BEBPA 2021 US Bioassay Conference

22-25 March 2021

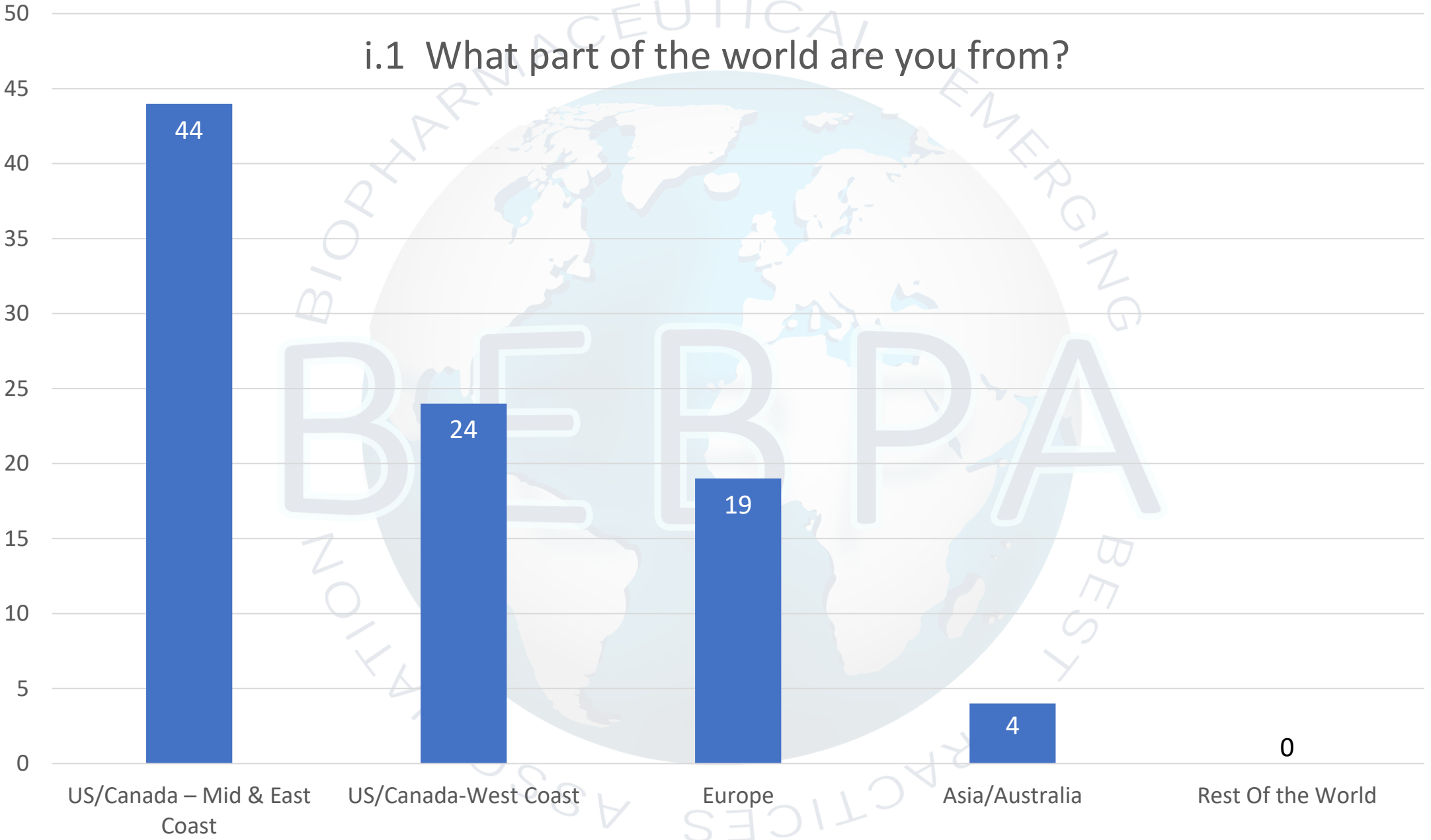
*Our 4th **VIRTUAL** Conference!*

Audience Survey

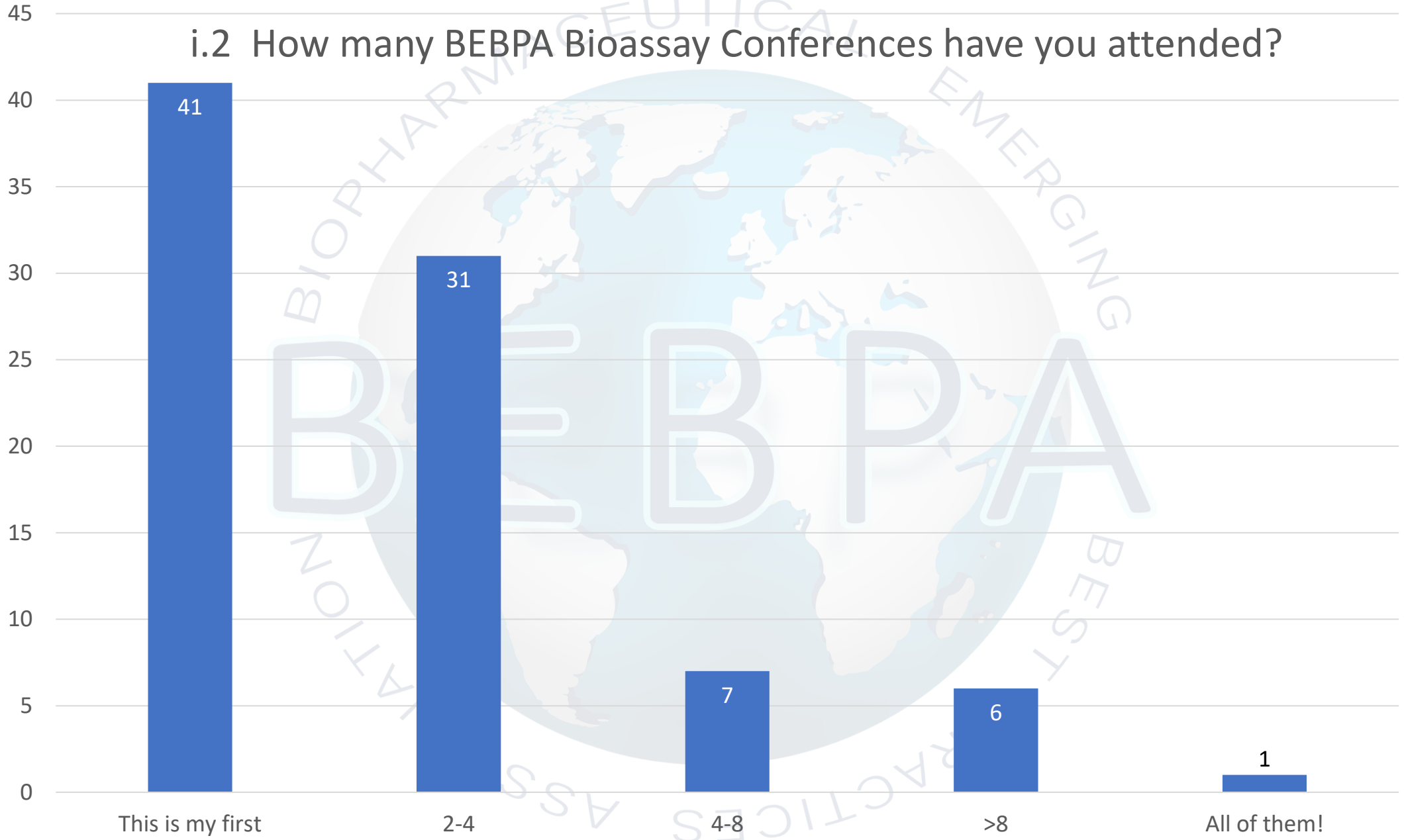
Welcome & Introduction

By: Laureen Little

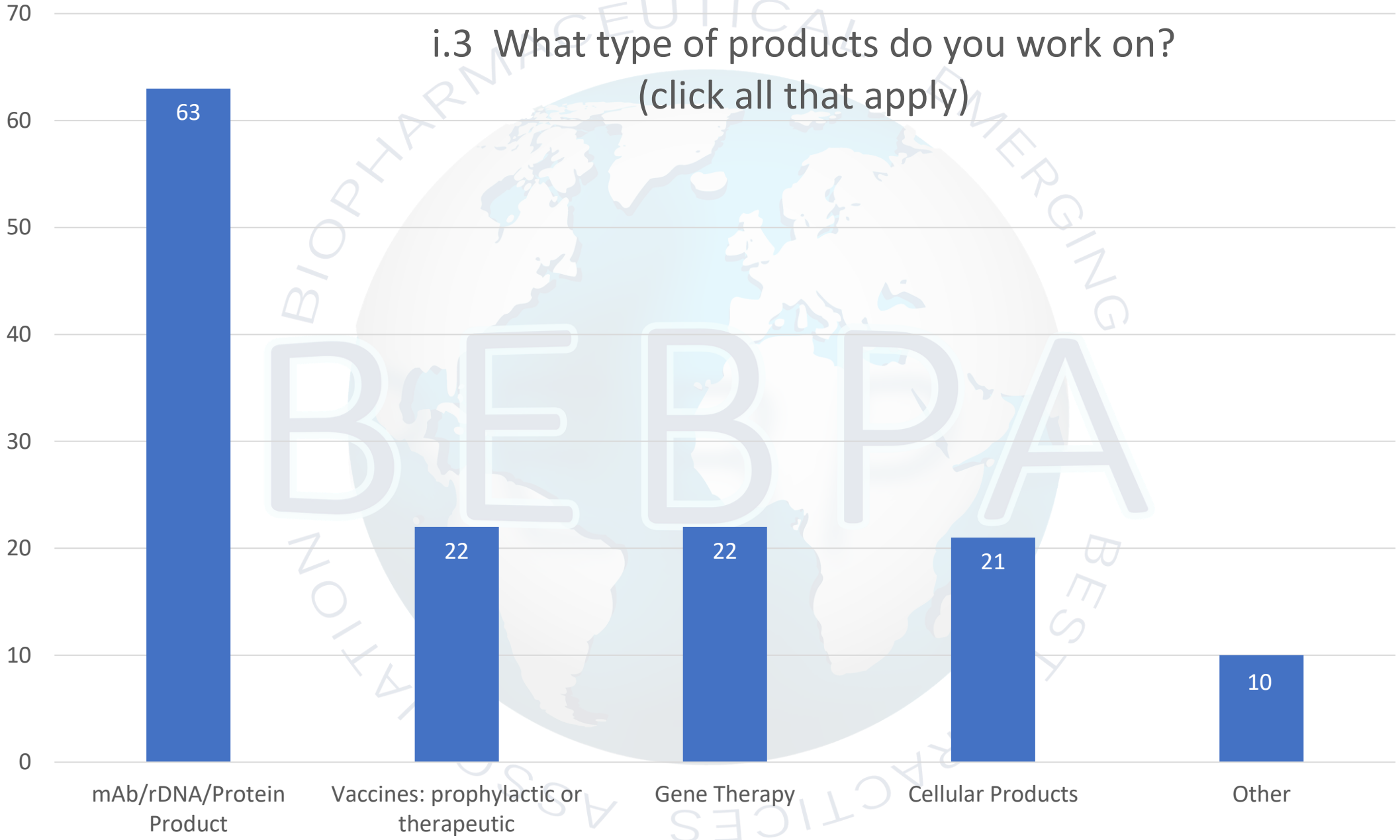
i.1 What part of the world are you from?



i.2 How many BEBPA Bioassay Conferences have you attended?

