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Second Open Scientific EIP Symposium

Wrap-Up and Look Forward

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Congratulations

- **To the Poster authors for sharing their work with us**
- **To the speakers for their wonderful talks**
- **To the working group leaders for their ability to “herd cats”**
- **To Philippe and Wim and the entire organizing team for a very successful conference**
- **To Huub for his foresight and vision for bringing the EIP into existence**
- **Finally, to the participants of this Symposium!**

What Have We Learned:

- **A lot more than I could possibly discuss in 30 minutes!**
- **Aggregates are bad, but we are still not exactly sure why!**
- **Pharmaceutical companies need to understand that: Hippos are bad**
- **Our opening address set a fabulous tone for this conference**

Some Symposium “Gems”

DISCLAIMER: The items described represent the opinion of the presentor and have not been endorsed by Amgen!!!!

Some Symposium “Gems”

- **The critical importance and simplicity of “Foreign + Danger = Immune Response”**
- **The concept of “self vs non-self” should really be changed to “changing self vs non-self”**

Some Symposium “Gems”

- **The importance of understanding how aggregates differentially induce T Cell and B Cell responses**
- **The clear take home message that Aggregation of therapeutic proteins is a risk factor that as an industry and scientific community we should try very hard to understand**

Some Symposium “Gems”

- **There remain important unanswered questions in the assessment of therapeutic protein immunogenicity such as:**
 - **We need new assay platforms, especially new platforms to help us understand the concept of “neutralizing antibodies” like the one presented by Michael Tovey**
 - **We are all struggling to answer the question of anti-therapeutic protein Ab assay performance in the presence of soluble drug**
 - **The use of acid dissociation followed by addition of FAB fragments to block re-association of Ab-drug complexes represents a clever new approach**
 - **While the majority of Ab responses are inconsequential, there remain cases that have important clinical relevance**

Some Symposium “Gems”

- **Very nice talks shared with us by PhD candidates**

Some Symposium “Gems”

- **Understanding prediction of immunogenicity has made incredible advances in the past 10 years, important work such as that described with transgenics should continue to advance our knowledge**
- **The work being done by groups focusing on the cellular aspect is critical to help us understand the contributions of the players in immunogenicity, especially interesting is better defining the role of dendritic cells in stimulating initiation of an immune response**

Some Symposium “Gems”

- **Cross company contributions to “white papers” while painful and protracted, are genuinely helpful in improving how we approach immunogenicity evaluations**

Some Symposium “Gems”

- **While it is extremely complex to understand the nature of aggregates, it is worth the effort to figure it out, and realistically, we will not solve the puzzle without that important analytical piece....
no pressure Wim!!!**

Fast Forward to 2107

- My “look forward”

100th Open Scientific EIP Symposium

- **Congress President**
 - Huub Schellekens (of course!!)
- **Keynote Address Polly Matzinger (US Govt stopped allowing retirement in 2012)**
 - Title: Nothing left to talk about... they finally believed me and it's solved

100th Open Scientific EIP Symposium

Take Home Messages

- **Immunogenicity against Therapeutic Proteins officially ruled to be non-existent**
- **All risk factors have been identified and thresholds clearly documented**
- **Assays now have single Ab molecule sensitivity with 100% specificity and are available on e-bay**
- **In the rare instance of a rogue Ab, the new instant tolerizing kit is available**
- **Hyppos extinct**

Thank You

