Generics for Long-Acting Injectables: Building a Pathway to Success

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Why are Generics for Long-Acting Injectables (LAI) Complicated?

- An in vivo release controlling mechanism that needs to work for months
  - Limited predictive in vitro methods for product development
- Pharmacokinetic bioequivalence studies often need patients and take months to years
- Importance of understanding and characterizing the polymeric materials

GDUFA Tools for Generic LAI

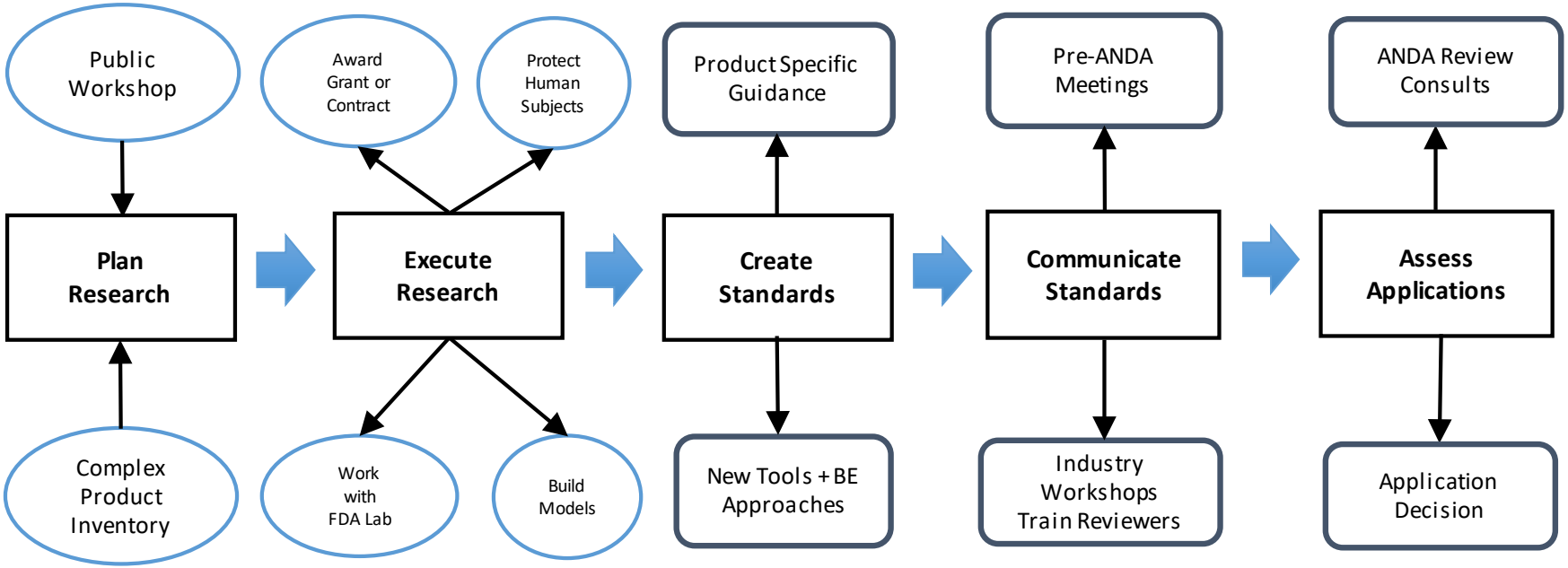
- Problem
  - Limited generic competition in the LAI space
- Solution
  - GDUFA support for scientific tools
    - Research program
  - GDUFA support for regulatory tools
    - Product specific guidance, pre-ANDA meetings

GDUFA: Generic Drug User Fee Amendments Commitment letter: https://www.fda.gov/media/101052/download

Product Specific Guidance for Generic Drug Development: https://www.accessdata.fda.gov/scripts/cder/psg/

Pre-ANDA (abbreviated new drug application) meeting guidance: https://www.fda.gov/media/107626/download

Office of Research and Standards Operational Model



The Office of Research and Standards (ORS) is a multidisciplinary **Office** that plans and conducts **Research** and translates the results into generic drug **Standards**

GDUFA Research Investment in LAI

- Research began in 2013
  - Focus: in vitro to in vivo correlations
  - Focus: polymer characterization
  - Focus: modeling and simulation for both the formulation and pharmacokinetic studies
- FDA staff and many of our collaborators will be speaking today

Research Outcomes

- See GDUFA research reports on LAI
  - https://www.fda.gov/drugs/generic-drugs/generic-drugs-guidances-reports
- More than 20 publications
- More than 80 posters/presentations at scientific meetings
- 12 Product Specific Guidances for LAI
- 24 pre-ANDA meetings on LAI

Keys to Success for Complex Generics

- Why is the reference product (RLD) complex?
- What is the scientific and regulatory landscape
  - Guidances and Citizen Petitions
- Pay attention to the science
- Use the pre-ANDA program
- Monitor changes in the RLD and the regulatory landscape during ANDA review
  - Be mindful of standard “simpler” issues such as Q1Q2 that impact ANDA development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