2026 Asia Bioassay Conference

4-6 November 2026

Incheon, Republic of Korea

BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION

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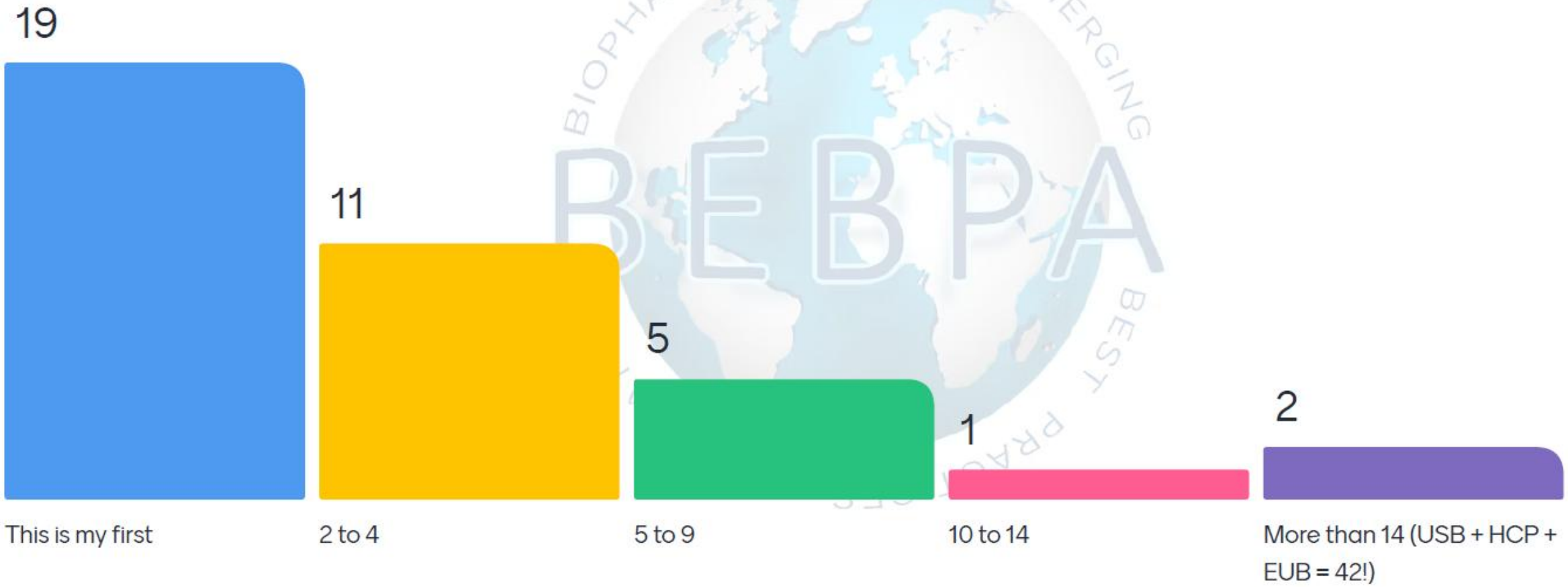
Welcome Back & Introduction

Laureen Little
Principal Consultant
Quality Services
BEBPA President

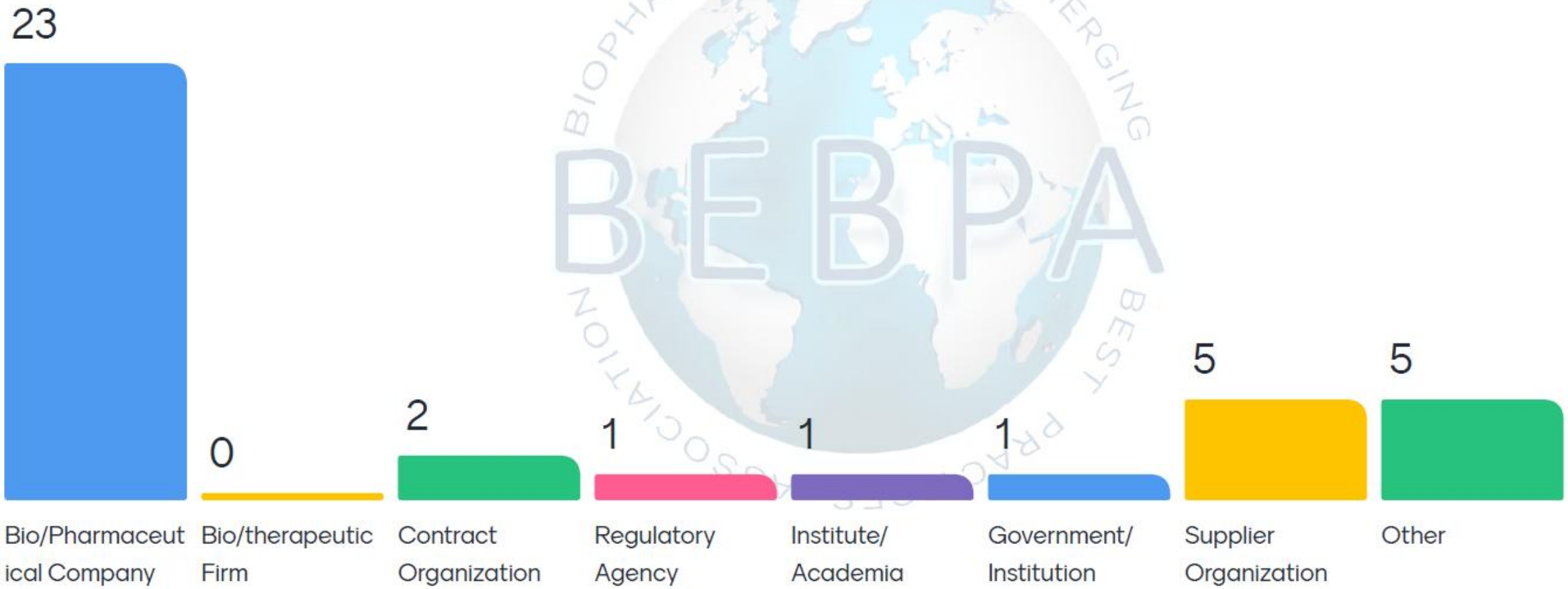
Day 1 - Intro Audience Surveys

BEBPA PHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION

i.1 How many BEBPA Conferences have you attended?

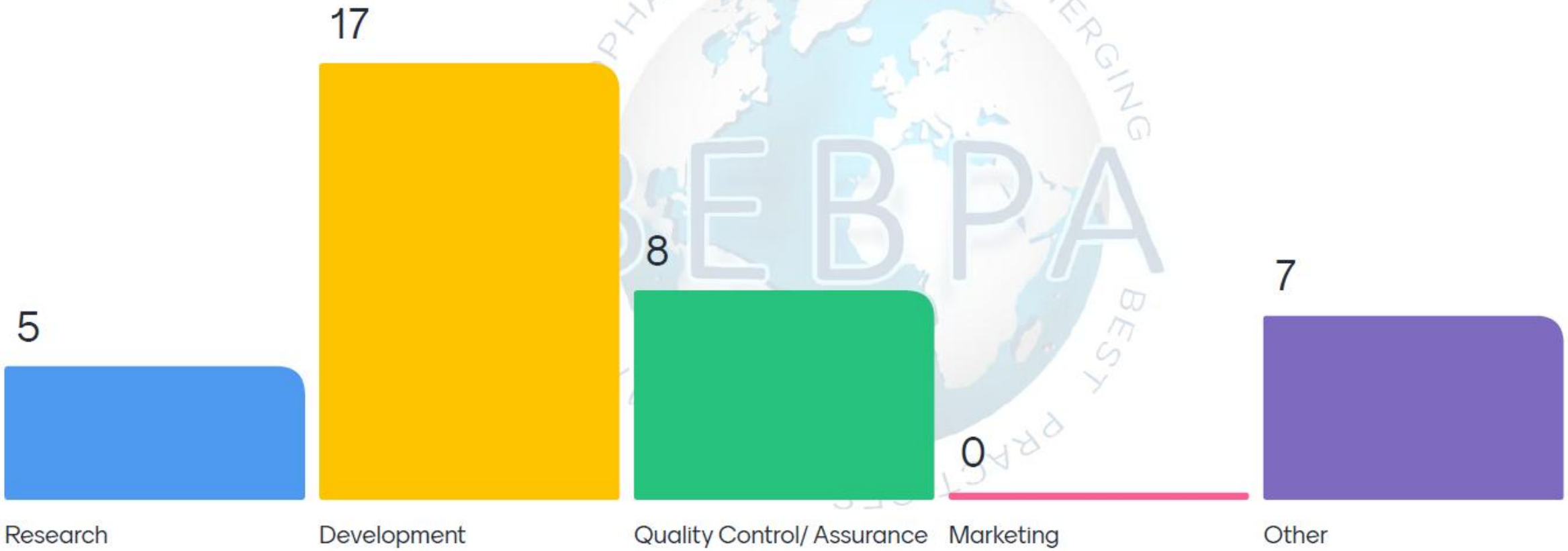


i.2 What type of organization do you work for?

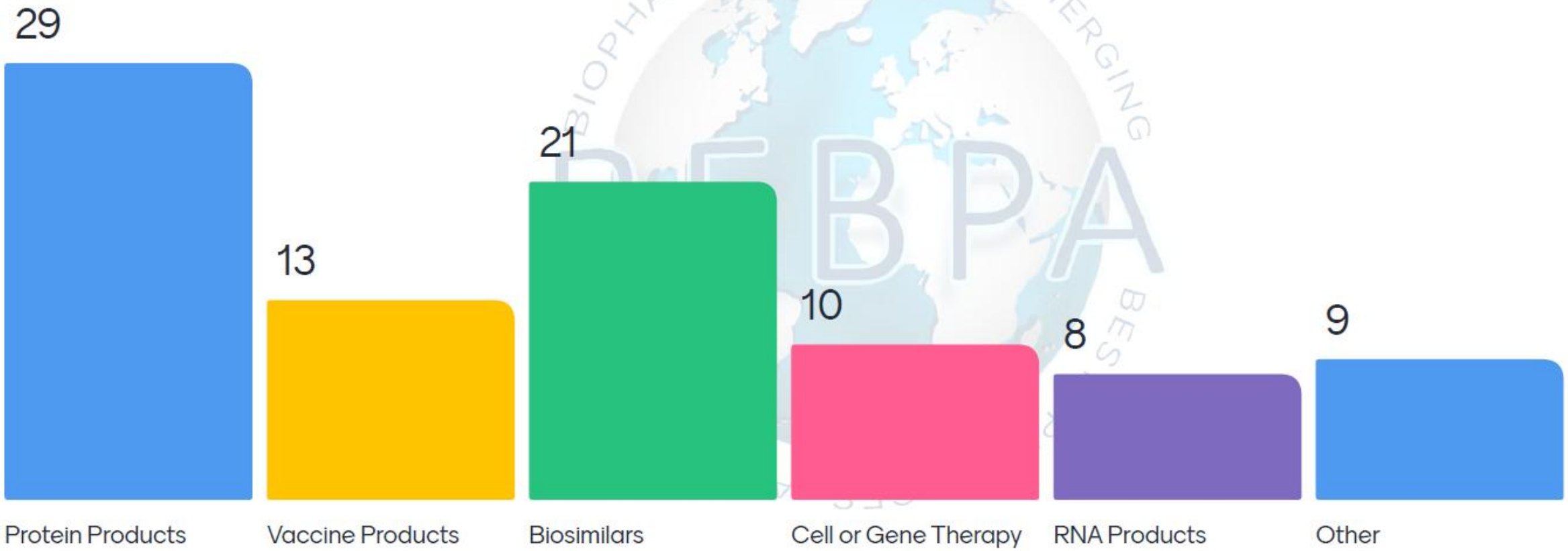


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i.3 What part of the organization do your work for?

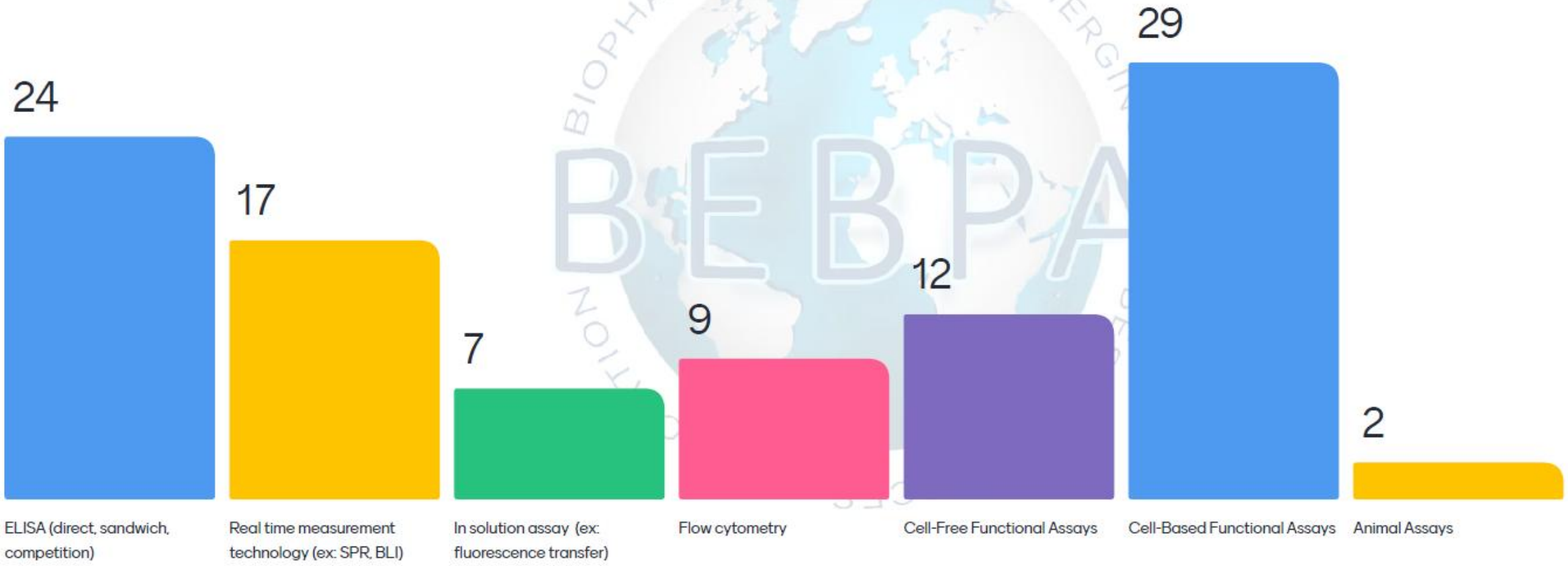


i.4 What type of products do you work with? (Check all that apply)



