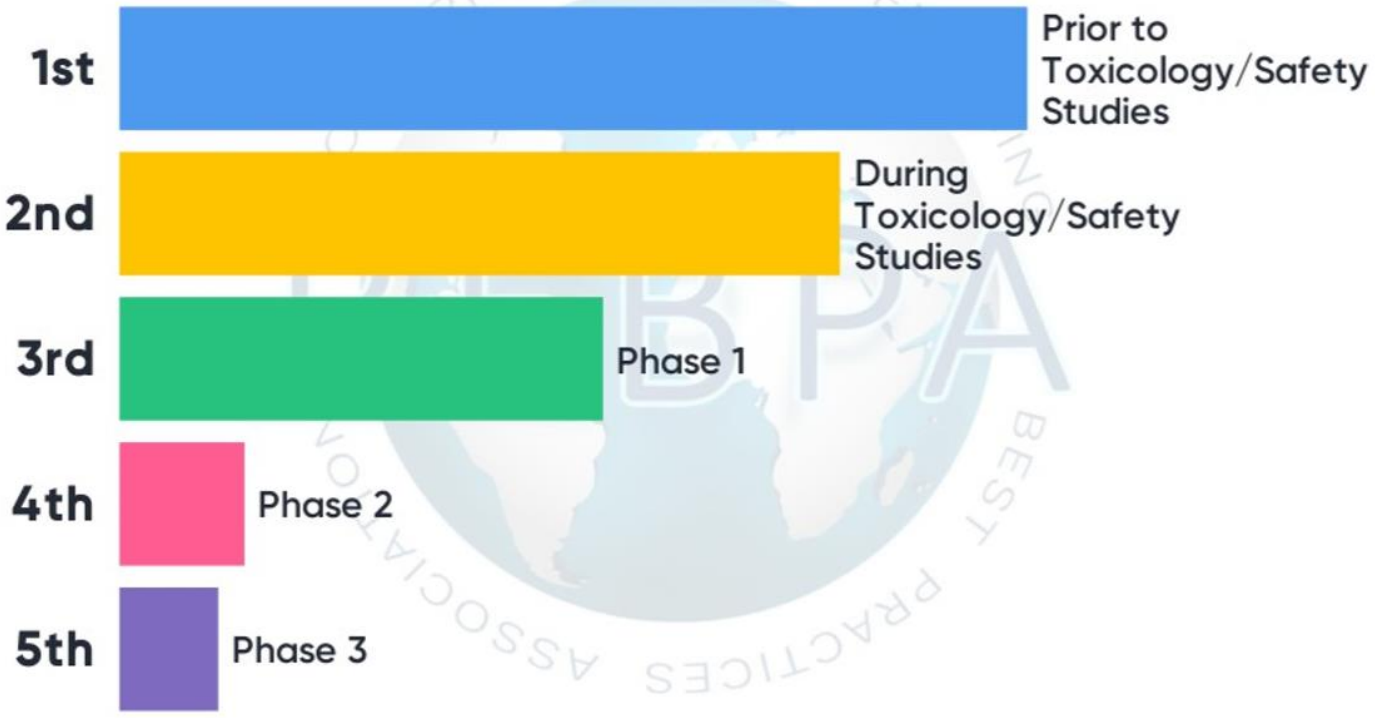
BEBPA 2019 EUR Bioassay Conference

25-27 September 2019
Prague, Czechia

Session 1: Bioassay Lifecycles

Session Chair: Laureen Little

When do you typically start developing your potency assay?



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When do you perform validation of your potency assay?

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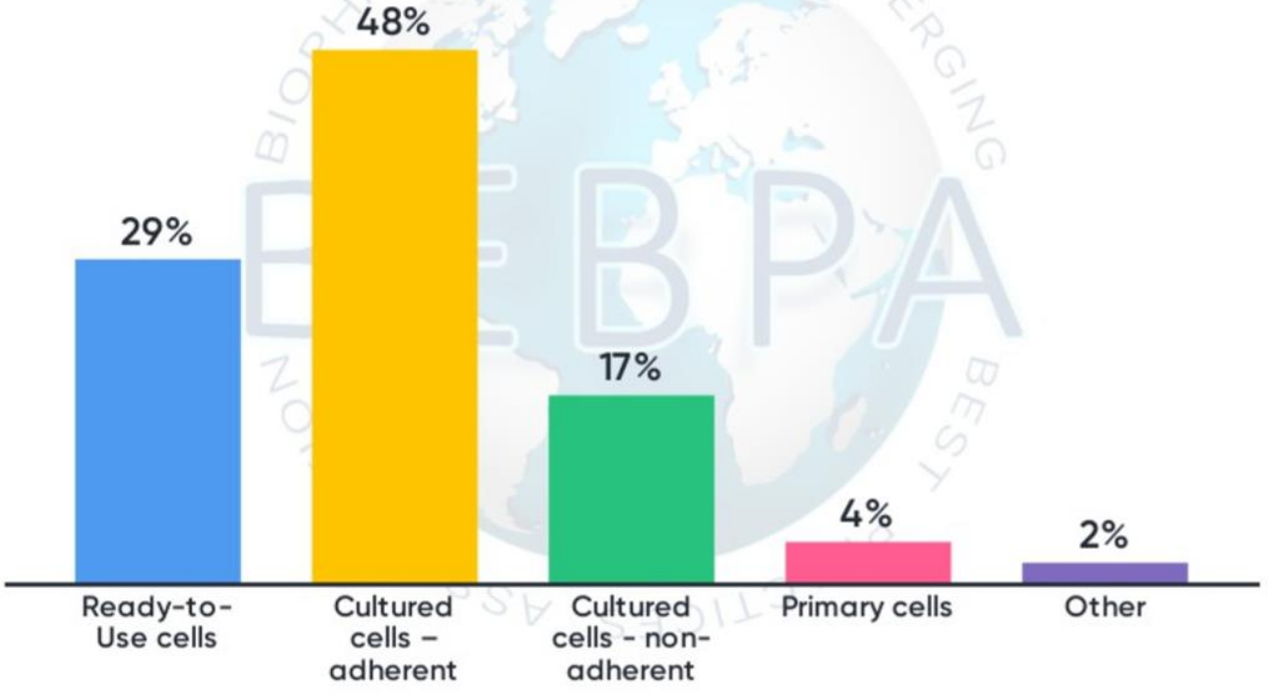
Session 2: Hot Topics: Ready-to-Use Cells

Session Chair: Laureen Little

What type of cells do you use for your cell-based potency assay?



