

## 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
<b>Welcome</b>	Opening Remarks and Introductions	Nicholas King	<a href="#">Slides</a> <a href="#">Video Recording</a>
<b>Keynote Address</b>	Perspective on Translating New Drug Development Tools into Regulatory Use	David Strauss	<a href="#">Slides</a> <a href="#">Video Recording</a>
	Overview of Qualification and Application to CIVM	Jeffrey Siegel	<a href="#">Slides</a> <a href="#">Video Recording</a>
<b>DILI and CIVM</b>	Complex In Vitro Models for DILI – Challenges & Opportunities: A Clinical Hepatology Perspective	Mark Avigan	<a href="#">Slides</a> <a href="#">Video Recording</a>

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

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

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

September 29, 2023: 9:00 AM – 3:00 PM EST

<b>Topic</b>	<b>Summary</b>	<b>Speakers</b>
<b>Welcome</b>	Opening Remarks	Nicholas King
<b>Keynote Address</b>	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
<b>Session 4: Breakout Sessions to Draft a Qualification Outline</b>		
<b>Breakout Session</b>	Drafting a Qualification Outline Utilizing Sessions 1, 2 and 3	4 Groups led by: Klaus Romero, Graham Nicholas King, Katrina
<b>Lunch Break</b>		
<b>Breakout Session Summary</b>	Summary of Breakout Sessions	Klaus Romero, Graham Nicholas King, Katrina
<b>Panel Discussion</b>	Reflecting on Refined Contexts of Use	Klaus Romero Daniel Levner Nakissa Sadrieh David Strauss Eric Cohen
<b>Closing Comments</b>	Closing Remarks and Next Steps	Nicholas King
<b>END OF WORKSHOP</b>		