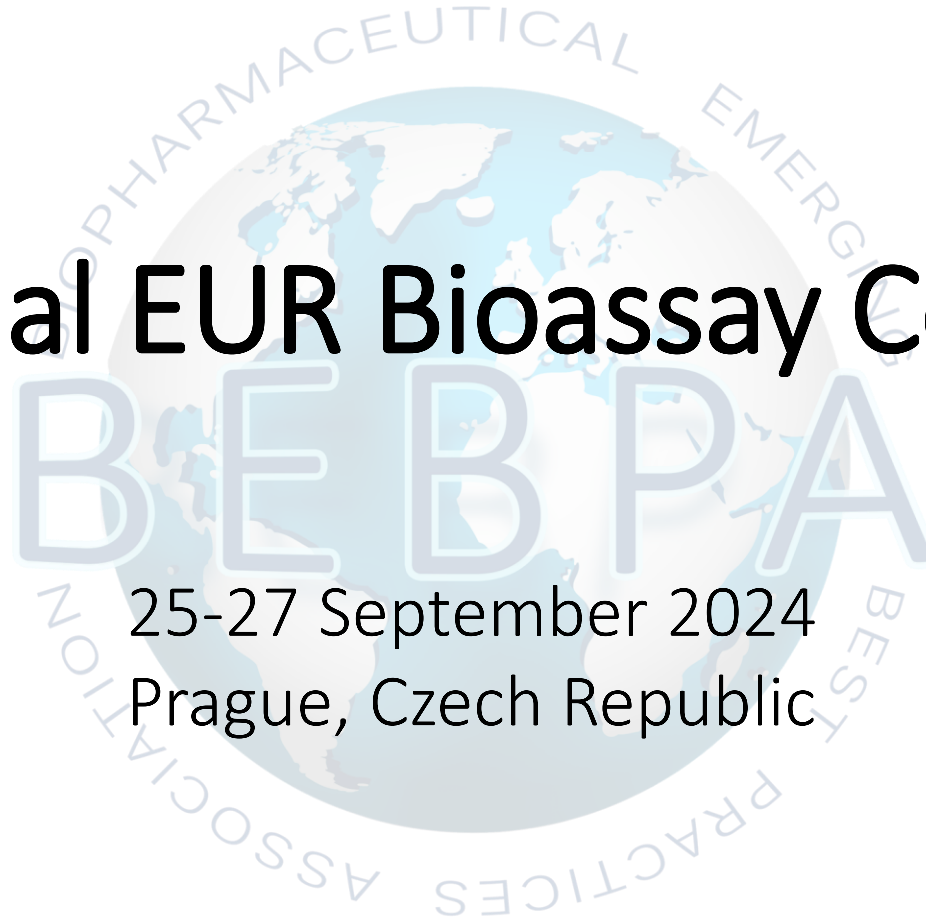
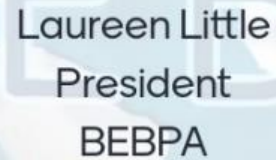
17th Annual EUR Bioassay Conference



25-27 September 2024
Prague, Czech Republic

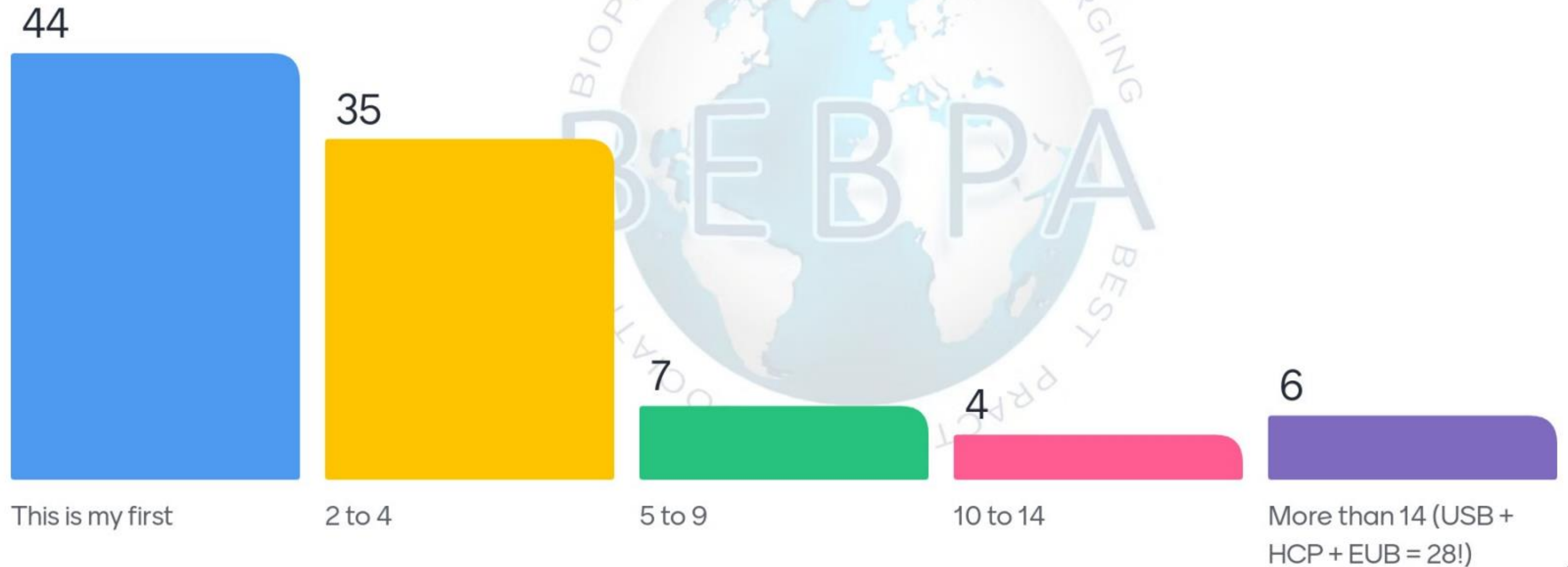
Welcome Back & Introduction



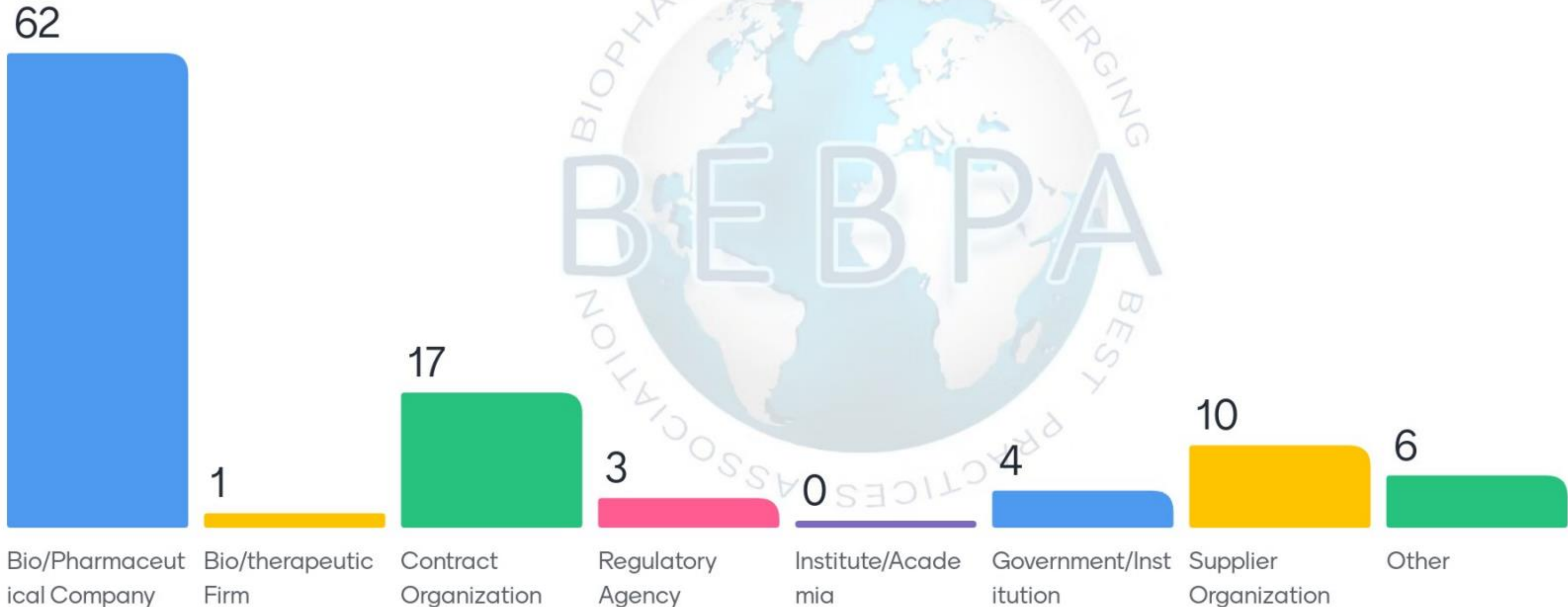
Laureen Little
President
BEBPA

Audience Surveys

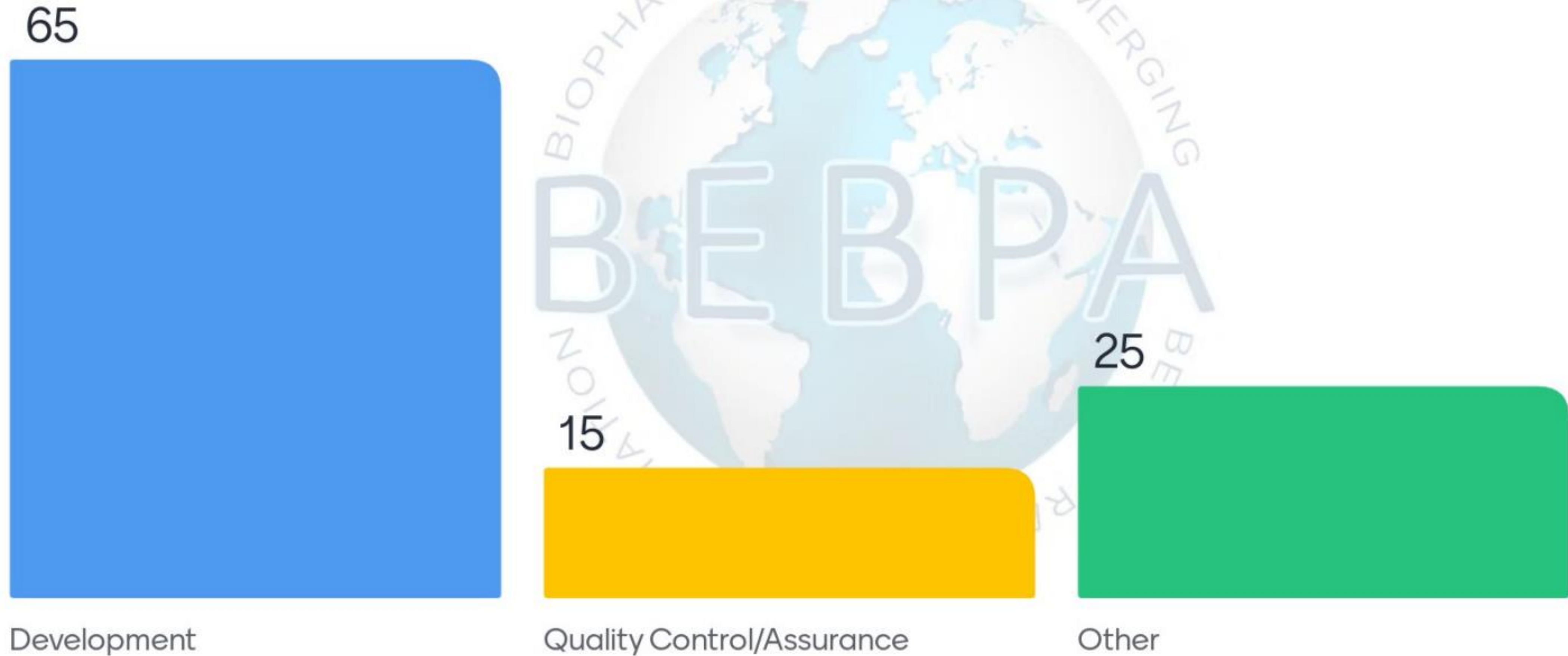
i.1 How many BEBPA Conferences have you attended?



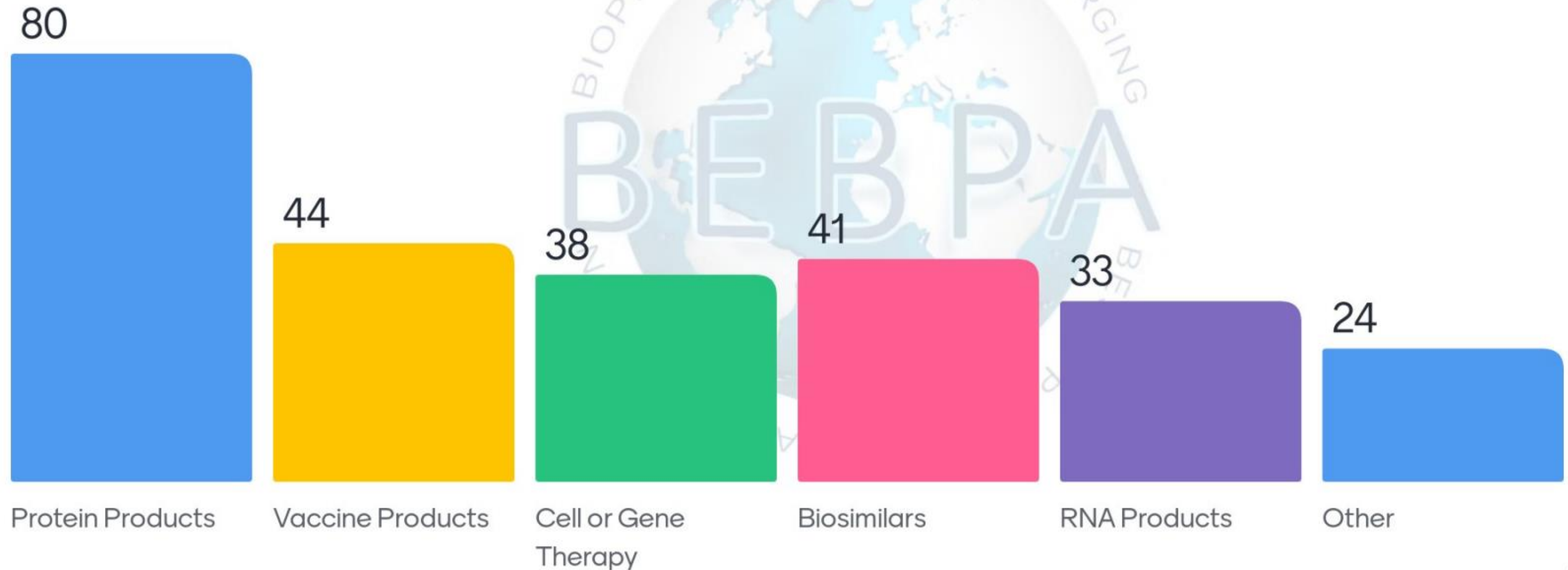
i.2 What type of organization do you work for?



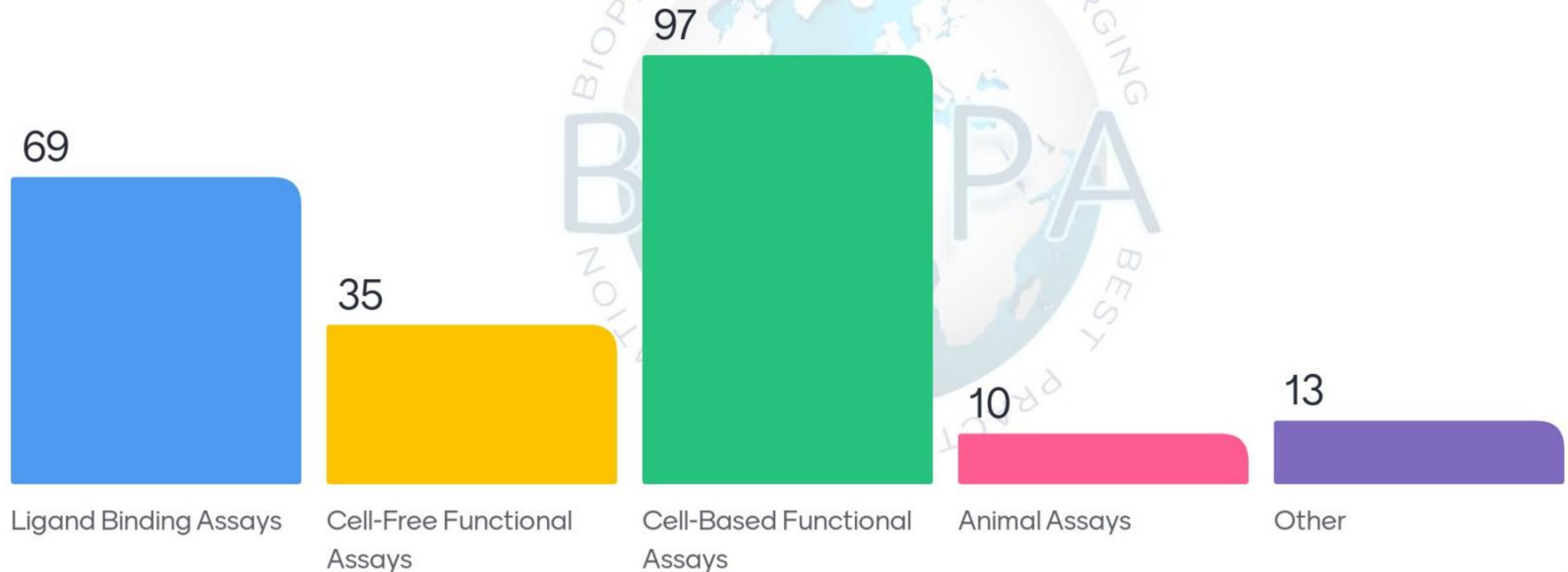
i.3 What part of the organization do your work for?



i.4 What type of products do you work with? (Check all that apply)



i.5 What type of assays do you develop? (Check all that apply)