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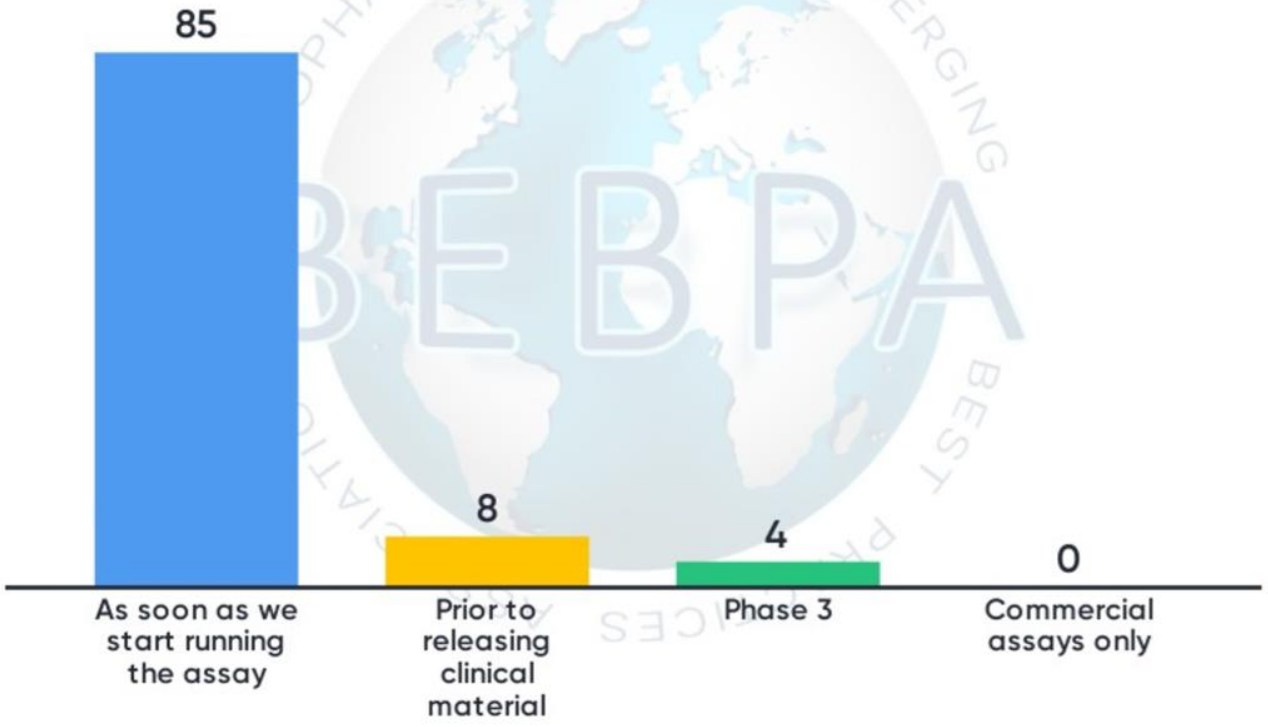
Session 3: Assessing Similarity

Session Chair: Perceval Sondag

When do you initiate assessing similarity between reference and test dose-response curves?



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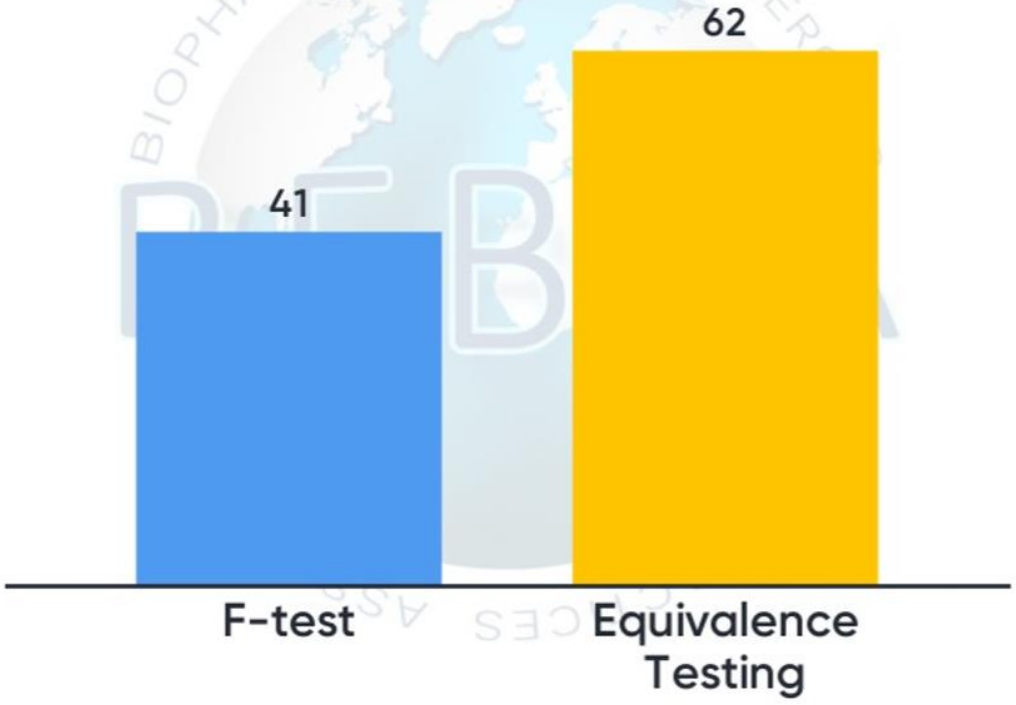
How do you assess similarity of your reference vs. test sample dose-response curve?



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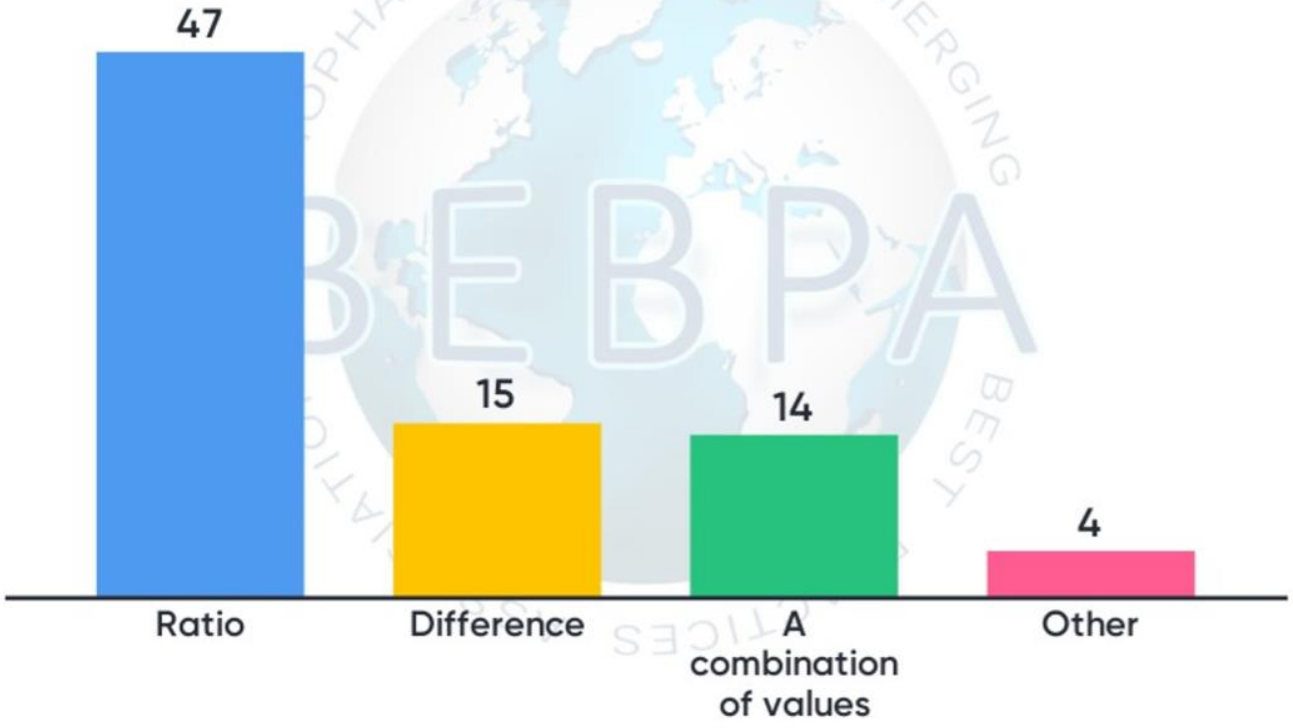
If you do equivalence testing, do you use ratios and differences of the reference vs. test samples parameters?



