BEBPA 2020 EUR Bioassay Conference

21-24 September 2020

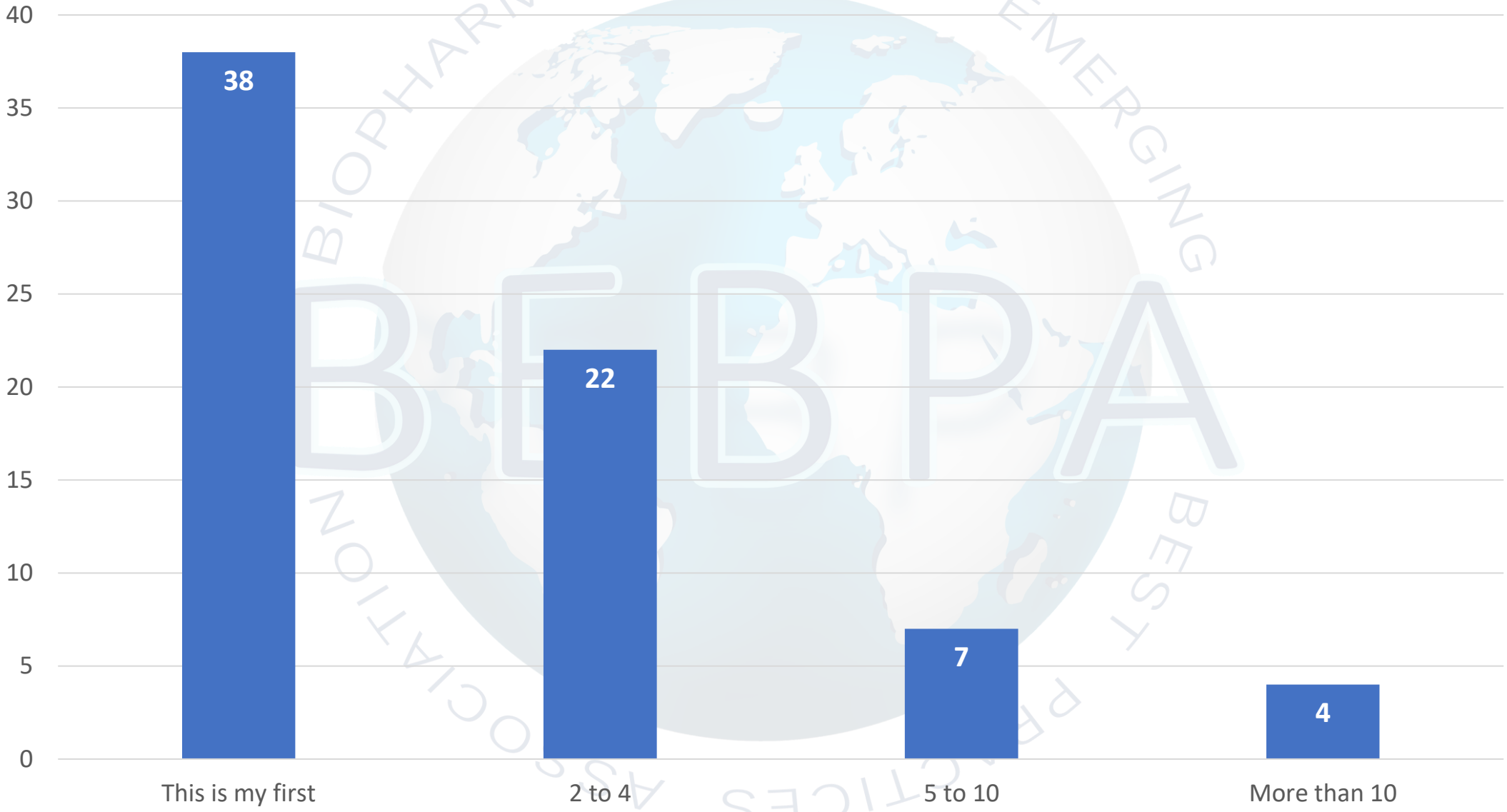
*Our 2nd **VIRTUAL** Conference!*

Audience Survey

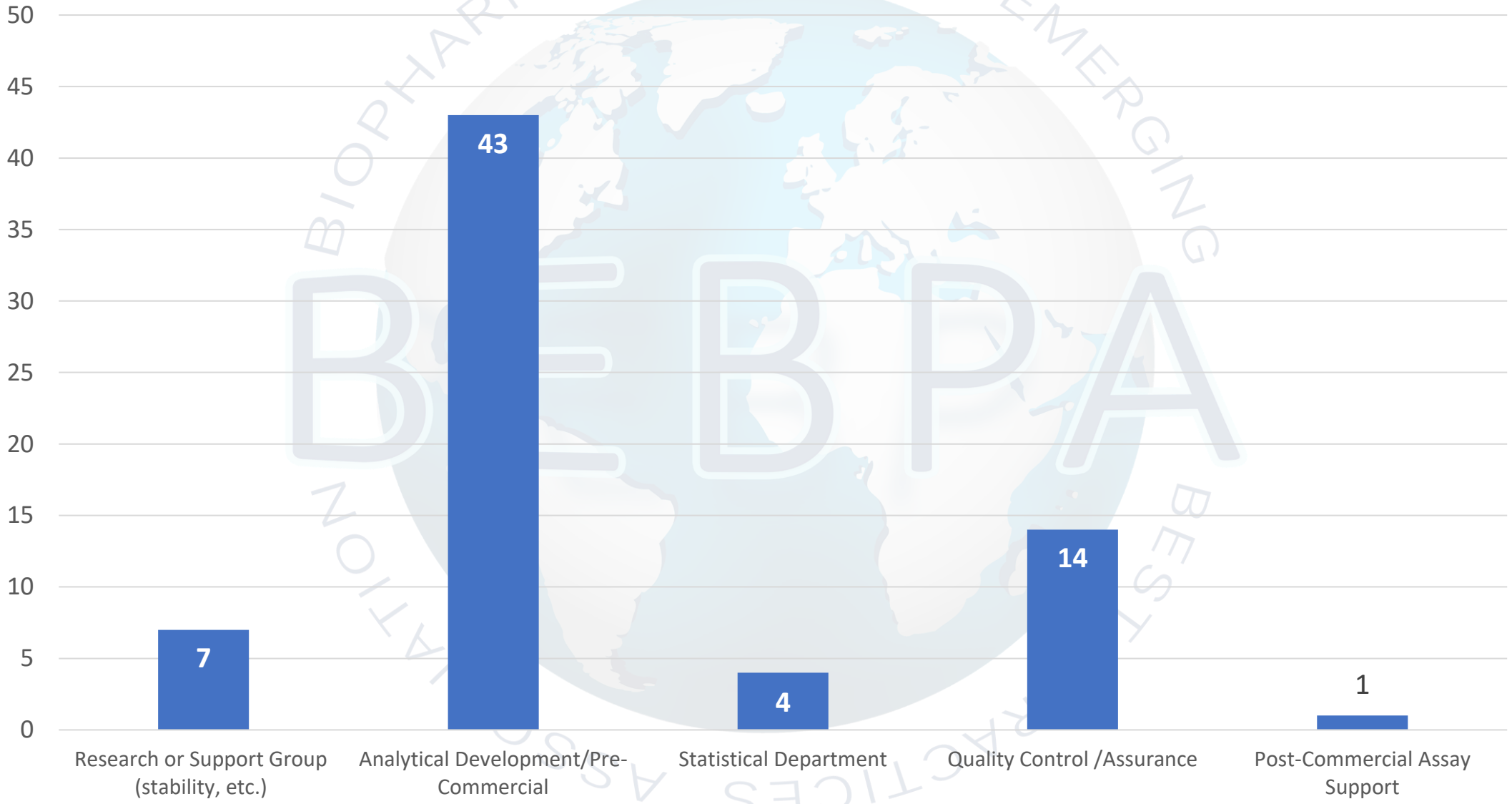
Welcome & Introduction

By: Laureen Little

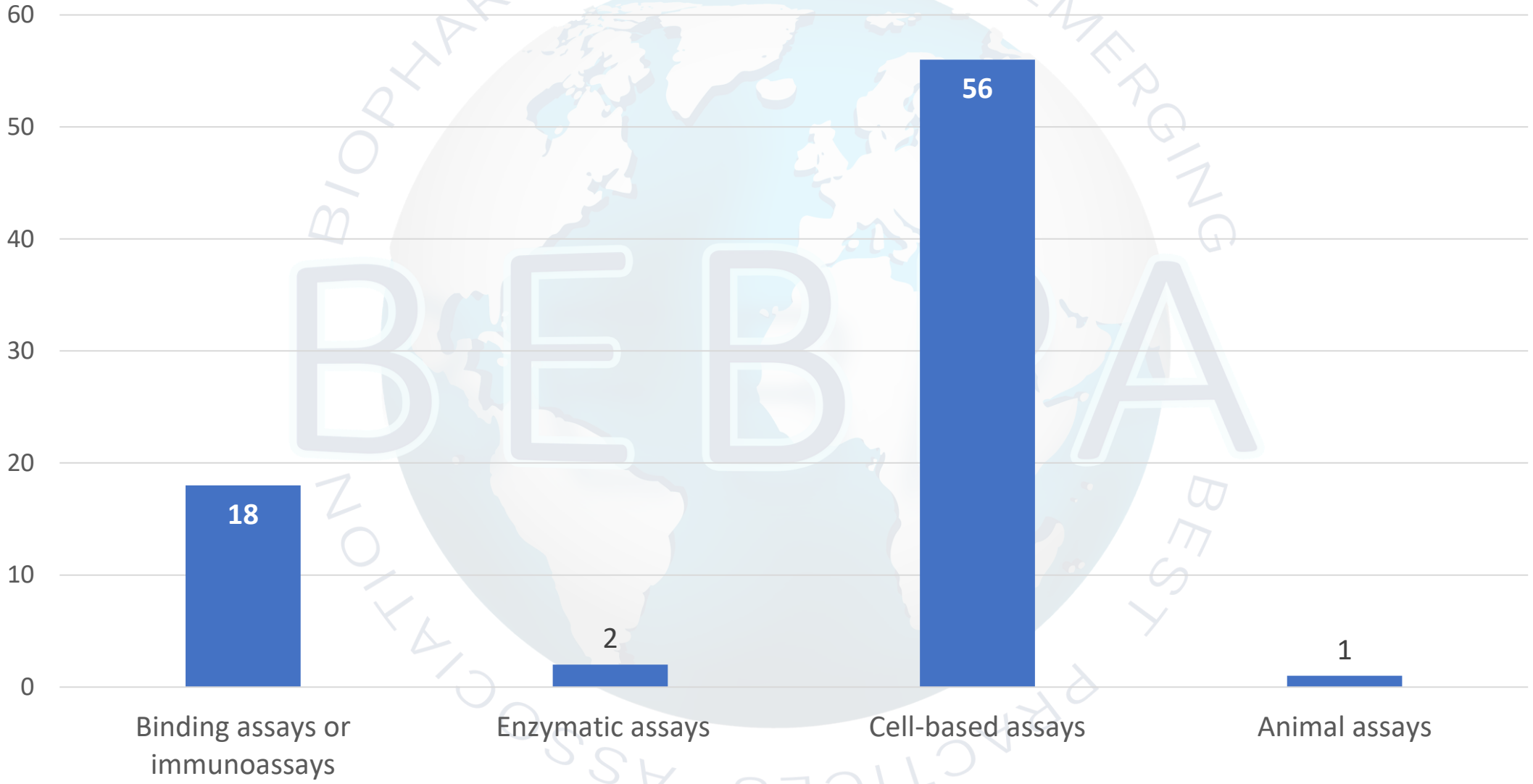
i-1 How many BEBPA Bioassay Conferences have you attended?



