18th Annual EUR Bioassay Conference

24-26 September 2025

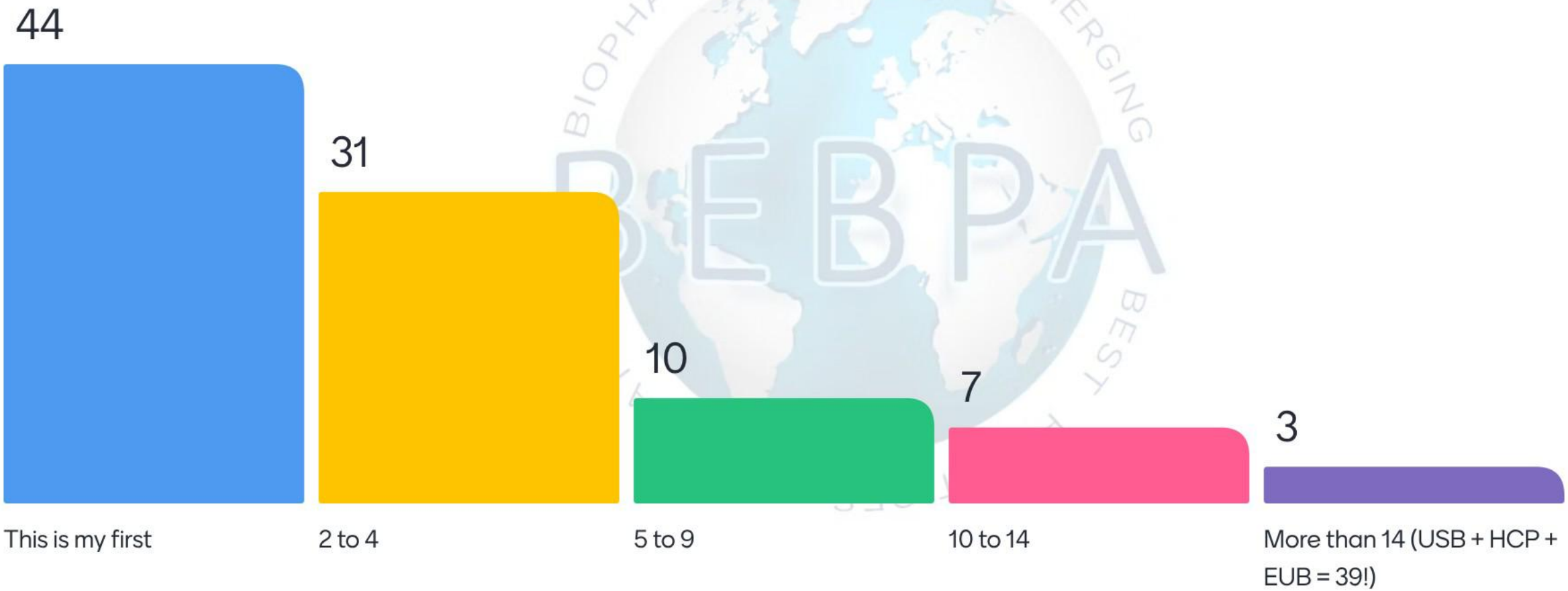
Rotterdam, Netherlands

Welcome Back & Introduction

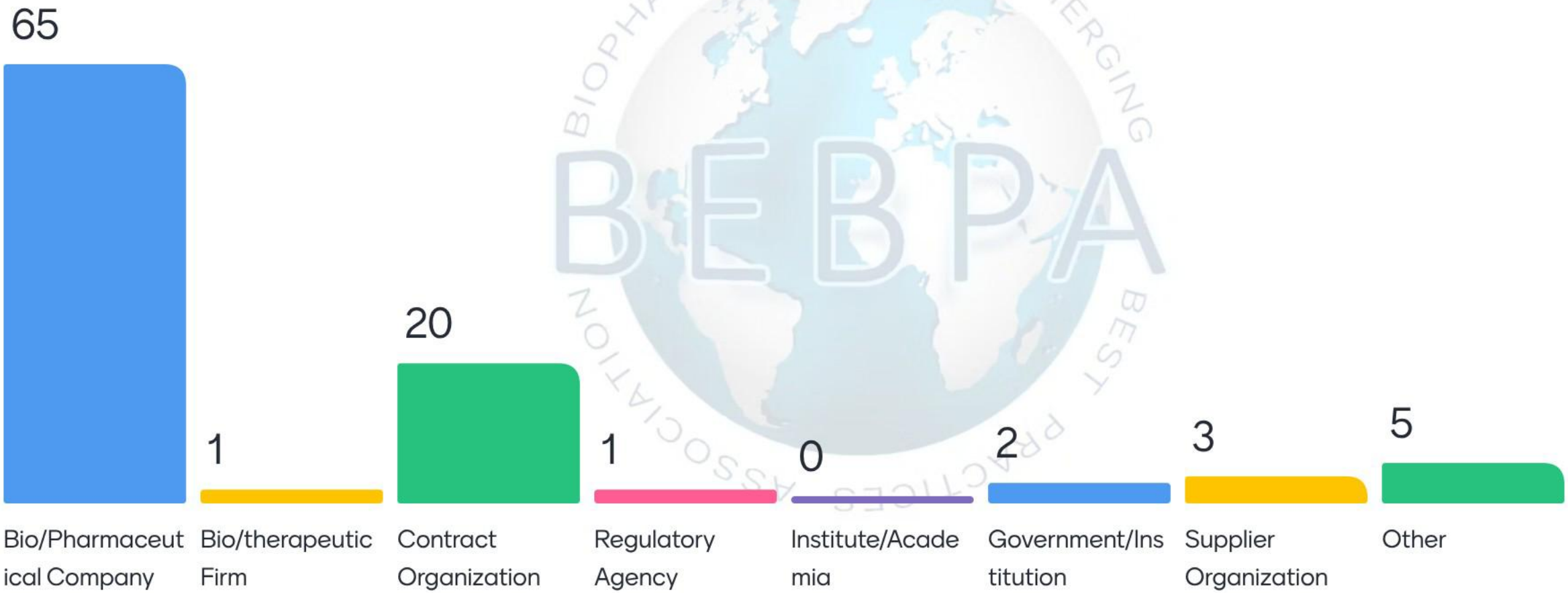
Laureen Little
Principal Consultant
Quality Services
BEBPA President

Day 1 - Intro Audience Surveys

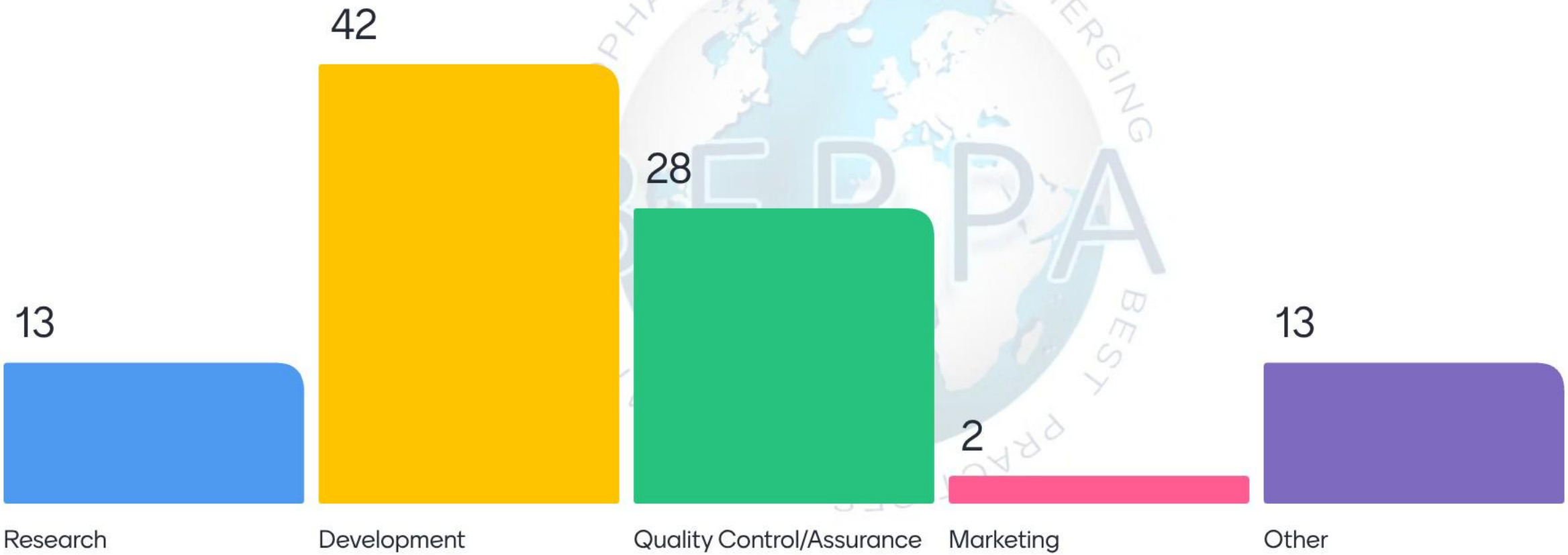
i.1 How many BEBPA Conferences have you attended?



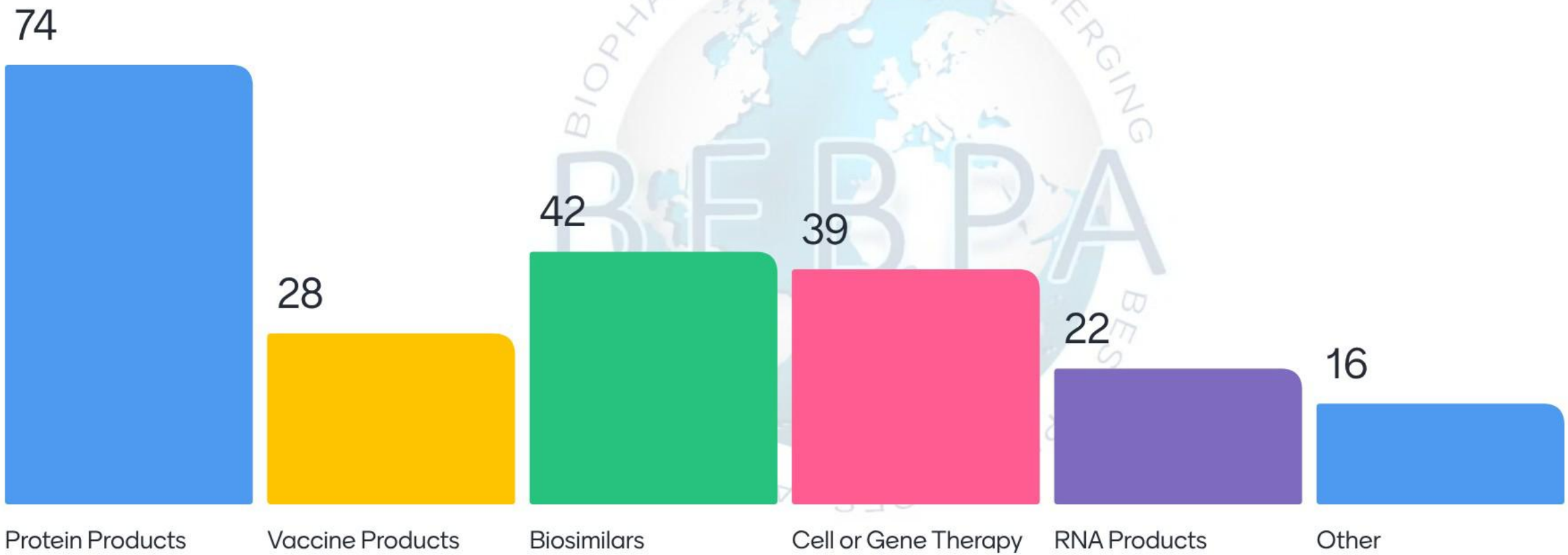
i.2 What type of organization do you work for?



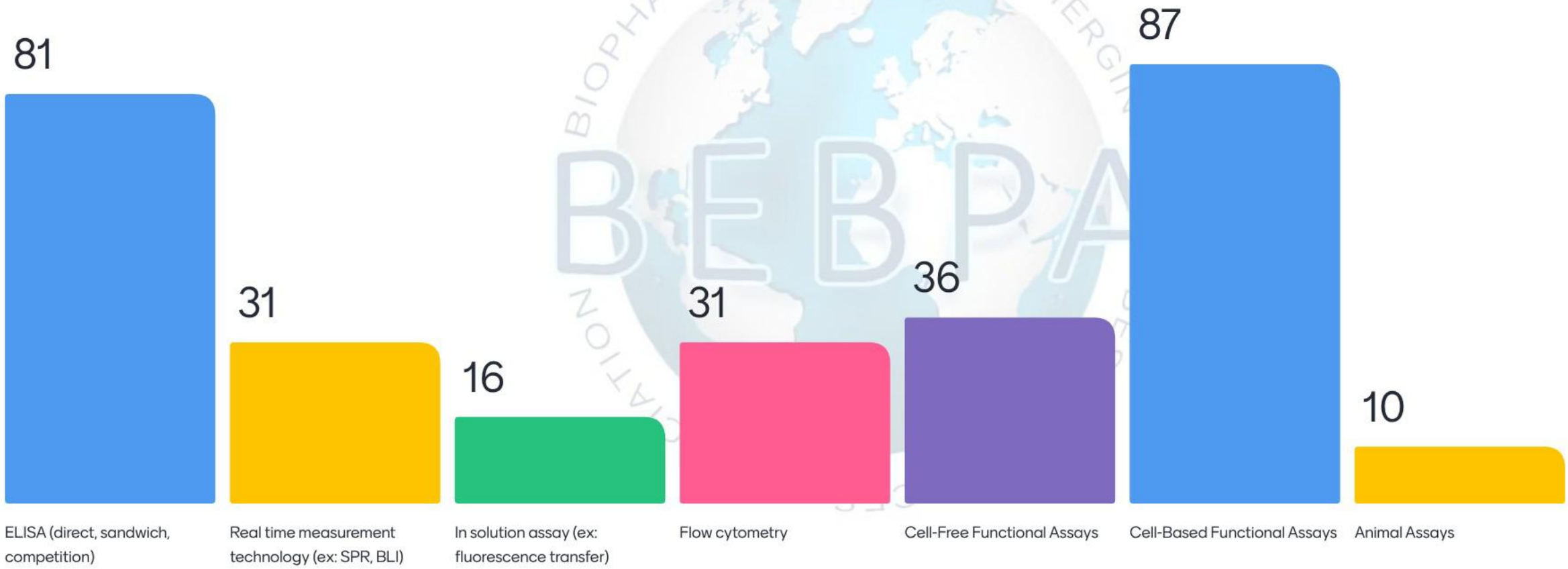
i.3 What part of the organization do your work for?