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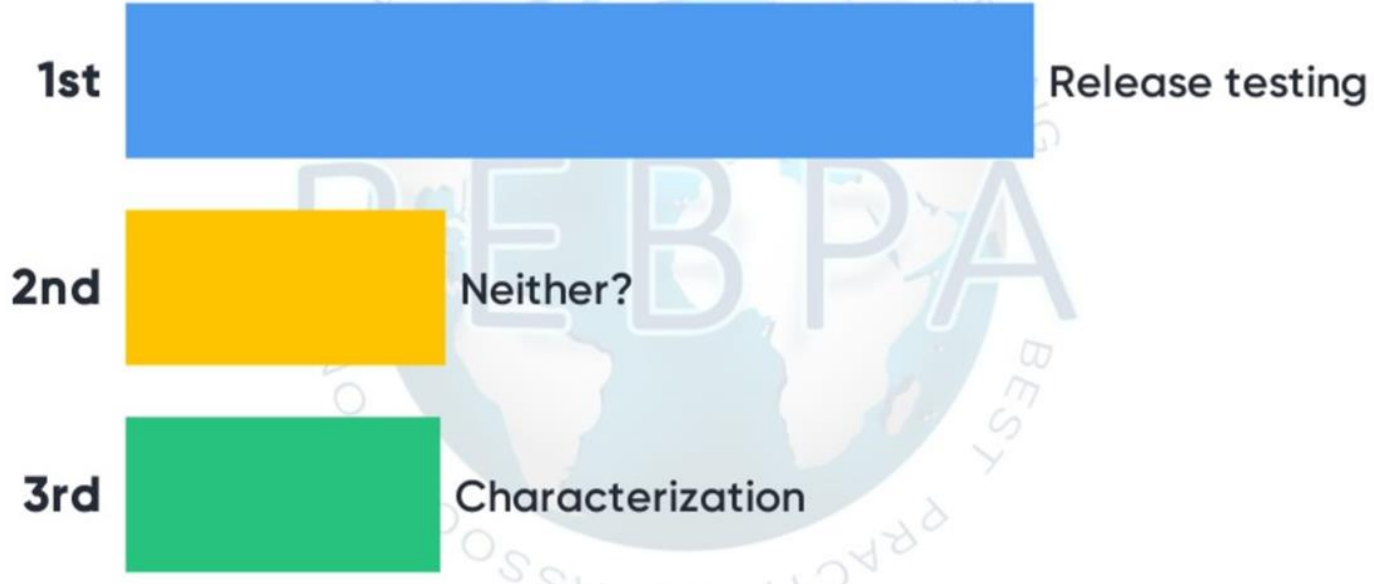
Session 4: Bridges Over Troubled Water

Session Chair: Han-Joachim Wallny

Do you do a formal assay comparability program when introducing a new potency assay for:



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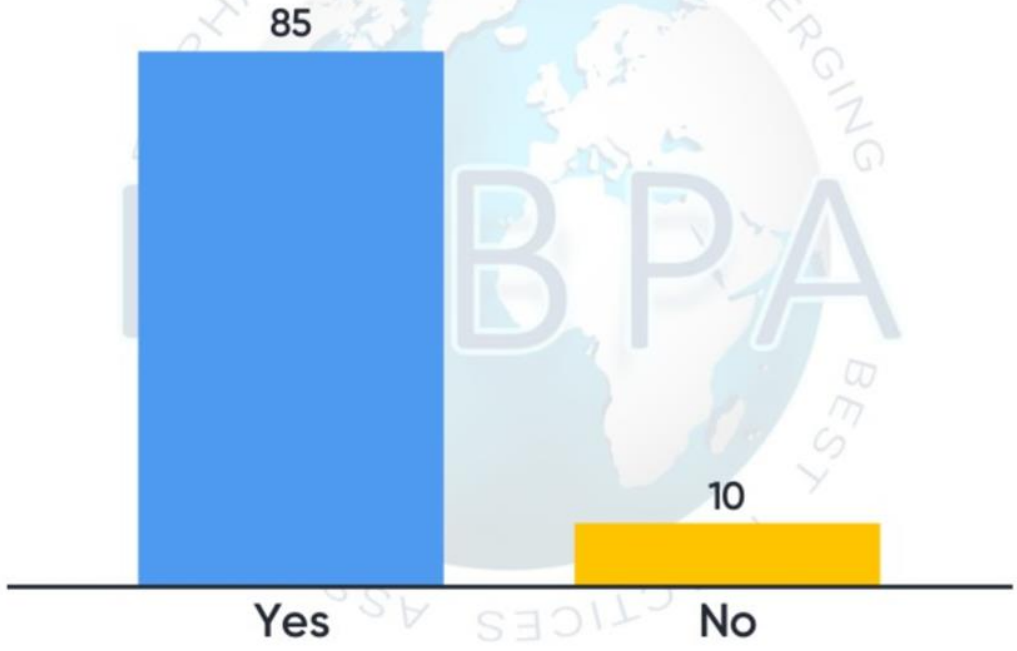
Have you seen differences between two assays you have compared?



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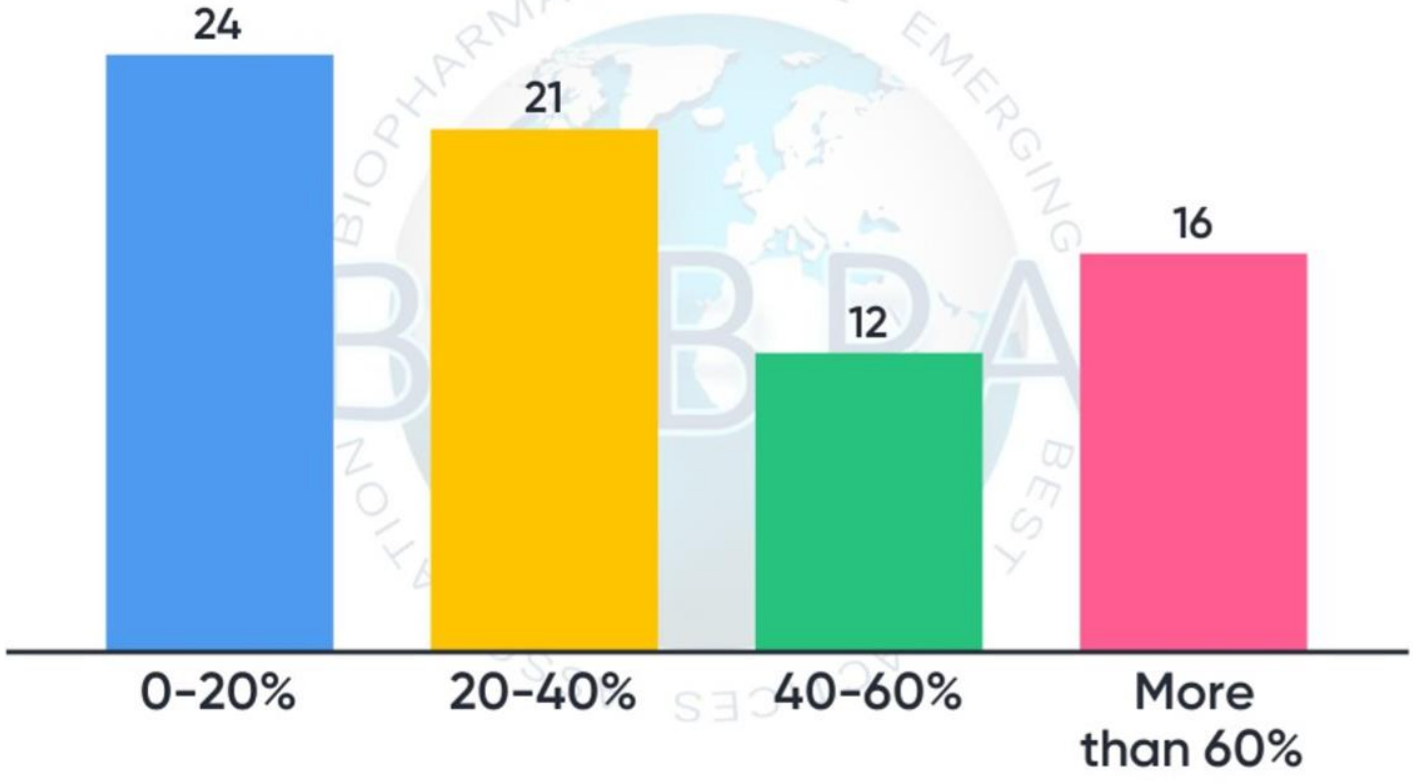
If yes, in approximately how many percent of cases?