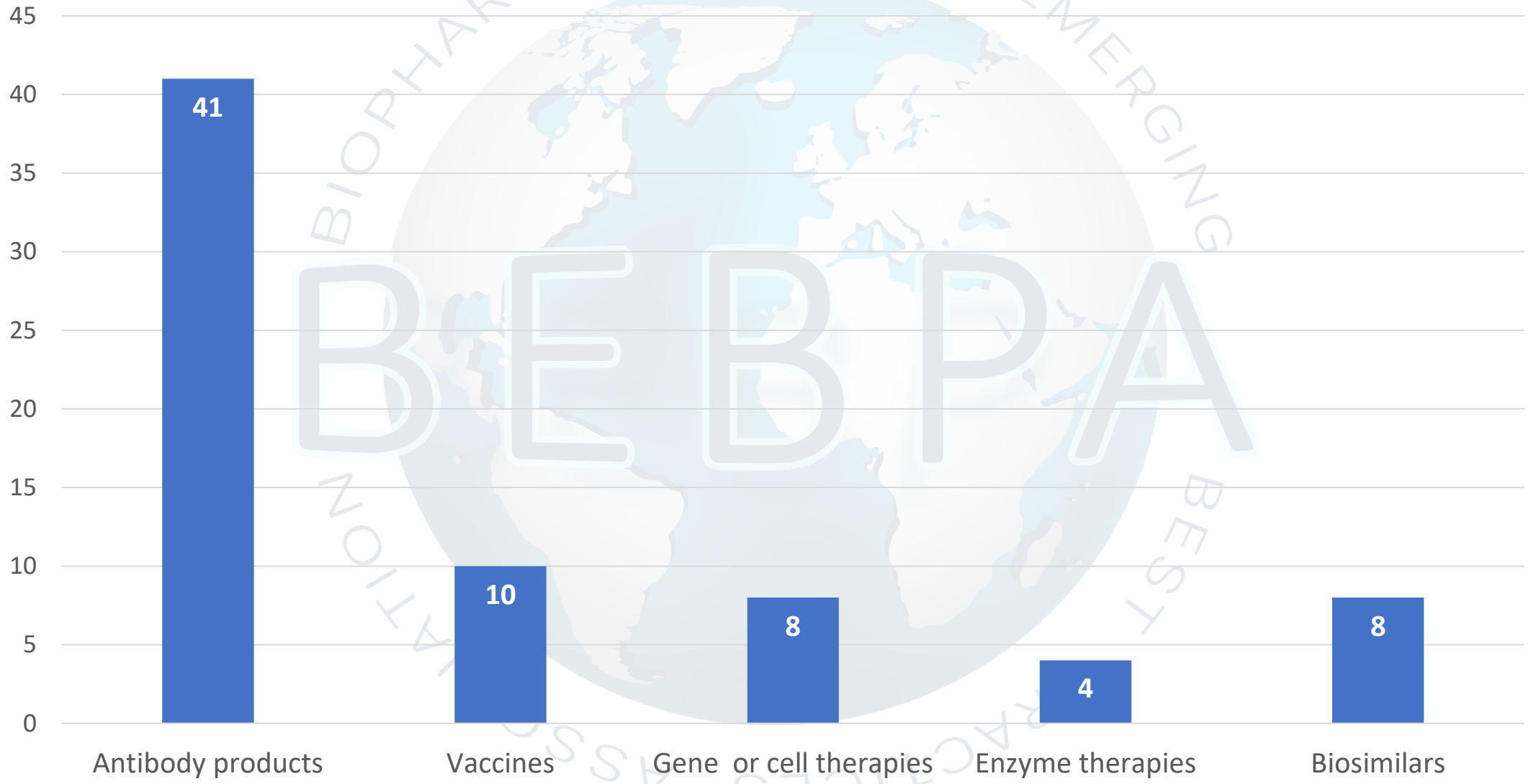
i-2 What part of the organization do you work in?



i.3 What are the main types of potency assays you use?



i.4 What product types do you mostly work on?

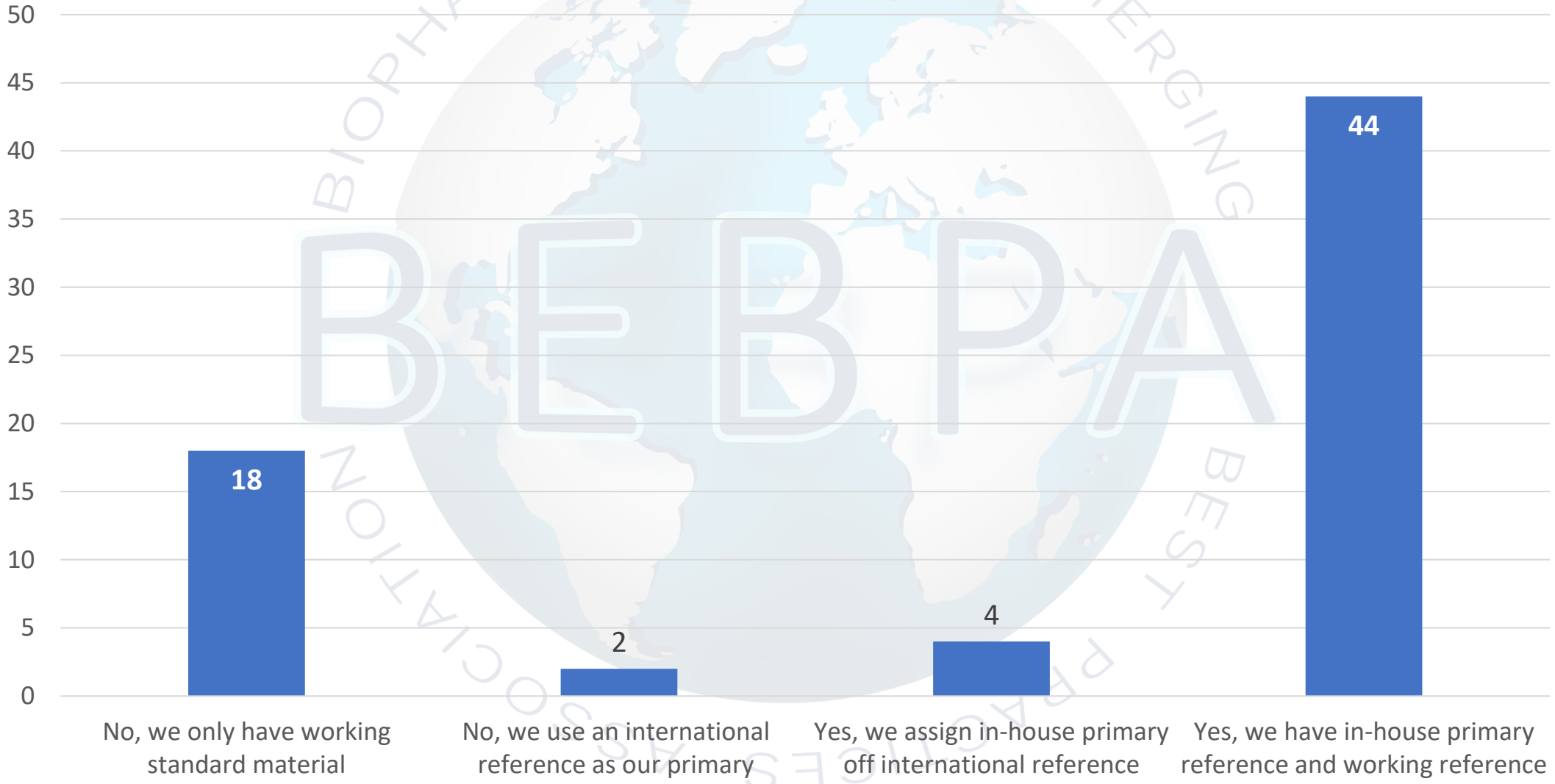


Session 1: Handling Product References and Performing In-Depth Product Characterization

