

Day 2: Welcome!

Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches

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GDUFA Science and Research

GDUFA II's pre-abbreviated new drug application (pre-ANDA) [program](#) supports development of complex generic drug products by:

Addressing complex scientific issues for PSG development

Communicating with applicants (pre-ANDA meetings) to help clarify regulatory expectations for prospective applicants early in the development cycle

Reducing time in the pipeline from concept to development to market by helping applicants develop more complete application submissions

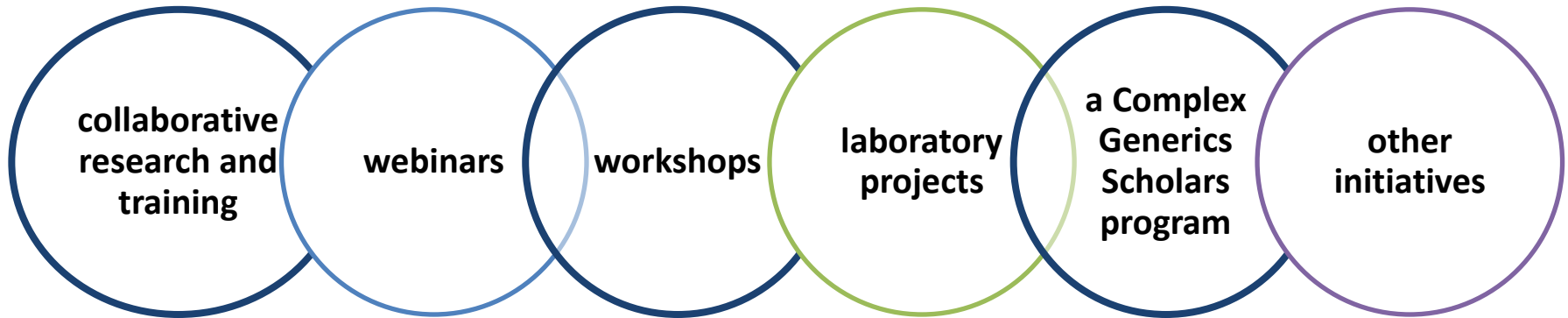


Innovative Methods

- Model-supported bioequivalence recommendations
- Model-integrated evidence
- Novel quantitative tools
- Model-assisted global harmonization efforts

Center for Research on Complex Generics

Enhancing research collaborations with industry through:





Thank you!



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