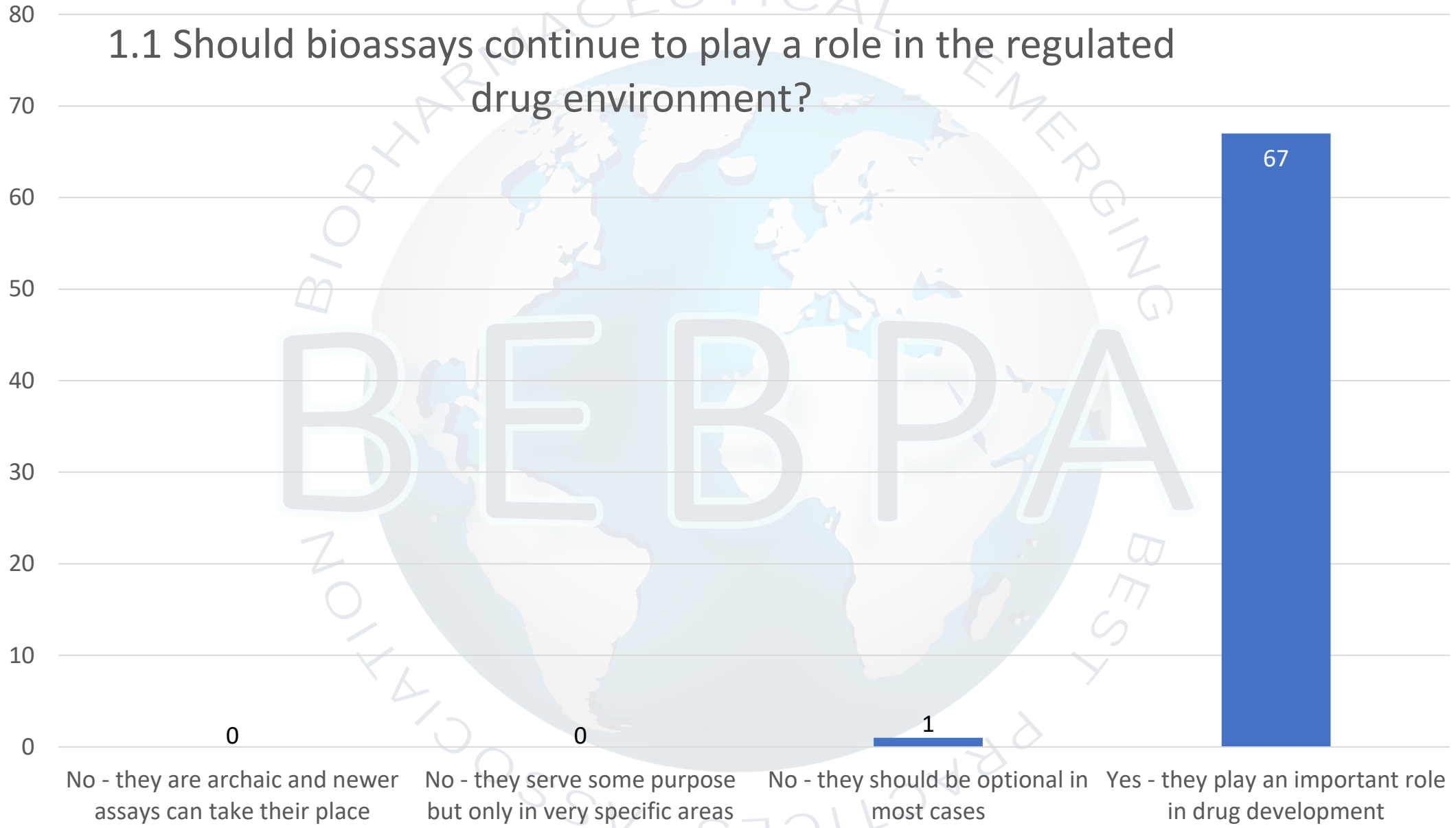


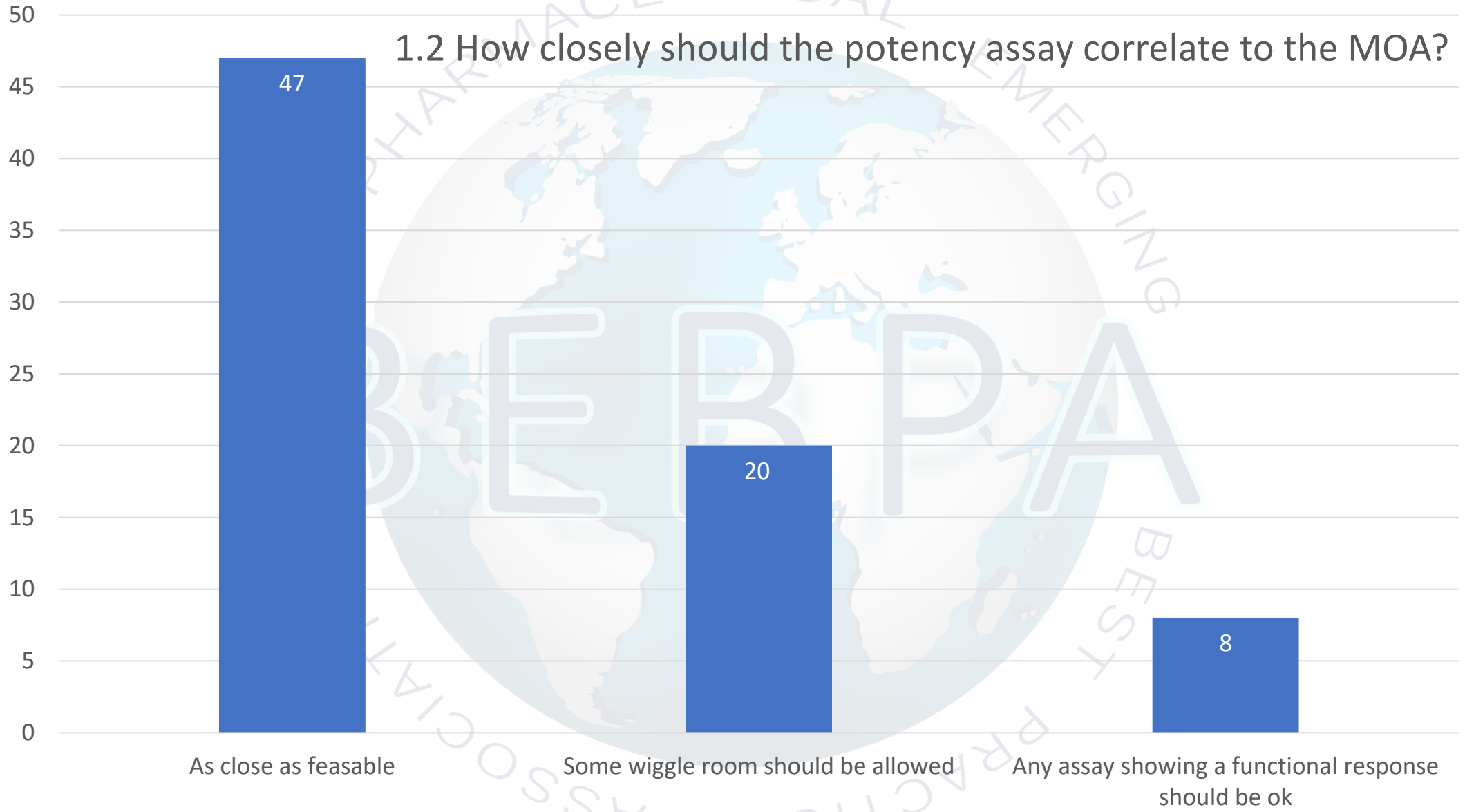
i.3 What type of products do you work on? (click all that apply)