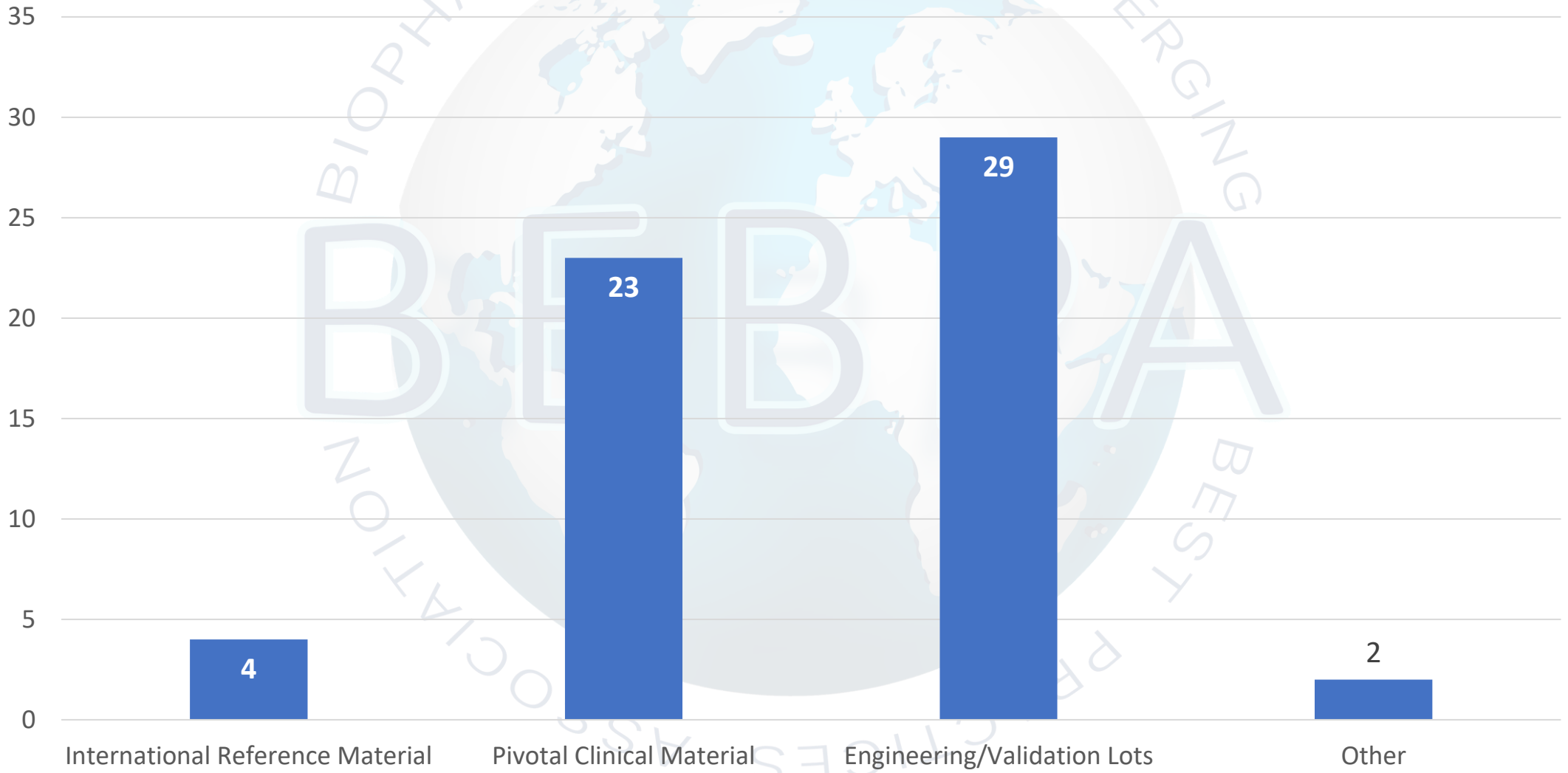
Session Chair: Hans-Joachim Wallny

1.1 Is an international or recognized reference (e.g., USP, NIBSC, WHO) available for your product(s)?

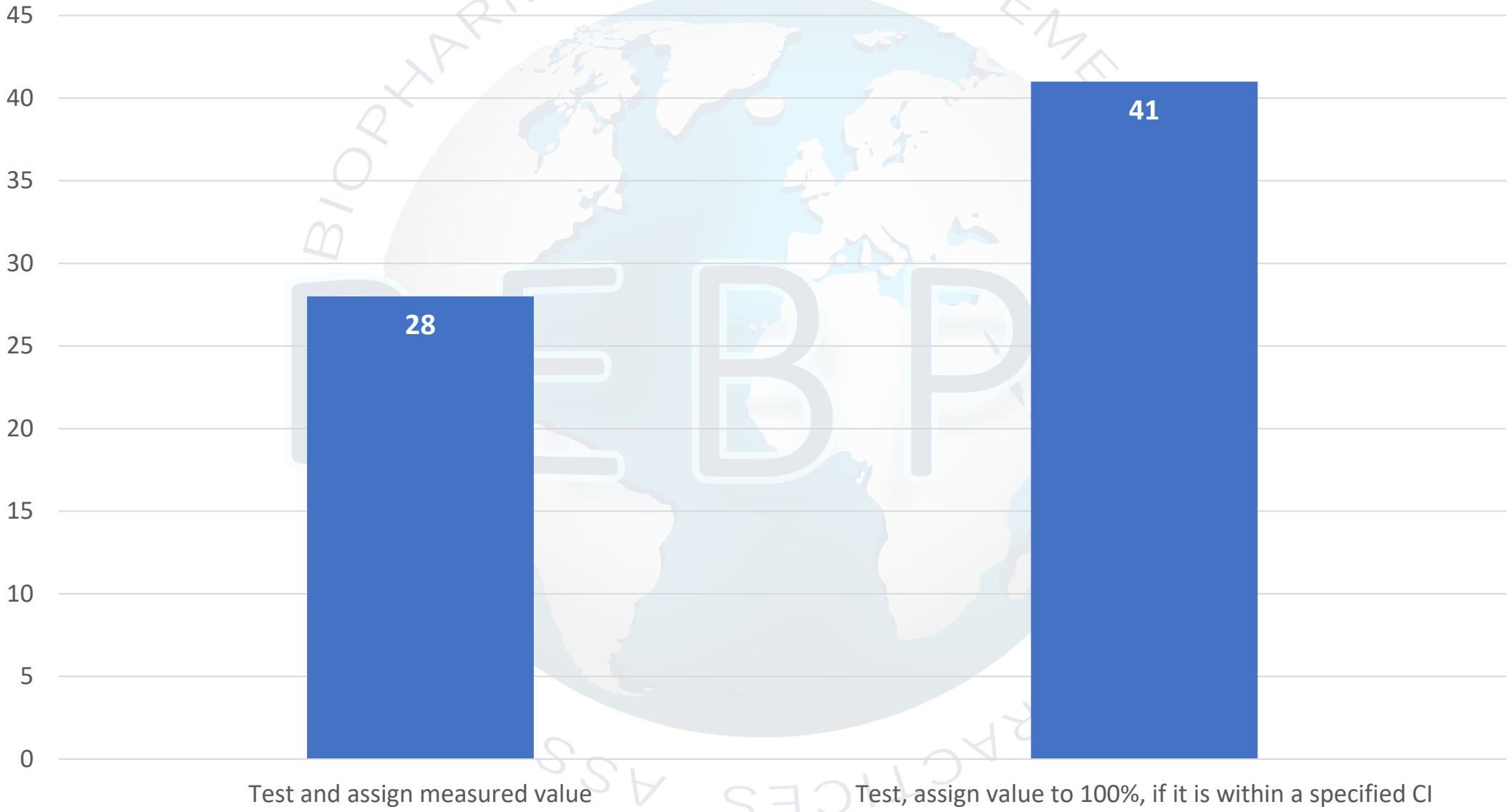
1.2 Do you have a two-tiered reference system (one with primary and secondary reference material)?



1.3 What is the typical source of your primary reference material?



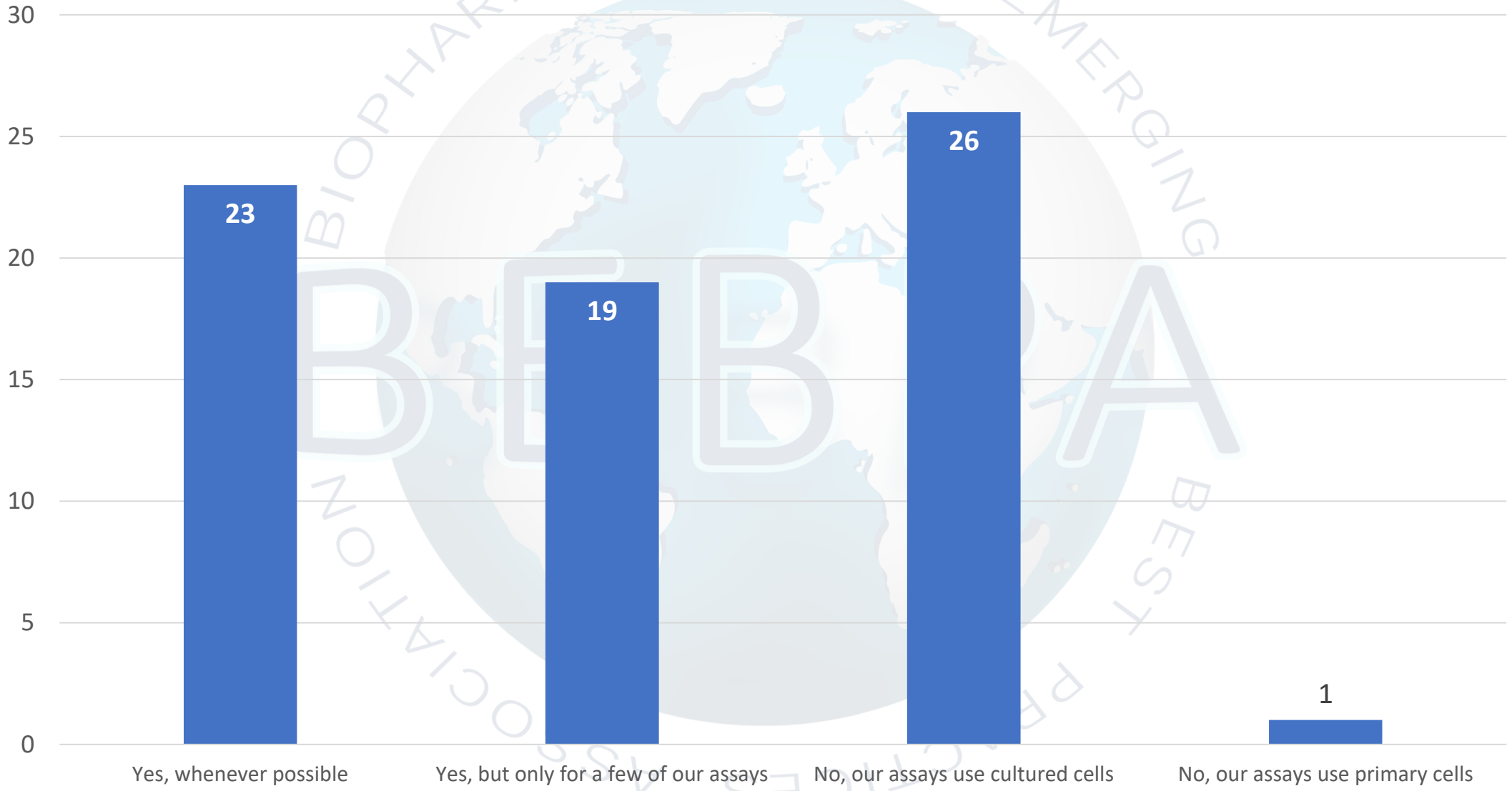
1.4 How do you value assign your working reference?



