

2026 BIOANALYSIS Symposium



IMMUNOLOGIX
LABORATORIES



October 1, 2026



08:00 AM - 07:00 PM



Le Méridien Boston, Cambridge

MEETING AGENDA

AGENDA	TOPIC	TIME
Registration and Continental Breakfast	Attendees are welcome to register and enjoy breakfast before the meeting begins	8:15 - 8:45 AM
Moderator Welcome and Intro Session One	Dr. Lauren Stevenson: <i>Context-of-Use-Driven Integrated Bioanalysis</i>	8:50 - 9:00 AM
Keynote	Dr. Leslie Gordon: <i>The Progerin Biomarker: Promise, Challenges, and the Journey to Cure Children with Progeria</i>	9:00 - 9:40 AM
Integrated Bioanalysis & Context of Use	Dr. Steven Piccoli: <i>Delivering Designer Diagnostics: Critically Crafting the Context of Use</i>	9:40 - 10:00 AM
Integrated Bioanalysis & Context of Use	Dr. John Canfield: <i>Context-of-use-Guided Development and Validation of a Transthyretin Immunoassay: A Framework for Biomarker Assay Design</i>	10:00 - 10:20 AM
Coffee Break	Attendees are welcome to enjoy coffee and tea during a short break until talks resume	10:20 - 10:35 AM
Integrated Bioanalysis & Context of Use	Dr. Devangi Mehta: <i>Rethinking immunogenicity: an integrated approach reveals the PK/PD impact of pre-existing and drug-sustaining ADA</i>	10:35 - 11:00 AM
Integrated Bioanalysis & Context of Use	Panel Discussion: <i>Context-of-Use and Integrated Analysis</i>	11:00 - 11:20 AM

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 AGENDA	 TOPIC	 TIME
Moderator Intro Session Two	Dr. Lauren Stevenson: <i>Risk Assessment and Shifting Paradigms</i>	11:20 - 11:30 AM
Risk Assessment and Shifting Paradigms	Dr. Vibha Jawa: <i>Evaluating Risk Profile of a Molecule Across the Therapeutic Development Lifecycle: Leveraging New Approach Methodologies from Discovery to Clinical Translation</i>	11:30 - 11:55 AM
Lunch Break	Attendees are invited to join us for a networking lunch	Noon - 1:00 PM
Risk Assessment and Shifting Paradigms	Dr. Mohsen Rajabi: <i>Clinical Relevance of Therapeutic Peptide Immunogenicity</i>	1:00 - 1: 25 PM
Risk Assessment and Shifting Paradigms	Dr. Michael Partridge: <i>Neither Fish nor Fowl: A New Paradigm for Immunogenicity Assessment and Bioanalysis of Oligonucleotide Therapeutics</i>	1:25 - 1:50 PM
Risk Assessment and Shifting Paradigms	Dr. Lauren Stevenson: <i>Fitting the purpose, not the paradigm - key considerations for COU-driven ADA biomarker assay validation</i>	1:50 - 2:05 PM
Risk Assessment and Shifting Paradigms	Panel Discussion: <i>Risk Assessment and Shifting Paradigms</i>	2:05 - 2:25 PM
Coffee Break	Attendees are welcome to enjoy coffee and tea during a short break until talks resume	2:25 - 2:40 PM

MEETING AGENDA

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Moderator Intro Session Three	Dr. Lauren Stevenson: <i>Regulatory Perspectives</i>	2:40 - 2:45 PM
Regulatory Perspectives	Dr. Chris Stebbins: <i>Advancing Beyond Standalone NAb Assays: Integrated Immunogenicity Assessment in Drug Development</i>	2:45 - 3:10 PM
Regulatory Perspectives	Dr. Susan Kirshner: <i>Host Cell Protein Risk Assessments to Identify and Mitigate Immunogenicity Risk of Therapeutic Protein Products</i>	3:10 - 3:35 PM
Regulatory Perspectives	Dr. Daniela Verthelyi: <i>Regulatory and Scientific perspectives on leveraging NAMs To Reduce and Replace Clinical Trial Requirements for Complex Generics and Biosimilars: A focus on Innate immune activation and inflammation</i>	3:35 - 4:00 PM
Regulatory Perspectives	Panel Discussion: <i>Regulatory Perspectives</i>	4:00 - 4:15 PM
All Sessions	Extended Panel Discussion: <i>All Speakers, All Topics</i>	4:15 - 5:00 PM
Networking Reception	Attendees are welcome to join us in the Rooftop Garden for a Networking Reception	5:00 - 7:00 PM