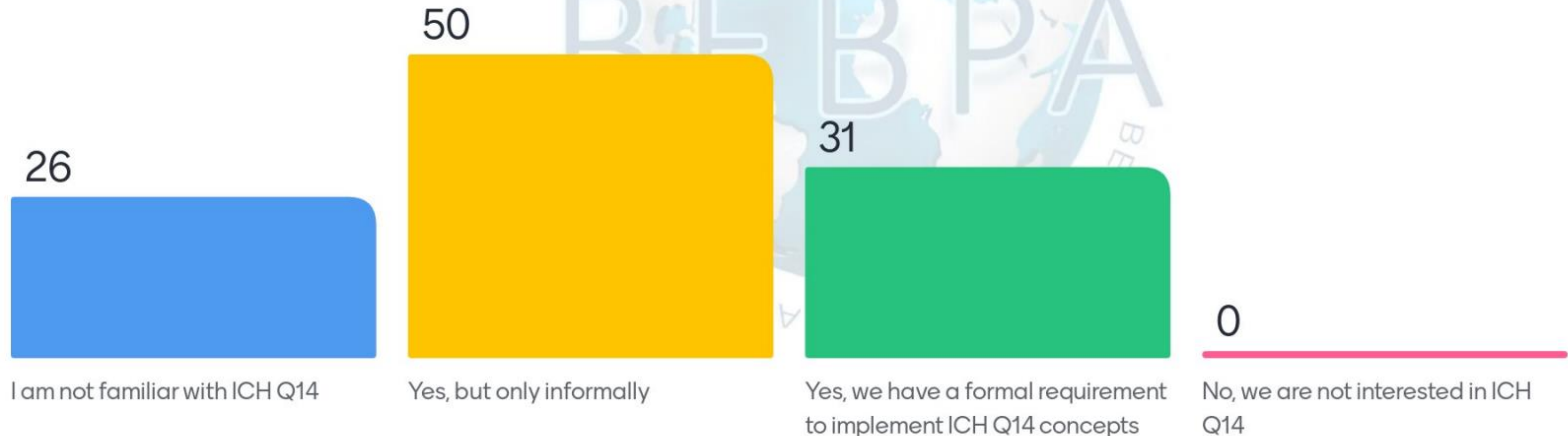


Session 1: Developing Assays for a Regulated Environment

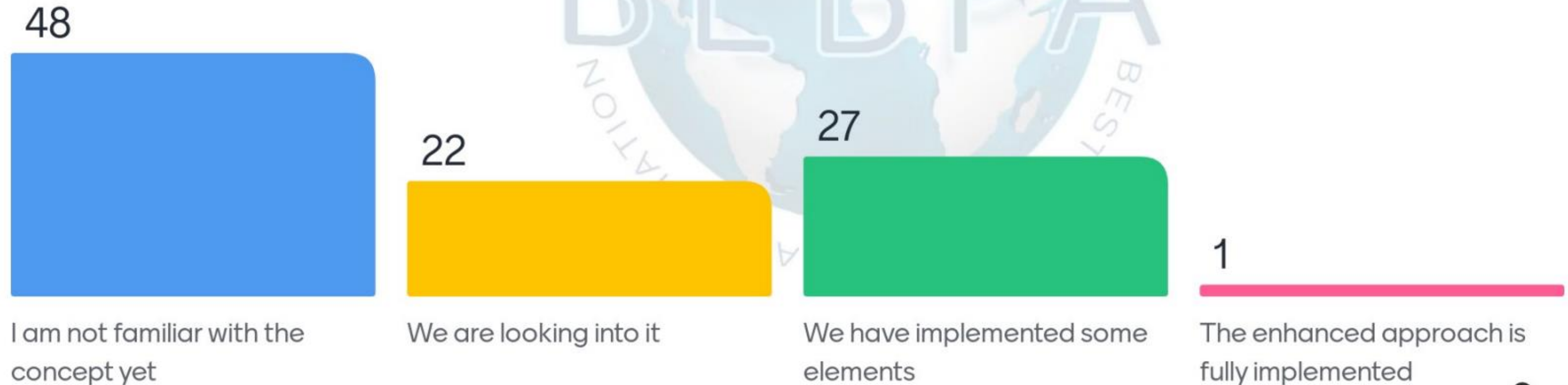
Session Chair: Laureen Little
President
BEBPA

Audience Surveys

1.1 Are you using concepts from ICH Q14 during development of your potency assays?

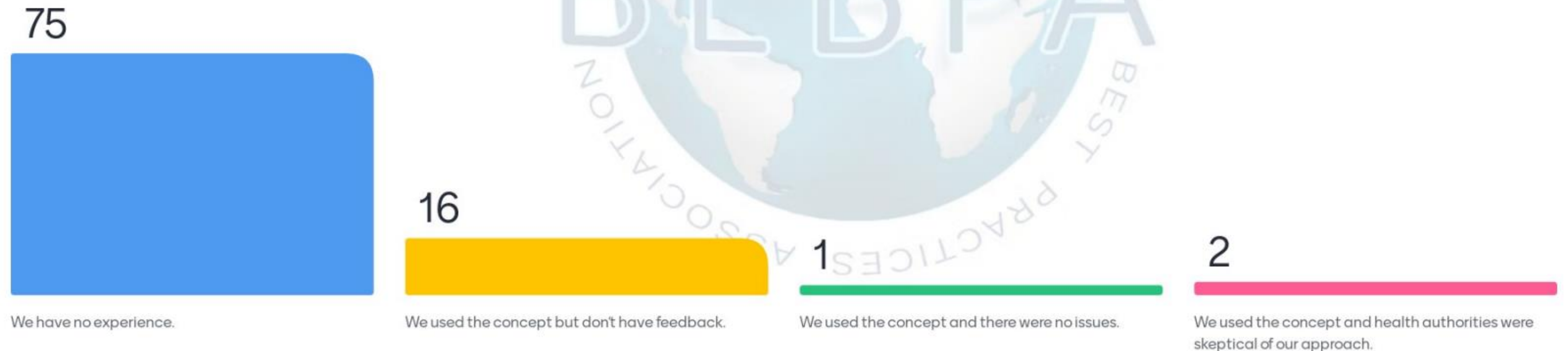


1.2 ICH Q14 describes an "enhanced approach" to method development. What is current status of the "enhanced approach" for your bioassay development?

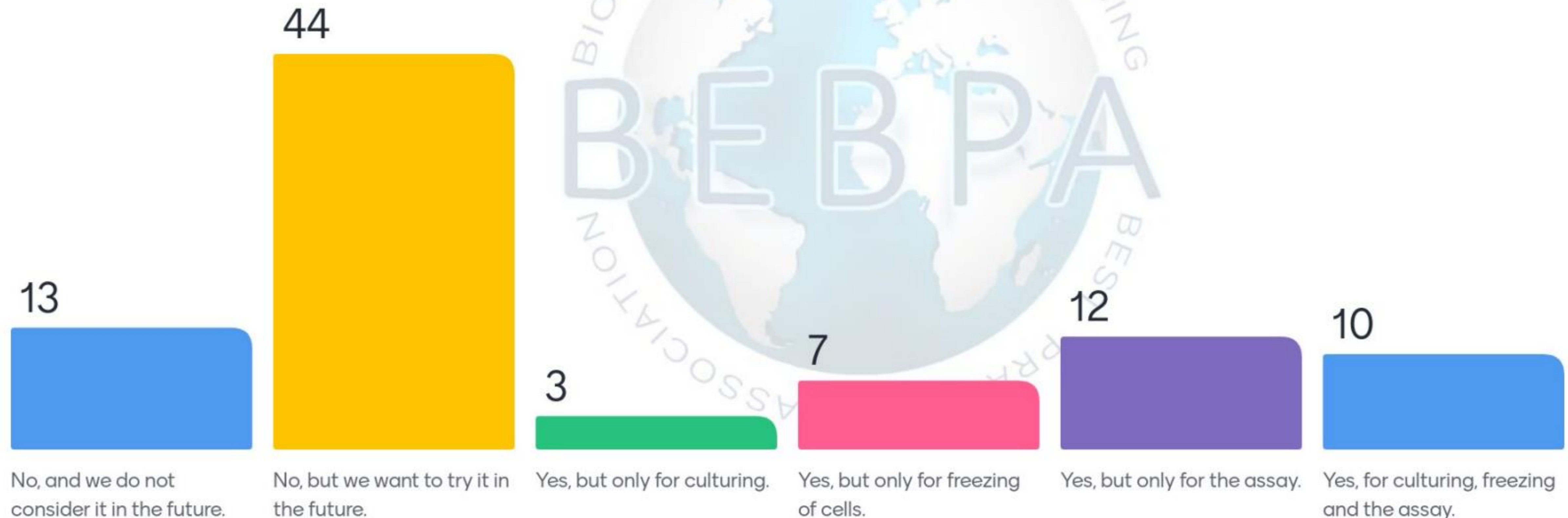


1.3 What elements of the "enhanced approach" have you implemented? (Multiple answers possible)

1.4 Have you filed an analytical procedure developed using the ICH Q14 enhanced approach? How was this received by health authorities?



1.5 Do you currently use serum-free medium in potency assays?

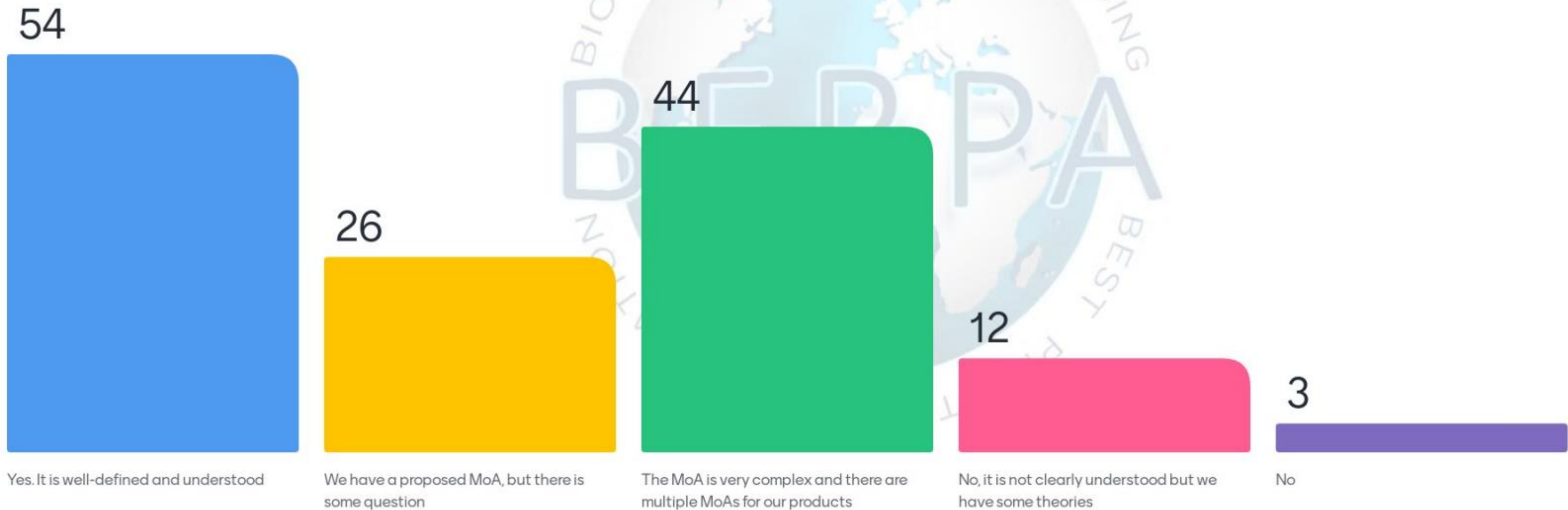


Session 2: Potency Assay Development: It Can Be Done!

Session Chair: Hans-Joachim Wallny
Executive Director Scientific and Strategic Excellence TPPM
Novartis Pharma AG Switzerland
Managing Director - Wallny BiotechConsulting
BEBPA Board of Directors

Audience Surveys

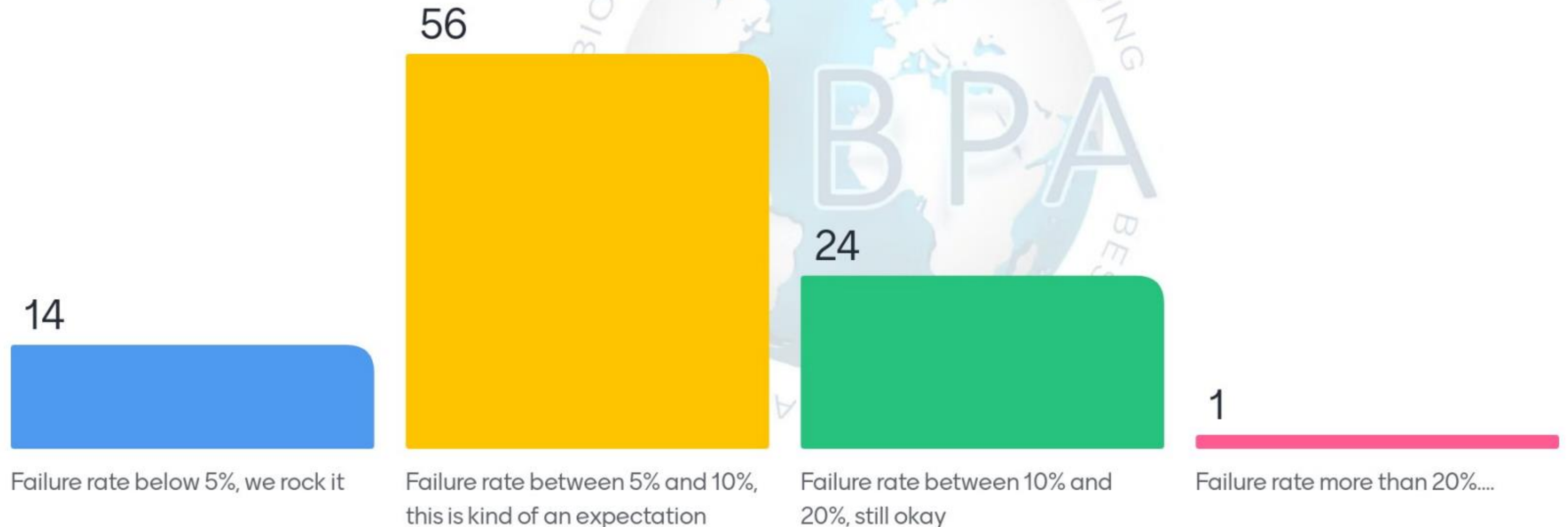
2.1 Do you understand the Mechanism of Action (MoA) of your products?



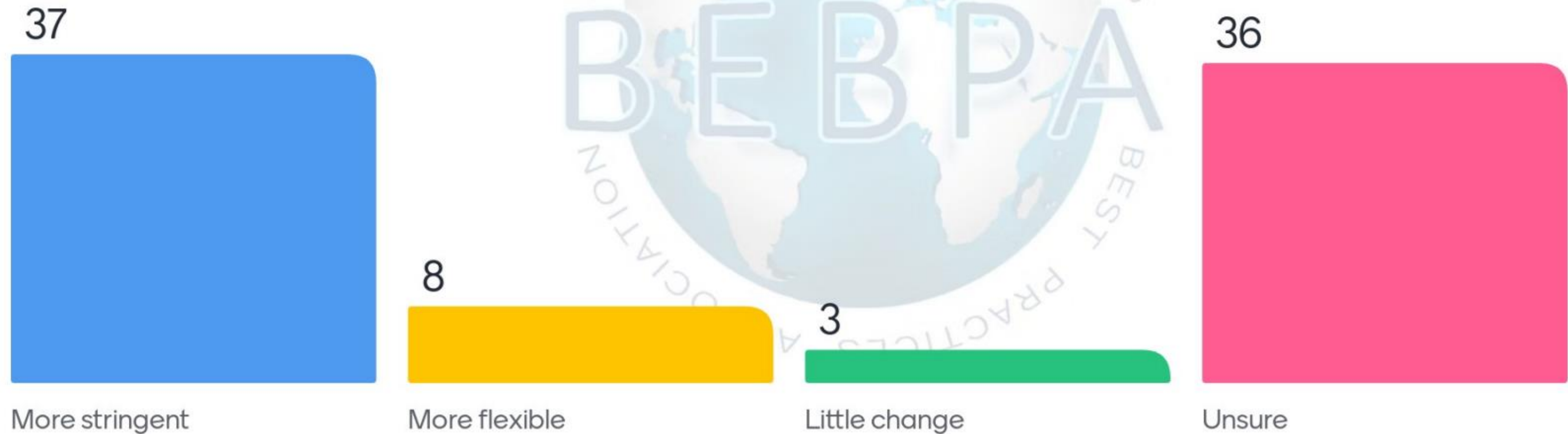
2.2 What is your current challenge for the bioassay you are working on?

Analytical range	Establishing a platform approach	Primary cells	Specificity
Assessing sensitivity		Primary cells	Specificity
Automation	Get right target cells	Reagents	Specificity
Automation	High variability	Recoveries	Stable cells
Automation	Lack of linearity	Reference standards	Statistics
Automation	Low signal to noise	Reference standards	Statistics
Automation	Material shortage	Reproducibility	Suitability criteria
Bioassay statistics	Matrix effects	Reproducibility	Tech transfers
Bridging to older method	MoA	Reproducibility	Tight timelines
BSA lot sensitivity	MoA	Reproducibility	Time and costs
Capacity	MoA	Reproducibility	Timeline
Challenging cell line’s protein expression	MoA modelling	Reproducibility	Timeline
	MoA primary cells	Robustness	Validity
Closeness to clinical effects	MoA Reflectiveness	Robustness	Variability
closeness to patient safety	MoA Reflectiveness	Robustness of some assays	Variability
Complex MoA	Narrow assay range	Sample size	Variability
Critical reagents	Outliers	Scaling up	Variability
Detection of the MoA	Parallel Lines	Sensitivity	Variability
Development time	Parallellism	Similarity assessment for not widely used fitting models	Variability
Equivalent	Precision		Variability
Equivalent Margins development	Precision		Variability

2.3 How robust are the bioassays you have developed on average?



2.4 How do you predict overall regulatory frameworks for ATMP products evolving in the next 5-10 years?



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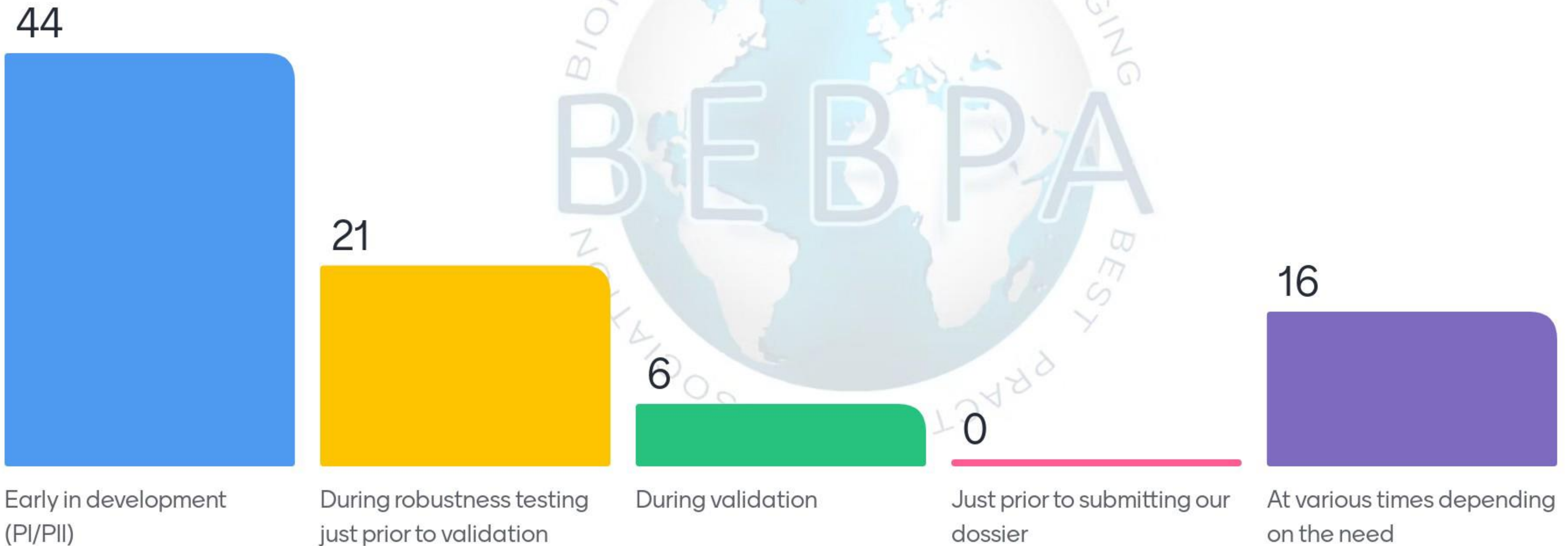
Session 3: How to Know If Your Assay Is Good Enough?

