EIP Assay Working Group Update

Veerle Snoeck
On behalf of the assay working group

EIP, 25-27 Feb 2019, Lisbon

EIP European Immunogenicity Platform

ADA Assays

Working group charter

Problem statement – Activities in order of priority:

1. Collect data about assay-related feedback from FDA and EMA. This may include different topics, such as positioning and source of the positive controls, drug tolerance and many more.

2. The assay strategy for multi-domain drugs seems to be unclear and will be discussed within our group.

3. Improvement of sensitivity/drug tolerance of NAb assays

4. Scientific value of stability assessments

5. What is required for preclinical validation/context of use

... Canvas group member for other topics and level of interest in proposed topics…

In scope:

Clinical ADA /Nab assays

Non-clinical ADA assays – to be discussed

Project Lead(s):

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Key deliverables and output

1. General feedback on guidelines (different regions)

- collecting feedback from team members is ongoing
- the goal is to bring these topics together and identify major points of challenges

Output

- Knowledge sharing
- Create awareness of issues/challenges.
- Identify topics to be discussed with Agencies - Influence Industry/regulators
- Present combined feedback at EIP open symposium and at other meetings

Timelines

- Collection data — by end of March 2019
- Discussion within in the team - April to July

Key deliverables and output

2. Assay strategy for multi-domain drugs

- Discuss and provide different assay strategy approaches available to evaluate domain specificity for multidomain biologics.
  - List advantages and disadvantages
  - Provide info on critical steps and guidance during assay development
- work-out and alignment on best assay strategy to evaluate domain specificity for multidomain biologics in function of nature of biologic, immunogenicity risk, availability of positive controls

Output

- Position paper
- Present at EIP open symposium and at other meetings

Timelines

- Discussion meetings – March till June 2019
- Drafting proposal – Sept – Dec 2019

Meetings schedule

- TC once per month
- at least one F2F meeting per year – focused on specific topic(s) – to be determined

- Joining the EIP assay working group?
- Questions or suggestions?
- Contact
  - Arno Kromminga
  - Jo Goodman
  - Veerle Snoeck