Regulatory Panel Discussion

Presenter: Jo Goodman and Michaela Golob on behalf of EBF

Immunogenicity Focus Workshop
27th September 2016
Lisbon

Questions

- Thanks to everyone that submitted questions
- Selected common themes
- If your question fell off….ask it anyway !!
- Use of breaks for further discussion

Clinical Analysis

1. What constitutes a “pivotal trial”?
2. What constitutes high risk?
   - How is the risk assessment handled and when?
3. What is the minimum required for early phases?
4. Timing of sample analysis (batched vs. real time)?
5. Interpretation of results – how is this handled and what is needed?
6. What is an acceptable threshold of inconclusive results?

Assays

1. At what clinical stage should a validated assay be available?
2. When are the draft EMA and FDA guideline/guidance documents on assays expected to be finalised?
3. What is the expected sensitivity for NAb assays?
4. In cases where there is a substantial amount of circulating metabolite would this change the immunogenicity assay testing strategy?
5. Is a medium positive control necessary and does it add value?
   - Could a low PC control be the only one that is critical?