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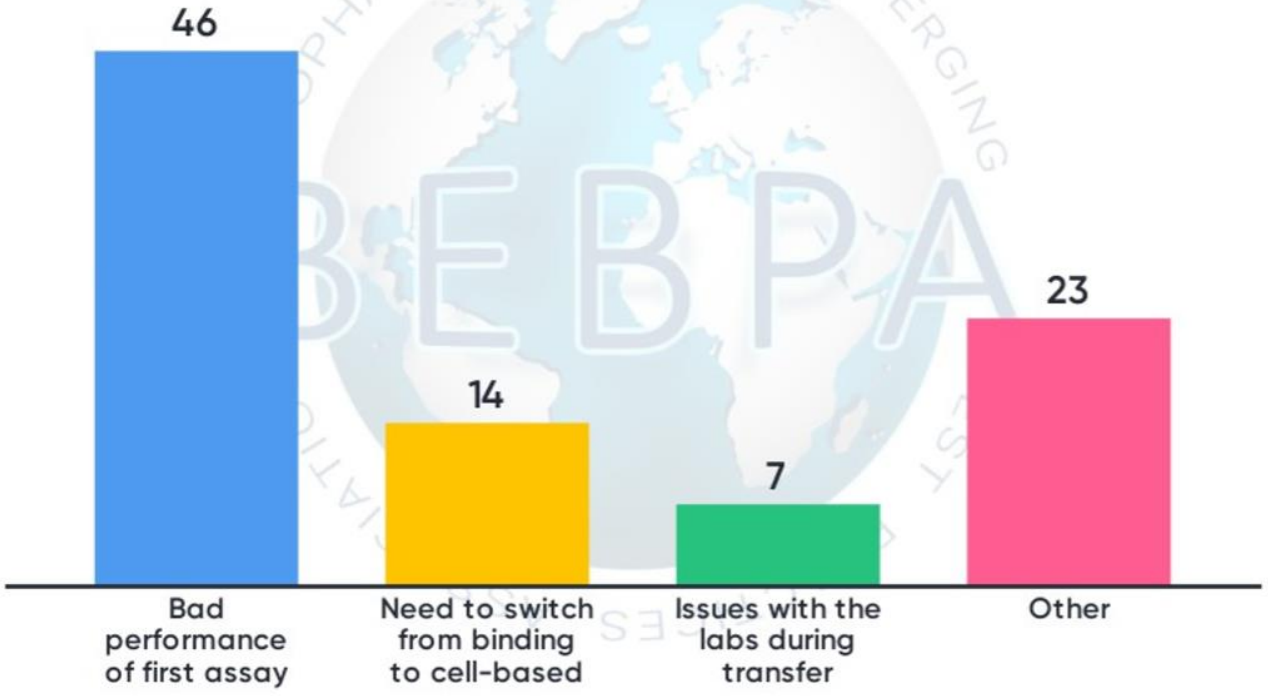
For what reasons have you done assay replacement?



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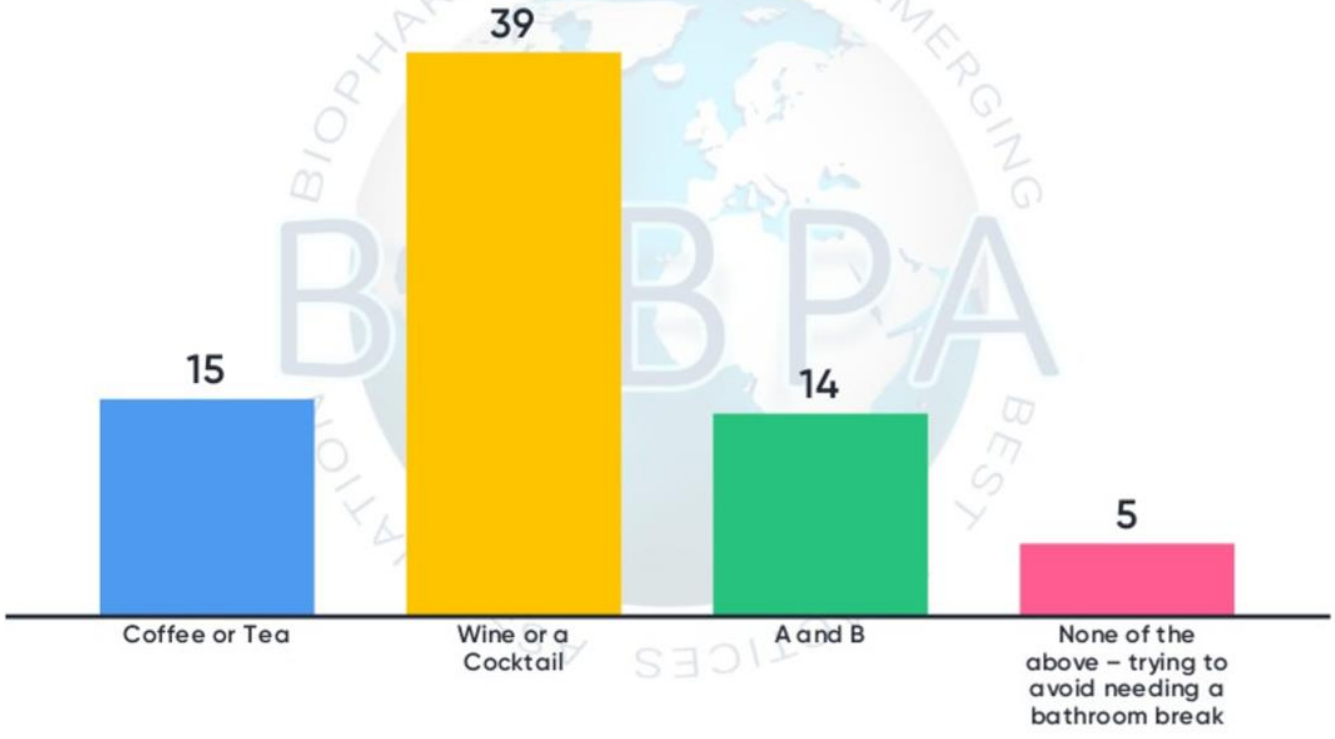
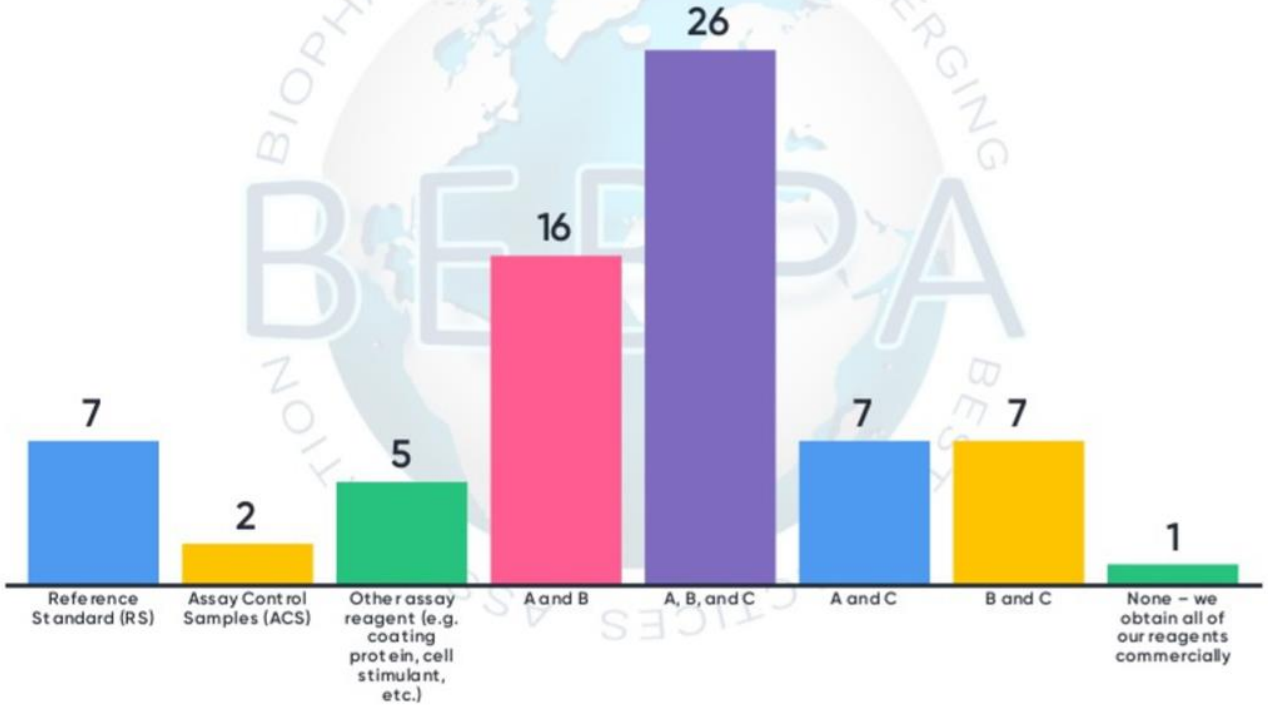
Session 5: Vaccine Product Bioassays

