2024 Complex In Vitro Model: Qualification Framework Public Workshop

Critical Path Institute's (C-Path) Predictive Safety Testing Consortium (PSTC) announced the second public workshop on evidentiary considerations for regulatory assessment and qualification of complex in vitro models (CIVMs). Building upon outputs from the first workshop held in September 2023, attendees included individuals from health authorities, academia, model developers, and the pharmaceutical industry. The workshop provided a platform for attendees to discuss and deliberate on the evidentiary considerations for regulatory assessment and qualification of complex in vitro models. Attendees worked towards achieving a consensus on the model standards and features to improve the performance of CIVMs as a tool for drug development and regulatory assessment.

The meeting included sessions from key opinion leaders on general considerations for qualification, as well as interactive breakout sessions focusing on specifics related to different organ systems and disease models. The breakout participants had the opportunity to engage in discussions and deliberations on the evidentiary considerations for regulatory assessment and qualification of complex in vitro models.

The public workshop was held on September 26 and 27, 2024 in Bethesda, Maryland at The Bethesdan Hotel (8120 Wisconsin Ave, Bethesda, MD 20814).

Click here to see speaker bios.

2024 Complex In Vitro Model (CIVM) Qualification Framework Public Workshop: Day 1

September 26, 2024: 9:00 AM – 5:30 PM EST

Session	Time	Length (min)	Topics	Presenters and Panelists	Link
Opening Remarks	9:00 AM	15	Welcome and Introduction (set stage)	Klaus Romero (C-Path)	Sess
Keynote Address	9:15 AM	30	FDA Perspective on Qualification (ISTAND)	York Tomita (US FDA – ODES/DBIRBD)	Sess
	9:45 AM	30	European Perspective on Qualification	Sonja Beken (Belgian Federal Agency for Medicines and Health Products (FAMHP))	Sess
Break	10:15 AM	15	Refreshment Break	—	
Session 1: Global Perspective and Discussion of Use	10:30 AM	10	C-Path Workshop #1	Graham Marsh (C-Path)	Sess
		10	Incorporation of New Approach Methodologies (NAMs) and/or Weight of Evidence (WoE) in guidance documents utilized by FDA/CDER: ICH-S5(R3) and ICH-S1B(R1) Addendum	Amy Avila (US FDA)	Sess
		10	EURL ECVAM Perspective on OoC Standardization and Qualification	Monica Piergiovanni (European Commission)	
		10	Standardization of MPS Engineering: Challenges and Opportunities	Darwin Reyes-Hernandez (NIST)	
		10	CEN CENELEC Standardization Document	Andries van der Meer (EuROocs)	Sess
		10	IQ MPS Qualification/Validation Perspective?	Rhiannon Hardwick (BMS)	Sess
		10	Japanese initiative for the proposal of an OECD Test Guideline: TG417 Toxicokinetics	Seiichi Ishida (NIHS)	Sess
	11:40 AM	45	Panel Discussion	Graham Marsh, Darwin Reyes-Hernandez, Klaus Romero, Session Speakers	Sess
Break (Lunch)	12:15 PM	90	Lunch	—	

Session 2: Applying Specific examples to broader application	1:45 PM	20	Lessons Learned in Precision Medicine	Mike Pacanowski (US FDA)	Sess
		20	Human on a chip system to enable regulatory submission for efficacy	James Hickman (Hesperos)	
		20	Qualification of a Human 3D Liver-on-Chip Model: Establishing a Cross-pharma trial to evaluate ADME and Toxicity Predictions in Pre-clinical Development	Andre Rodrigues (UCB)	
	2:45 PM	45	Panel Discussion – broad takeaways and how can we use those learnings	Session Speakers + Nakissa Sadrieh (US FDA) + Julie Frearson (Charles River) + Deidre Dalmas	Sess
Break	3:30 PM	15	Break	—	
Session 3: Context of Use	3:45 PM	10	Translational Centers for Microphysiological Systems (TraCe MPS) – Qualifying MPS as Drug Development Tools (DDTs)	Passley Hargrove-Grimes (NIH/NCATS)	Sess
		10	TraCe MPS Drug Development Tools for Pregnancy and Women's Health	Ramkumar Menon (University of Texas)	Sess
		10	University of Rochester and Duke University: Barrier MPS	Jim McGrath (University of Rochester)	Sess
		10	University of Pittsburgh: Patient-derived Biometric Liver MPS	Mark Schurdak (University of Pittsburgh)	Sess
		10	University of Washington and Mount Sinai School of Medicine: Kidney MPS	Jonathan Himmelfarb (Mount Sinai)	Sess

4:45 PM	45	Panel Discussion – COU discussion and critiques, unmet regulatory need	Passley Hargrove-Grimes (NIH/NCATS), Dmitriy Krepkiy (NIH/NCATS), Ivan Rusyn (Texas A&M University), Ramkumar Menon, Jim McGrath, Joan Adamo, Mark Schurdak, Jonathan Himmelfarb, Mary McElroy (Charles River), Vanitha Sekar (US FDA), Rodney Rouse (US FDA)	Session Recording	
Closing Remarks	5:30 PM	15	Day 1 Summary and Thanks	Nicholas King (C-Path)	

Complex In Vitro Model (CIVM) Qualification Framework Public Workshop: Day 2
September 27, 2024: 9:00 AM – 2:10 PM EST

Session	Time	Length (min)	Topics	Presenters and Panelists	Links
Opening Remarks	9:00 AM	10	Welcome	Graham Marsh (C-Path)	Session Recording
Keynote Address	9:10 AM	20	Perspective on Translating New Drug Development Tools into Regulatory Use	David Strauss (US FDA)	Session Recording
	9:30 AM	15	General evidentiary considerations	Ksenia Blinova (US FDA)	Session Recording Slides
Session 4: Breakout Sessions	9:45 AM	15	Breakout session structure and goals	Graham Marsh	
	10:00 AM	30	Breakout session assignments / coffee break	—	

10:30 AM	60	Cardiac	Ivan Rusyn (Texas A&M University) Jordan Pomeroy (US FDA) Natalie Simpson (US FDA)	Session Recording	
		GI / Gut	Tomasz Kostrzewski (CN-Bio) Kevin Ford (US FDA)	Session Recording	
		Kidney	Deidre Dalmas Aliza Thompson (US FDA)		
		Neuro	Pelin Candarlioglu (Vivodyne) Amy Avila (US FDA)		
		Disease Modeling	Tyna Dao (US FDA) James Hickman (Hesperos)	Session Recording	
Break (Lunch)	11:30 AM	90	Lunch	—	
Session 4: Breakout Sessions	1:00 PM	90	Post-Lunch breakout session wrap up (5 breakouts)		
	2:30 PM	50	Breakout Session Recaps	Breakout session facilitators (5)	Session Recording
Closing and Meeting Summary	3:20 PM	15	Closing and Next Steps	Nicholas King	