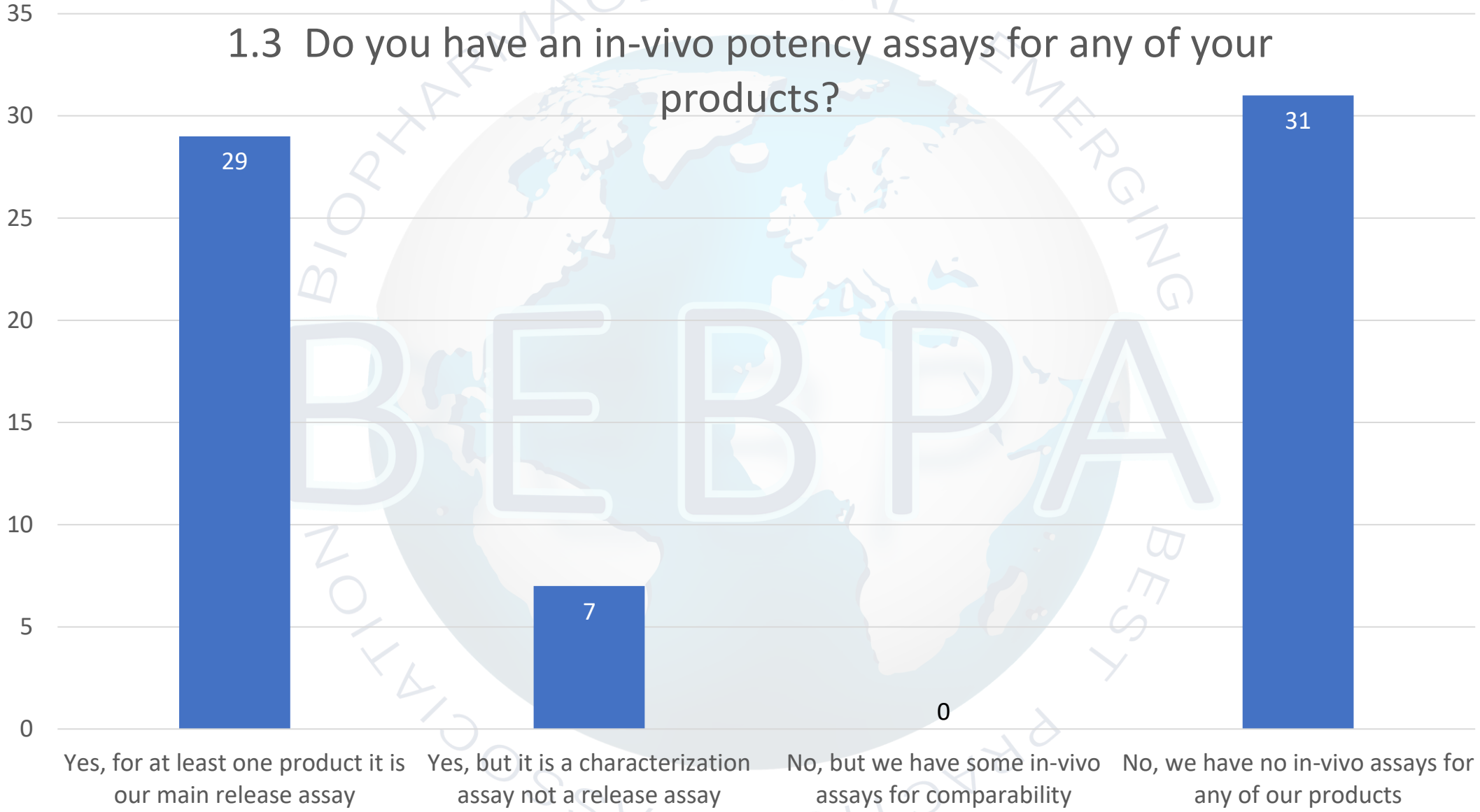
Session 1: Assay Regulatory Insights and Potency Method Development

Session Chair: Laureen Little

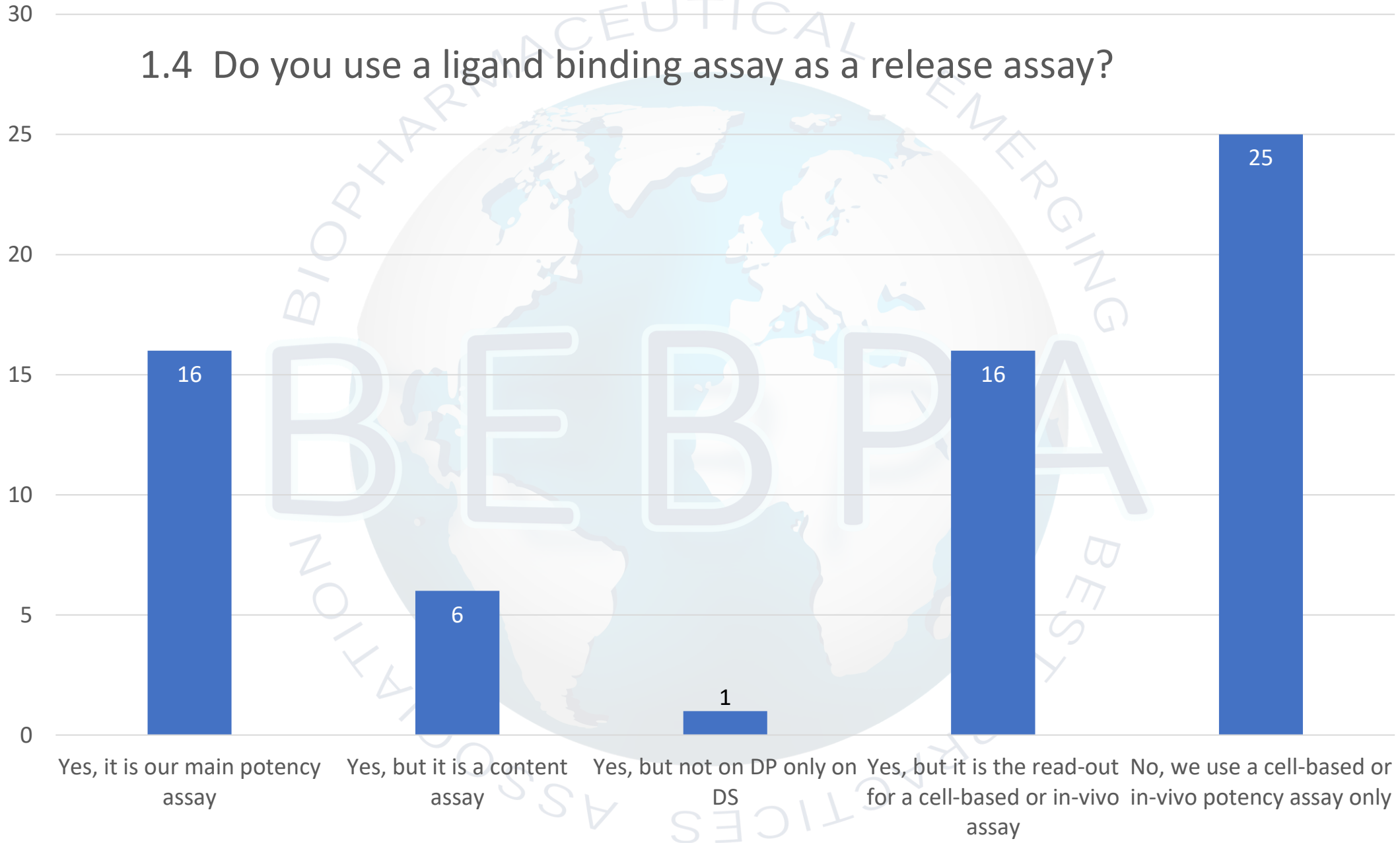

1.1 Should bioassays continue to play a role in the regulated drug environment?
80
70
60
50
40
30
20
10
0
0
0
1
67
No - they are archaic and newer assays can take their place
No - they serve some purpose but only in very specific areas
No - they should be optional in most cases
Yes - they play an important role in drug development


1.2 How closely should the potency assay correlate to the MOA?
50
45
40
35
30
25
20
15
10
5
0
47
20
8
As close as feasable
Some wiggle room should be allowed
Any assay showing a functional response should be ok

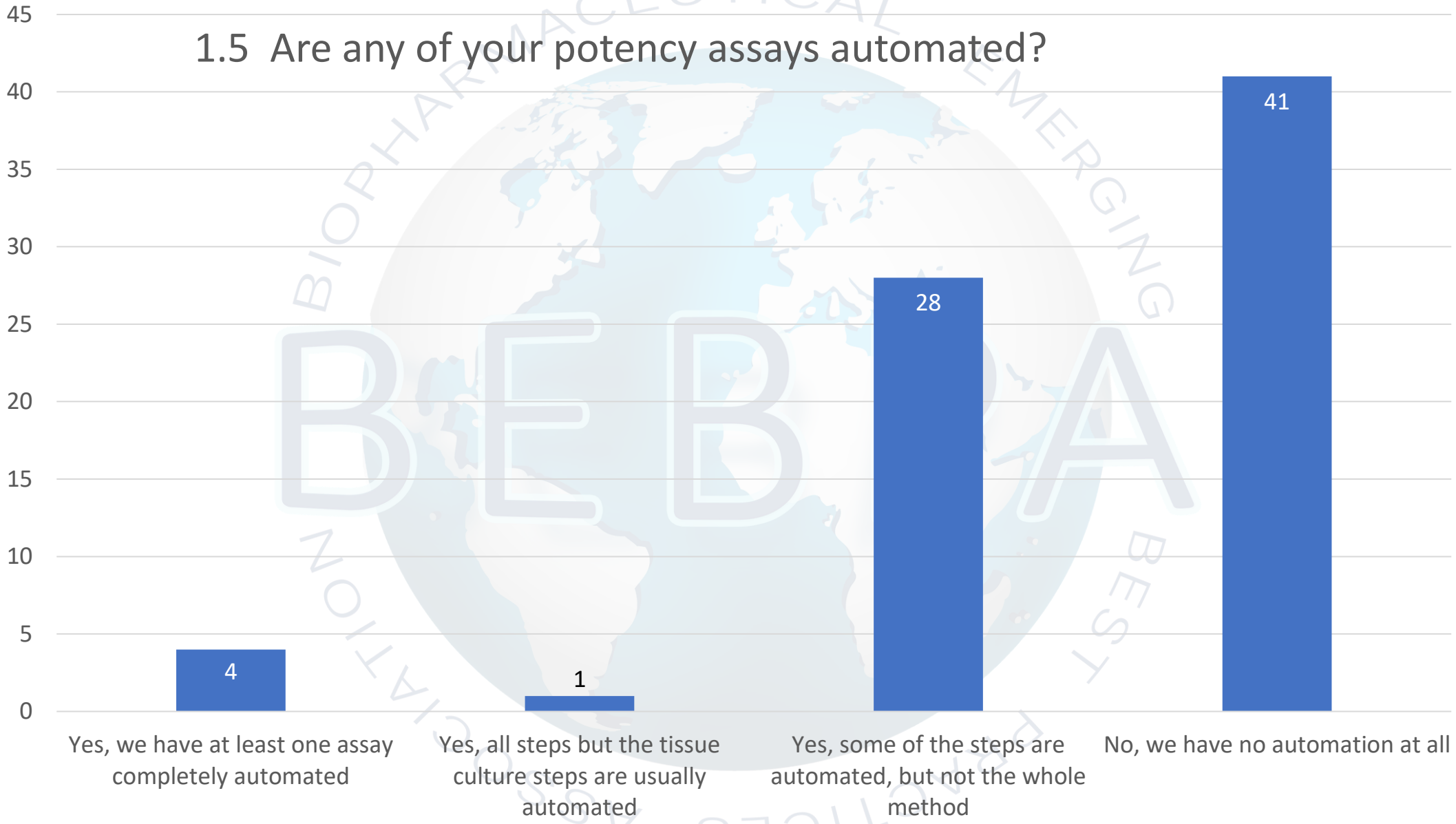
1.3 Do you have an in-vivo potency assays for any of your products?