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)

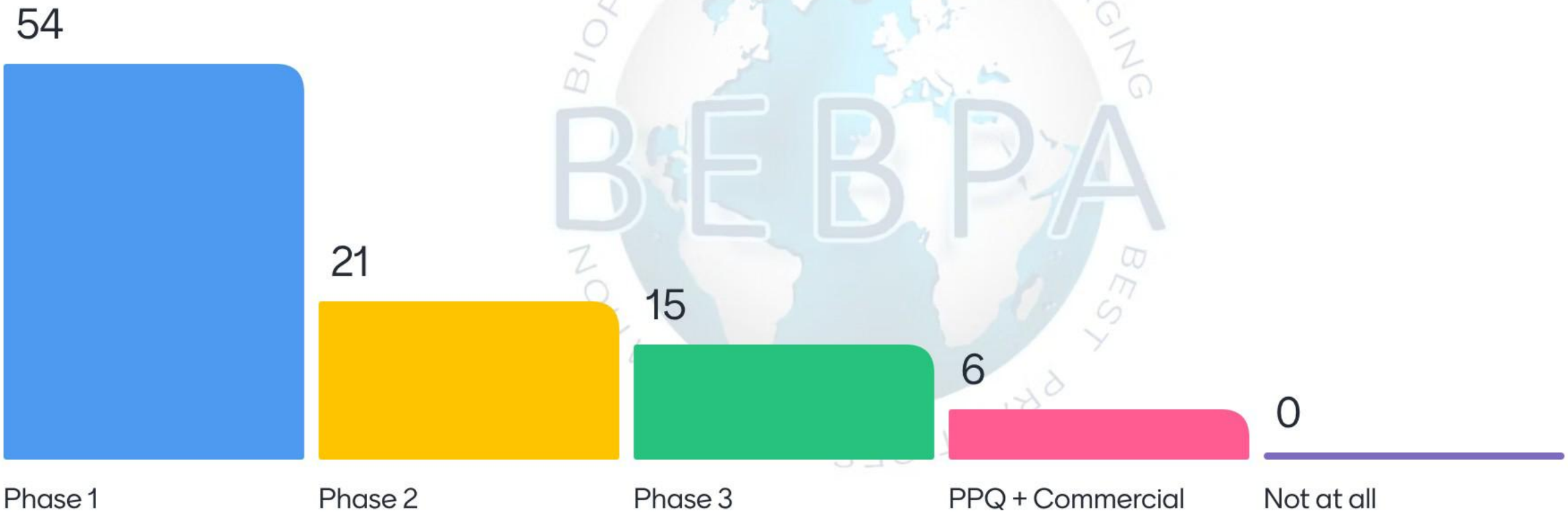


Day 1 Audience Surveys

Session 1: Regulatory Aspects of the Potency Assay

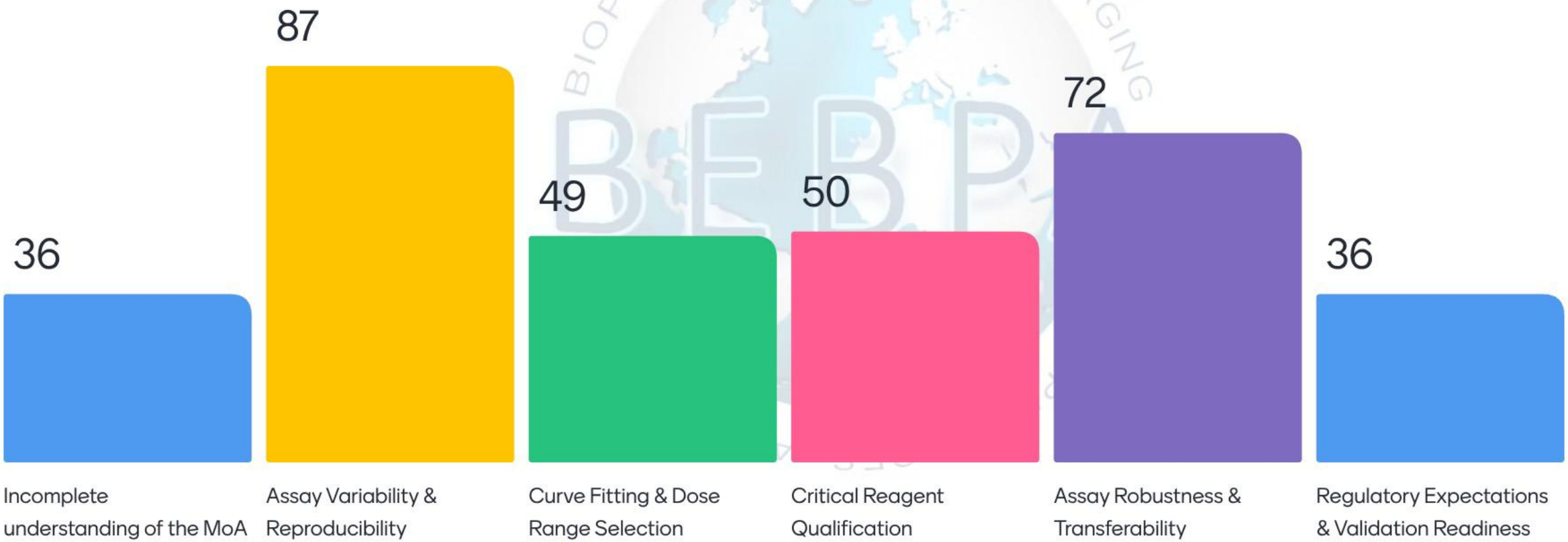
Session 2: Potency Assay for Novel Products

1.1 At what clinical stage would you usually implement functional potency methods in your release and stability panel?

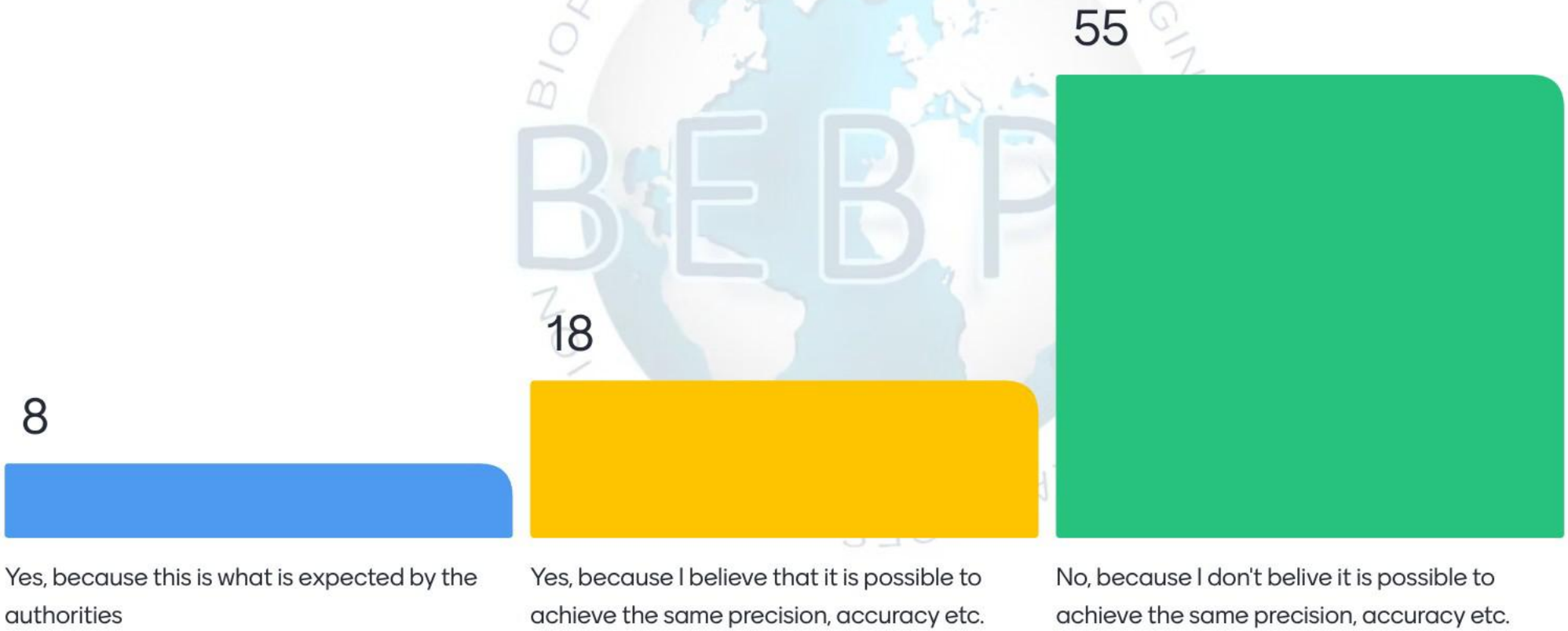


1.2 How many different potency methods per product do you ultimately have in R&S testing to assure potency of your product?

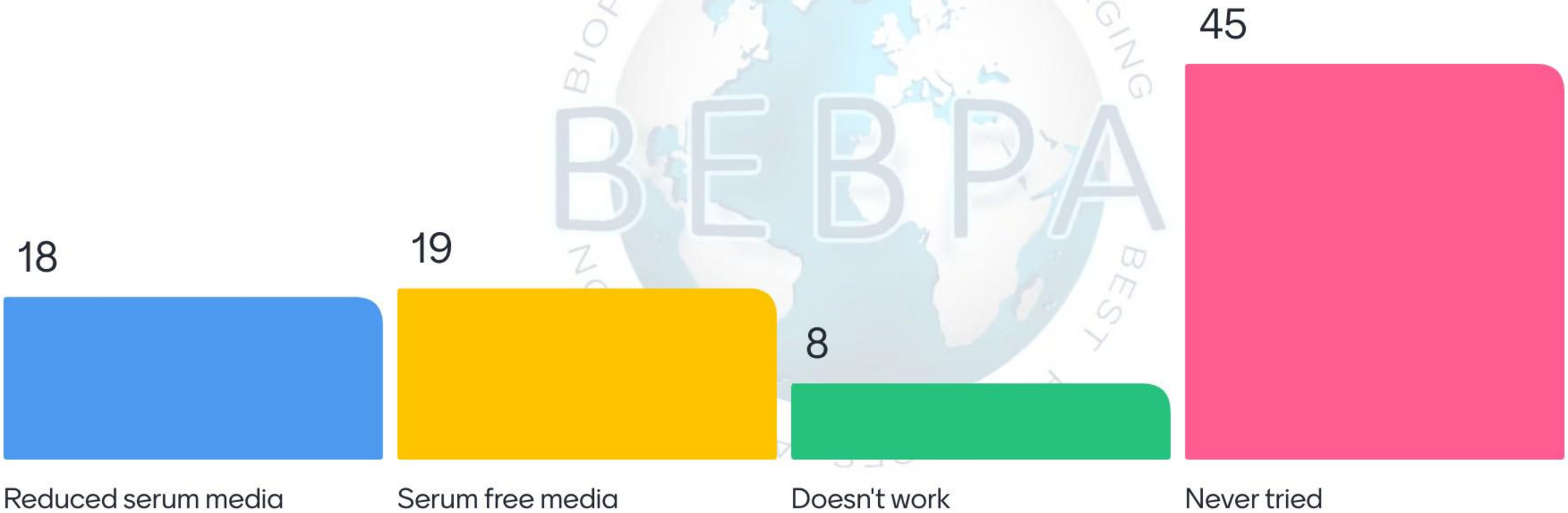
1.3 What challenges did you face during the development of a functional potency assay?



1.4 Would you apply the same acceptance criteria for cell-based potency assays for non-protein APIs as for protein APIs?



1.5 Do you use serum free or reduced serum in your cell culture?



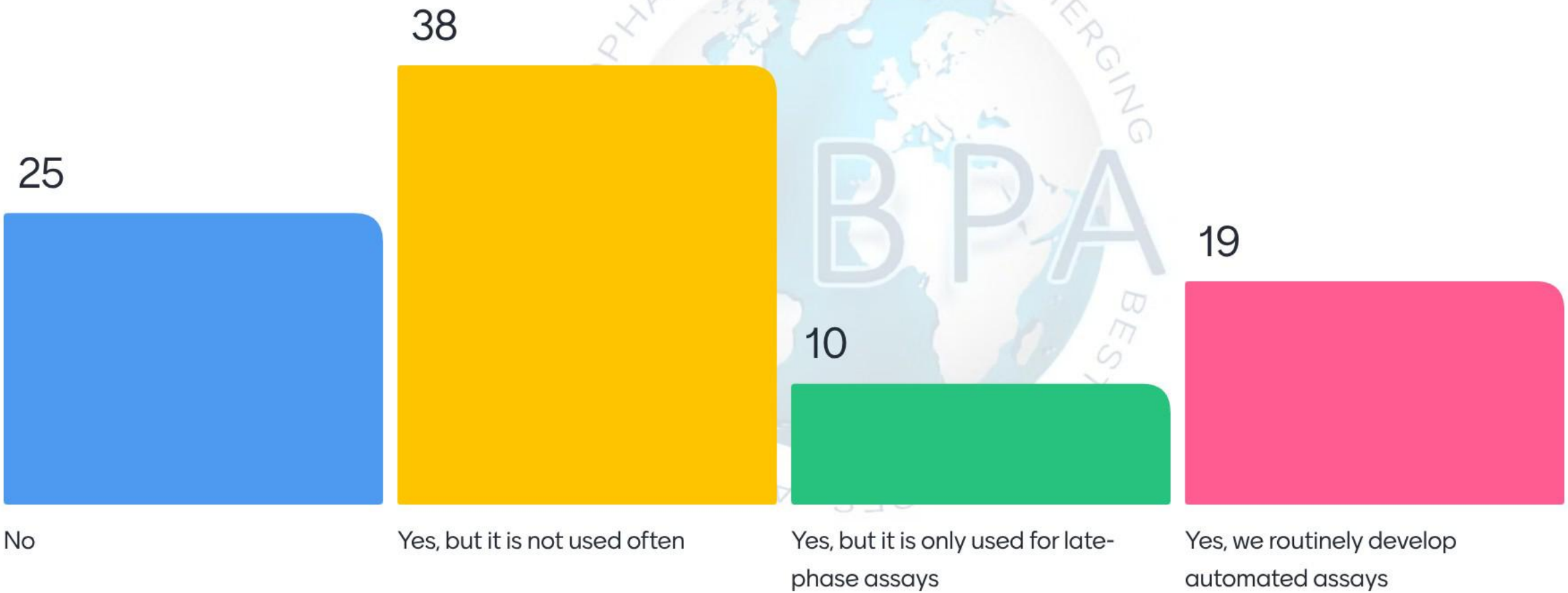
90

Day 2 Audience Surveys

Session 3: Replacing Old Technology Assays

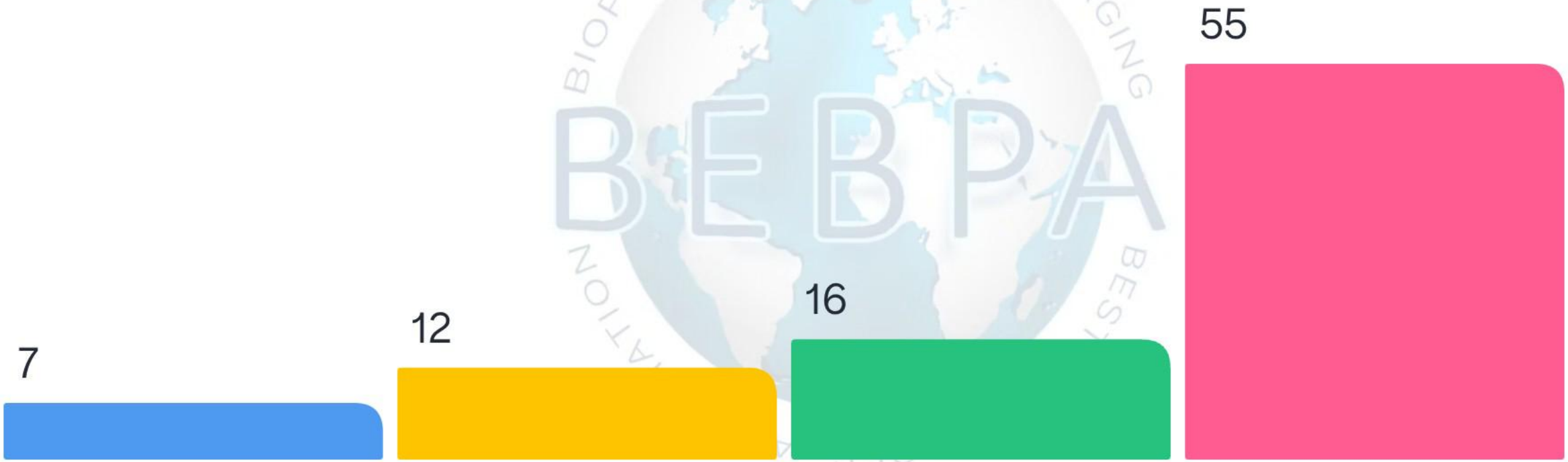
Session 4: AI & Automation for Bioassays

