

Evidentiary Considerations for Integration of Biomarkers in Drug Development Symposium

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On August 21st, the University of Maryland's Center of Excellence in Regulatory Science and Innovation (M-CERSI), the U.S Food and Drug Administration (FDA), and the Critical Path Institute co-sponsored a symposium titled "Evidentiary Considerations for Integration of Biomarkers in Drug Development" at the University of Maryland School of Pharmacy.

The **objective** of the symposium was to begin to define and ultimately codify the scientific and regulatory expectations for the qualification of biomarkers.

Two types of biomarker were discussed:

- Safety biomarkers
- Biomarkers used for trial enrichment

The symposium format was designed to elicit participant feedback on defining evidentiary standards based on hypothetical biomarker qualification projects with varying contexts of use.

The one-day symposium brought together leading scientists and researchers from industry, academia, and the FDA, and provided a unique opportunity for participants to gain a greater perspective on biomarker development and application of biomarkers in preclinical and clinical research. Topics covered included:

- An overview of biomarkers in drug development
- Biomarker qualification
- Evidentiary considerations for biomarker utilization in drug development

[Tom Benthin](#) summarized the sessions graphically during the Symposium and you may view these images [here](#).

Proceedings from the symposium are available [here](#).

Presentations

Agenda	Presentation Videos
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Introduction:

- Welcome – Dr. James Polli and Dr. Natalie D. Eddington
- Keynote Address – Dr. Janet Woodcock



Session 1: Overview of Biomarkers in Drug Development (Chair: Dr. Shashi Amur)

- [FDA's efforts to encourage biomarker development and qualification](#) – **Dr. Shashi Amur**
- [Evidentiary considerations for integration of biomarkers in drug development: Statistical considerations](#) – **Dr. Aloka Chakravarty**
- [Assay validation and reproducibility considerations for biomarkers used in drug development](#) – **Dr. Lisa McShane**



Session 2: Evidentiary Considerations for Clinical Safety Biomarkers (Chair: Dr. John-Michael Sauer)

- [Mechanisms of drug toxicity and relevance to pharmaceutical development](#) – **Dr. Fred Peter Guengerich**
- [A Case Study – Clinical Safety Biomarkers – including methodological considerations](#) – **Dr. John-Michael Sauer**
- [Statistical considerations for clinical safety biomarkers](#) – **Dr. Robin Mogg**



Session 3: Evidentiary Considerations for Biomarker-Based Enrichment of Clinical Study Populations to Increase Efficacy or Safety of Drugs (Chairs: Dr. Klaus Romero and Dr. Arlene Chapman)

- [Biomarker-based Enrichment of Clinical Study Populations](#) – **Dr. Scott Patterson**
- [Neuroimaging Enrichment Biomarkers for CNS Diseases](#) – **Dr. Adam Schwarz**
- [Case Study: Polycystic Kidney Disease – From Bench to Bedside](#) – **Dr. Arlene Chapman**
- [Statistical Considerations for BQ for Biomarker-based Enrichment in Clinical Studies](#) – **Dr. Suzanne Hendrix**