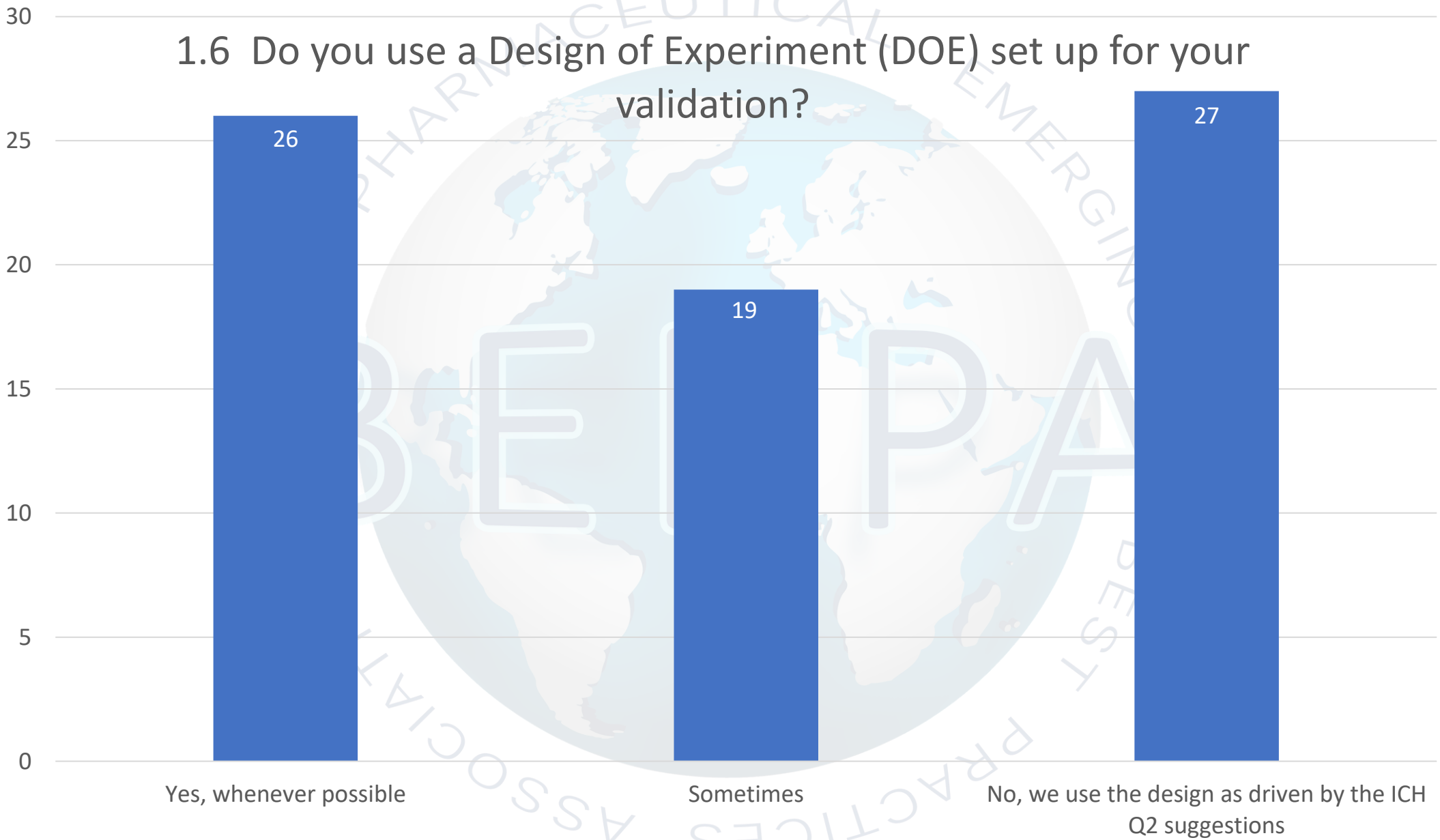


1.4 Do you use a ligand binding assay as a release assay?



1.5 Are any of your potency assays automated?

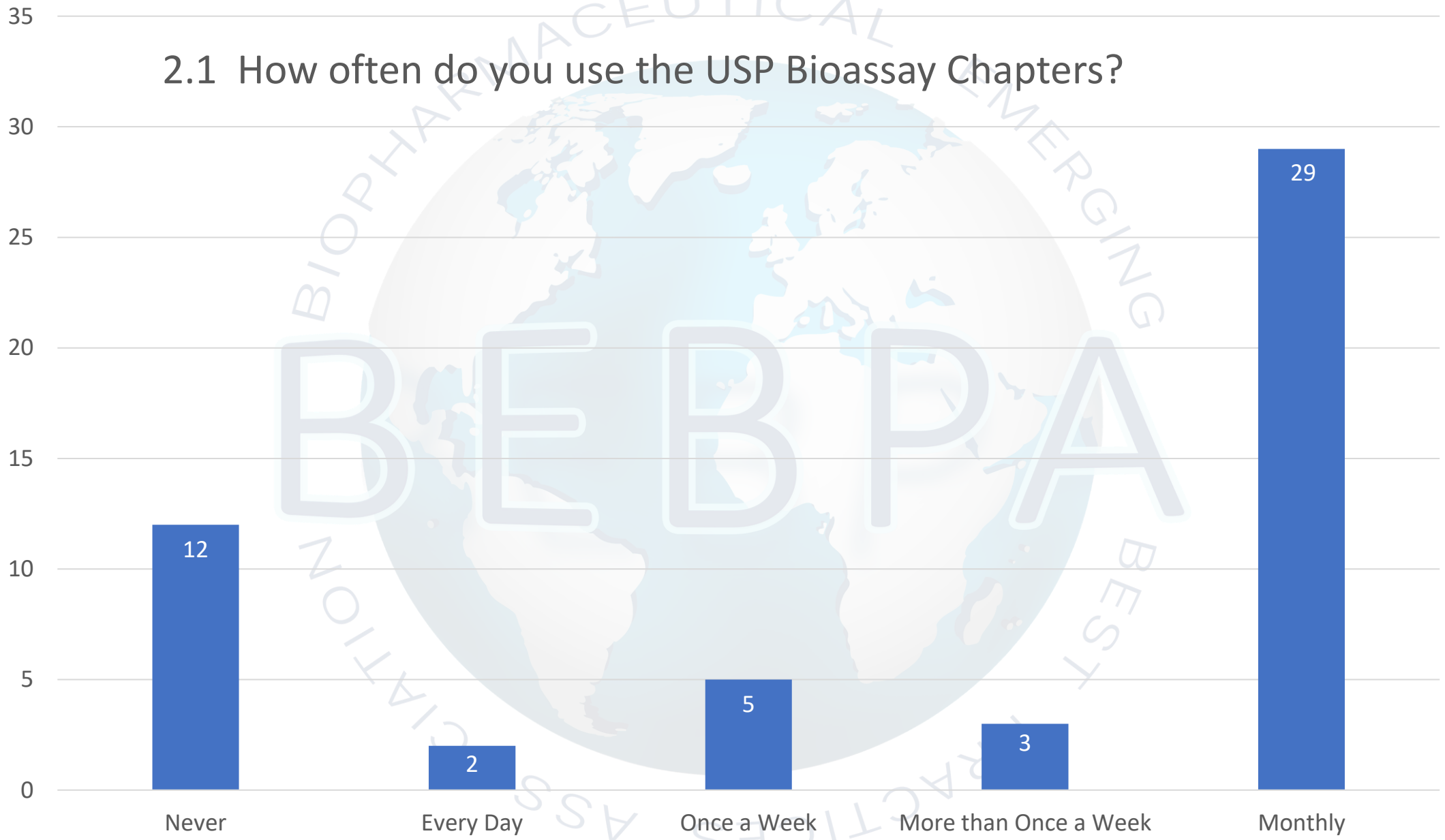



1.6 Do you use a Design of Experiment (DOE) set up for your validation?
30
25
20
15
10
5
0
26
19
27
Yes, whenever possible
Sometimes
No, we use the design as driven by the ICH Q2 suggestions

