2025 BioSafe Annual Meeting
April 7 - 9, 2025
F. Hoffmann-La Roche
Basel, Switzerland

(All times in Central European Standard Time – GMT+1)

Monday, April 7		
12:00 PM	Registration	
12:45 PM	Host Welcome Message	TBD (Ulrike H.)
12:50 PM	BioSafe Annual Meeting Welcome & Opening Remarks	Sean Ottinger and Lori Aschenbrenner
1:00 PM	Overview of Proposed Task Force	Cam Holland
Session 1: Considerations for Immunosuppressive Drugs 1:15 – 3:15 PM Chairs: Andrea Kiessling (Novartis) & Oliver Thomas (Amgen)		
1:15 PM	Overview on Nonclinical Safety Assessment, Immunosuppression Profile and Opportunistic Infections of Iscalimab in Non-Human Primates	Tina Rubic (Novartis)
1:40 PM	"The Trouble with ICANS" … Clinical Safety Considerations for T-cell Engaging Therapies	Eva Rossman and Nick Flinn (Roche)
2:05 PM	Considerations for Immunological Assay Design When evaluating immunosuppressive molecules	Amanda Lucchini (Labcorp)
2:30 PM	Beyond MABEL: An integrative approach to first in human dose selection of immunomodulators by the Health and Environmental Sciences Institute (HESI) Immuno-Safety Technical Committee (ITC)	Ryan Polli (Novartis)*
2:55 PM	Panel Discussion Q&A	All Speakers
3:15 PM	Coffee Break	
Session 2: Decoding in-vitro Approaches to Off-target Safety Assessment 3:45 – 5:45 PM Chairs: Smita Salian-Mehta (Gilead) & Katy Fraser (Merck) & Leslie Bosseler (J&J)		
3:45 PM	Cell-based protein arrays for the selectivity evaluation of biological products	Axel Vicart (Novartis)
4:10 PM	Strategies for off-target assessment with non-host target molecules and retrospective case study examples	Smita Salian-Mehta (Gilead)
4:35 PM	Integrated Assessment of Polyreactivity and Polyspecificity for Biologics	Cam Holland (J&J)
5:00 PM	Panel Discussion and Audience Survey	All Speakers
Open Night		

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Tuesday, April 8		
7:45 AM	Breakfast	
Breakout Sessions & Networking 8:30 AM – 10 AM		
8:30 AM*	Option 1: Challenges for addressing off target binding for biologics: Alternatives to Tissue Cross Reactivity (TCR)	Cam Holland (JNJ) & Lori Aschenbrenner (Labcorp)
	Option 2: NHP use…less talk more action: Industry and FDA perspective	Wendy Freeburn (JNJ)
	Option 3: Review & Discussion of proposed 2025 FDA/BioSafe/DruSafe Meeting Topics	Sean Ottinger (Novartis)
	Option 4: Transgenic Mouse Models for Safety Testing	Josep Monne (Roche)
	Option 5: TBD	TBD
9:30 AM*	Networking @ Main Foyer	
10:10 AM	Coffee Break	
Session 3: Safety Strategies and Considerations for Gene Therapies 10:40 – 12:15 PM Chairs: Sarah Benjamin (J&J) & Amanda Lucchini (Labcorp)		
10:40 AM	Risk of vertical transmission in gene therapy products	Basel Assaf (Sanofi)
11:05 AM	Developing AAV-based ocular gene therapies: from practicalities to common toxicities	Helen Booler (Novartis)
11:30 AM	Considerations in development of CPTX2309: In vivo CAR-T via targeted lipid nanoparticle	Aric Frantz (Capstan)
11:55 AM	Panel Discussion Q&A	All Speakers
12:15 PM	Lunch	
Session 4: Oligonucleotides drugs – a new era 1:30 – 3:30 PM Chairs: Michaël Maes (J&J) & Helen Lightfoot (Roche)		
1:30 PM		Jen Sisler (Lilly)
1:55 PM		Lakshmi Raj (Novartis)
2:20 PM	Recommendations for the assessment of hybridization-dependent off-targets of antisense oligonucleotides (ASOs) and small interfering RNAs (siRNAs)	Jean-Christophe Hoflack (Roche)
2:45 PM	Opportunities for More Tailored Approaches to Genotoxicity Testing for Oligonucleotide Therapeutics: Outcome of an Industry Survey	Franziska-Regenass-Lechner (Roche)
3:15 PM	Coffee Break	

Session 5: Navigating Regulatory Pathways for Innovative Biologics 3:45 – 5:45 PM Chairs: Ulrike Hopfer (Roche) & Bindu Bennet (AstraZeneca)		
3:45 PM	Case study: Regulatory Interactions and Path to IND For a Novel Antibody-protein Conjugate	Aude Chefdeville (CRL) & Pia Kasperkovitz (BrightPeak)
4:10 PM	Nonclinical Perspectives on ATMPs and GMOs: Considerations for Global Regulatory Submissions	Jason Aligo (JNJ)*
4:35 PM	What is a relevant animal species and when to forgo NHP safety studies - Learnings from recent HA interactions with mAbs in Oncology	Sven Kronenberg (Roche)
5:00 PM	In Vitro-Only Approach to IND: Moving Beyond NHP Relevance	Gautham Rao (Genentech)
5:25 PM	Panel Discussion Q&A	All Speakers
6:00 PM	Reception	

Wednesday, April 9		
7:45 AM	Breakfast	
Session 8: 3Rs 8:15 – 10:1 AM Chairs: Sarah Gould (CRL) & Anna Bottomley (ToxStrategies)		
8:15 AM	Where Are We Today with the 3Rs	Sarah Gould (CRL)
	Virtual Control	Lars Mecklenburg (Labcorp)
		Adi Wasserkrug (JNJ)
		Franck Chanut (Sanofi)
9:05 AM	Virtual Control Panel Discussion	All Virtual Control Speakers
9:15 AM	*Species Selection*	
	Species Selection, Defining Relevance and What About Rabbits?	Sarah Gould (CRL)
	What Role Can Species Selection Play in the 3R's: Using Case Studies	Oliver Thomas (Amgen)
10:15 AM	Coffee Break	
10:30 AM	Readout from Break Sessions	Breakout Session Facilitators
11:30 AM	Update from Biosafe NAMs Task Force	Jacintha Shenton (Amgen)
11:50 AM	Closing Remarks	Sean Ottinger, Lori Aschenbrenner
12:00	**Feedback from General Membership and Closing Remarks**	

*Breakout Discussion Topics and Networking will only be available to in person attendees
*Virtual speakers