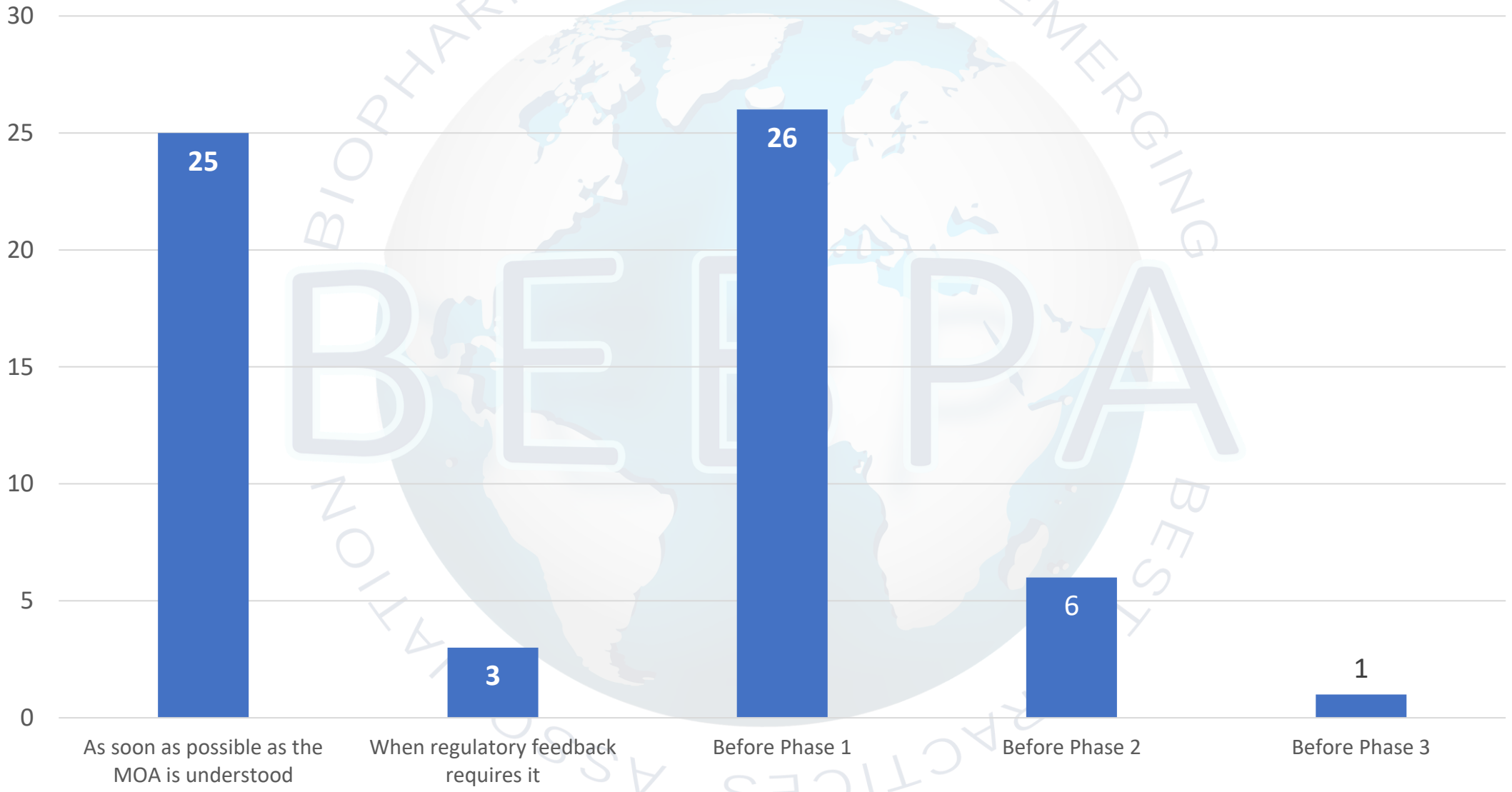
Session 2: Assay Development

Session Chair: Sian Estdale

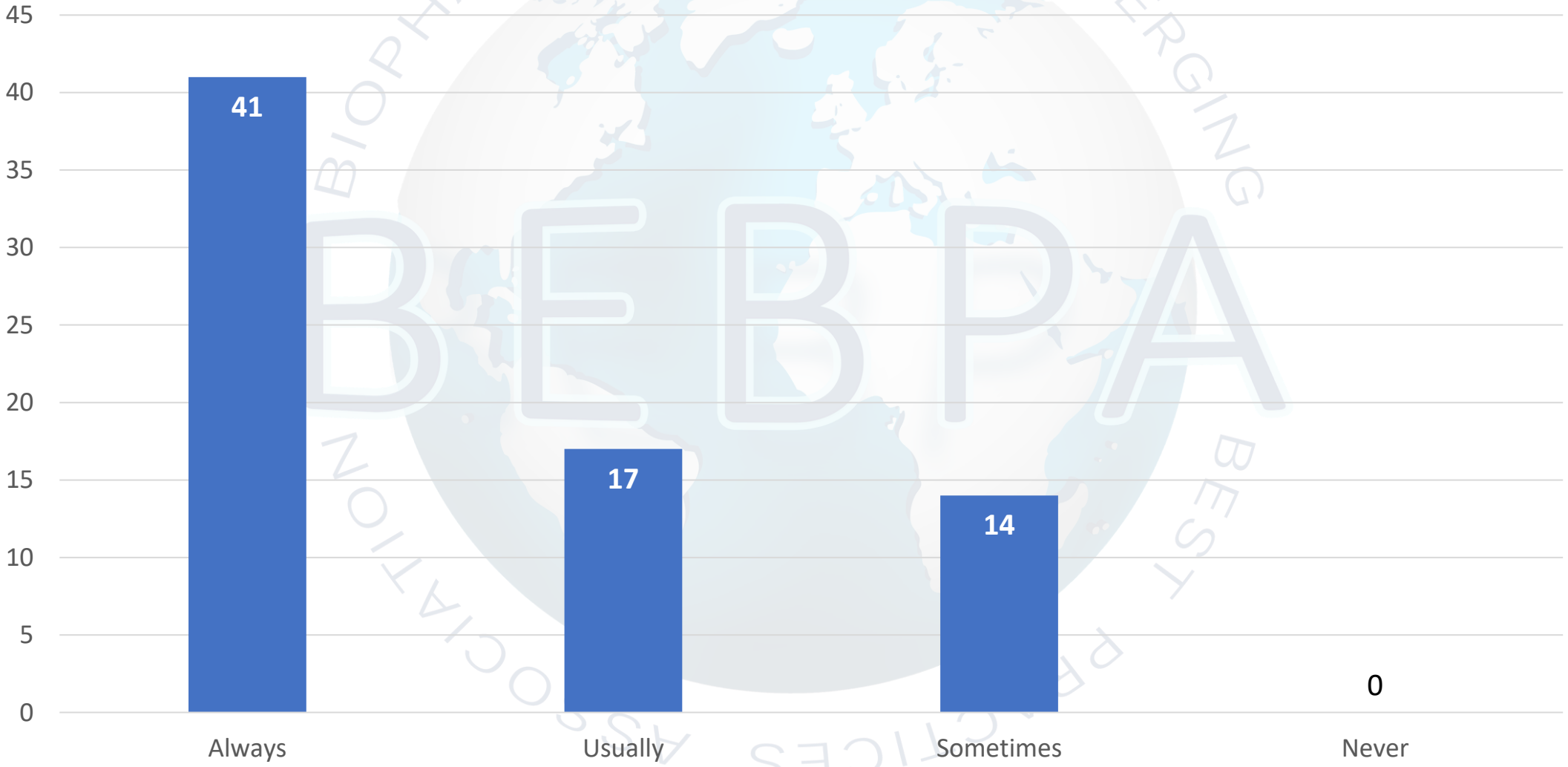
2.1 Do you use frozen-ready-to-use cell banks?