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



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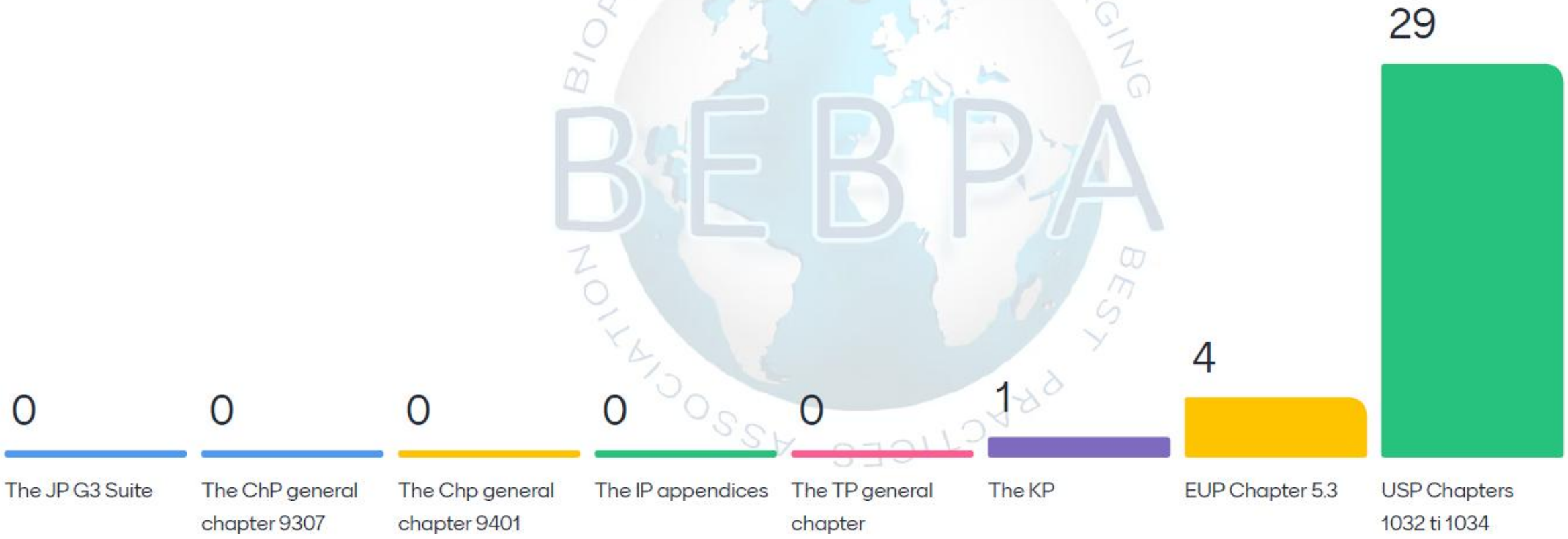
Day 1 Audience Surveys

Session 1: Regulatory Aspects

Session 2: Development

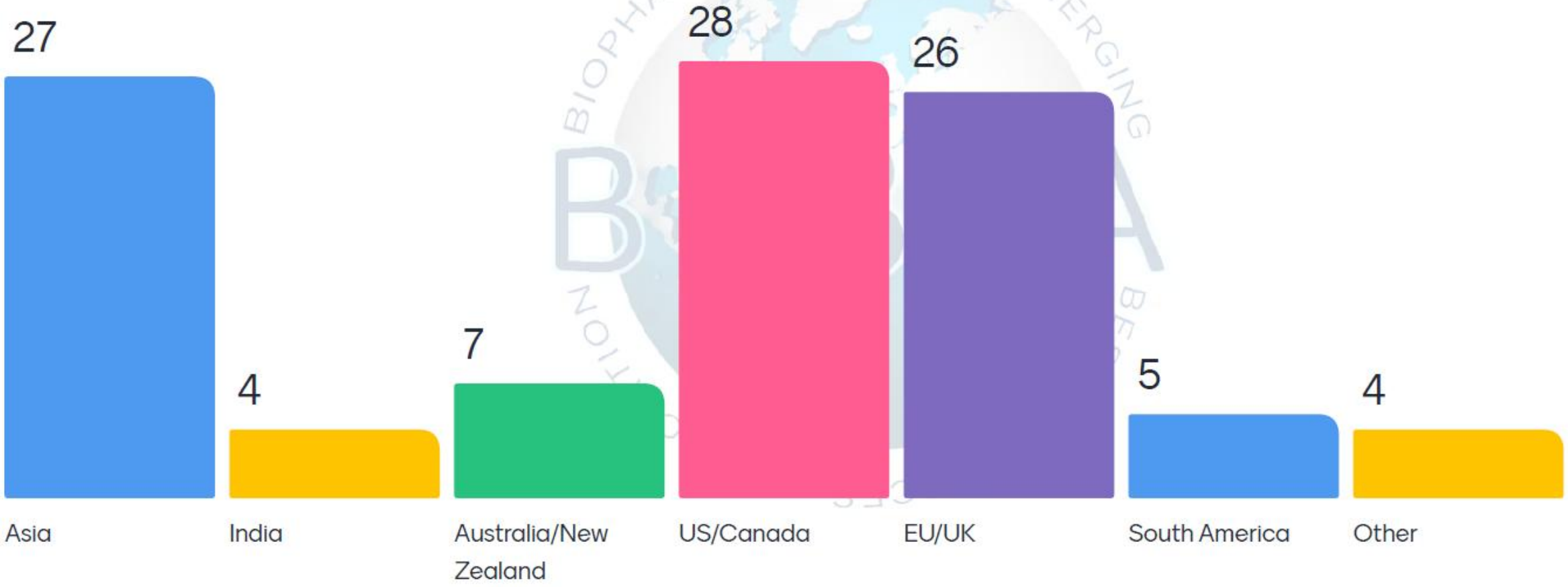
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1.1 Which Pharmacoepia do you follow for your data analysis of potency assays?

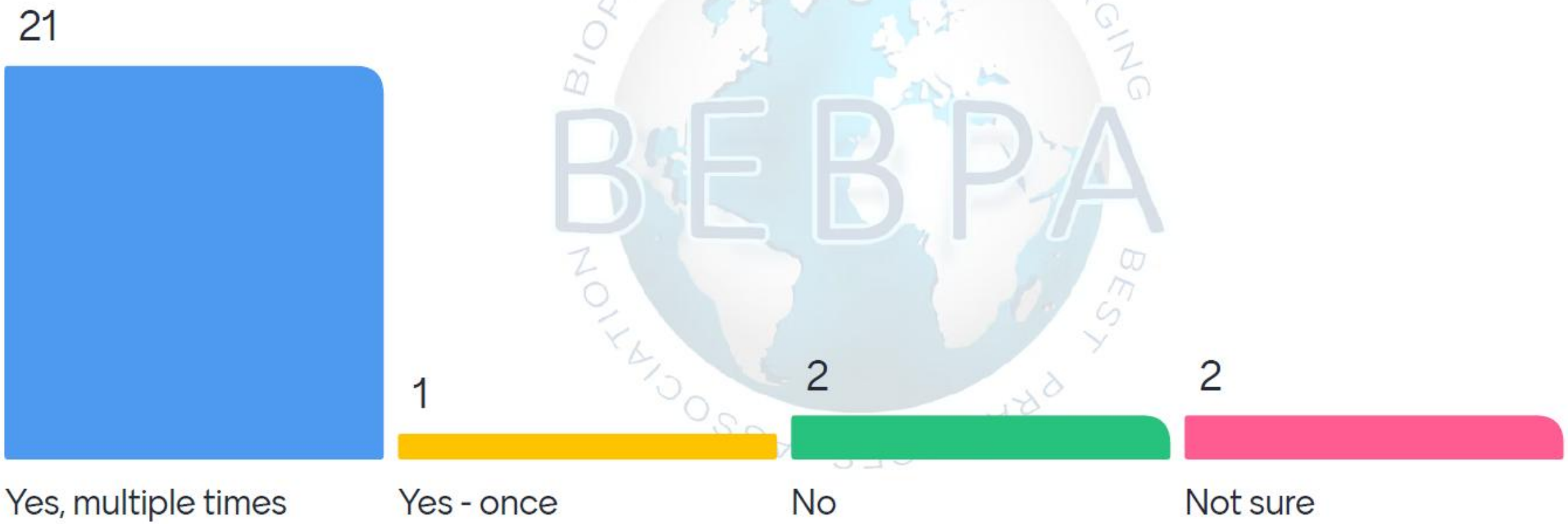


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1.2 Which global regions have you submitted data for product approval?

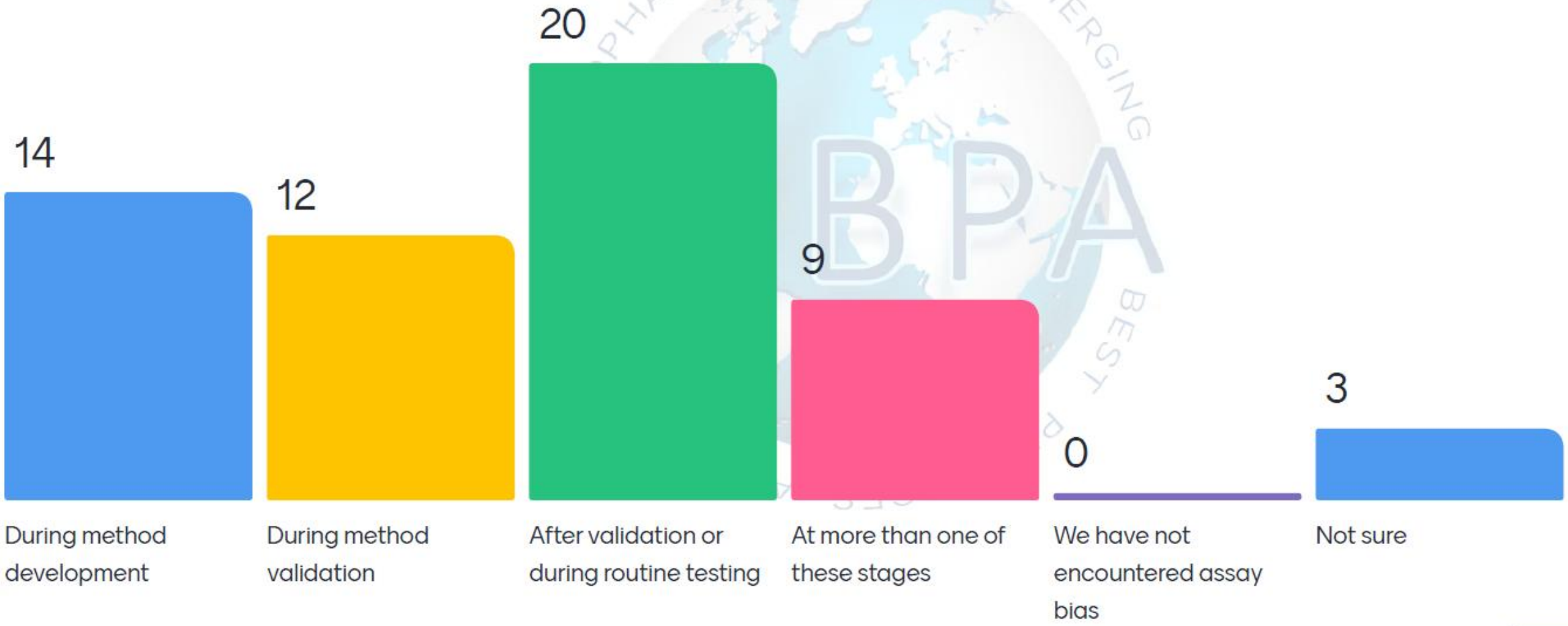


1.3 Has your organization ever identified an apparent potency shift that was ultimately attributed to assay bias rather than product quality?



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1.4 At what stage has your organization identified unexpected assay bias?



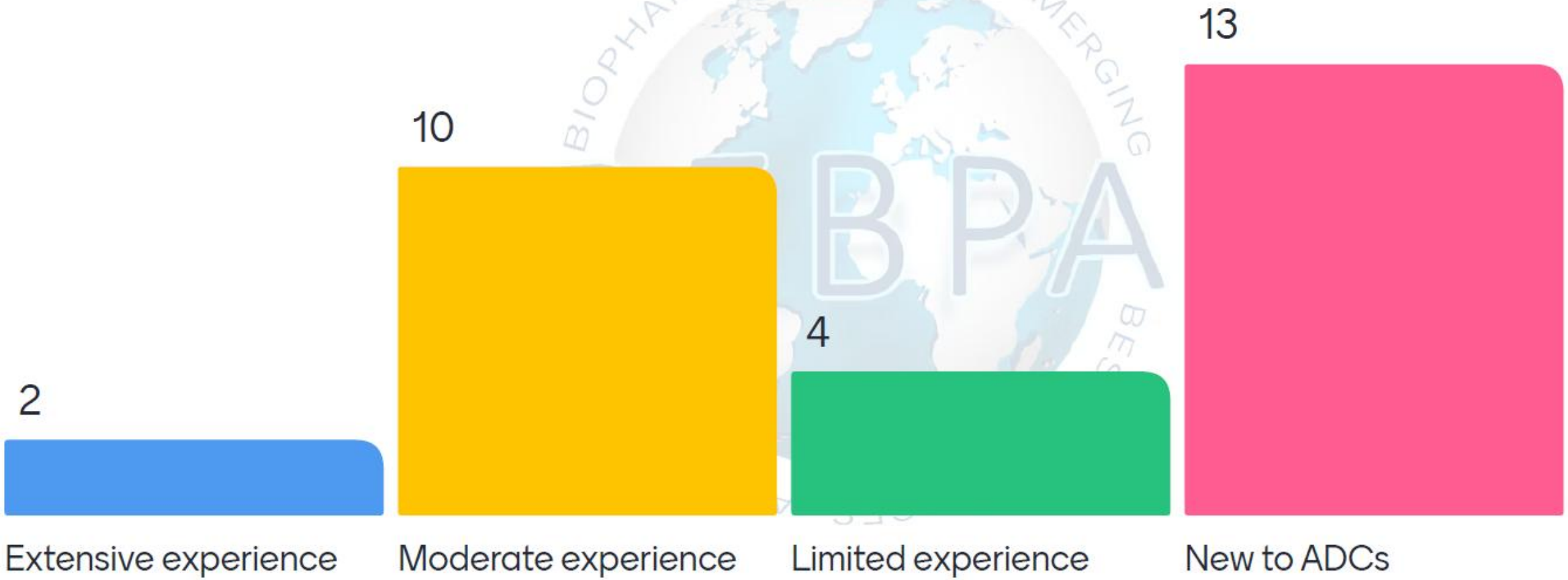
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Day 2 Audience Surveys

