confirmatory trials.
Orphan Drug Status	Orphan drug status is available for drugs intended to treat rare diseases where the sponsor receives various incentives including tax credits for clinical trials.
Qualified Infectious Disease Product	Through the GAIN Act that was passed in 2012, drugs in development may be designated as a qualified infectious disease product (QIDP) if they are targeting certain types of infectious diseases. QIDPs are eligible for fast track and priority review status.
Breakthrough Therapy	Breakthrough therapy designation is typically received early in drug development when the IND (investigational new drug) is filed, where the sponsor receives significant guidance on their drug development program from the FDA.

Methods: We analyzed the FDA Drug Approval Database entitled, "Compilation of CDER New Molecular Entity (NME) Drug and New Biologic Approvals" for anti-infective therapies that were approved after 2000. Anti-infective therapies were defined as agents that were used to treat or prevent infectious diseases and include antibiotics, antivirals and antifungals. Our analysis focused on a comparison of the percentage of approved anti-infective agents that used each of the aforementioned designations across 2 decades (2001-2010 & 2011-2020). A drug may have one, none, or multiple of these designations.

Results. There were significant differences in the percentage of anti-infective agents approved with priority review, fast track and accelerated approval in 2001-2010 compared to 2011-2020 (See Results Figure 1) BTD and QIDP did not exist until 2012, thus preventing comparisons between decades.

QIDP.
- Between 2012-2020, 16 anti-infectives have been approved with QIDP. From 2017-2020, 40% (n=10) of approved anti-infectives had QIDP.

Orphan Drug Status:
- Between 2017-2020, 32% of anti-infectives approved have the orphan drug designation.

Comparison of FDA Expedited Drug Development Programs use between 2001-2010 and 2011-2020

Comparison of FDA Expedited Drug Development Programs use between 2001-2010 and 2011-2020

Program Type	% of Products Approved via Program Type in 2001-2010	% of Products Approved via Program Type in 2011-2020	P Value
Fast Track Designation*	49%	78%	0.007
Priority Review *	31%	60%	0.004
Accelerated Approval *	18%	3%	0.03
Orphan Drug Status	5%	19%	0.07
Qualified Infectious Disease Product^	N/A	35%	N/A
Breakthrough Therapy^	N/A	17%	N/A

*P Value less than .05
^Programs started in 2012

Conclusion. Our findings indicate Priority Review and Fast Track use has increased since 2010 among anti-infective products. Additionally, our analyses indicate that since 2017 there has been increased use of Orphan Drug Status and QIDP. However, there has been limited use of Breakthrough Therapy and Accelerated Approvals. These two pathways should be increasingly considered by academia, industry and the FDA to further expedite innovative anti-infective development.

Disclosures. **All Authors**: No reported disclosures

1236. Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine (PCV20) in Healthy Infants in the United States

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Session: P-56. New Drug Development

Background. A 20-valent pneumococcal conjugate vaccine (PCV20) is being developed to extend protection against pneumococcal disease beyond that of the 13-valent pneumococcal vaccine (PCV13). This is the first safety and immunogenicity study of PCV20 in healthy infants.

Methods. This randomized, double-blind study enrolled and randomized (1:1) healthy infants ≥ 42 to ≤ 98 days of age to receive a 4-dose series of either PCV20 or PCV13 (control) at 2, 4, 6, and 12 months of age. Local reactions and systemic events were assessed for 7 days after each vaccination; adverse events (AEs) and serious AEs (SAEs) were collected throughout the study. PCV20 immune responses (serotype-specific immunoglobulin G [IgG] and opsonophagocytic activity [OPA]) were measured in sera 1 month after the third infant dose and the fourth dose at 12 months of age.

Results. There were 460 subjects enrolled, with 416 and 391 subjects receiving 3 and 4 doses, respectively. Local reactions and systemic events were predominantly mild to moderate in severity and similar among vaccine groups. There were no related SAEs or deaths reported. PCV20 elicited IgG responses 1 month after the third dose with boosting after a fourth dose. OPA responses were also observed.

Conclusion. PCV20 was well tolerated with a safety profile similar to PCV13. PCV20 elicited immune responses to all 20 vaccine serotypes.

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1237. Robust Adjuvant Activity and Dose-sparing Potential of the Novel Semisynthetic Saponin Adjuvant TQL1055 for Seasonal and Pandemic Influenza

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Session: P-57. New Vaccines

Background. Vaccination against both seasonal and pandemic influenza requires effective adjuvants to maximize the utility of limited antigen and to enhance immunogenicity in hyporesponsive at-risk populations. First-generation natural saponins are potent immuno-enhancers but are reactogenic and have supply constraints. As part of