July 8-10, 2025 | Boston, MA

www.adc-toxicity.com

3rd Annual

adc Toxicity Summit

Preventing, Predicting & Mitigating ADC Toxicities

Improving Prediction & Translation of ADC Toxicities to Drive More Tolerable ADCs Successfully into & Through Clinical Development

Expert Speakers Include:

John Kwon
Associate Director
AstraZeneca

Anna Engstrom
Senior Principal Scientist & Toxicologist Safety Assessment
Genentech

Paolo Tarantino
Clinical Research Fellow
Dana-Farber Cancer Institute

Raymond Evers
Senior Director, Global Translational & Drug Metabolism Pharmacokinetics Sciences Lead
Johnson & Johnson

Ronnie Yeager
Project Director, Emerging Therapeutic Platforms
AbbVie

Zenta Tsuchihashi
Senior Director, Clinical Safety & Pharmacovigilance
Daiichi Sankyo

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Your Expert Speakers

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Andy Judd
Medicinal Chemist
AbbVie

Anna Engstrom
Senior Principal Scientist & Toxicologist Safety Assessment
Genentech

Brian Manning
Director, Business Development
28bio

Carole Harbison
Associate Scientific Fellow, Pathology
Takeda

Elia Segui
Research Fellow
Dana-Farber Cancer Institute

Grace Lytle
Executive Director, Ocular Medical
AbbVie

John Kwon
Associate Director
AstraZeneca

Julia Kristensson
Associate Director
Bicycle Therapeutics

Jutta Deckert
VP, Research & Development
Iksuda Therapeutics

Kristin Decker
Associate Director Pharmacology & Toxicology
Heidelberg Pharma

Neel Pasricha
Assistant Professor of Ophthalmology
University of California

Nicolas Quesnot
Senior Scientist, Preclinical Safety
Debiopharm

Paolo Tarantino
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Senior Director, Global Translational ADME, Translational PK/PD & Investigative Toxicology
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Ronnie Yeager
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AbbVie

Shashi Ramaiah
Preclinical, Translation & Biomarker Expert
Independent

Sonia Jain
Research Associate Radiation Oncology
Mayo Clinic

Steven Everett
Chief Executive Officer
MaveriX Oncology

Yu-Tzu Tai
Associate Director
Oxford Biotherapeutics

Zenta Tsuchihashi
Senior Director, Clinical Safety & Pharmacovigilance
Daiichi Sankyo

Pre-Conference Workshop Day
Tuesday, July 8, 2025

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Morning Coffee & Check In — 8.00

Workshop A — 9.00

Predicting & Mitigating Toxicities Associated With Current and Novel Payloads in ADC Development

As ADC development expands to new payload classes, understanding how to predict, minimize, and manage toxicity is critical for early-stage drug development.

This interactive workshop will provide hands-on discussions and case studies to help:

- Preview the current landscape of novel payloads in preclinical and clinical development
- Understand how novel payloads impact ADC toxicity? Exploring the mechanisms of emerging payload classes, including their on- and off-target toxicity risks
- Case Study: What can we learn from past ADC failures? – Reviewing clinical and preclinical toxicity data to identify early warning signals for payload-driven toxicities
- Interactive Discussion: What are the key challenges in predicting payload toxicities and how do we tailor the preclinical safety characterization for novel payloads?

Workshop Leaders

Anna Engstrom
Senior Principal Scientist & Toxicologist Safety Assessment
Genentech

Raymond Evers
Senior Director, Global Translational ADME, Translational PK/PD & Investigative Toxicology
Johnson & Johnson

Lunch Break — 12.00

Workshop B — 1.00

Rethinking Patient Selection for Addressing Unique Toxicity Challenges From ADC Therapy – Balancing Risk & Access

Current ADC trials often exclude high-risk patients due to concerns about toxicity - but is this the best approach? This session will explore how ADCs work and why they cause toxicity, how we can better predict and manage adverse events in the clinic (with a focus on breast cancer), and how new molecules may help overcome existing toxicity challenges. Rather than defaulting to exclusion, how can we move toward more personalized, risk-adapted ADC development?

Join this workshop to discuss topics such as:

Why Do ADCs Cause Toxicities? Mechanistic Insights

- Understanding the structure and function of ADCs and how payloads, linkers, and targets contribute to specific toxicity profiles.
- Tissue distribution, off-target effects, and class-related toxicities

Managing toxicity without eliminating patients from treatment

- Who is at higher risk of ADC toxicity? The role of clinical characteristics, pre-existing conditions, and predictive biomarkers. Example: Patients with pre-existing lung disease and ADC-induced interstitial lung disease (ILD)

Can we better manage ADC toxicity in the clinic?

