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Working Group Update 2025 & Outlook

IMMUNOGENICITY ASSAYS

Denise Sickert
on behalf of the EIP Immunogenicity Assay Working Group

Immunogenicity Assay Working Group Members

Team Leads:

Linlin Luo – Merck &Co (Lead); Karin Benstein – Sanofi (Co-Lead); Marina Ichetovkin – Merck & Co (Co-Lead)

Team Members:

- Alison Johnson – LabCorp
- Anna-Lucia Buccarello – Fresenius-Kabi
- Carina de Lemos Rieper – Lundbeck
- Christine Blain – KCAS Bio
- Denise Sickert – Roche
- Elodie Cousin – KCAS Bio
- Gnana Oli Rajaraman – Aicuris
- Issa Jyamubandi - Intertek
- Jo Goodman – Celerion
- Joanna Grudzinska-Goebel – Bayer AG
- Katrin Deiser – Sandoz
- Laura Geary – Resolian
- Lysie Champion – Celerion
- Marc-Olivier Montjovent – Sanofi
- Martin Ullmann – Fresenius-Kabi
- Matthias Reichel – Bioagilytix
- Michael Tovey – Svar
- Rene Wuttke – Debiopharm
- Stefanie Elm – Amgen
- Susana Liu – Pfizer
- Wibke Lembke – Celerion
- Yvonne Katterle – Bayer AG

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Our Mission

- The **Immunogenicity Assay Working Group** is part of the Strategy Working Group and was founded in 2021.
- The goal of the Working Group is for the members to exchange their company's practices on immunogenicity assay related topics and work to publish industry best practices as recommended by EIP.
- Currently, discussion topics include: all stages of humoral immunogenicity (or anti-drug antibody (ADA)) assays, including assay cross validation
- The Group's website is https://e-i-p.eu/working-groups
- The Group's Teams site is Immunogenicity Assays | General | Microsoft Teams

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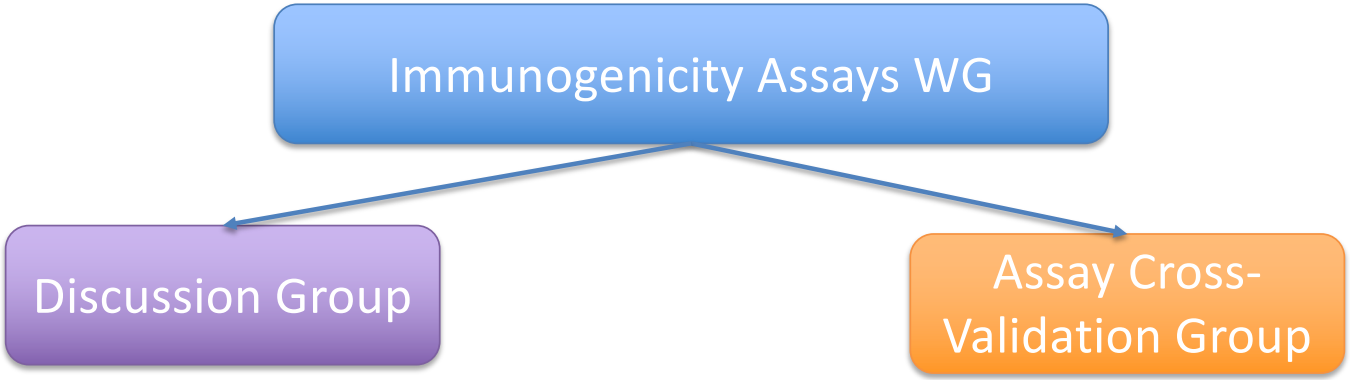
Immunogenicity Assay Subteams



- Meets 2nd Tuesday
- Mandate: Modernize ADA testing paradigms, Provide a forum to discuss all assay issues
- Focus: Tackle emerging technical hurdles, debate assay trends, and streamline general procedures for ADA testing

- Meets 4th Tuesday
- Mandate: Publication of a consensus EIP recommendation paper
- Focus: Align varying company practices into unified publication addressing regulatory and practical comparability strategies

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Discussion Group

- Throughout 2025, the group shared internal case studies and evaluated modernized strategies for ADA testing paradigms
  - ***Scientific Strategy:*** Evaluated shifting away from traditional tiered approaches by utilizing Signal-to-Noise ratios, omitting the confirmatory tier, and discussed strategies for multi-domain therapeutics
  - ***Alignment & Research:*** Shared internal data and regulatory feedback on fit-for-purpose non-clinical validations, assay acceptance limits, and replacing NAb assays with PK/PD data
  - ***Timing & Logistics:*** Addressed operational challenges for in-study cut points with limited sample sizes (e.g., orphan indications) and interpreted evolving Chinese guidelines for duplicate analysis

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Assay Cross-Validation Group

- Throughout 2025, the group focused on gathering data and drafting a consensus publication regarding assay cross-validation
  - ***Alignment:*** Mapped individual company strategies and initiated a comprehensive literature review encompassing HA guidelines
  - **Testing Timing & Logistics:** Evaluated when cross-validation testing is necessary using ICH M10 guidelines as a starting point and addressed the logistical hurdles of moving samples in and out of China
  - ***Publication Strategy:*** Finalized the consensus publication structure—featuring survey results, literature reviews, and EIP recommendations—and evaluated formatting requirements for target journals
  - ***Draft Status:*** Finalized manuscript outline, assigned writing sections and completed the first draft

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Outlook 2026

- EIP Assay Subteam has established several high-priority topics to tackle in 2026, driven by member case studies
  - ***In-study Cut Points:*** Deep dive into screening and confirmatory cut points for limited sample sizes
  - ***Non-specific Background:*** Exploring technical approaches to avoid drug-independent interference, focus on omitting the confirmatory cut point while applying a 1% False Positive Rate
  - ***Signal-to-Noise & Biomarker Approaches:*** Comparing S/N trending against traditional cut points, re-evaluating if 3 tiers are still necessary for patient risk interpretation, and establishing how to successfully approach regulatory authorities with this data
  - ***Singlicate Analysis & Regional Guidelines:*** Continuing to refine singlicate analysis for LBAs and continuing to interpret evolving guidance from China

Thank you!

Steffi Michael Yvonne LINLIN Wibke Gnana Laura Anna Elodie Rene Lysie Carina Susana Karin Alison Denise Jo Marc-Olivier Martin Christine Issa Katrin Matthias Susana Joanna

If you are interested to join, please contact:

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