

# Today's Meeting Agenda

Time	Description	Presenter
8:00 am	Breakfast	
8:30 am	<b>Welcome, Introduction, and Meeting Objectives</b>	Dr. Chirag Parikh
	NIH sponsored Consortium Studies and NIH Vision	Dr. Robert Star
8:50 am	<b>C-Path Overview &amp; Success Stories</b>	Dr. Martha Brumfield
9:20 am	FDA Perspectives	Dr. ShaAvhrée Buckman-Garner
9:30 am	<b>Objectives for the Consortium</b>	Dr. Kumar Sharma
9:45 am	Break	
10:00 am	FDA Qualification Process	Dr. Shashi Amur
10:20 am	EMA Novel Methodology Procedures	Dr. Thorsten Vetter
10:35 am	Panel Discussion: <i>What are the Challenges and Needs of Industry?</i> Moderator – John-Michael Sauer	Dr. Gary Friedman Dr. Dennis Address Dr. Irene Nunes Dr. Frank Czerwiec
11:35 am	Lunch	
12:35 pm	Panel Discussion: <i>What are the Regulatory Challenges and Needs?</i> Moderator – Aliza Thompson	Dr. Norman Stockbridge Dr. Shashi Amur Dr. Ameeta Parekh Dr. Thorsten Vetter
1:35 pm	Panel Discussion: <i>Academic Insights for Biomarker Priorities and Candidate Pilot Project(s)</i> Moderators – Chirag Parikh and Kumar Sharma	Dr. Joseph Bonventre Dr. Paul Palevsky Dr. Hiddo J. Lambers Heerspink Dr. Ronald Perrone
2:35 pm	Break	
2:50 pm	The Nuts and Bolts of Forming a Consortium	Steve Broadbent
3:20 pm	Summary and Conclusion	Dr. Jonathan Himmelfarb

- Bring together many stakeholders to identify biomarker needs for the field of kidney disease
- Needs of industry
- Guidance from FDA/EMA
- Goals for the academic nephrology community/NIDDK
- Initial steps forward