- Risk mitigation strategies: pre-treatment, monitoring, dose adjustments
- Clinical management with a focus on breast cancer ADCs

Looking to the Future in ADC Development

- Are next-generation ADCs solving the toxicity problem - or just shifting it?
- How do we design ADCs with better tolerability while maintaining efficacy?
- Novel payloads, targets, and bispecific ADCs

Workshop Leaders

Paolo Tarantino
Clinical Research Fellow
Dana-Farber Cancer Institute

Elia Segui
Research Fellow
Dana-Farber Cancer Institute

End of Pre-Conference Workshop Day — 4.00

Scientific Program Day One
Wednesday, July 9, 2025

8.00 **Morning Coffee & Check-In**

Grace Lytle
Executive Director, Ocular Medical
AbbVie

8.55 **Chair's Opening Remarks**

Maximizing the Translational Relevance of *In Vivo* Studies to Better Understand & Mitigate Clinical Toxicities with ADCs

Jutta Deckert
VP, Research & Development
Iksuda Therapeutics

9.00 **Comparing Toxicity Tolerability From Payloads in Non-Human Primates & Humans to Understand the Translatability of the ADC Candidate**

- Reviewing toxicity across ADC platforms to identify recurring safety signals
- Comparing toxicities of different payload classes in NHPs versus humans to better assess translatability
- Exploring novel ADC design approaches to mitigate platform liabilities

Ronnie Yeager
Project Director, Emerging Therapeutic Platforms
AbbVie

9.30 **Implementing Rodent Models for ADC Payload Characterization to Support Discovery Screening & Inform on Pre-Clinical Species Relevance for Translation of Safety Profiles**

- Recapitulating clinically relevant ADC toxicity in an acute rodent IV infusion model for payloads to increase efficiency / reduce costs within discovery for payload screening
- Utilizing infusion models to better understand potential species-specific sensitivities to toxicities
- Giving Merit for infusion model to inform on anticipated ADC payload PK exposures respective of SOC / comparator drugs to aid in understanding potential risk benefit for an ADC approach

10.15 **Morning break & Speed Networking**

The ideal opportunity to get face-to-face with many of the brightest minds in ADC toxicity to engage with attendees for important in-depth conversations.

Bridging the Multidisciplinary Gap Between Clinic & Translational Studies to Improve the Prediction & Communication of ADC Toxicity & Create Safer Treatment Plans

Zenta Tsuchihashi
Senior Director, Clinical Safety & Pharmacovigilance
Daiichi Sankyo

11.00 **Exploring Predictive Biomarkers for Drug-Induced Pulmonary Toxicities – Enhertu Experience**

- Overviewing biomarkers for drug induced pulmonary toxicities
- Defining responsibility by discussing who should lead clinical sample-based translational research for safety?
- Addressing the gap between tox teams (preclinical) and clinical safety teams
- Case study: Interstitial lung disease (ILD) concerns in HER2-targeted ADCs – how are biomarkers in blood helping refine prediction and how can we monitor and treat ADC toxicities

Neel Pasricha
Assistant Professor of Ophthalmology
University of California

11.30 **New Multicenter Interspecialty Consensus on ADC Ocular Adverse Event Reporting to Improve Communication Between Eye Care Providers & Oncologists**

- Understanding the ocular toxicities from ADCs and what constitutes a severe ocular adverse event
- Addressing the challenges of quantitatively assessing ocular toxicities with the current terminology criteria for adverse events (CTCAE) by mixing eye signs and symptoms
- Using our learnings to standardize the grading scales of ocular toxicities to better communicate eye findings to oncologists to create a safer ADC treatment plan with less toxicity

Scientific Program Day One
Wednesday, July 9, 2025

12.00 **Safety Characterization & Risk Mitigation Using Translational Biomarkers for ADC Toxicity With Peripheral Neuropathy**

Shashi Ramaiah
Preclinical, Translation & Biomarker Expert
Independent

- Overviewing the current landscape of biomarkers and how they are applicable to ADC toxicities
- Introducing how precompetitive consortia will enable novel predictive tools for de-risking toxicities – using the European Union Innovative Health Initiative TransBioline as an example
- Exploring a case study to discuss neuro-biomarkers to de-risk peripheral neuropathy observed with ADC platforms
- Interactive discussion: What are the key areas that needs precompetitive biomarker tools and how do we develop novel screening tools?

