



U.S. Food and Drug Administration

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**Measurement in Clinical Trials: Review and Qualification of  
Clinical Outcome Assessments; Public Workshop  
October 19, 2011—White Oak, MD**

## Agenda

Welcome and House-keeping Considerations	5 min	Co-Chairs: <b>Laurie Burke, Marc Walton</b>	8:30 am 8:35 am
Introduction: Why Good Measurement Principles Matter	20 min	CDER perspective, measurement, and public-private partnerships; <b>Janet Woodcock</b>	8:35 am 8:55 am
Session 1: Nomenclature and Measurement	2 min 30 min 20 min 20 min 15 min	Chair: <b>Laurie Burke</b> Nomenclature for clinical outcome assessments; <b>Marc Walton</b> Endpoints to address treatment benefit including replacement endpoints; <b>Thomas Fleming</b> Panel discussion: John Alexander, Julie Beitz, Edward Cox, Sharon Hertz, John Jenkins, Lisa Kammerman, Elektra Papadopoulos, Anne Pariser, Bob Rappaport, Robert Temple, Ellis Unger, Maria Isaac, Todd Edwards, Thomas Fleming, Jeremy Hobart, Nathaniel Katz, Nancy Kline Leidy, John Powers Open floor discussion	9:00 am 10:30 am
BREAK	15 min		10:30 am 10:45 am
Session 2: Context of Use	2 min 10 min 30 min 15 min 15 min	Chair: <b>Marc Walton</b> Clinical trial outcome assessment review: Concept definition and context of use; <b>Laurie Burke</b> Importance of context during COA qualification; <b>John Powers</b> Panel discussion: Julie Beitz, Edward Cox, Sharon Hertz, John Jenkins, Lisa Kammerman, Elektra Papadopoulos, Anne Pariser, Mary Parks, Bob Rappaport, Robert Temple, Joseph Toerner, Ellis Unger, Maria Isaac, Todd Edwards, Thomas Fleming, Jeremy Hobart, Nathaniel Katz, Nancy Kline Leidy, John Powers Open floor discussion	10:45 am 12:00 am

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LUNCH	45 min		12:00 pm 12:45 pm
Session 3: Content Validity, Reliability and Variability	2 min	Chair: <b>Marc Walton</b>	12:45 pm 2:45 pm
	30 min	Content validity: Important measurement principles for PROs and extension to ClinRO and ObsRO; <b>Jeremy Hobart</b>	
	35 min	Reliability, validity and source of variability in measurement; <b>Nathaniel Katz</b>	
	25 min	Panel discussion: John Alexander, Julie Beitz, Sharon Hertz, Lisa Kammerman, Sandra Kweder, Elektra Papadopoulos, Anne Pariser, Richard Pazdur, Bob Rappaport, Joseph Toerner, Ellis Unger, Maria Isaac, Todd Edwards, Thomas Fleming, Jeremy Hobart, Nathaniel Katz, Nancy Kline Leidy, John Powers	
	25 min	Open floor discussion	
BREAK	15 min		2:45 pm 3:00 pm
Session 4: Measure Development in Pediatrics and Rare Diseases	2 min	Chair: <b>Laurie Burke</b>	3:00 pm 4:00 pm
	15 min	Patient- and observer-reported measurement in pediatrics; <b>Todd Edwards</b>	
	15 min	Measurement issues in rare diseases; <b>Nancy Klein Leidy</b>	
	15 min	Panel discussion: John Alexander, Sharon Hertz, Lisa Kammerman, Sandra Kweder, Elektra Papadopoulos, Anne Pariser, Richard Pazdur, Tassinari Melissa, Joseph Toerner, Ellis Unger, Maria Isaac, Todd Edwards, Thomas Fleming, Jeremy Hobart, Nathaniel Katz, Nancy Kline Leidy, John Powers	
	10 min	Open floor discussion	

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<p>Session 5: Collaborative Processes for COA Development and Dissemination</p>	<p>35 min</p>	<p>Chair: <b>Marc Walton</b> Overview of partnerships for COA qualification CDER's public-private partnership programs; <b>ShaAvhree Buckman</b> FDA's public-public partnership with NIH; <b>Rochelle Fink</b> CDER's partnership with FLU-PRO; <b>John Powers</b> CDER's partnership with the Foundation for NIH; <b>David Wholley</b> CDER's partnership with the Critical Path Institute PRO Consortium; <b>Stephen Coons</b> CDER's partnership with EXACT-PRO; <b>Nancy Kline Leidy</b> CDER's partnership with PROOF; <b>Patrick Marquis</b> FDA-EMA MOU interactions concerning COA qualification; <b>Maria Isaac</b></p>	<p>4:00 pm 4:45 pm</p>
	<p>10 min</p>	<p>Open floor discussion</p>	
<p>Wrap up</p>	<p>15 min</p>	<p>Co-Chairs: <b>Laurie Burke, Marc Walton</b></p>	<p>4:45 pm 5:00 pm</p>