BEBPA 2021 EUR Bioassay Conference

20-23 September 2021

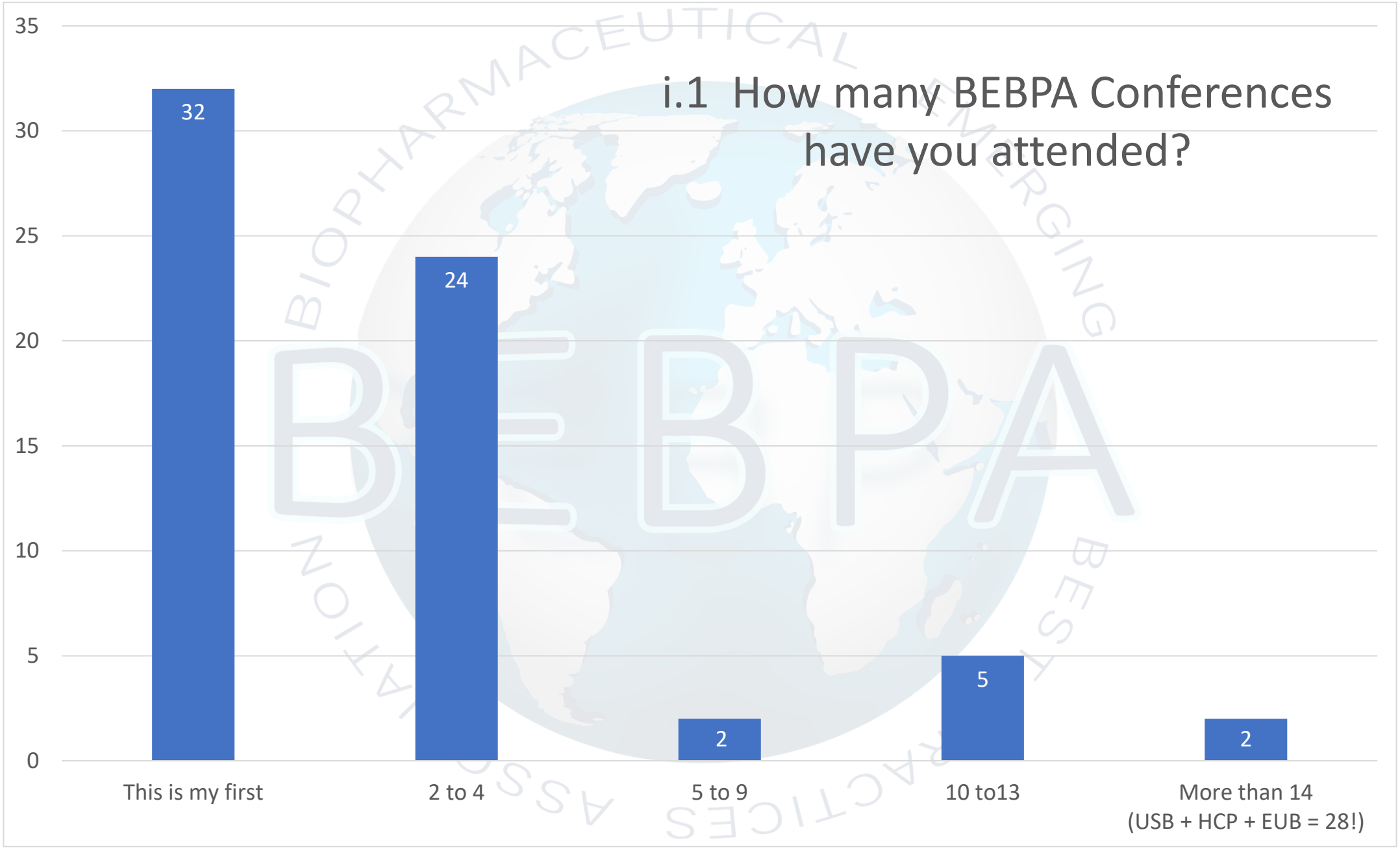
14th Annual EUR Bioassay Conference

Audience Survey

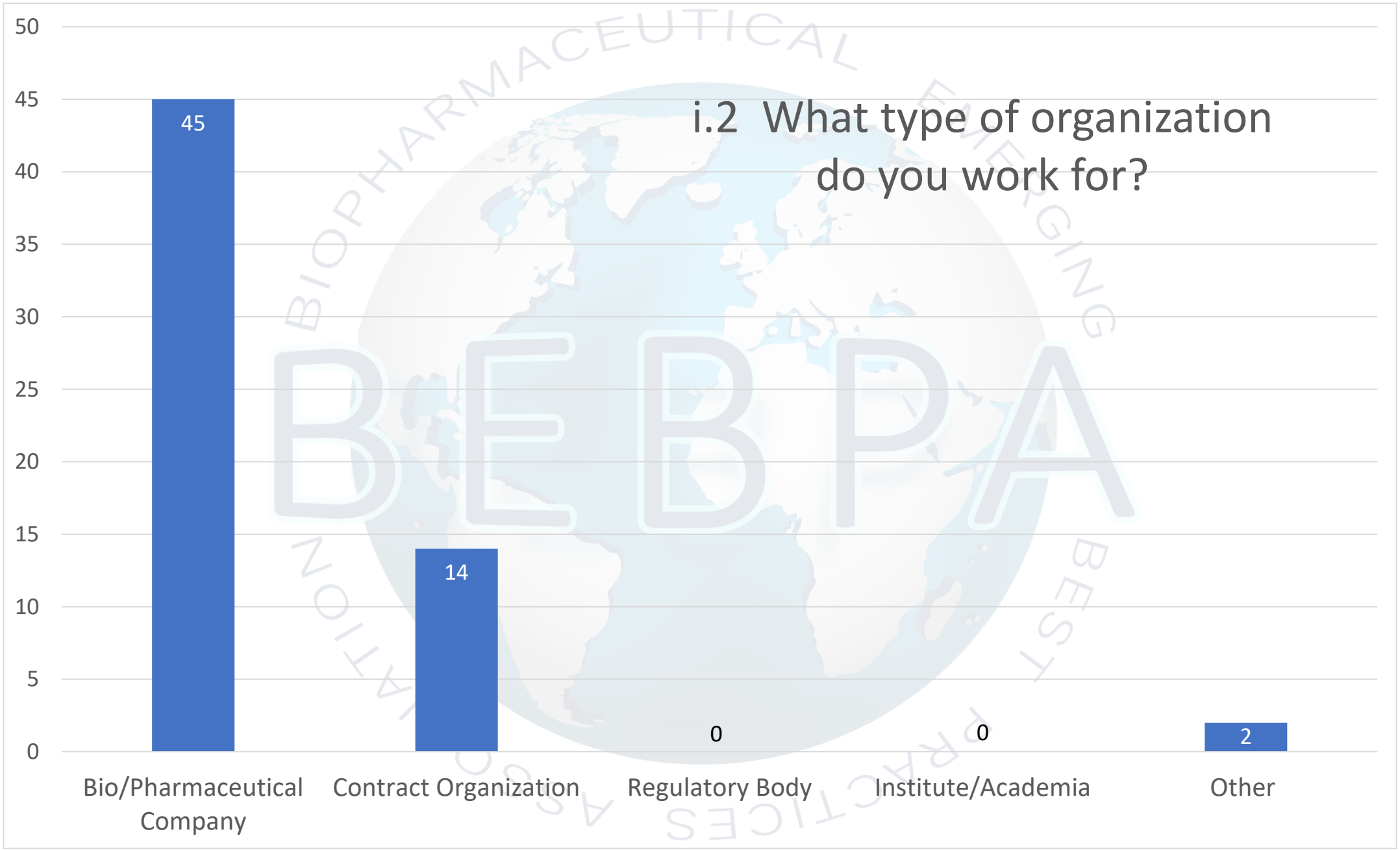
Welcome & Introduction

By: Laureen Little

i.1 How many BEBPA Conferences have you attended?



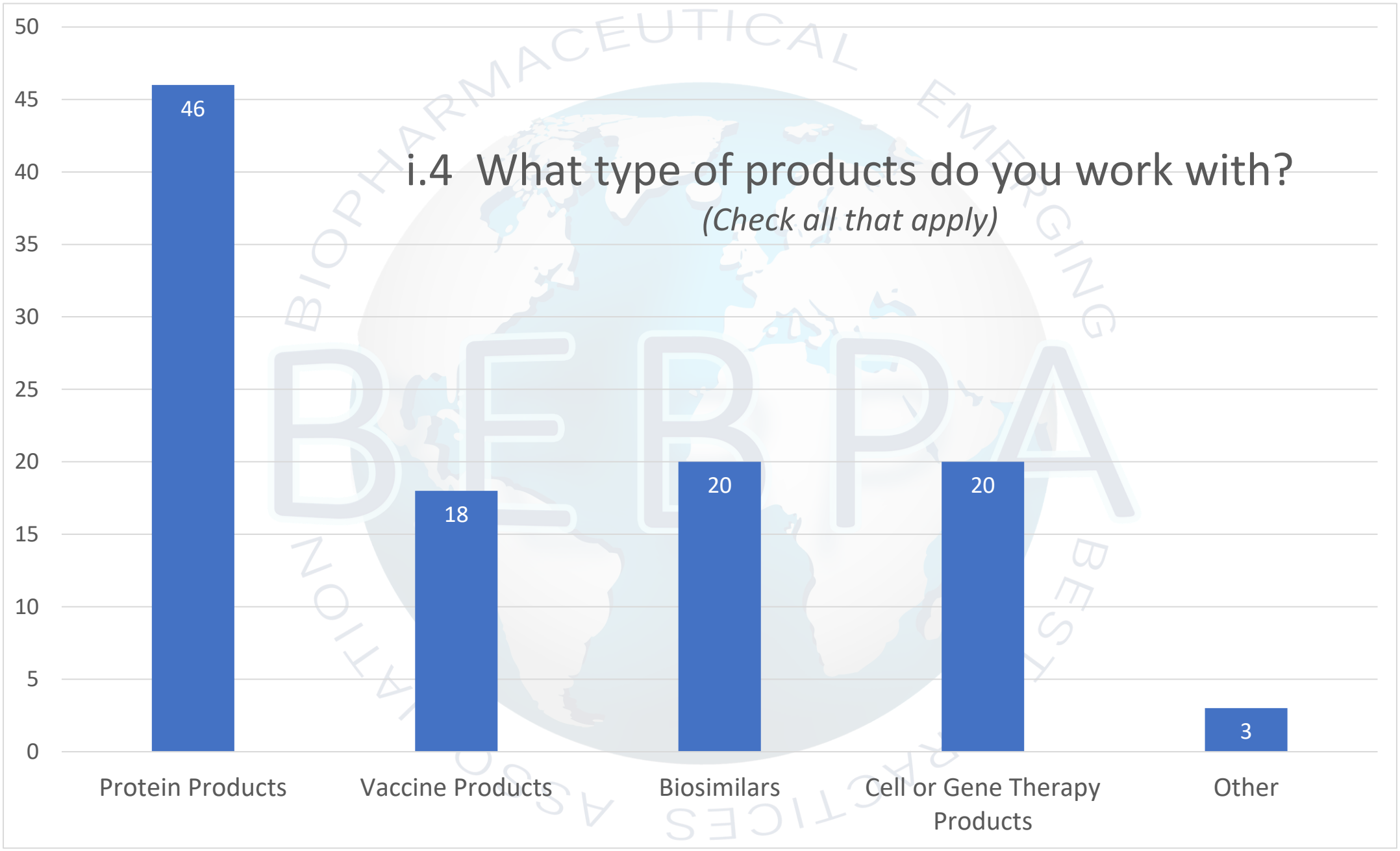
i.2 What type of organization do you work for?



i.3 What part of the organization do you work in?

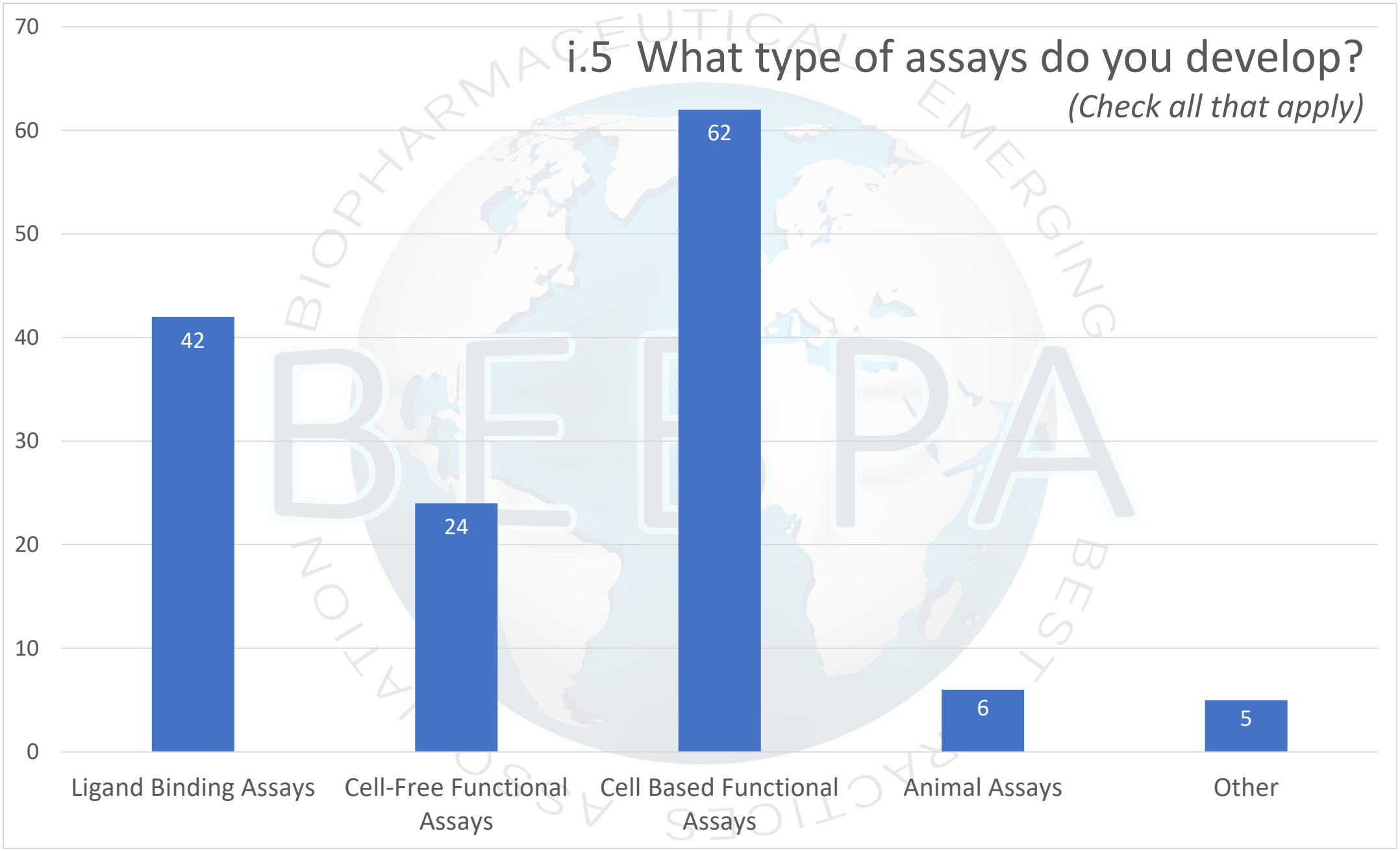
i.4 What type of products do you work with?