2.1 Do you have automation available in your lab?

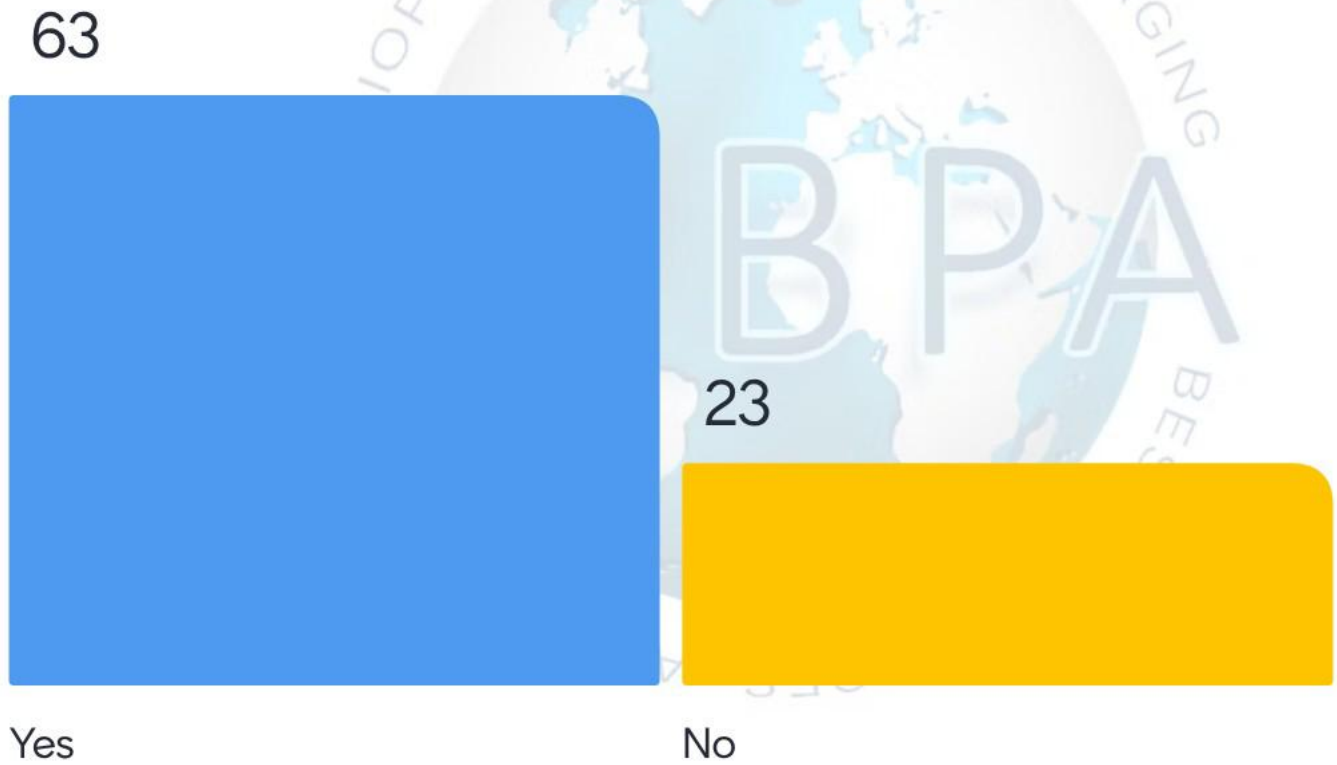


2.2 What is in your view the biggest advantage in automating cell-based bioassays?

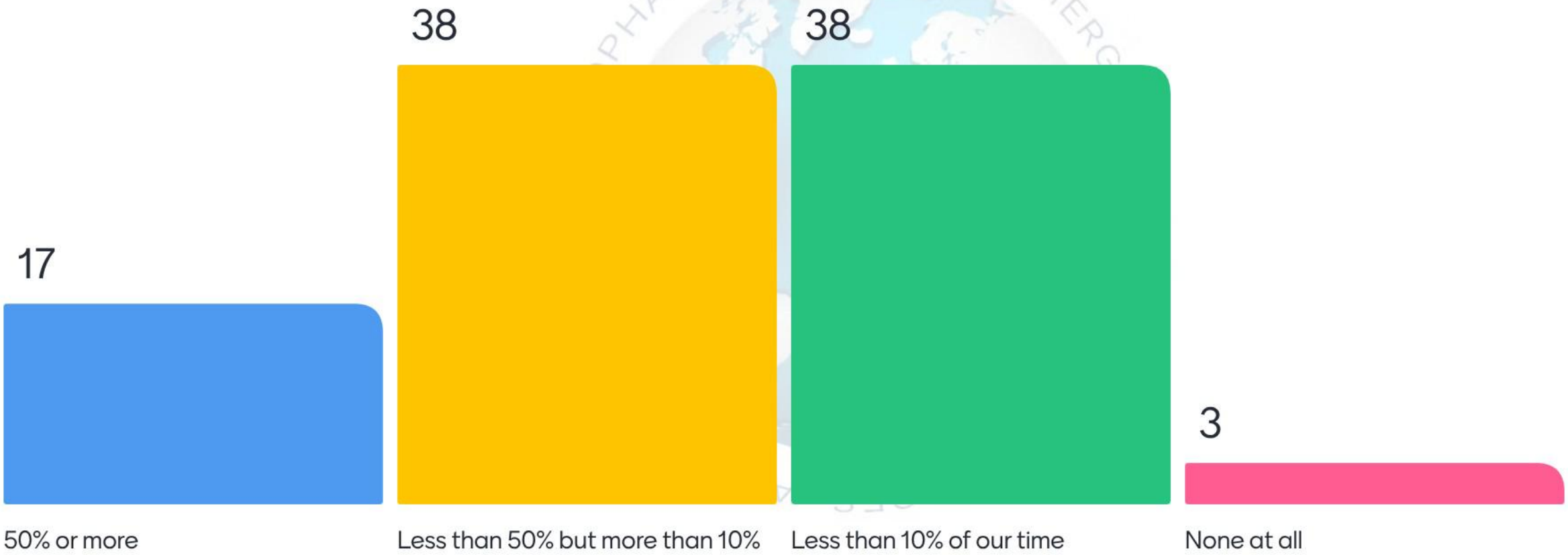
2.3 Do your bioassays usually require similarity before estimating relative potency?



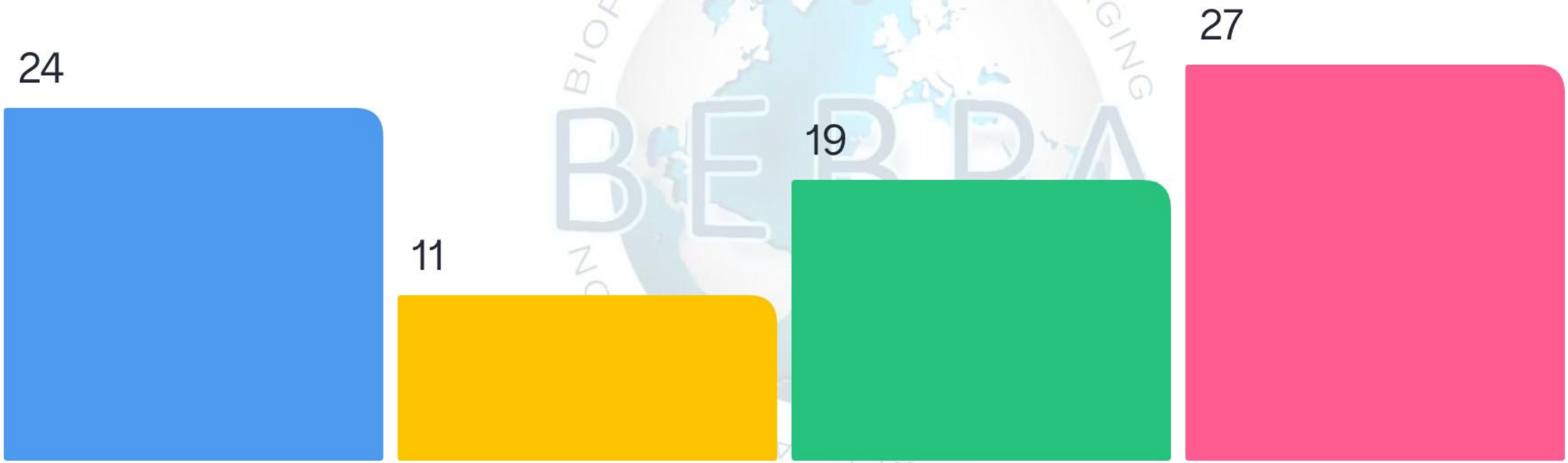
2.4 Are you concerned about bias in relative potency due to allowed non-similarity



2.5 How much effort do you invest into improvement of established assays?



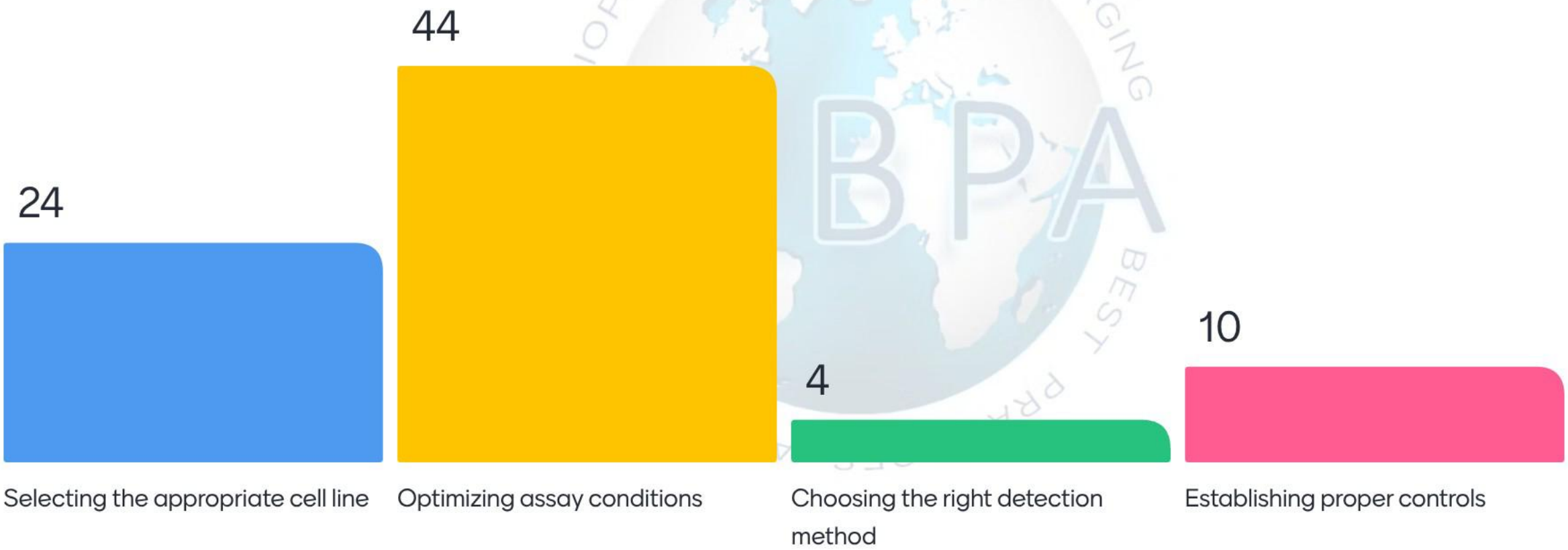
2.6 Have you had any regulatory input when you are attempting to replace an older method?



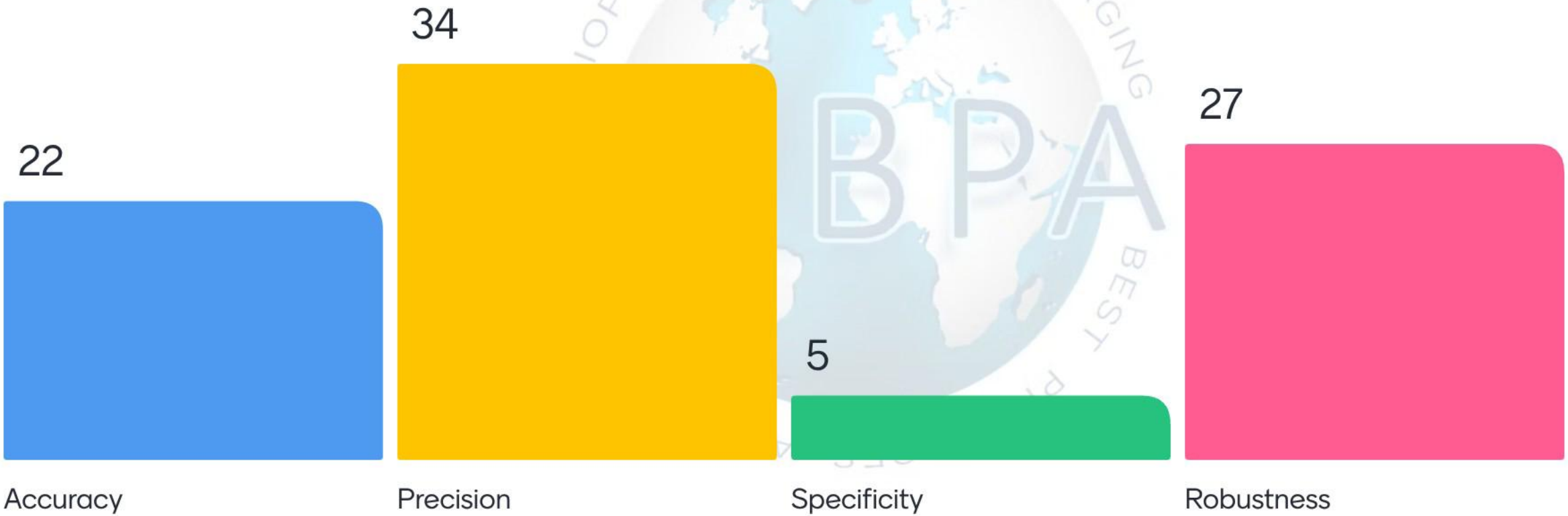
Day 3 Audience Surveys

Session 5: Validation

3.1 Which step do you consider most critical in developing a robust and reproducible cell-based assay?



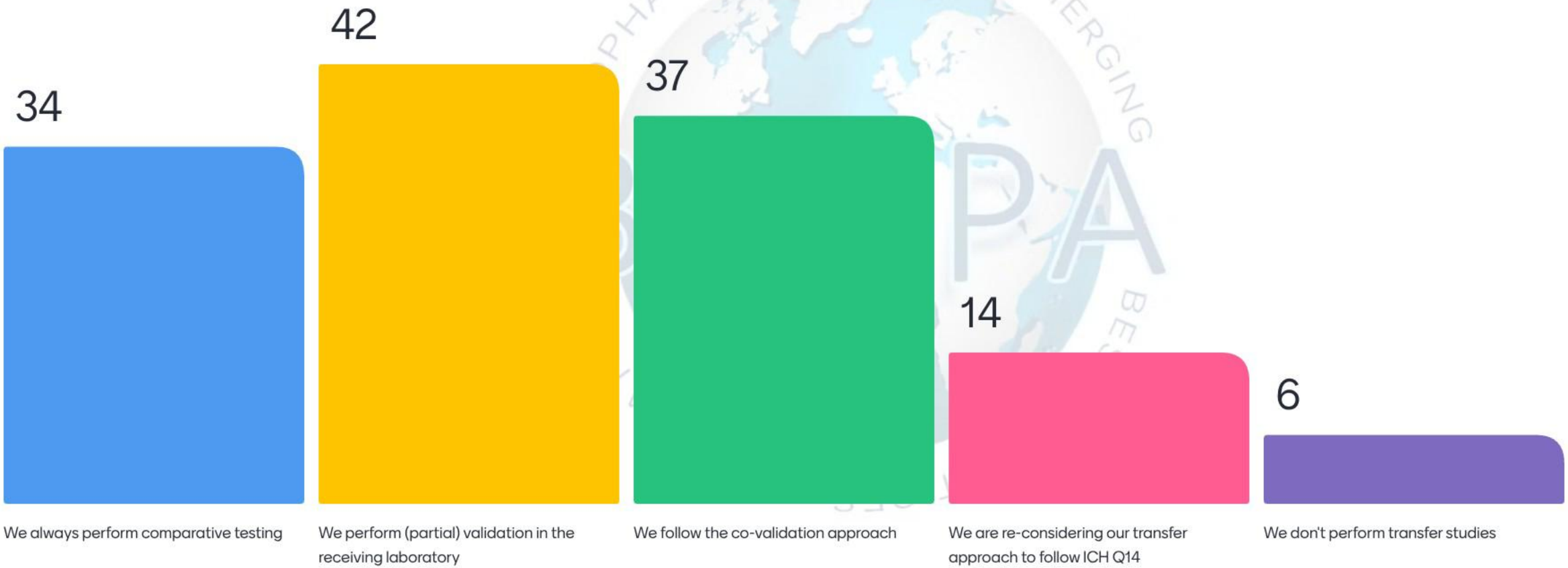
3.2 Which validation parameter do you find most challenging to achieve in practice?