Session Chair: Nancy Niemuth
Statistical Consultant
Act Two Consulting

Audience Surveys

3.1 When do you establish similarity system suitability criteria?



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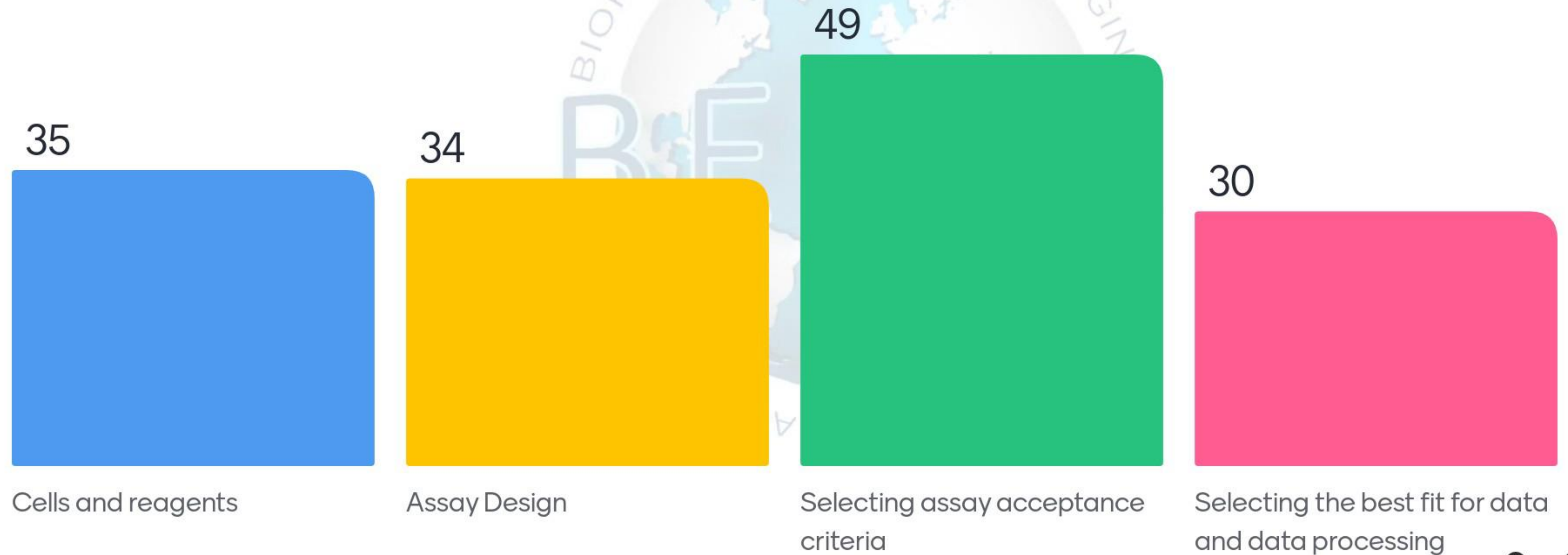
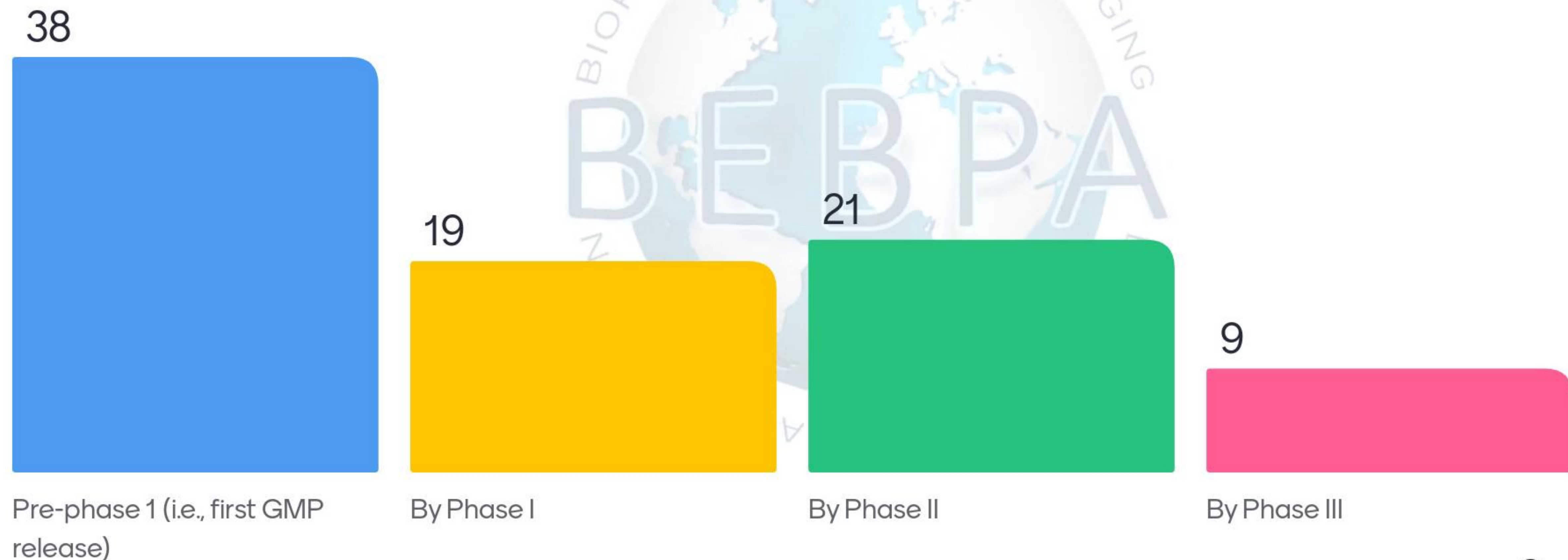
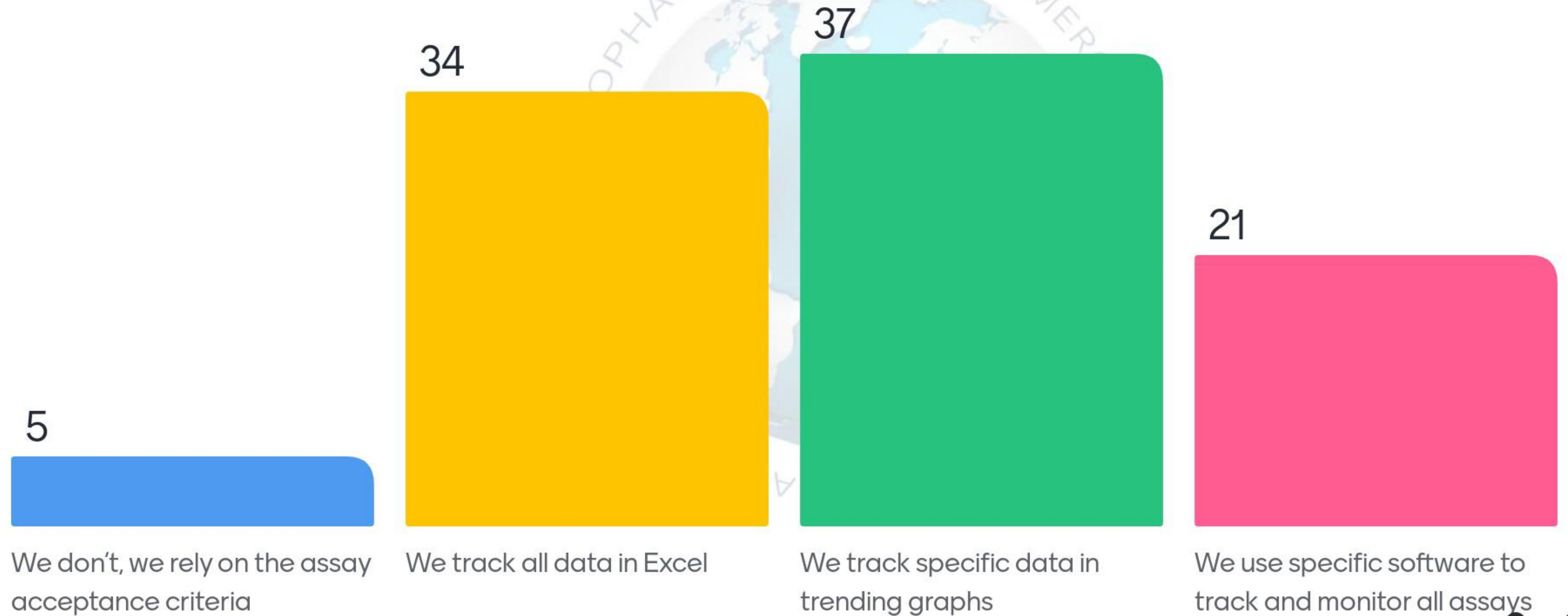
3.2 Which areas of CBA development to you thank are the most challenging?



3.3 How soon would you use a functional bioassay for GMP release?



3.4 How do you monitor your bioassay?



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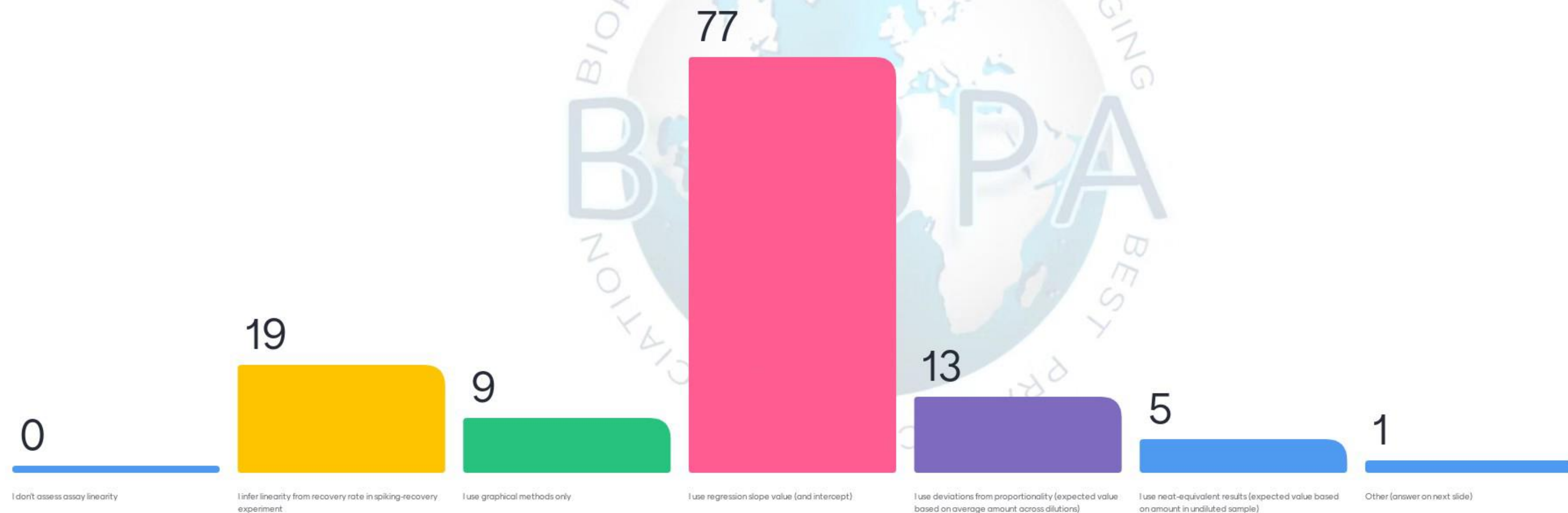
3.5 Which metrics do you use for linearity assessment?



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3.5a Other *(Which metrics do you use for linearity assessment?)*

52 responses

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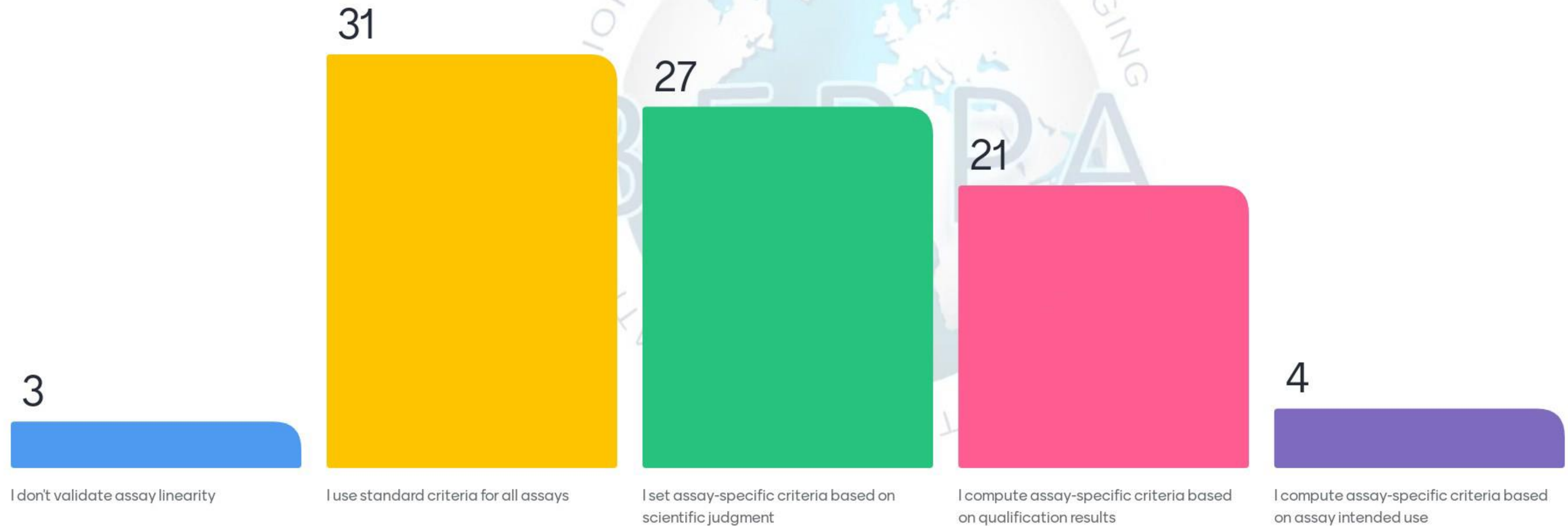
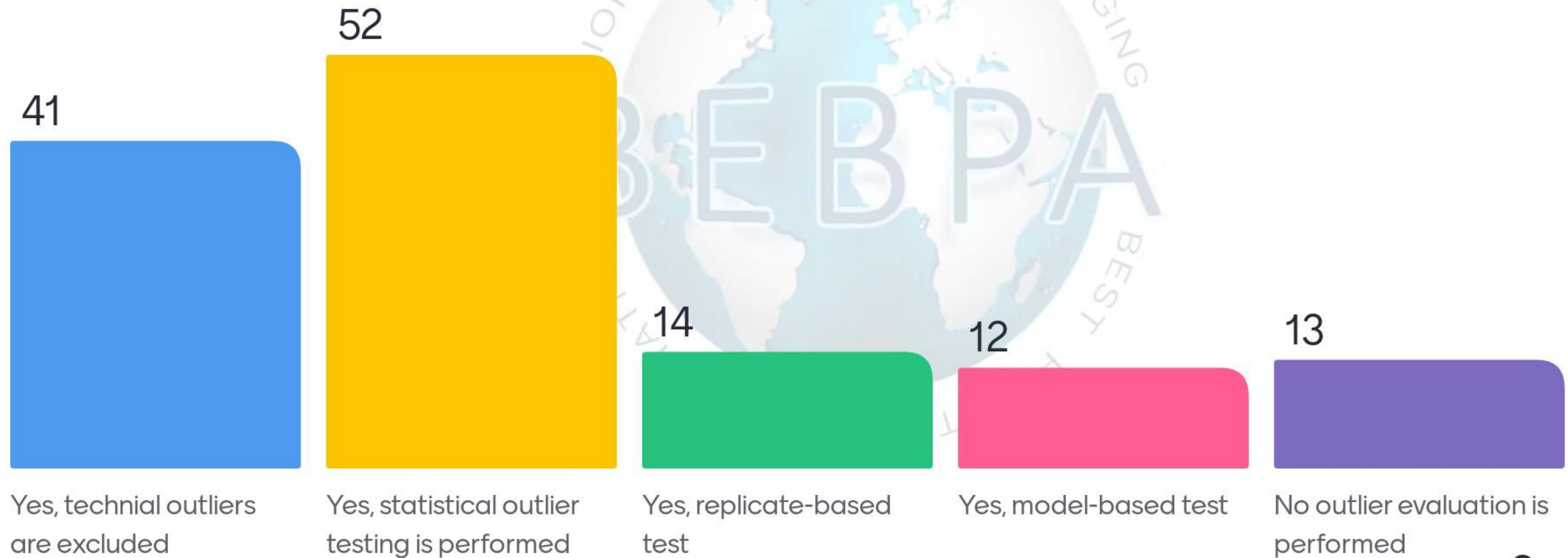
3.6 How do you derive linearity validation criteria?