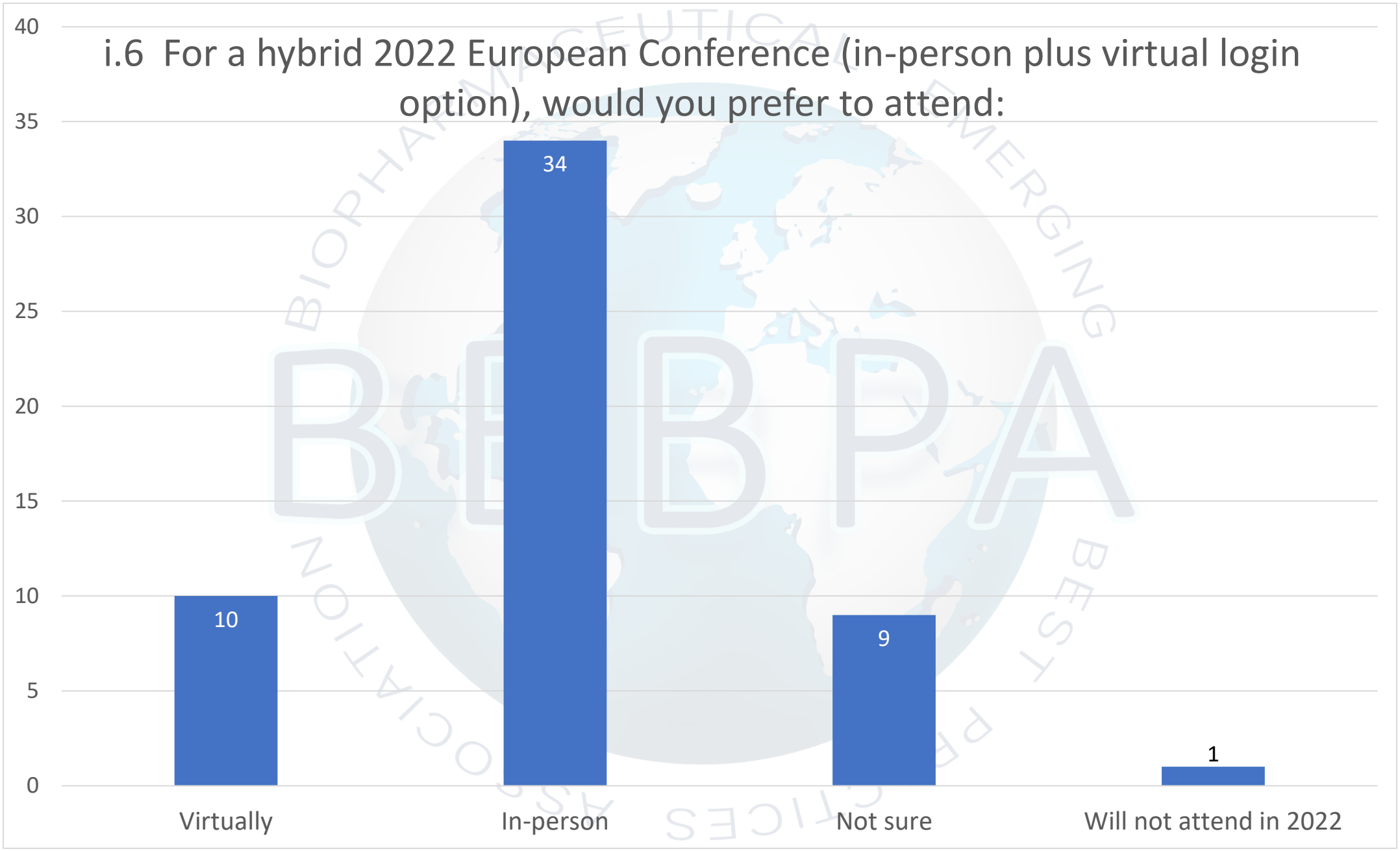
(Check all that apply)

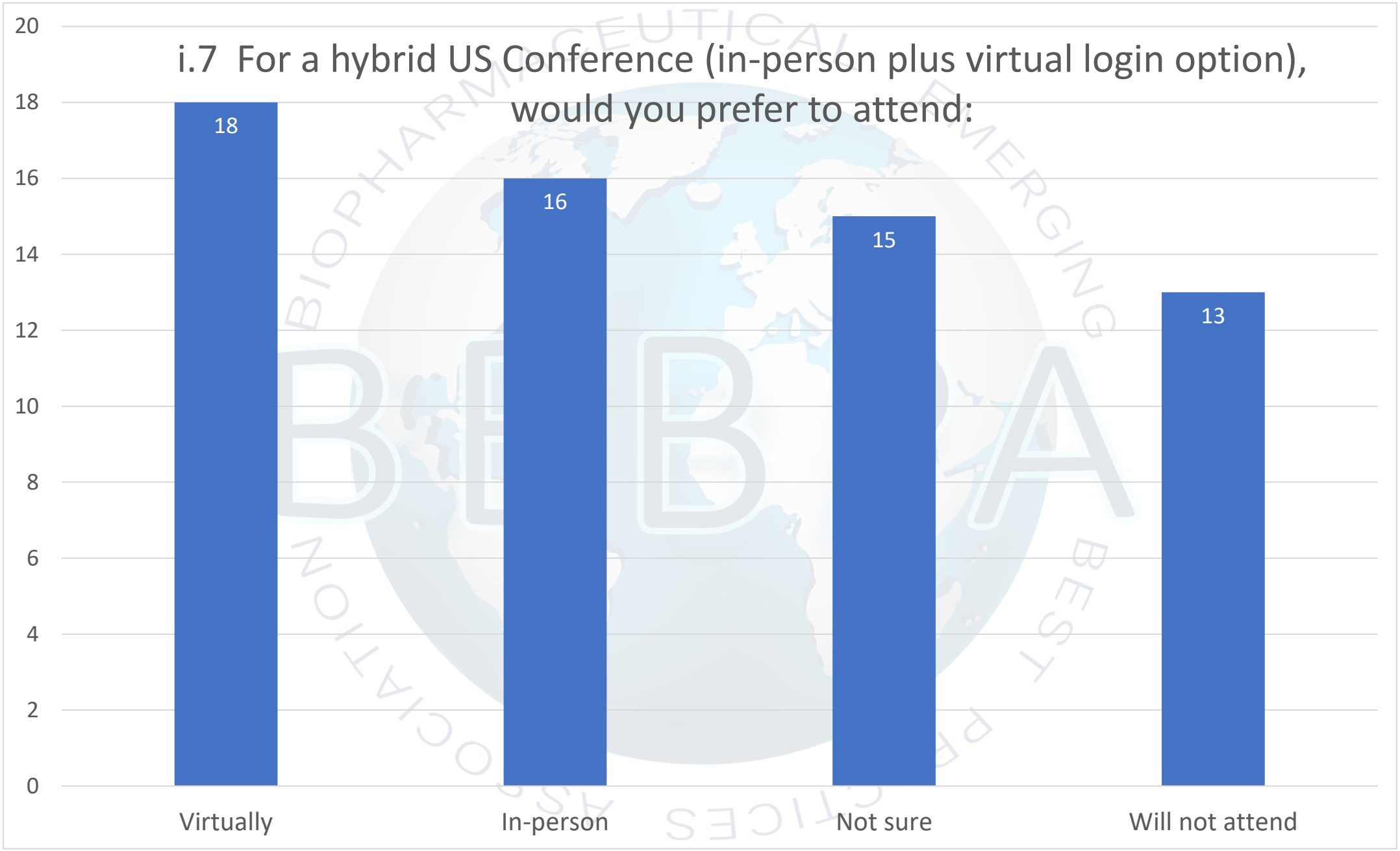


i.5 What type of assays do you develop?

(Check all that apply)



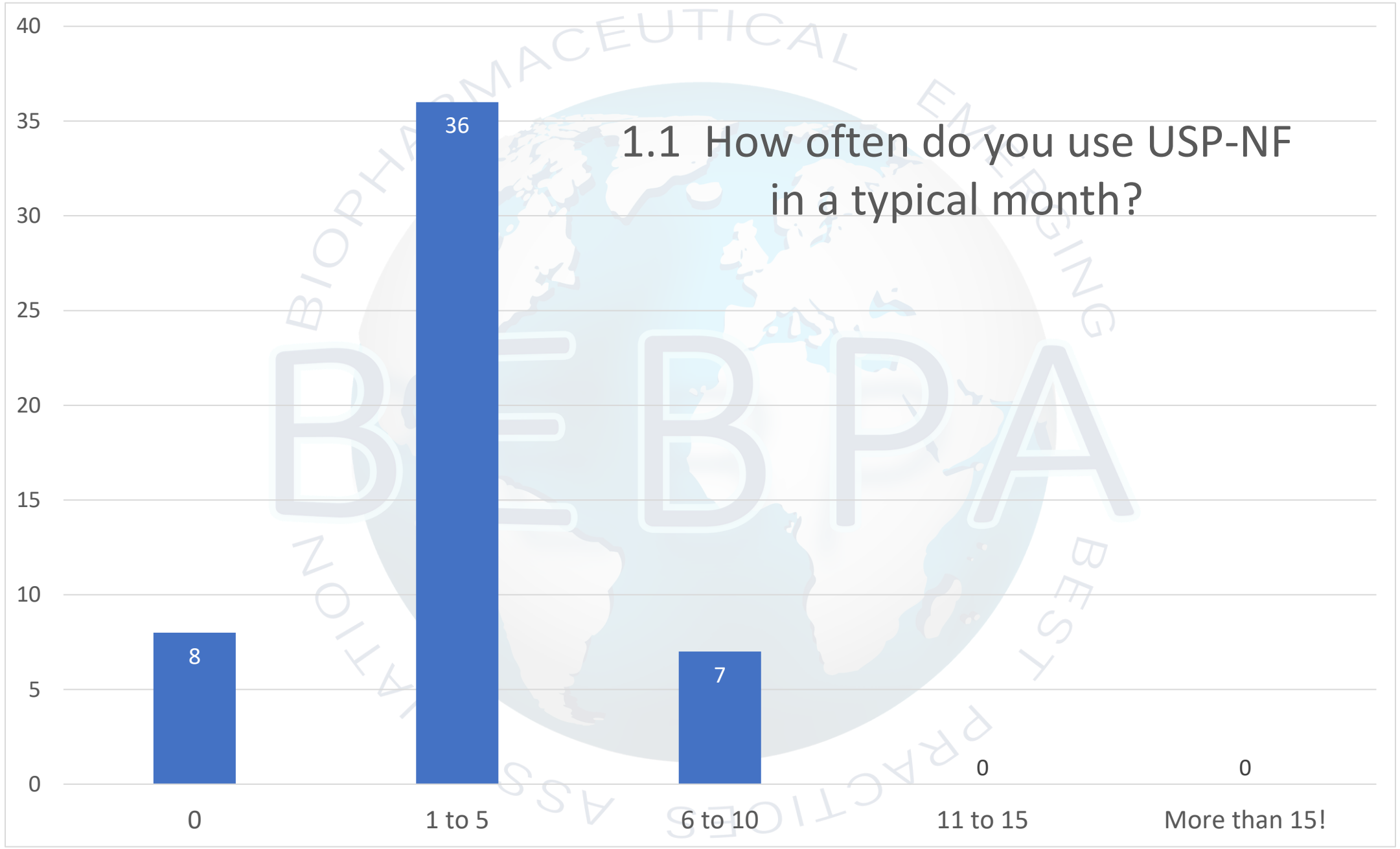

i.6 For a hybrid 2022 European Conference (in-person plus virtual login option), would you prefer to attend:
40
35
30
25
20
15
10
5
0
10
34
9
1
Virtually
In-person
Not sure
Will not attend in 2022


i.7 For a hybrid US Conference (in-person plus virtual login option), would you prefer to attend:
20
18
16
14
12
10
8
6
4
2
0
18
16
15
13
Virtually
In-person
Not sure
Will not attend