Session Chair: Kristin Clement

Since this is the last workshop of the day – which beverage would be most preferred to get you through this final daily dose of science?



Which critical reagents do you routinely have to create, characterize, and monitor your in-house?



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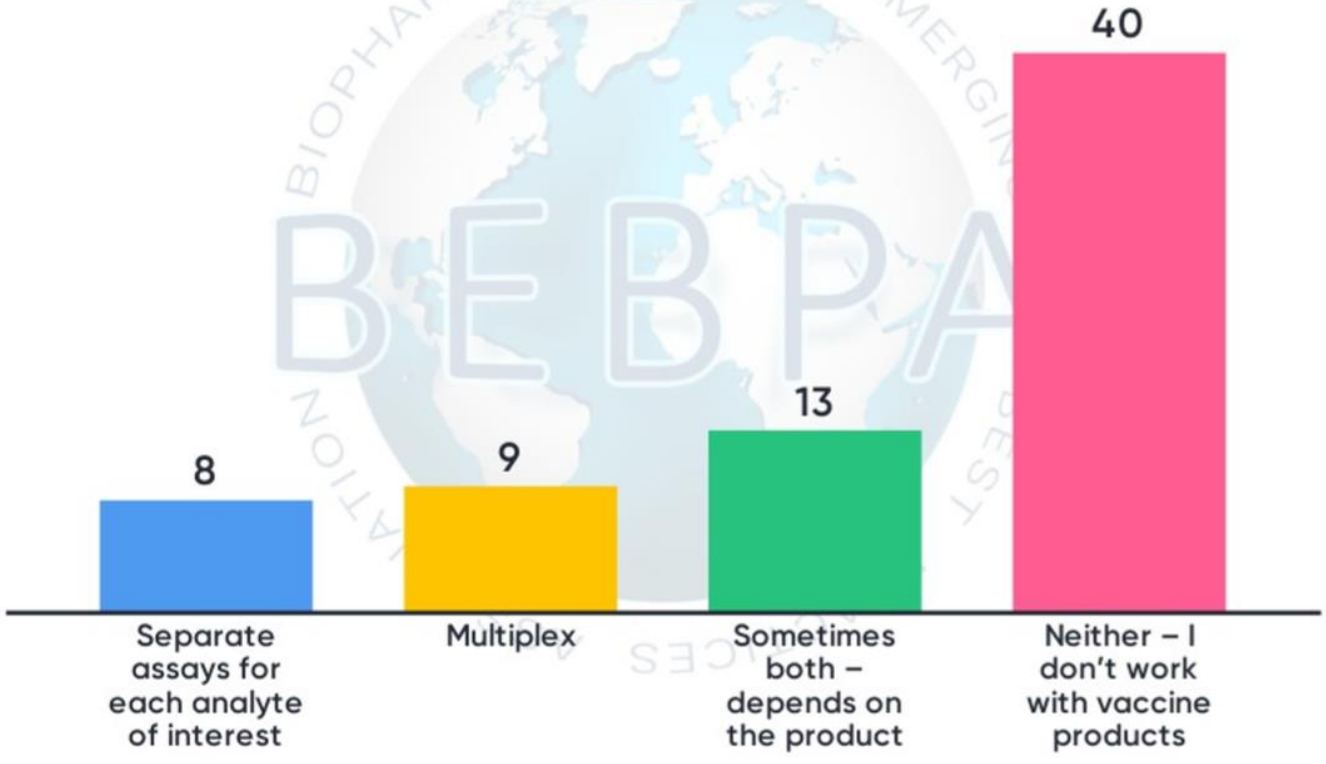
For a combination vaccine, do you prefer to develop separate assays or a multiplex assay to evaluate immunogenicity or efficacy?



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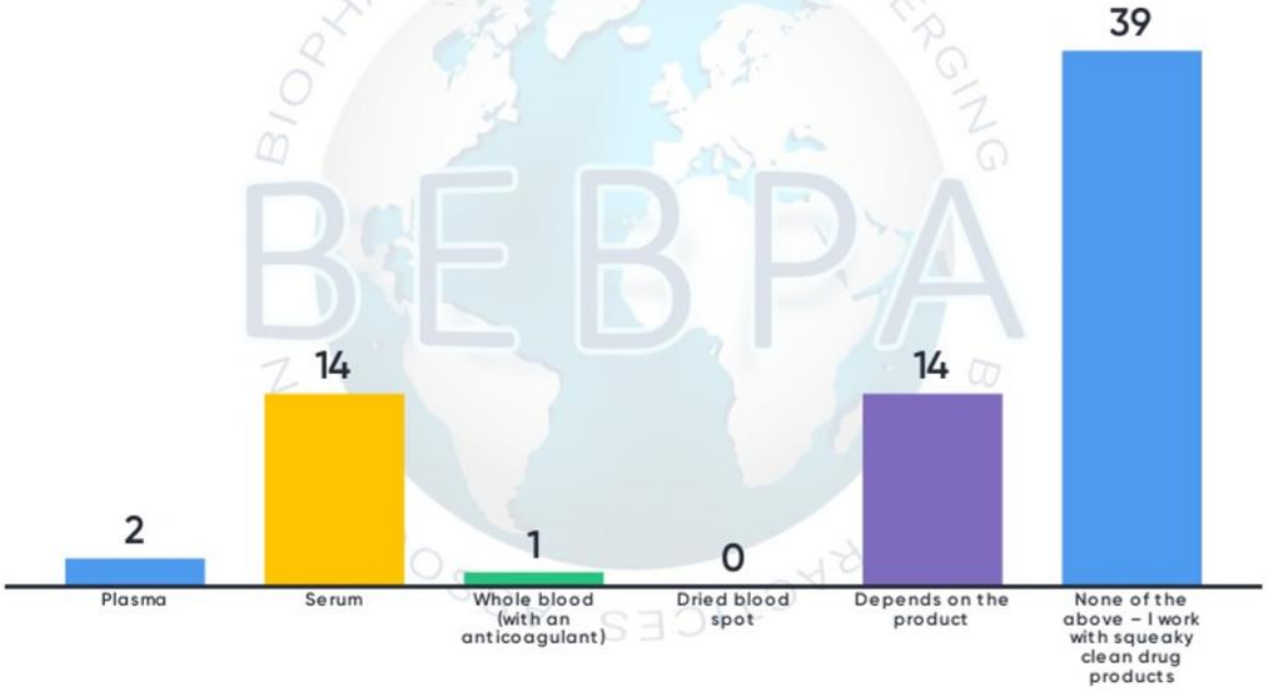
What is your default or preferred matrix of choice for a vaccine immunogenicity or efficacy assay?