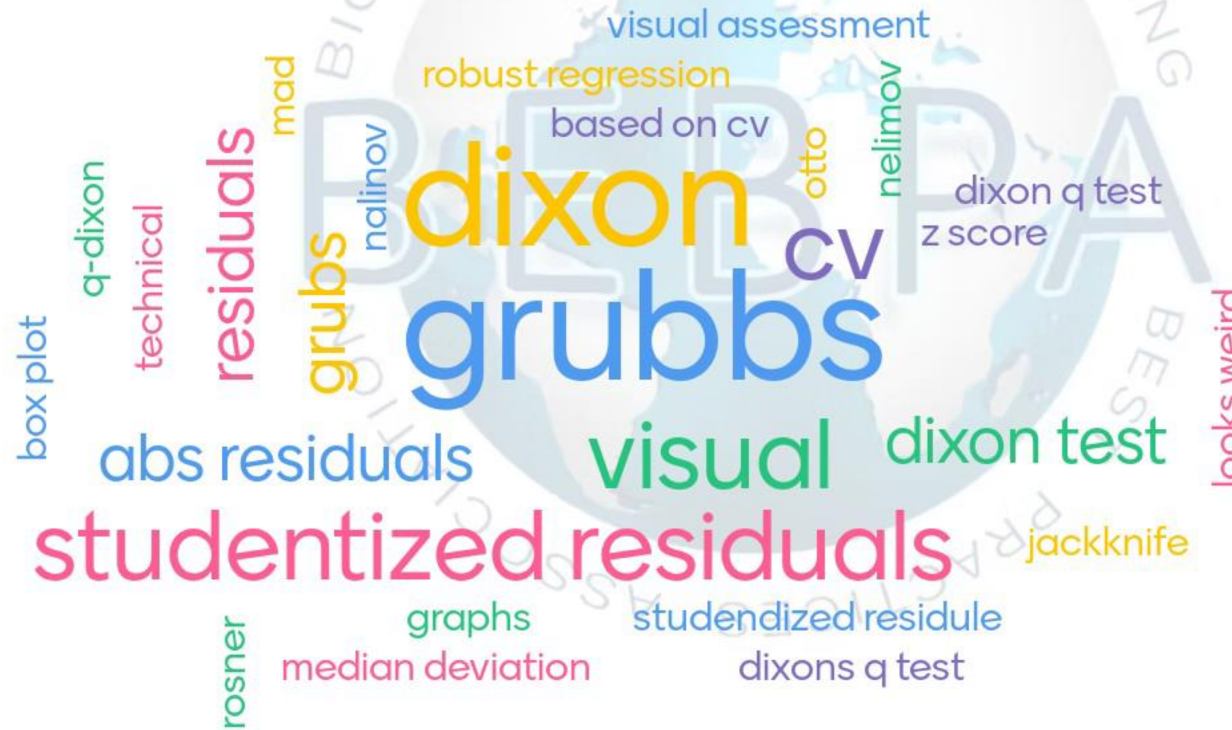


3.7 Do you perform outlier evaluation and exclusion?



3.8 What kind of outlier evaluation do you perform?

67 responses



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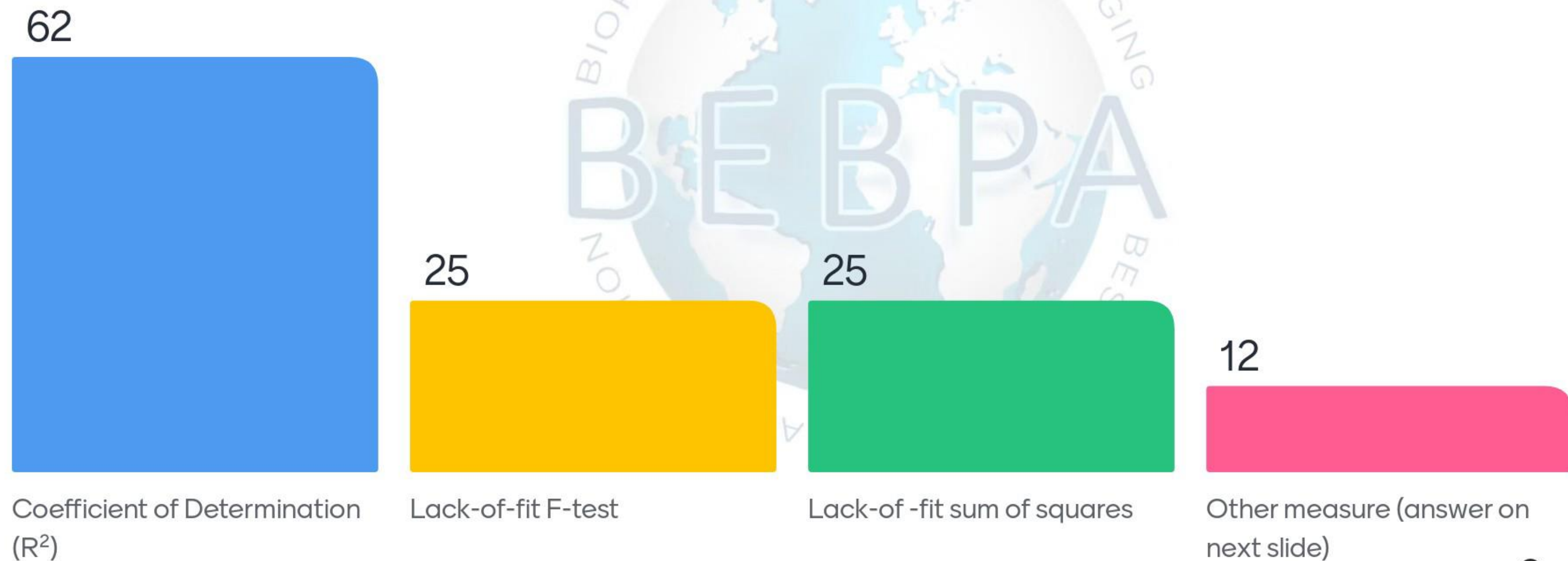
3.9 Which measure for adequacy of the model-fit do you use?



3.9a Other measure *(Which measure for adequacy of the model-fit do you use?)*

34 responses

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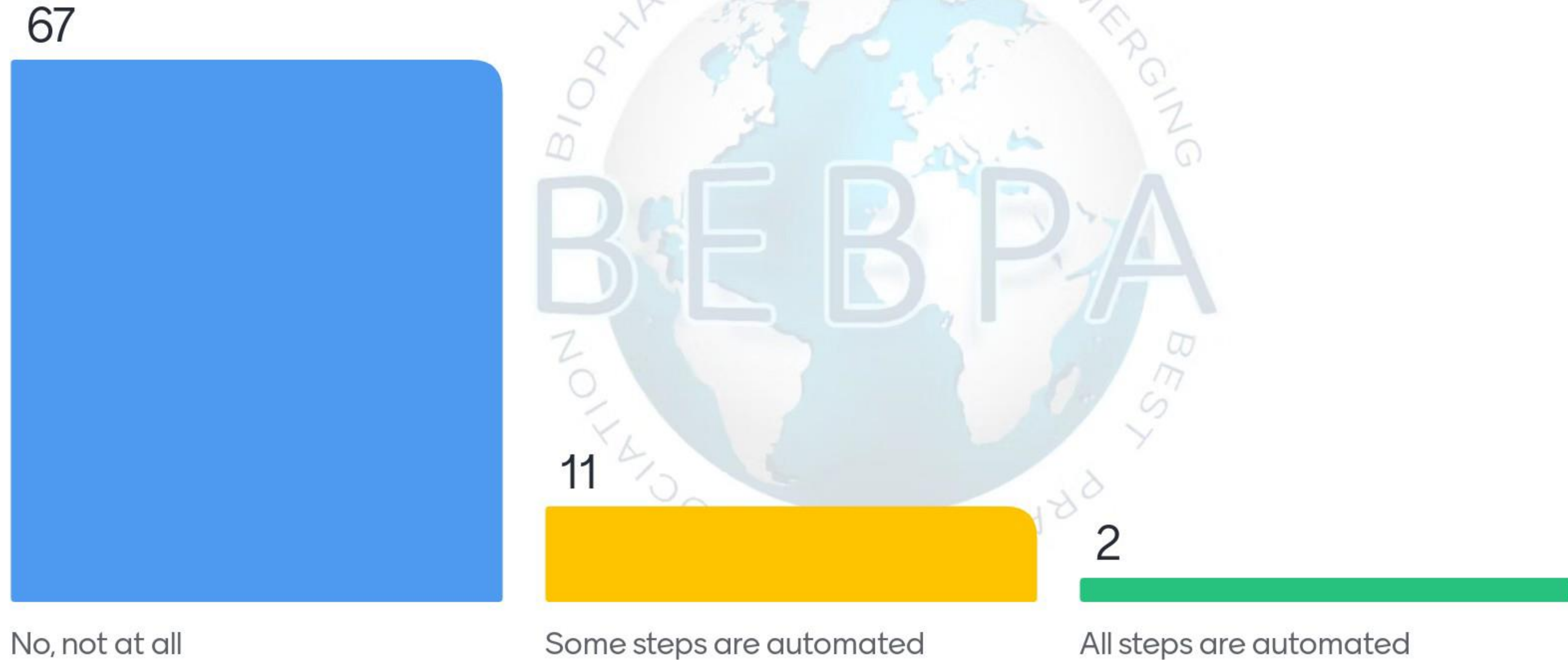
27

Session 4: Automation

Session Chair: Siân Estdale
Consultant
BEBPA Board of Directors

Audience Surveys

4.1 Is your tissue culture automated?



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4.2 Which Software do you use for your potency assays? *(Multiple answers allowed)*

130 responses

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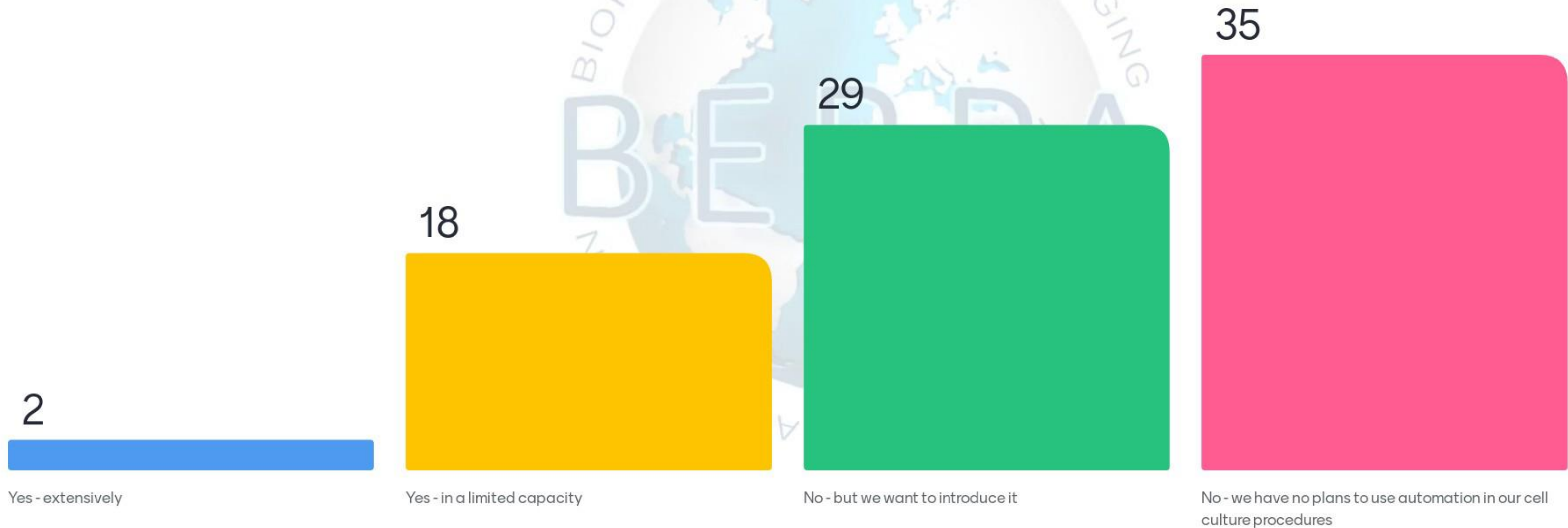
81

4.3 Do you automate any of your cell culture procedures?



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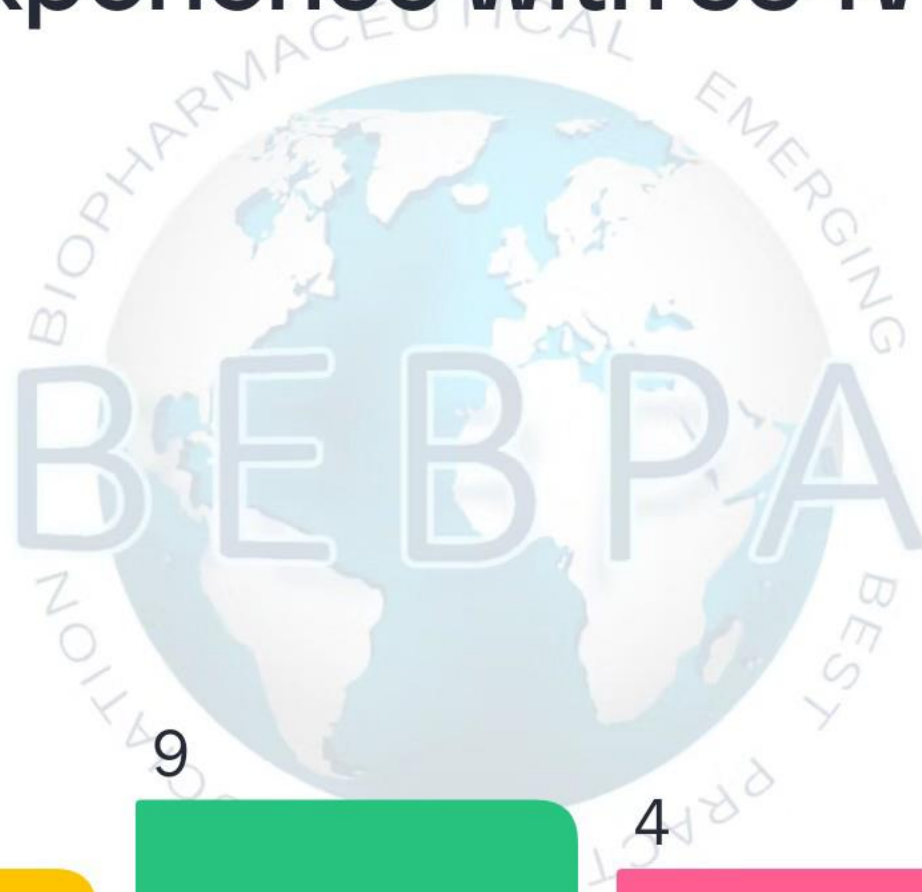
4.4 What's your experience with 384W format bioassays?



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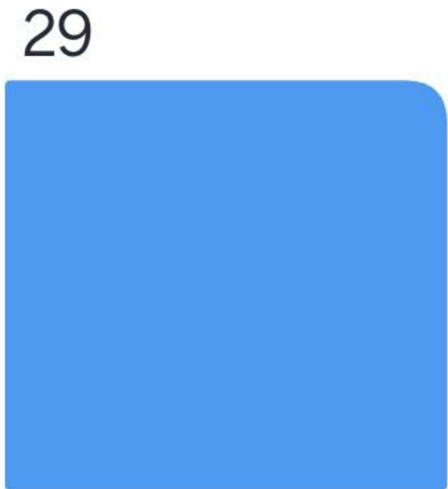


We've done some tests with 384W assays, but no qualified methods yet.

4

We have a 384W format ELISA running in development.

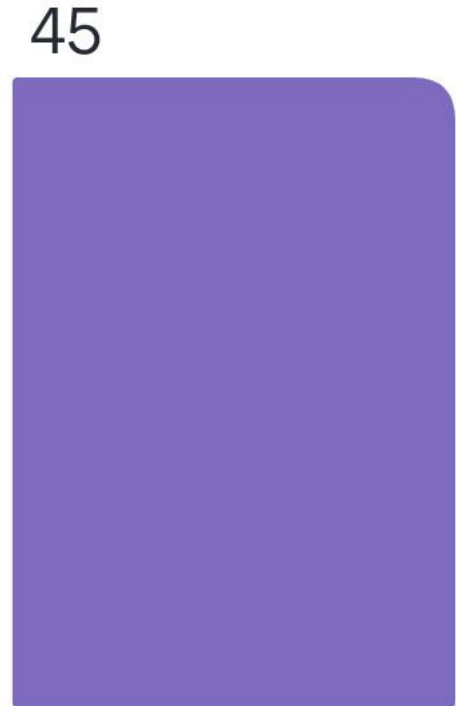
9

We have a 384W format cell based bioassay running in development.

4

We have a 384W format assay running in QC.

45



We never tried 384W plate formats for bioassays.

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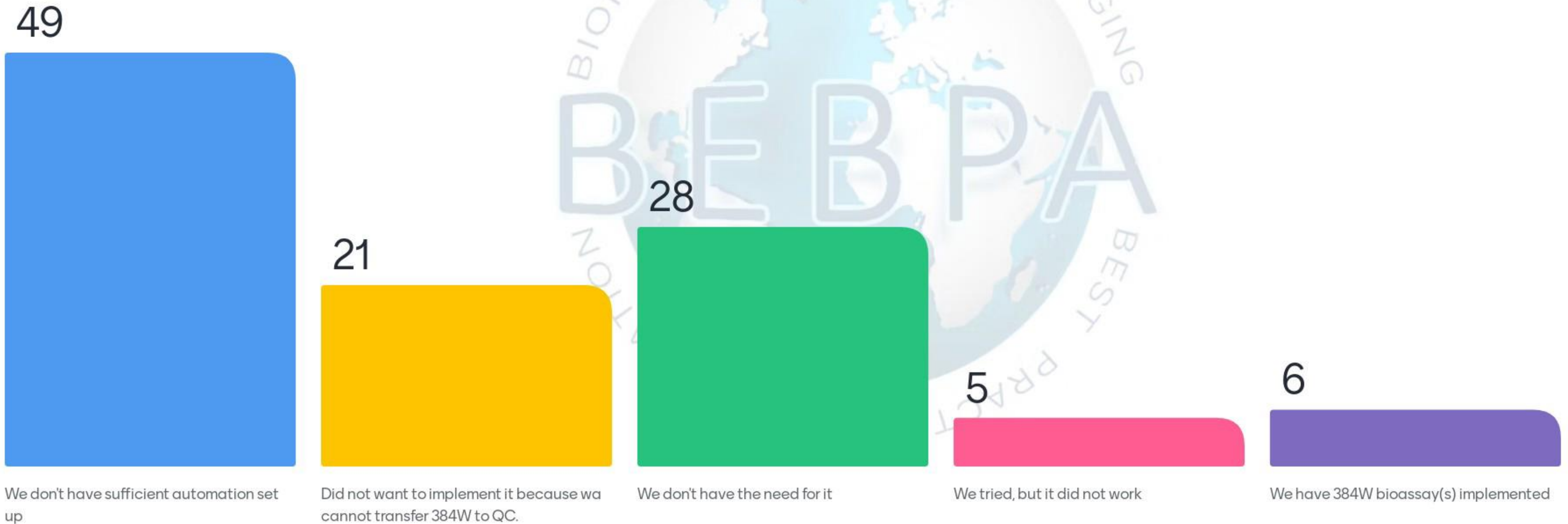
4.5 What's the reason behind *not* implementing 384W bioassays?



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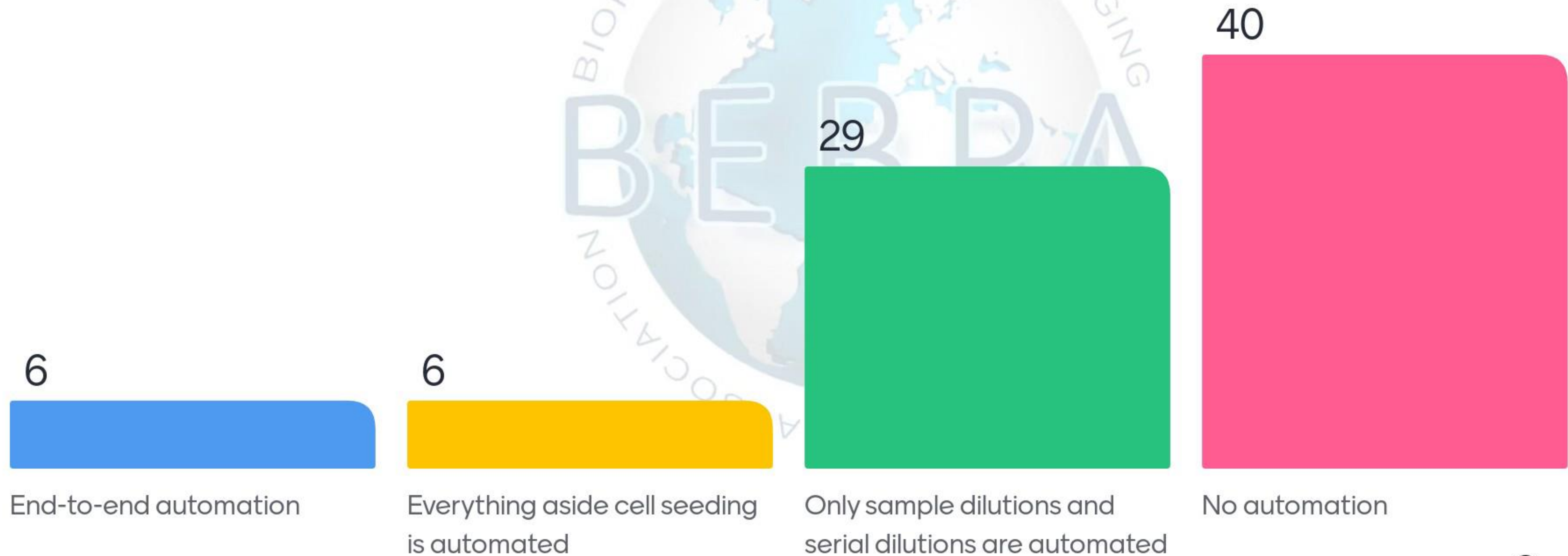
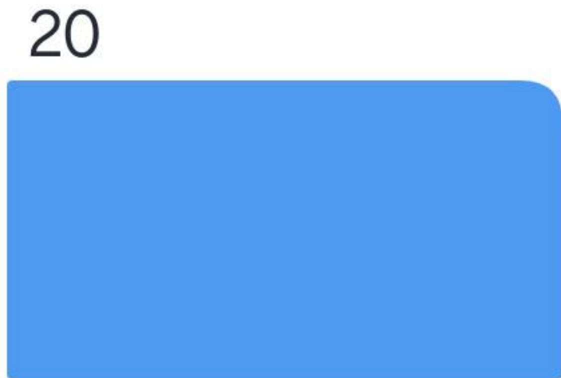
4.6 To what extent are your cell-based assays automated?