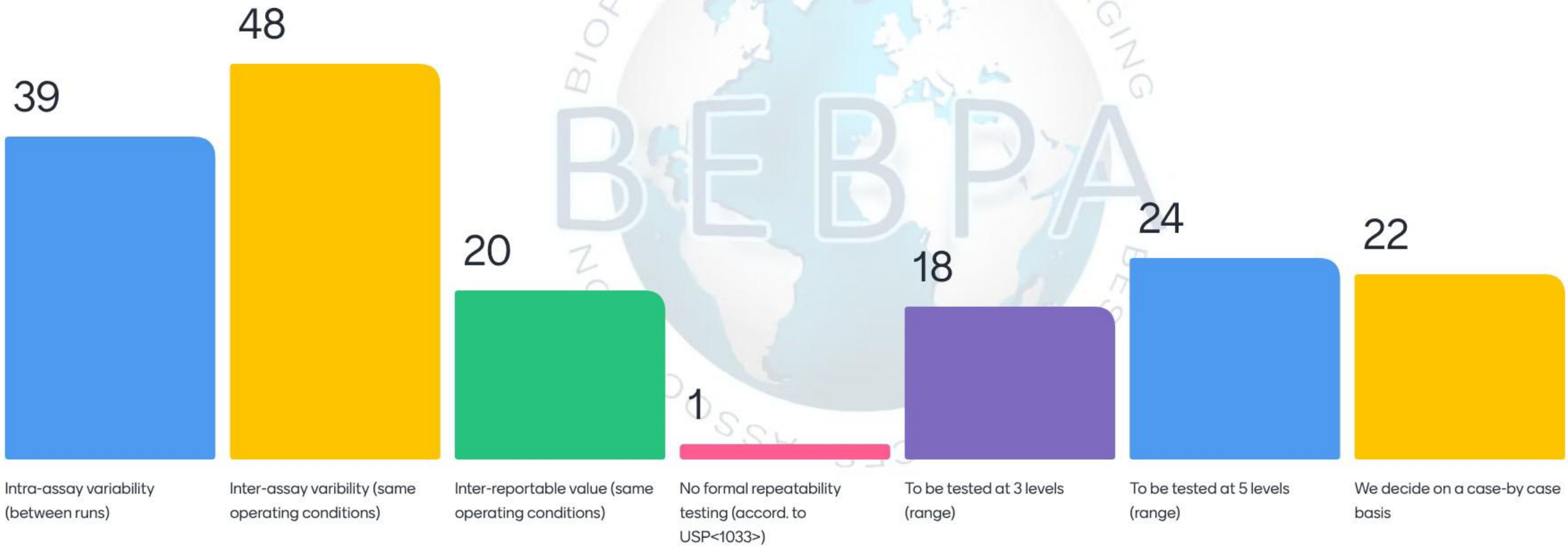
88

3.3 On which individual values is the design in your validation and robustness studies based?

3.4 Which analytical procedure and transfer approach do you follow?



3.5 How do you test for repeatability during validation? Do you also change the testing based on the revision of ICH Q2?



18th Annual EUR Bioassay Conference

WORKSHOPS

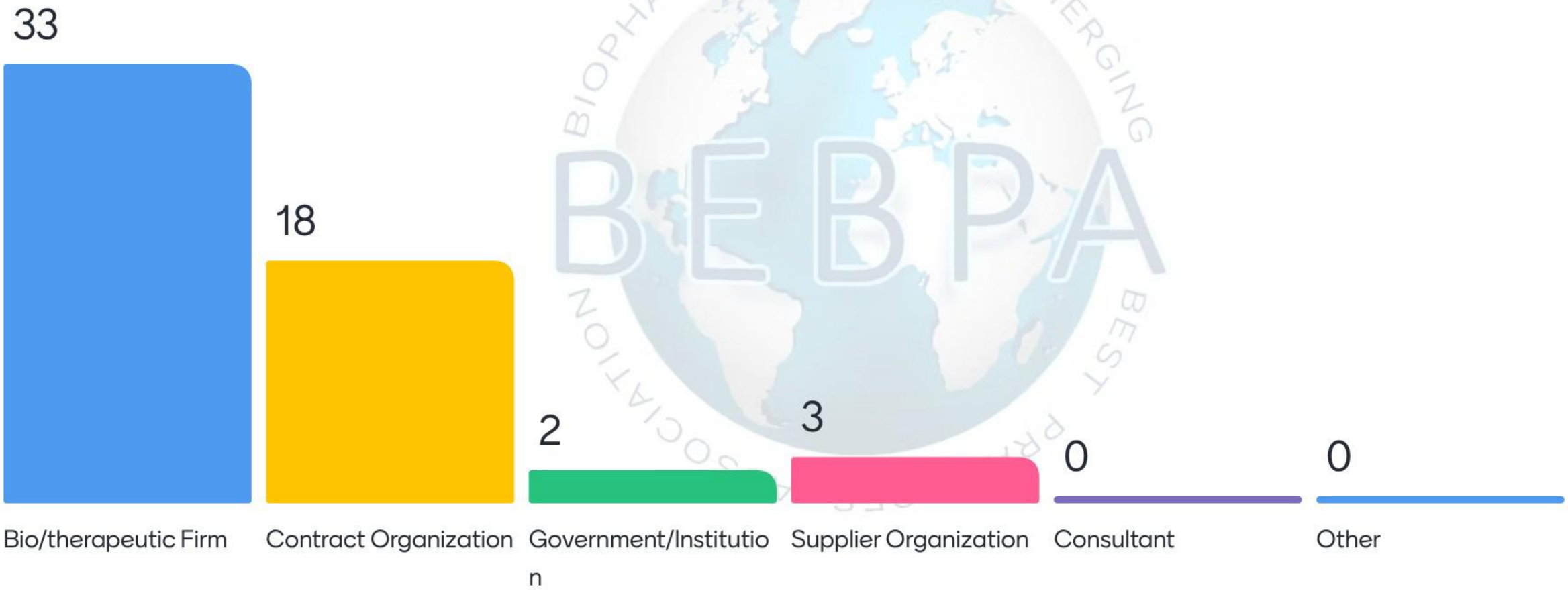
24-26 September 2025

Rotterdam, Netherlands

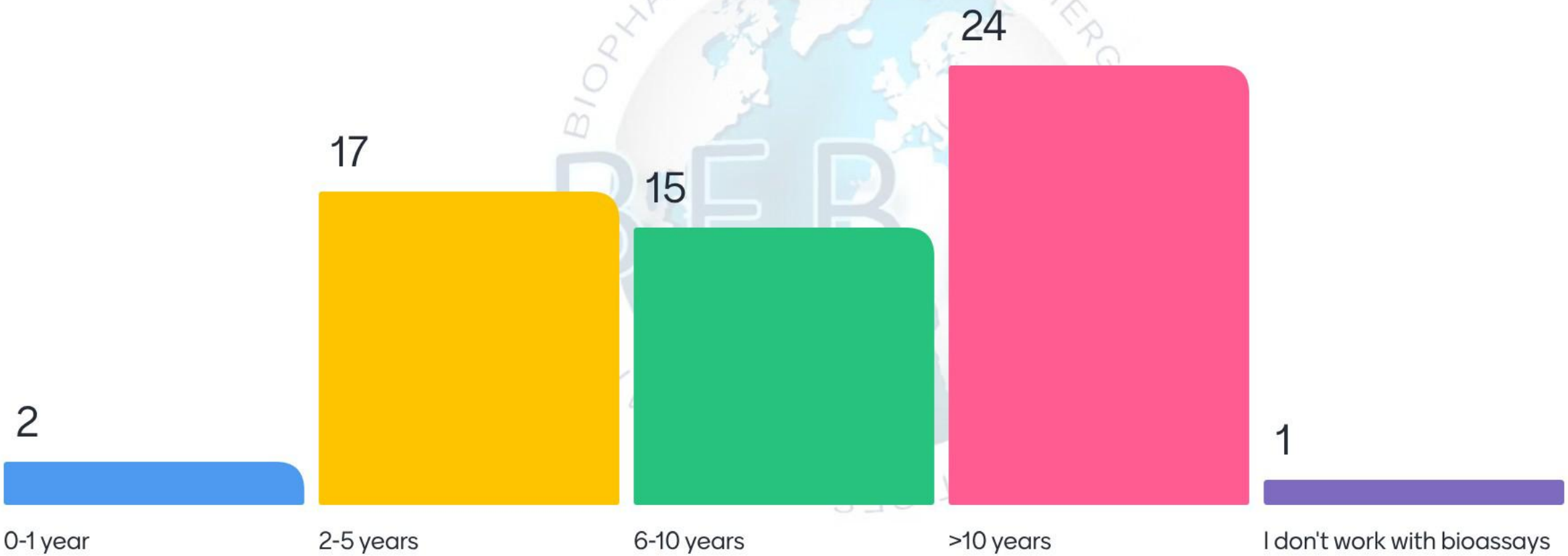
Workshop 1 Audience Surveys

Housekeeping Activities of Potency Assay

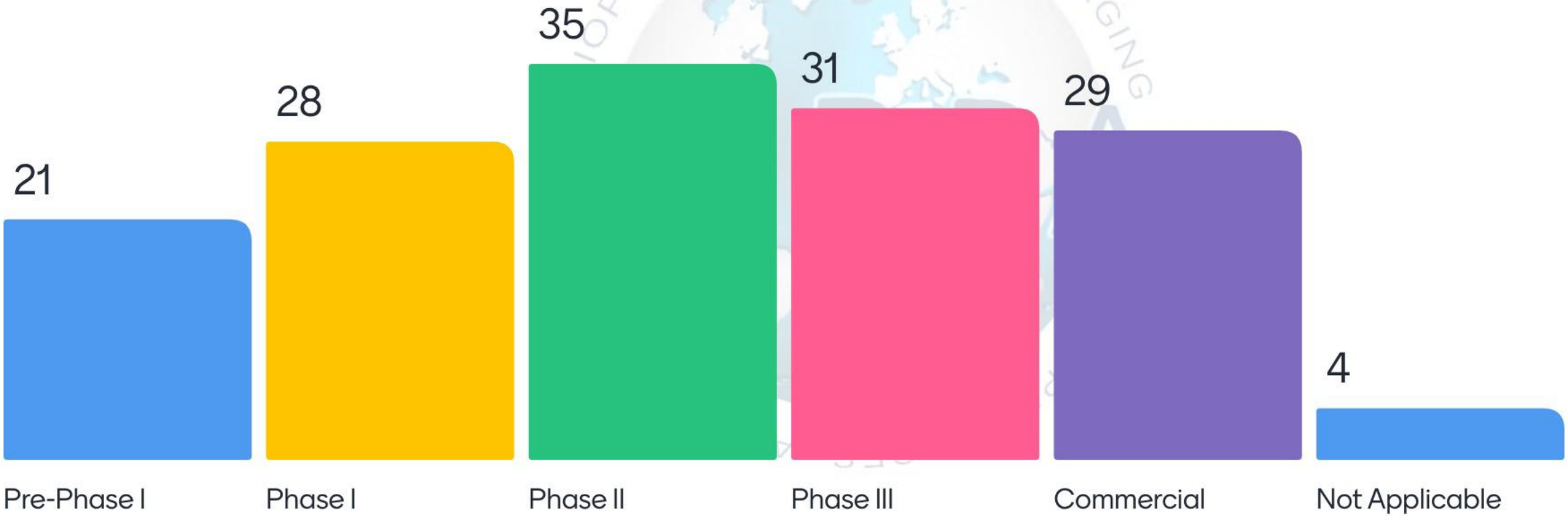
W1.1 What kind of organization do you work with?



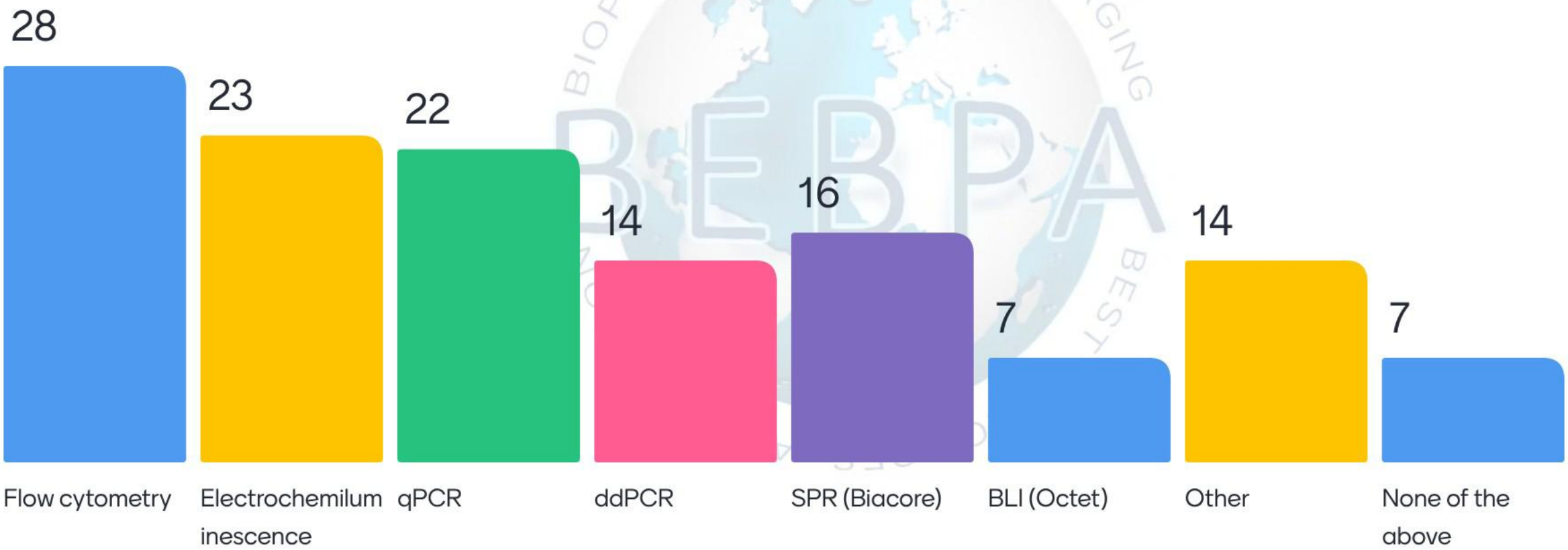
W1.2 How long have you worked with bioassays



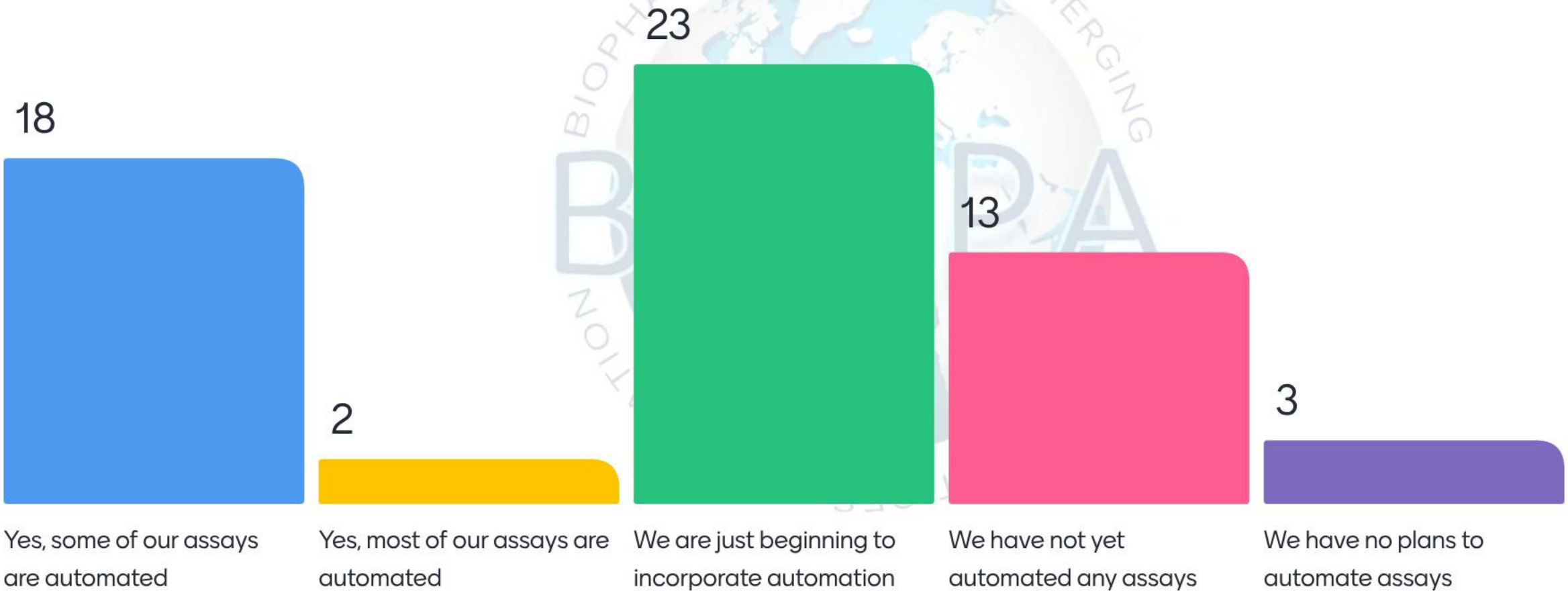
W1.3 In which phase are the molecules you support running potency bioassays?