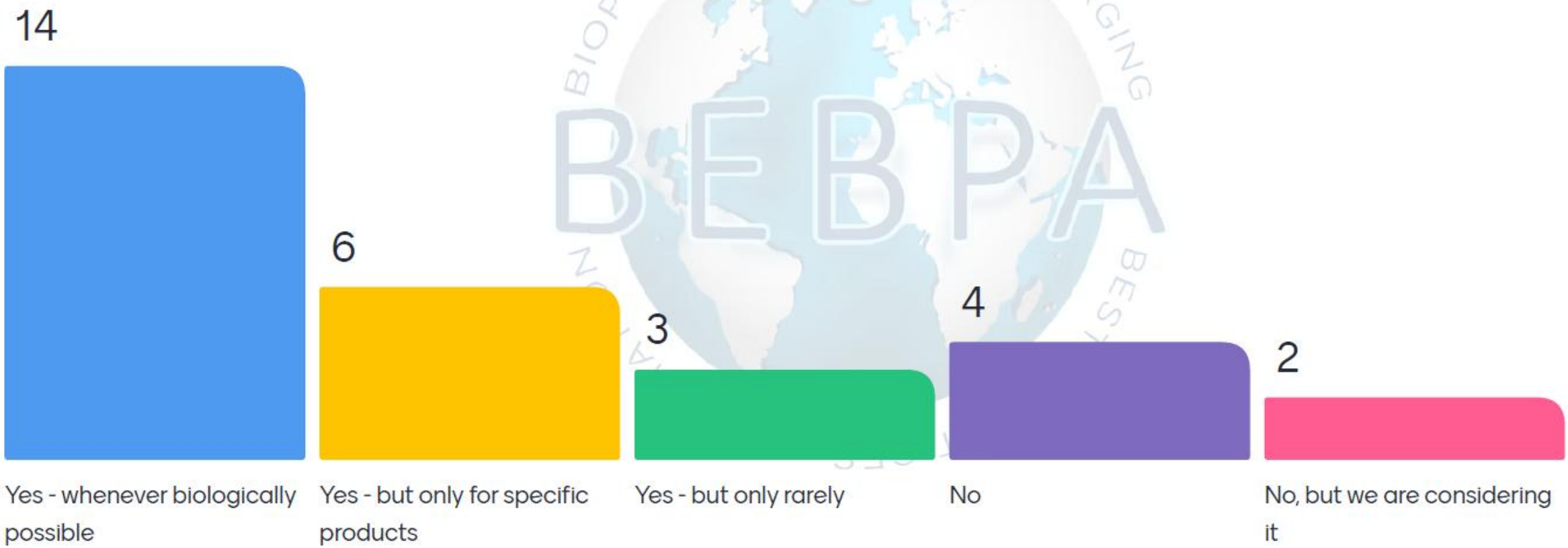
Session 2: Product Specific Potency Assays

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2.1 How would you rate your experience with ADCs (antibody drug conjugates)?

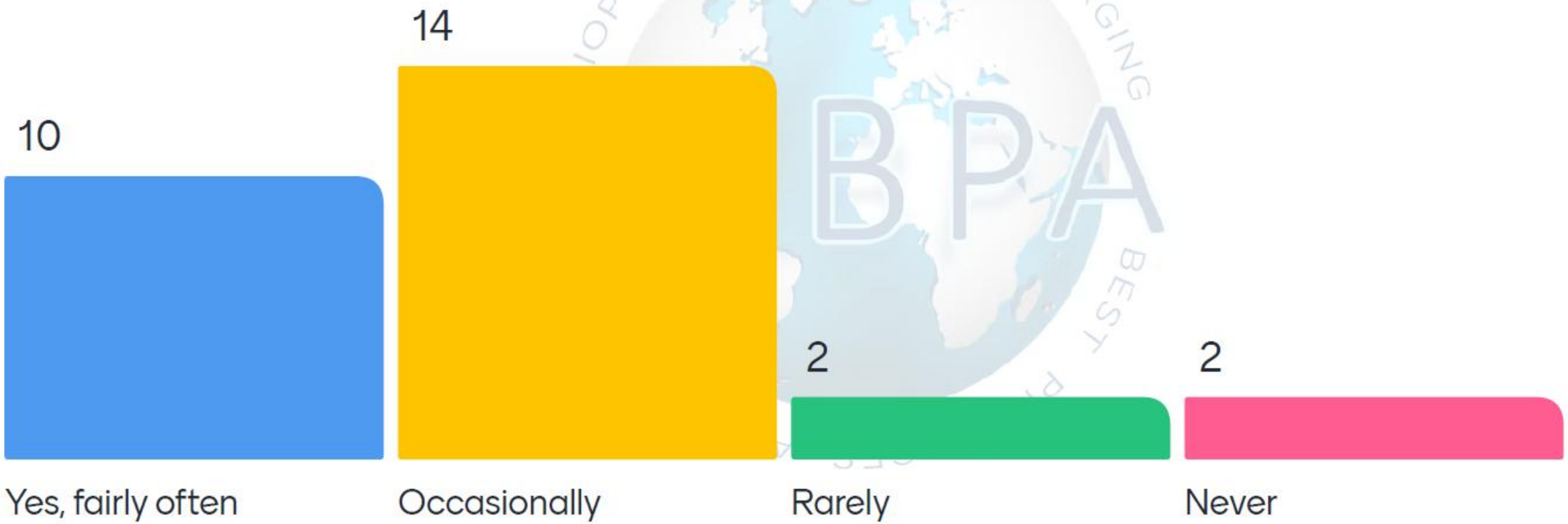


2.2 Have you used Frozen-Ready-to-USE (FRTU) cells in your cell-based bioassays?



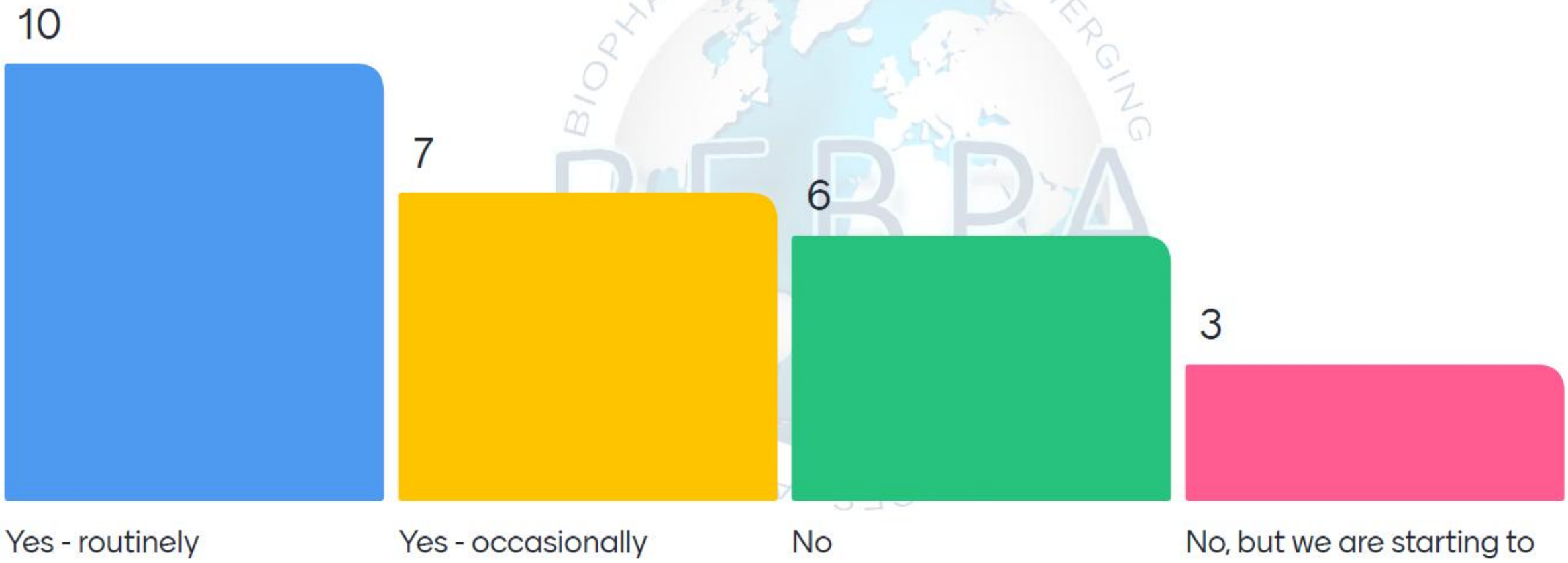
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2.3 Have you seen small structural changes to the product which alter the dose-response curve in your potency assay?



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2.4 Do you do early development knowing that your assay will need to be automated?

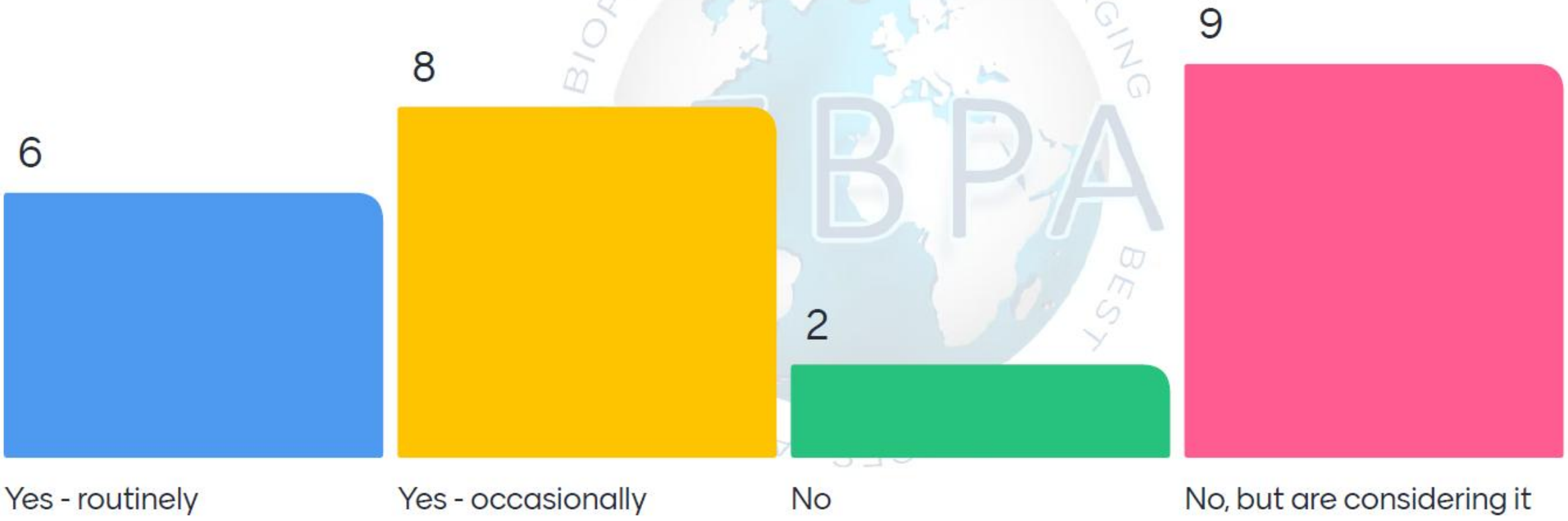


Day 3 Audience Surveys

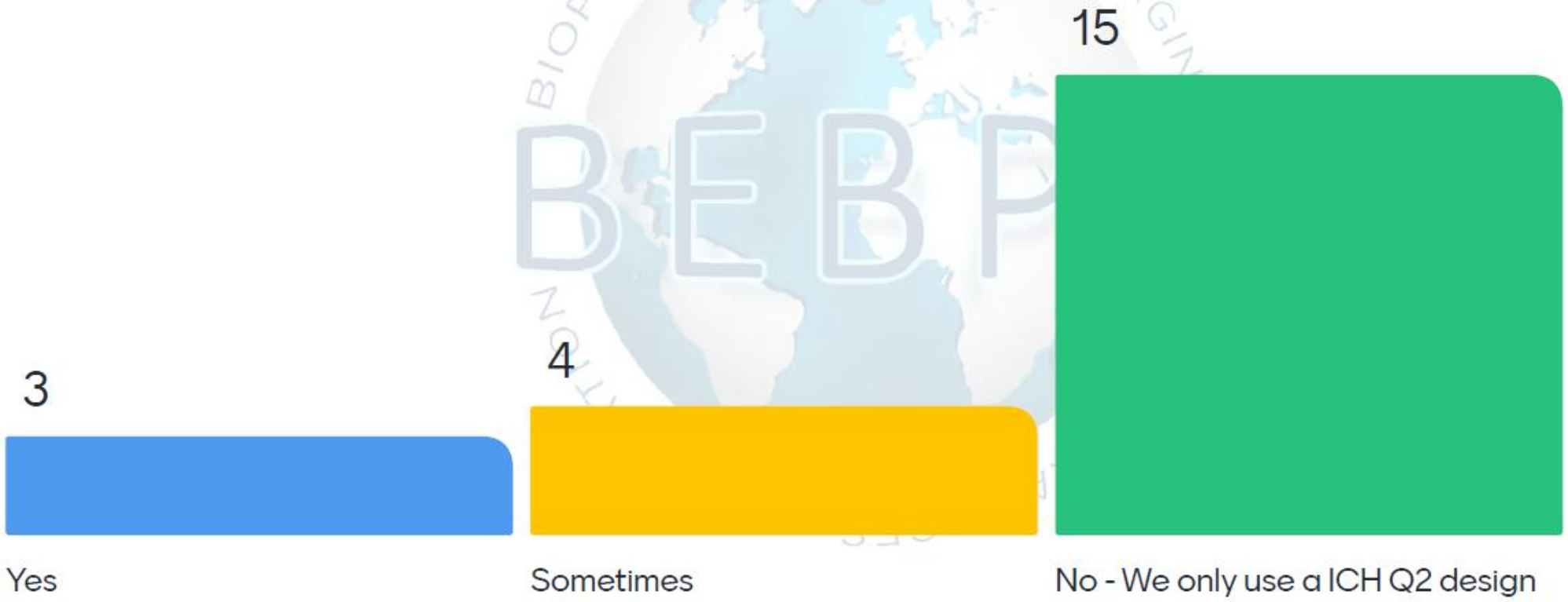
Session 4: Accelerating Assay Development with DoE