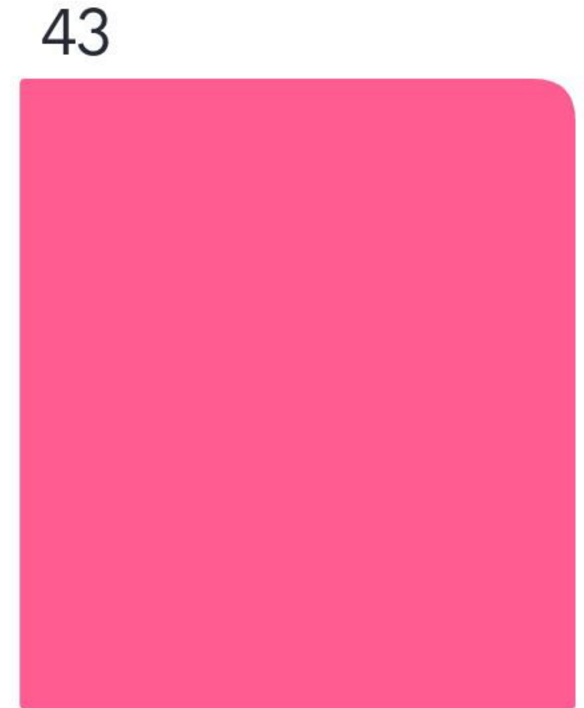
4.7 How do you handle pipetting of cells with a liquid handler?



We have the liquid handler enclosed in a biosafety cabinet designed for the robot

We have a liquid handler system on the bench, without any special enclosure

We have a smaller dispenser placed in a biosafety cabinet



We always pipette cells using a manual pipette

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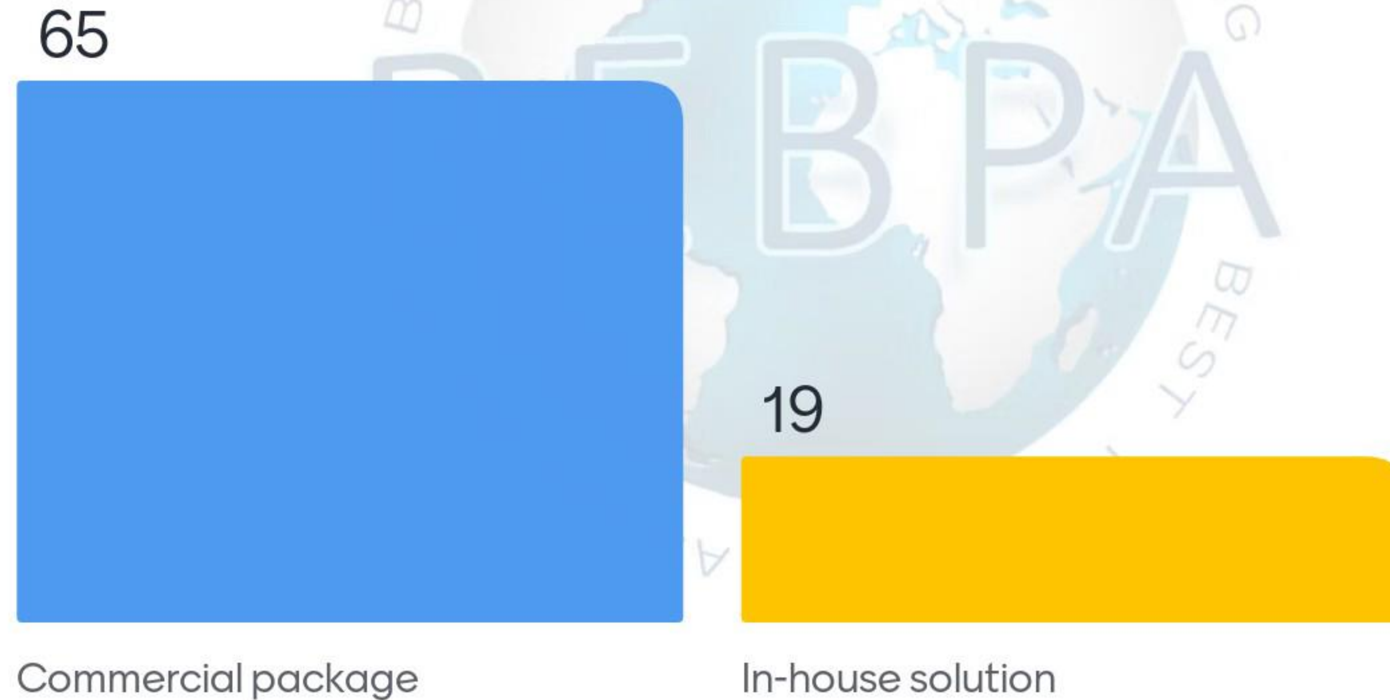
4.8 Statistical analysis of bioassay results: do you use a commercial software or an in-house solution?



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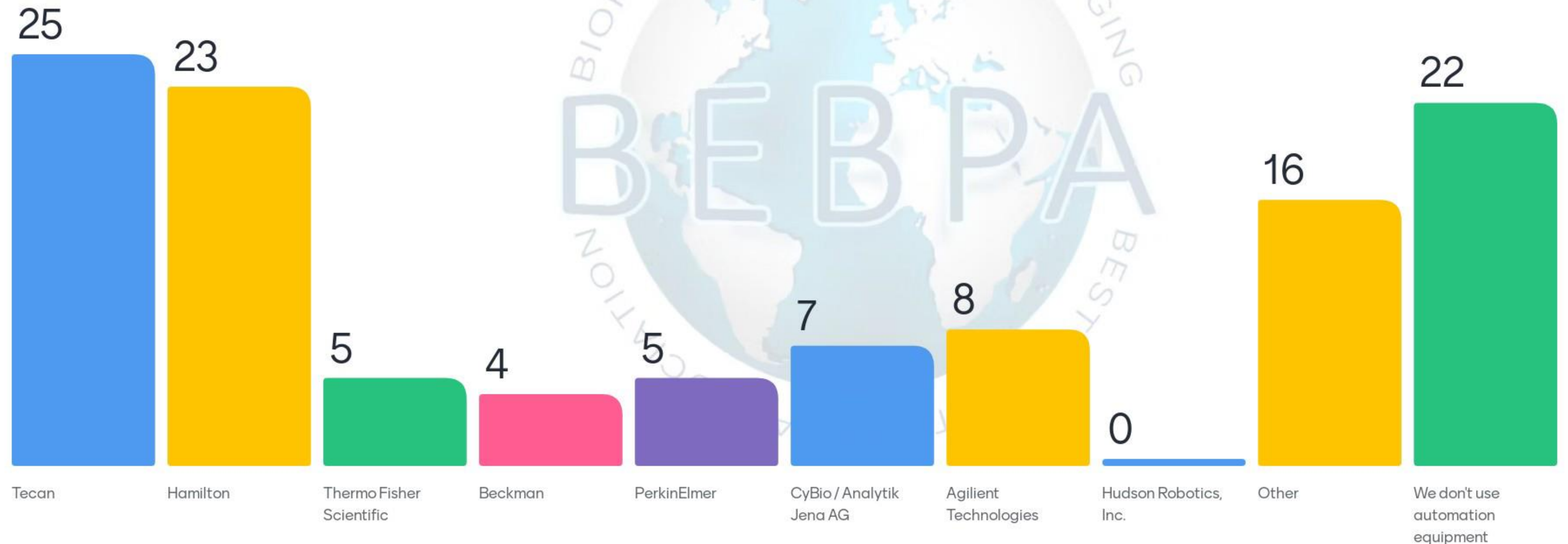
4.9 What brand of *large* laboratory automation equipment do you use the most?



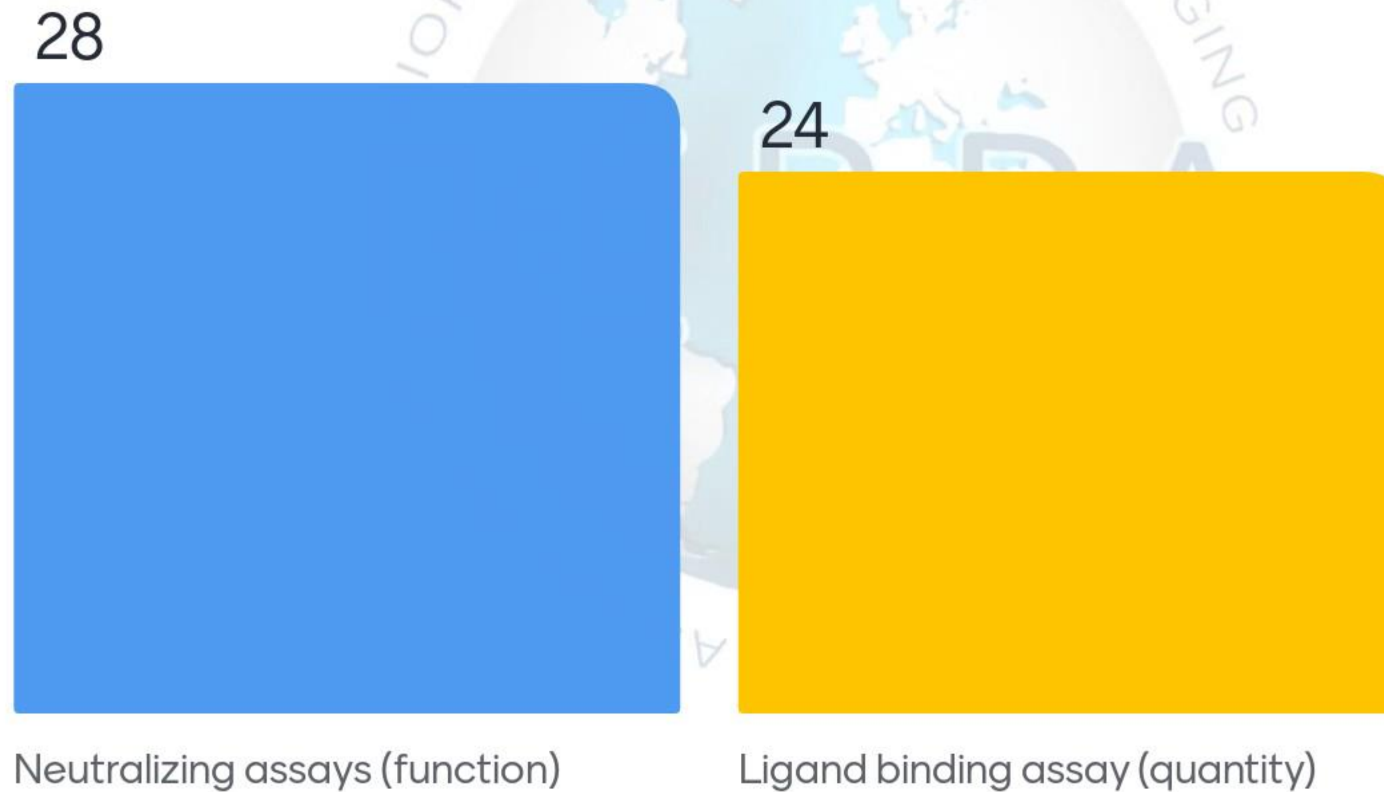
INTEREST GROUP SURVEYS

Interest Group 1: Developing and Validating Clinical Assays for Vaccine Products

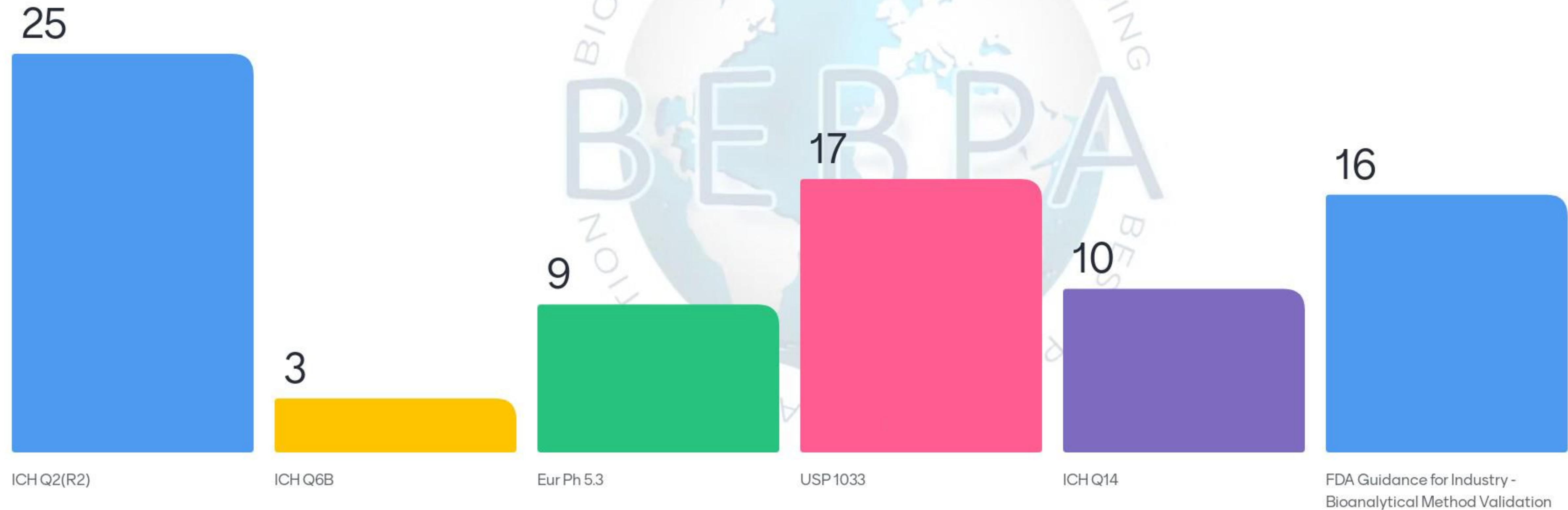
Interest Group 1 Leader:
Nancy Niemuth
Statistical Consultant
Act Two Consulting

Audience Surveys

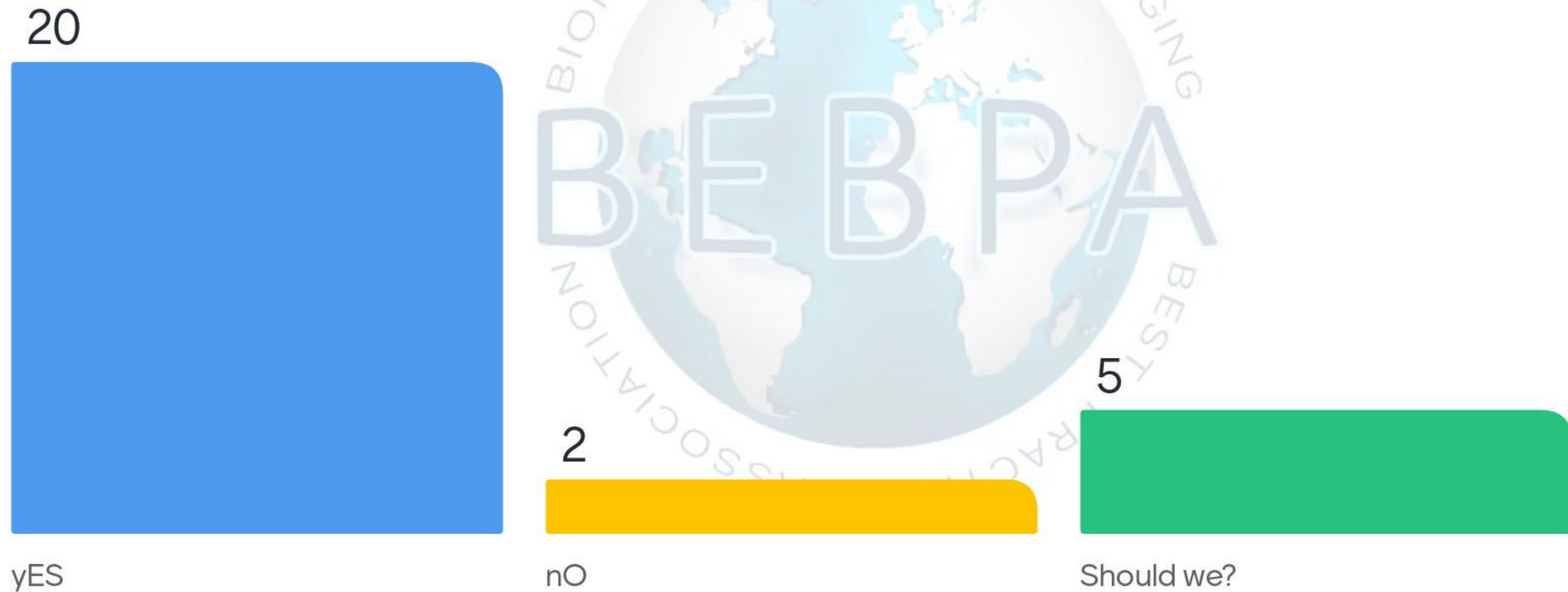
IG1.1 Should clinical assays for vaccine products include:



IG1.2 Which validation guidance do you use?



IG1.3 Do you include real life samples in your clinical assay validation?