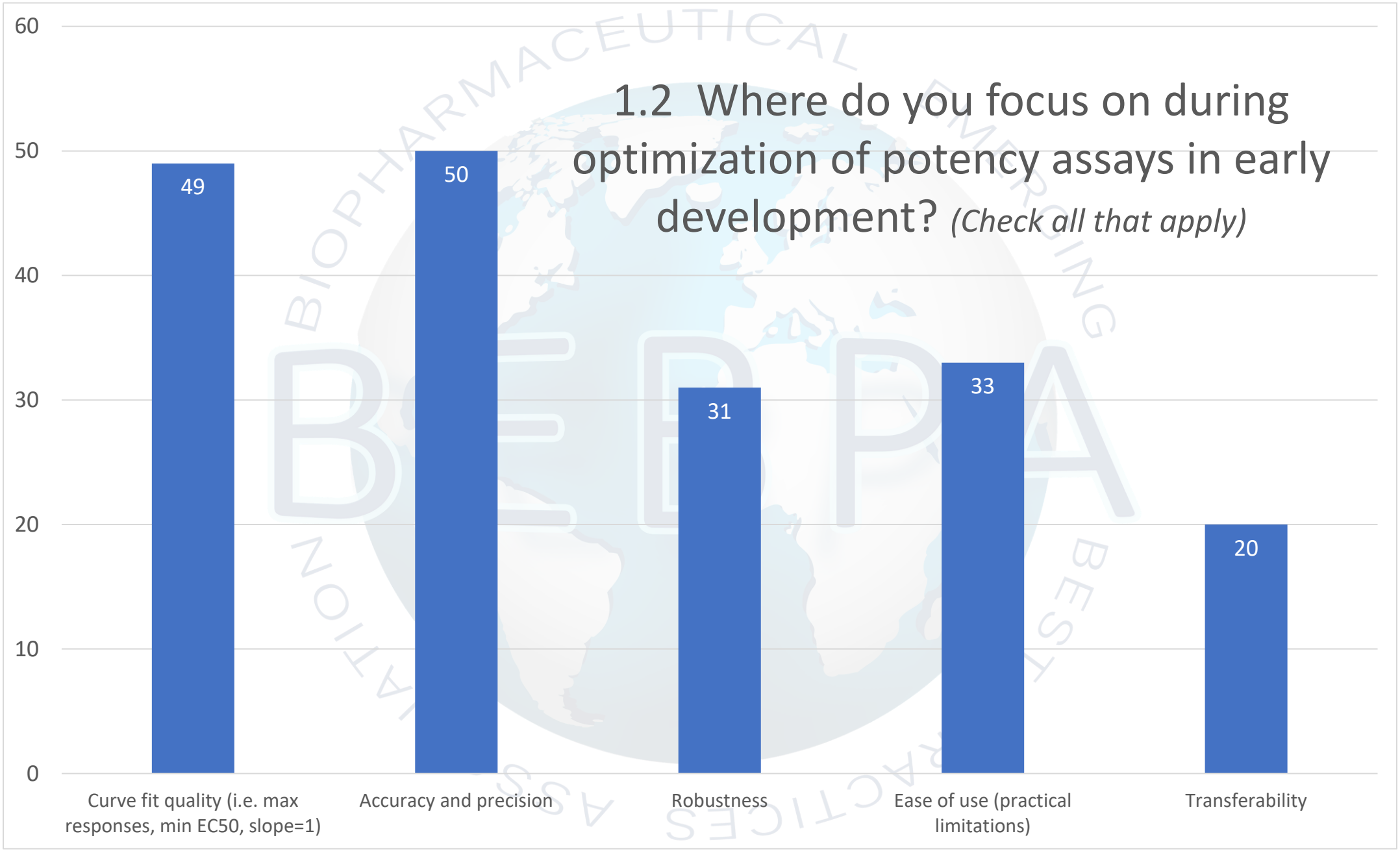
Session 1: Developing Potency Bioassays

Session Chair: Laureen Little

1.1 How often do you use USP-NF in a typical month?

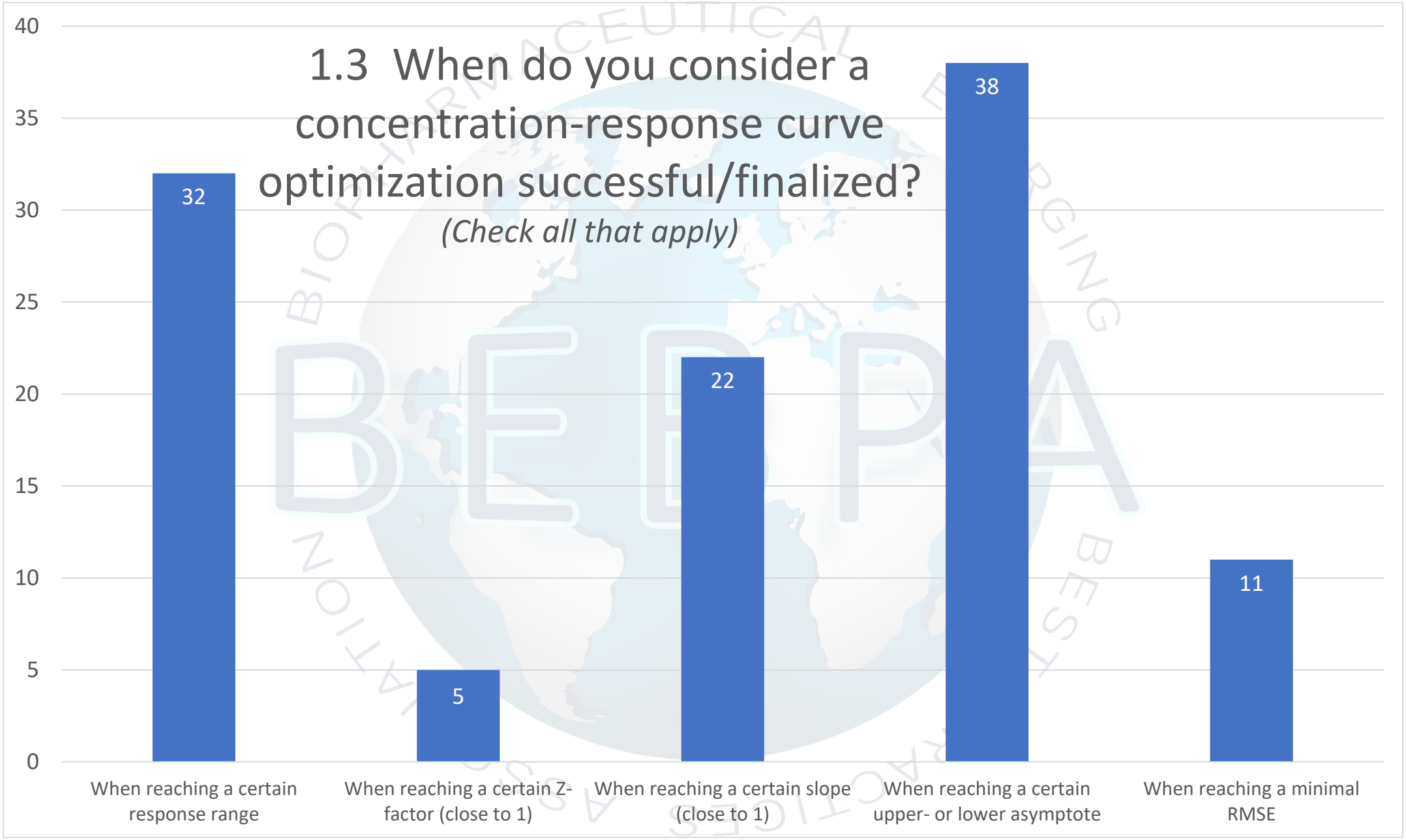


1.2 Where do you focus on during optimization of potency assays in early development? *(Check all that apply)*



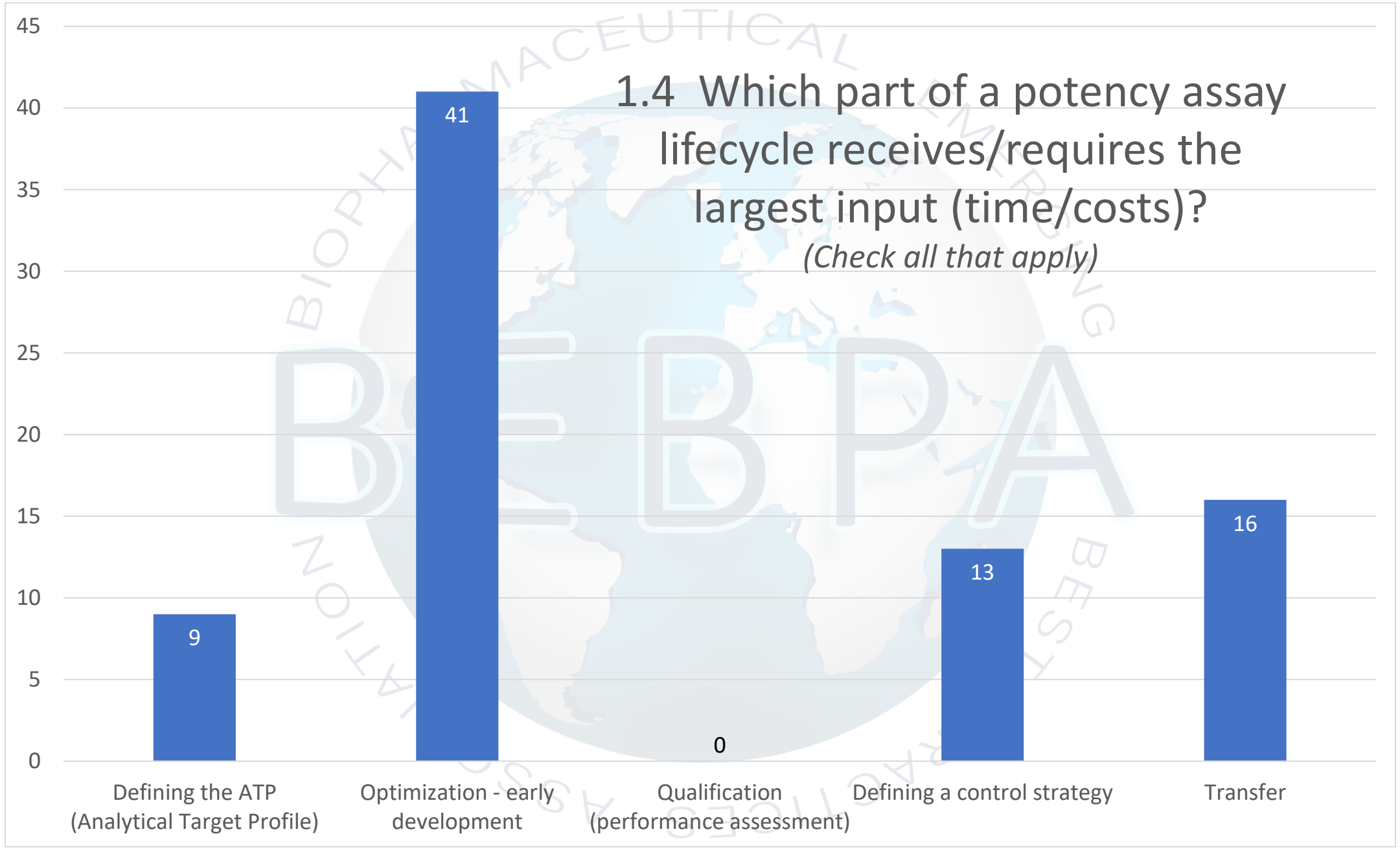
1.3 When do you consider a concentration-response curve optimization successful/finalized?

(Check all that apply)



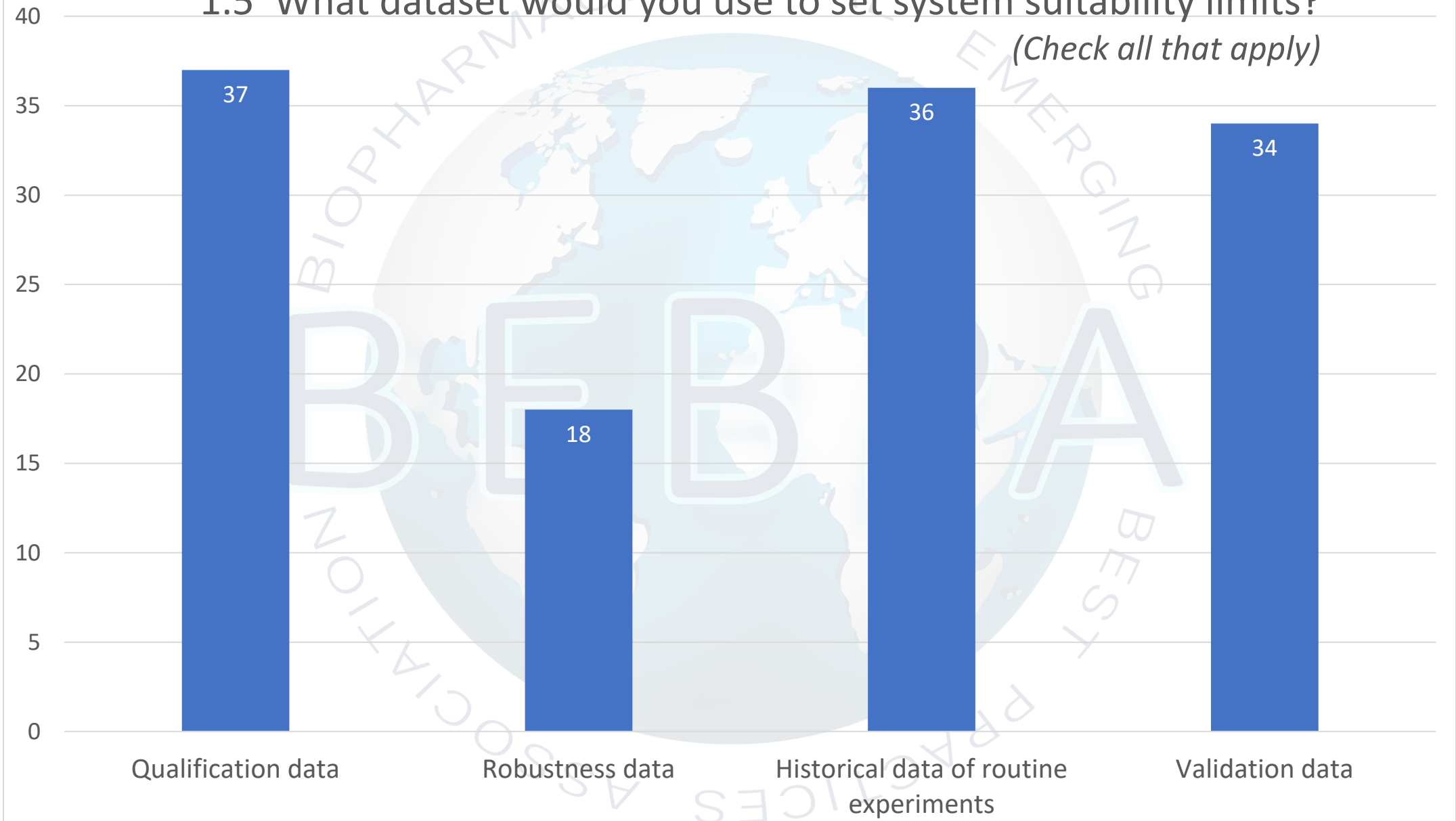
1.4 Which part of a potency assay lifecycle receives/requires the largest input (time/costs)?

(Check all that apply)

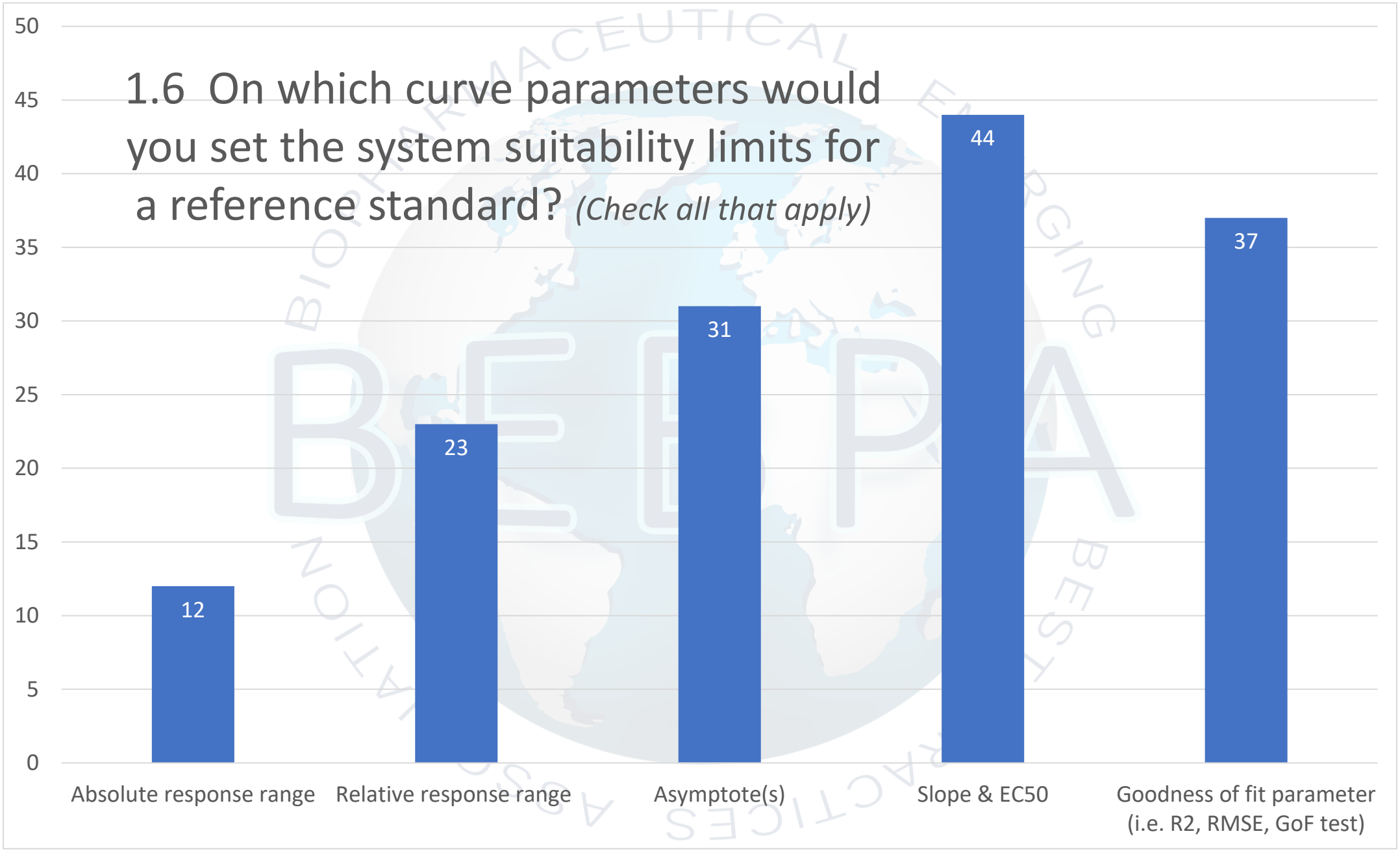


1.5 What dataset would you use to set system suitability limits?

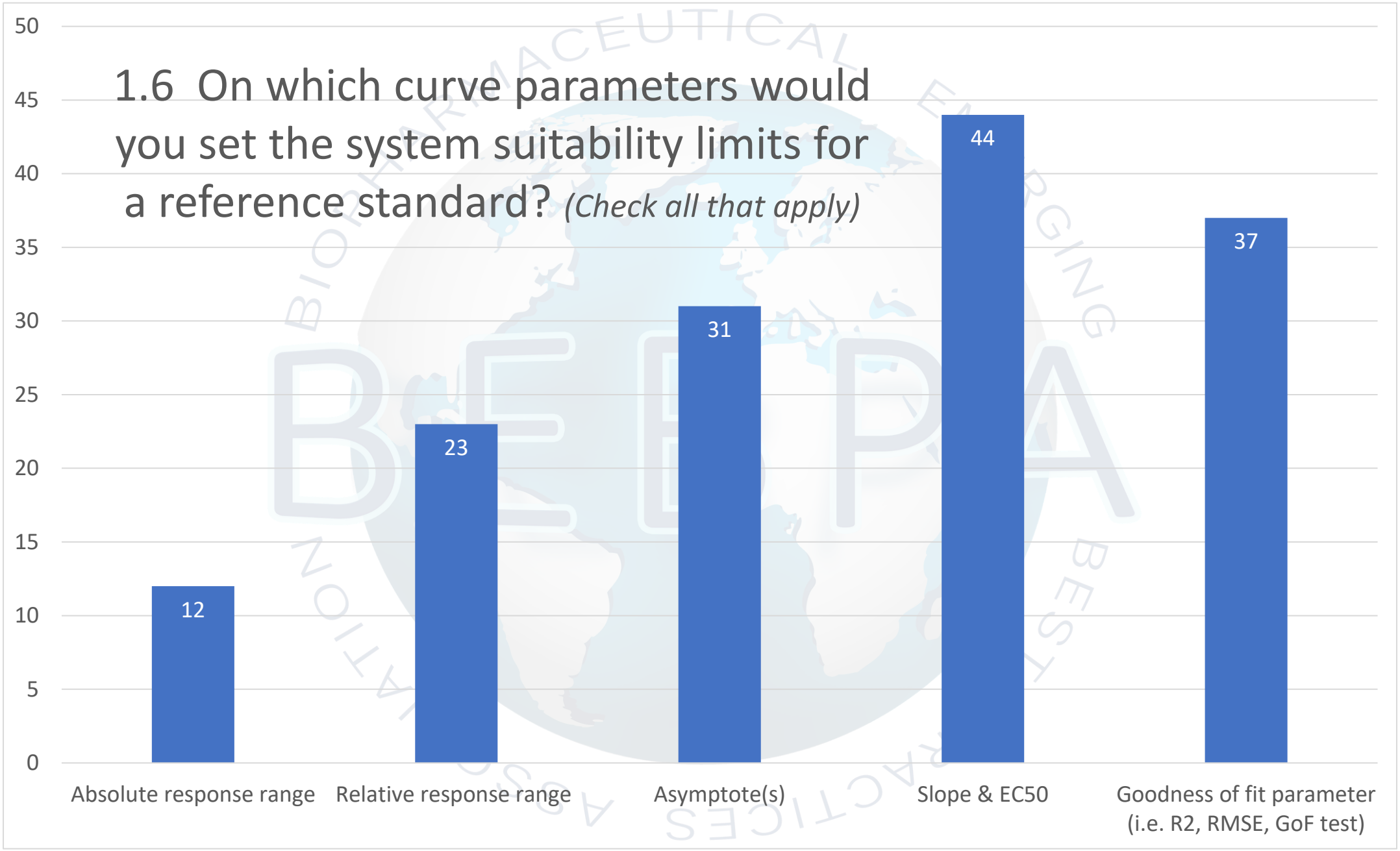
(Check all that apply)



1.6 On which curve parameters would you set the system suitability limits for a reference standard? *(Check all that apply)*

