

PDPs and Alternative IP Management/Tech Transfer Strategies for Improved Global Health

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TB ALLIANCE

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

The Need for New TB Drugs

- Complex 6-9 months treatment with a 4 drug combination regimen
- No new anti-TB drug in over 40 years
- TB/HIV co-infections fueling each other
- MDR-TB is on the rise
- Unattractive market for private sector
- No capitalization of public sector research



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The TB Alliance

- Independent, international Product Development Partnership founded in October 2000
- Non-profit organization
- Headquarters in New York City
 - Offices in Brussels and Cape Town
- Entrepreneurial, virtual R&D approach
 - Out-source R&D to public and private partners
- Pro-active fundraising
 - Over US \$200 million raised
- Support ~ 200 FTE worldwide and 35 FTE in-house



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Our Mission

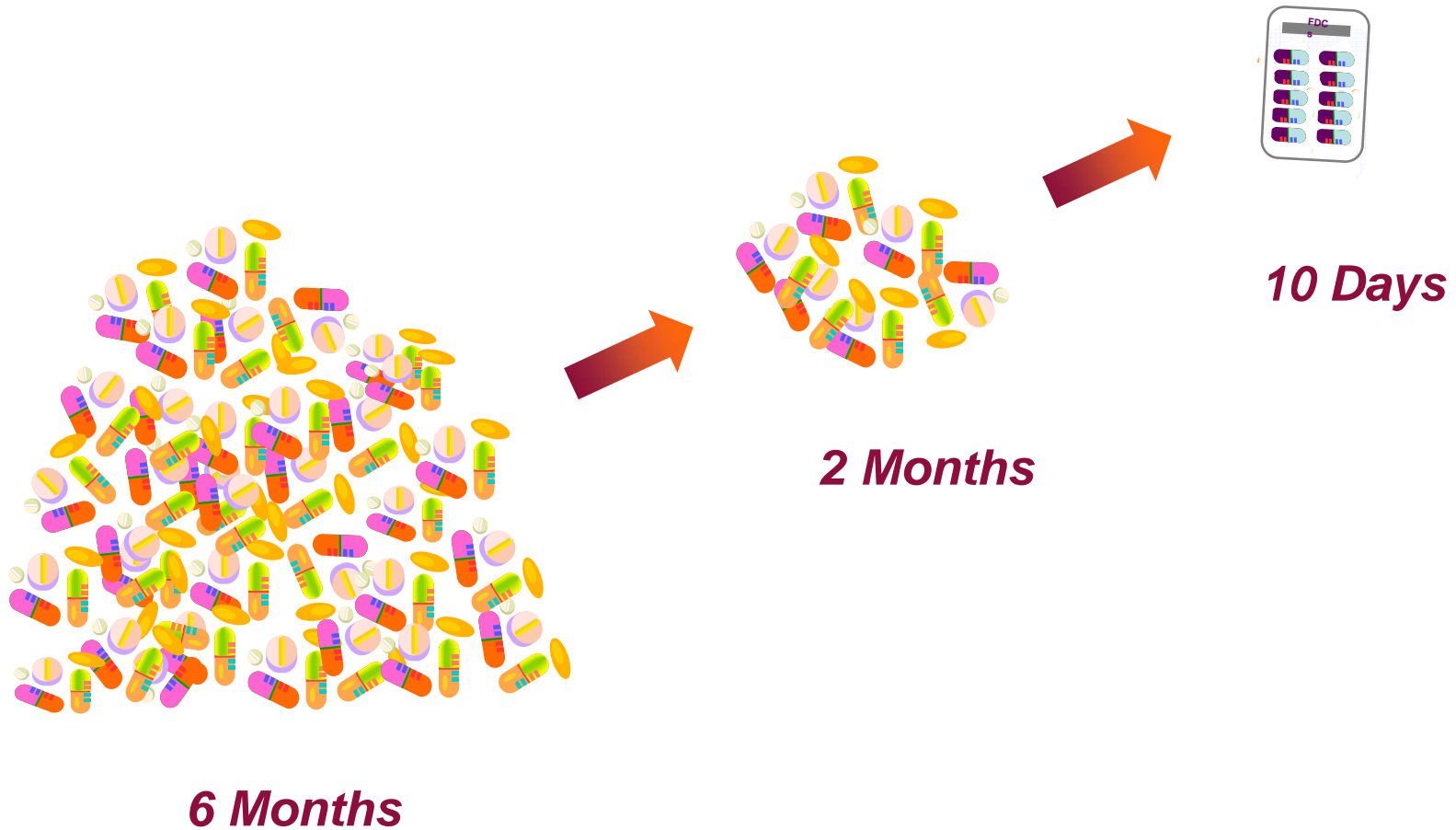
- Develop an entirely new therapeutic regimen that will shorten or simplify the treatment of tuberculosis
- Coordinate and act as catalyst for global TB drug development activities
- Ensure Affordability, Adoption and Access (AAA Strategy)