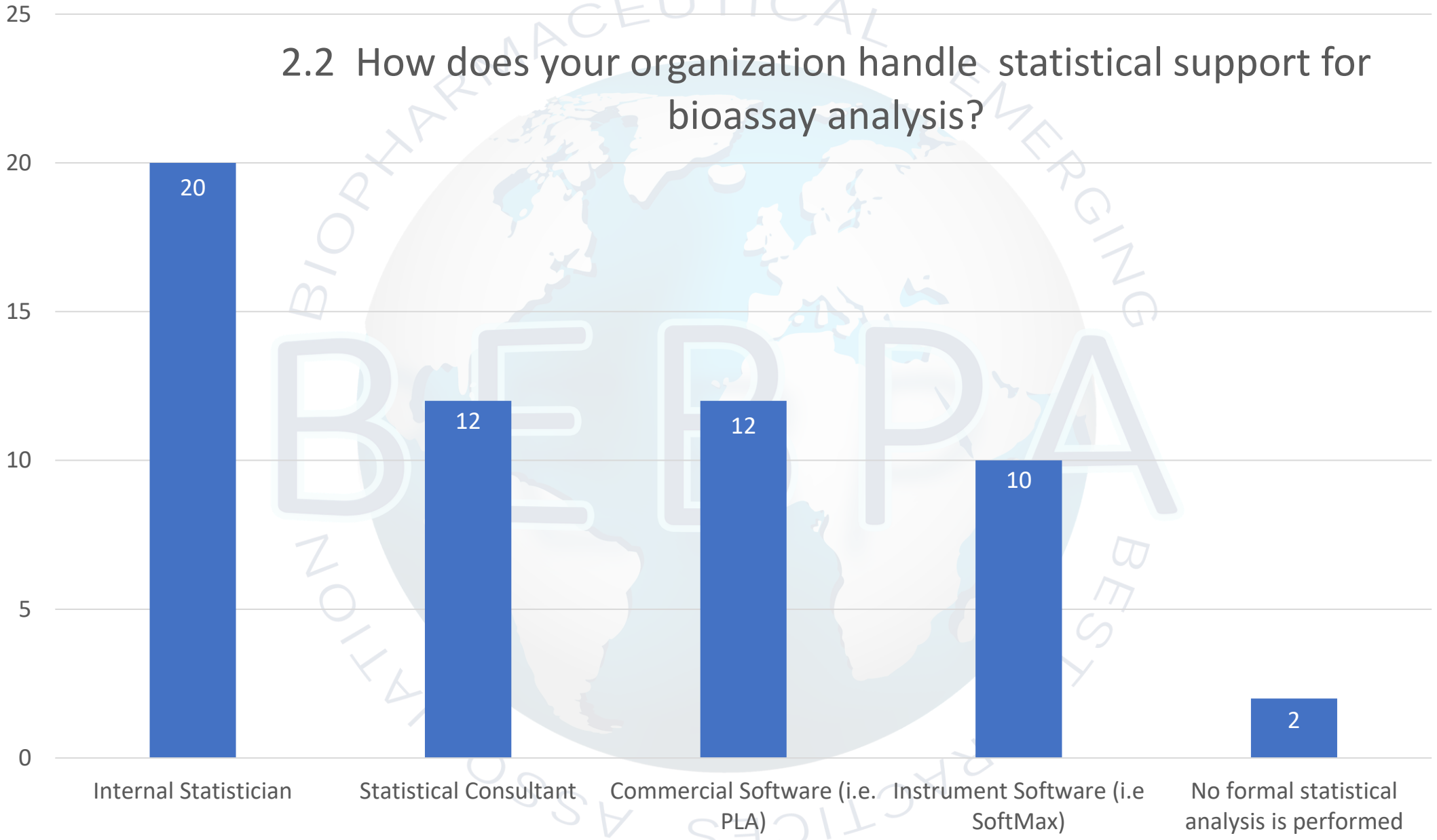
Session 2: Method Development Tools

Session Chair: Nancy Niemuth

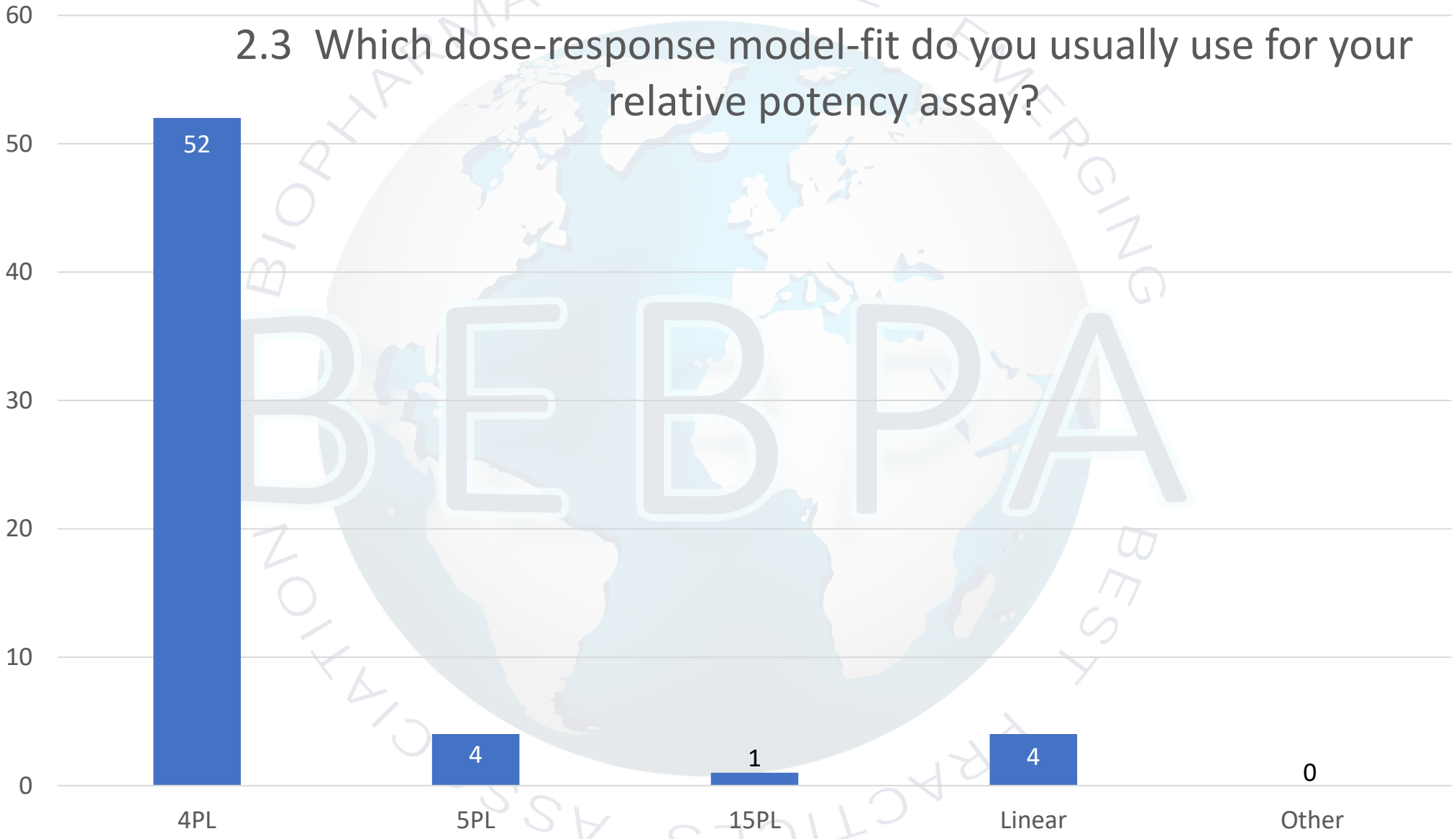
2.1 How often do you use the USP Bioassay Chapters?



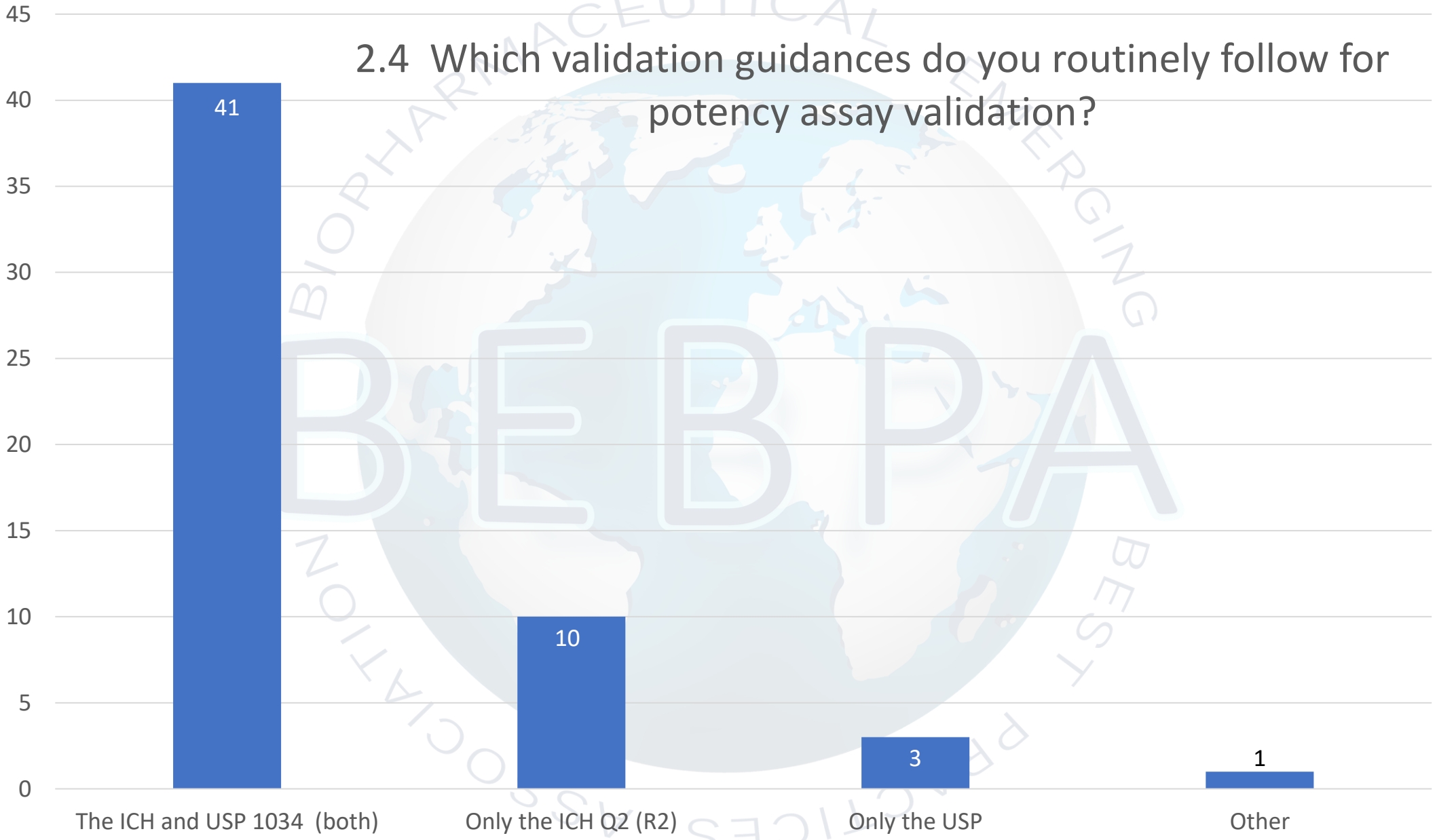
2.2 How does your organization handle statistical support for bioassay analysis?