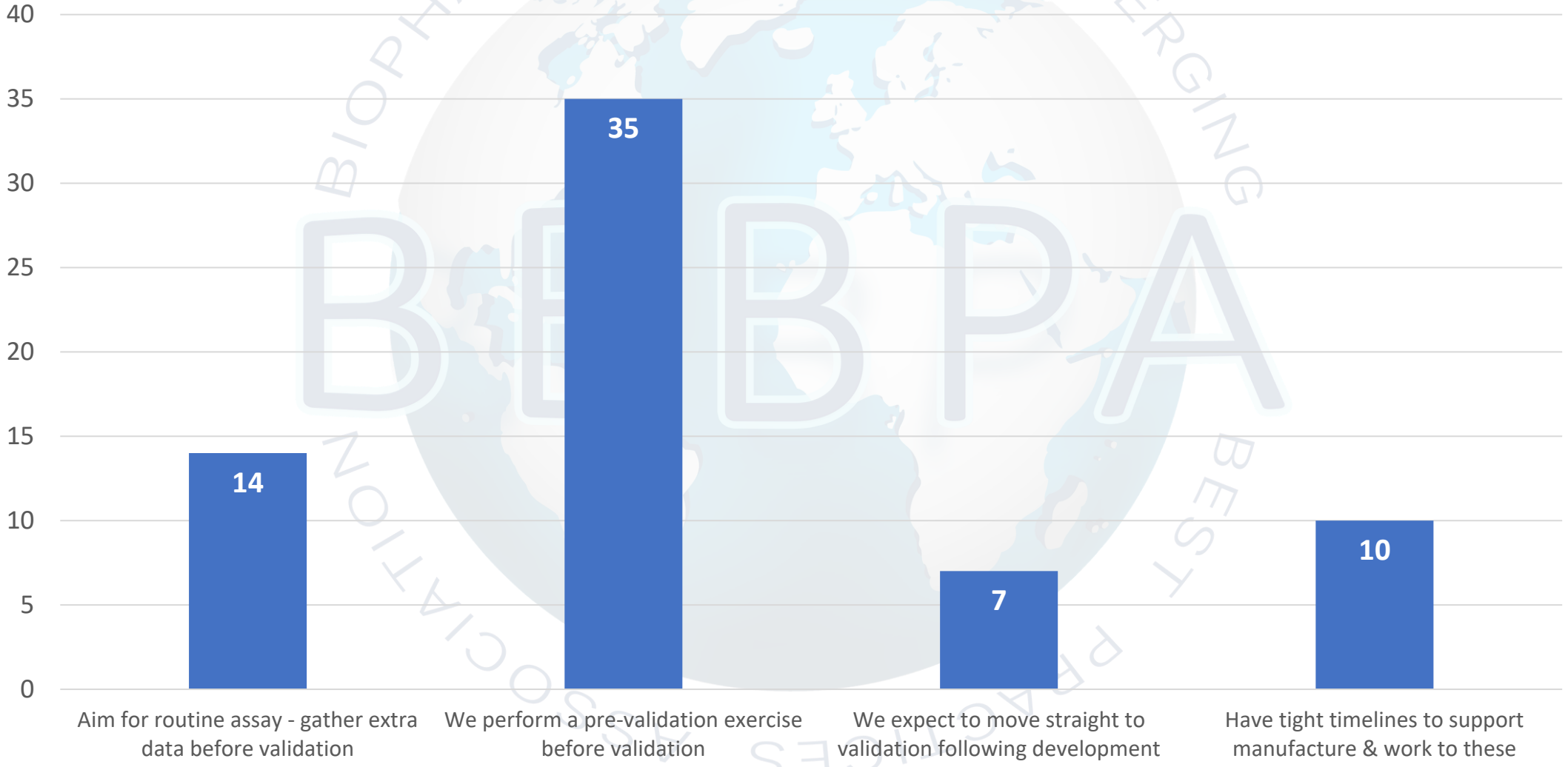
2.2 When do you start assay development?



2.3 Do you include robustness parameters in your development?



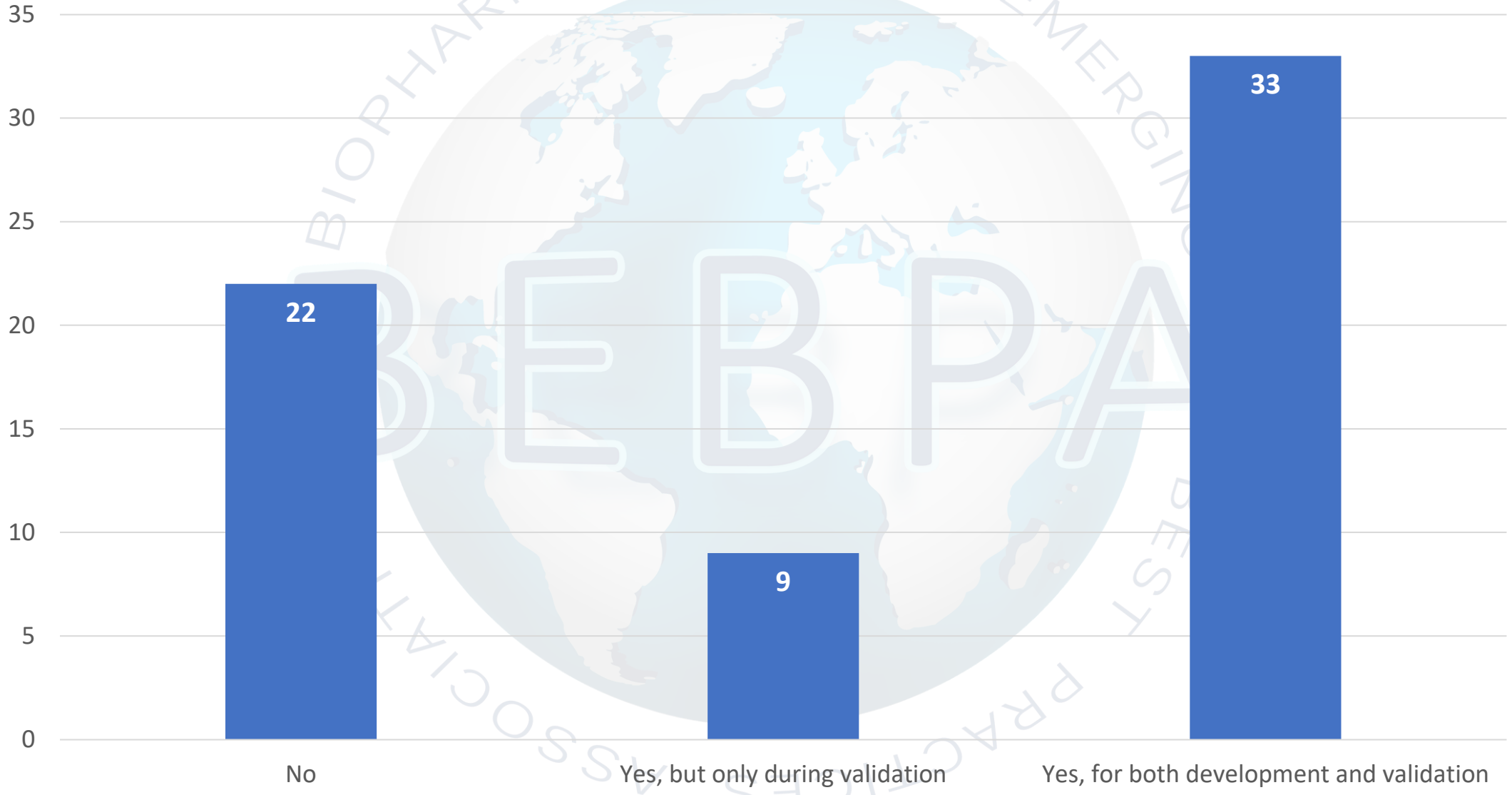
2.4 How quickly do you expect to move from development to validation?



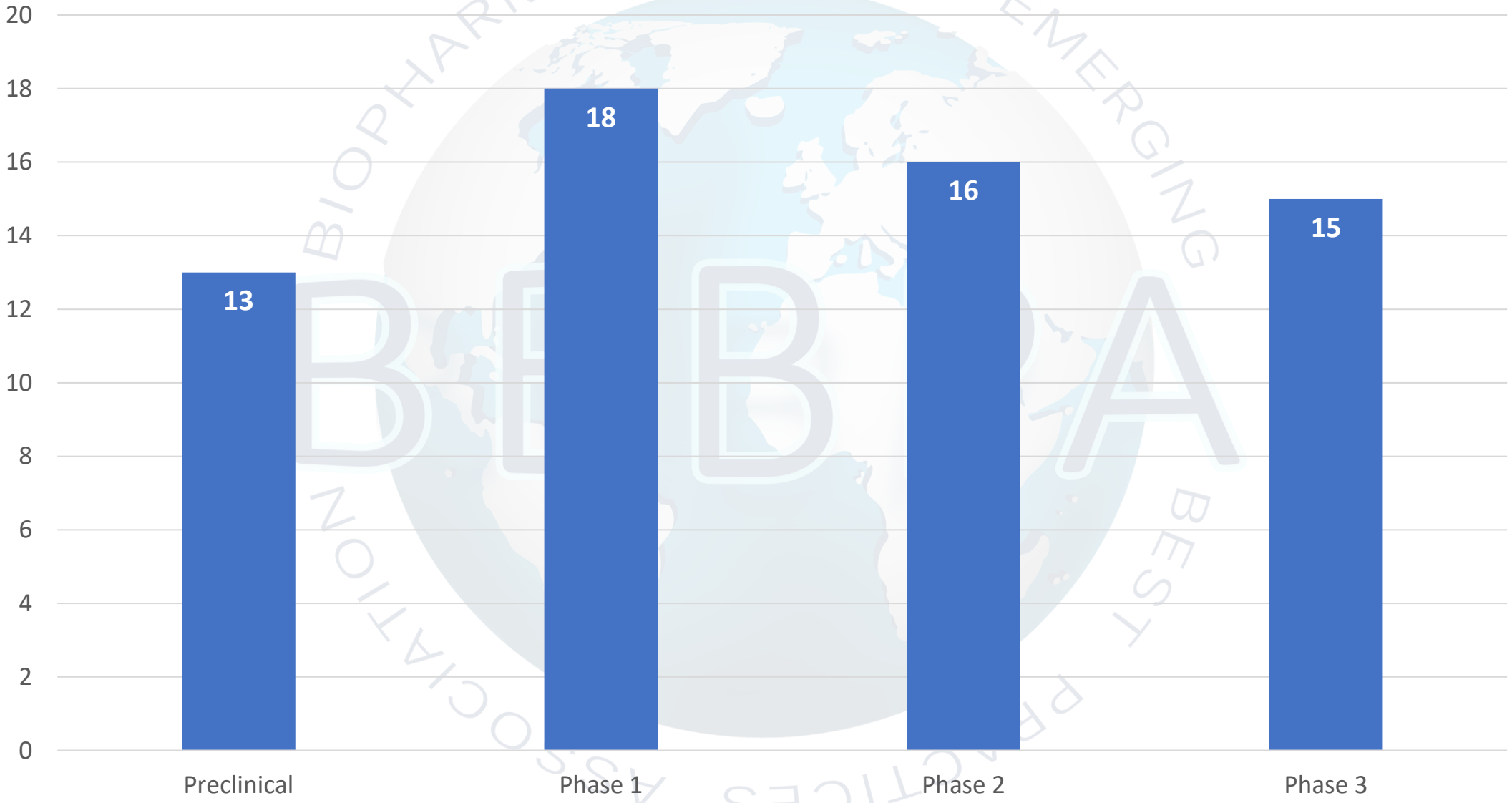
Session 3: Lifecycle: Early Development to Post Commercial