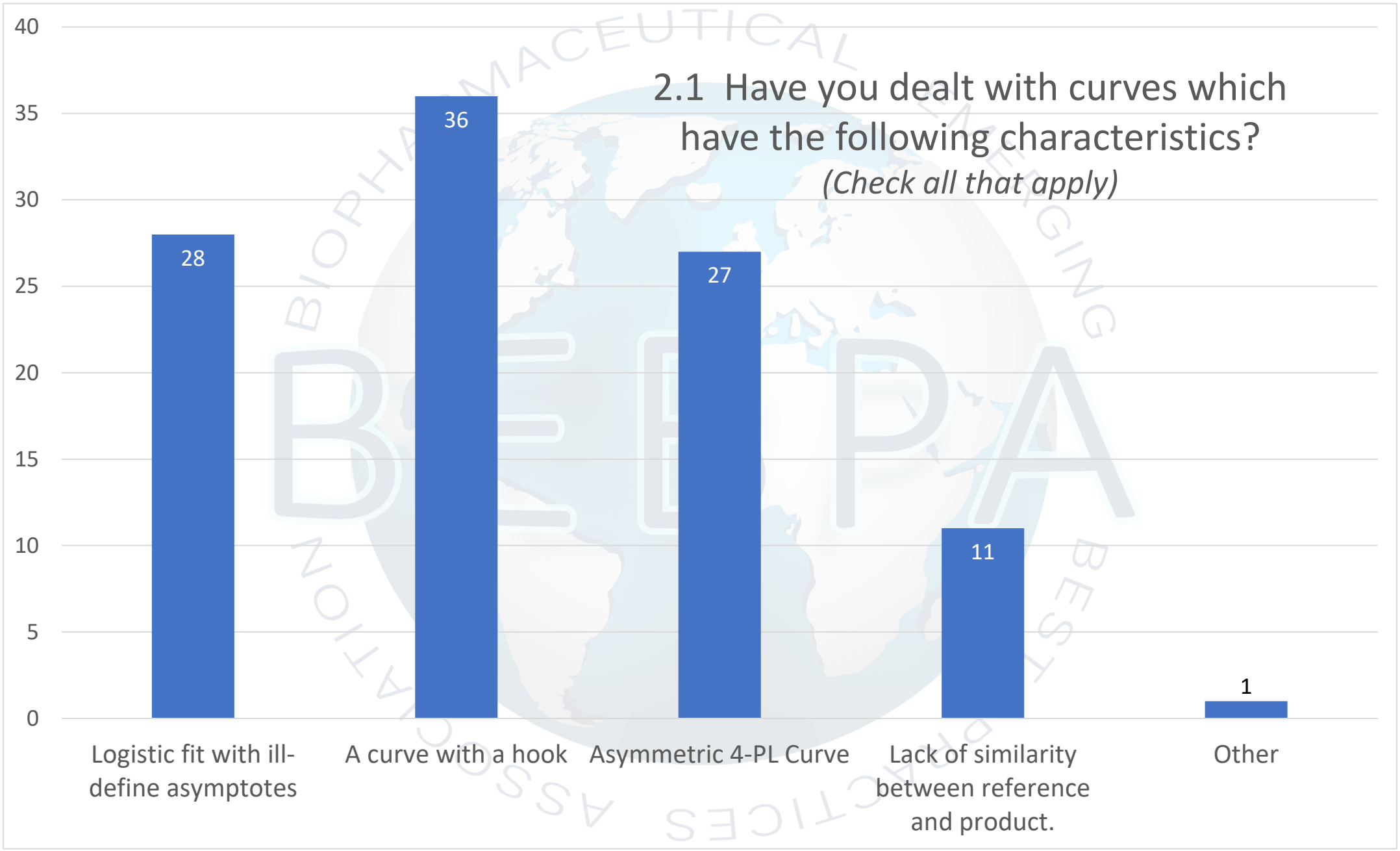


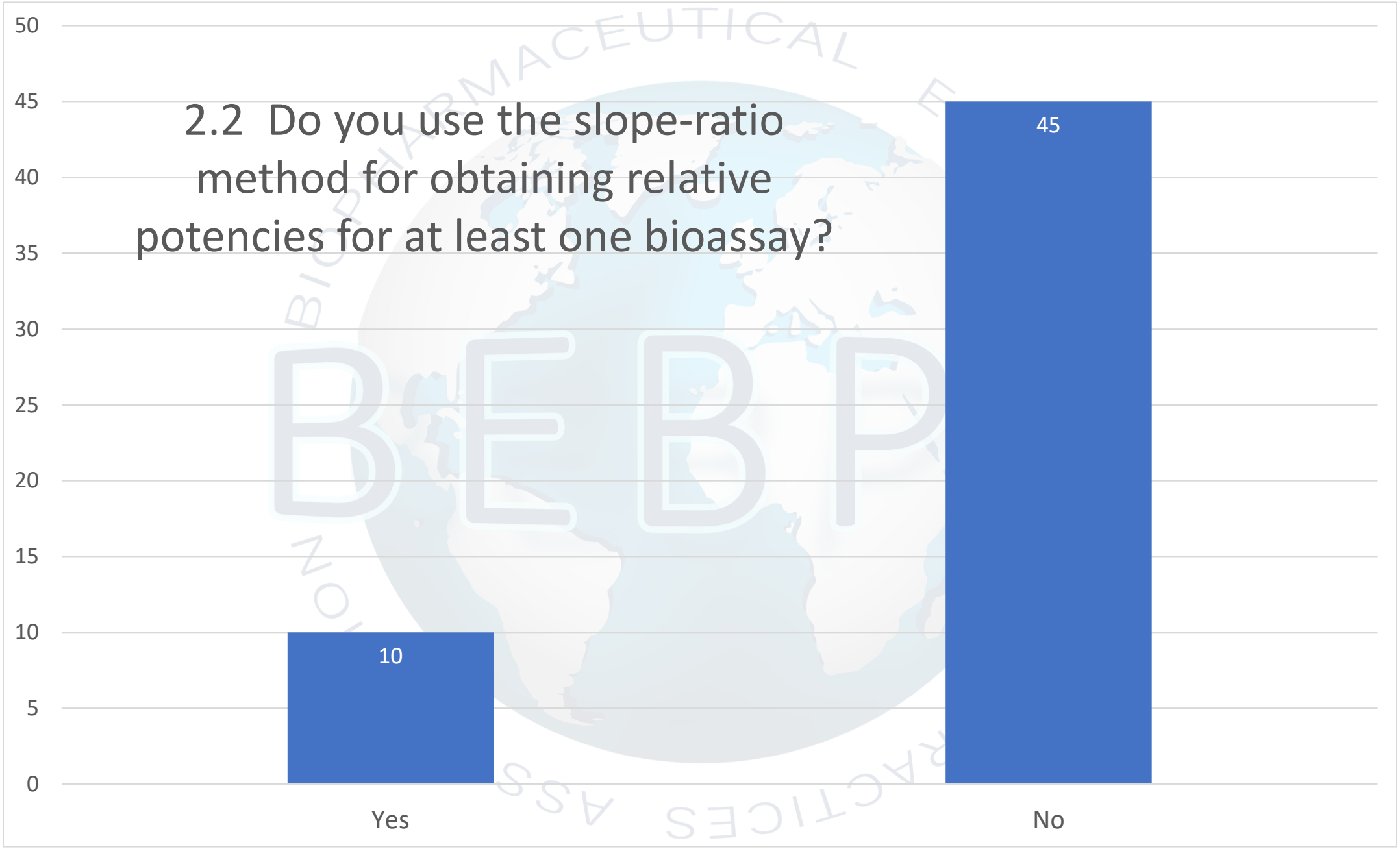
1.6 On which curve parameters would you set the system suitability limits for a reference standard? *(Check all that apply)*



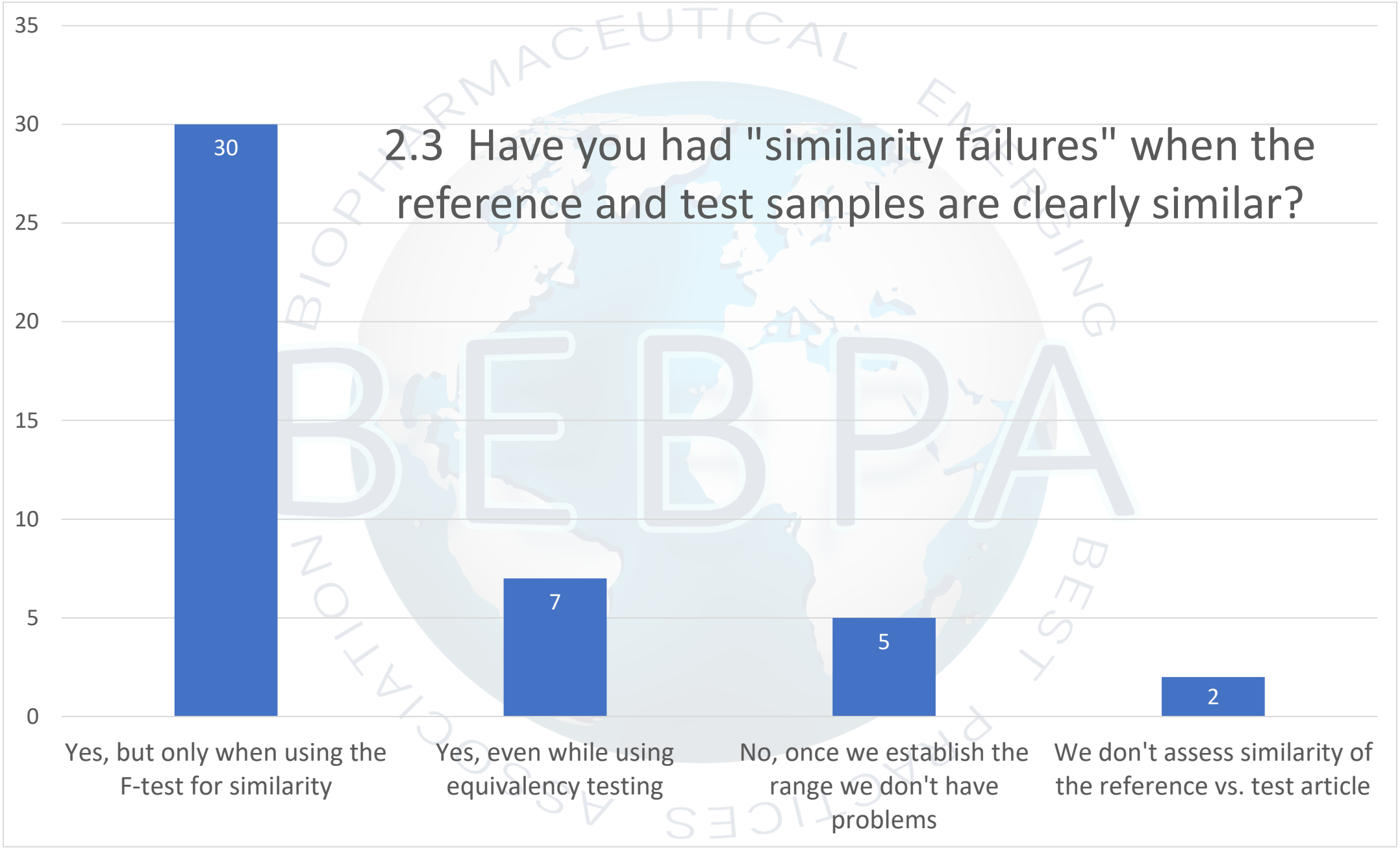
Session 2: Dealing with “Unorthodox” Dose-Response Curves

Session Chair: Perceval Sondag


2.1 Have you dealt with curves which have the following characteristics?
(Check all that apply)
40
35
30
25
20
15
10
5
0
28
36
27
11
1
Logistic fit with ill-define asymptotes
A curve with a hook
Asymmetric 4-PL Curve
Lack of similarity between reference and product.
Other

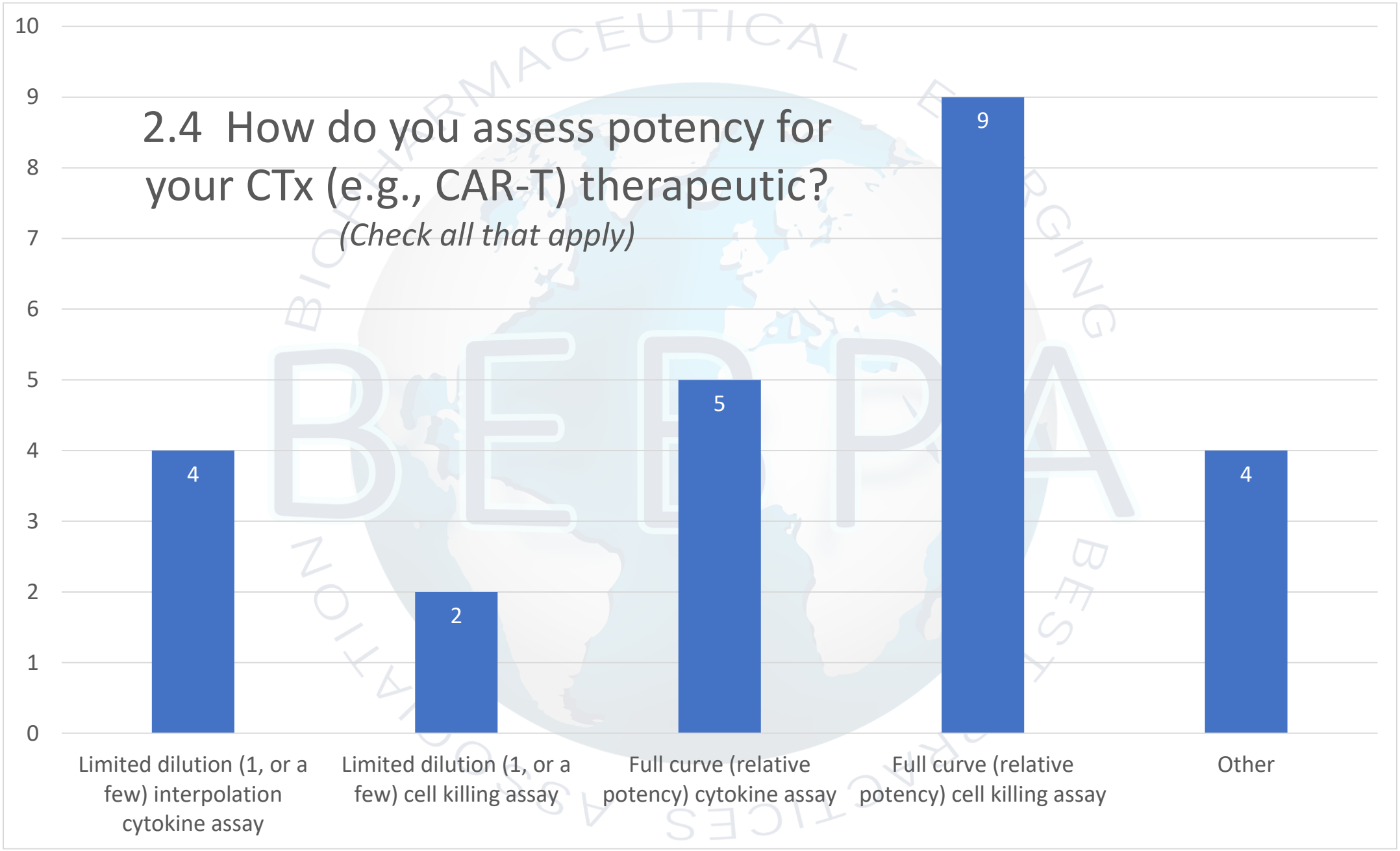

2.2 Do you use the slope-ratio method for obtaining relative potencies for at least one bioassay?
50
45
40
35
30
25
20
15
10
5
0
10
45
Yes
No

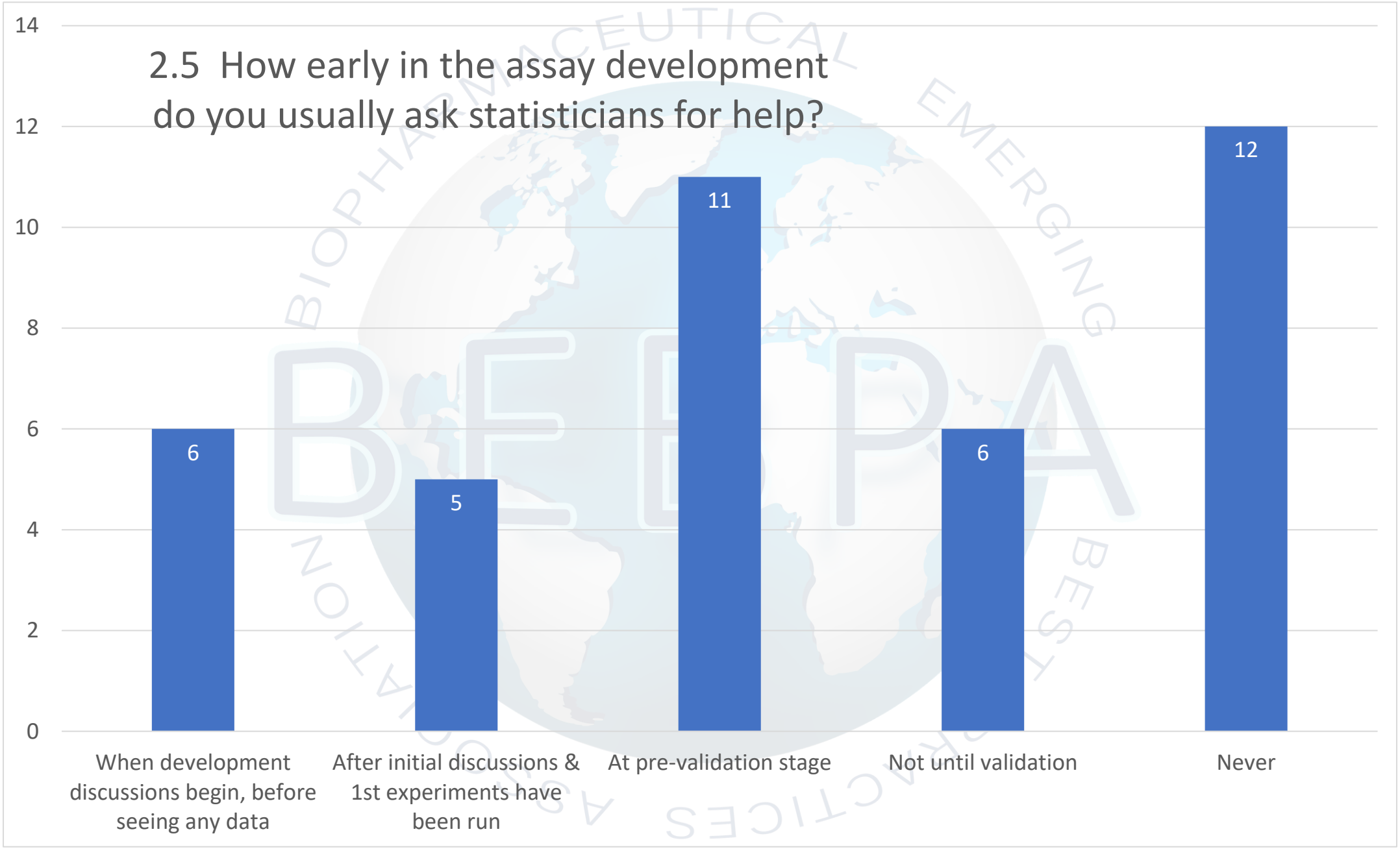
2.3 Have you had "similarity failures" when the reference and test samples are clearly similar?



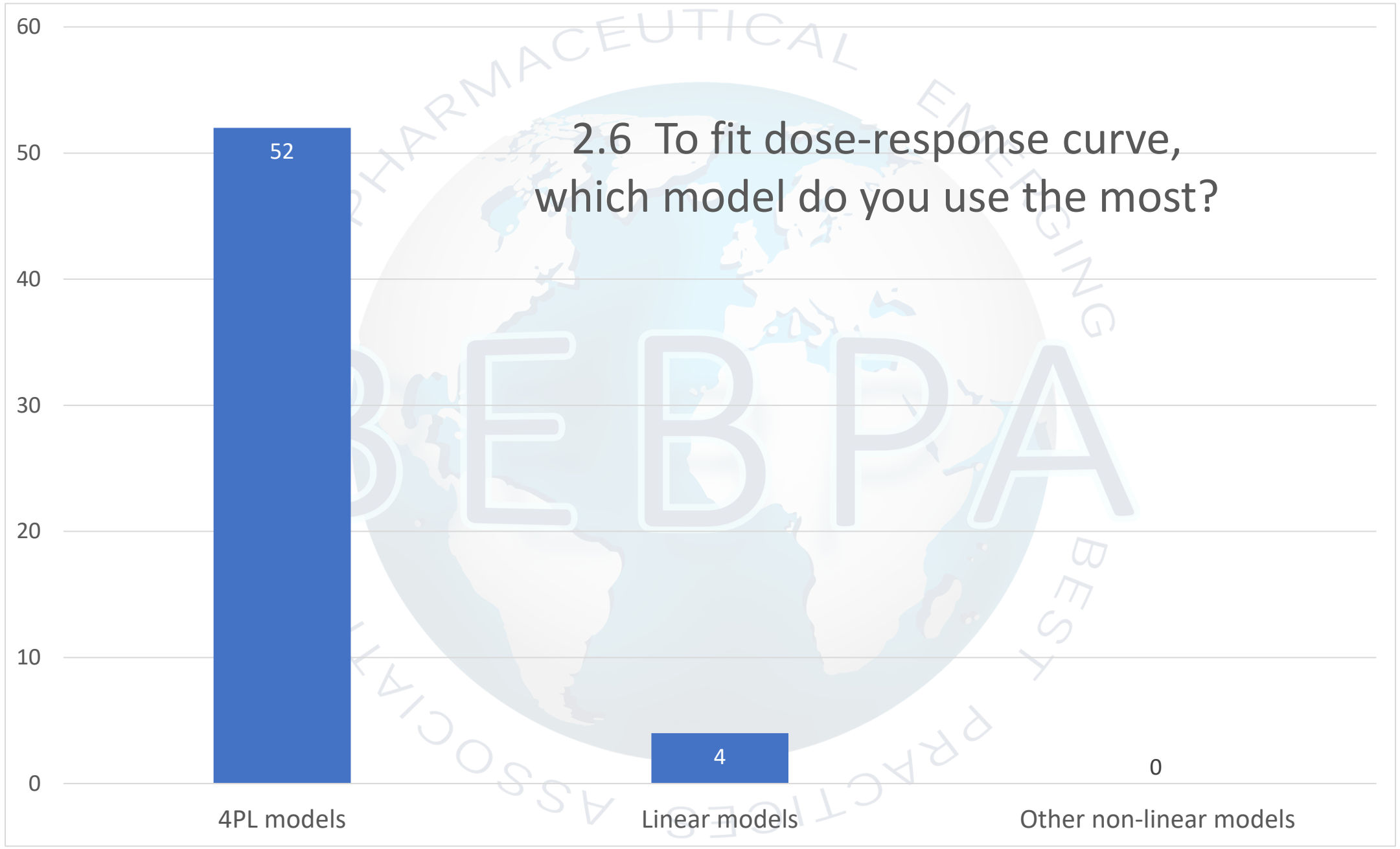
2.4 How do you assess potency for your CTx (e.g., CAR-T) therapeutic?

