Regulatory Panel Session

DDT-KD Consortium

"What are the Regulatory Challenges and Needs?"

Moderator:

Dr. Aliza Thompson (FDA)

Panelists:

Dr. Norman Stockbridge (FDA)

Dr. Shashi Amur (FDA)

Dr. Ameeta Parekh (FDA)

Dr. Thorsten Vetter (EMA)

What are the Regulatory Challenges and Needs?

DDT-KD Consortium

1. Evidentiary standards for biomarker qualification- What are they? What should they be?

2. Timelines for biomarker qualification- Why does it take so long to qualify a biomarker? Is Consortium “burn out” an issue and if so, how have we tried to address it?

3. Resource constraints- How should we decide which biomarker submissions to accept? Should we be devoting resources to qualifying prognostic biomarkers?

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