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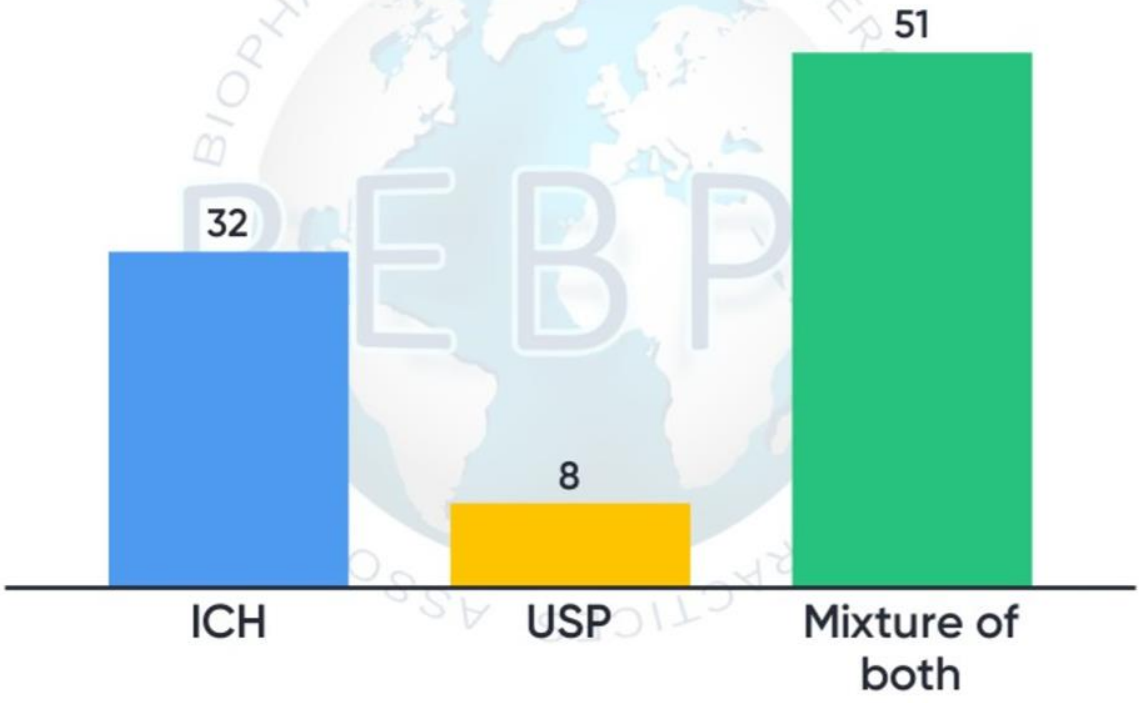
Session 6: Product Specific Case Studies

Session Chair: Sian Estdale

Do you perform ICH style validations or have "USP-like" validations?



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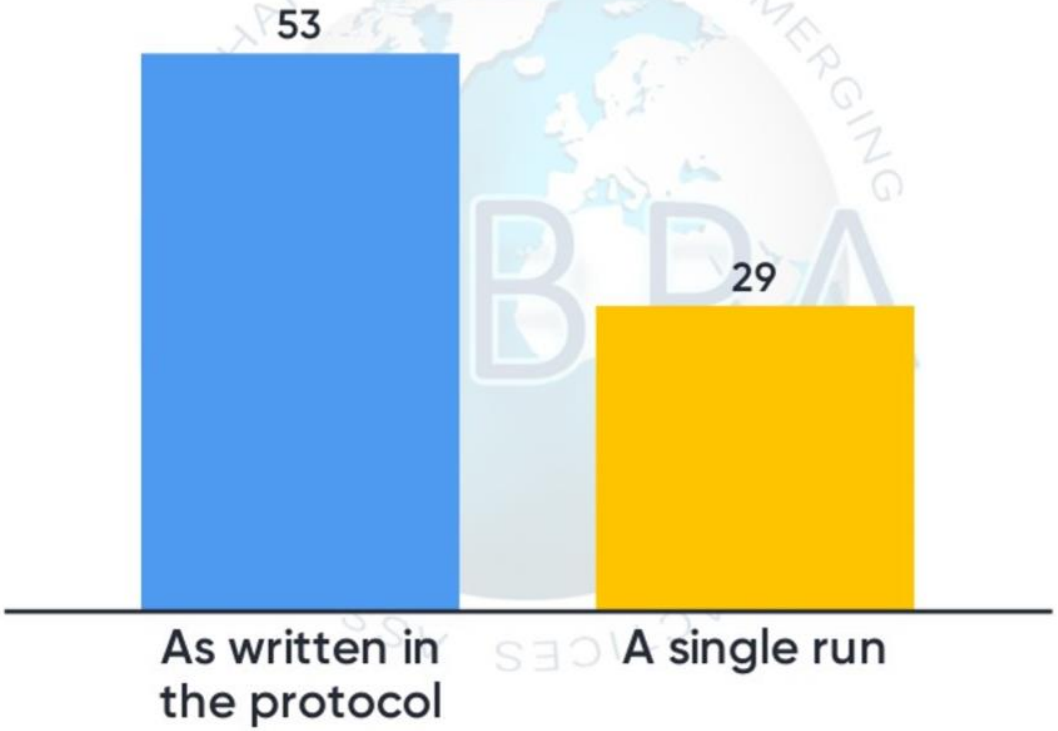
(Explanation needed) Do you validate utilizing the precise number of runs per reportable value as described in the Assay protocol