(Check all that apply)



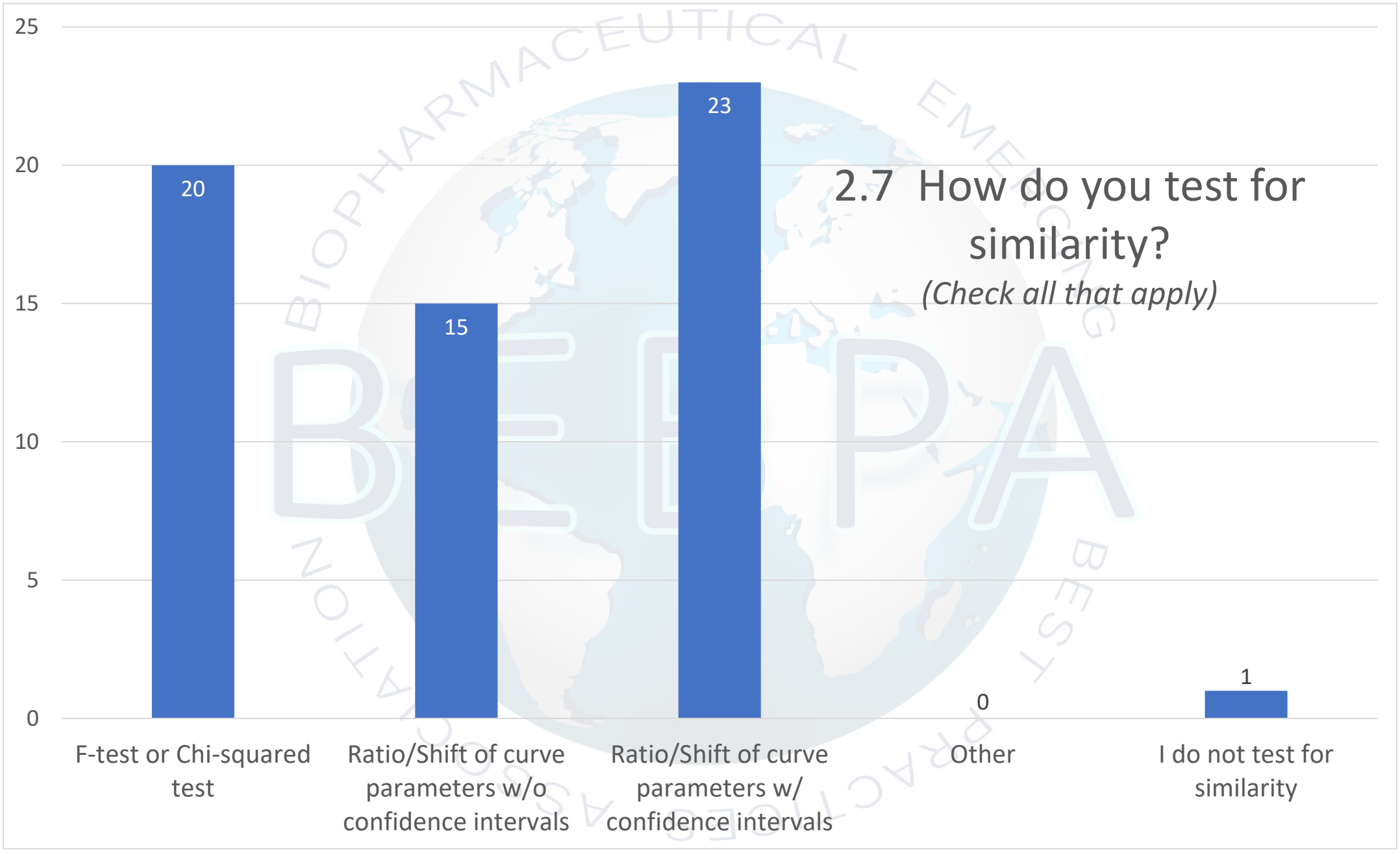

2.5 How early in the assay development do you usually ask statisticians for help?
14
12
10
8
6
4
2
0
6
5
11
6
12
When development discussions begin, before seeing any data
After initial discussions & 1st experiments have been run
At pre-validation stage
Not until validation
Never

2.6 To fit dose-response curve, which model do you use the most?



2.7 How do you test for similarity?

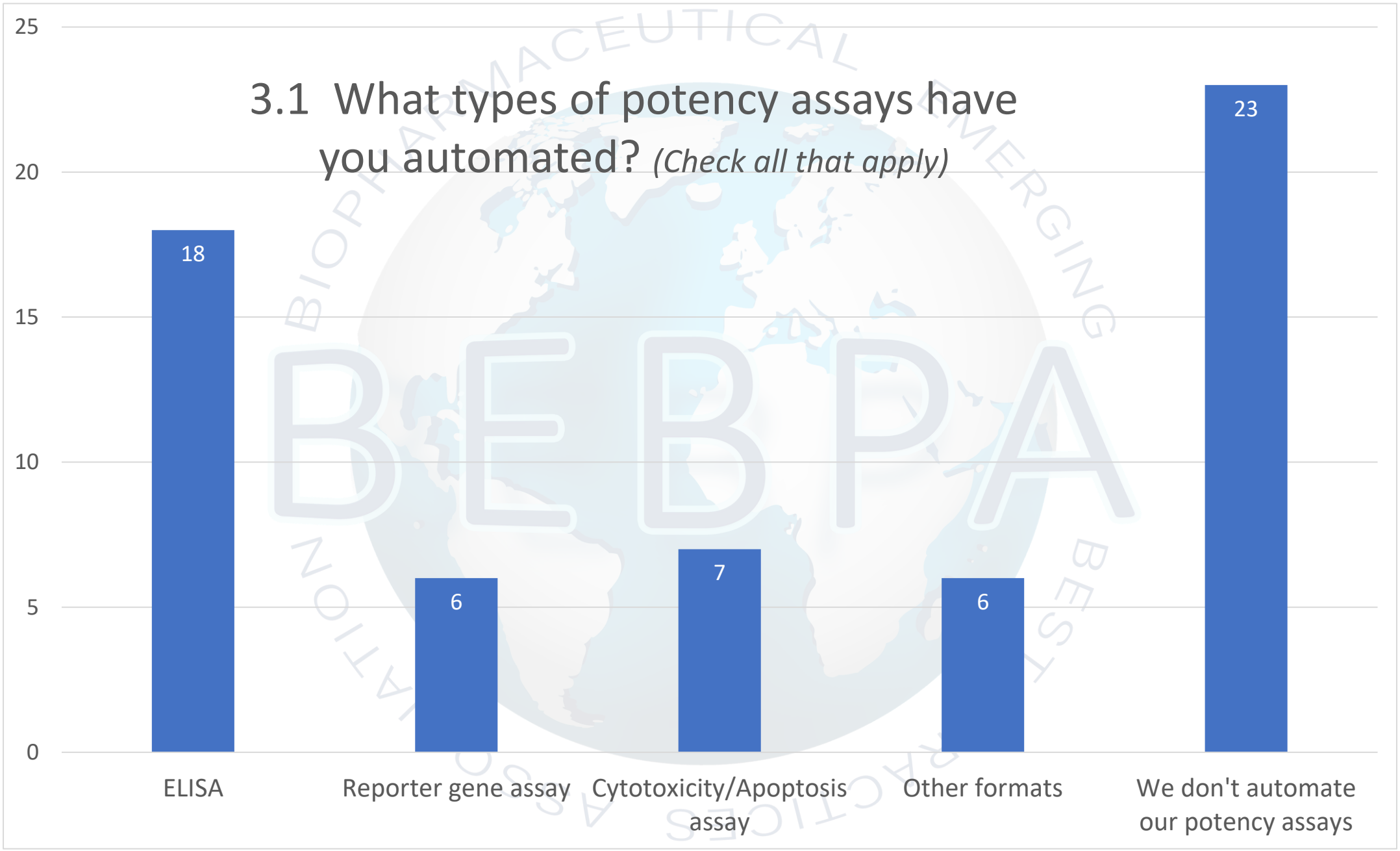
(Check all that apply)



Session 3: Looking Forward: Automation Miniaturized Bioassays and Novel Statistical Approaches

