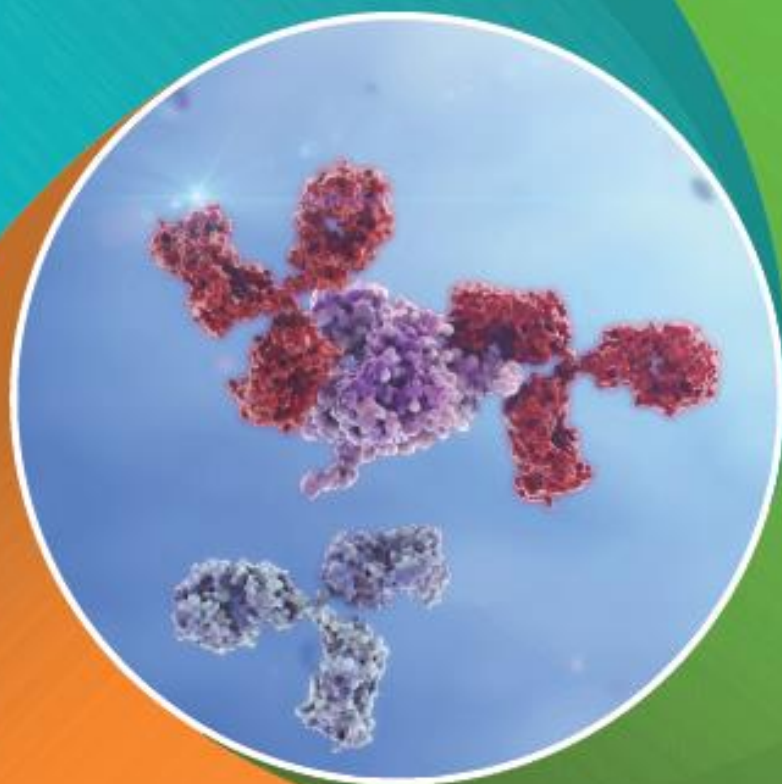


**FDA—CERSI**

OCTOBER 3-4, 2018

Collaborative Workshop on  
Predictive Immunogenicity  
for Better Clinical Outcomes