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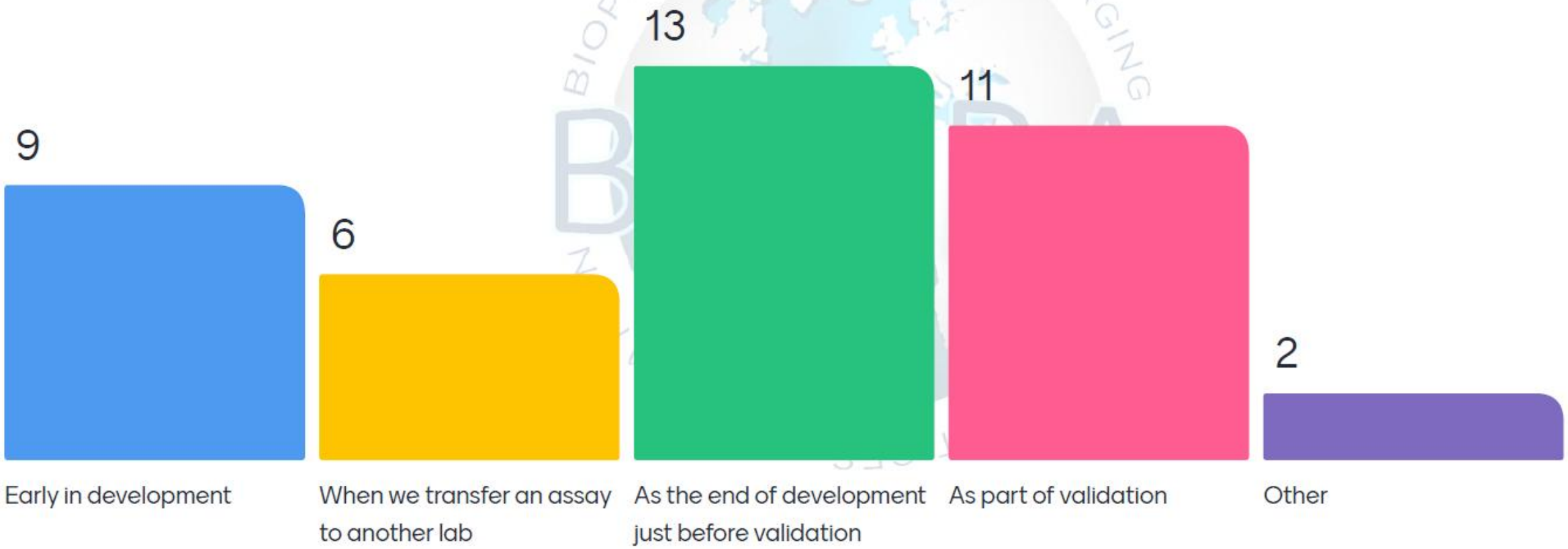
3.1 Do you use DoE for assay development? (Not including validation or robustness testing)?



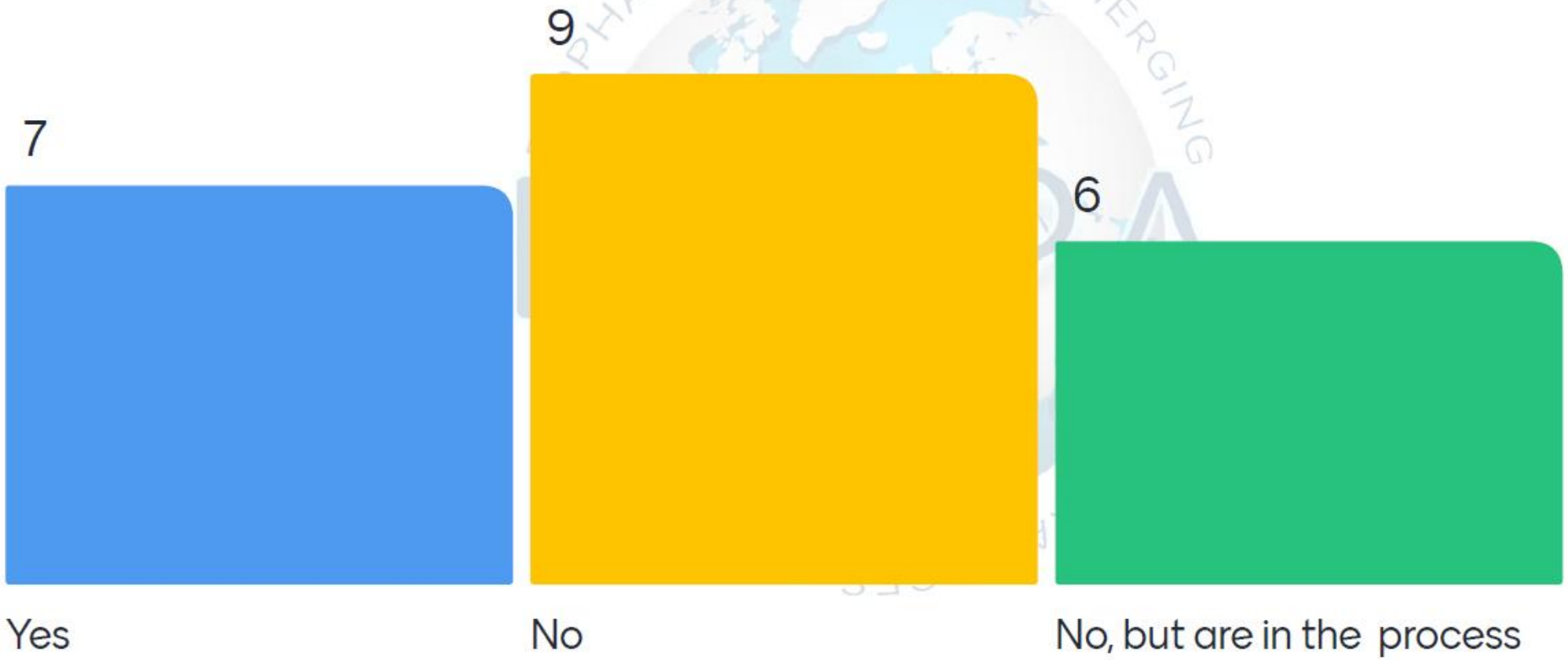
3.2 Do you use DoE to design bioassay validation?



3.3 When do you do robustness testing for your potency assay?



3.4 Have you ever competlely changed potency assays during late-phase development!!?

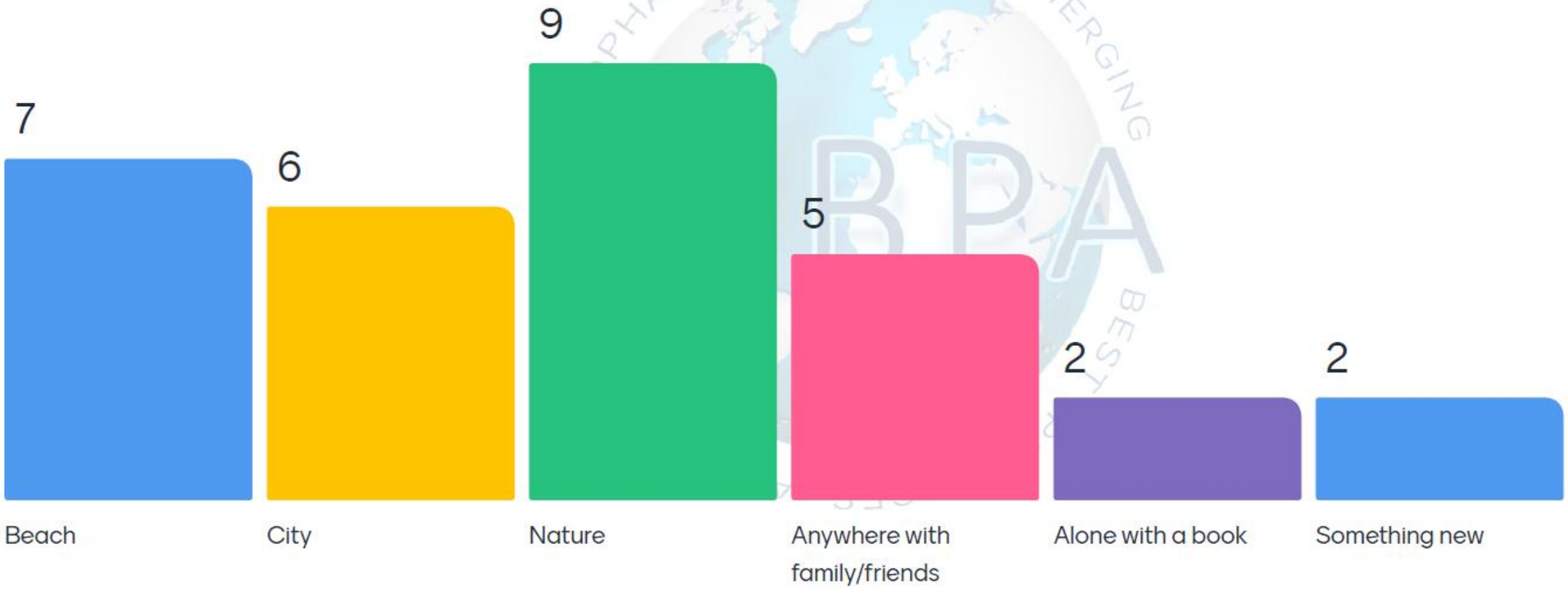


Education Session 1 Audience Surveys

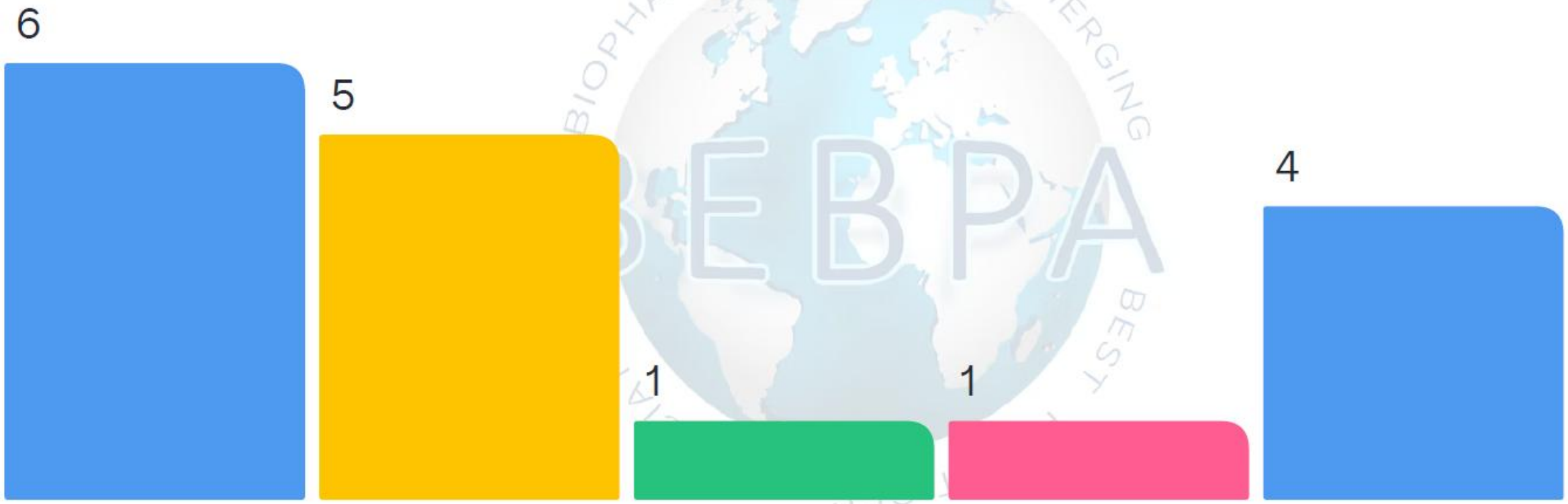
Bioassay Basics

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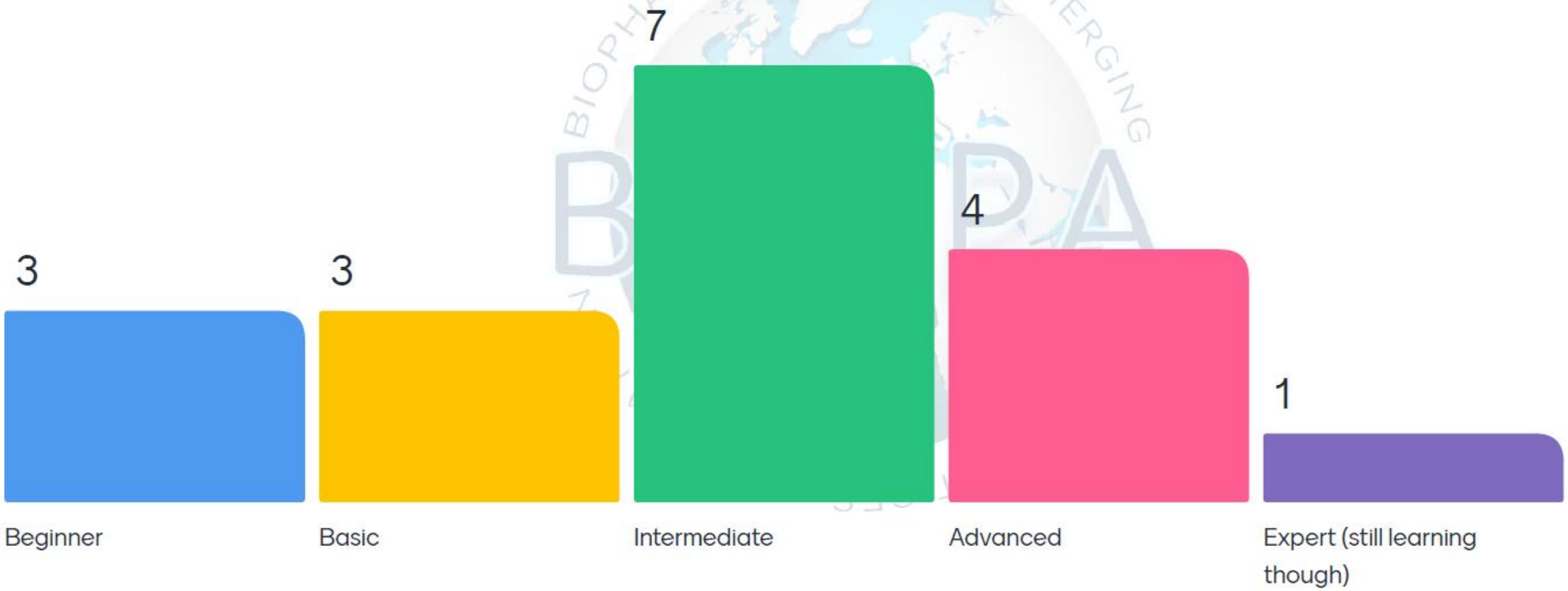
(*Practice!*) E1.1 What is your favorite vaction?



E1.2 What organization do you represent?



