U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research

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AAM GRX+BIOSIMS CONFERENCE

Streamlining Biosimilars Development

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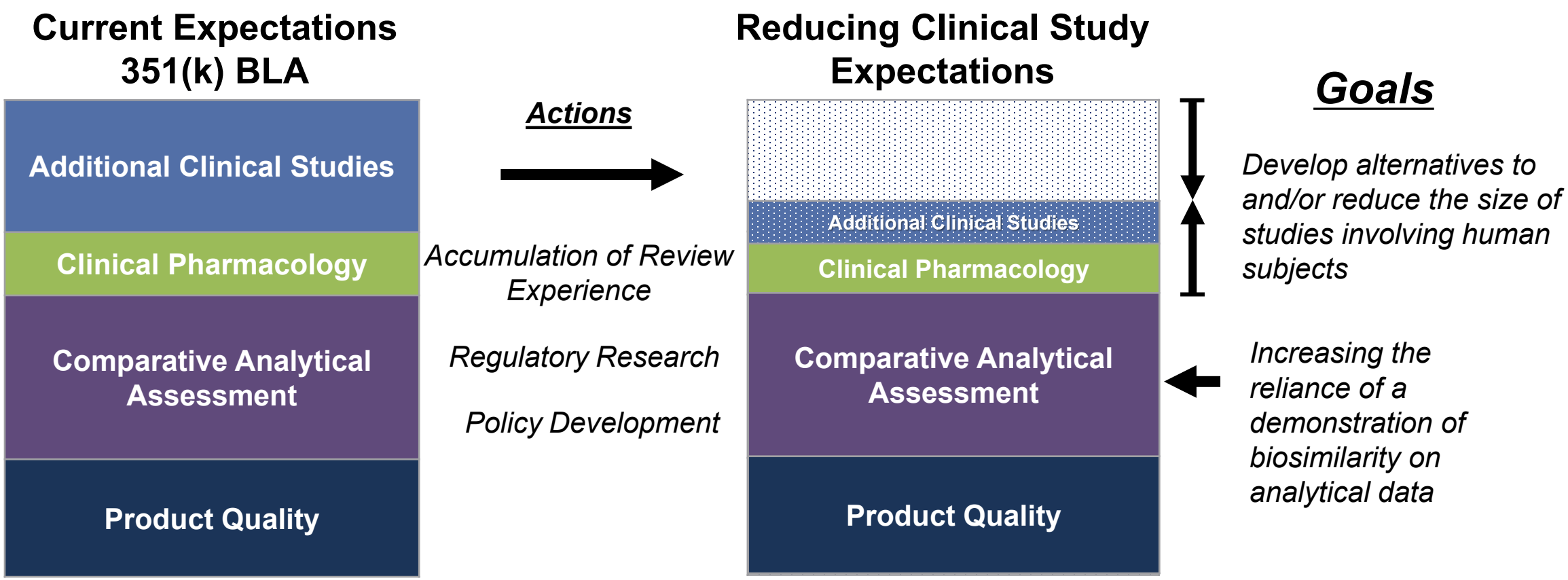
Improving Efficiency of Biosimilar Development



Reaching our Goals

- 60 Approved Biosimilars to 17 Reference Products, including: mAbs, fusion proteins, growth factors, insulins

- Conduct scientific and regulatory research projects
- Publish results and provide education

- Engage internal and external stakeholders
- Communicate new/revised recommendations

What's on the horizon?

1. Increase confidence in comparative analytical data

- Conduct research

Research Priority A: Characterize relationships between product quality attributes with clinical performance

- *Landscape Assessment of Biosimilar Submissions*

- Develop and provide more detailed educational materials and disseminate broadly
  - Who?
    - FDA staff, health care providers, patients, caregivers, advocates, payors, other government agencies
  - How?
    - Webinars, professional conferences, college degree curriculum, Medscape CE Courses, targeted presentations, social media engagement

FDA/Global Efforts to Streamline Biosimilar Development

2. Refine clinical study expectations

- Recordings and slides from the public meeting days available at **FDA.Gov** (link)
- Workshop Summary Report including from regulators only sessions available at **IPRP.global** (link)

Summary

First event of its kind to convene both global regulators and public speakers on this topic

- *Public sessions:*
  - *Utility and limitations of CES*
  - *Biosimilar development challenges*
- *Regulators only sessions:*
  - *Jurisdiction survey and current perspectives*
  - *Risk-based considerations for when a CES is/is not useful*
  - *Next steps for BWG*

IPRP BWG Workshop

- ## Selected Key Takeaways
  - Both regulators and industry recognize limitations of CES
  - Conservative approach historically taken due to timing of stepwise approach
  - CES cannot resolve concerns that remain due to uncertainty about analytical or PK data
  - PK comparison is more sensitive than a CES to detect product quality differences
  - A variety of risk-factors may contribute to CES expectations
    - Limited experience with product type
    - Vulnerable or rare patient population
    - Immunogenicity concerns

- ## Current and Future Steps

1) Refine concepts (e.g., risk-based framework) for determining whether a comparative efficacy study would be helpful pre-approval
   - Based on characteristics of the Reference Product, including:
     - how well characterized and predictable are product quality attributes
     - how susceptible efficacy/safety might be if those are altered
   - Doesn't require stepwise approach (presumes high analytical similarity will be met for approval)

2) Draft and publish a concept paper on the topic

What's on the horizon?

- IPRP BWG Concept Paper on a framework for evaluating the need/utility of CES to support biosimilar approvals
- CDER Guidance Agenda (July 2024)
  - Considerations in Demonstrating Interchangeability with a Reference Product: Update (Published June 2024)
  - Scientific Considerations in Demonstrating Biosimilarity guidance (Revision 1)

Thank You

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