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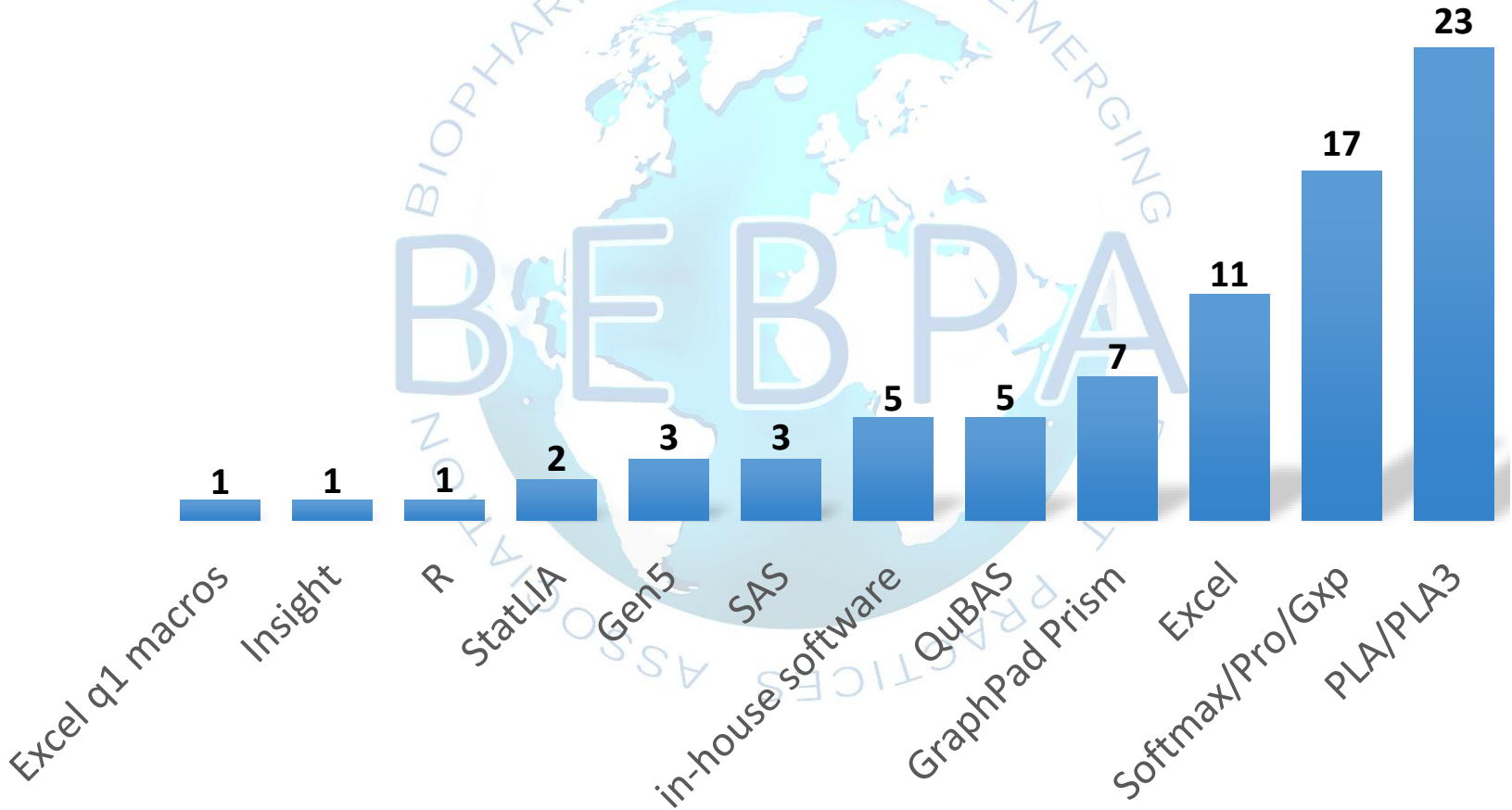
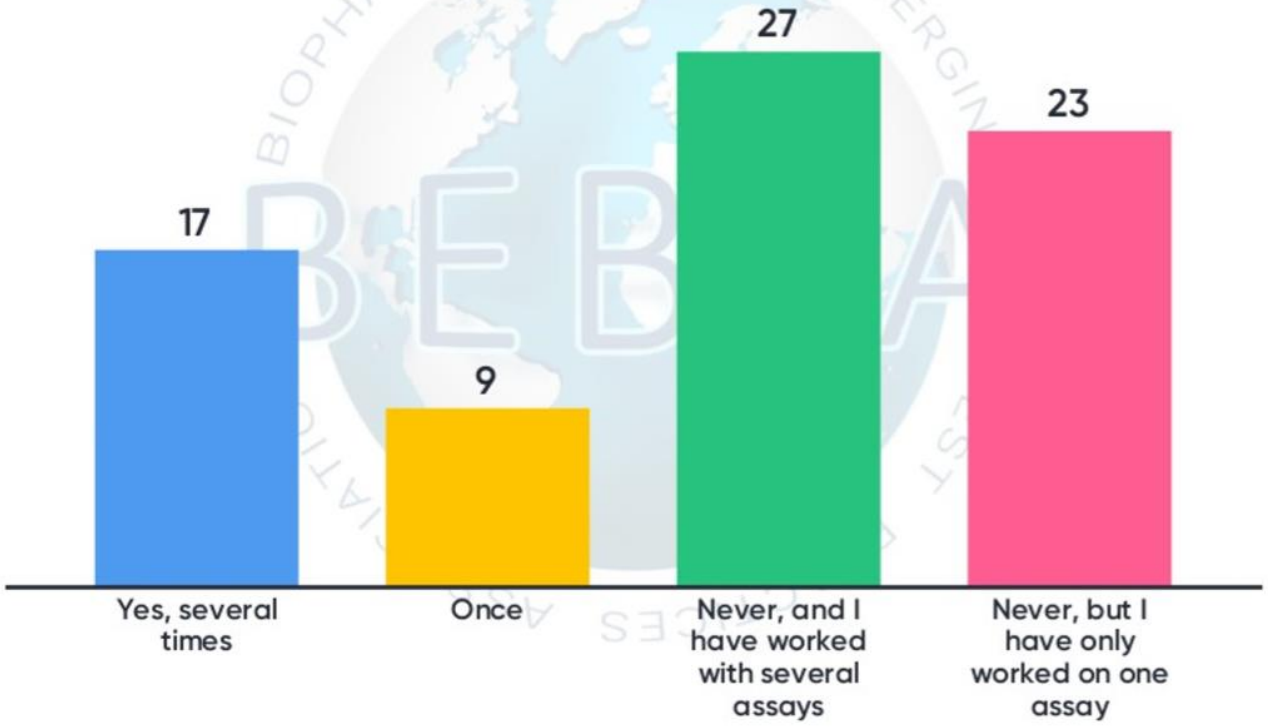
Session 7: Calculating Potency

Session Chair: Mike Merges

Which software do you use to perform your potency calculation?



Have you ever had regulatory scrutiny/questions about the potency calculations?



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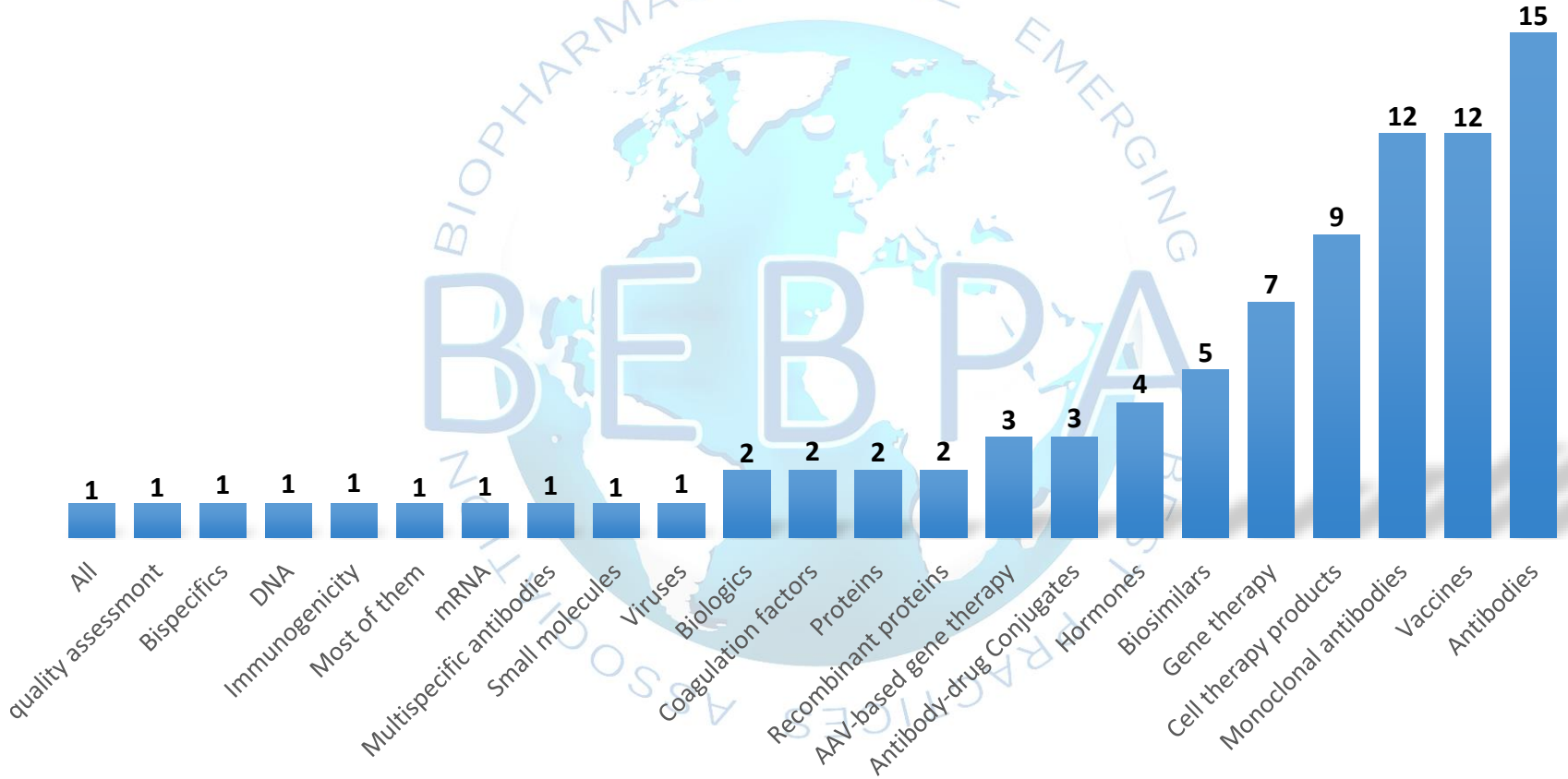
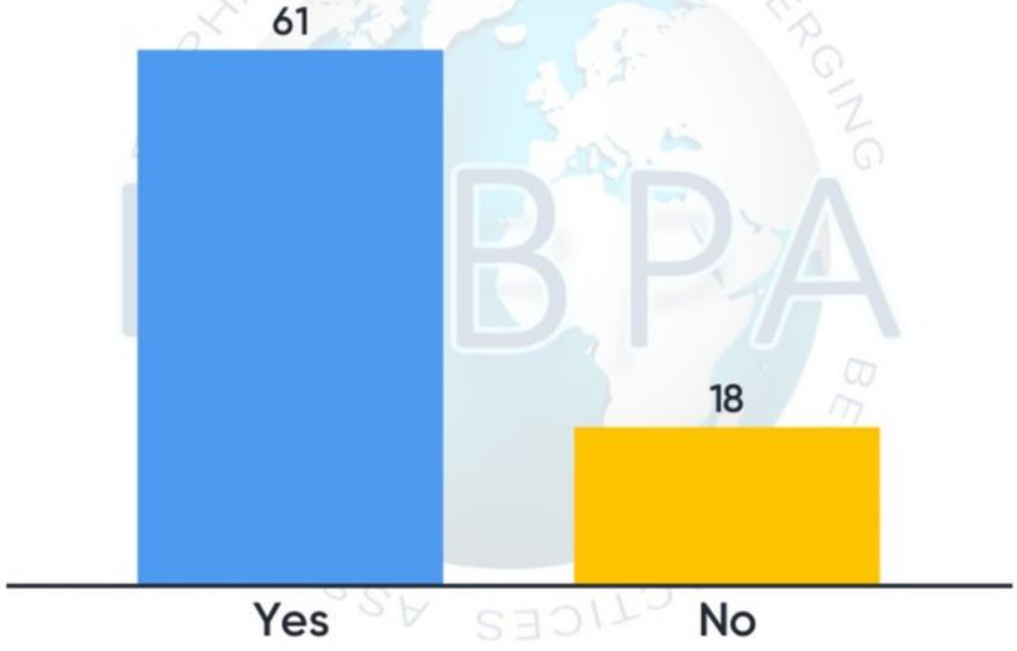
Session 9: Potency Assays for Complex Products: Gene Therapy and Cell-Based Product