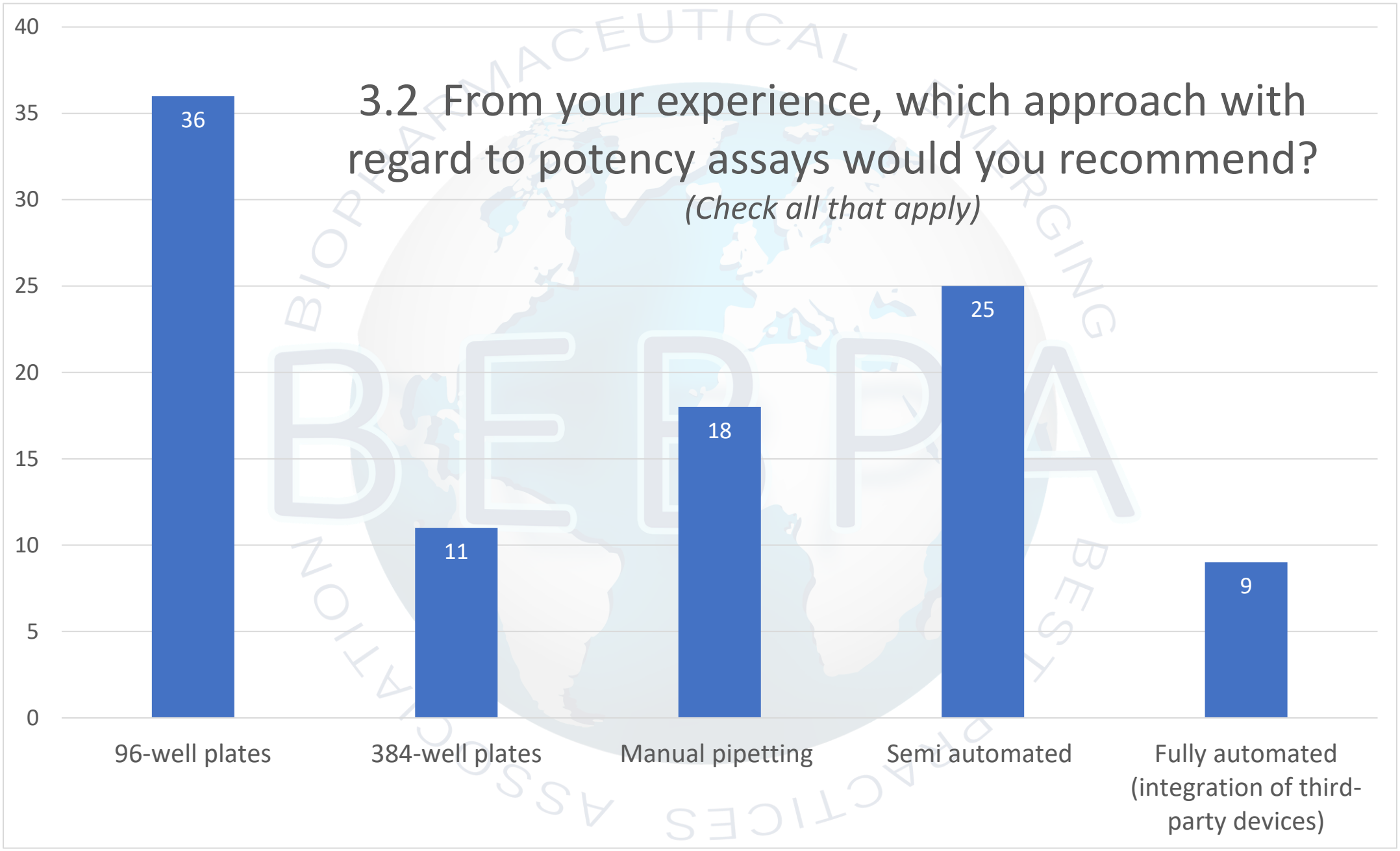
Session Chair: Steven Walfish

3.1 What types of potency assays have you automated? *(Check all that apply)*

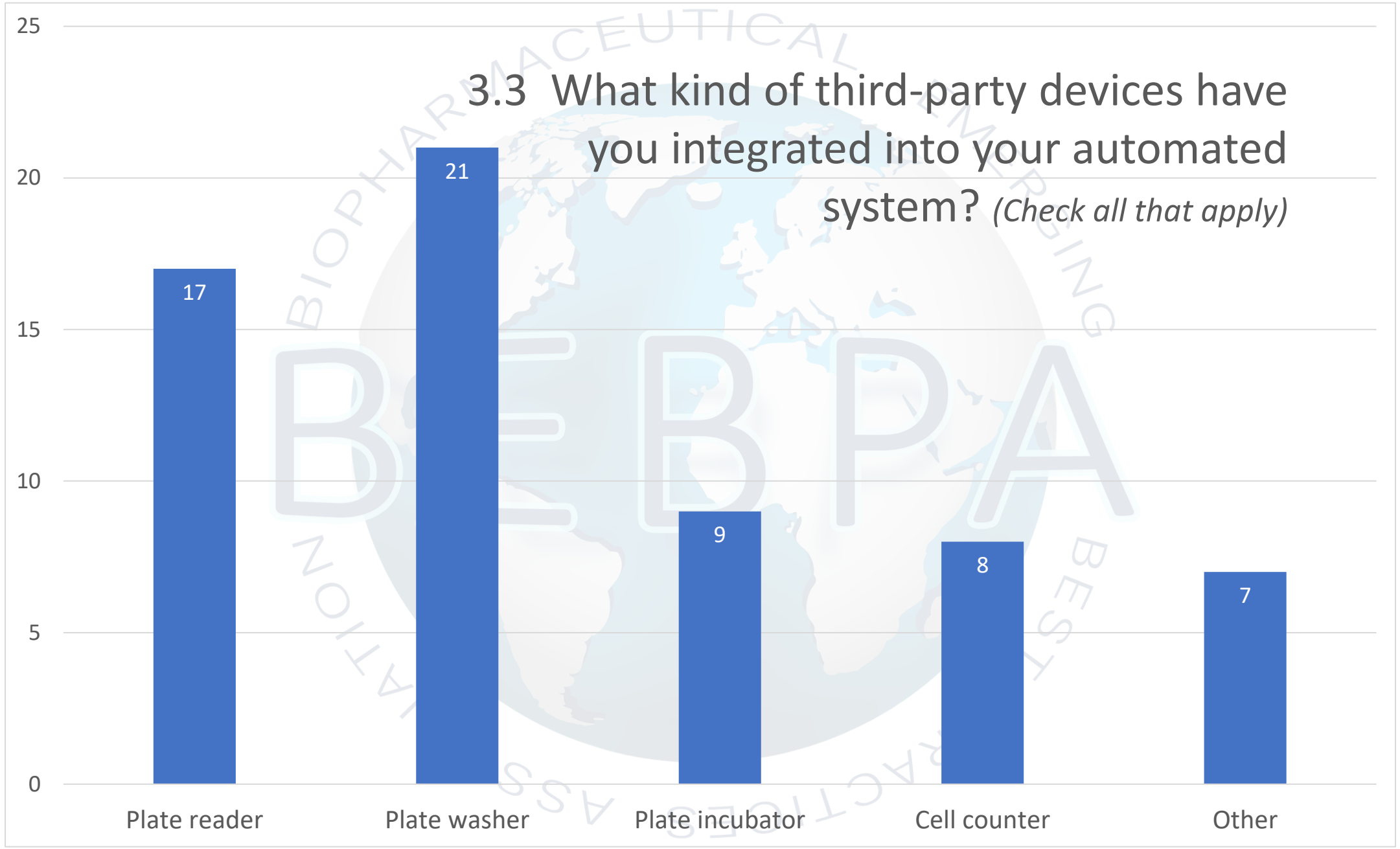


3.2 From your experience, which approach with regard to potency assays would you recommend?

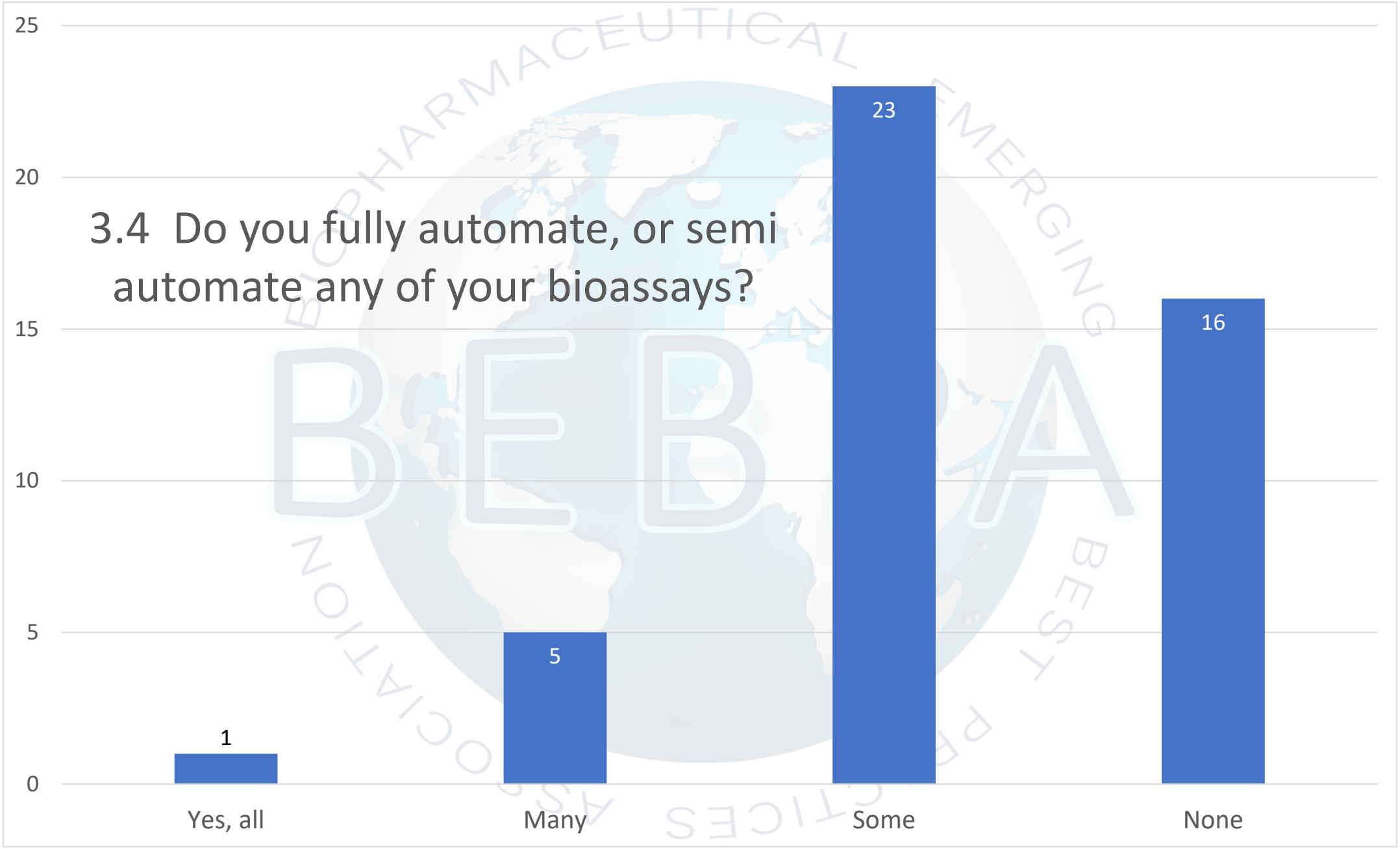
(Check all that apply)



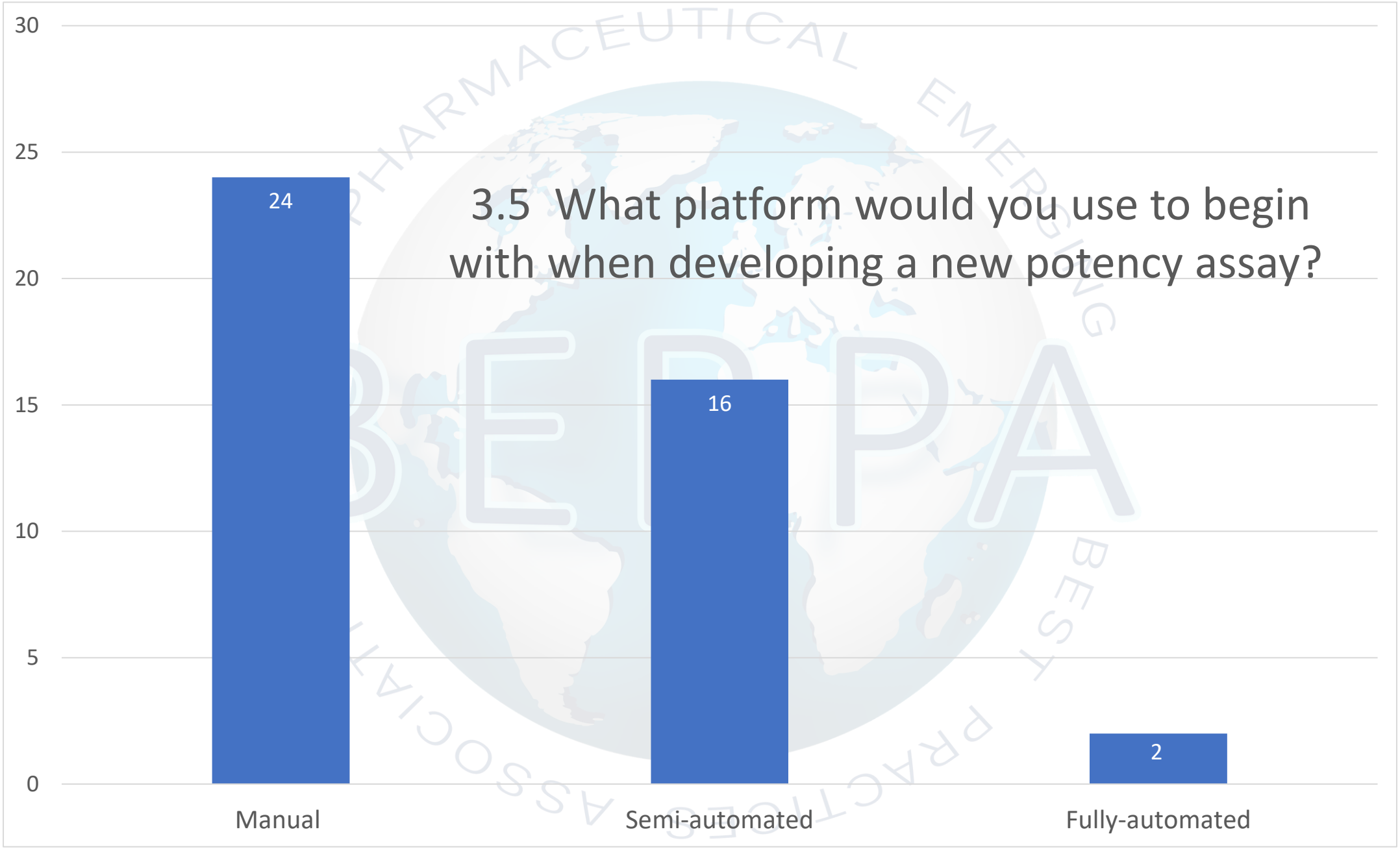
3.3 What kind of third-party devices have you integrated into your automated system? *(Check all that apply)*

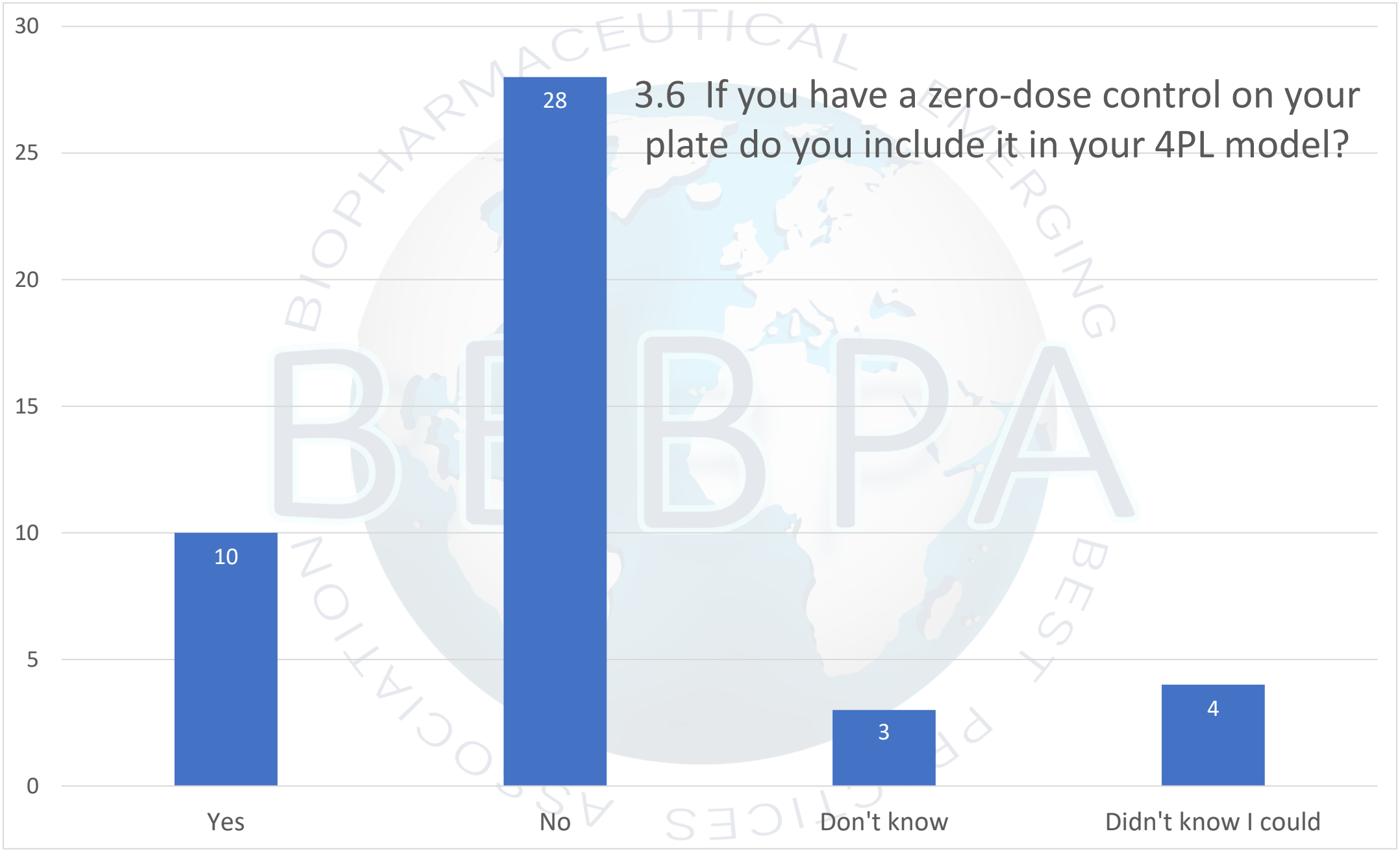


3.4 Do you fully automate, or semi automate any of your bioassays?

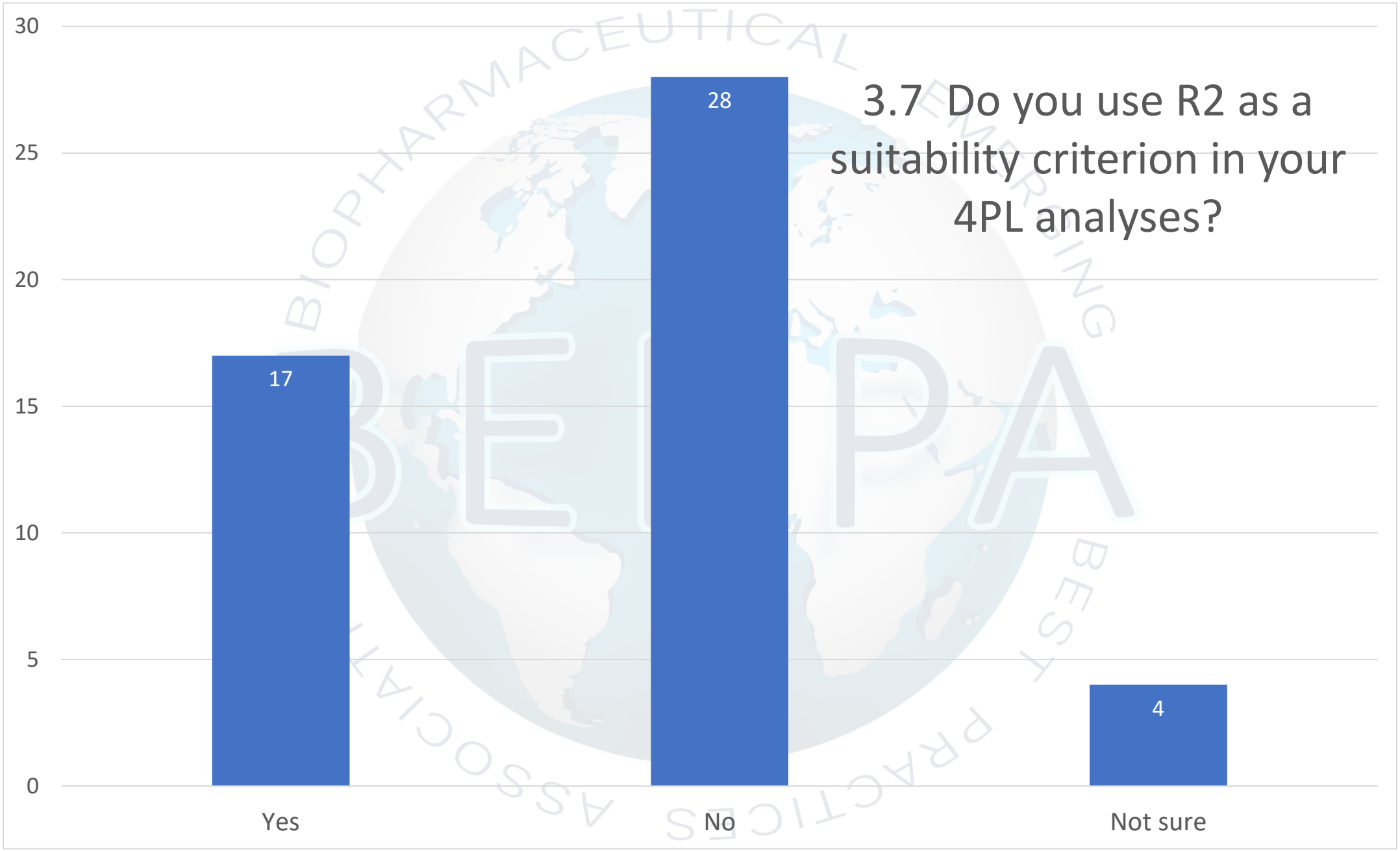


3.5 What platform would you use to begin with when developing a new potency assay?

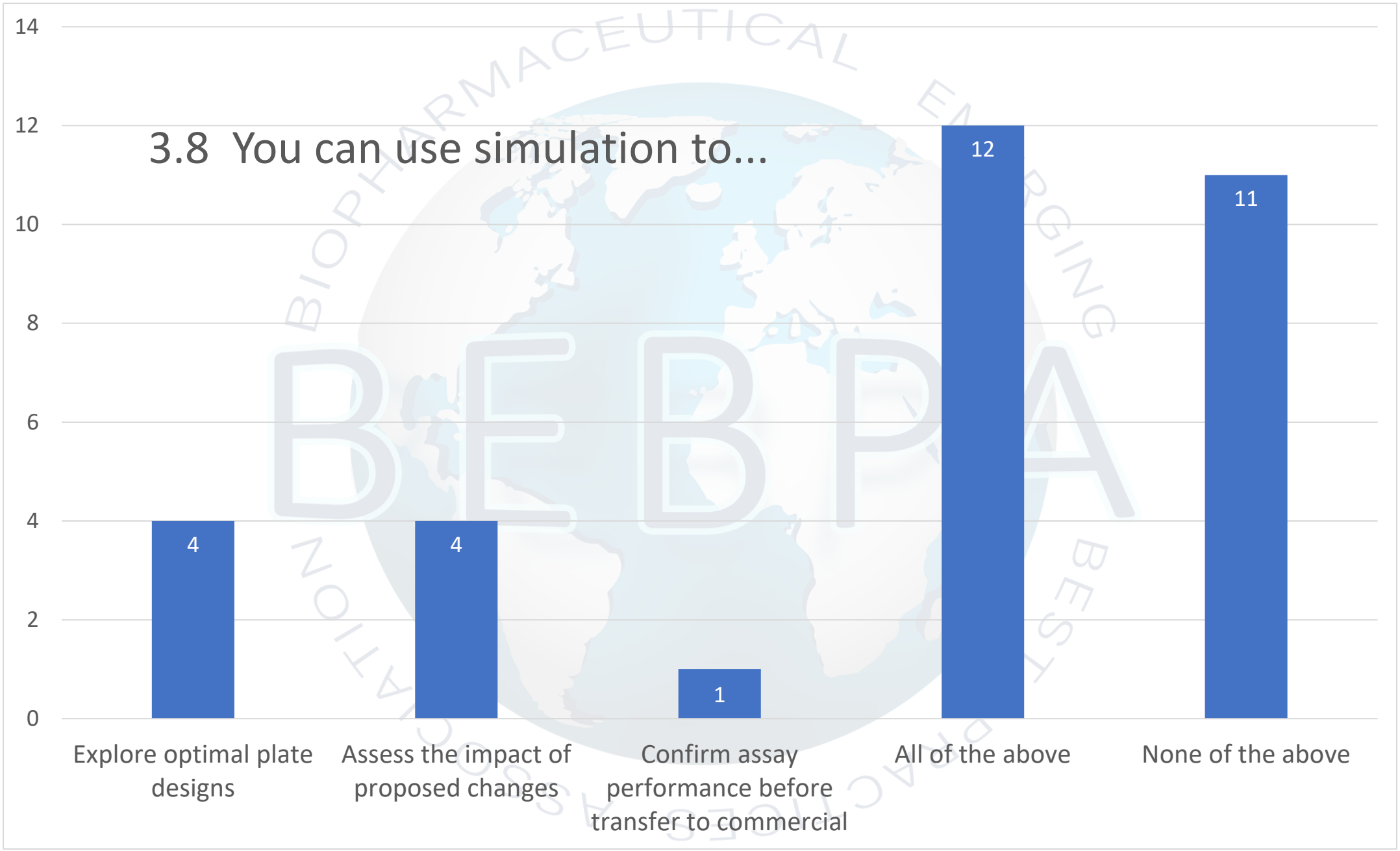



3.6 If you have a zero-dose control on your plate do you include it in your 4PL model?
30
25
20
15
10
5
0
10
28
3
4
Yes
No
Don't know
Didn't know I could

