EIP
European Immunogenicity Platform

10th Open Scientific EIP Symposium on Immunogenicity of Biopharmaceuticals

Session 4: Biosimilars

EIP
European Immunogenicity Platform

1. EIP Biosimilars Working Group update
2. Immunogenicity assessment for an adalimumab biosimilar – Anita Rudy
3. Clinical and regulatory issues in immunogenicity testing for insulins – Sandeep Anthayle

EIP
European Immunogenicity Platform

EIP Biosimilars Working Group update

Martin Ullmann

Working Group Members

- Annick de Vries, Sanquin
- Arno Kromminga, ipm-biotech
- Dan Mytych, Amgen
- Gregor Schaffar, Sandoz
- James Munday, Covance
- Janka Ryding, Wieslab
- Jasja Wolthoorn, Sanquin
- Martin Ullmann (Lead), Fresenius-Kabi
- Sophie Tourdot, EIP & Pfizer

Working Group Project Charter

Problem statement:

How to evaluate IMG in the context of biosimilars?

- When ADAs show no clinical impact and ADA incidence are comparable, is it necessary to do a full evaluation (e.g. kinetics ….)?
- How to best validate an ADA/NAb assay for Biosimilars
- How to best measure ADA/NAb for Biosimilars
- How to extrapolate in the context of only one disease population, eventually even being immune suppressed and with limited immunogenicity data?
- Review 483's and come up with recommendations ..?
- How to generate data to support inter-changeability (e.g. number of times switching) in different regulatory context (EMA/FDA)
- Understand what the perspective on IMG is for a non-bioanalytical person? E.g. medical, commercial, …..? Once defined, (how) can we adapt to better meet such "expectations"?

Working Group Project Charter

Key Deliverables

- ❑ Publication
- ❑ Workshop
- ❑ Presentation at EIP etc.
- ❑ Questionnaire (pre-conference and within conference)
- ❑ Explore collaboration with academia to advance/understand IMG

Key stakeholders

- ❑ Scientist working within biosimilars and on immunogenicity
- ❑ Biosimilar companies interested to advance their understanding of IMG
- ❑ Regulatory authorities