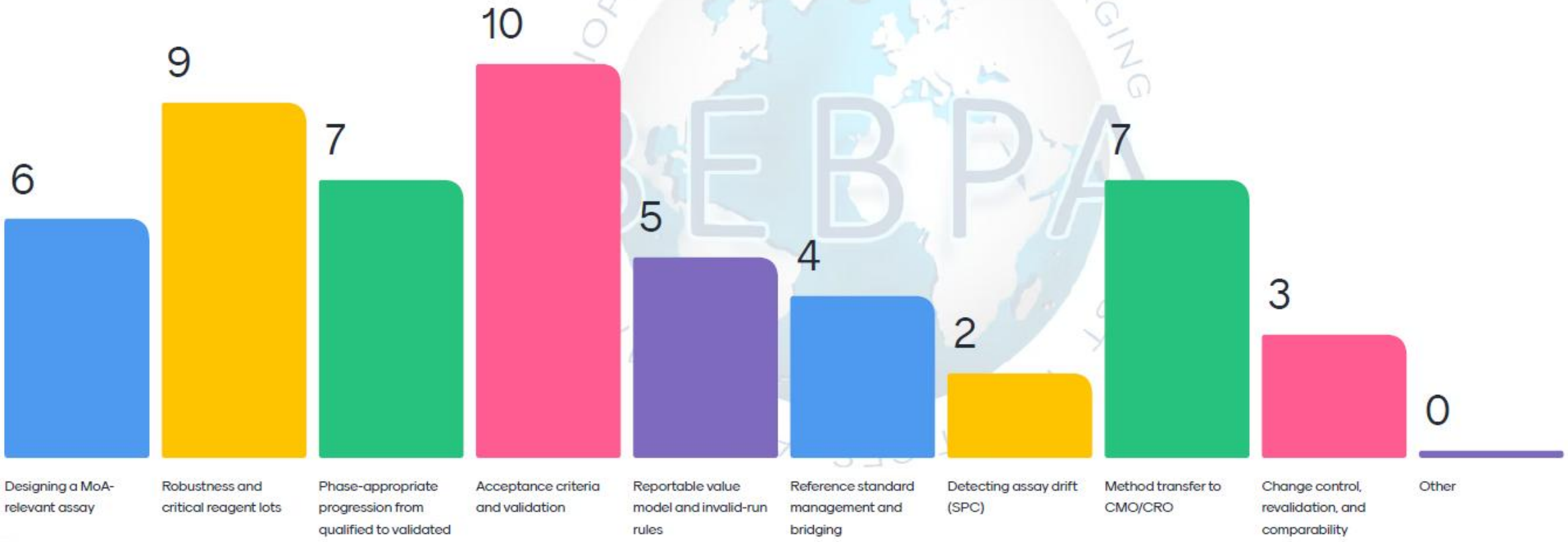
E1.3 How would you rate your proficiency level in bioassays?



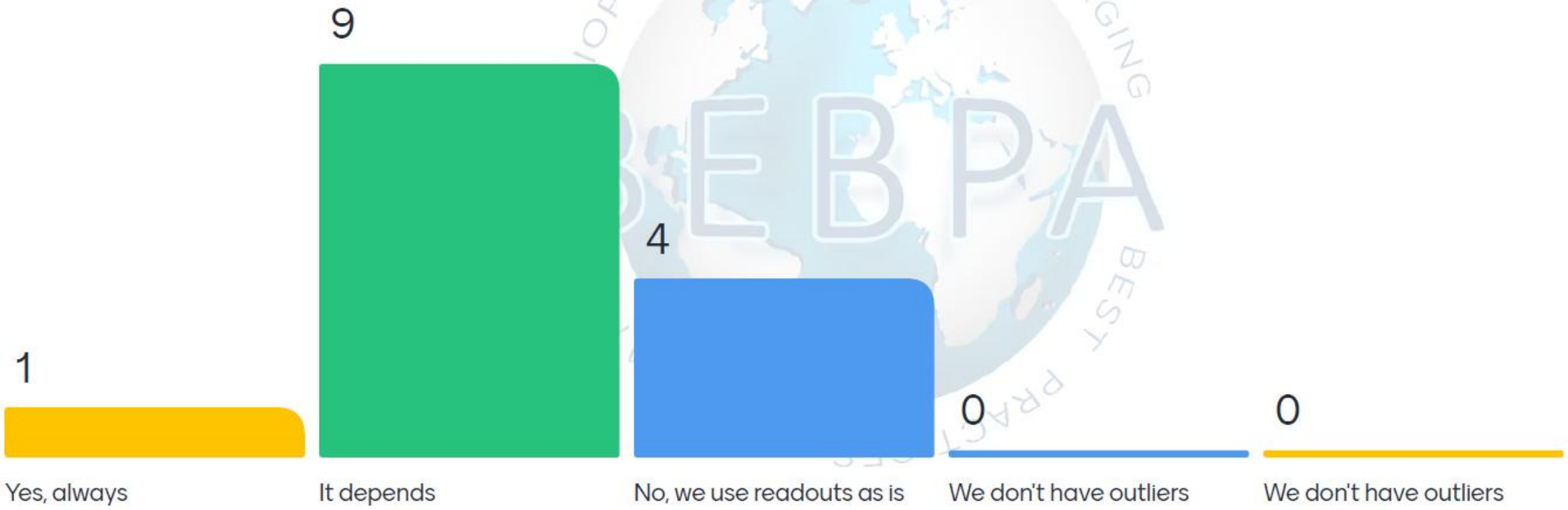
BIOPHARMACEUTICAL EMERGING

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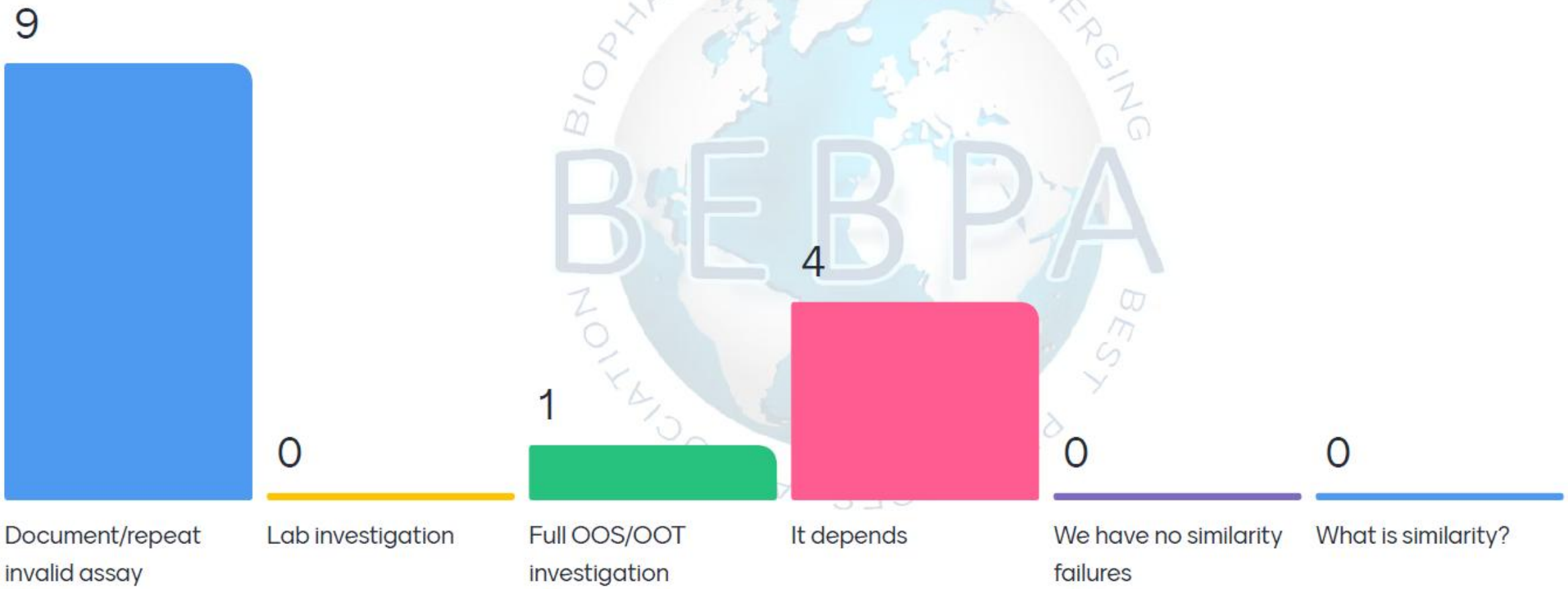
E1.4 Which bioassay lifecycle challenge is most critical for you, now or ahead?



E1.5 Do you use an outlier's detection for your assay's readouts?

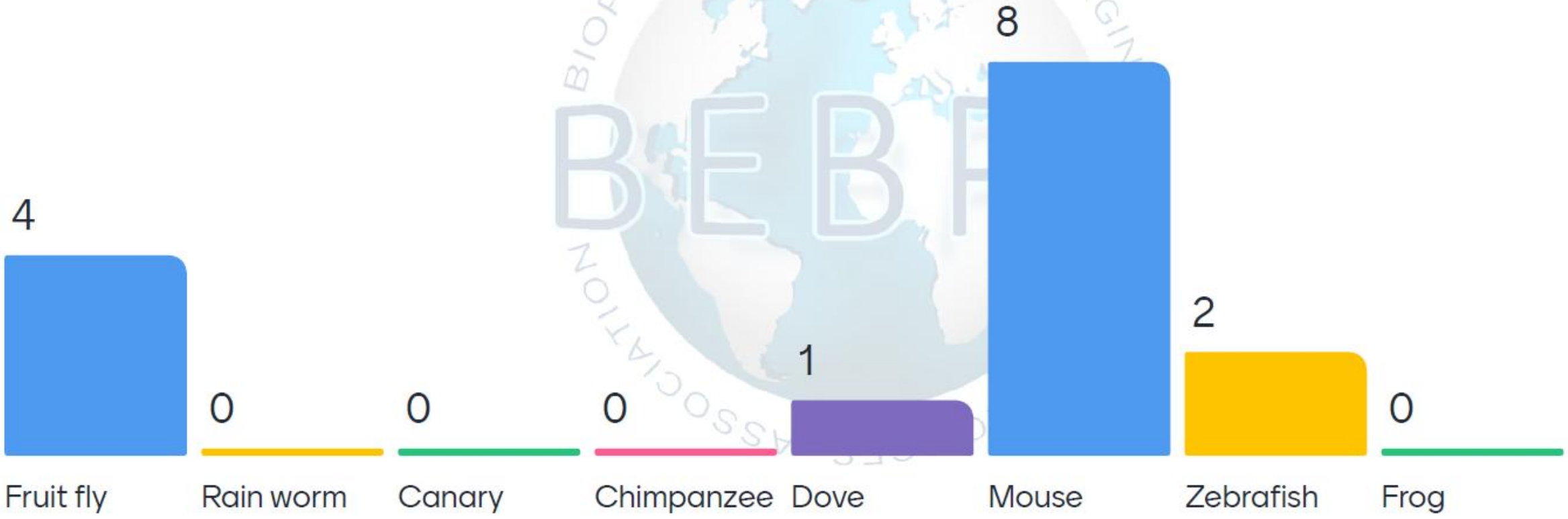


WS1.6 A potency assay fails parallelism (similarity) in QC, so there is no reportable value. How does your Quality unit handle it?



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WS1.7 Which organism was first documented in the literature as an in vivo model to measure potency?



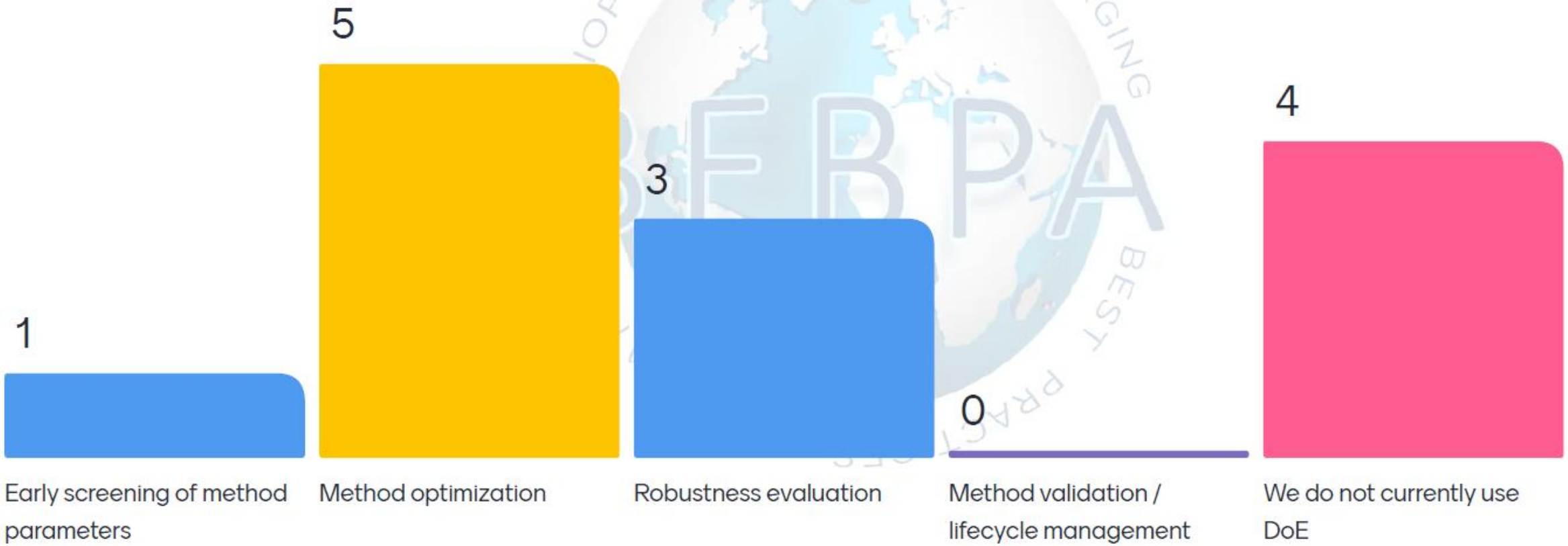
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Education Session 2 Audience Surveys

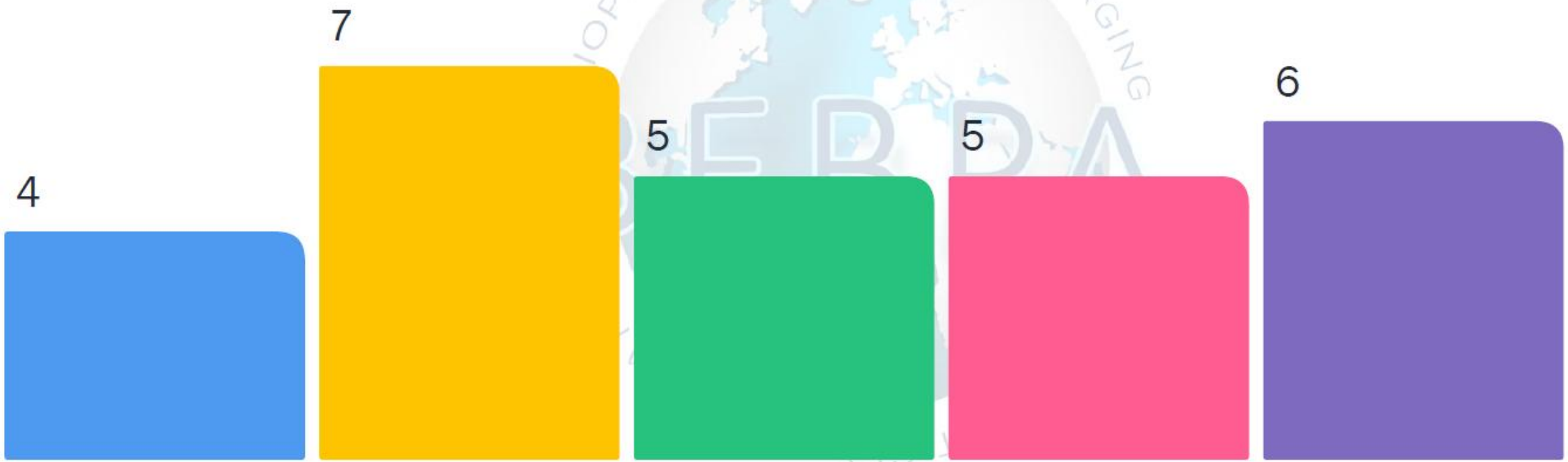
Using Design of Experiments (DoE) in Assay Development

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ES2.1 At which stage of analytical method development do you primarily use DoE?