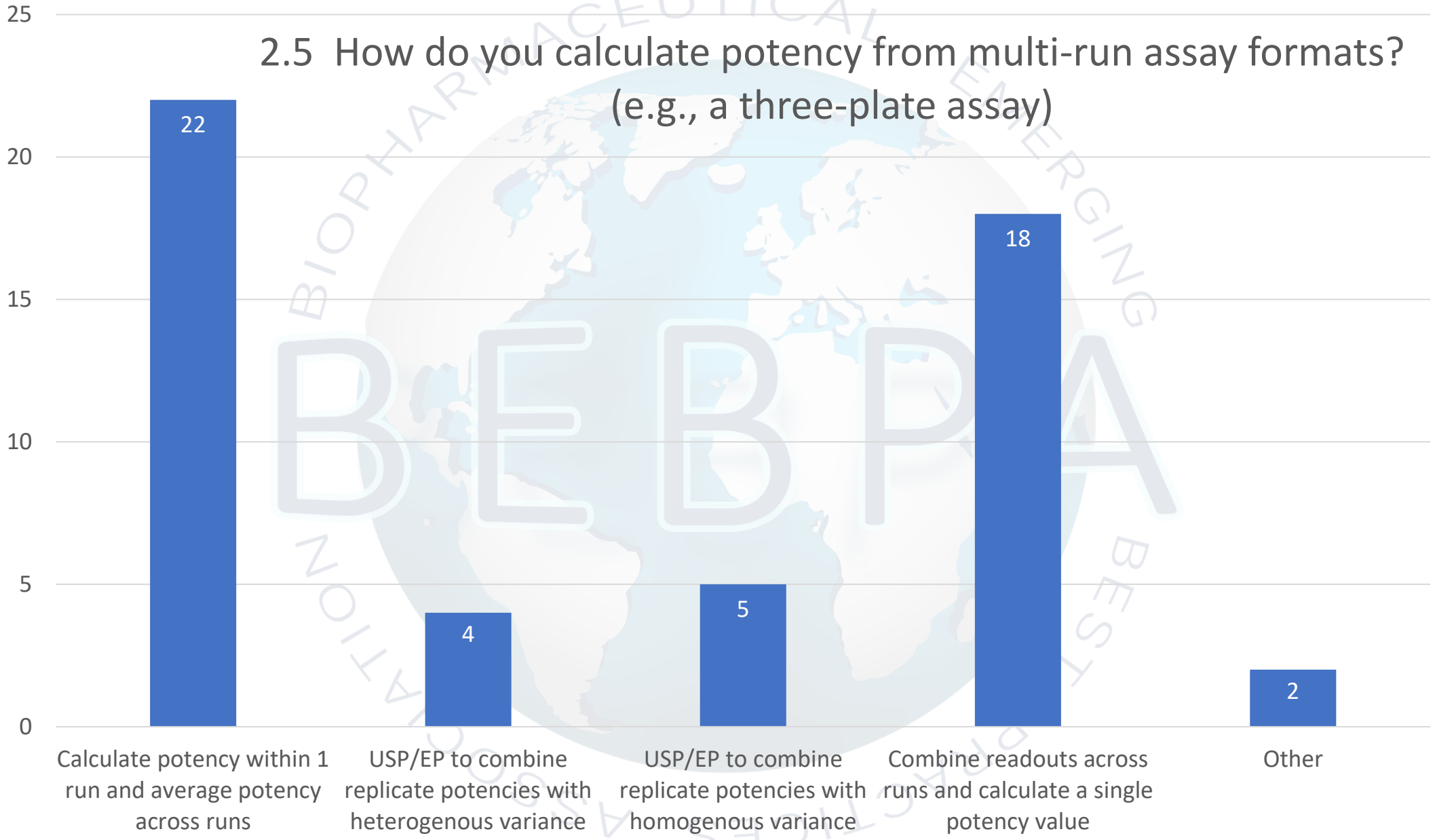
2.3 Which dose-response model-fit do you usually use for your relative potency assay?



2.4 Which validation guidances do you routinely follow for potency assay validation?



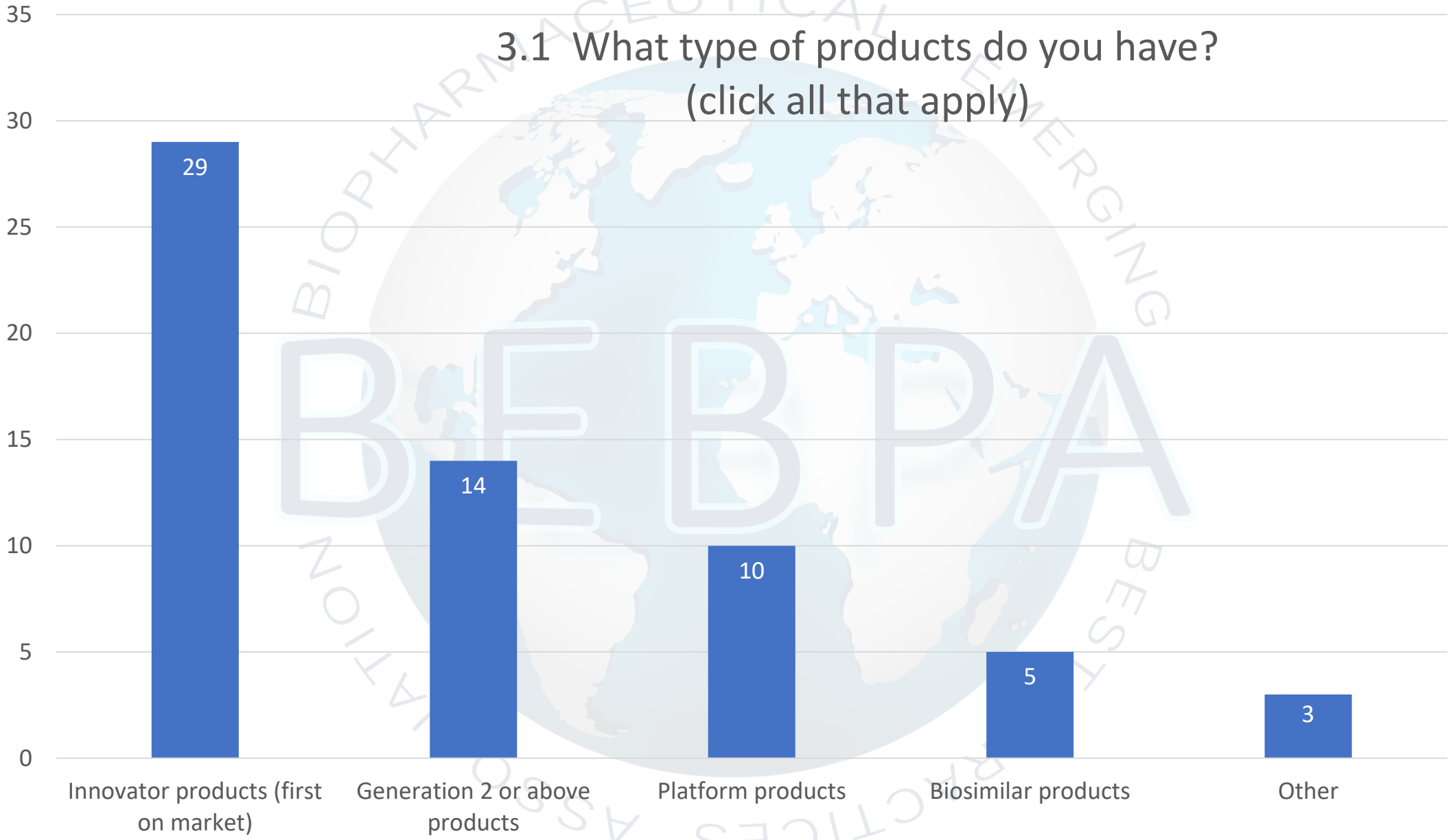
2.5 How do you calculate potency from multi-run assay formats? (e.g., a three-plate assay)