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Our Vision



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Profile of a New TB Drug

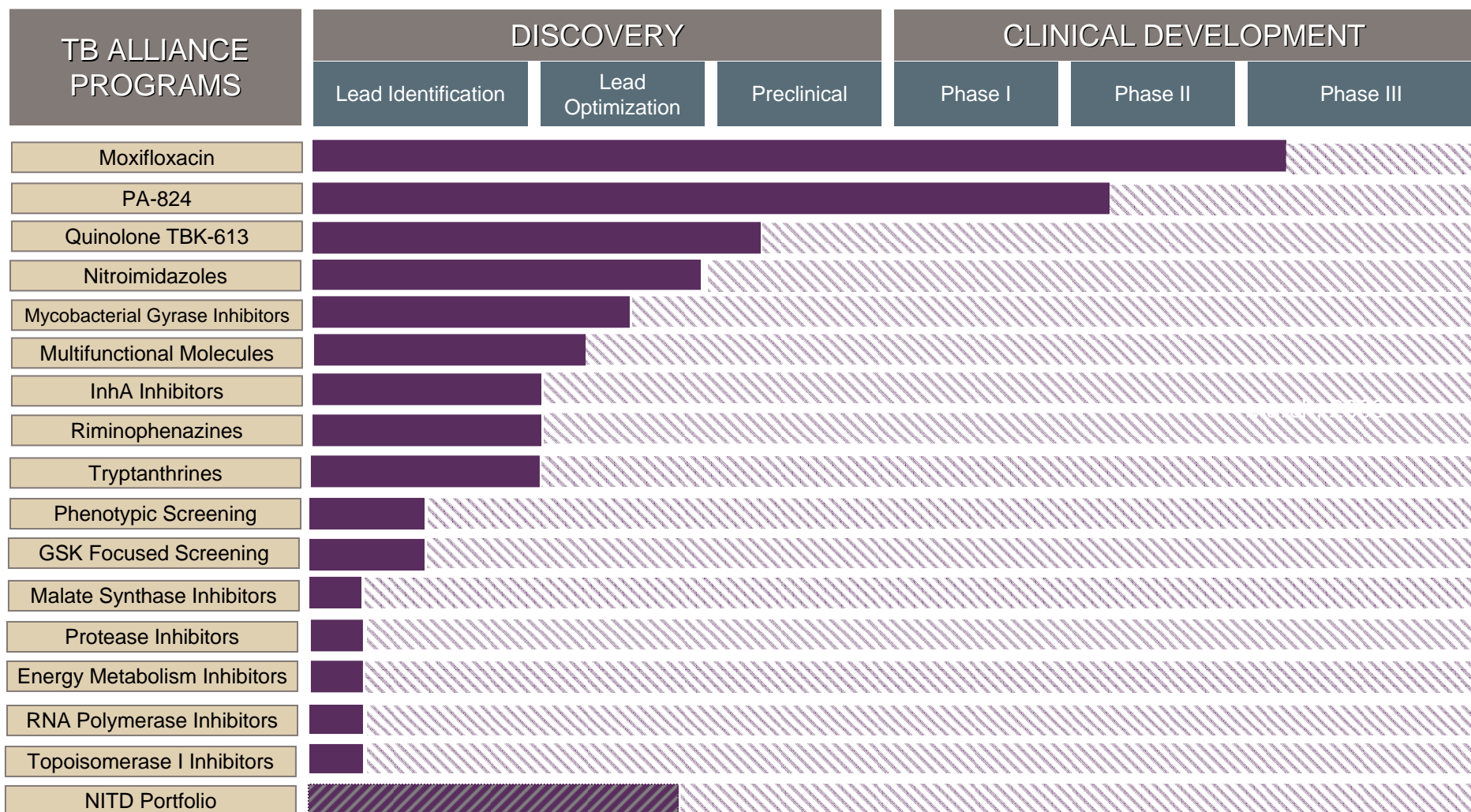
- Shorten treatment to less than 2 months
- Novel mechanism of action (MDR/XDR-TB)
- Orally active
- Once daily or intermittent therapy
- Compatible with HIV treatment
- Low cost of goods



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TB Alliance Portfolio



Chiron/Novartis

- PA-824 – novel nitroimidazole
- Discovered by Pathogenesis, Inc.
- Distinct mechanism of action
- Potent activity against both active and slow growing *M.tb.*
- Possesses both bactericidal and sterilizing activity



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PA-824

- Worldwide exclusive license in 2002 for the treatment of tuberculosis
- Defined scientific milestones
- Grant-back option
- Manufacturing rights
- No royalties in endemic countries
- Presently in Phase II clinical trials



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Bayer HealthCare

- Moxifloxacin - fluoroquinolone antibiotic
- Orally active
- Once-a-day dosage
- Marketed in 141 countries for the treatment of several acute respiratory and uncomplicated skin and soft tissue infections
- Novel mechanism of action against tuberculosis by inhibition of DNA gyrase



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The Partnership

- Clinically assess the efficacy and safety of moxifloxacin as a front-line agent for the treatment of TB
- Trials to be run in Brazil, Canada, South Africa, Spain, Tanzania, Uganda, the United States and Zambia
- More than 3,000 TB patients will be enrolled
- If successful, register moxifloxacin for a TB indication



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Bayer Commitments

- Donate moxifloxacin for each clinical trial site
- Cover costs of regulatory filings
- Provide moxifloxacin at an affordable price for patients with TB in the developing world



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