Session Chair: Jane Robinson

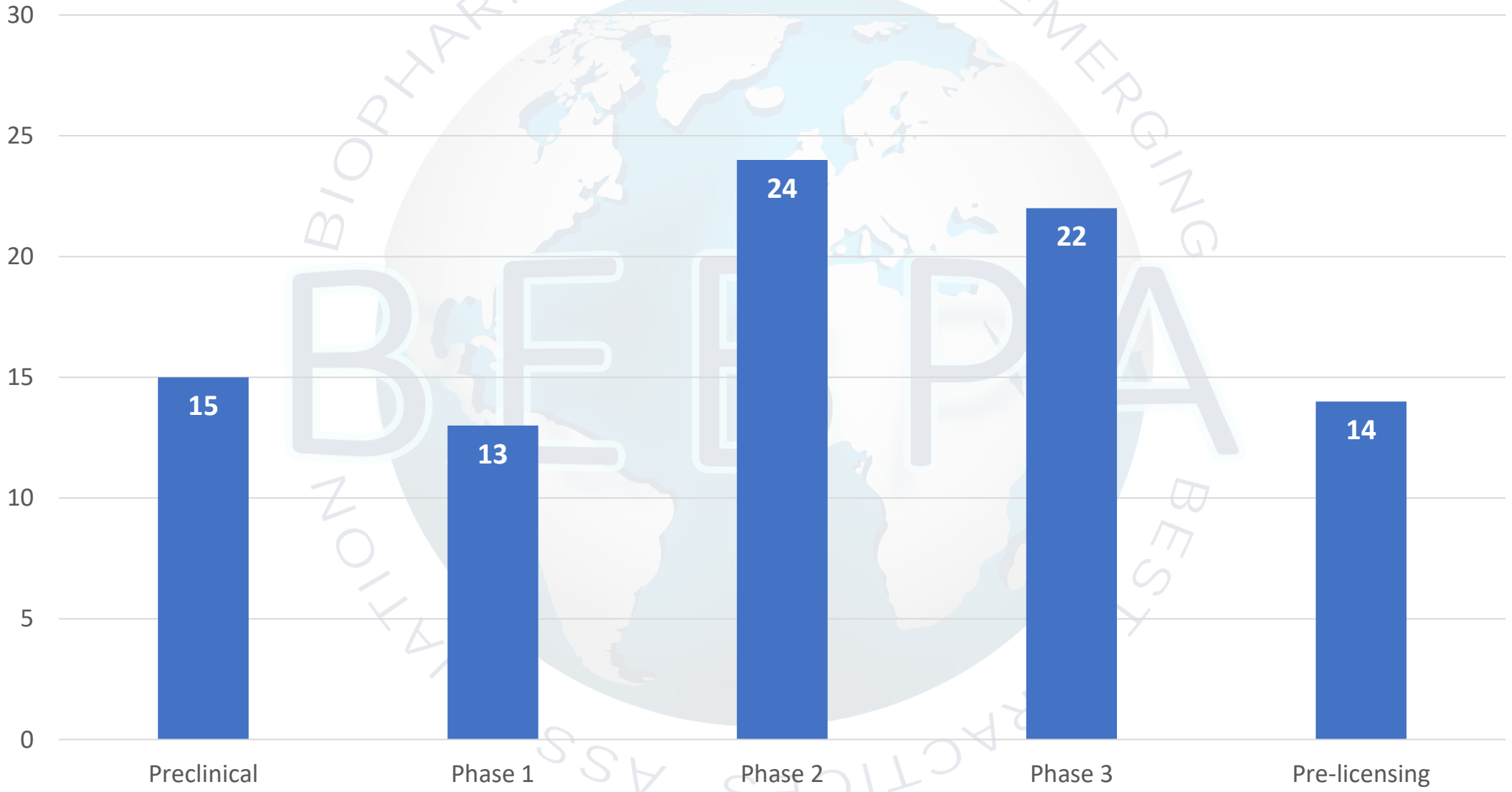
3-1 Do you use DOE for assay development?



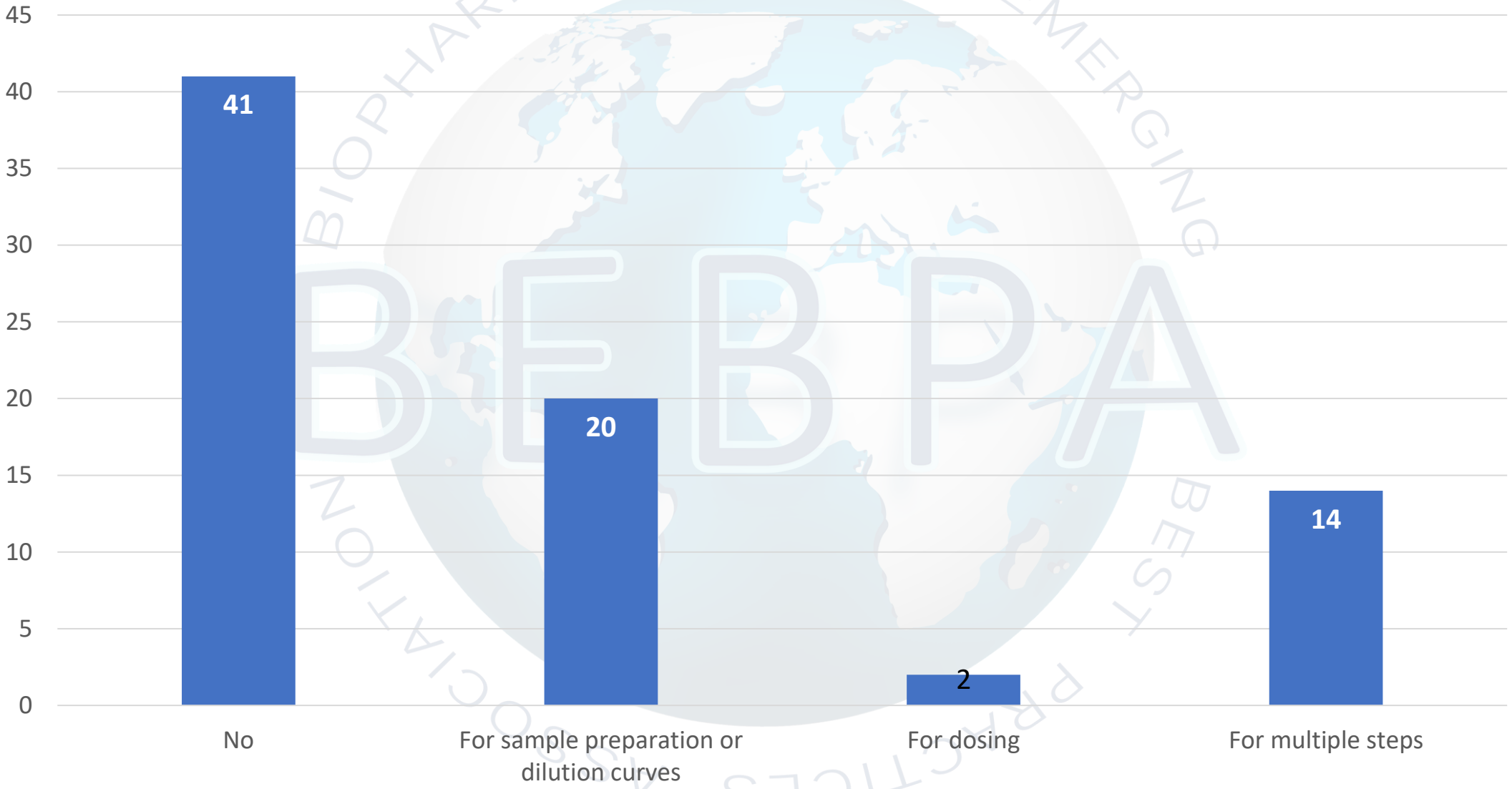
3.2 When do you usually perform validation of your assay?



