

PSTC 15-year Anniversary Webinar Series



2021 Webinar Series

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Join scientists from PSTC member companies, health authorities and other key opinion leaders during the PSTC 15-year Anniversary Webinar Series where they will share information about collaborative cutting-edge science taking place within the consortium's working groups and engage in discussion on the complexities and opportunities surrounding safety biomarkers and biomarker qualification.

Each webinar in the series will include pre-recorded presentations available to attendees for two weeks prior to the webinar event date. The webinar will then begin with a short summary of the presentations, followed by a live panel discussion comprised of the presenters, PSTC and C-Path members and staff, regulatory agency representatives and others.

The webinars are open to all who have an interest in translational and safety sciences, including PSTC member companies, industry, consortia, academic scientists, and health authorities. A list of these webinars is provided below.

May 26, 2021 – 10:00 AM US ET

Clinical Kidney Safety Biomarker, Composite Measure

Presenters and Panelists: Stefan Sultana, MD; Warren Glaab, PhD; Gary Friedman, MD, MS; Aliza Thompson, MD, MS; Steve Piccoli, PhD; and, John-Michael Sauer, PhD

C-Path's [Predictive Safety Testing Consortium](#) (PSTC) invites you to this free webinar, the first in its 15th anniversary educational webinar series, to explore the clinical kidney safety biomarker composite measure qualified by the U.S. Food and Drug Administration in 2018 to aid drug developers in detecting kidney

tubular injury in phase 1 clinical trials. Pre-recorded presentations will provide an overview of the biomarker, discuss how the biomarker is applied during drug development, explore case examples from recent studies, and offer insights into emerging and future work in kidney safety biomarkers. On May 26 at 10:00 AM US EDT, presenters and panel members will engage in real-time discussion about clinical kidney safety biomarkers, the role of these biomarkers in drug development, and the regulatory impact of biomarker qualification. Ample time will be provided for attendees to ask questions and engage in discussion.

Presentation	Speakers
Introduction to Urinary Kidney Safety Biomarkers for the Detection of Drug-induced Kidney Injury	John-Michael Sauer , Critical Path Institute (C-Path)
PSTC—FNIH Composite MeasureRenal Tubular Injury Biomarker Panel for Phase 1 Studies	Stefan Sultana , AstraZeneca
Case Studies: AstraZeneca Case Studies: Multiple and Single ascending dose Phase 1 Studies Merck Co., Inc Case Study: Translational Kidney Safety Biomarkers for Drug Development	Stefan Sultana , AstraZeneca Warren Glaab , Merck Co., Inc.
Future Work to Advance Utilization of Biomarker Panels: Reaching Beyond Phase 1 Study Application	Gary Steven Friedman , Pfizer PSTC Representative
Q&A/Panel Discussion Live: May 26, 2021 10:00—11:30 am US ET	<u>Moderator:</u> John-Michael Sauer , C-Path <u>Panelists:</u> Aliza Thompson , U.S. FDA Stefan Sultana , AstraZeneca Warren Glaab , Merck Co., Inc. Gary Friedman , Pfizer Steven Piccoli , Sun Pharmaceutical Advanced Research Center

August 25, 2021 – 10:00 AM US ET **Alternative Solutions in Safety Assessment**

C-Path's [Predictive Safety Testing Consortium](#) (PSTC) invites you to this free webinar, the second in its 15th anniversary educational webinar series, to explore the use of alternative solutions in safety assessment in drug development, including microphysiological systems (MPS) and In Vitro models. Pre-recorded presentations will provide an overview of current alternatives being used throughout Industry, highlight how alternative solutions are being investigated for use within specific PSTC working group studies and collaborations, offer a regulatory perspective on these alternatives, and offer insights into emerging and future work in this area. Presenters and panel members will engage in real-time discussion about these alternative solutions, the role of these emerging alternative play in drug development decision making, and the

regulatory impact and future of alternative solutions such as MPS and various In Vitro models. Ample time will be provided for attendees to ask questions and engage in discussion.

Presentation	Speakers
<u>Application of Complex In Vitro Models in Discover and Development</u>	Deidre Dalmas , GlaxoSmithKline
<u>PSTC Nephrotoxicity Working Group in the in vitro space</u>	Lauren Lewis , Takeda
<u>Understanding the Utility of Complex In Vitro Models in Therapeutic Development</u>	Madhu Lal-Nag , US FDA
<u>Q&A/Panel Discussion</u>	<u>Moderator:</u>Nicholas King, C-Path <u>Panelists:</u> Deidre Dalmas, GlaxoSmithKline Shuyan Lu, Johnson & Johnson Warren Glaab, Merck Co., Inc. Keith Tanis, Merck Co., Inc. Lauren Lewis, Takeda Madhu Lal-Nag, U.S. FDA

November 3, 2021 – 10:00 AM US ET

Biomarkers of Effect: Safety Biomarkers as Disease Biomarkers

C-Path's [Predictive Safety Testing Consortium](#) (PSTC) invites you to this free webinar, the third in its 15th anniversary educational webinar series, to explore the use of safety biomarkers as disease and/or efficacy biomarkers. Pre-recorded presentations will provide an examples of safety biomarkers being explored as disease/efficacy biomarkers throughout Industry, the translational potential of safety biomarkers, and offer a regulatory perspective on the use of safety biomarkers in a translational approach. On November 3 at 10:00 AM US EDT, presenters and panel members will engage in real-time discussion about the expanded use of safety biomarkers, the role these biomarkers play in drug development decision making, and the regulatory impact and future of safety biomarkers. Ample time will be provided for attendees to ask questions and engage in discussion.

Presentation	Speakers
<u>Biomarkers of Effect: Defining the relationship of safety biomarkers and disease biomarkers with respect to biomarker qualification</u>	John-Michael Sauer , Critical Path Institute (C-Path)
<u>GLDH: A journey from biomarker qualification to improving medical care</u>	Jiri Aubrecht , Sarepta Therapeutics
<u>SKM biomarkers in drug-induced and disease-related muscle injury: Yesterday and Tomorrow</u>	Tanja Zabka , Genentech

<u>Biomarker Discovery: Detection of Injury, Recovery from Injury, to Response to Intervention</u>	Gary Steven Friedman , Pfizer PSTC Representative
<u>Q&A/Panel Discussion</u>	<u>Moderator:</u> Nicholas King, C-Path <u>Panelists:</u> John-Michael Sauer, C-Path Jiri Aubrecht, Sarepta Therapeutics Tanja Zabka, Genentech Ameeta Parekh, U.S. FDA Jeffrey Siegel, U.S. FDA Terina Martinez, C-Path Deidre Dalmas, GlaxoSmithKline Warren Glaab, Merck Co., Inc.

January 26, 2022 – 10:00 AM US ET

Collaboration Begets Innovation—PSTC relationships leading the way for collaborative work outside the consortium

[Registration: Click here to register for the PSTC Webinar Series](#)