12.30 **Lunch Break**

1.30 **Panel Discussion: Strengthening Cross-Disciplinary Collaboration to Improve ADC Toxicity Prediction & Management**

The lack of structured communication between translational teams, oncologists, and ophthalmologists creates a major barrier in ADC toxicity prediction and management. This panel will explore how to establish a collaborative care model that improves early detection, toxicity grading, and back-translation for ADC toxicities like ILD and ocular inflammation.

Discussion points include:

- How can we better educate clinical trial investigators to recognize and escalate ILD/ocular toxicities and what early intervention or prevention strategies can prevent discontinuations?
- How can we treat patients once the toxicities have been established? Can patients be re-challenged with ADC drugs following previous ADC associated toxicities?
- What can clinical specialists teach preclinical teams about improving ADC toxicity models and at what point of ADC treatment should each specialist be involved to achieve proactive toxicity mitigation?
- How can we design models that better reflect real-world toxicities in ocular, pulmonary, and systemic tissues and what are the safety/toxicity profiles that would be deemed acceptable success ADC drugs through to the clinic

Grace Lytle
Executive Director, Ocular Medical
AbbVie

Neel Pasricha
Assistant Professor of Ophthalmology
University of California

Zenta Tsuchihashi
Senior Director, Clinical Safety & Pharma-covigilance
Daiichi Sankyo

Yu-Tzu Tai
Associate Director
Oxford Biotherapeutics

2.30 **Afternoon Break & Poster Session**

This is an informal session to help you connect with your peers in a relaxed atmosphere and forge new and beneficial relationships. With an audience of ADC experts working in toxicology, pathology, preclinical development and translational sciences you will have the opportunity to display a poster presenting your work. Additionally, you have the chance to review others' posters displaying cutting-edge work from drug discovery right through to exciting clinical trial updates.

Addressing the Toxicity Challenges Associated With Dose Limiting Toxicities to Optimize Dosing Regimens With ADC Therapies

3.30 **Predicting & Mitigating Immune-Related Toxicities to Extend Clinical Dose Escalation With an Immune ADC (iADC)**

Carole Harbison
Associate Scientific Fellow, Pathology
Takeda

- Utilizing nonclinical data to facilitate safe iADC starting dose selection
- Leveraging reverse translation to evaluate mitigation strategies for observed toxicities
- Applying learnings to optimize efficacy and safety in the clinic

4.00 **Translating Toxicity Profiles of Amanitin-Based ADCs From Nonclinical Models to Clinical Studies & Leveraging the Knowledge to Guide Dose Optimization**

Kristin Decker
Associate Director Pharmacology & Toxicology
Heidelberg Pharma

- Examining how the nonclinical profile of HDP-101 can predict clinical safety and efficacy outcomes
- Comparing the PK and toxicity profile of amanitin-based ADCs between nonclinical models, predictive modelling and patients
- Exploring strategies to refine the pharmacokinetics and optimize the dosing regimens of HDP-101 to improve the therapeutic window

Grace Lytle
Executive Director, Ocular Medical
AbbVie

4.30 **Chair's Closing Remarks**

4.45 **End of Scientific Program Day One**

Scientific Program Day Two
Thursday, July 10, 2025

7.30 **Morning Coffee & Check-In**

Jutta Deckert
VP, Research & Development
Iksuda Therapeutics

8.25 **Chair's Opening Remarks**

Reviewing Current & Novel *In Vitro* & Pre-Clinical Models to Better Predict ADC Toxicity in the Clinic

John Kwon
Associate Director
AstraZeneca

8.30 **Overcoming the Limitations of *In Vitro* Models to Predict ADC Toxicity**

- Exploring why *in vitro* efficacy and *in vivo* toxicity results often fail to correlate by discussing the disconnect between cytotoxicity assays and whole-organ toxicity and identifying better biomarkers for *in vitro* screening
- Discussing whether 2D monocultures are sufficient for predicting ADC-induced off-target toxicity, bystander effects, and immune-related toxicities
- Understanding the role computational modelling and AI play in improving *in vitro* predictions - how can mathematical models integrate *in vitro* data to predict clinical toxicity outcomes?