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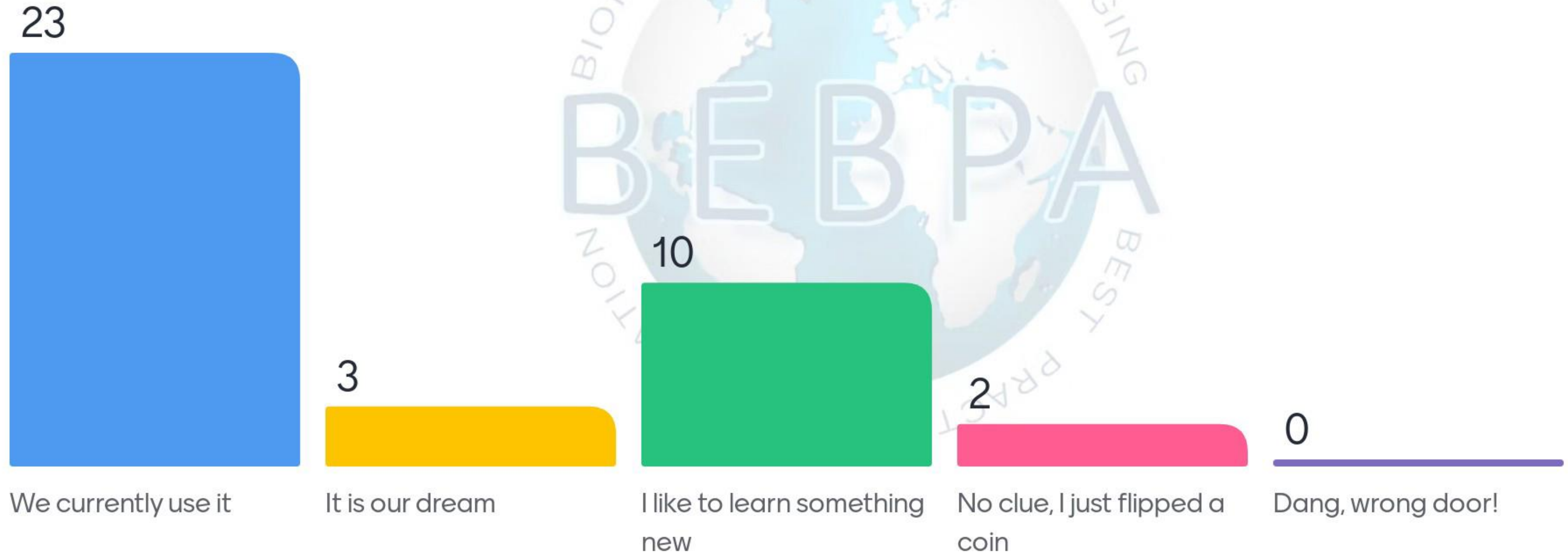
Interest Group 2: Flow Cytometry Assays

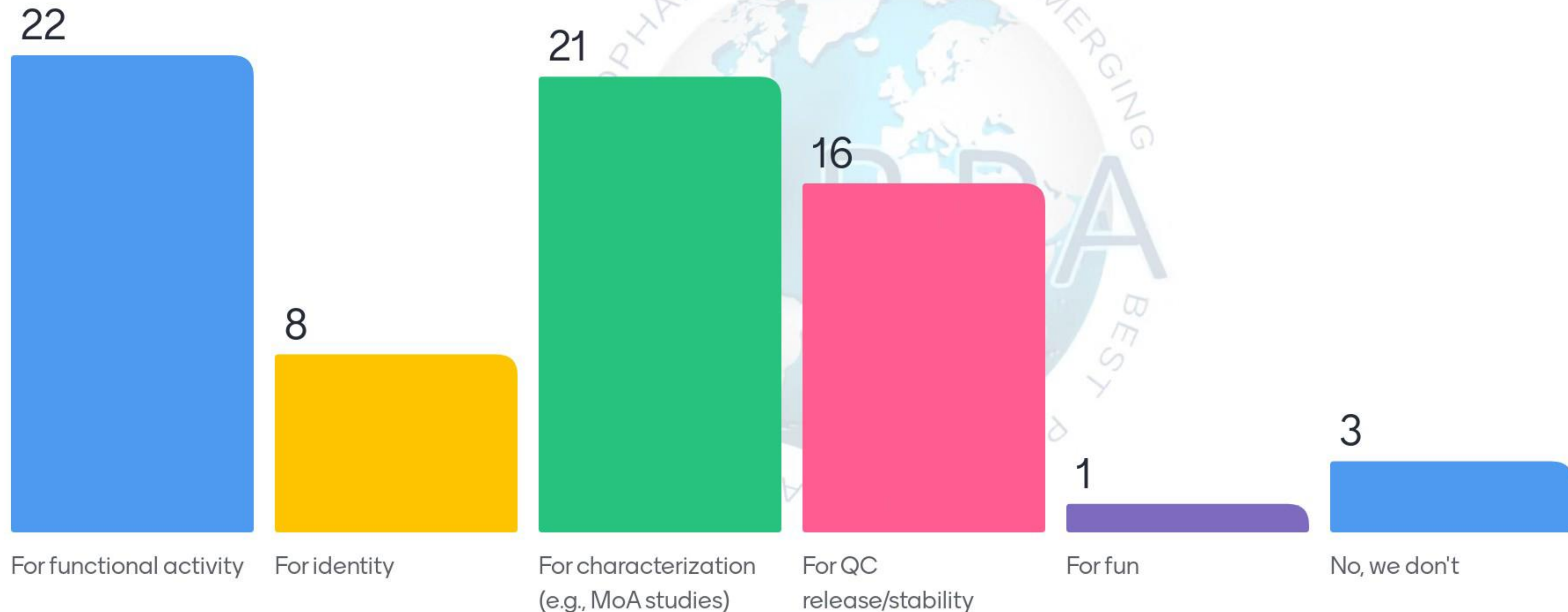
Interest Group 2 Leader:
Anton Stetsenko
Principal Consultant
BioQual Consulting

Audience Surveys

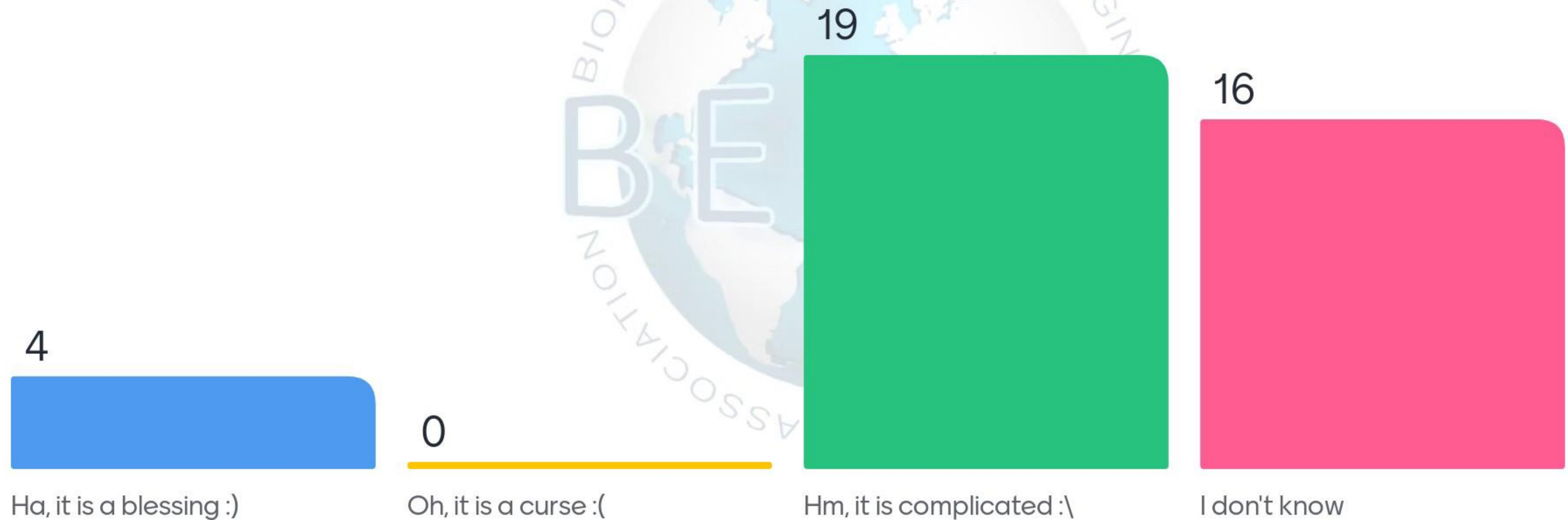
IG2.1 Why did you chose Flow Cytometry (FC) interest group?



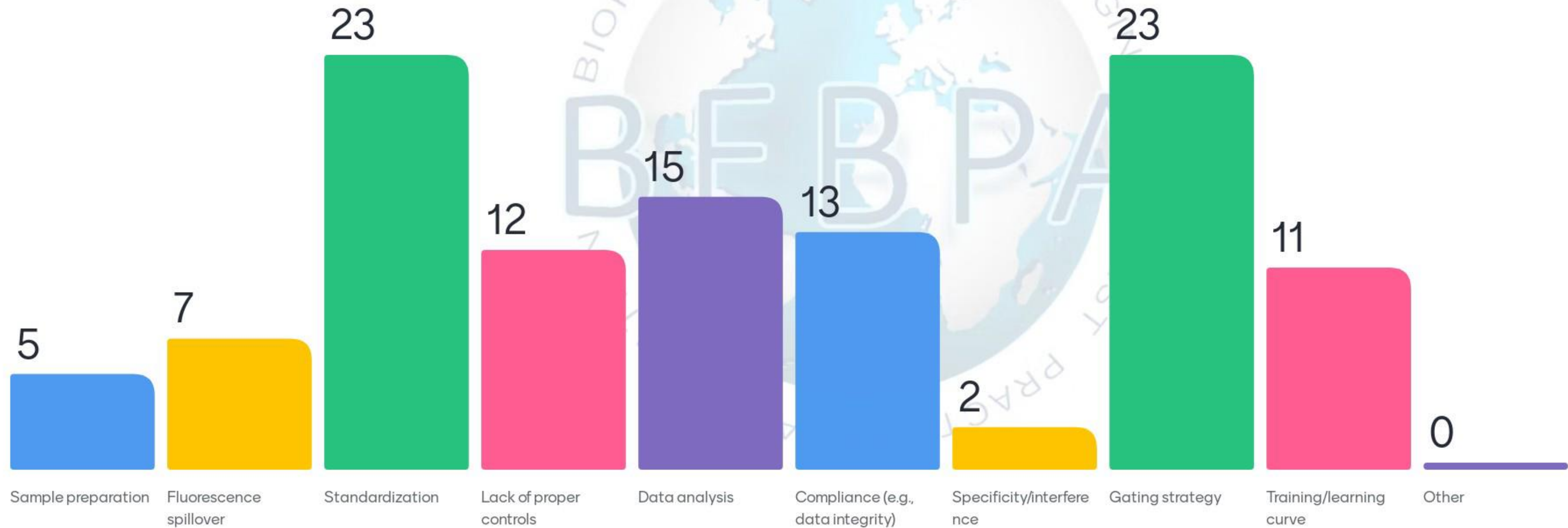
IG2.2 We use (or plan to use) FC...



IG2.3 What do you think about FC application in the CMC field?



IG2.4 What do you think is a biggest FC challenge in the CMC?



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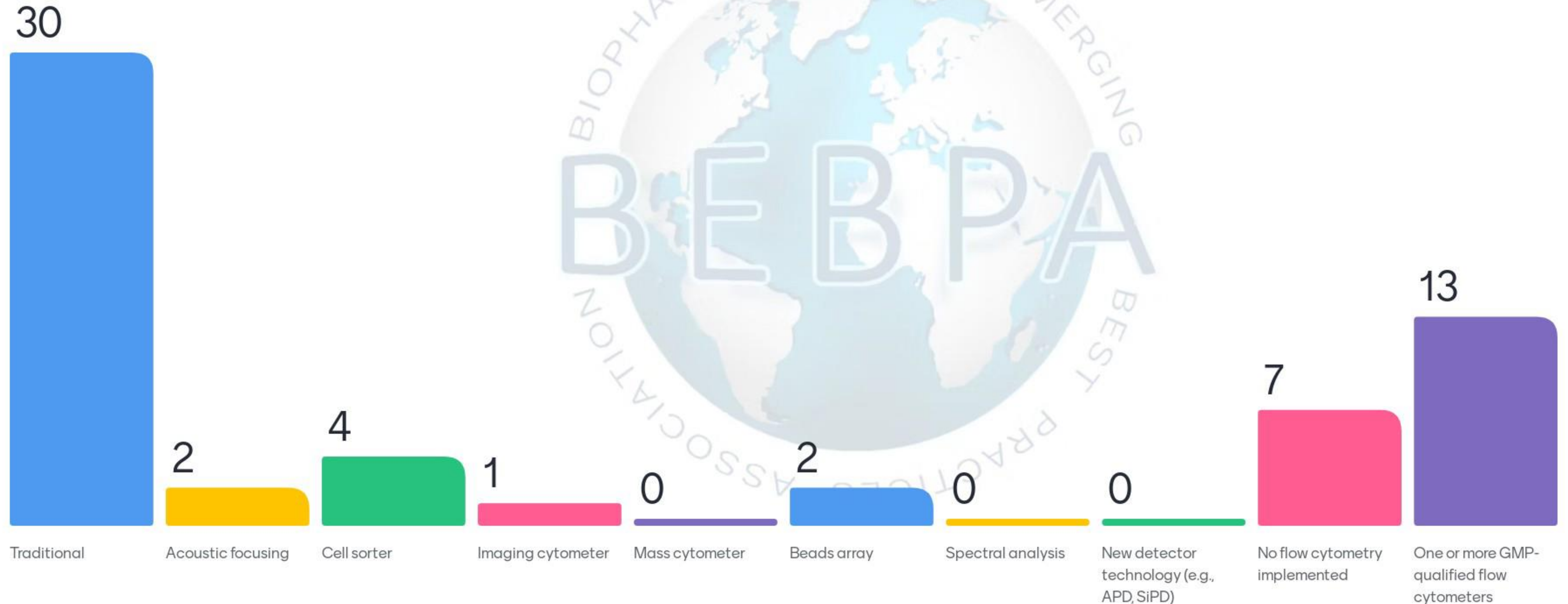
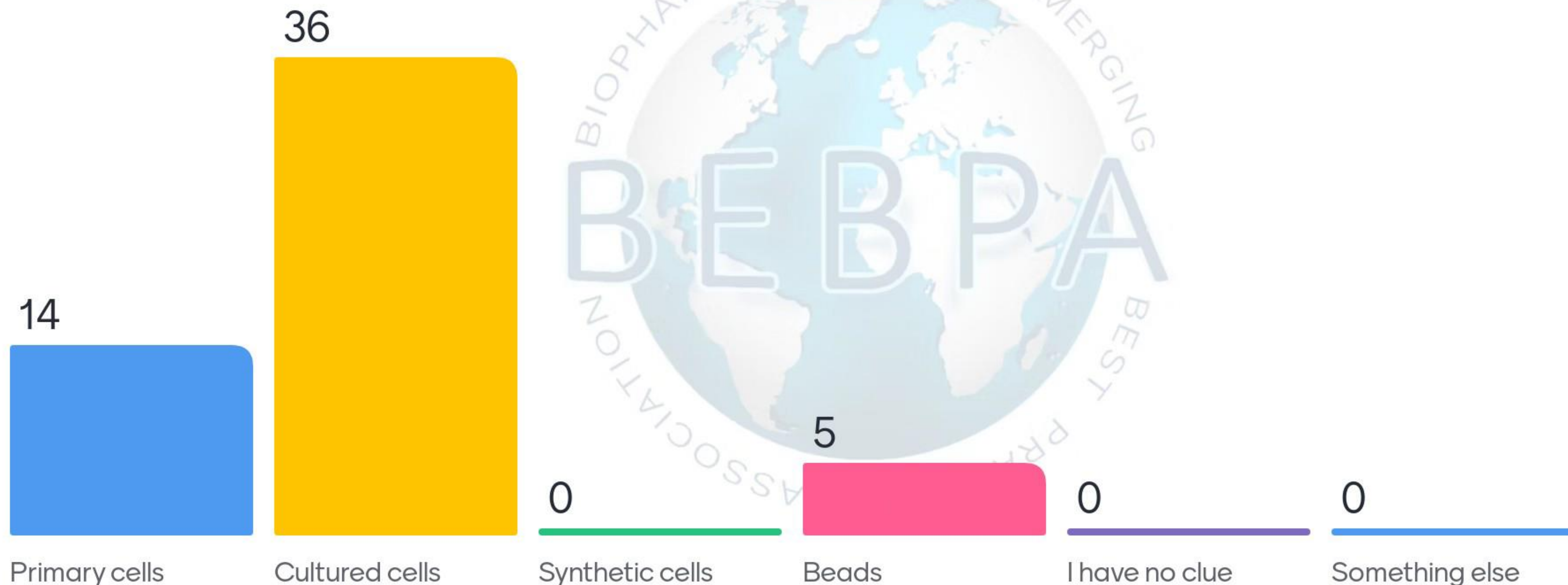
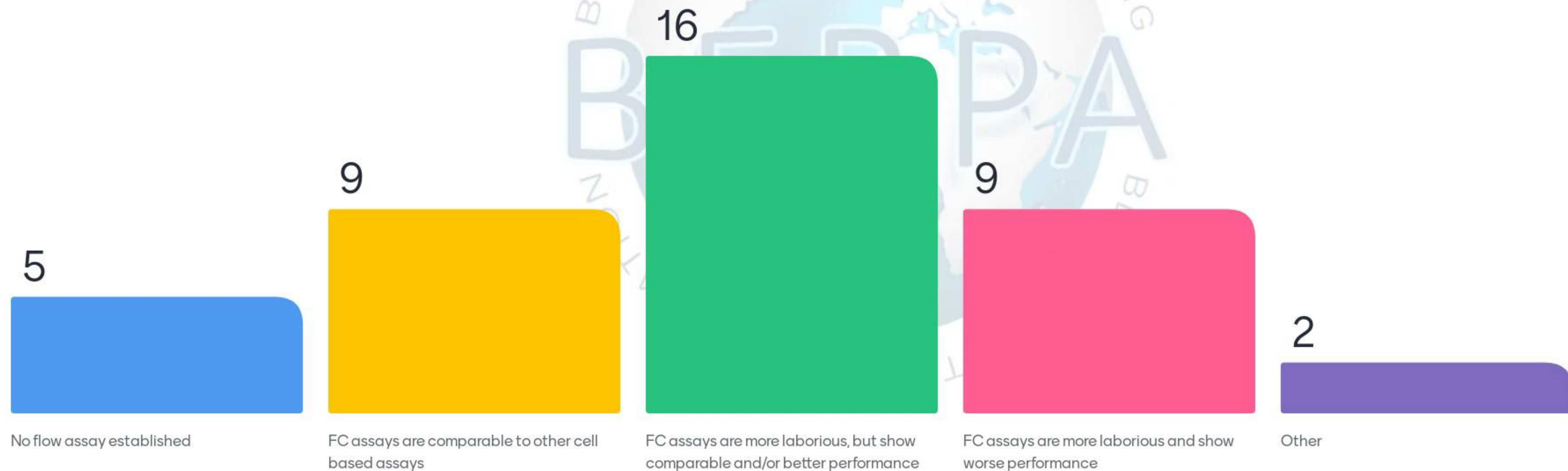
IG2.5 What type of FC do you use?