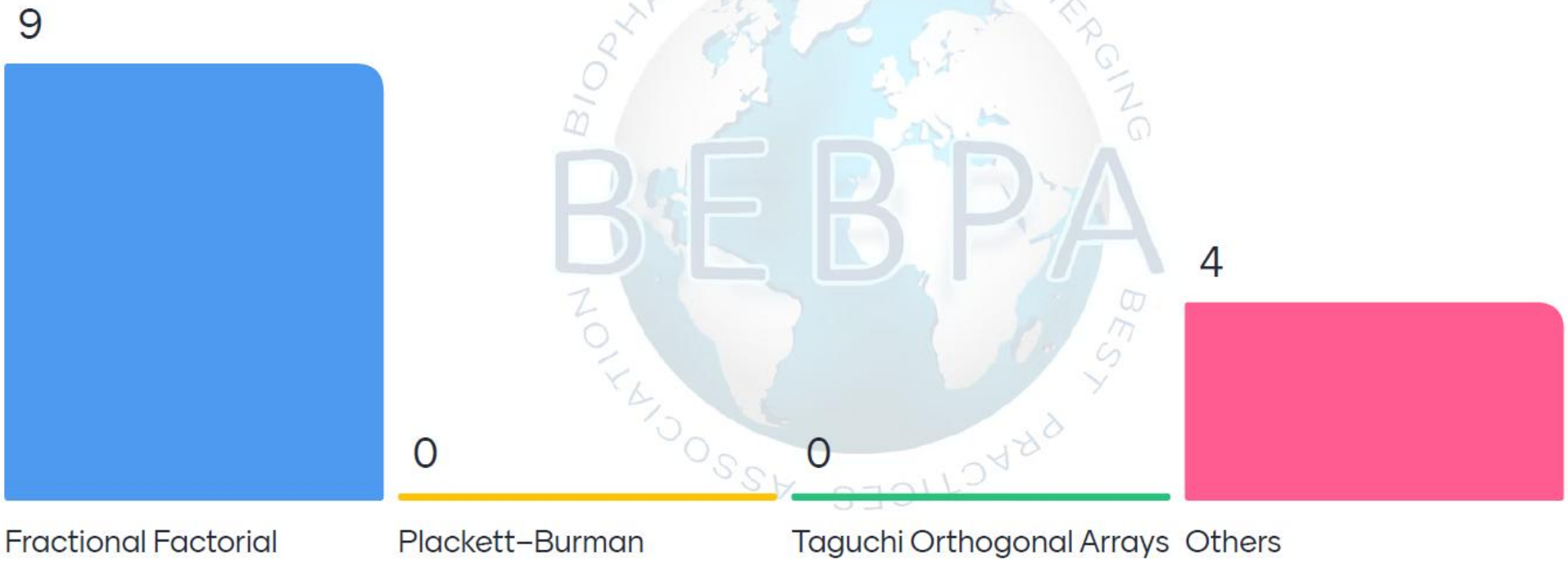


ES2.2 What do you consider the biggest advantage of DoE compared with one-factor-at-a-time (OFAT) experimentation?



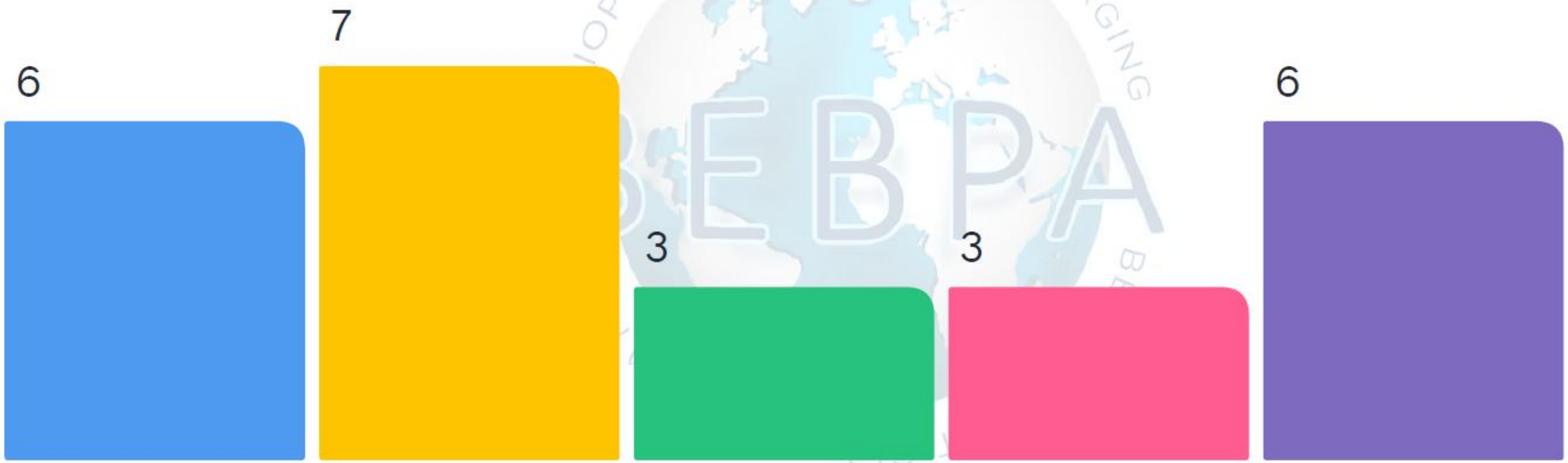
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ES2.3 Which screening design do you generally use?



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ES2.4 What is the biggest challenge when applying DoE in your company?



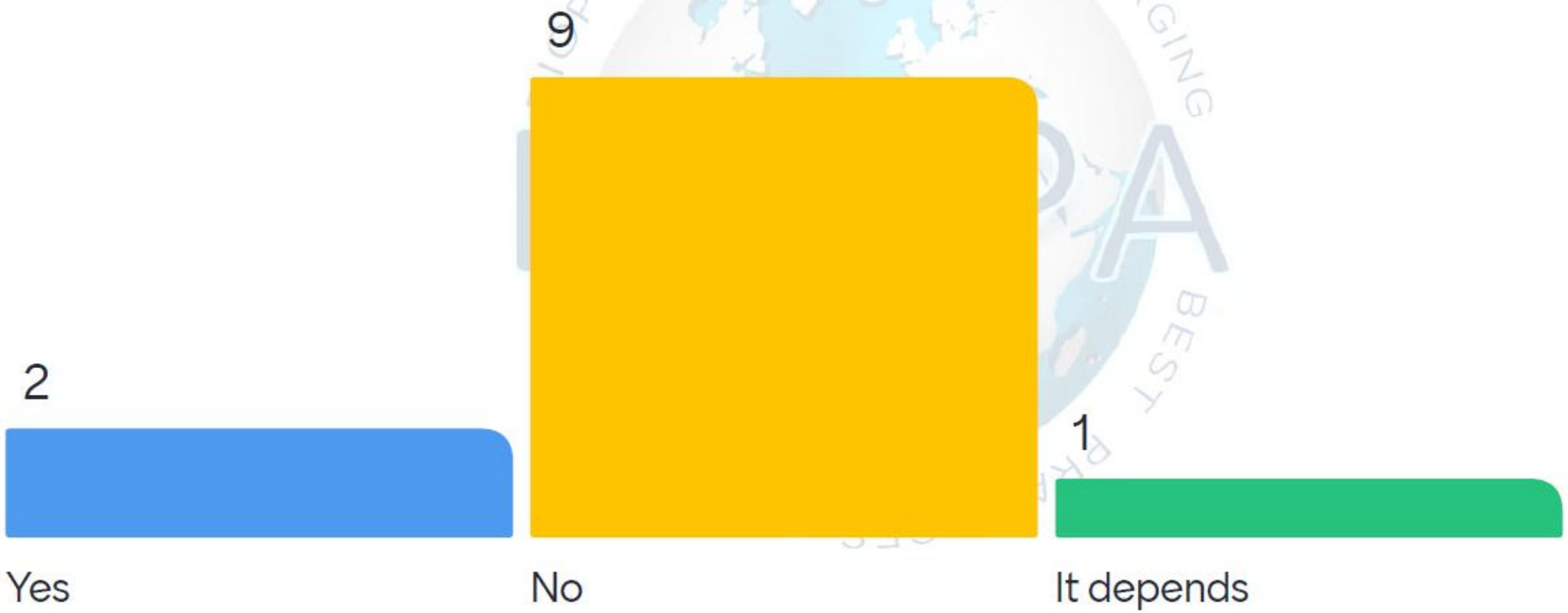
Education Session 3 Audience Surveys

Are You Confident? Or Is It An Outlier?

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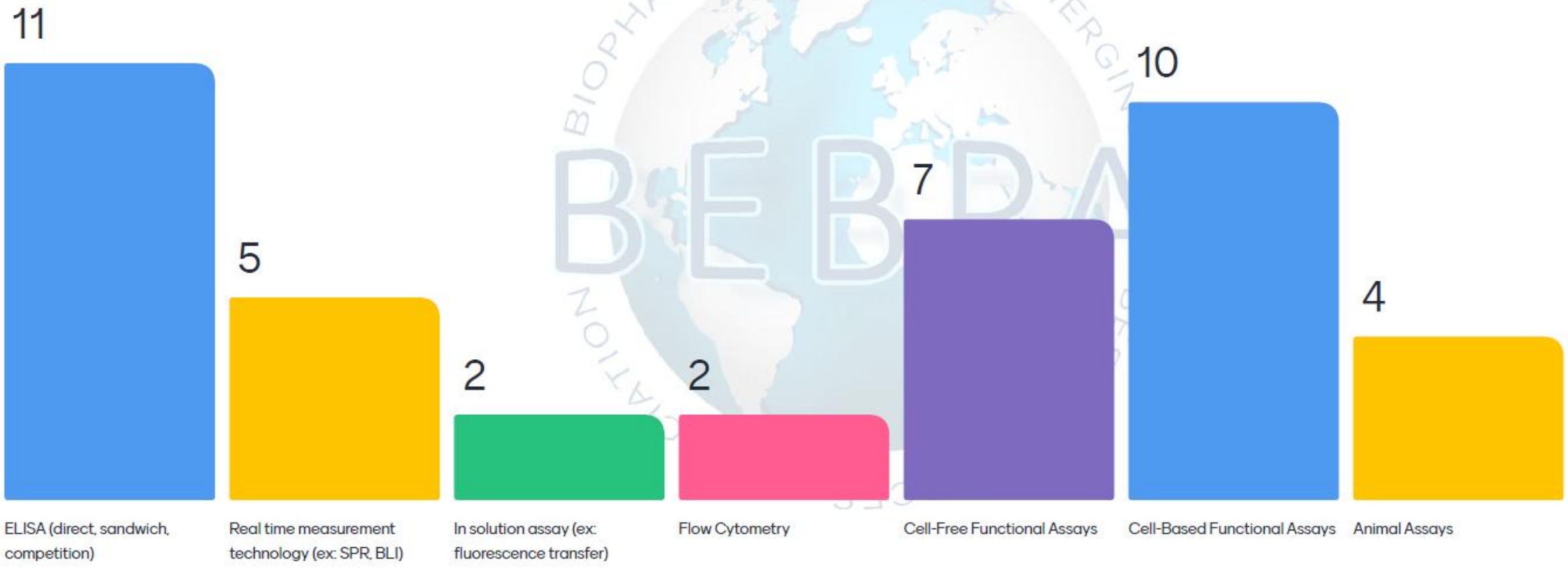
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ES3.1 Potency is estimated at 100% with a 95% CI of 95-105%. Does this mean there is a 95% chance the true potency lies between 95% and 105%?