Andy Judd
Medicinal Chemist
AbbVie

9.00 **Targeted Delivery of BCL-XL Selective Inhibitor Alleviates On-Target Toxicity of Systemically Dosed Inhibitors in Preclinical Models**

- Understanding how a pre-clinical mechanism-based cardiotoxicity of BCL-XL small molecule inhibitors led to the utilization of an antibody-targeted approach that has potential to differentiate from known platforms
- Reviewing the ADC approach manifested a novel BCL-XL toxicity in kidney
- Considering payload property modification contributed to establishing a TI suitable for clinical dosing

Sonia Jain
Research Associate
Radiation Oncology
Mayo Clinic

9.30 **Exploring How Advanced Human-Derived Pre-Clinical Systems Can Be Optimized for ADCs to Predict & Mitigate Toxicities**

- Examining the benefits of patient-derived xenograft (PDX) models in replicating tumor microenvironment-driven toxicity, specifically when developing neuronal cultures *in vitro* to evaluate the cytotoxicity index with the efficacy and on neurons
- Discussing the neuronal toxicities mediated by the bystander capable payload to manage the heterogeneity of Glioblastoma
- Evaluating the limitations of scalability, reproducibility, and long-term viability of patient-derived cell cultures for ADC toxicity testing

Brian Manning
Director, Business Development
28bio

10.00 **Rethinking Peripheral Neuropathy Models: A Human Approach to Preclinical Testing**

- Preclinical drug development often fails due to poor translation from animal models to human physiology.
- Peripheral neuropathy is difficult to assess using 2D cell cultures or animal models, as they fail to replicate 3D nerve structure and functional electrophysiology.
- To address this, 28bio developed PNS-3D technology, a human, complex in vitro organoid model designed for preclinical testing of disease-, medication-, and toxin-induced neuropathies.

10.15 **Morning Break & Speed Networking**

The ideal opportunity to get face-to-face with many of the brightest minds in ADC toxicity for important in-depth conversations.

Leveraging Your ADC Design to Minimize Toxicity Whilst Maintaining Efficacy

Jutta Deckert
VP, Research & Development
Iksuda Therapeutics

11.00 **Evaluating Emerging ADC Designs to Understand Their Impact on Safety Profiles – Where Are We Headed?**

- Reviewing new ADC designs and how they may lead to improved safety profiles such as reduced neutropenia and GI toxicities
- Discussing the challenges of preclinical to clinical translation of safety profiles - how can we design ADCs to be safer based on preclinical evaluation?
- Exploring how ADC design innovations will support future differentiation and improve clinical benefit in the future

Scientific Program Day Two
Thursday, July 10, 2025

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Raymond Evers
Senior Director, Global Translational ADME, Translational PK/PD & Investigative Toxicology
Johnson & Johnson

11.30 Leveraging ADME Characterization of Linker Payloads for ADCs to Minimize Toxicity

- Exploring the extent of what early ADME characterization of free payloads is relevant from a safety perspective
- Discussing what the key ADME properties contributing to developing a safe ADC payload are
- Diving into what the translatable assay platforms are to measure bystander effect

Steven Everett
Chief Executive Officer
MaveriX Oncology

12.00 Highlighting Emerging Linker Technologies That Optimize Payload Release & Clearance to Improve Safety Profiles

- How can we engineer linkers to control payload clearance and mitigate toxicity? – Understanding how modifying linker chemistry can influence payload retention and off-target effects
- Targeting linker cleavage mechanisms for precision payload release – how tumor-specific protease linkers can help reduce systemic exposure, and why protease expression in normal tissues complicates ADC safety
- Exploring linker technologies that optimize stability, selective cleavage, and controlled clearance to create the next generation of safer ADCs

12.30 Lunch Break

1.30 Roundtable discussion: Navigating Evolving Regulatory Expectations for ADC Toxicity Models – Bridging *In Vivo*/*Vitro* Approaches

Join this roundtable discussion to gain a better understanding of what is currently approved by regulatory agencies, how they are adopting to new safety models, and how we can navigate regulatory challenges with ADC toxicity models.