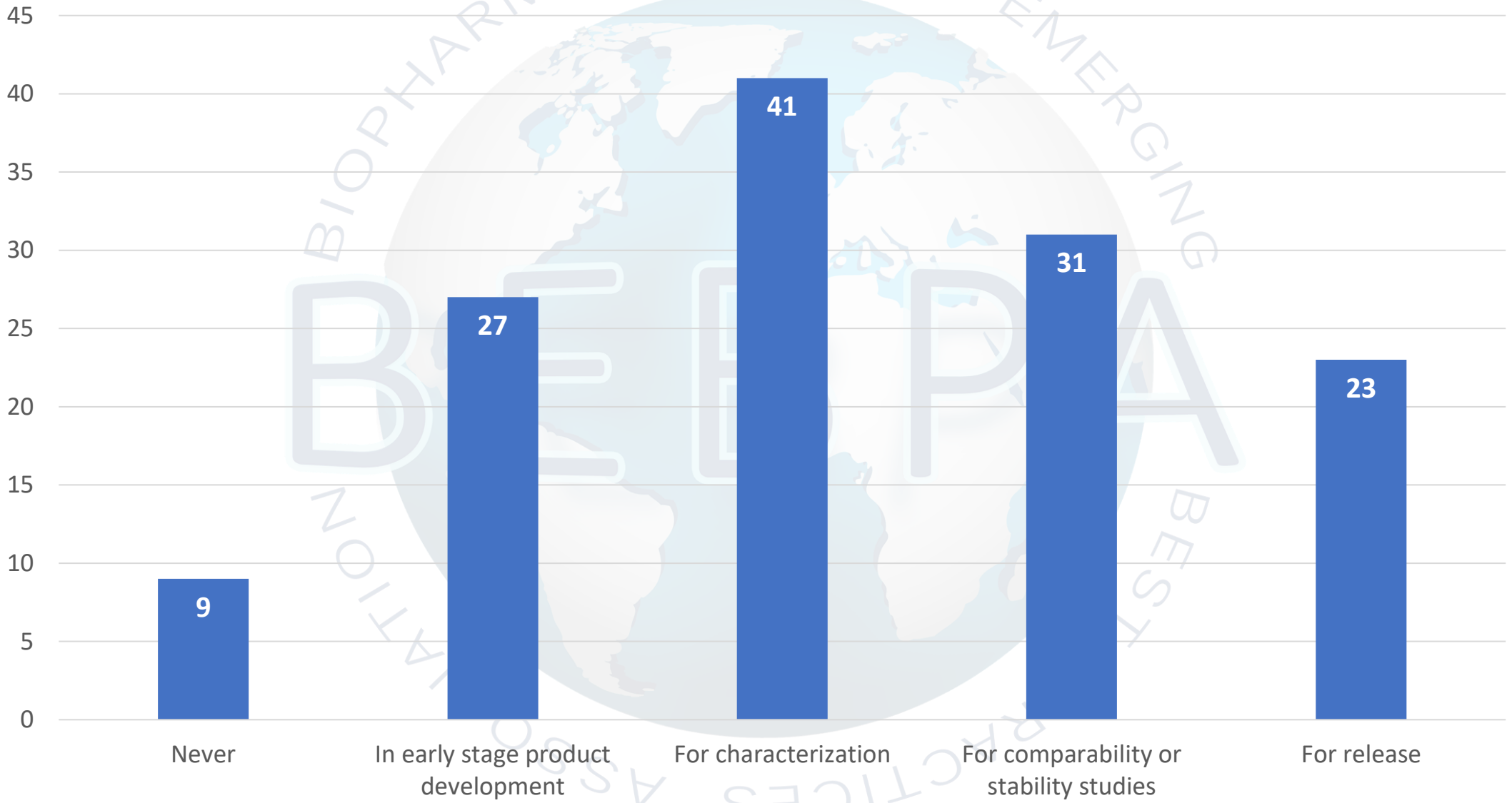
3.3 At what stage have you replaced a potency assay?



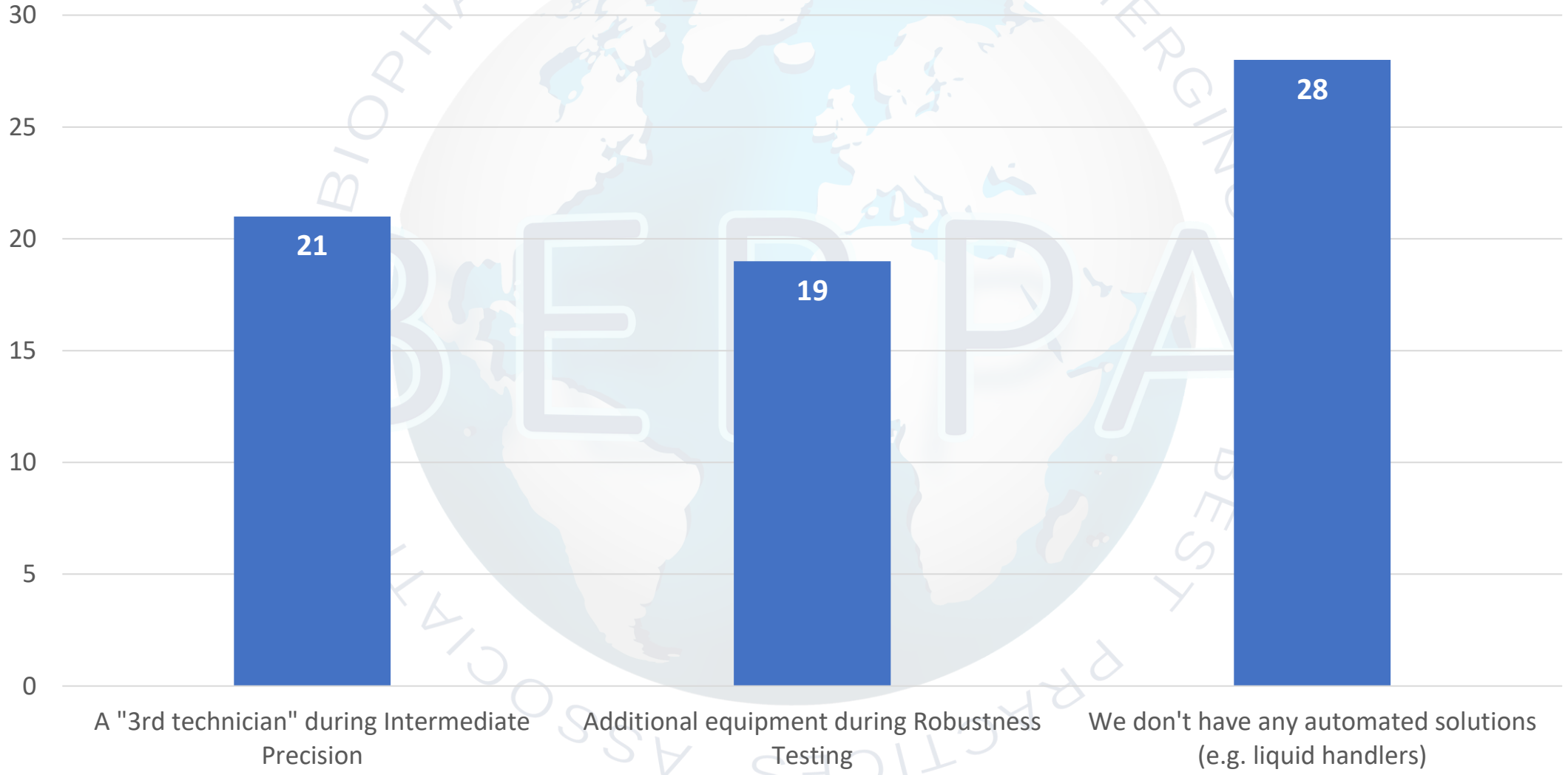
3.4 Have you automated any of your potency assays?



3.5 Do you use multiple potency assays for a single product?



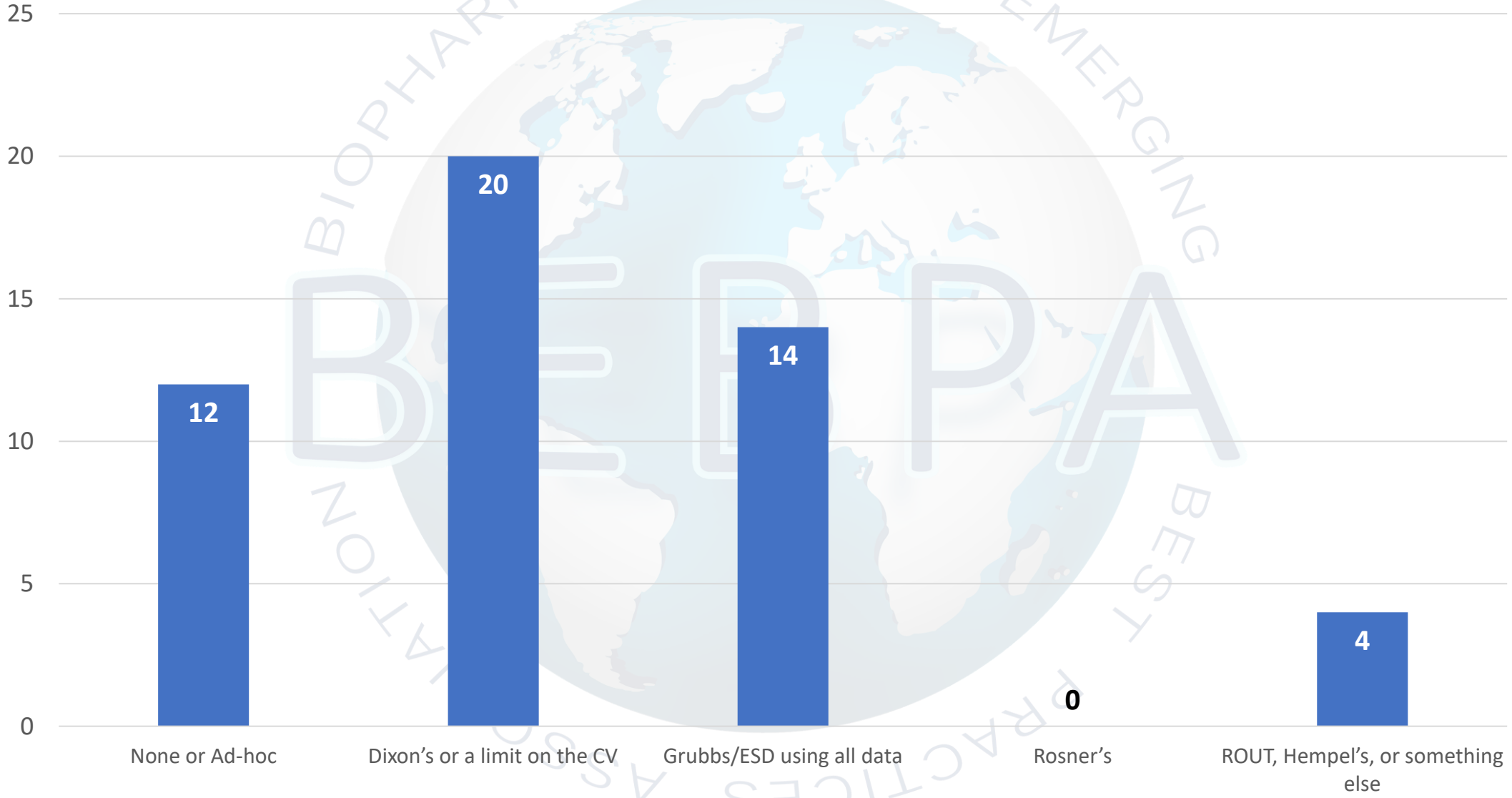
3.6 During assay validation, the automated solution (e.g. liquid handler) should be considered as:



