

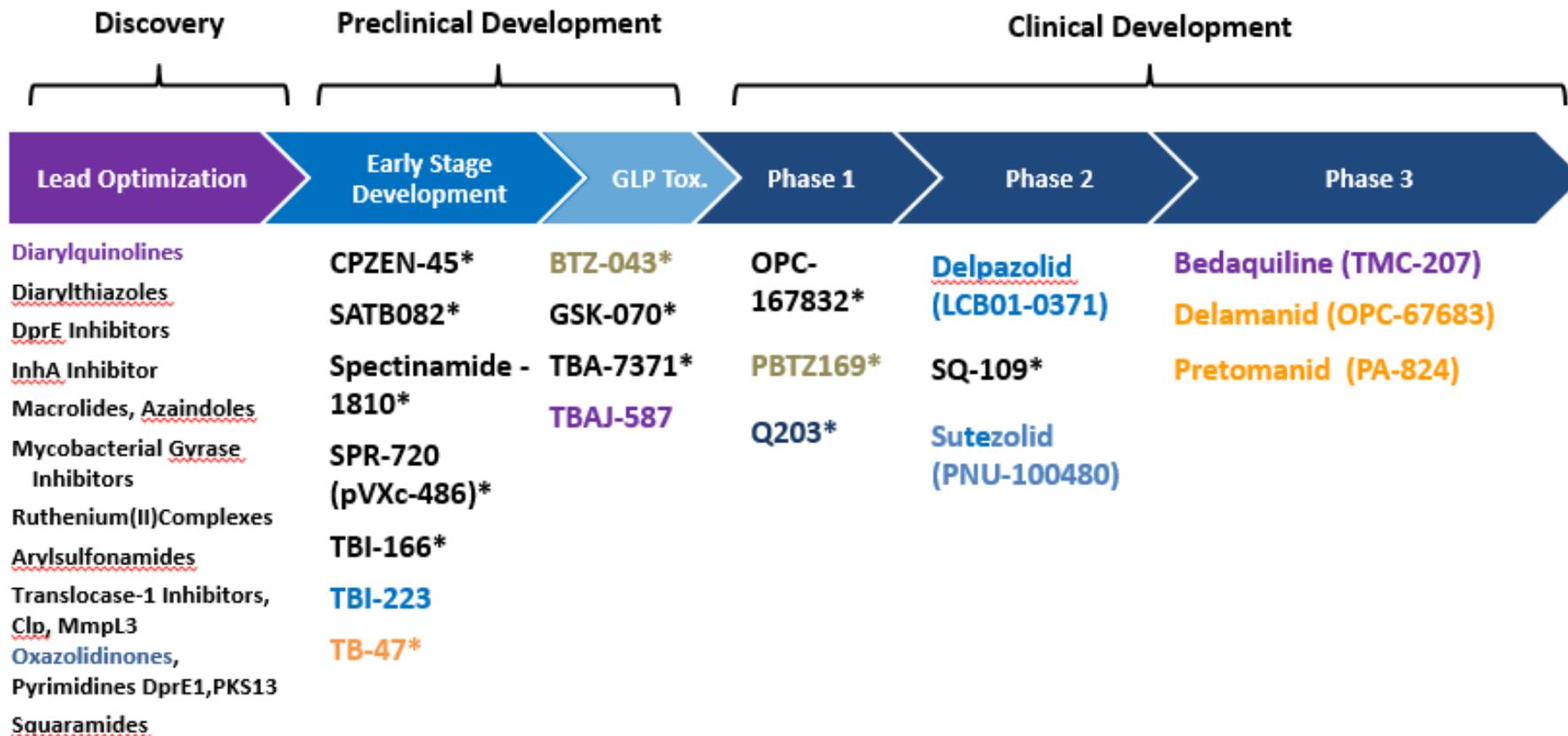


Critical Path to TB Drug Regimens Role in Facilitating TB Drug Development

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- **Mission:** The Critical Path to TB Drug Regimens (CPTR) is a cross-sector initiative that aims to speed the development of safer and shorter duration anti-tuberculosis (TB) drug regimens.
- **CPTR Objectives:**
 - Drug development tools and methodologies to support go/no-go decisions during each stage of research and development.
 - Curation of supportive data through establishment of collaboration network to support new methods and tool validation (and ensure public access wherever possible).
 - Developing pathways for assessing new TB treatment regimens that include drugs that are not yet individually approved.
 - Providing regulatory excellence in the development, validation, and advancement of these drug development tools and methodologies.

Global New TB Drug Pipeline ¹



*New chemical class. Known chemical classes are color coded: **fluoroquinolone**, **rifamycin**, **oxazolidinone**, **nitroimidazole**, **diarylquinoline**, **benzothiazinone**, **imidazopyridine amide**.