Session 3: Reference Standards for Potency Assays

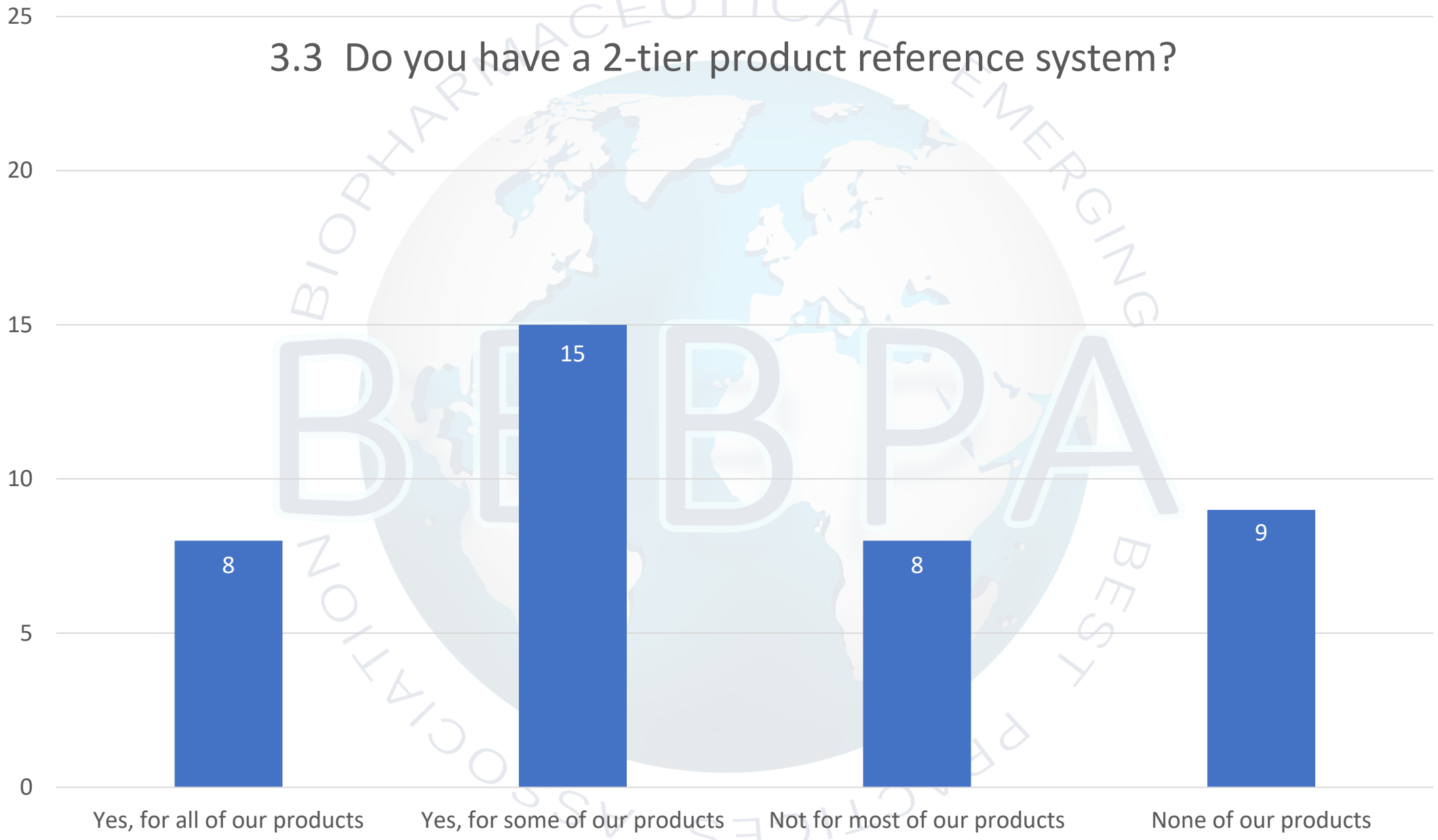
Session Chair: Sian Estdale

3.1 What type of products do you have? (click all that apply)



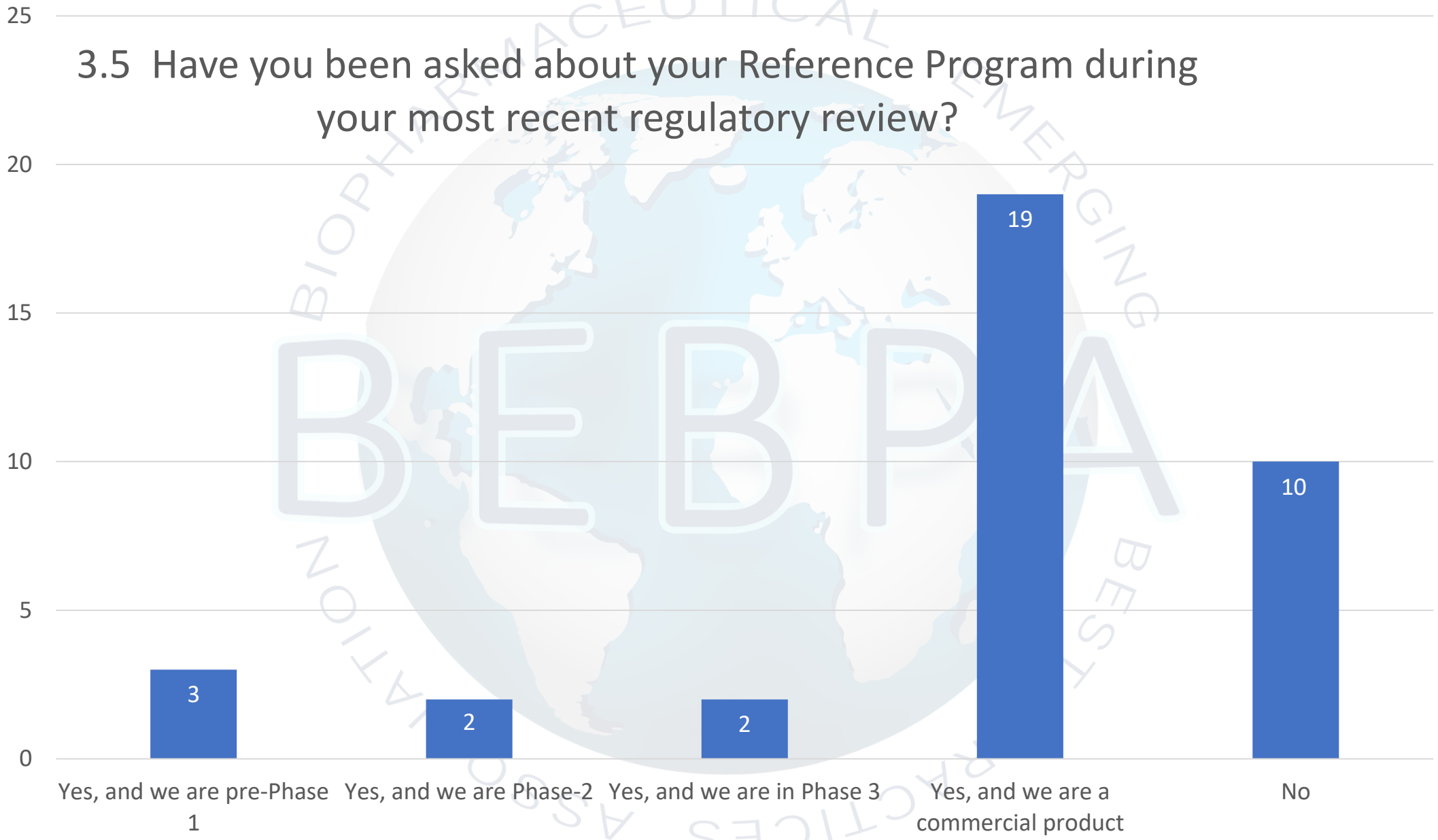
3.2 Is there an international reference available for your product(s)?

