

SUMMARY PAGE

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TITLE OF RCA: Project PRISM (PrecisionFDA Regulatory Information Service Module)

FDA Component: Center for Biologics Evaluation and Research (CBER);
Center for Drug Evaluation and Research (CDER); Office of
Digital Transformation (ODT)

FDA Principal Investigators:

CBER: Virginia Hussong, Mark Gray, Ronald Fitzmartin

CDER: Chao (Ethan) Chen, Jesse Anderson

ODT: Elaine Johanson

Collaborator: Bayer AG and Boehringer Ingelheim International GmbH

Collaborator Principal Investigator: Vada Perkins

TERM OF RCA: Three (3) years from the Effective Date

ABSTRACT OF THE RESEARCH PLAN:

This research collaboration will demonstrate the feasibility of interactive and collaborative regulatory and scientific review, as well as submission validation utilizing FDA's production regulatory cloud platform, known as PrecisionFDA. The project will utilize actual regulatory data suitable for submission to the FDA, as well as third-party tools that FDA currently uses, i.e., for eCTD (electronic Common Technical Document) and study data review / validation. However, no submissions or activities involved in this plan take the place of an official regulatory submission and/or review process.

Practical, real-world use cases will test the essential functions of collaborative review, receipt and archive of information against current solutions, utilizing novel regulatory and scientific tools and technologies that will enable enhanced sponsor/health authority interactions. Exchange and use of large submissions will be evaluated, a challenge that continues to grow. The collaborators are expected to gain important foundational insights into cloud-based regulatory and scientific solutions and processes that can improve the submission, review and ease of communications for human drug and biologics applications to FDA.

Results, findings and recommendations will be published after each phase, and can be utilized by external stakeholders and global regulatory health authorities to leverage regulatory and scientific platforms and processes that achieve greater efficiencies on a regional and international scale.