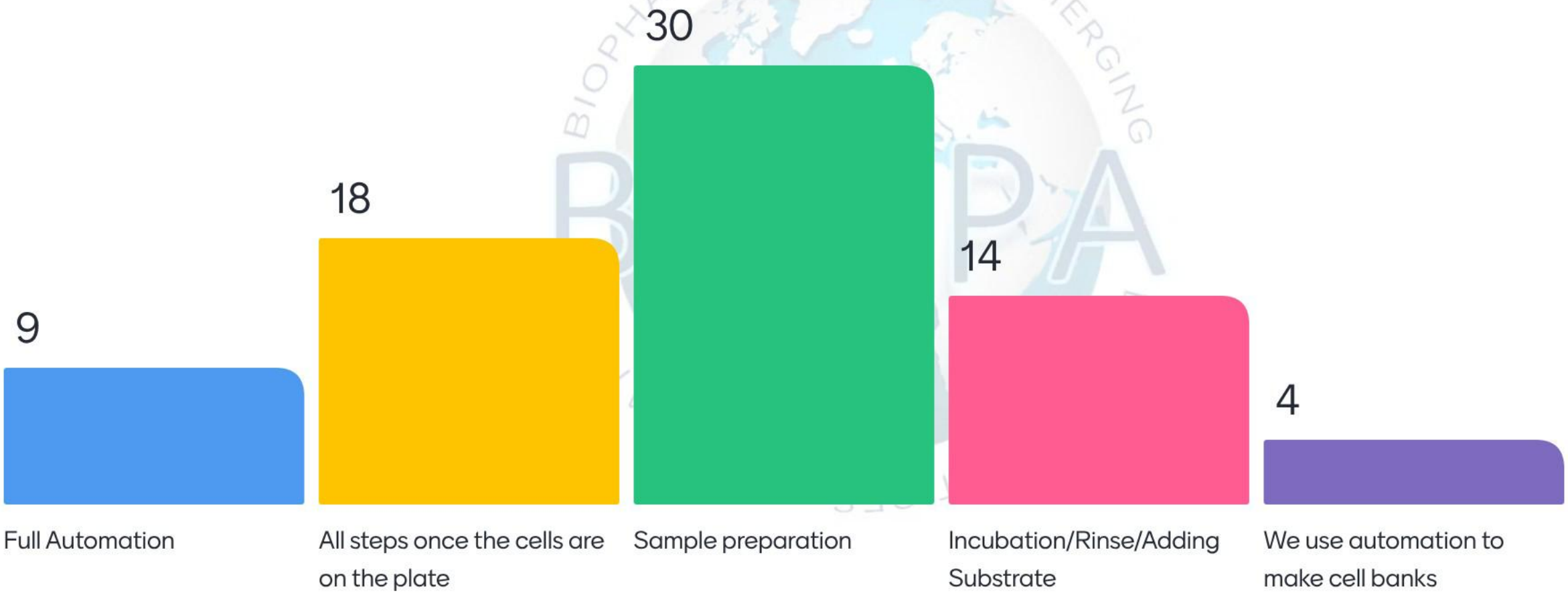
W1.4 What kind of readouts do you use for your bioassays apart from absorbance/luminescence/fluorescence?



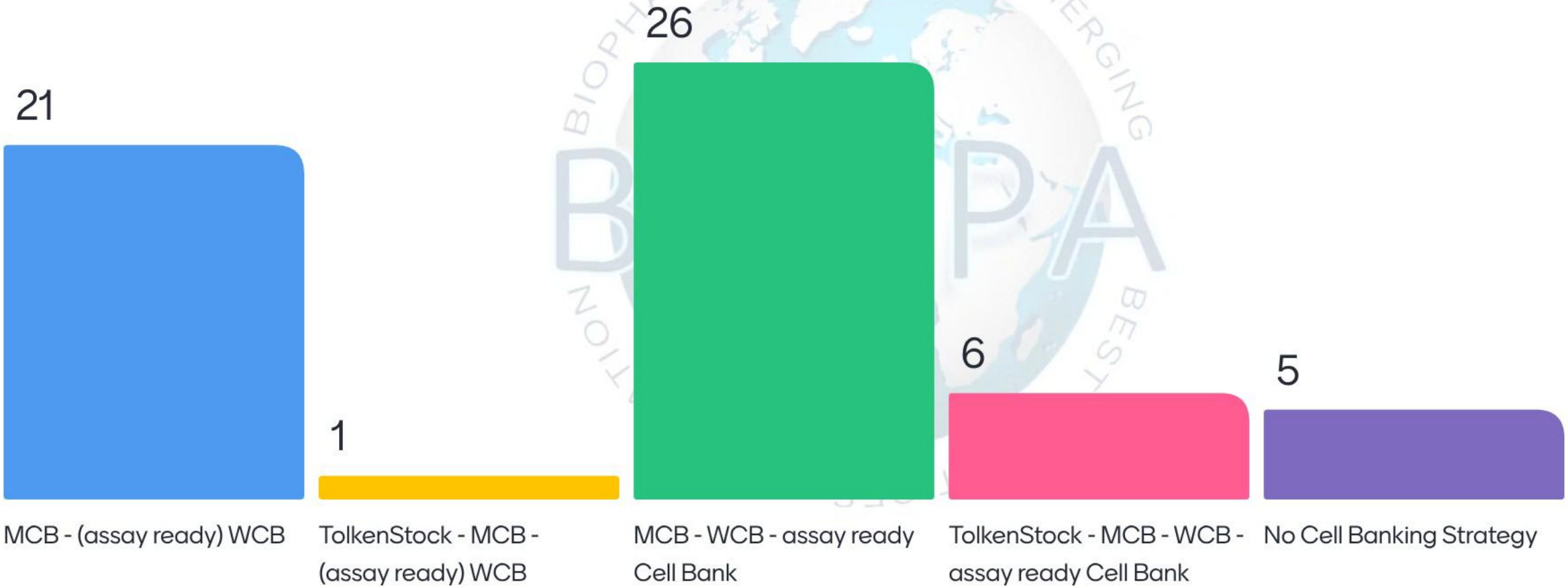
W1.5 Do you use automation in your assays?



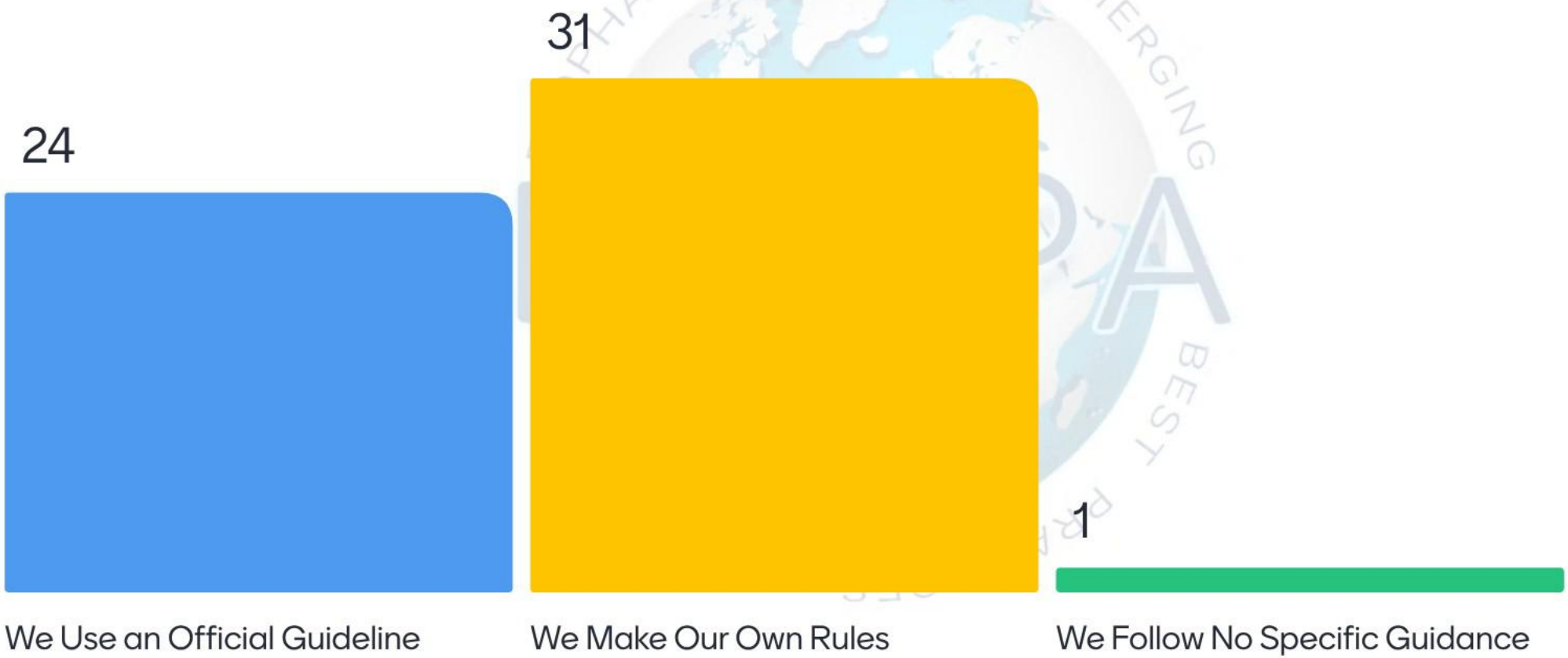
W1.6 If you automate your assays: what level of automation do you use?



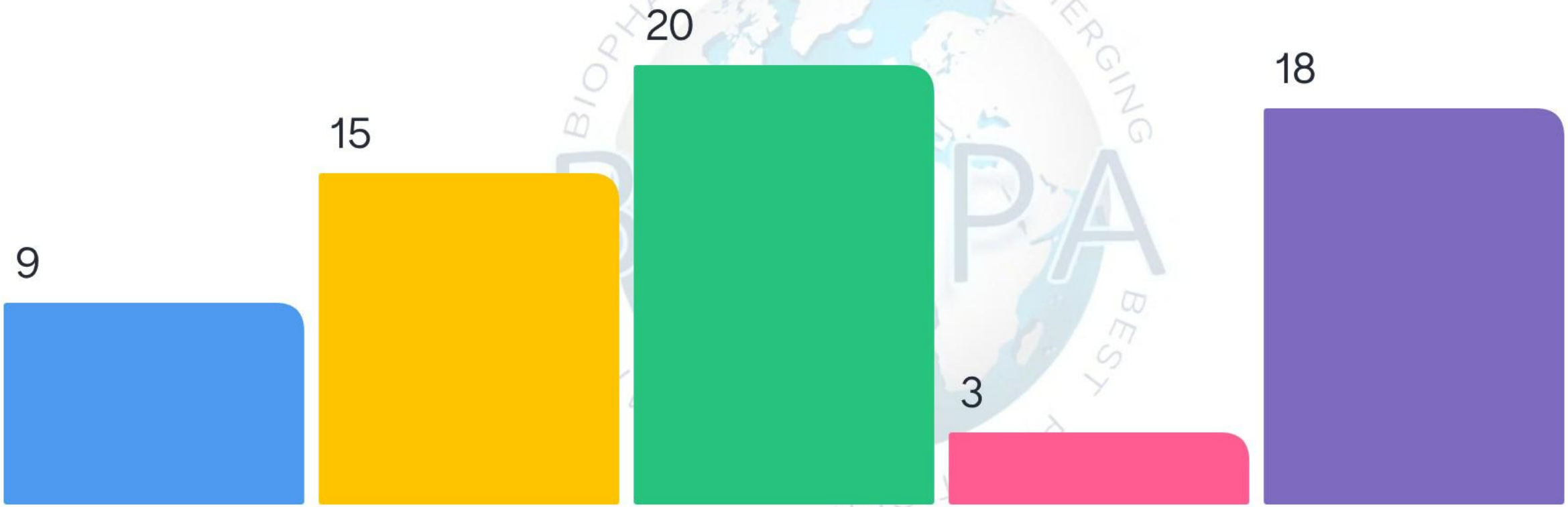
W1.7 What is Your Cell Banking Strategy?



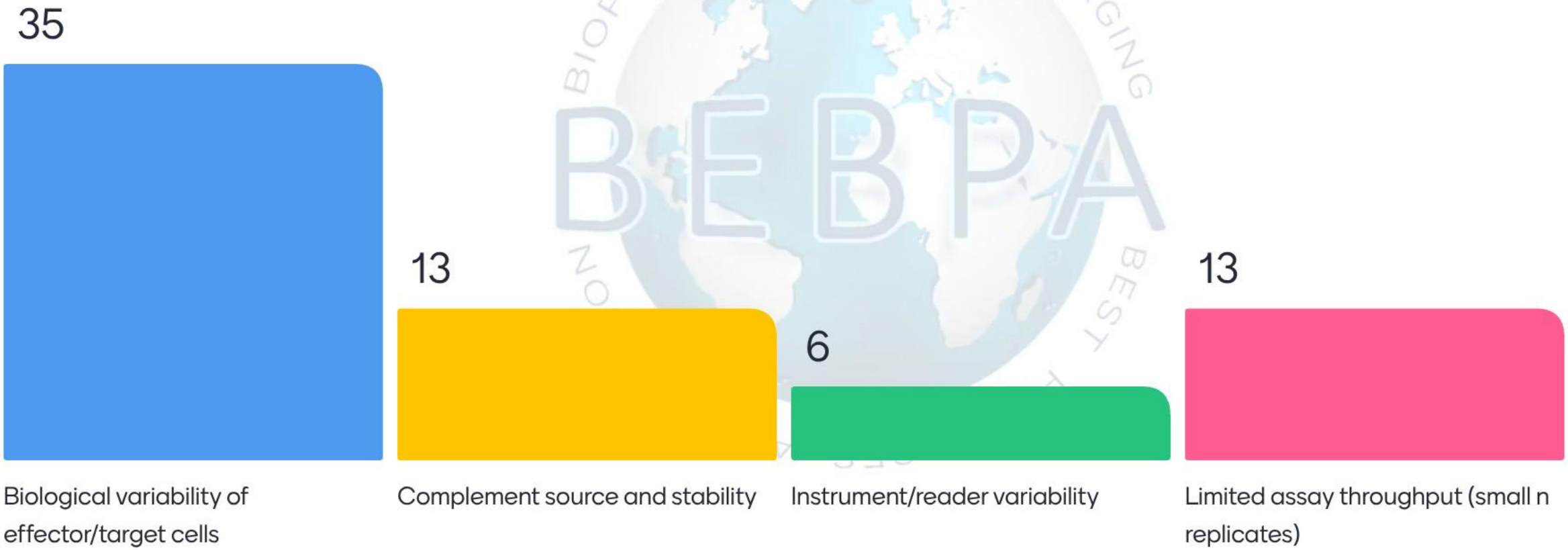
W1.8 Do you Follow a Guideline for the Qualification of Your Bioassay Cells?



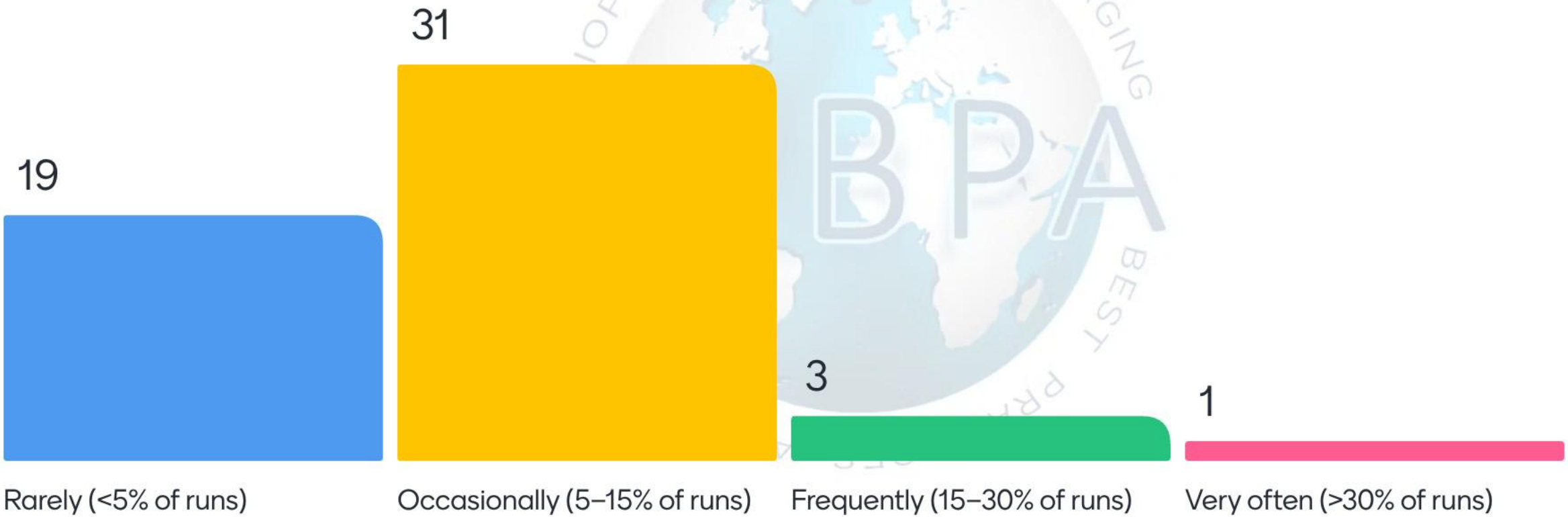
W1.9 How do you monitor %CV trends across multiple assay runs?