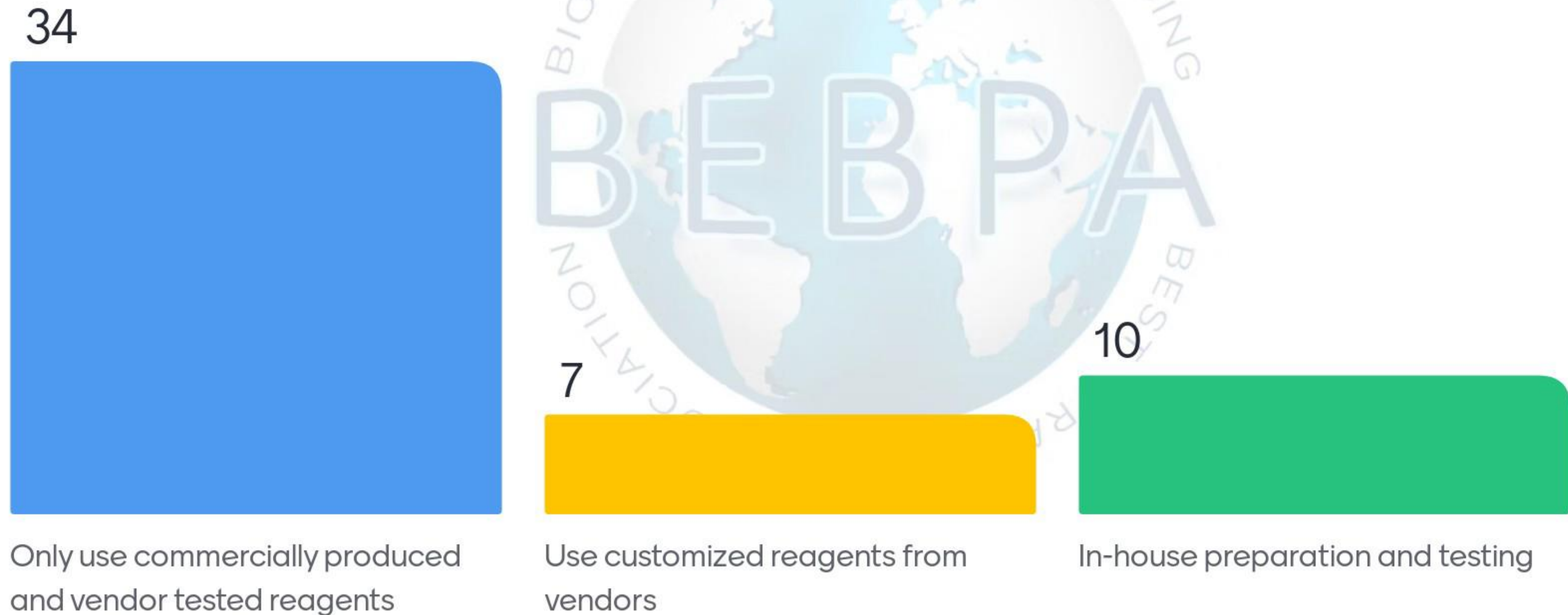
IG2.6 What type of sample do you use?



IG2.7 How is the convenience and performance of flow cytometer assays compared to other cell based assays in your lab?



IG2.8 How do you stock your critical reagents?

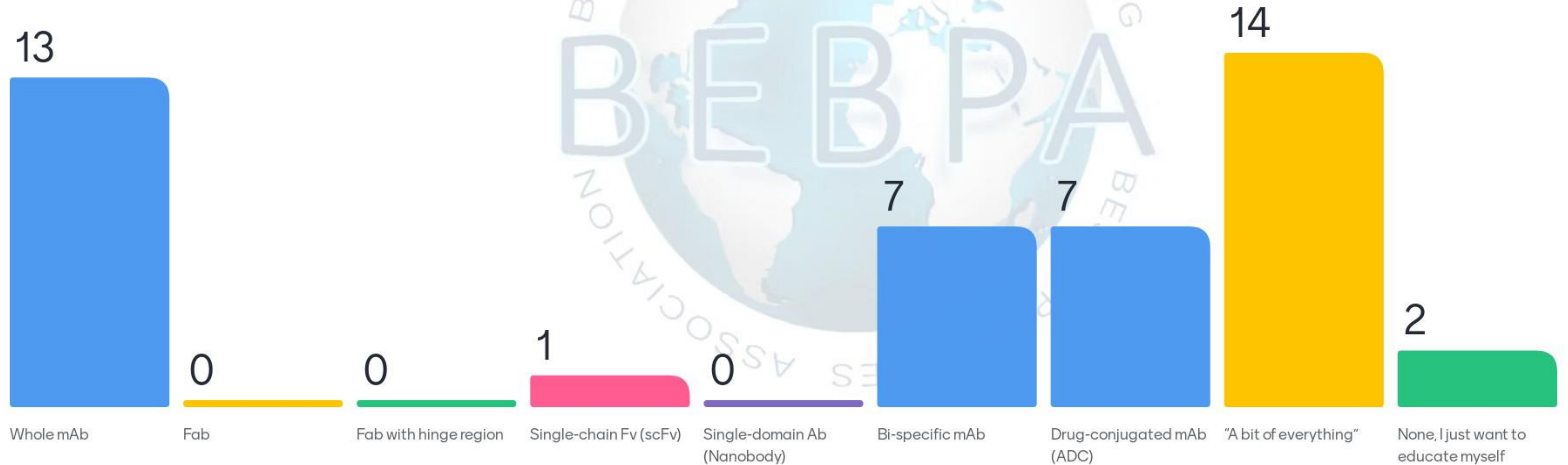


Interest Group 3: Characterizing Monoclonal Antibody Product

Interest Group 3 Leader:
Anton Stetsenko
Principal Consultant
BioQual Consulting

Audience Survey

IG3.1 What is the most comon type of monoclonal antibody products do you work with? Or want to learn about? STRUCTURE-based



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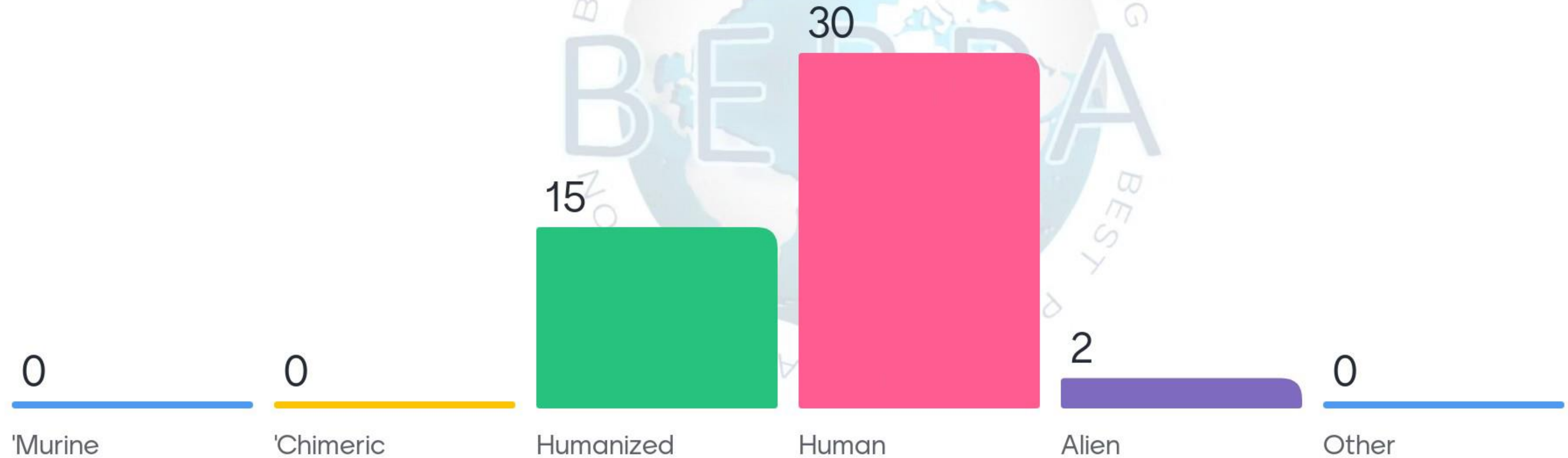
IG3.2(b) What is the most comon type of monoclonal antibody products do you work with? Or want to learn about? SOURCE-based



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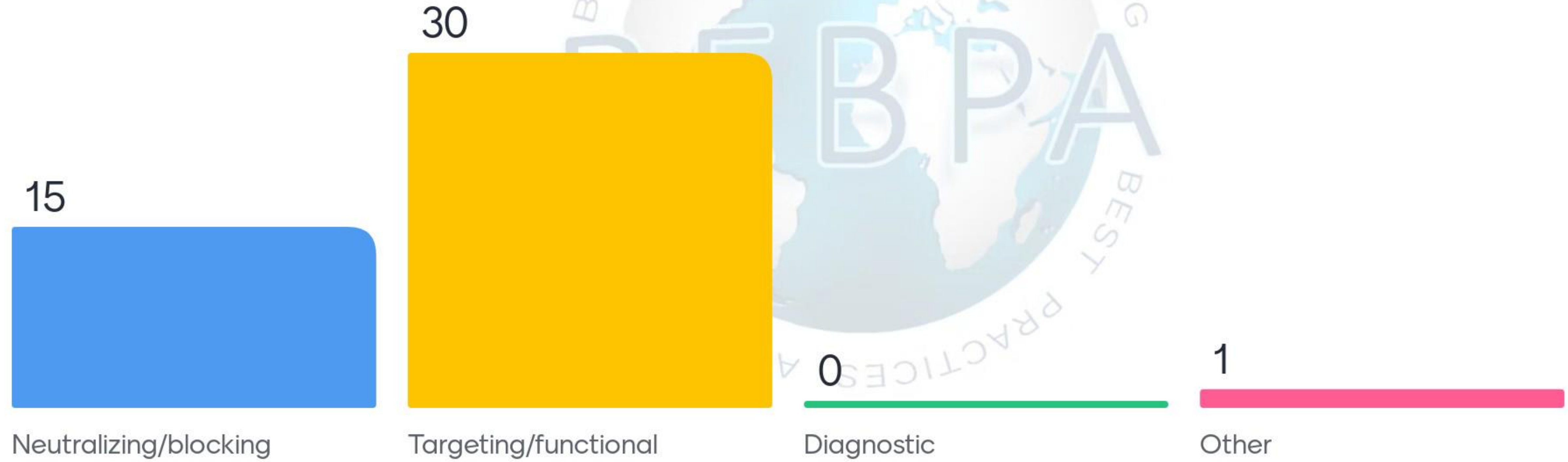
IG3.3 What is the most comon type of monoclonal antibody products do you work with? Or want to learn about? FUNCTION-based



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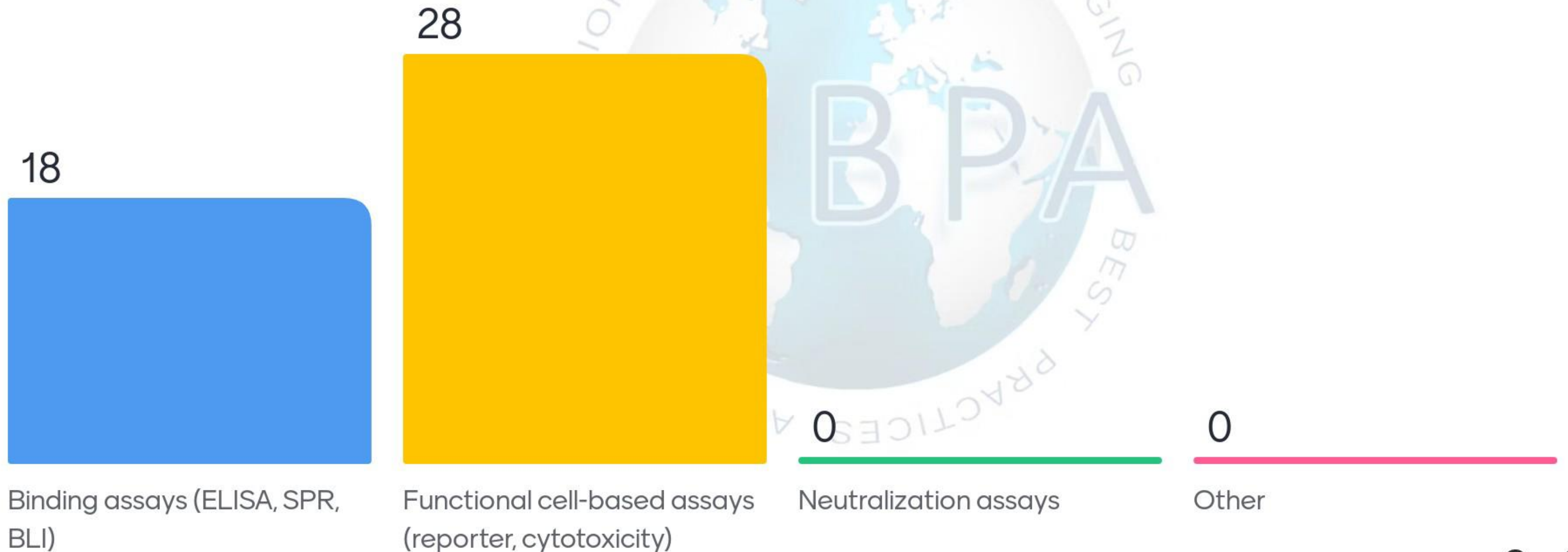
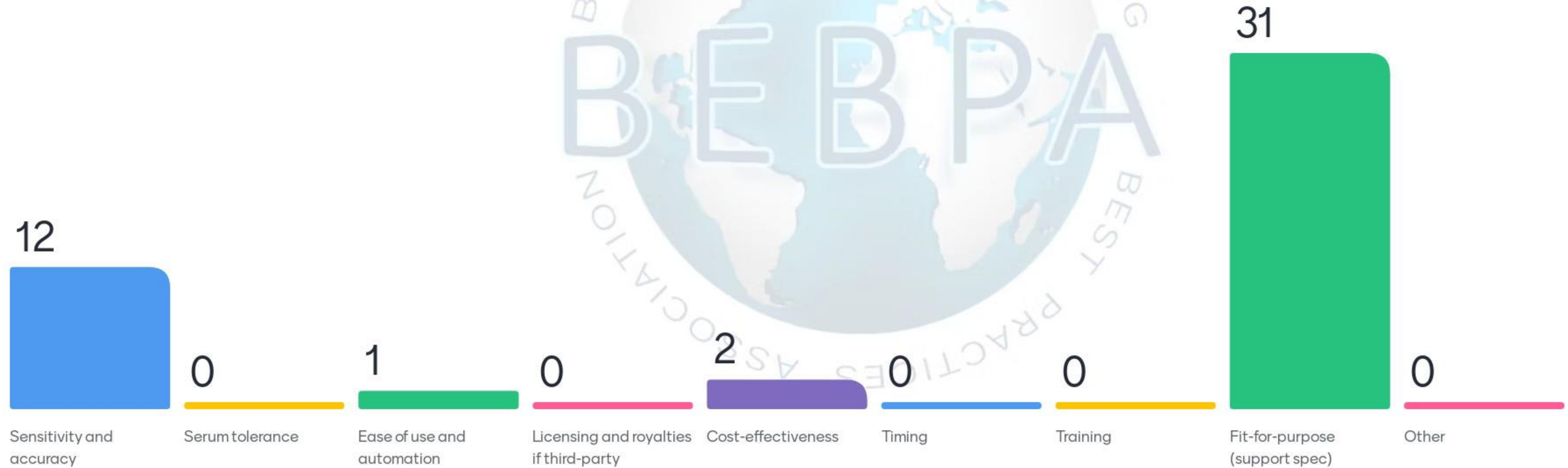
IG3.4 Which type of bioassay do you use most frequently to characterize antibody function?



IG3.5 When selecting bioassays for antibody potency and eventually QC release, which factor is most important to you?



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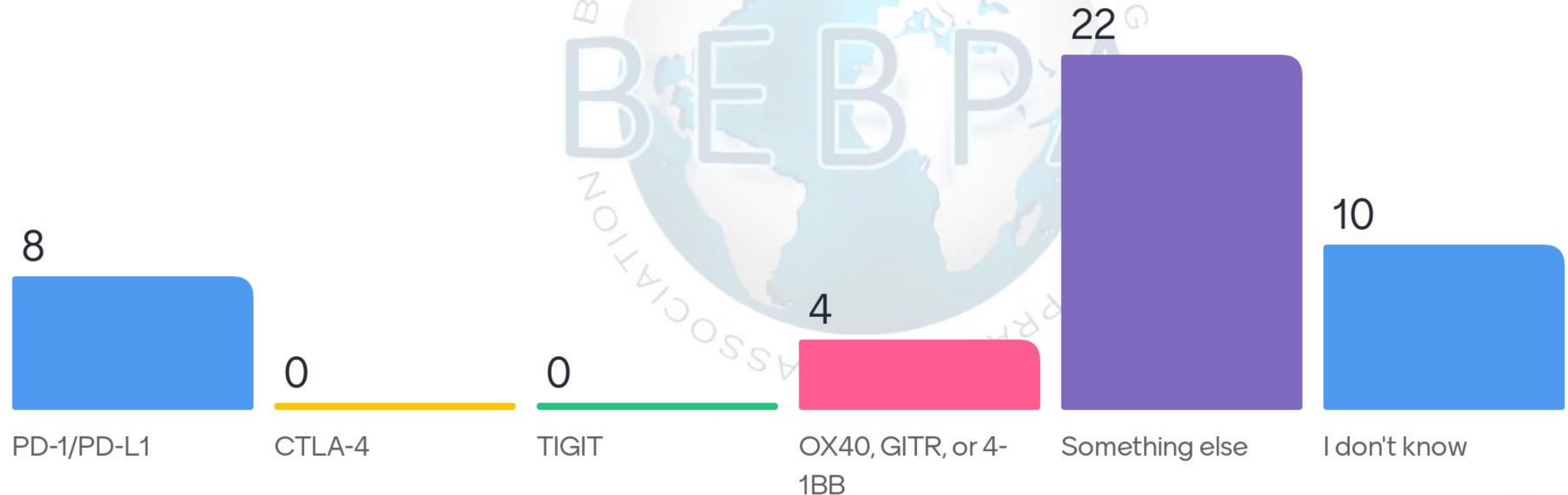
IG3.6 Which immune checkpoint or co-stimulatory target are you most focused on in your antibody development programs?



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IG3.7 How often do you assess the effector function (cytotoxicity) of therapeutic antibodies even though they are engineered to be Fc silent?

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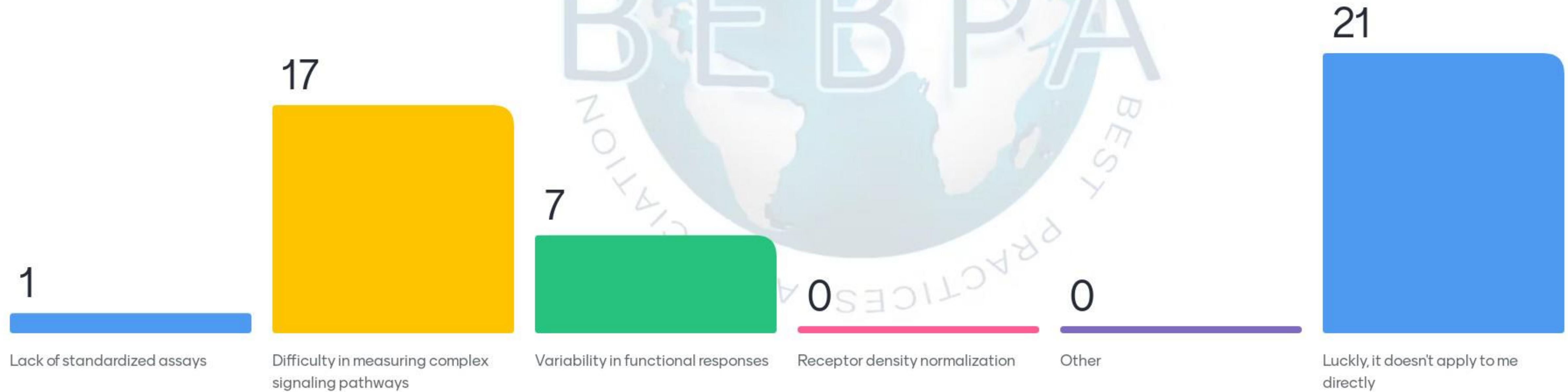
IG3.8 For novel immune checkpoints, which bioassay challenge is the most critical for your team? Or you anticipatet to be the most challenged?



