Complex In Vitro Model: Qualification Framework Public Workshop

Critical Path Institute's Predictive Safety Testing Consortium hosted a public workshop on September 28-29, 2023 in Bethesda, Maryland with stakeholders from the U.S. Food and Drug Administration, academia, model developers, and the pharmaceutical industry to improve complex in vitro model (CIVM) development. Attendees discussed model standards and features that will enable the qualification of liver CIVMs for regulatory assessment. Sessions included Developing Contexts of Use, Analytical Considerations for establishing CIVM and system performance, and Biological Performance Considerations for CIVM with appropriate test compounds and biomarker endpoints. The final agenda, including links to presentation slides, is posted below.

Complex In Vitro Model (CIVM) Qualification Framework Public Workshop: Day 1

September 28, 2023: 9:00 AM – 5:00 PM EST

Topic	Summary	Speakers	Links
Welcome	Opening Remarks and Introductions	Nicholas King	Slides Video Recording
Keynote Address	Perspective on Translating New Drug Development Tools into Regulatory Use	David Strauss	Slides Video Recording
	Overview of Qualification and Application to CIVM	Jeffrey Siegel	Slides Video Recording
DILI and CIVM	Complex In Vitro Models for DILI – Challenges & Opportunities: A Clinical Hepatology Perspective	Mark Avigan	Slides Video Recording

Industry Clinical Perspective on DILI and CIVM Application	Eric Cohen	Slides Video Recording	
Break			
Session 1: Developing Contexts of Use			
Developing Contexts of Use	Developing Contexts of Use Introduction	Klaus Romero	Slides Video Recording
	CDER/PharmTox (PTOX) Perspective on Potential Contexts of Use (COU)	Nakissa Sadrieh	Slides Video Recording
	Model Developer Perspective on Contexts of Use and Their Addressability	Daniel Levner	Slides Video Recording
	Panel Discussion	Klaus Romero Daniel Levner Nakissa Sadrieh David Strauss Eric Cohen	Video Recording
Lunch Break			
Session 2: Analytical Considerations – Model Characterization and Validation of Performance			
Analytical Considerations	Session 2 Introduction	Graham Marsh	Video Recording
	Identifying Appropriate CIVM for a COU	Deidre Dalmas	Slides
	Validating Appropriate CIVM for COU: Regulatory Challenges	Kevin Ford	Slides Video Recording

	Panel Discussion	Graham Marsh Deidre Dalmas Stephen Hahn Kevin Ford Tomasz Kostrzewski	Video Recording
Break			
Session 3: Biological Considerations – Necessary Study Performance Attributes as Related to the Specified Context of Use			
Biological Considerations	Session 3 Introduction	Nicholas King	Video Recording
	Pharma Perspective on the Development of Context of Use (CoU) for Liver Complex In Vitro Models (CIVM)	Ravi Kodihalli	Slides Video Recording
	Biomarkers and Meaningful Endpoints: Perspective from an FDA Research Lab	Qiang Shi	Slides Video Recording
	Panel Discussion	Nicholas King Qiang Shi Donna Mendrick Ravi Kodihalli Jonathan Jackson	Video Recording
Closing Comments	Day 1 Summary	Graham Marsh	Video Recording
END OF DAY 1			

Complex In Vitro Model (CIVM) Qualification Framework Public Workshop: Day September 29, 2023: 9:00 AM – 3:00 PM EST		
Topic	**Summary**	**Speakers**
Welcome	Opening Remarks	Nicholas King
Keynote Address	Lessons Learned from Developing Credibility Assessment Framework and Contexts of Use for Computational Models	Tina Morrison
	A Clinical Reviewer's Perspective on CIVM for Drug Development	Paul Skip Hayash
Session 4: Breakout Sessions to Draft a Qualification Outline		
Breakout Session	Drafting a Qualification Outline Utilizing Sessions 1, 2 and 3	4 Groups led by: Klaus Romero, Graham Nicholas King, Katrina
Lunch Break		
Breakout Session Summary	Summary of Breakout Sessions	Klaus Romero, Graham Nicholas King, Katrina
Panel Discussion	Reflecting on Refined Contexts of Use	Klaus Romero Daniel Levner Nakissa Sadrieh David Strauss Eric Cohen
Closing Comments	Closing Remarks and Next Steps	Nicholas King
END OF WORKSHOP		