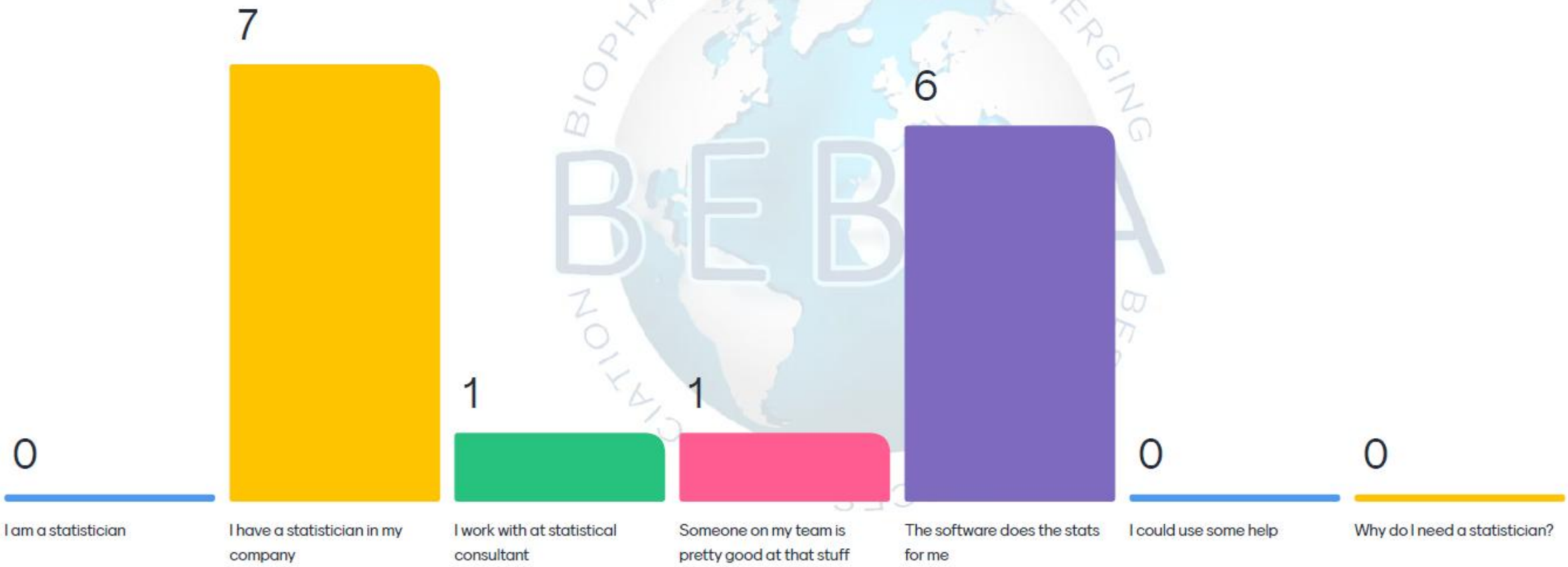


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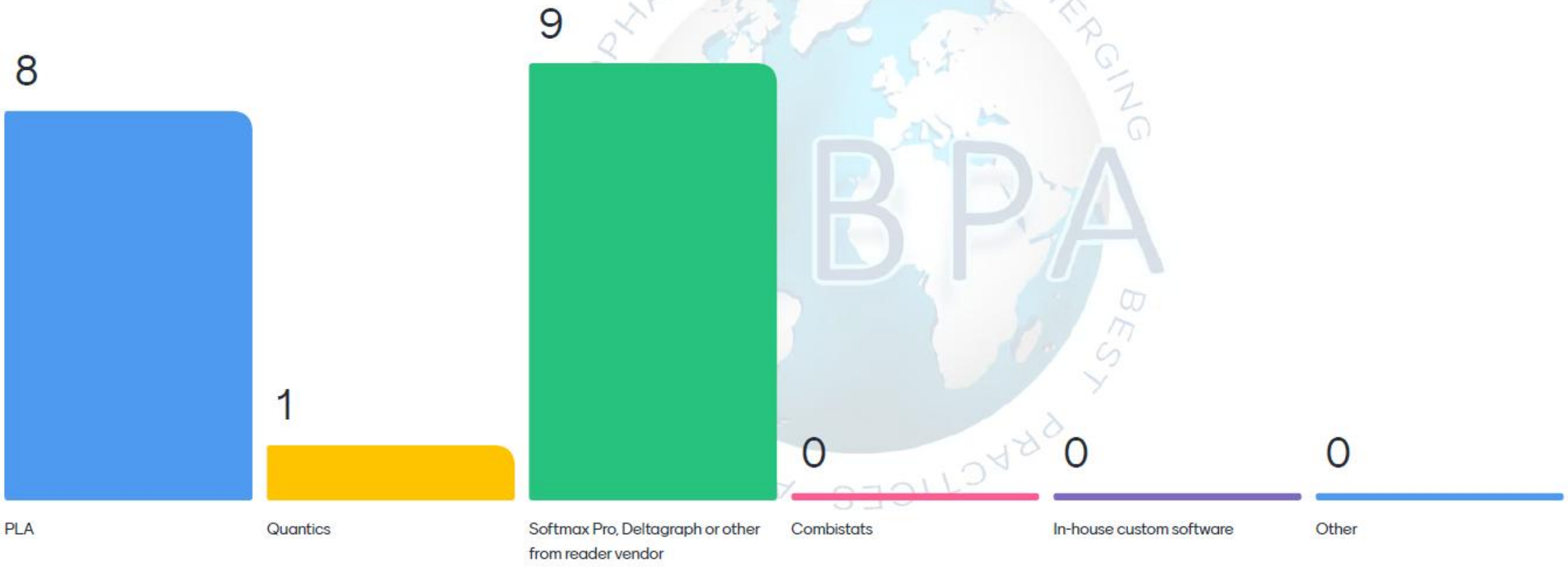
ES3.2 What type of assays do you develop? (Check all that apply)



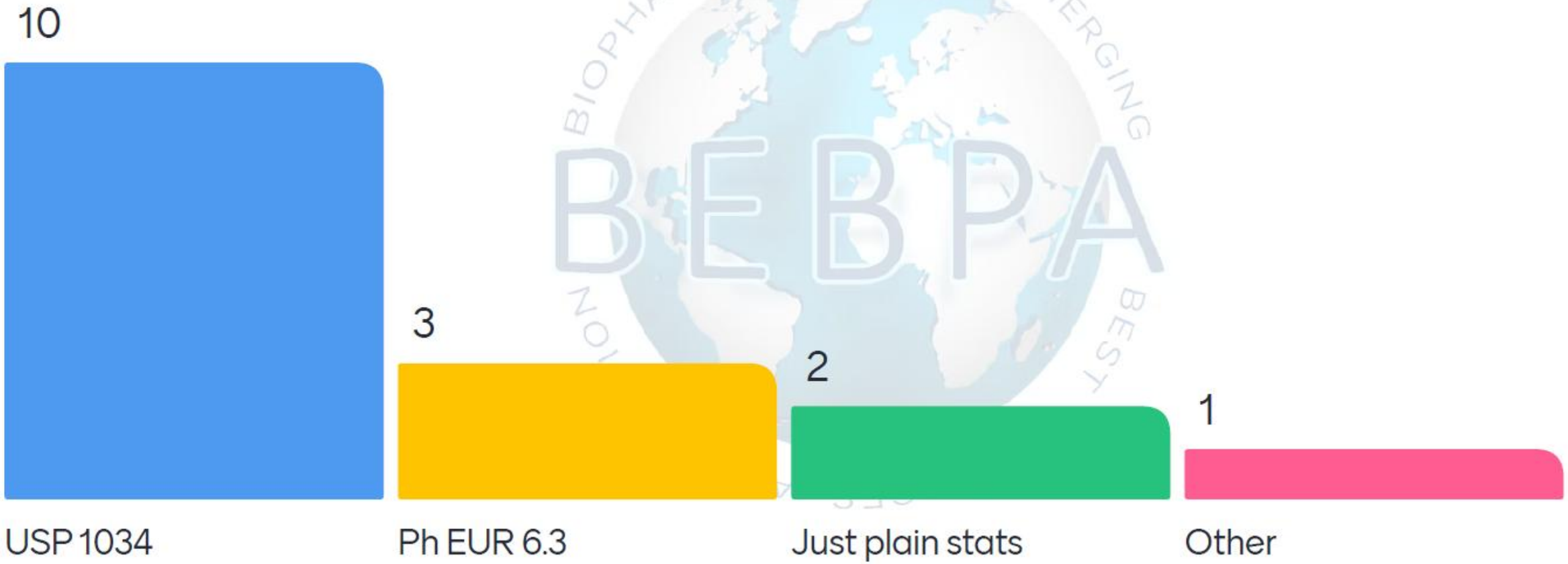
ES3.3 What kind of statistical support do you have?



ES3.4 What software do you use for assay analysis?

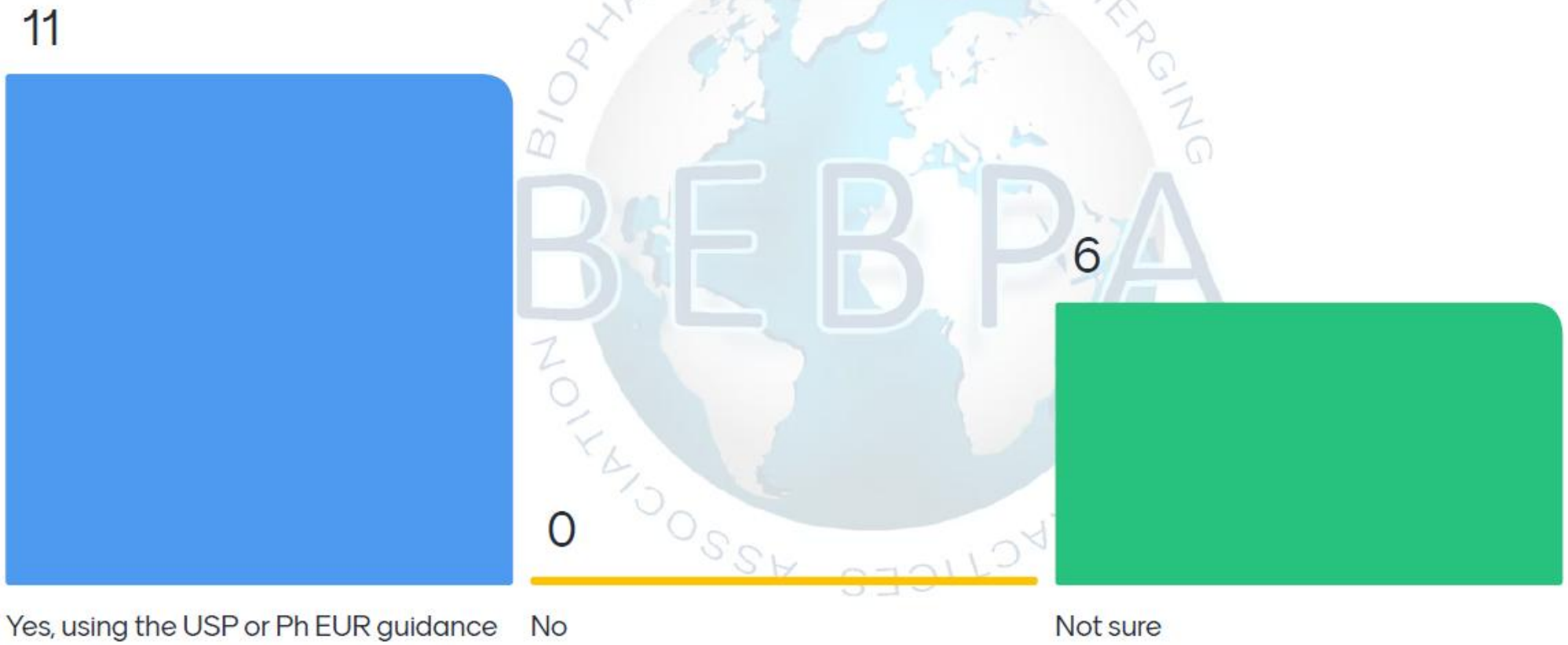


ES3.5 Which guidance do you use for combining results of multiple assays?

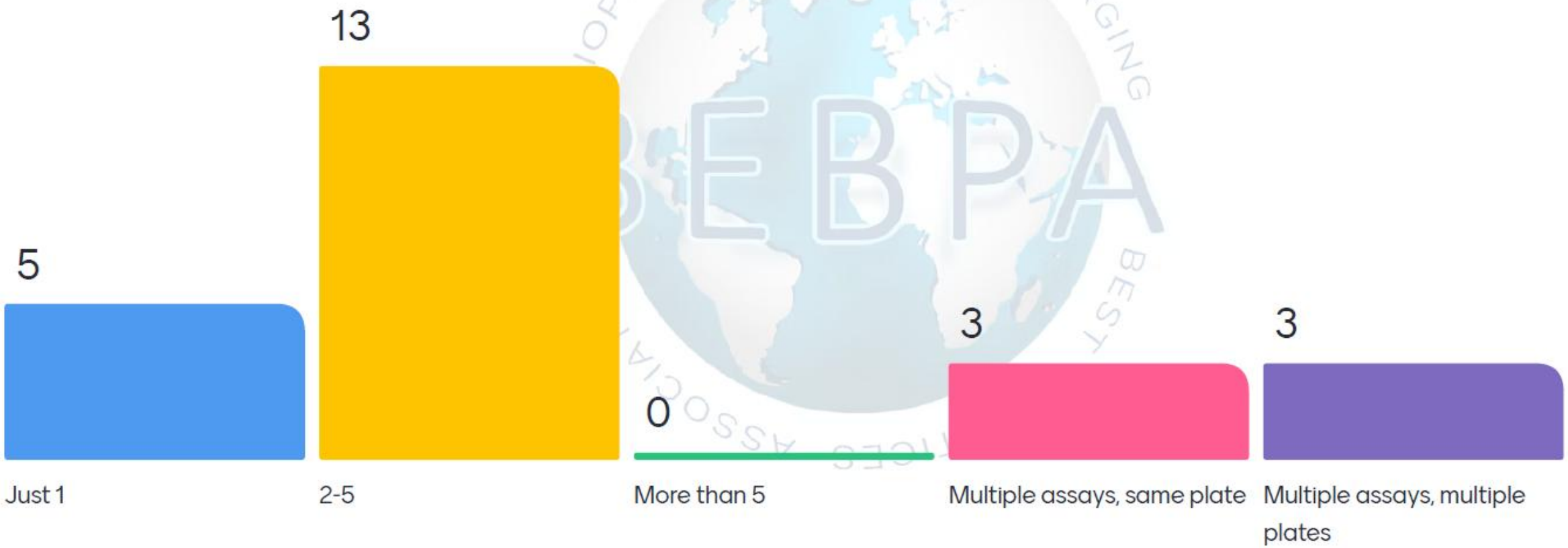


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ES3.6 Does your software support combining results of multiple assays?



ES3.7 How many assays do you use to produce a reportable value? Same plate or multiple plates?



