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17TH OPEN SYMPOSIUM OF THE EUROPEAN IMMUNOGENICITY PLATFORM (EIP) SUMMARY & OUTLOOK

Daniel Kramer (Sanofi), EIP Chairman on behalf of EIP

Immunogenicity of New Modalities

- Immunogenicity Risk Assessment is key for new modalities
  - Additional risks regarding activation of the innate immune system for LNP & AAV gene therapies and cellular immune responses against transduced cells
  - Innate immune responses seem to be the primary driver of immunogenicity against oligonucleotide therapeutics
    - GalNac siRNA seem to have a low potential to raise ADA responses
    - Anti-sense Oligonucleotides (ASOs) seem to have a higher immunogenic potential
- Several novel approaches to mitigate the pre-existing antibody issue for gene therapues
  - Imlifidase to degrade endogenous ADAs without longer term immunosuppression
  - Transient blockade of the CD28/B7 pathway (Abatacept or anti-CD40L) to transiently inhibit ADA responses to AAV capsid and transgene products

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Immunogenicity Assay & Sampling Strategy / Regulatory

- The current 3-tiered approach is under debate
  - S/N instead of titer to quasi-quantify the ADA response
    - Pretty good alignment within industry and authorities
  - Omitting the confirmatory assay
    - More data might be needed here
  - PK/PD & ADA data in lieu of a dedicated NAb assay
    - Seems to be acceptable but is dependent on the data
- "Bank and hold" immunogenicity samples may be possible with suitable scientific justification

Immunogenicity Risk Assessment

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Immunogenicity of Therapeutic Peptides

- Although peptides in general are regulated as “small molecules“, immunogenicity assessment for peptides (≥8 aa) is expected
  - The immunogenicity of therapeutic peptides can be pretty high with or without clear clinical impact (insulin)
- Cyclic peptides and peptides containing non-natural amino acids present real challenges to “predict“ their immunogenicity using in-silico tools

Immunogenicity Assay

- Drug- and target interference still present a major hurdle for immunogenicity assays (especially NAb assays)
- Positive controls are a key component of any immunogenicity assay
  - Monoclonal antibodies seem to provide several advantages (endless supply, easier to create domain specific controls,…)
- Hybrid LBA-LC-MS/MS is an interesting approach for isotyping
- In non-clinical development generic ADA assays might be used
- An early (and massive) ADA onset in NHPs might indicate a high immunogenicity risks for humans
  - Probably due to innate immune responses which are better conserved between NHPs and humans
  - More data are needed to prove this hypothesis

Biosimilars

- Latest draft guidance might not require head to head phase 3 clinical trials to assess immunogenicity
- Interestingly, (retrospectively) a real good correlation was observed between immunogenicity in single dose PK studies and phase 3 trials
  - Implication for originator ADA testing??????

Prediciton

- In-silico tools have improved significantly
  - Inclusion of pathogen cross-reactivity
  - “germline filtering” including human protein expression
- MAPPs could not detect false positives from in-silico
  - Two possibilities:
    - MAPPs not sensitive enough
    - Number of false positives in in-silico prediction lower than suspected
      - Would MAPPs on top of in-silico really add value

Clinical Relevance

- The immunogenicity reporting for clinical trials in the public domain is biased to low immunogenicity (as many dugs failing due to high immunogenicity and those are never published)

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Survey EIP Open Symposium 2026

Thank you for participating in our symposium. We hope you enjoyed yourself and that you benefitted from the event.

To help us continue to deliver a symposium that matches your needs and expectations we would be grateful if you could take a few minutes to complete our online feedback survey. All contributions are anonymous.

Yours sincerely,
Barbara Vercruyssen
Director Finance and Operations

Conference Report 2026

Proceedings of the 15th European Immunogenicity Platform Open Symposium on Immunogenicity of Biopharmaceuticals

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We will issue a conference report from the 17th EIP Open Symposium and will ask presenters for their contribution – stay tuned!

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Next EIP Open Symposium (2027)

Will be announced soon!!!

Stay tuned

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SPECIAL THANKS TO BARBARA!!!

Thanks for joining
and have a safe trip back

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