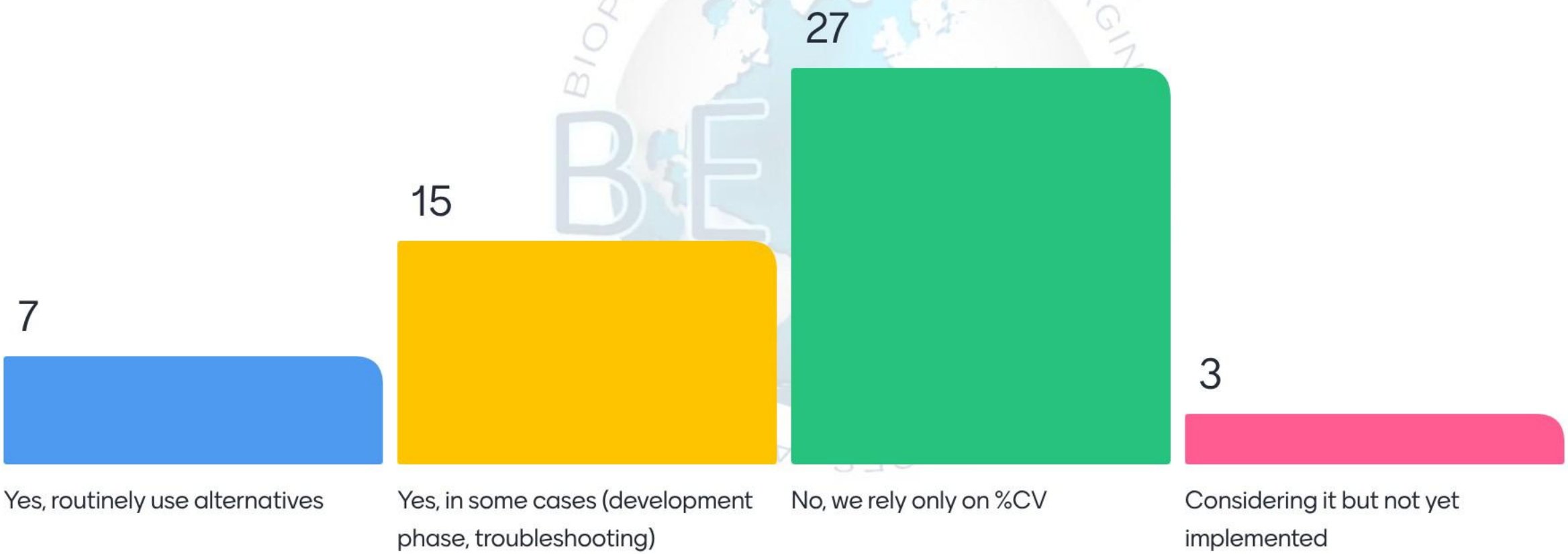
W1.10 What is the biggest challenge in reducing %CV for your CDC assay?



W1.11 How often do you encounter runs failing due to exceeding %CV acceptance limits?



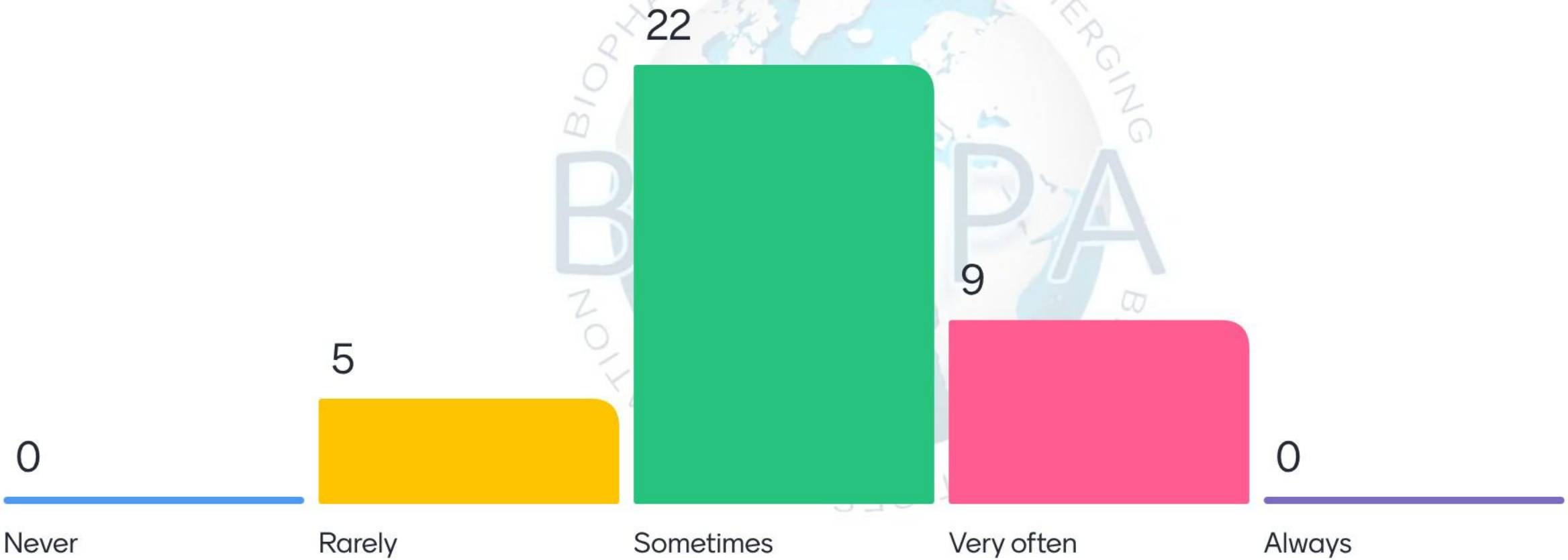
W1.12 Has your organization explored alternatives to %CV as the primary acceptance criterion for replicate variability?



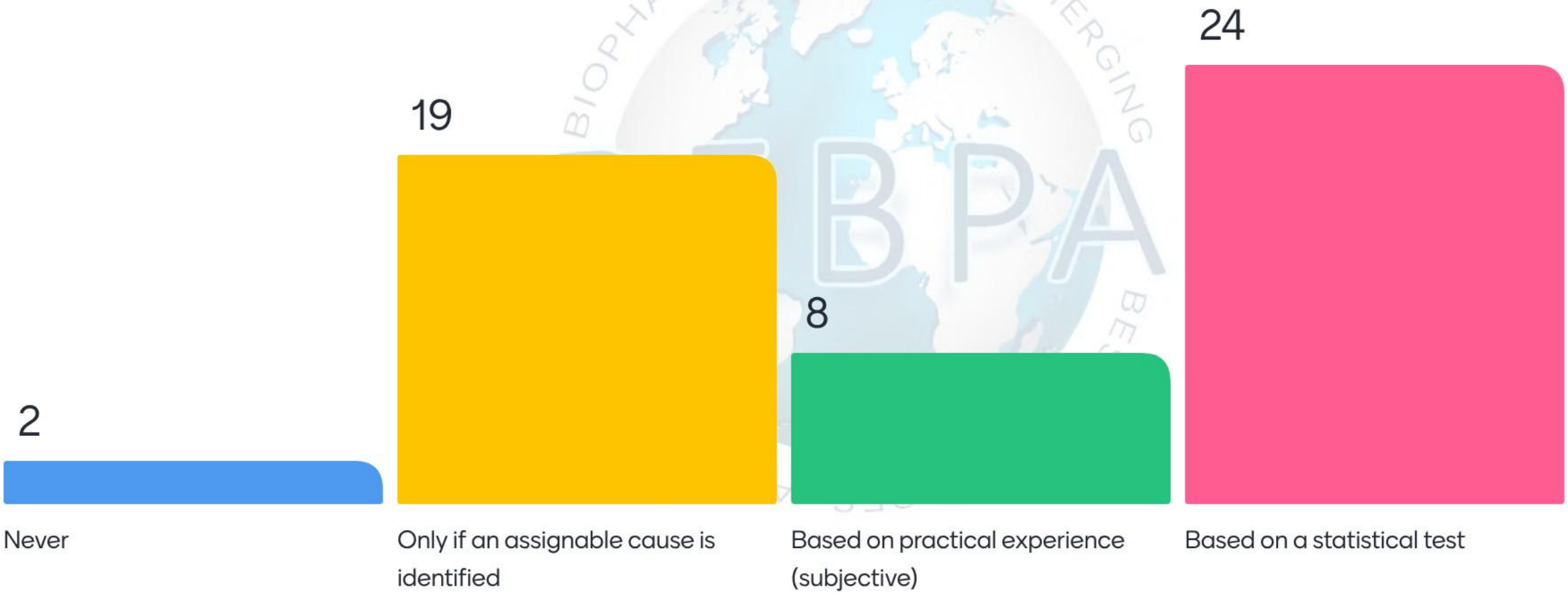
Workshop 2 Audience Surveys

Outliers in Bioassay Analysis: Navigating the Challenges

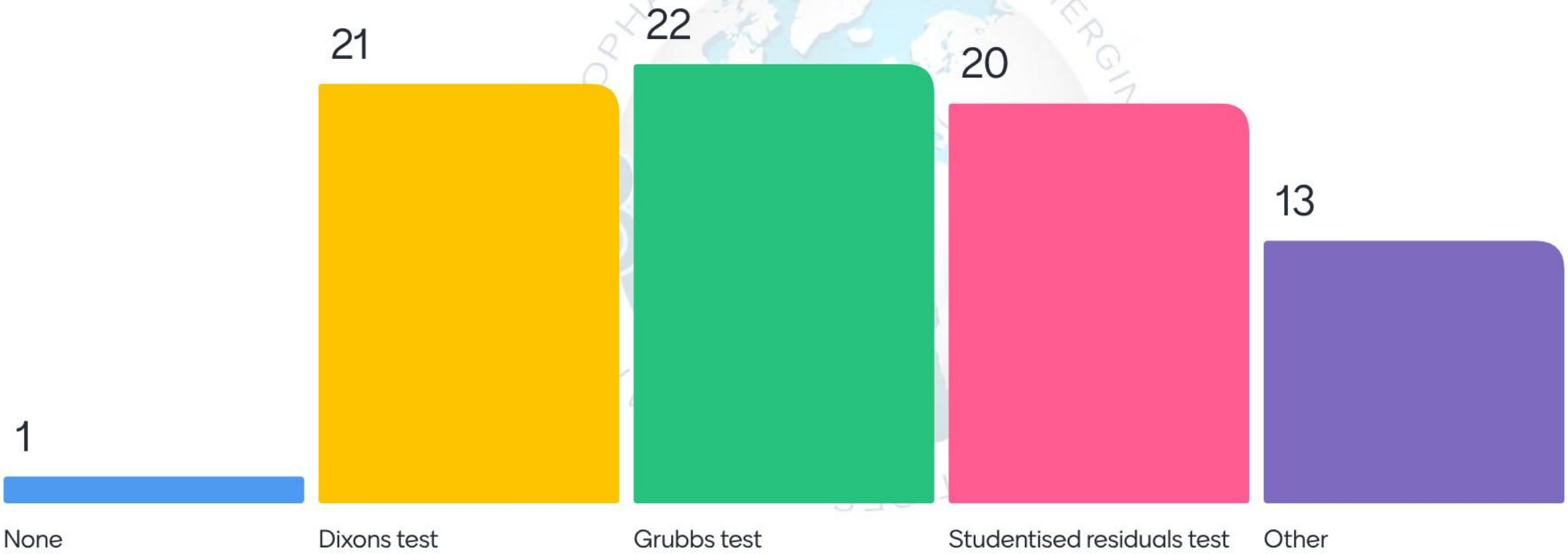
W2.1 How often do you see outliers in your bioassay data?



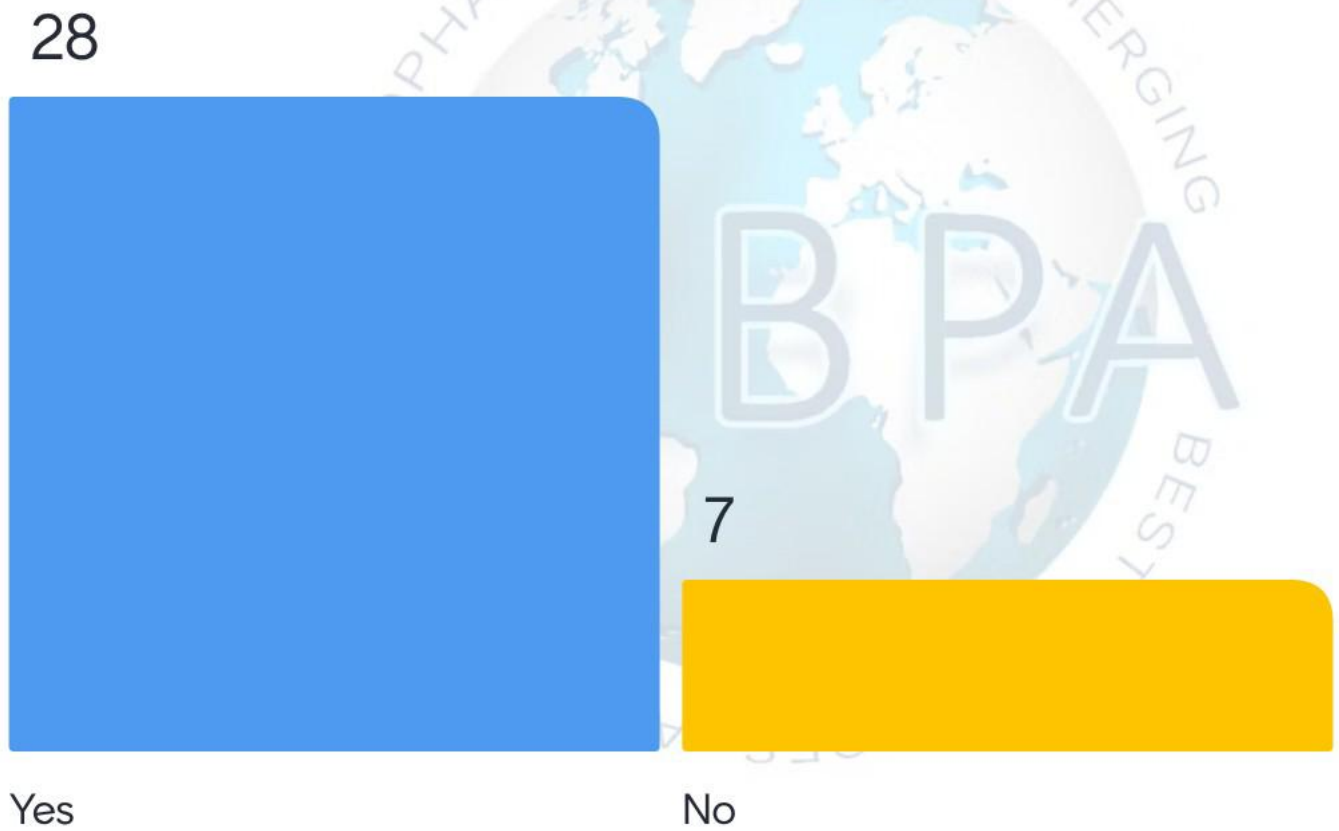
W2.2 When would you remove an outlier?