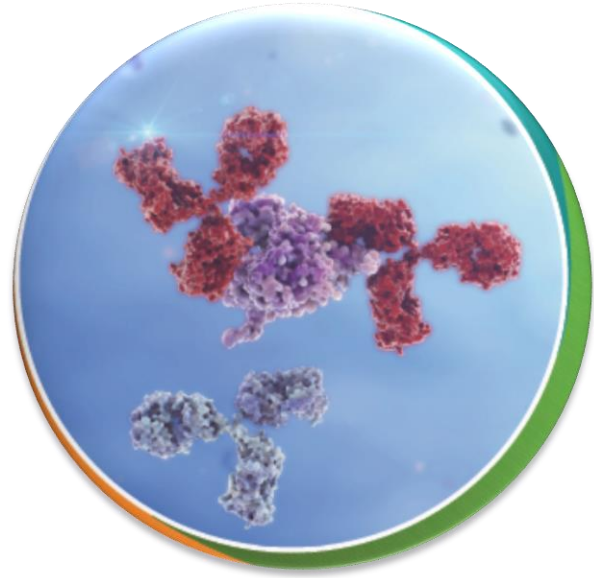


## DAY 1: PANEL DISCUSSION

## Recap of sessions



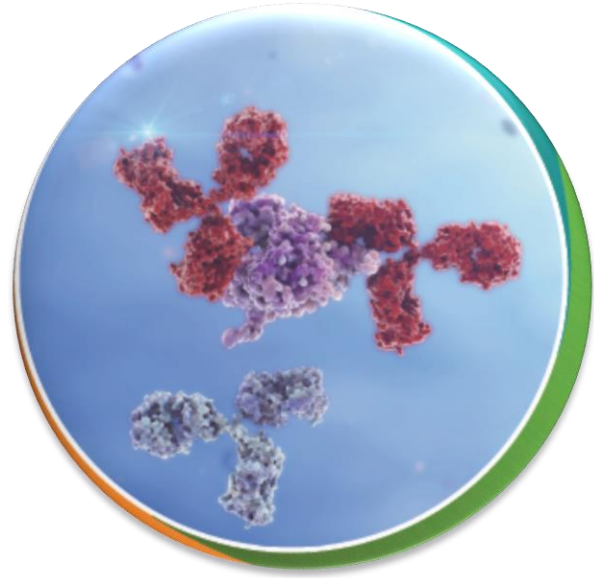
- ADVANCES IN UNDERSTANDING THE BIOLOGY OF T- & B-CELL RESPONSES AS IT APPLIES TO THE IMMUNOGENICITY OF THERAPEUTIC PROTEINS
- NEW ANALYTICAL TECHNIQUES AND IMPROVEMENTS IN EXISTING TECHNOLOGIES TO PREDICT IMMUNE RESPONSE TO THERAPEUTIC PROTEINS
- THE HUMAN COST AND THE ECONOMIC BURDEN: HOW IMMUNOGENICITY AFFECTS PATIENTS AND THE ECONOMIC BURDEN ON THE HEALTHCARE SYSTEM
- MATHEMATICAL MODELS THAT CAN INTEGRATE SEEMINGLY DISPARATE MEASUREMENTS RELATED TO IMMUNOGENICITY



The current repertoire of technologies for non-clinical immunogenicity prediction/risk-assessment. What do we need most: New technological innovations, computational power or better benchmarking?

ABIRISK/Industry perspective: Is there a value in studies that can evaluate the effectiveness of technologies used to assess immunogenicity risk?

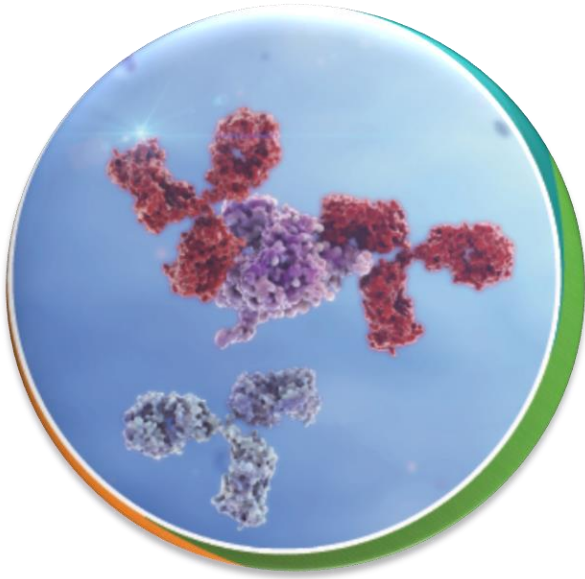
Is there an emerging consensus about what constitutes “risk” while making decisions during drug development?



The education of drug development teams and regulators:  
Is there a sufficient understanding on how to interpret  
and effectively use the information emerging from non-  
clinical studies?

Hypothesis driven approaches vs “Agnostic” approaches:  
what serves us better?

Immune responses are a numbers game. Approaches to  
make these numbers manageable?



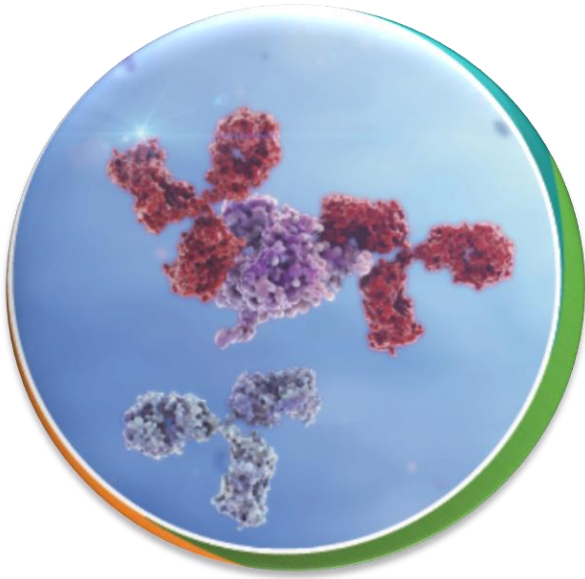
Are systems biology and modeling approaches useful for predicting immunogenicity?

Is the whole greater than the sum of its parts?

We can measure a lot!

What should we measure? Who should curate?

Models as a way of “expanding” our understanding from small clinical trials.



How can the costs to the medical system due to immunogenicity be better quantified?

Opportunity costs for industry? Could personalized approaches help—e.g. targeting drugs to specific populations and/or those with defined genetic or molecular markers?

How would such products be developed?

What considerations do we need for different populations and global development of products?