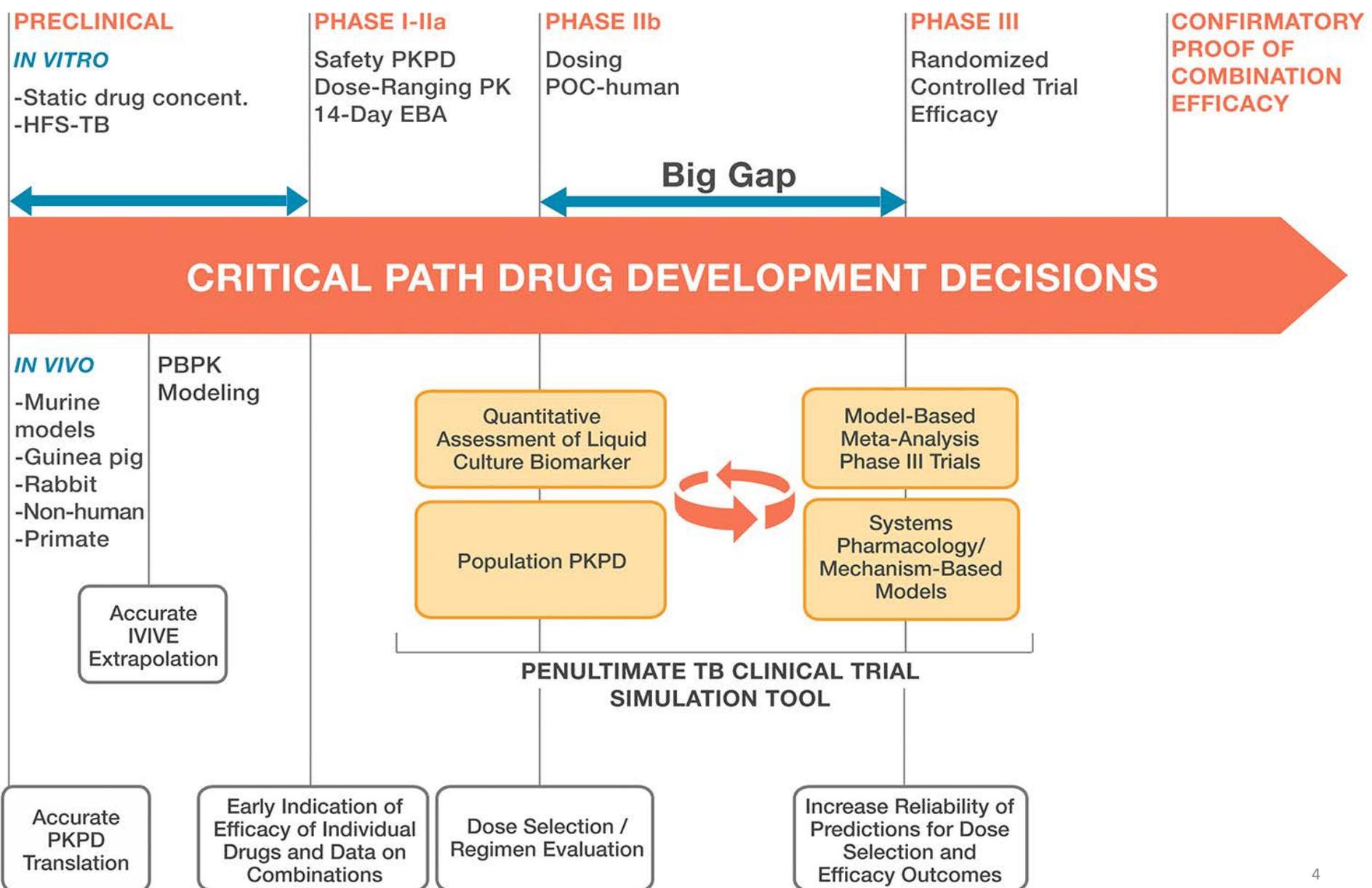
¹New Molecular Entities not yet approved, being developed for TB or only conditionally approved for TB. Showing most advanced stage reported for each. Details for projects listed can be found at <http://www.newtbdrugs.org/pipeline/clinical>

Ongoing projects without a lead compound series identified can be viewed at <http://www.newtbdrugs.org/pipeline/discovery>



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GAPS IN THE TB DRUG DEVELOPMENT PROCESS



Develop a translational roadmap (including preclinical models and supporting datasets) to guide advancement of entirely novel TB drug regimens:

Discuss how the principles of a rigorous, data-driven roadmap can contribute to the development of treatment courses that may include sequential combinations of existing and emerging drugs to lead to shorten treatment duration.

- Expand the translational roadmap to deliver new preclinical TB drug regimens that are safer, simpler and shorter for the treatment of DS, MDR and XDR TB.
- Develop best practices related to management of preclinical data and data sharing to accelerate regimen development.
- Facilitate input regarding the use of the roadmap to develop sequential combinations of current/novel antibiotics to arrive at a shorter course of treatment that has broad efficacy against DS and DR TB to expand the definition of “treatment regimens” for TB.
- Publish proceedings from the workshop in a peer-reviewed journal.

- Distinguish between the development and use of preclinical animal models and clinical data for research vs. drug development decision-making purposes.
- Review ongoing, contemporary activities to evaluate the predictive accuracy and applicability of murine models.
- Define gaps in data collection and application of murine models, emphasizing comparison of pharma and academic best practices and exploring areas for collaboration.
- Identify and plan activities for evaluation of additional non-murine animal models of TB for predicting clinical efficacy, including analyses of strengths and weaknesses.
- Current and emerging tools, including quantitative *in silico* drug models, to leverage animal model data to enable selection of drug combinations, dose levels and duration for subsequent clinical evaluation.



- Discussion of specific drug classes and specific regimens. Programmatic implementation of specific regimens
- Head-to-head comparisons of animal models without considering their utility for preclinical decision making (i.e. animal models supporting research)
- Host-immune modulation therapies