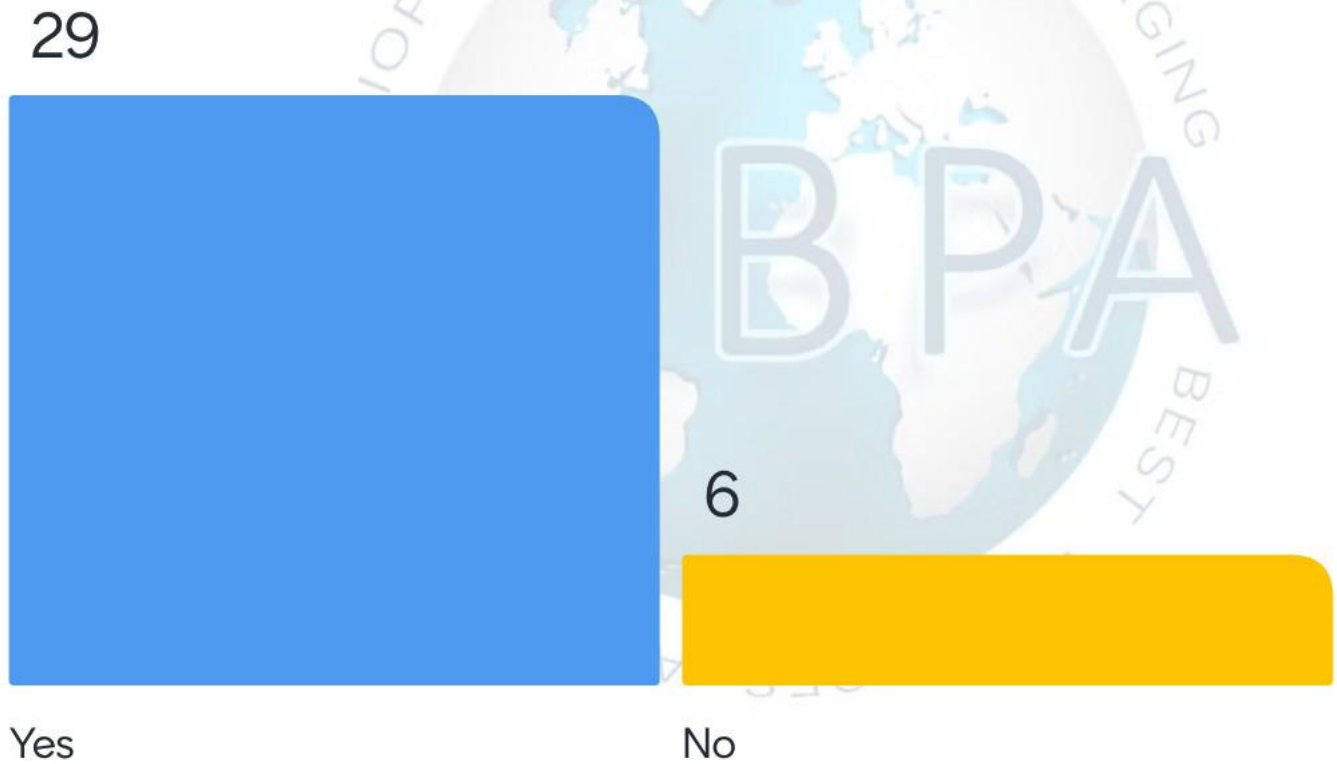
W2.3 What statistical outlier tests have you used?



W2.4 Do you use a criterion on %CV of replicates to identify potential outliers?



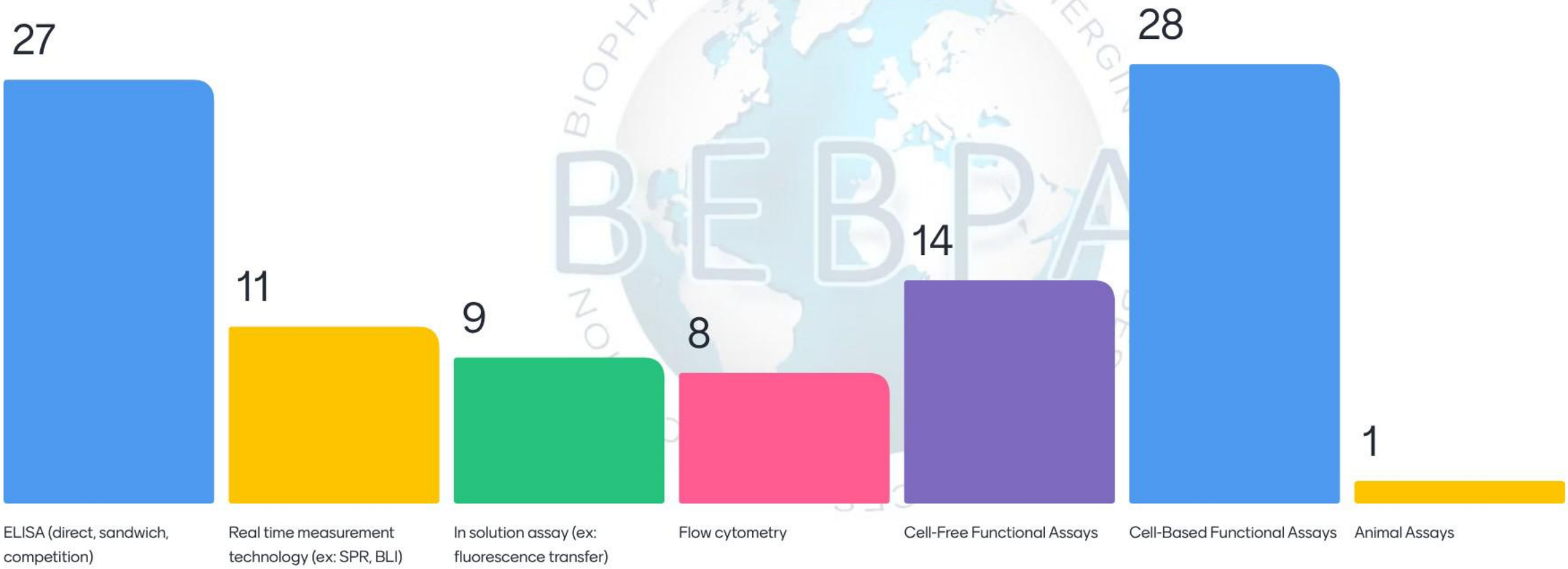
W2.5 Do you regard outlier management as a challenge for your assays and/or product lifecycle?



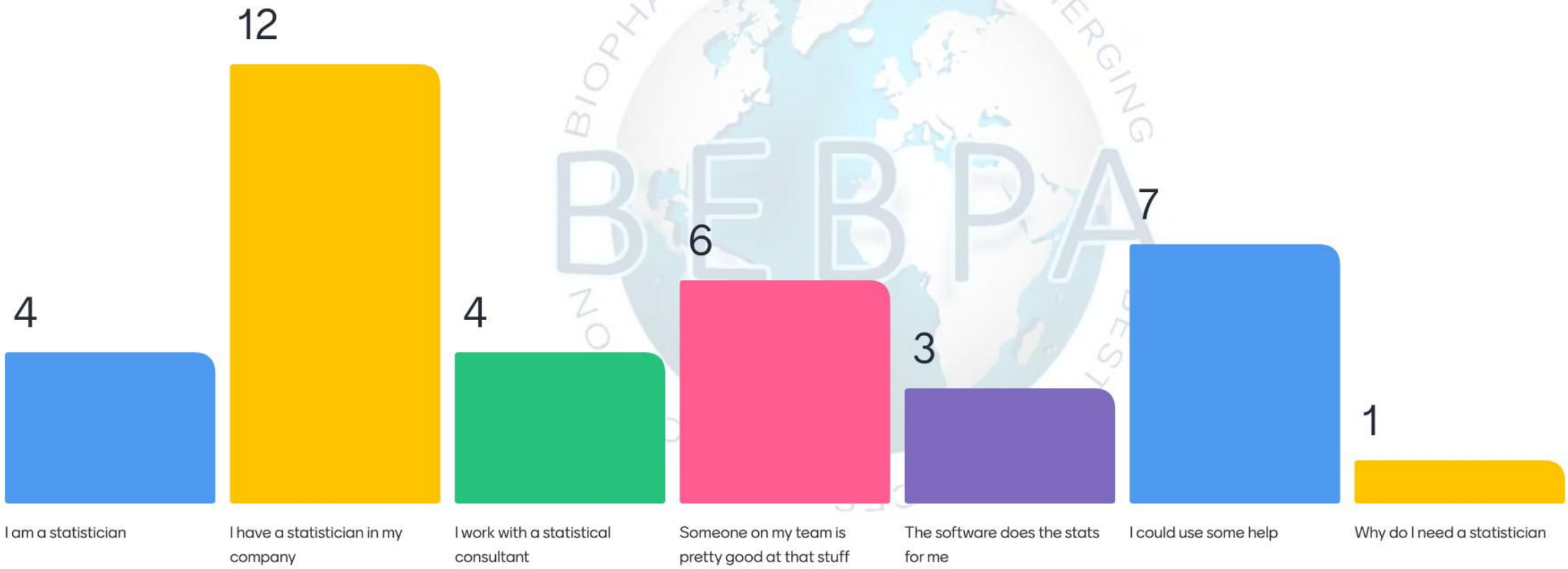
Workshop 3 Audience Surveys

The ABC's of Confidence Intervals

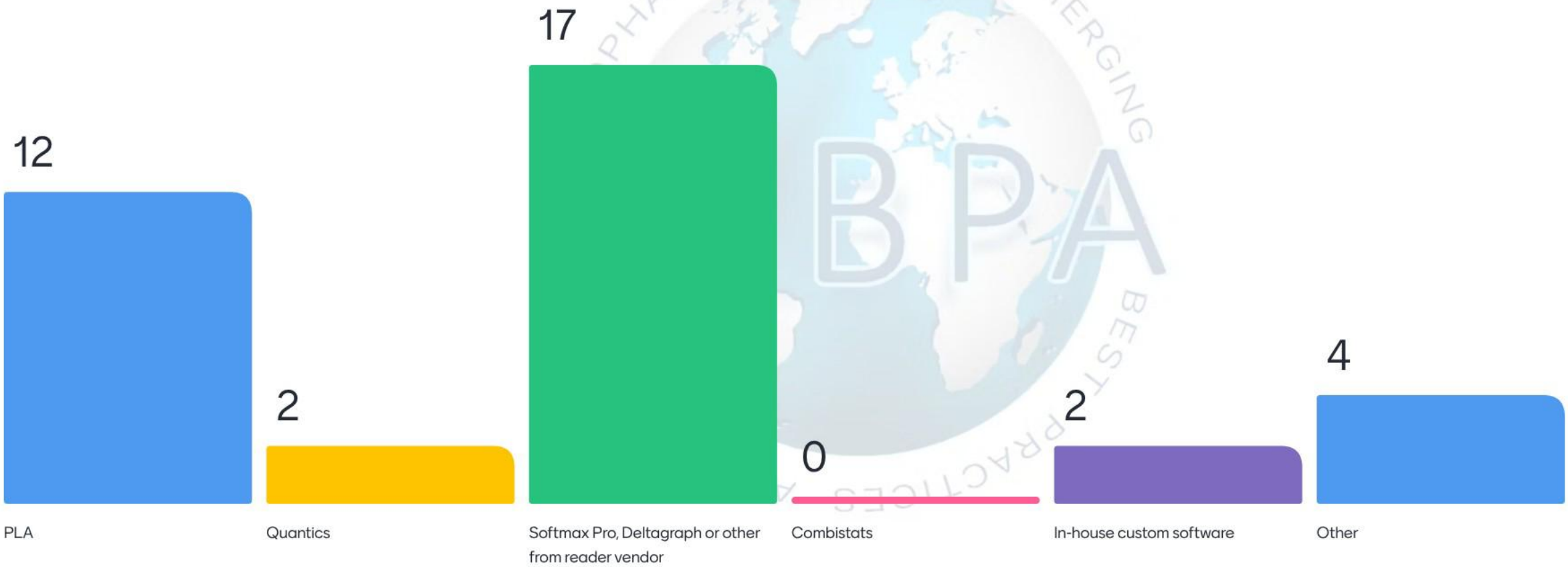
W3.1 What type of assays do you develop? (Check all that apply)



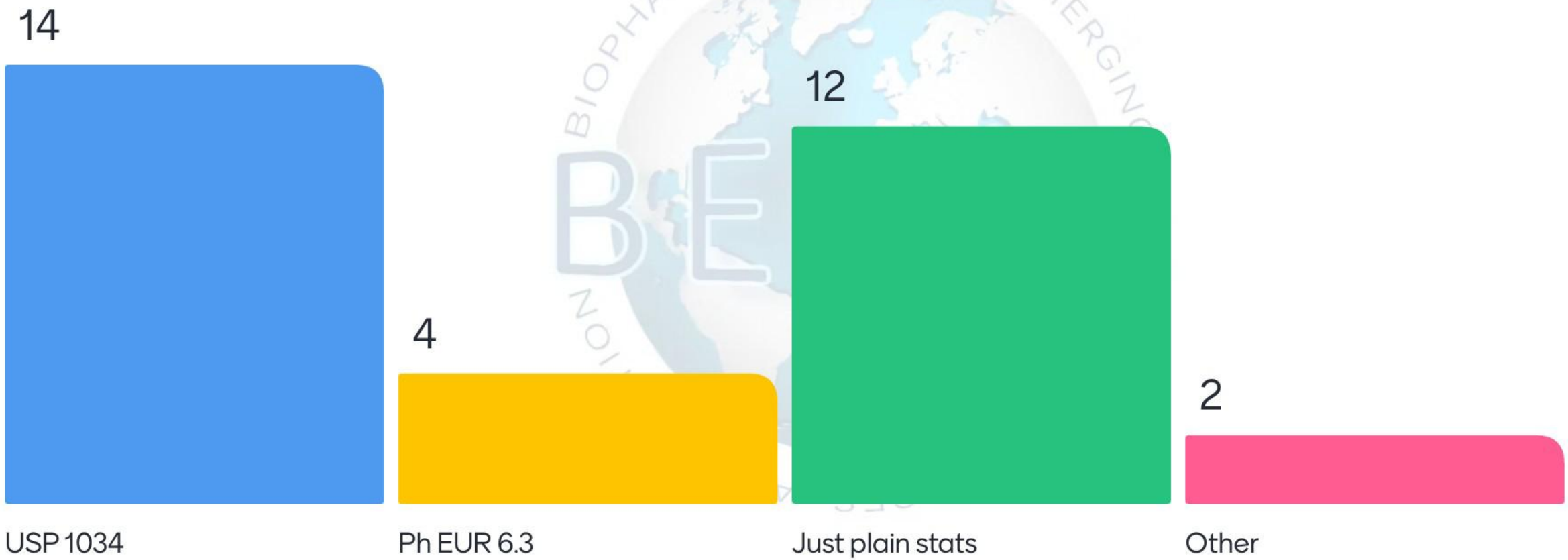
W3.2 What kind of statistical support do you have?