3.7 Do you use R2 as a suitability criterion in your 4PL analyses?

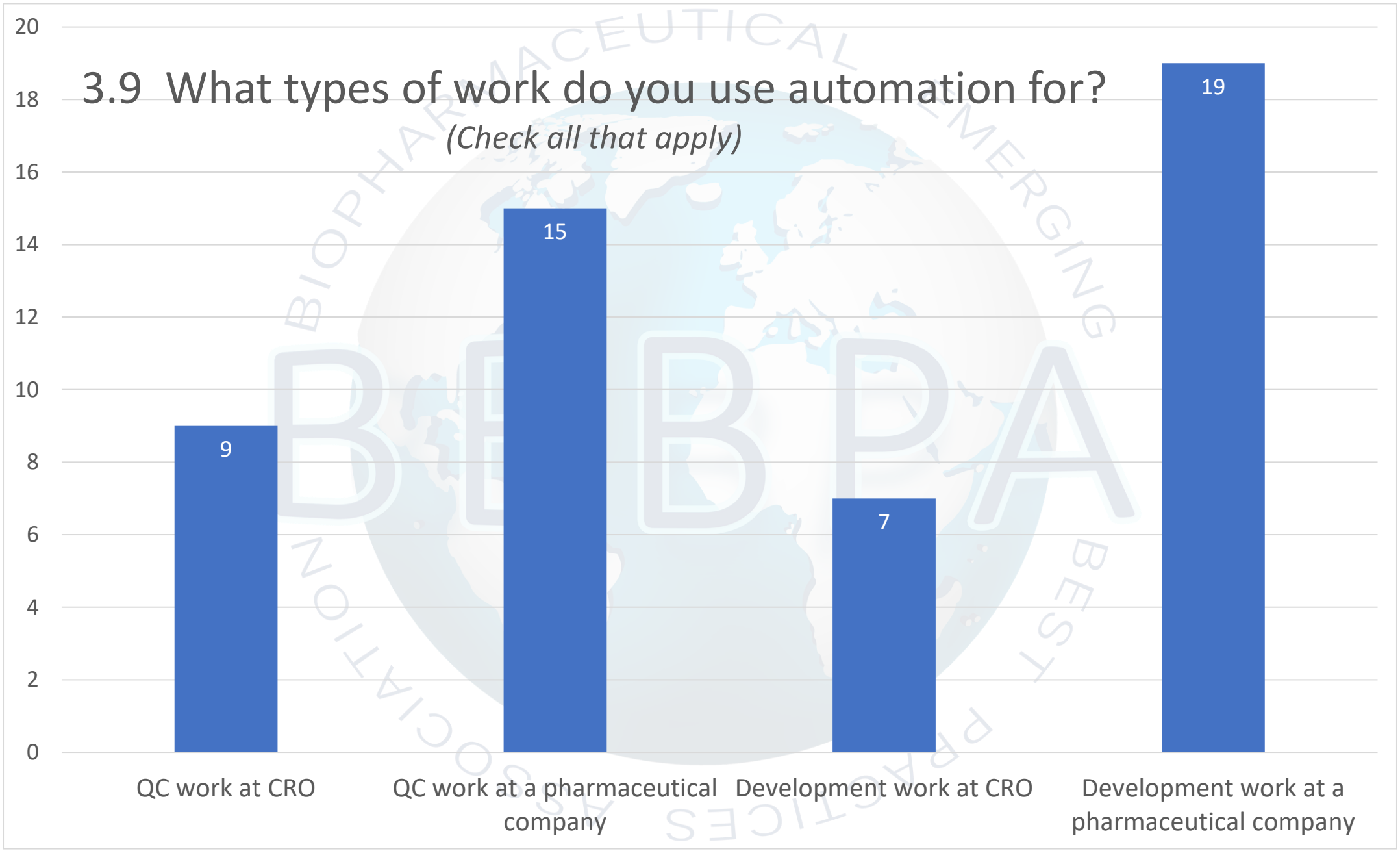


3.8 You can use simulation to...

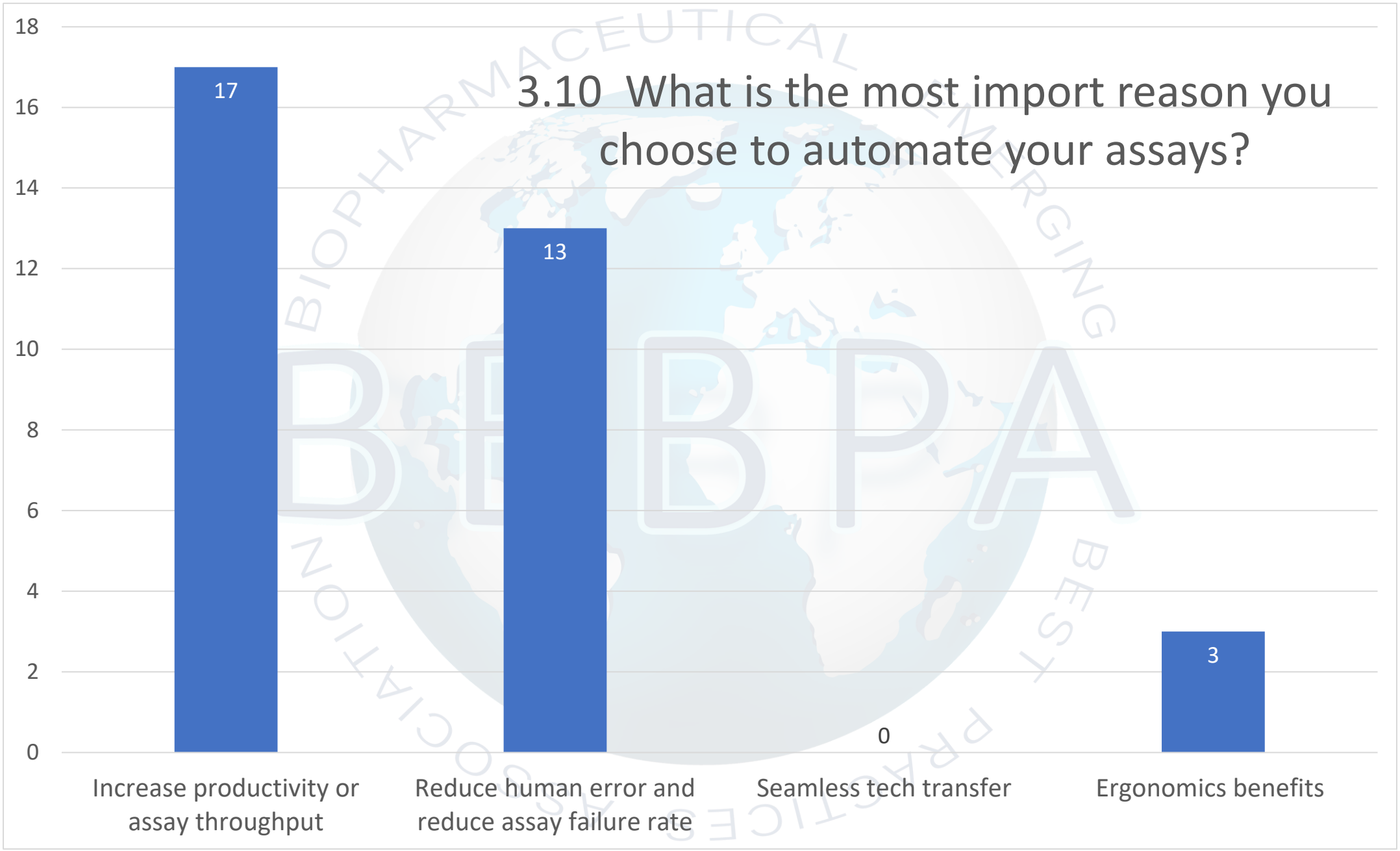


3.9 What types of work do you use automation for?

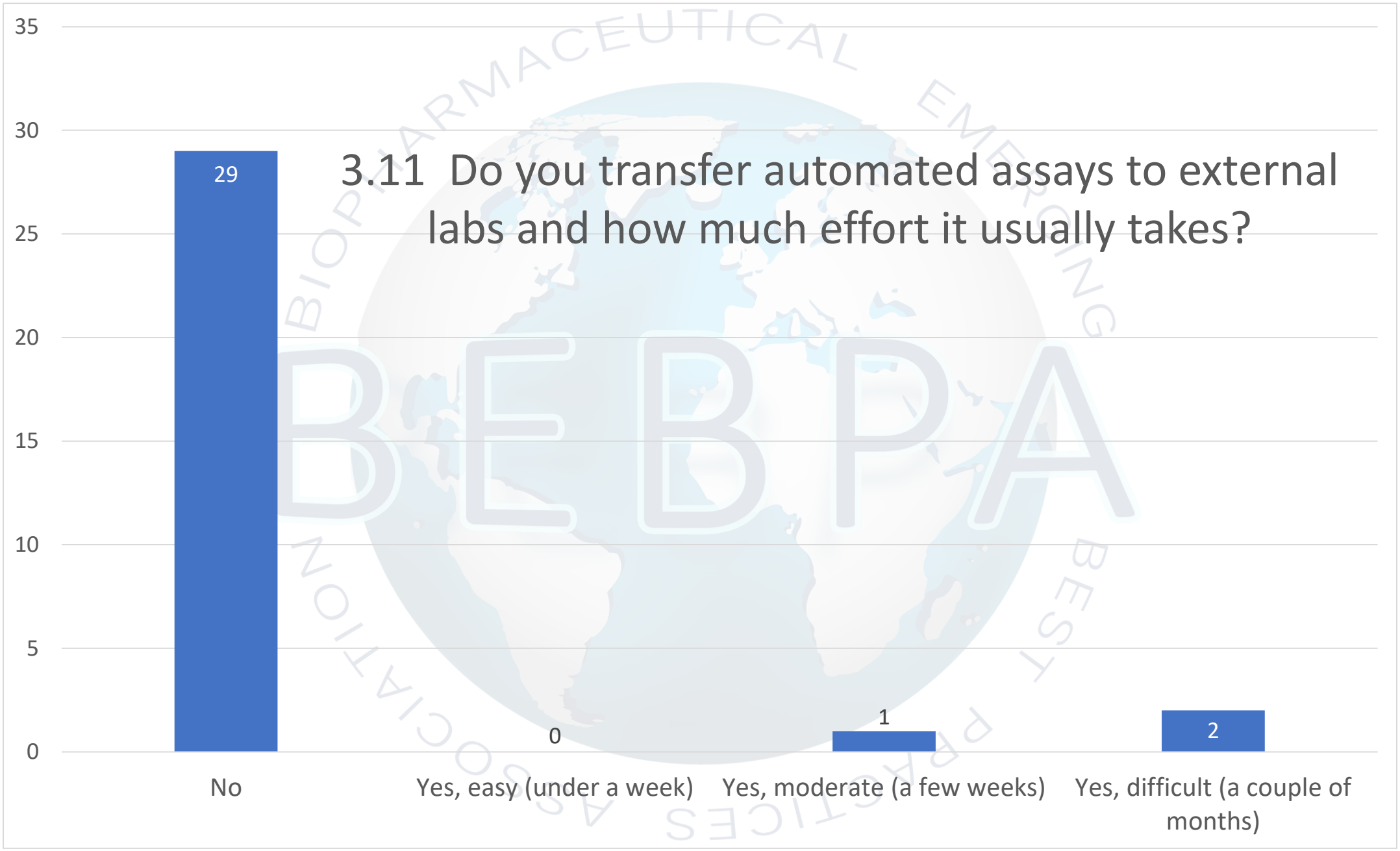
(Check all that apply)