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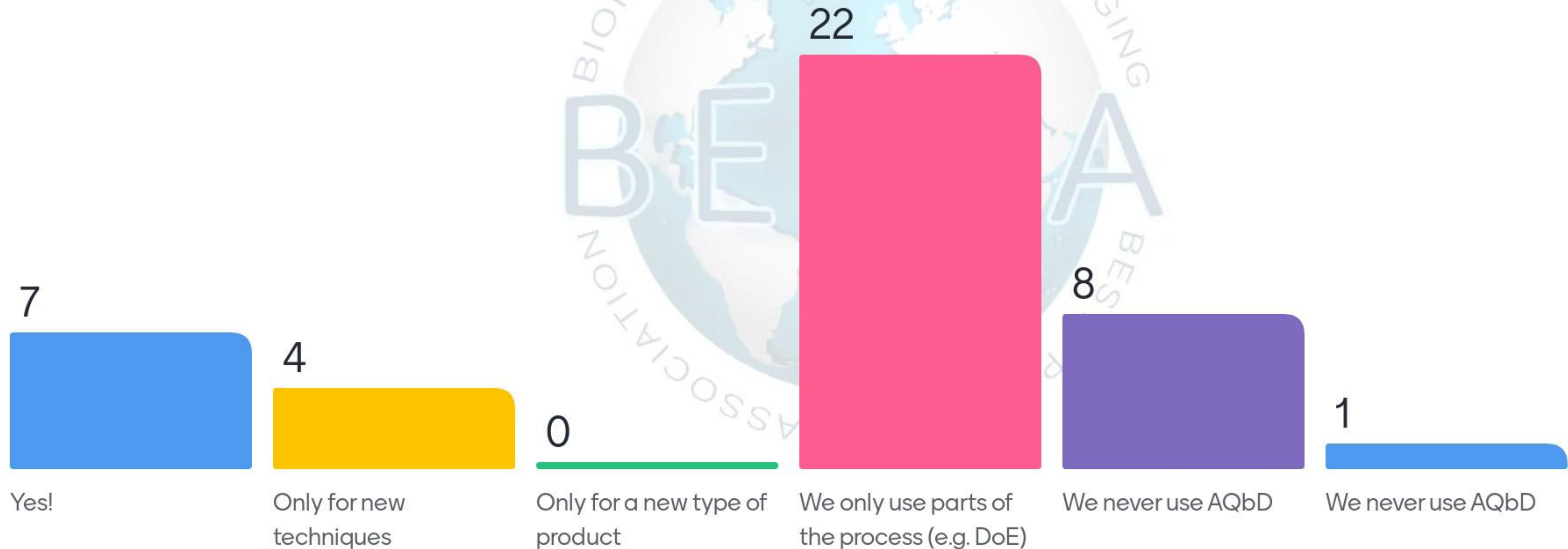
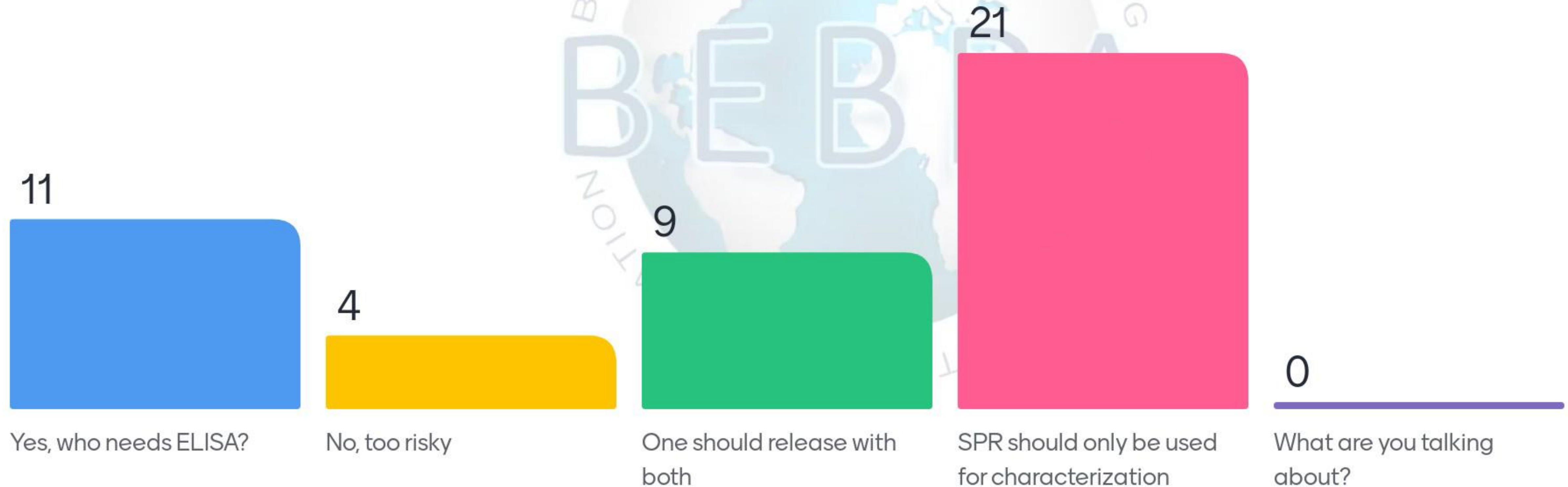
IG3.9 Do you follow the AQbD workflow for each of your method developments?



IG3.10 Can relative binding determination by SPR replace relative binding ELISA for BLA-enabled release/stability testing purpose?

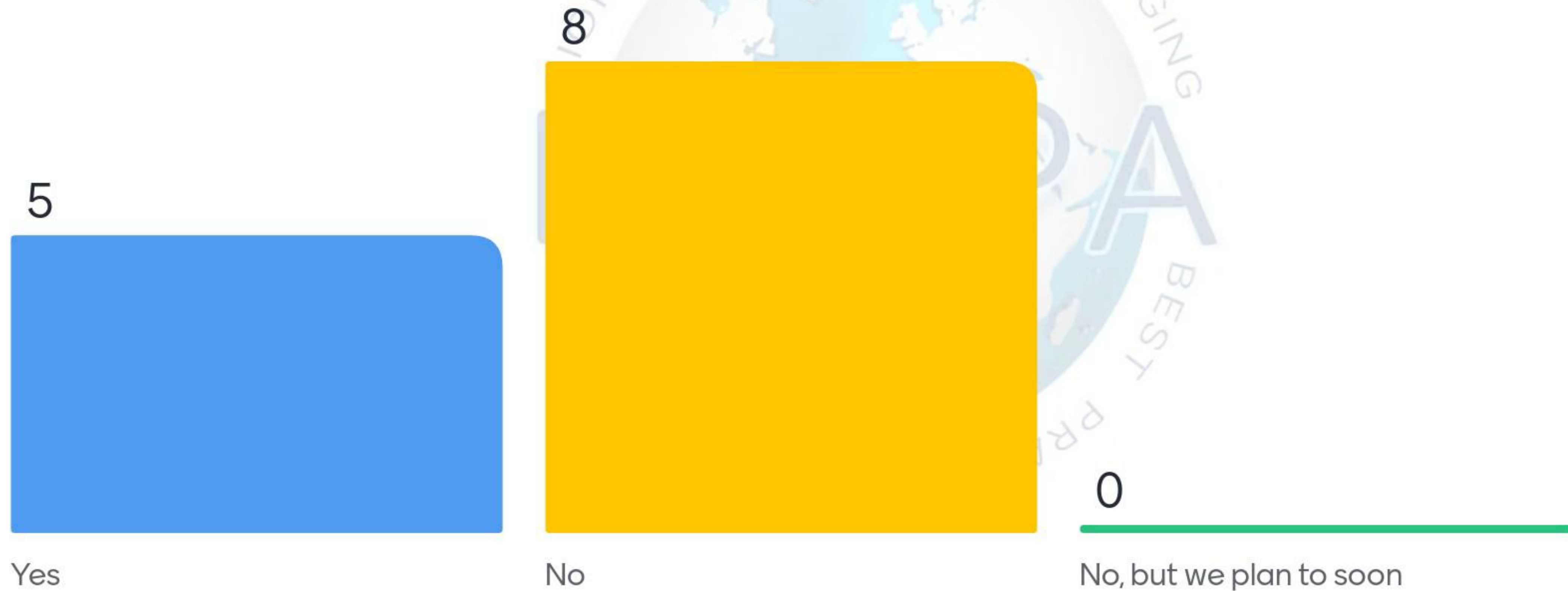


Interest Group 4: Developing and Validating Serum Bactericidal Bioassays

Interest Group 4 Leaders:
Sue Charlton
Head of Clinical Evaluation
UK Health Security Agency

Audience Survey

IG4.1 Are you currently running SBAs (*Serum Bactericidal Assays*) in your lab?



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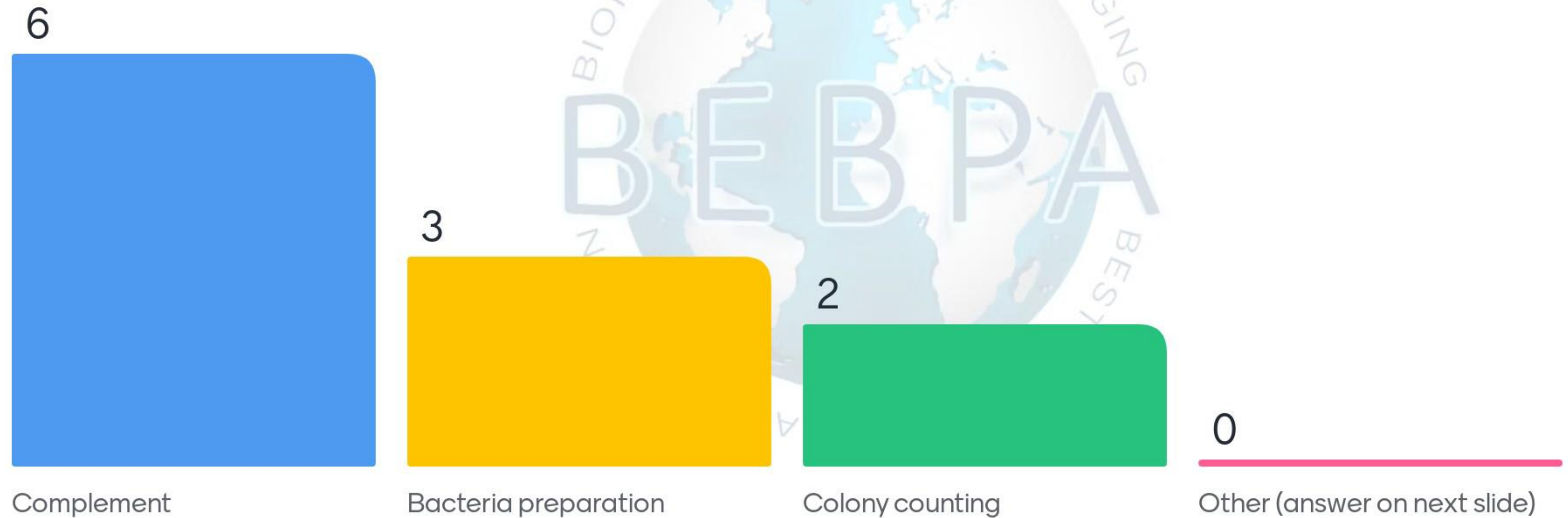
IG4.2 What factor do you think introduces the most variability to your assay?



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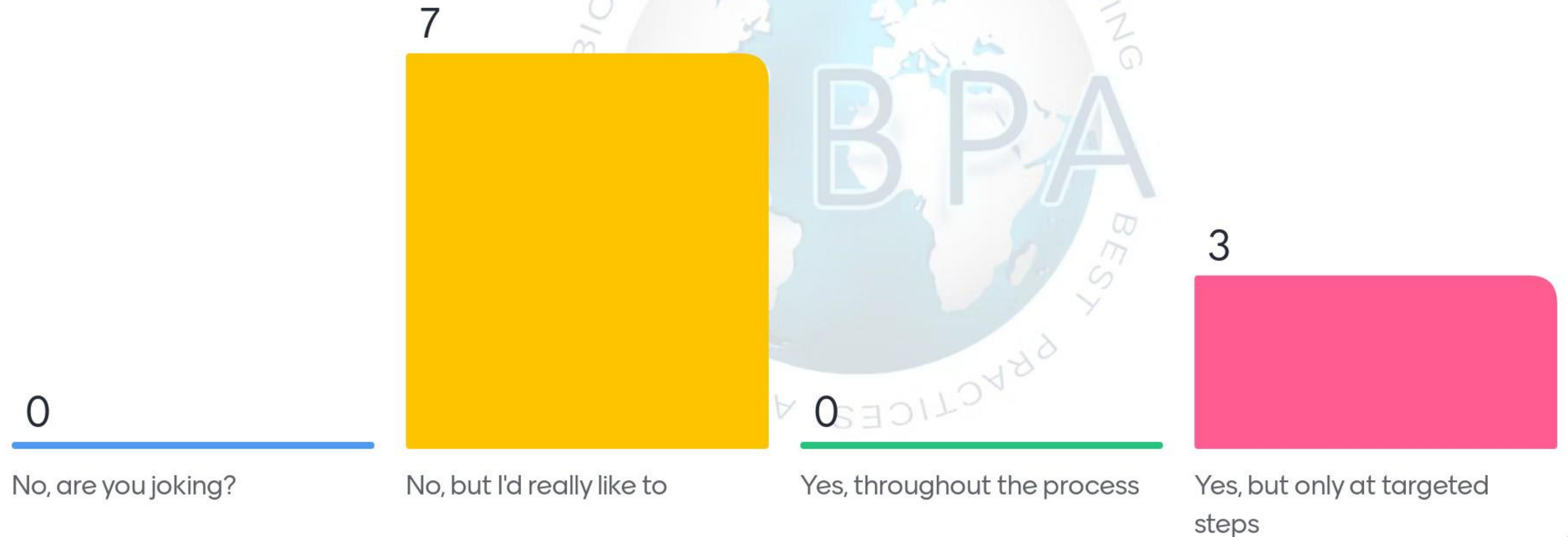
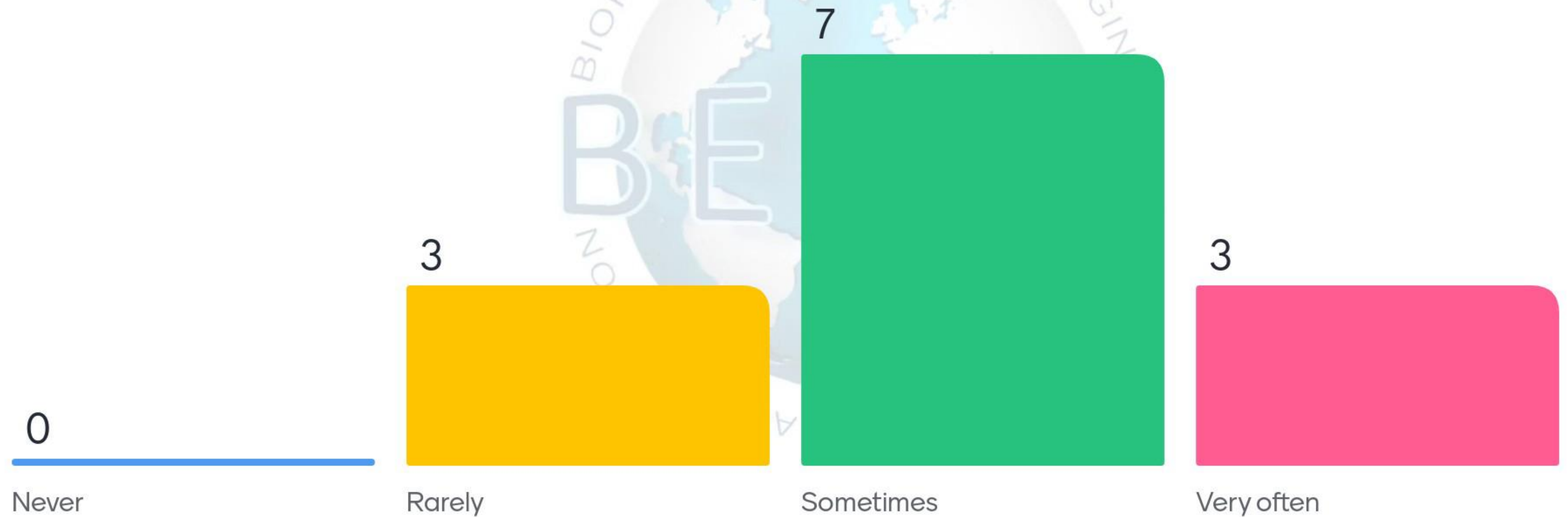
IG4.3 How many samples do you include in your assay validation?

IG4.4 Do you use automation in your SBA?



IG4.5 How often do you use DOE during assay development?



2
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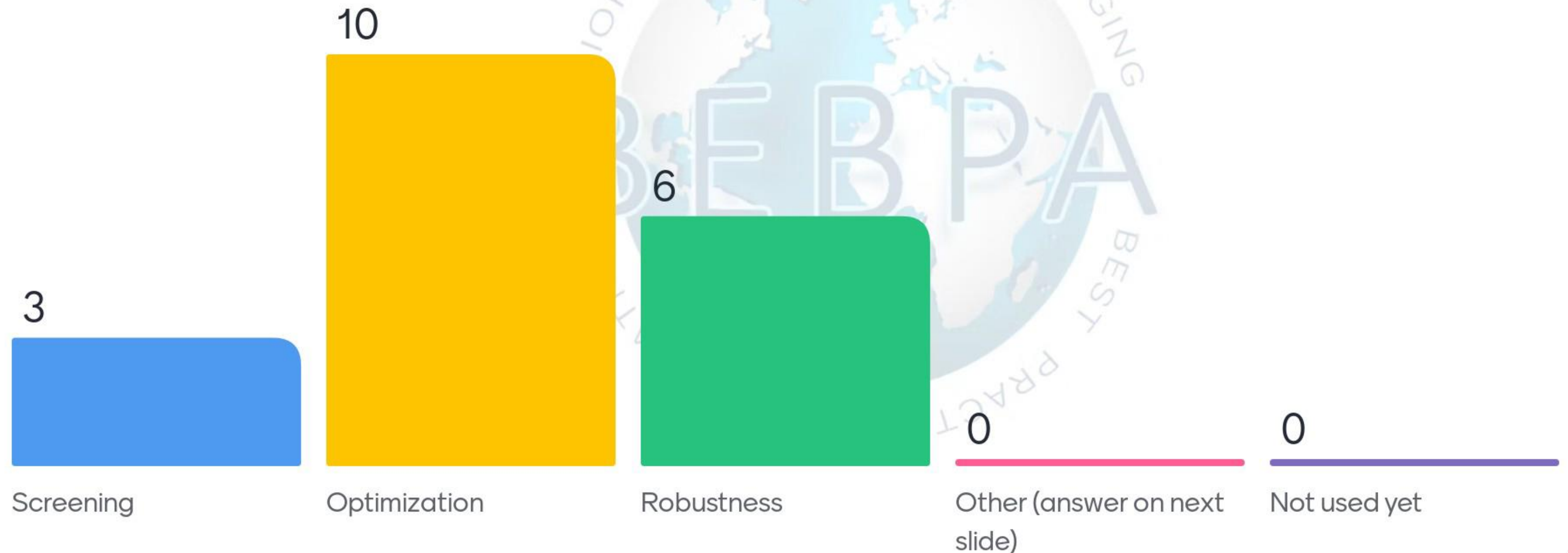
IG4.6 In which stage of assay development do you implement DOE?



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Thank you!!