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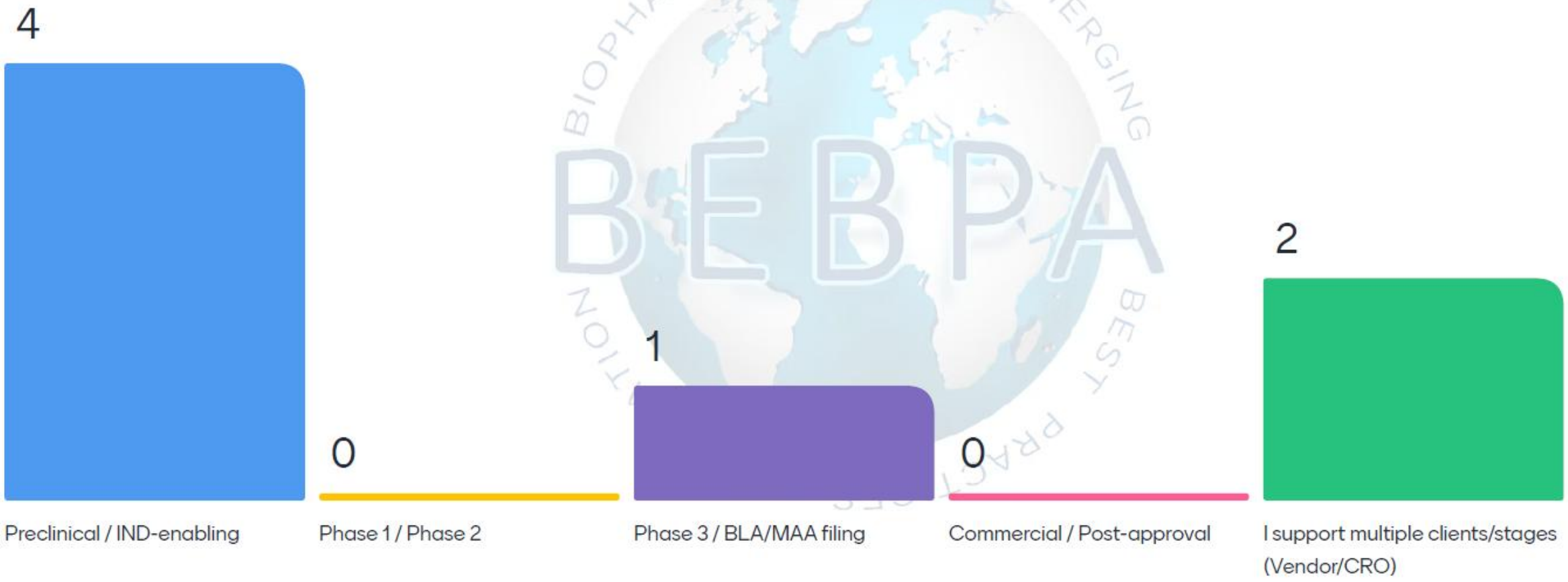
Education Session 4 Audience Surveys

Potency Assays for Advanced Therapeutic Medicinal Proteins (ATMP's)

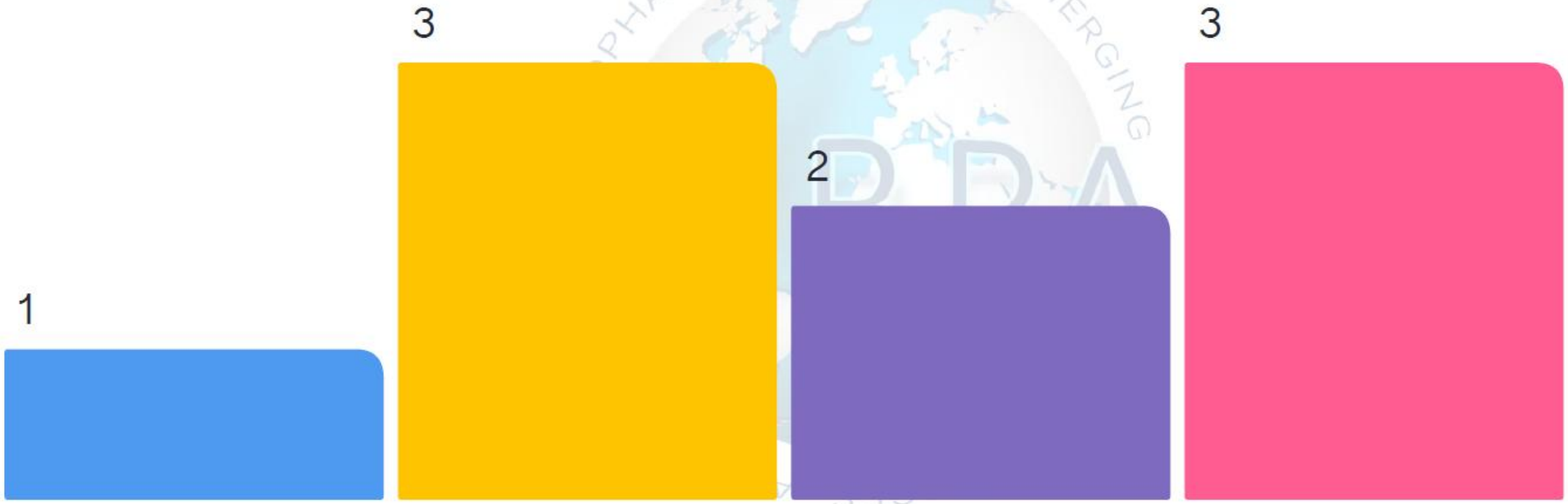
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ES4.1 What stage of development is your primary ATMP candidate currently in?



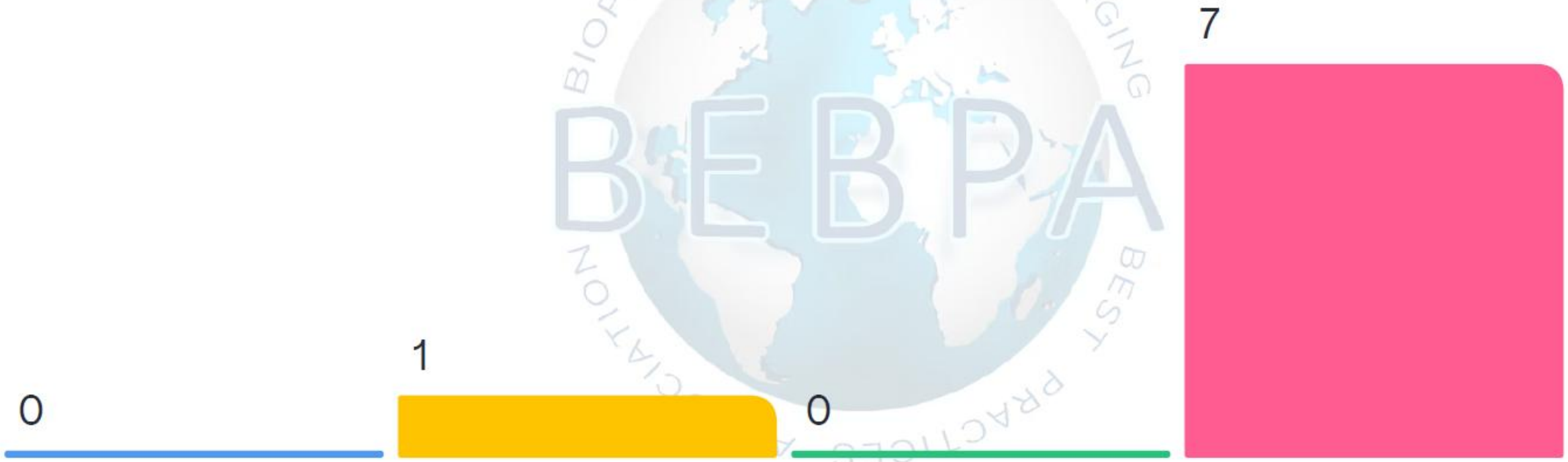
ES4.2 What is your primary ATMP product modality?



ES4.3 How are you approaching your potency assay design to satisfy global regulators?

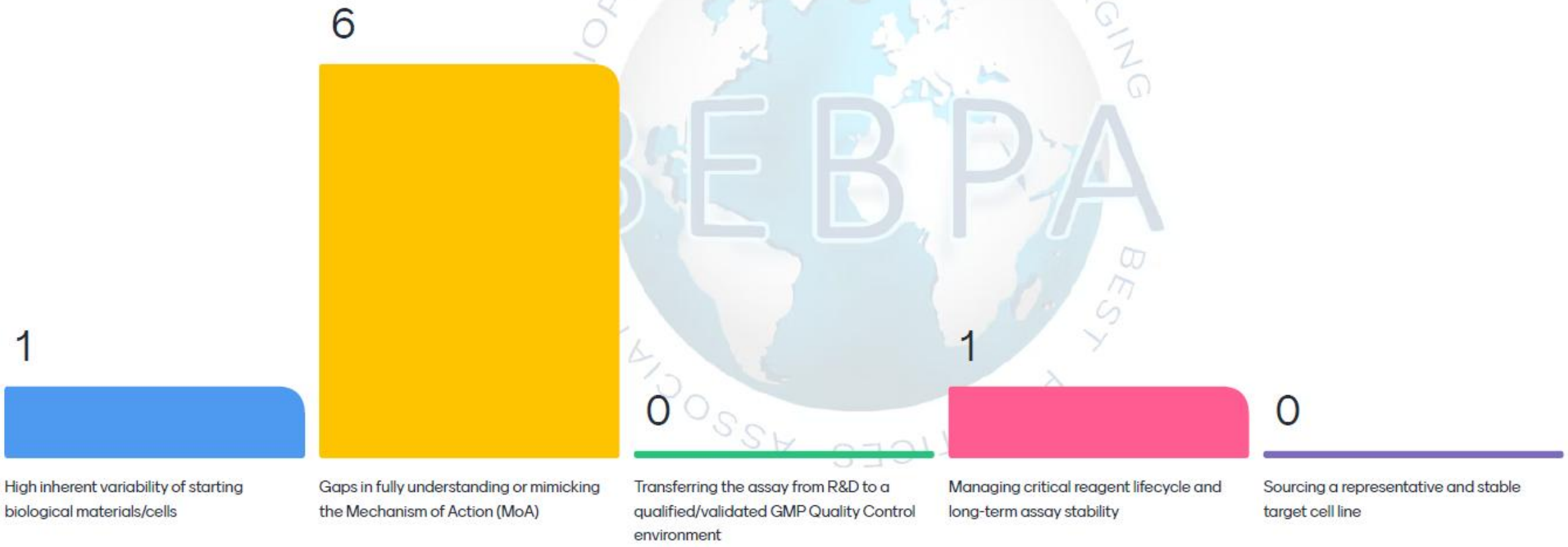


ES4.4 For AAV-based therapies, what is your team's stance on the traditional TCID50 (infectivity) assay for release panels?

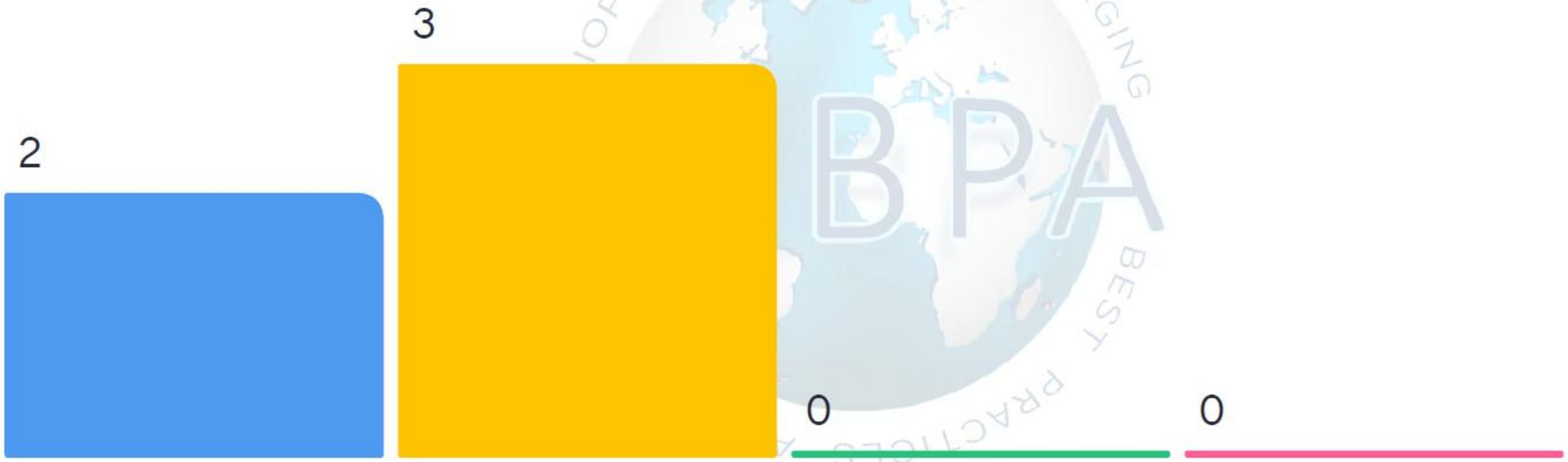


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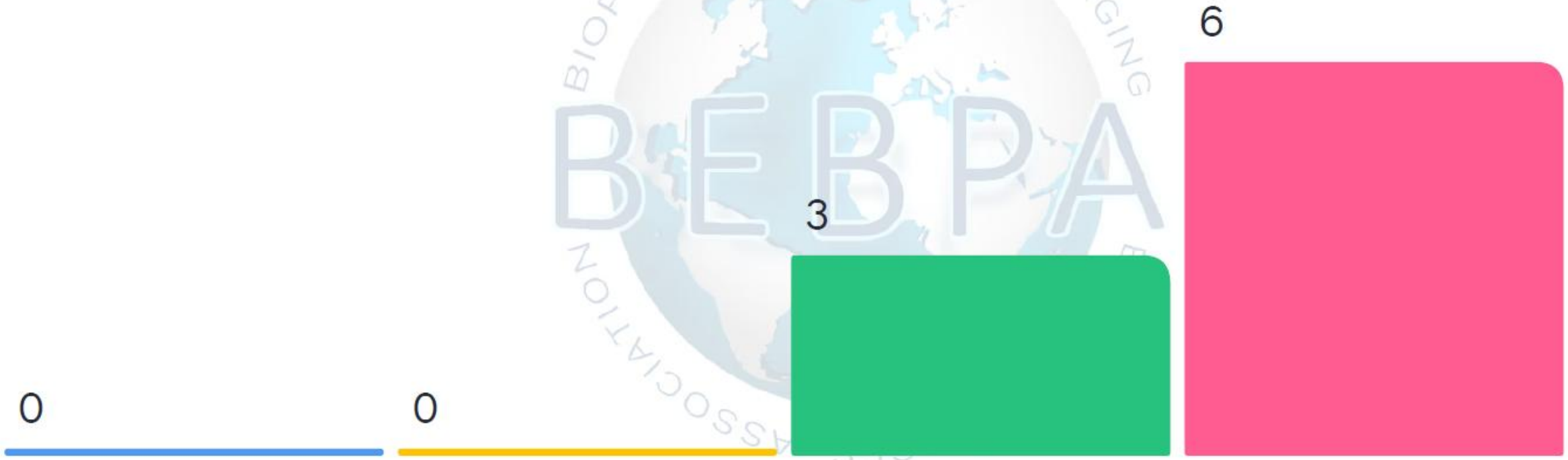
ES4.5 What is the single biggest bottleneck your team faces in ATMP potency assay development?



ES4.6 Have you ever experienced a clinical hold or major regulatory delay specifically due to potency assay deficiencies?



ES4.7 How has the FDA's shift from "Potency Testing" to a broader "Potency Assurance" control strategy impacted your pipeline?



Thank You!!