3.10 What is the most import reason you choose to automate your assays?

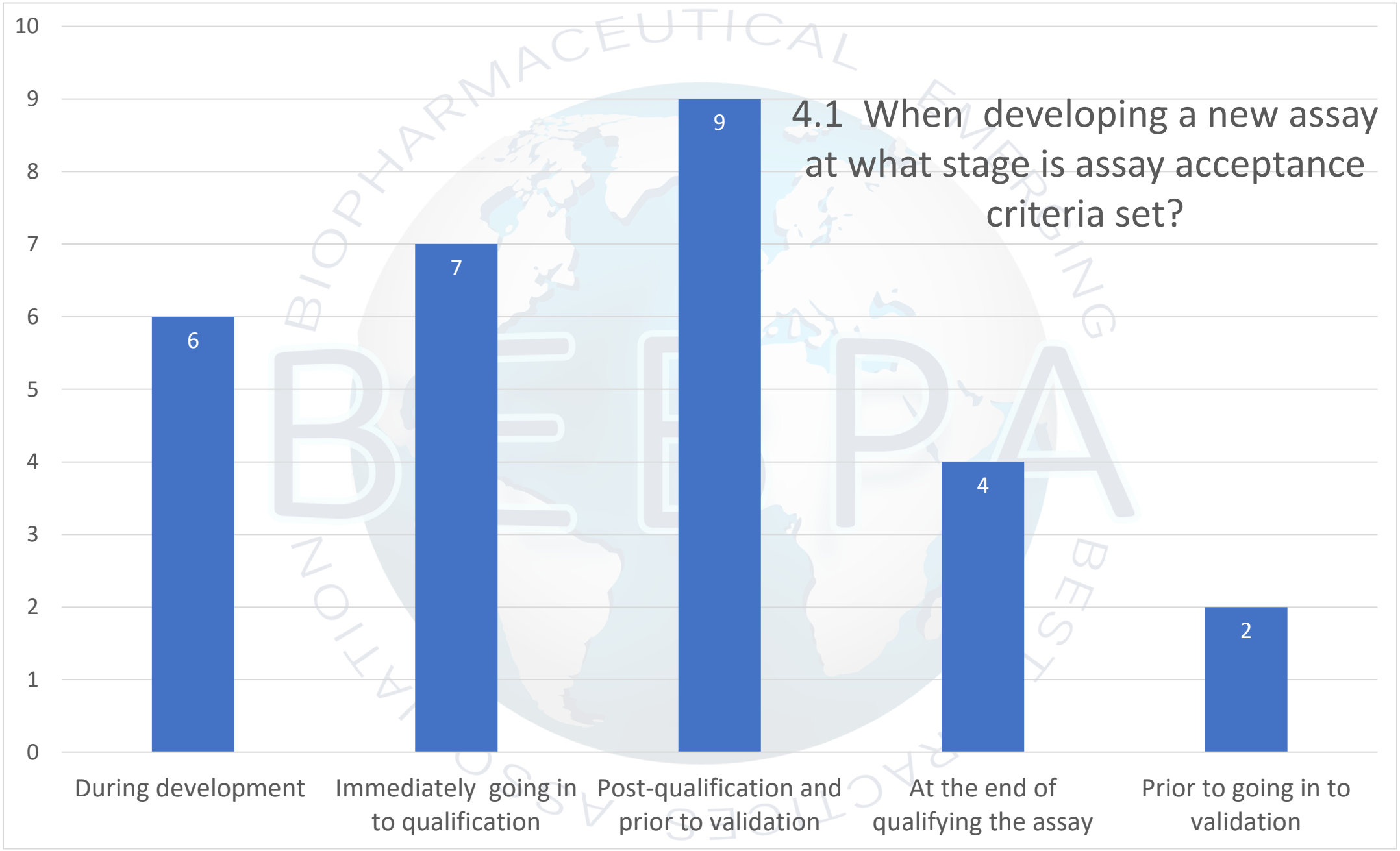


3.11 Do you transfer automated assays to external labs and how much effort it usually takes?

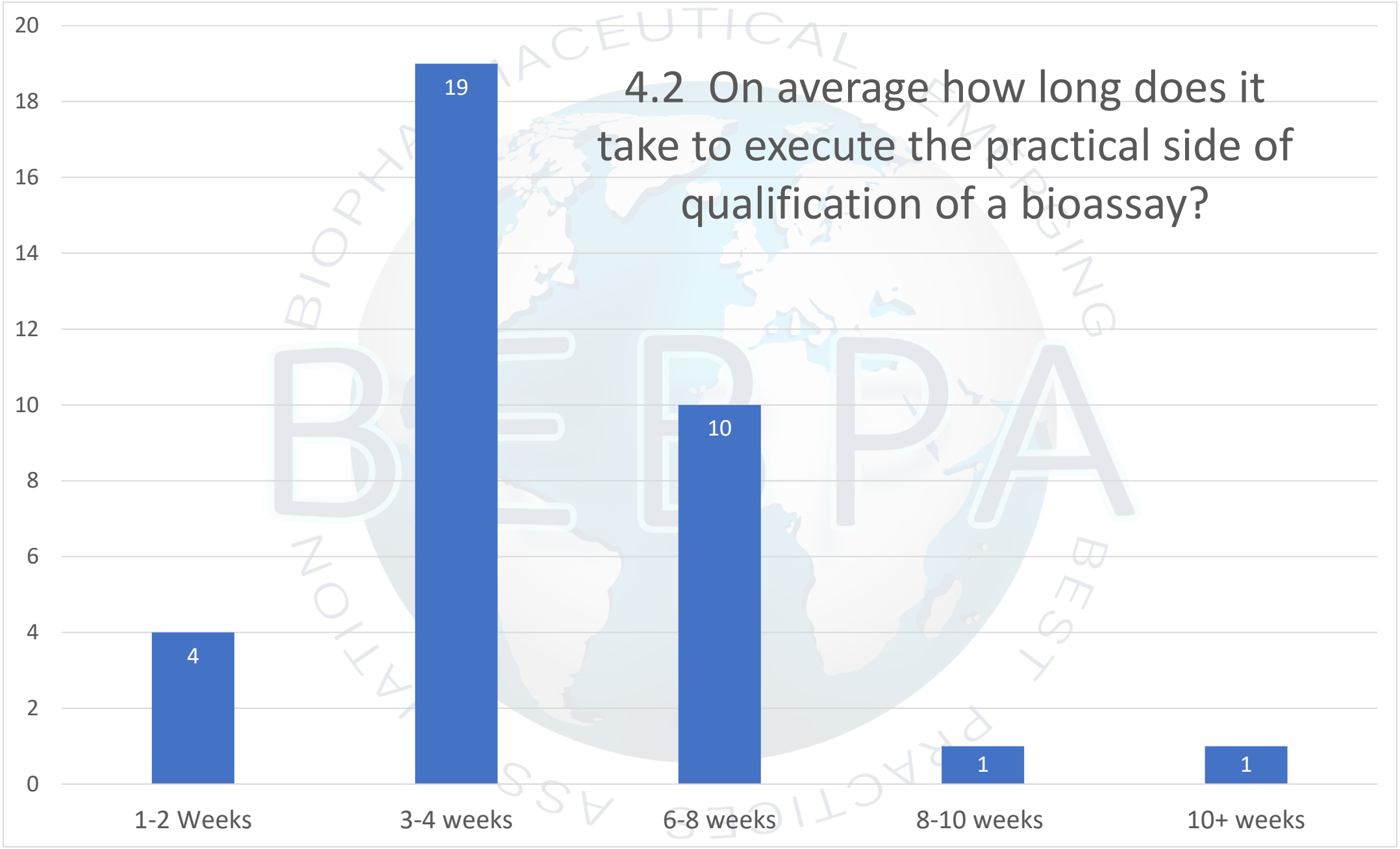


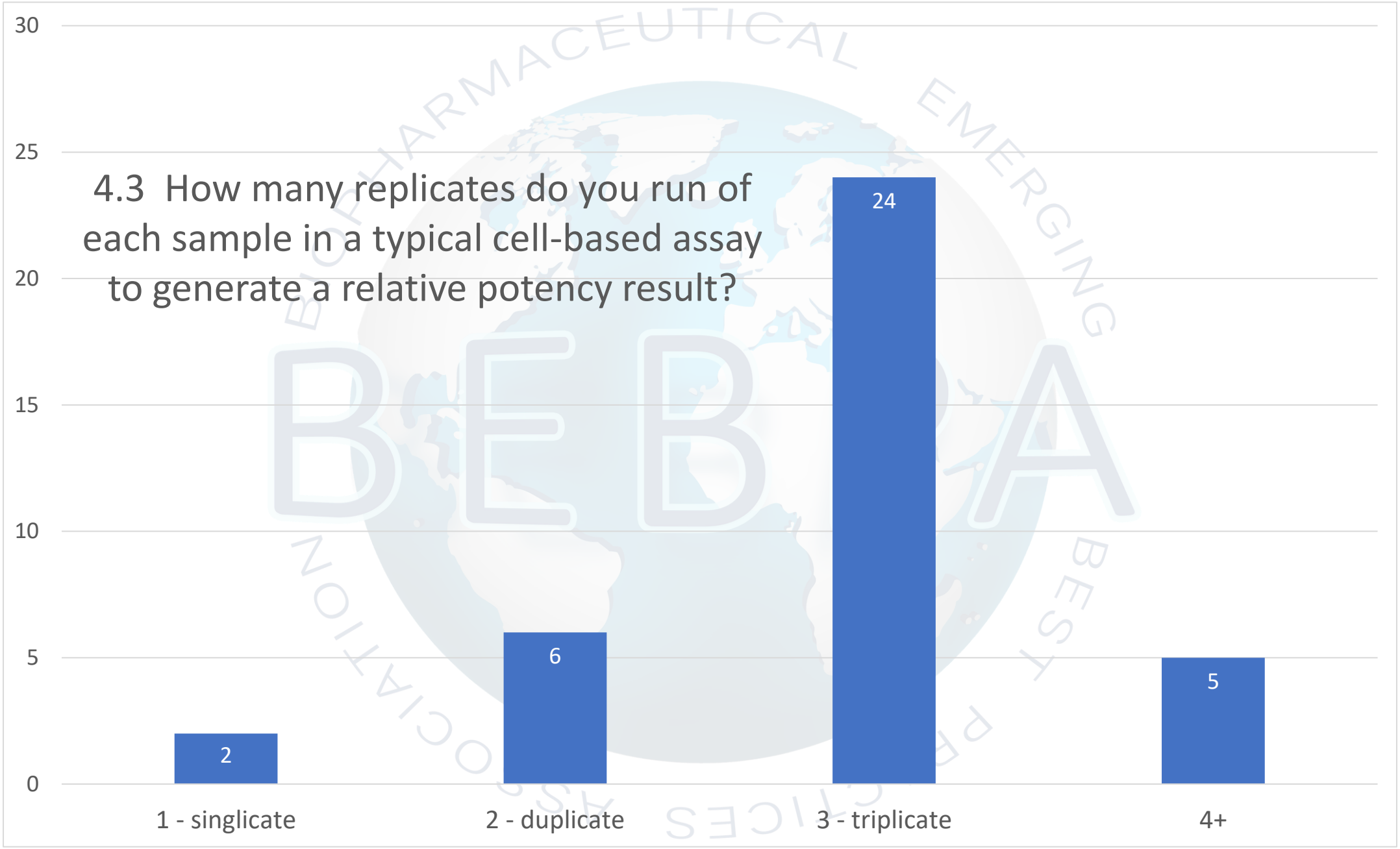
Session 4: Product Specific Case Studies

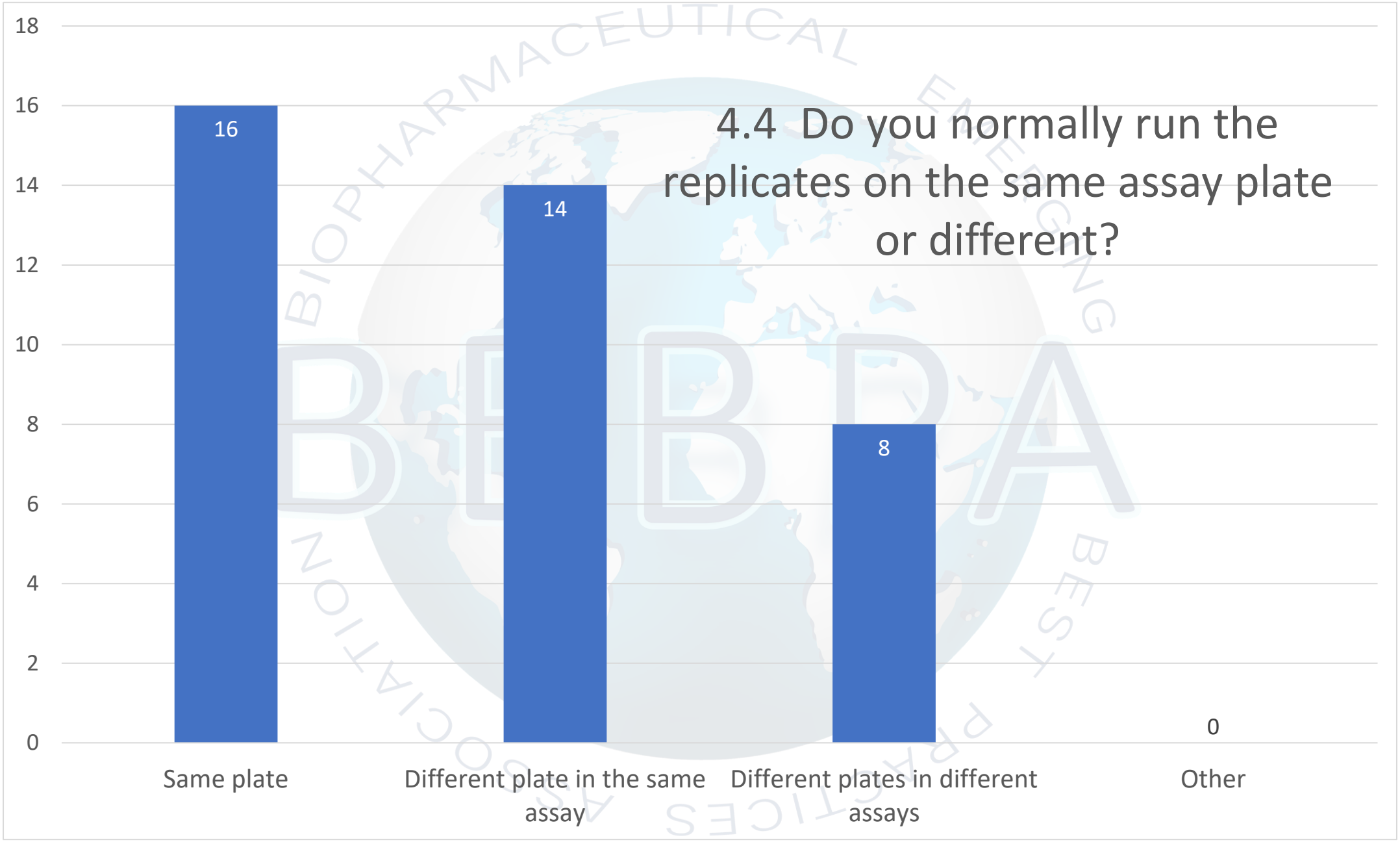
Session Chair: Sian Estdale


4.1 When developing a new assay at what stage is assay acceptance criteria set?
10
9
8
7
6
5
4
3
2
1
0
6
7
9
4
2
During development
Immediately going in to qualification
Post-qualification and prior to validation
At the end of qualifying the assay
Prior to going in to validation

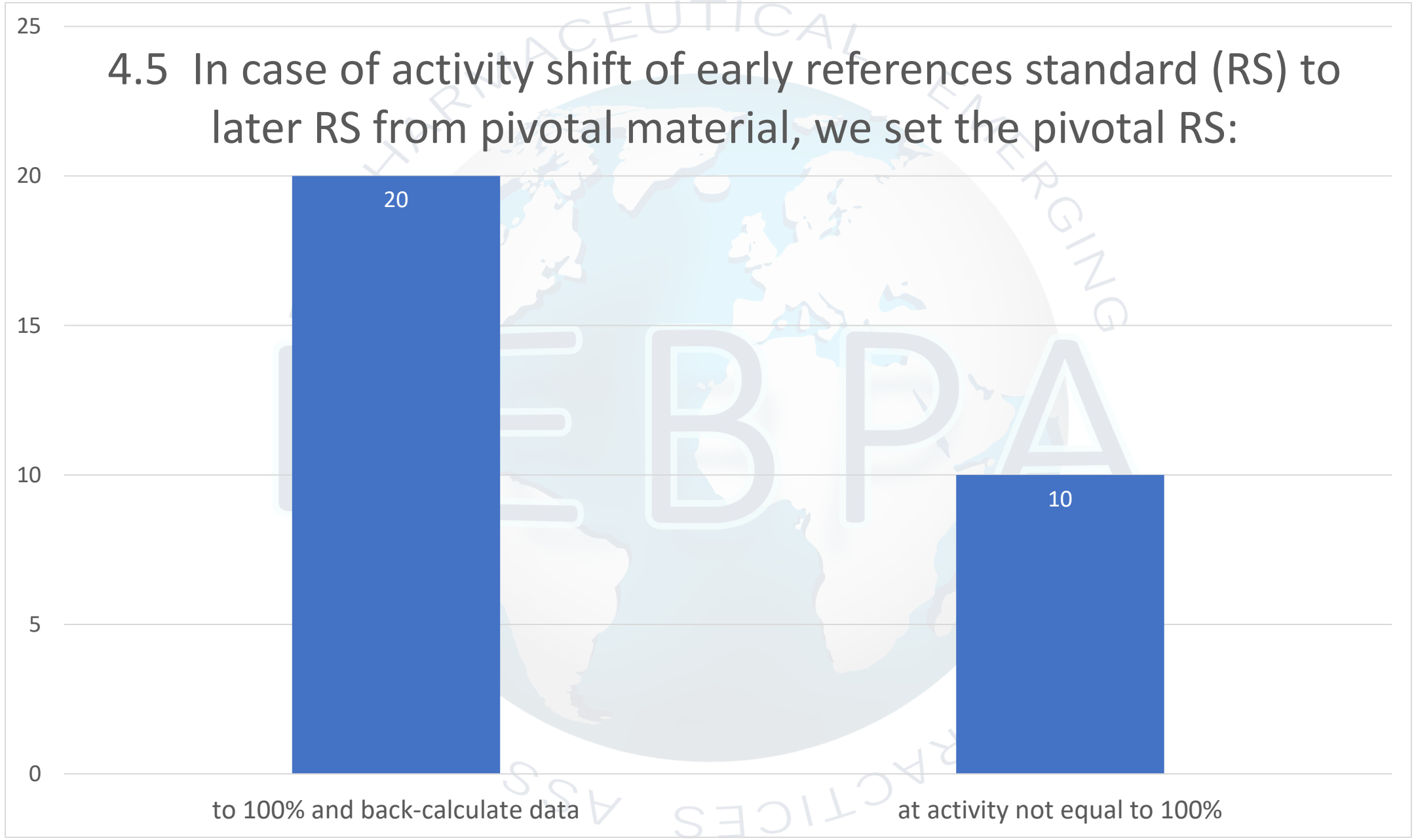
4.2 On average how long does it take to execute the practical side of qualification of a bioassay?



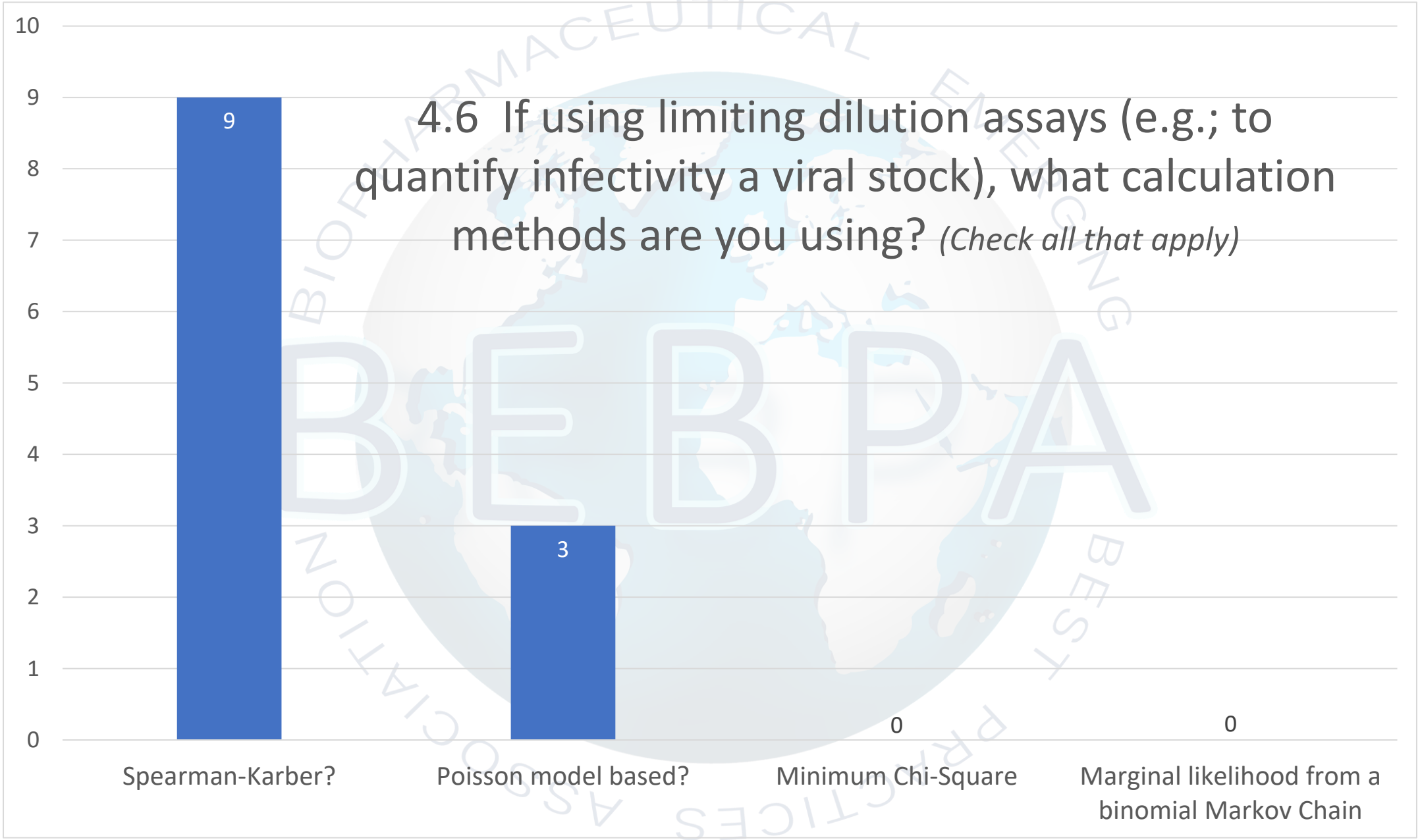

4.3 How many replicates do you run of each sample in a typical cell-based assay to generate a relative potency result?
30
25
20
15
10
5
0
2
6
24
5
1 - singlicate
2 - duplicate
3 - triplicate
4+


4.4 Do you normally run the replicates on the same assay plate or different?
18
16
14
12
10
8
6
4
2
0
16
14
8
0
Same plate
Different plate in the same assay
Different plates in different assays
Other

4.5 In case of activity shift of early references standard (RS) to later RS from pivotal material, we set the pivotal RS:



4.6 If using limiting dilution assays (e.g.; to quantify infectivity a viral stock), what calculation methods are you using? *(Check all that apply)*



THANK YOU

for attending BEBPA's 2021 EUR Bioassay Conference

We could not have done this without YOU!