- What models are currently approved by regulatory agencies for ADC safety assessments? Which approach should be favoured when no cross-reactive model is identified? Are there any precedents for ADCs?
- Are there species-specific limitations (ocular, pulmonary, systemic), and how can we improve predictivity?
- How are FDA and EMA responding to humanized *in vivo* and *in vitro* models for ADC safety testing?
- What validation criteria are required for *in vitro* models to be considered acceptable

Nicolas Quesnot
Senior Scientist, Preclinical Safety
Debiopharm

Investigating Protein-Drug Conjugates to Compare the Benefits & Challenges With Both & Predict Better Toxicity Mitigating Strategies

Julia Kristensson
Associate Director
Bicycle Therapeutics

2.30 Exploring Peptide-Drug Conjugates & Comparing Their Toxicity Profiles With Antibody-Drug Conjugates to Improve Reverse Translation

- Examining case studies where peptide-drug conjugates have translated toxicity data successfully into the clinic – learn from the successes
- Assessing where we can look to optimize the translation of toxicity data with ADCs by comparing ADCs with PDCs – using a reverse translational approach to minimize toxicities in preclinical studies
- Differentiating the biology of PDCs with ADCs and understanding how models can recapitulate the difference in clinical exposure

Jutta Deckert
VP, Research & Development
Iksuda Therapeutics

3.00 Chair's Closing Remarks

3.15 End of Scientific Program Day Two

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Your Partnership Opportunities

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Establish Yourself as the Leader in ADC Toxicology Services

With NHP shortages increasing the cost of *in vivo* studies, ADC drug developers are prioritizing better understanding the toxicity of their drug *in vitro* to improve asset prioritization and reduce costs. If you're an *in vitro* toxicity assay provider join us to establish your expertize in improved prediction and capture this growing market opportunity.

As ADC companies turn to Asian CROs to conduct their toxicology studies with price and reliability forefront of mind, logistical challenges still exist working in Asia. The **3rd ADC Toxicity Summit** offers the perfect venture to outline how you offer the perfect balance of cost, reliability, expertize and ease to work with.

With an audience of **toxicologists**, **pathologists**, and **preclinical and translational scientists**, they are the ones using your services, making this a stand-out opportunity to gain technical and business buy-in to your company.

Innovation Partner

28bio is a neurotechnology company engineering human brains at-scale exhibiting memory, learning and cognitive functions. Its Nexon™ platform integrates tissue engineering, neural interfacing, and AI to reverse today's neurological health crisis by improving the ability to predict which therapies will work in humans. 28bio is committed to advancing ethical standards in the development of brain organoid technology and engineered human cognition.

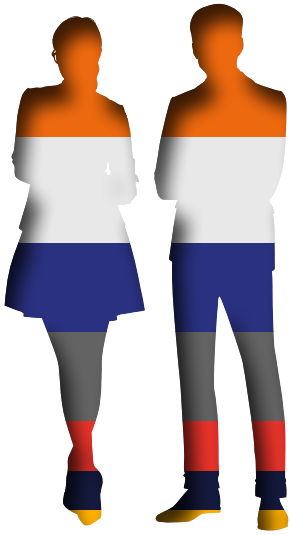
www.28bio.com

Event Partner

HUB Organoids, part of the Life Science Business of Merck KGaA, Darmstadt, Germany, specializes in the application of Organoid Technology to drug discovery, personalized medicine, and disease modeling. Founded in 2013 following the discovery of adult stem cells, HUB´s drug development platform uses advanced 3D organoid models derived from patient tissues, enabling more accurate and predictive research for preclinical testing and therapeutic development. HUB´s innovative platform accelerates the discovery of effective treatments by closely mimicking human biology and is available on a fee-for-service basis to scientists working in drug discovery and development in the therapeutic areas of oncology, inflammation/IBD, infectious diseases, and for toxicology investigation.

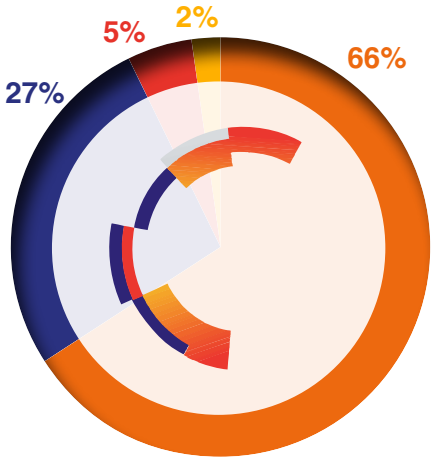
www.huborganoids.com

SENIORITY OF ATTENDEES*



- Director: 27%
- Scientist: 19%
- CxO: 16%
- President/VP: 16%
- Other: 9%
- Head: 7%
- Manager: 5%

TYPES OF COMPANIES ATTENDING*



*Statistics taken from 2nd ADC Toxicity Summit

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