3.3 Do you have a 2-tier product reference system?



3.4 Do you have a special group which handles only your product references?

3.5 Have you been asked about your Reference Program during your most recent regulatory review?

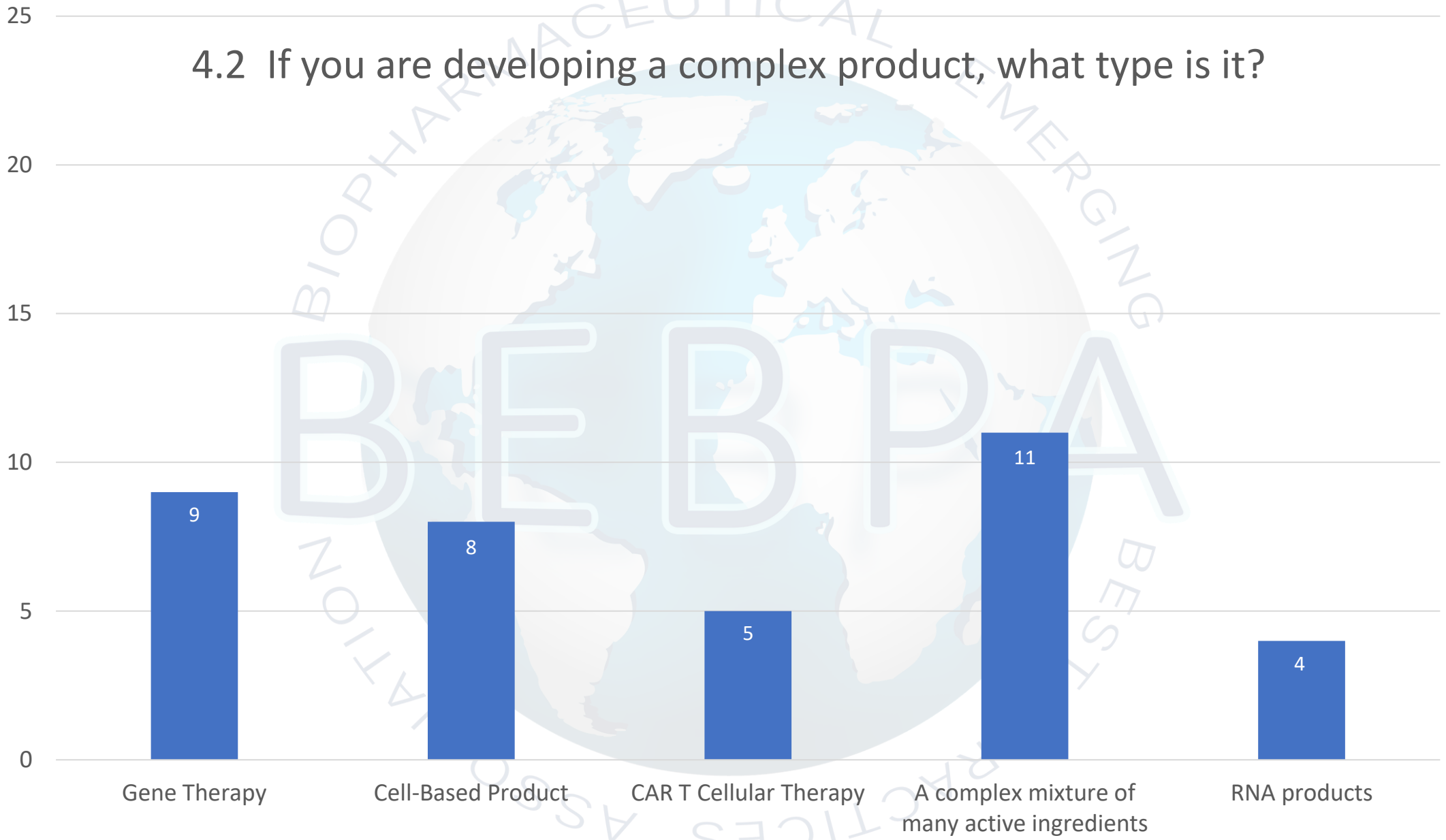


Session 4: Potency Assay Development for Complex Product

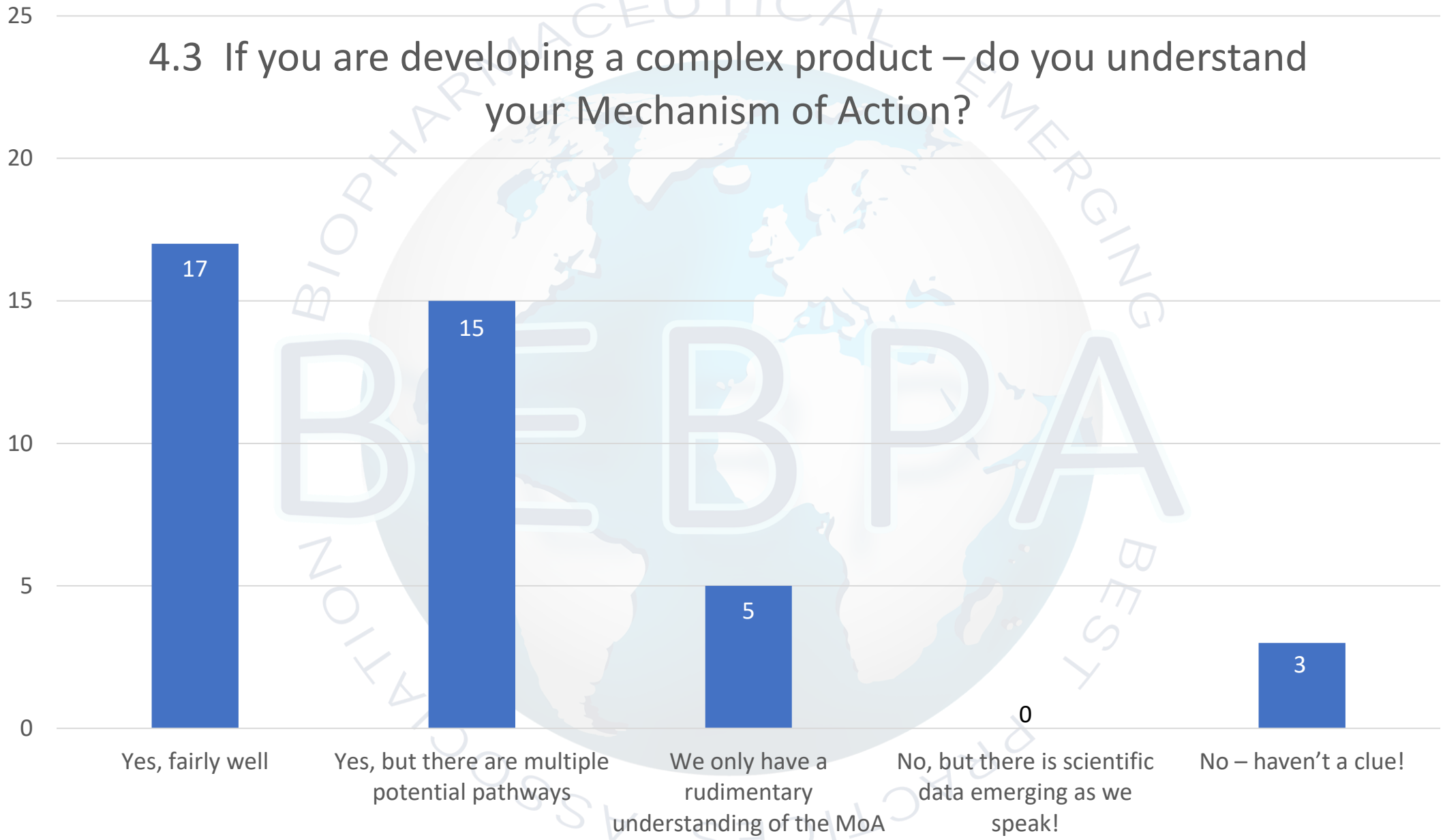
Session Chair: Kristin Clement

4.1 Are you developing a “complex” product?

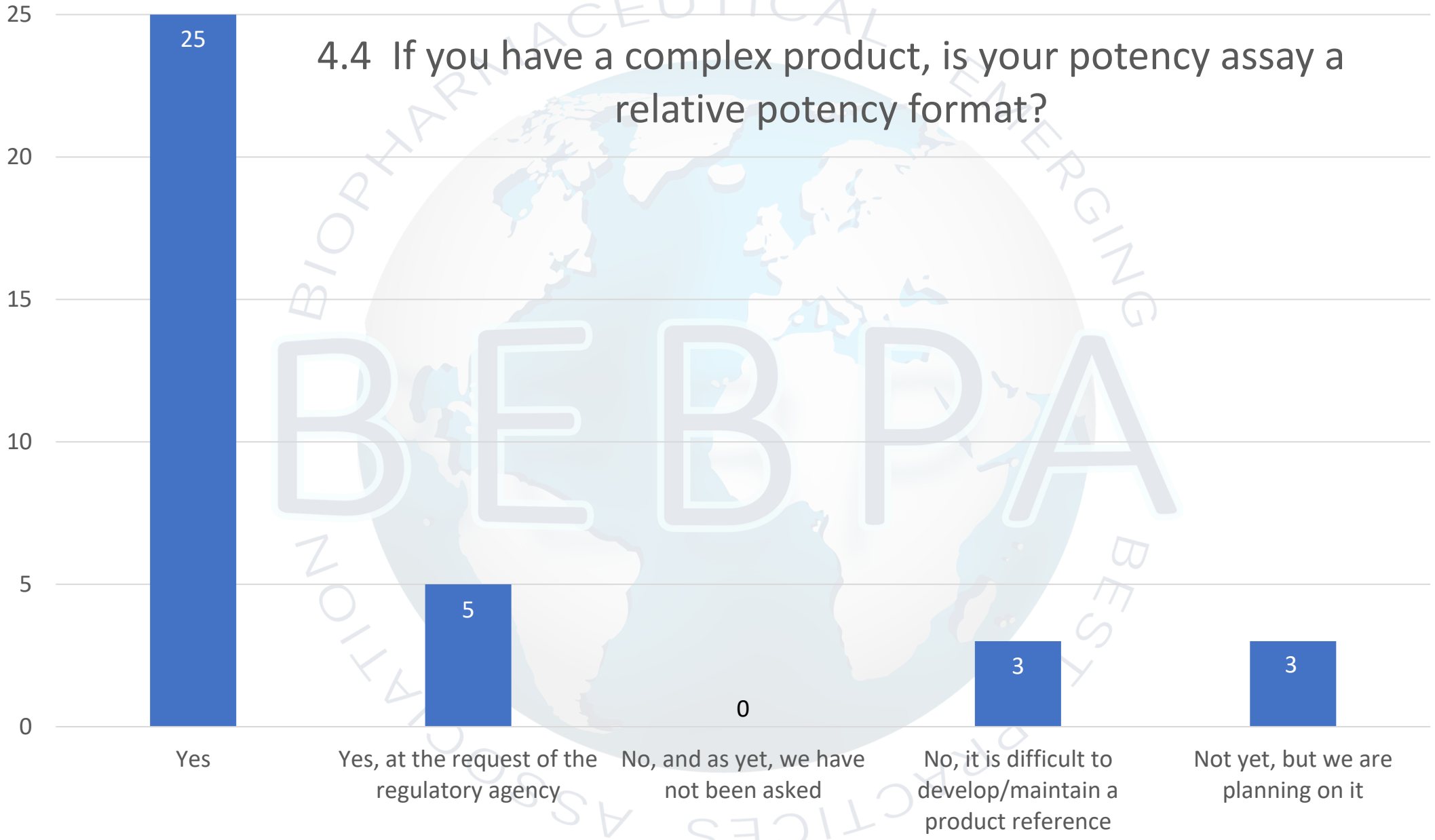
4.2 If you are developing a complex product, what type is it?



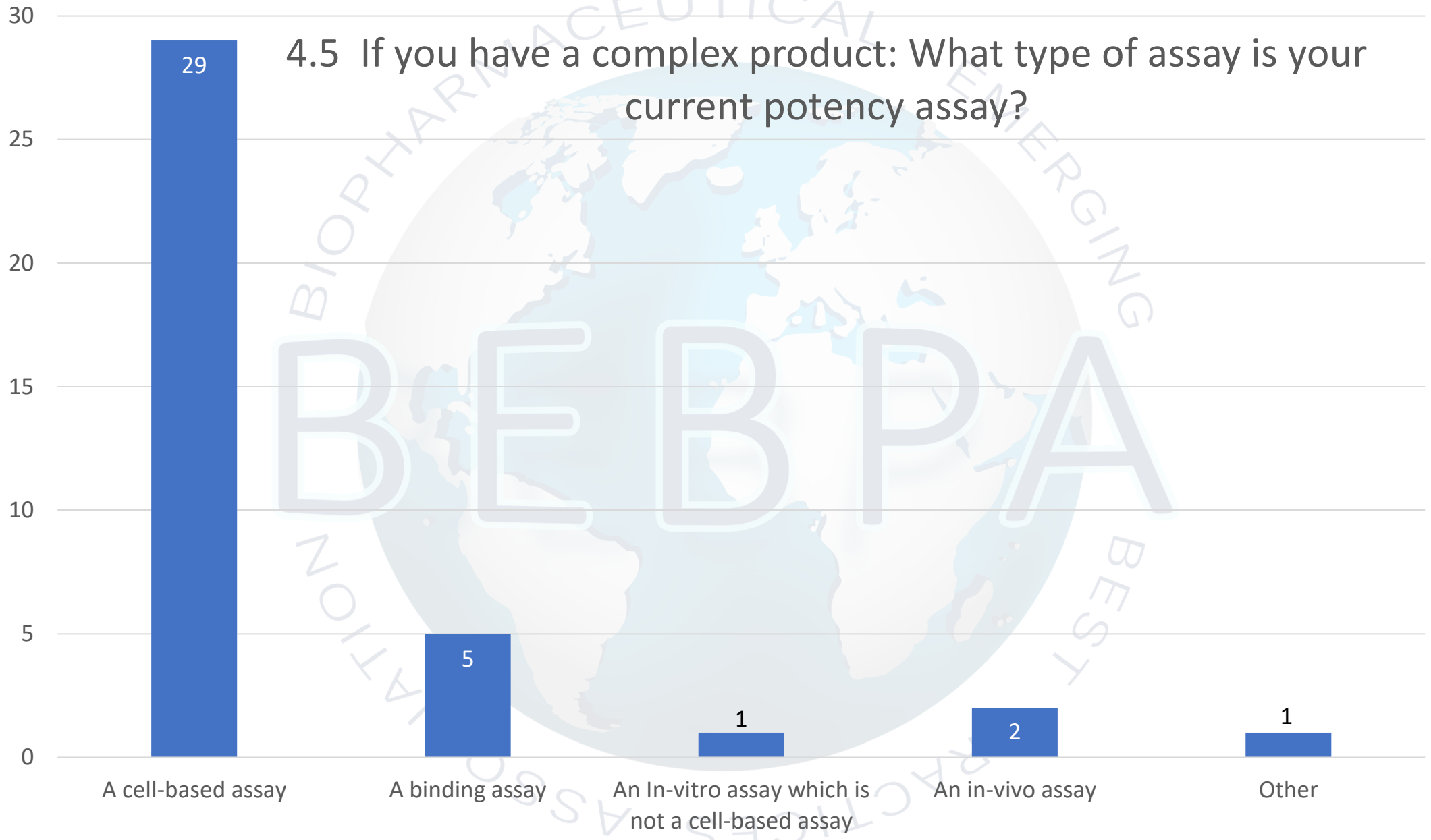
4.3 If you are developing a complex product – do you understand your Mechanism of Action?



4.4 If you have a complex product, is your potency assay a relative potency format?



4.5 If you have a complex product: What type of assay is your current potency assay?



THANK YOU

for attending BEBPA's 2021 US Bioassay Conference

We could not have done this without YOU!