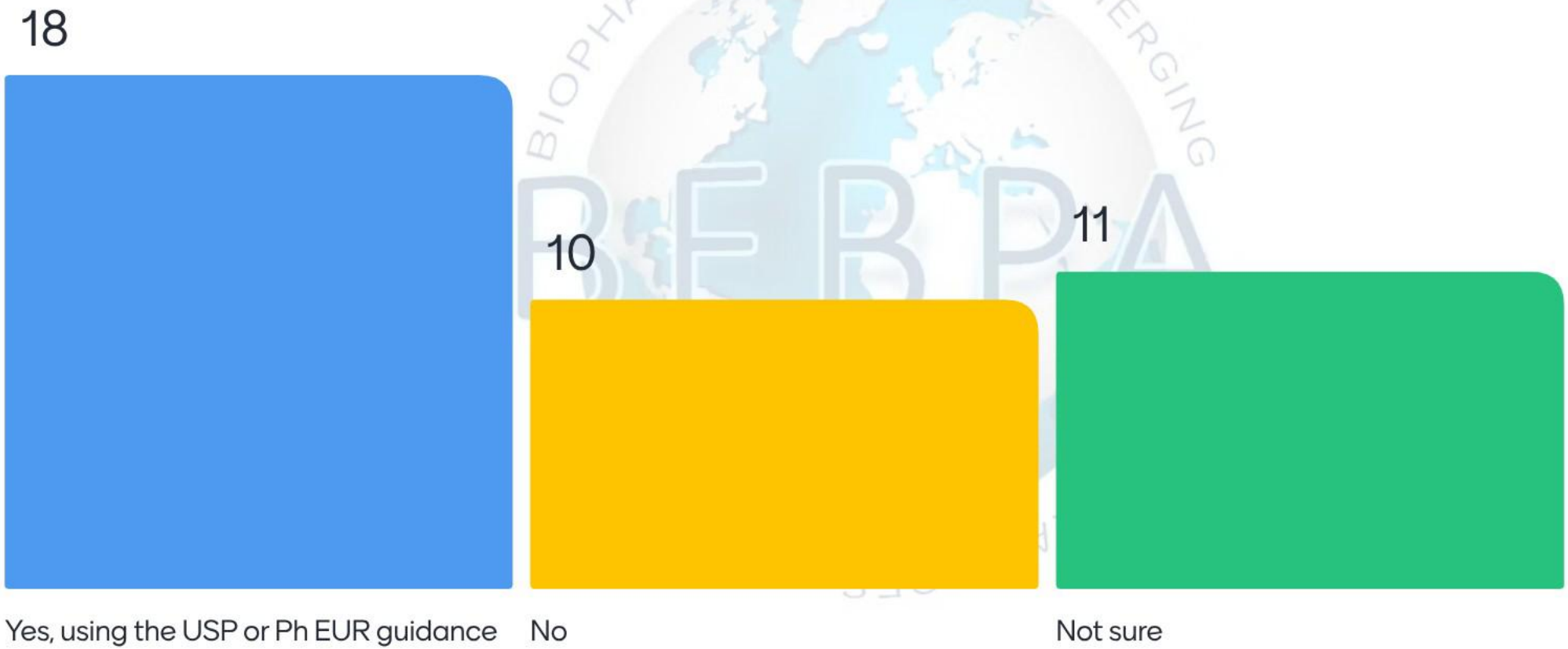
W3.3 What software do you use for assay analysis?



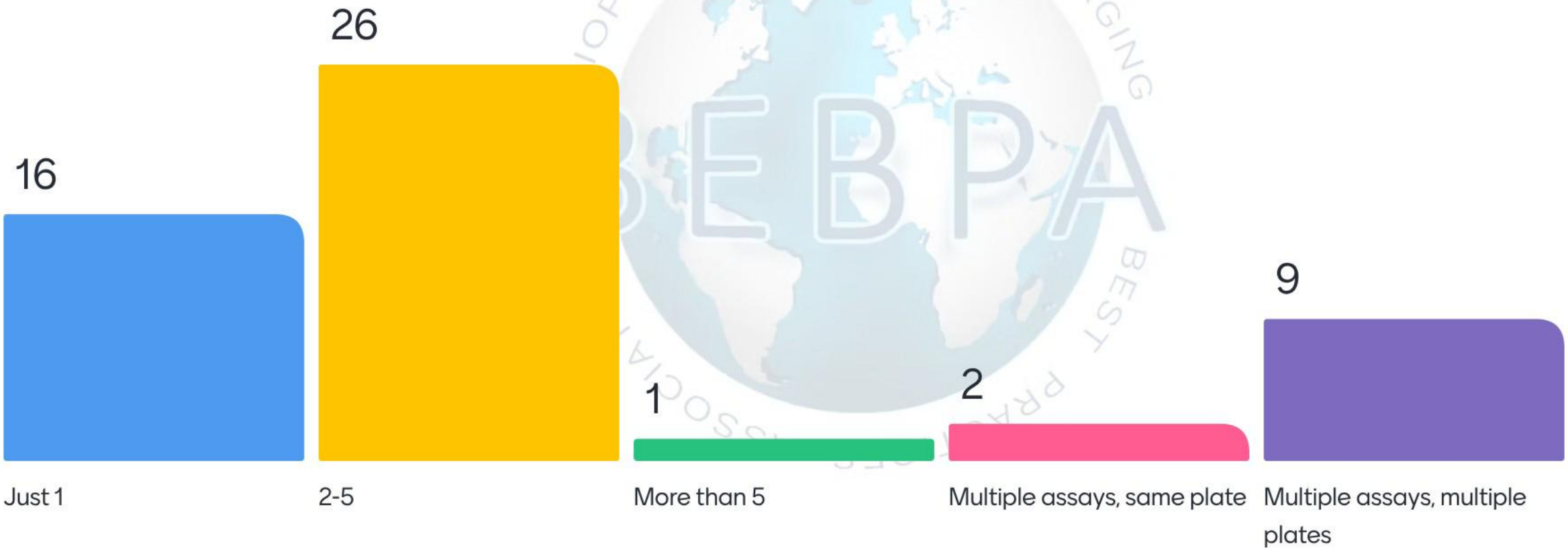
W3.4 Which guidance do you use for combining results of multiple assays?



W3.5 Does your software support combining results of multiple assays?



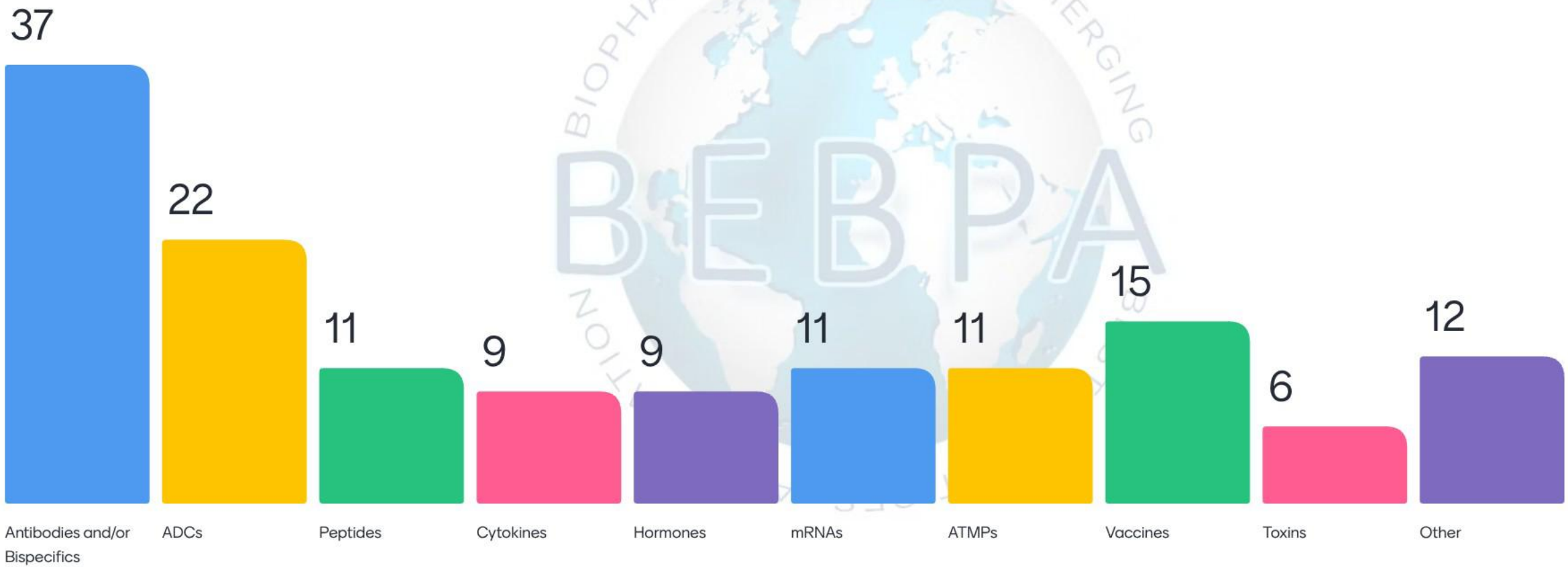
W3.6 How many assays do you use to produce a reportable value? Same plate or multiple plates?



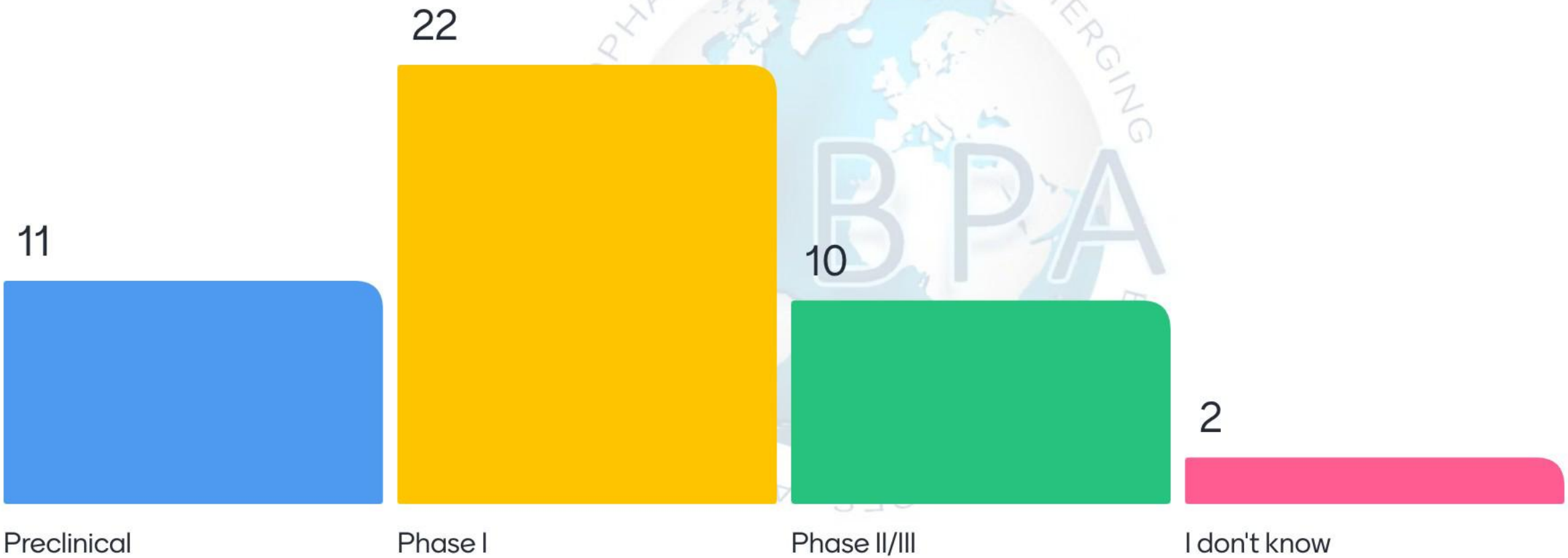
Workshop 4 Audience Surveys

Case Studies: Bioassays to Support Various Products

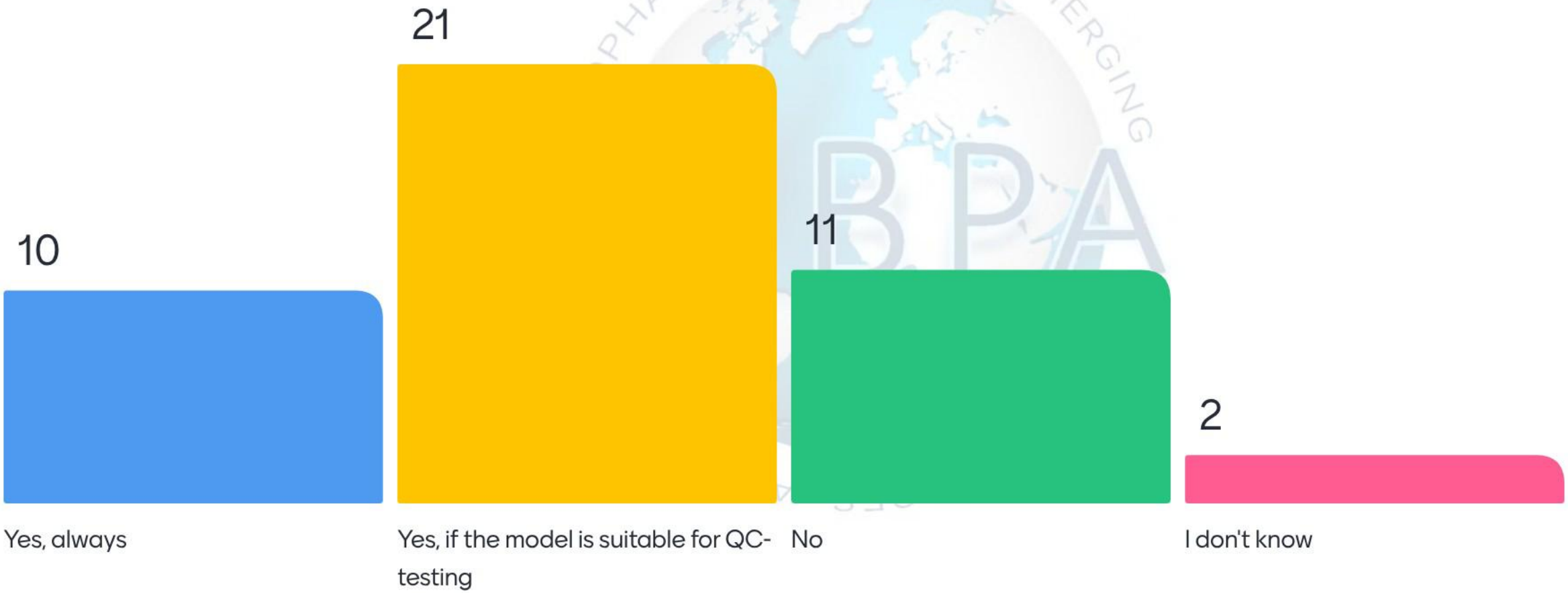
WS4.1 What modalities are you working with?



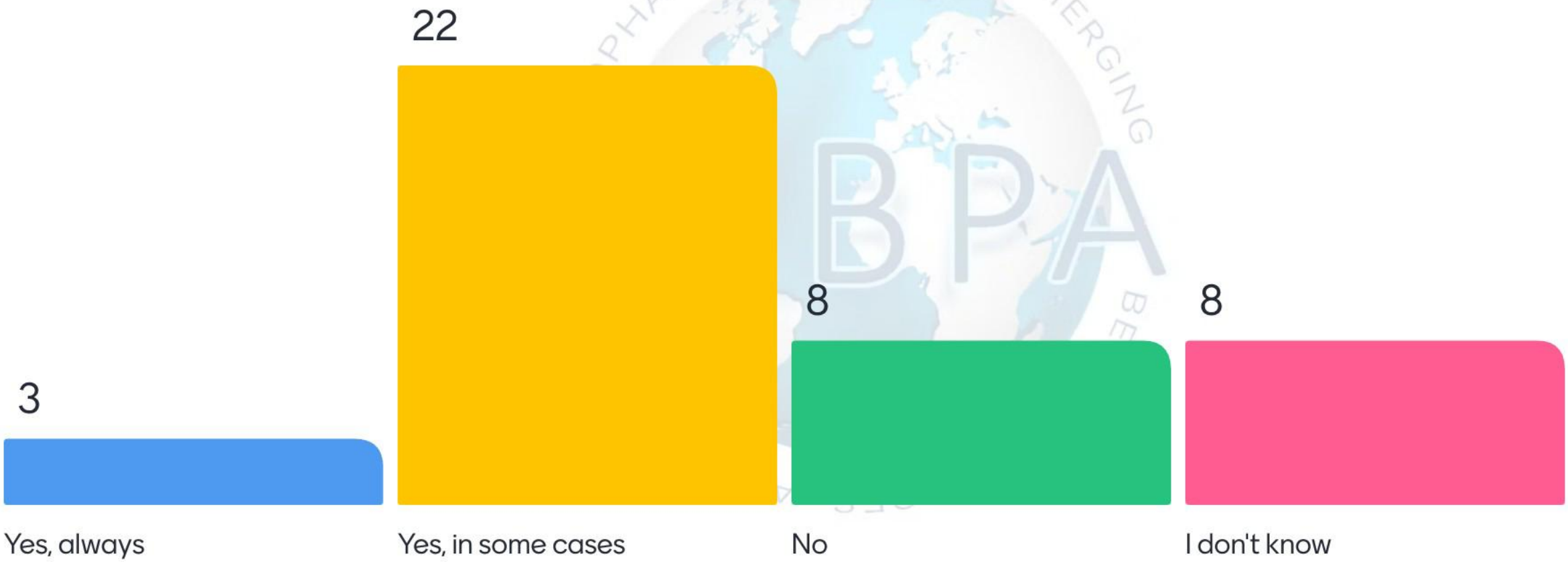
WS4.2 At which stage do you start working on a functional MoA-reflective bioassay?



WS4.3 Does the cell line used have to be representative of the species and cell type?



WS4.4 Do you develop your potency method according to a matrix approach?




BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION
BEBPA

Thank you!!