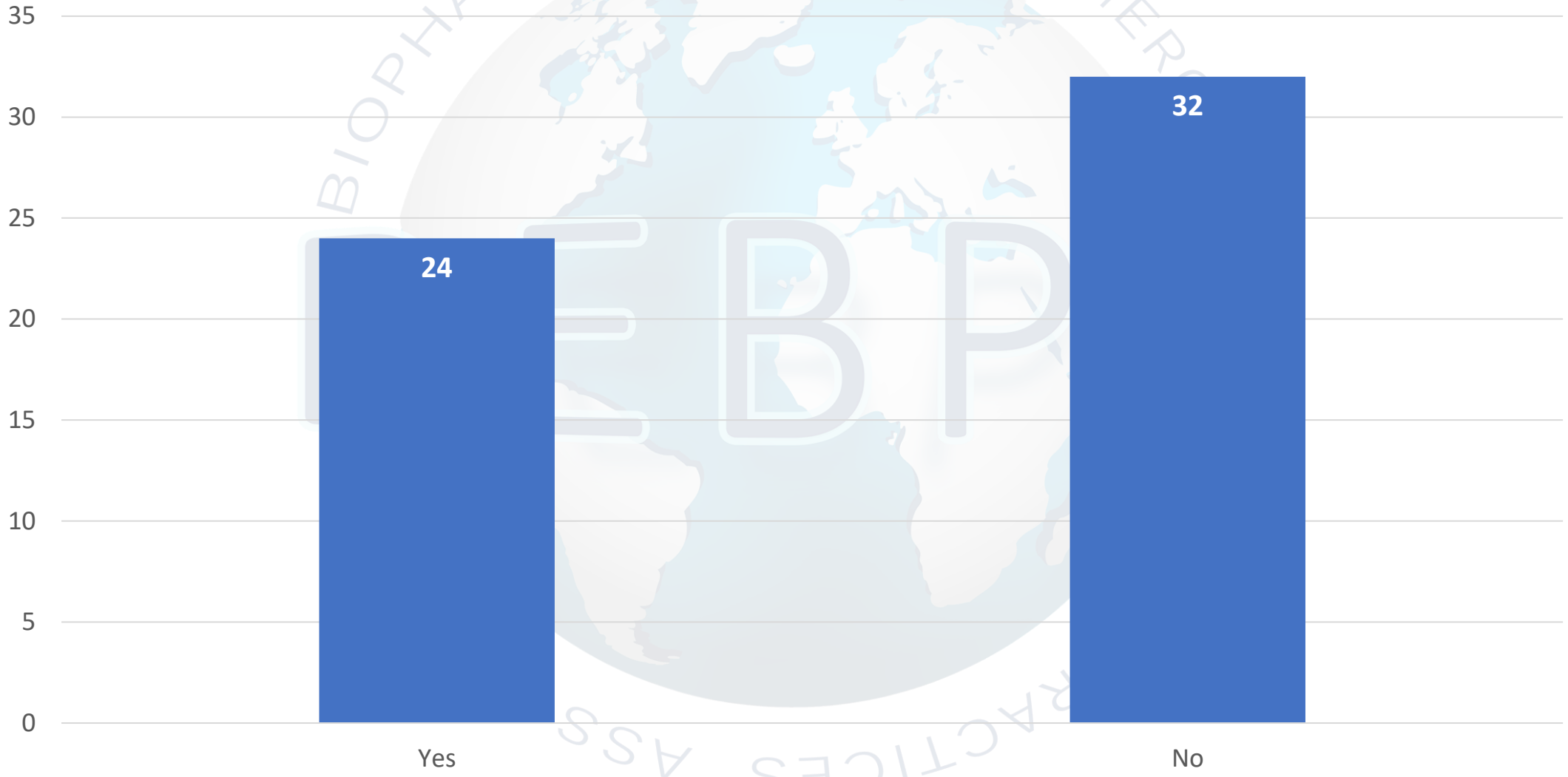
Session 4: Outliers: Their Significance and How to Deal with Them in a Regulated Environment

Session Chair: Bassam Hallis

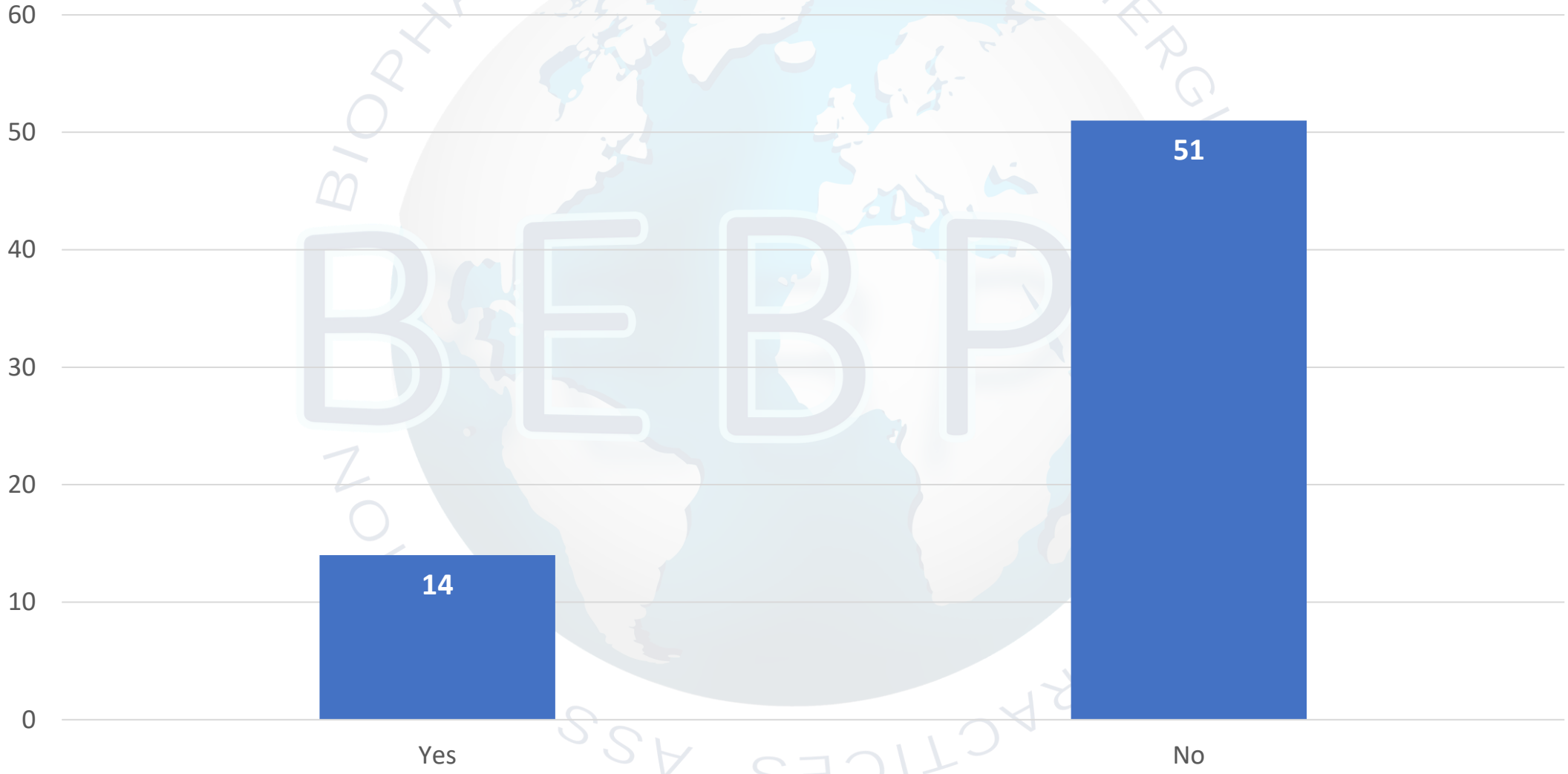
4-1 What outlier detection method do you use most often?



4-2 Do you have any sort of formal procedure for looking at outliers at multiple levels, such as wells and samples?



4-3 Do you periodically review outliers considering numbers and types of outliers by analyst, position, sequence, etc.?



THANK YOU

for attending BEBPA's 2020 EUR Bioassay Conference

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We could not have done this without YOU!