Session Chair: Roger Grau

What type of products do you work on?



Do you consider your product a complex or novel product?



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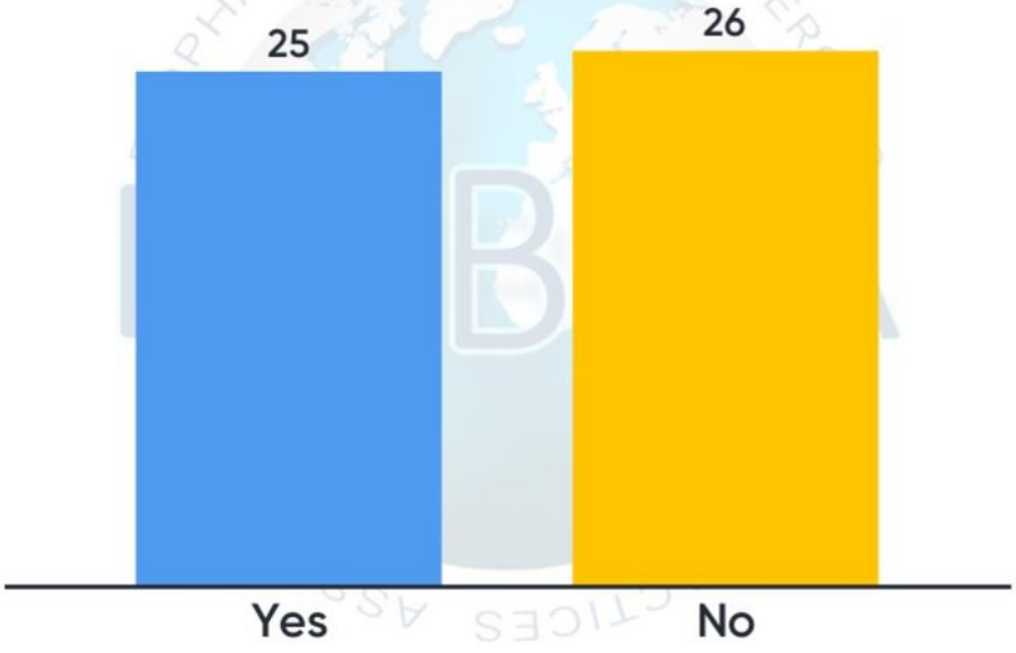
Session 10: Bioassays for Product Characterization

Session Chair: Bassam Hallis

Are you required to develop stability assays for the bedside product?



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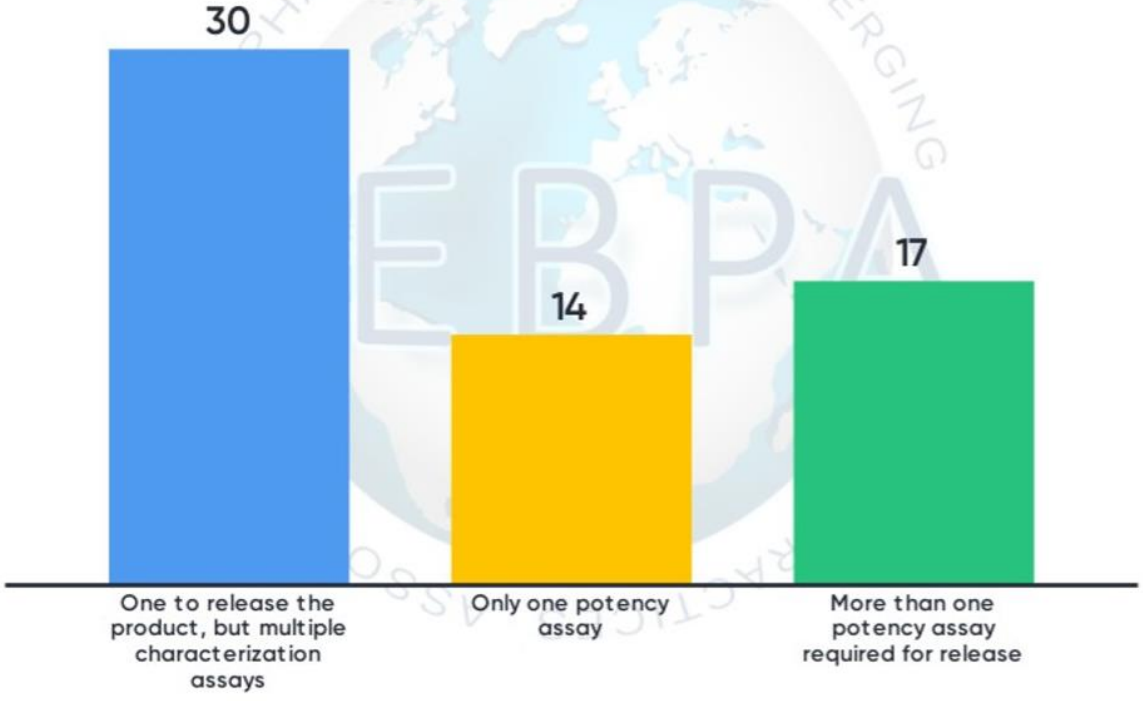
Do you have multiple potency assays to characterize/release your product?



Should Bassam be allowed to continue to chair the final session?


Thank you!!