BEBPA 2022 Host Cell Protein Conference

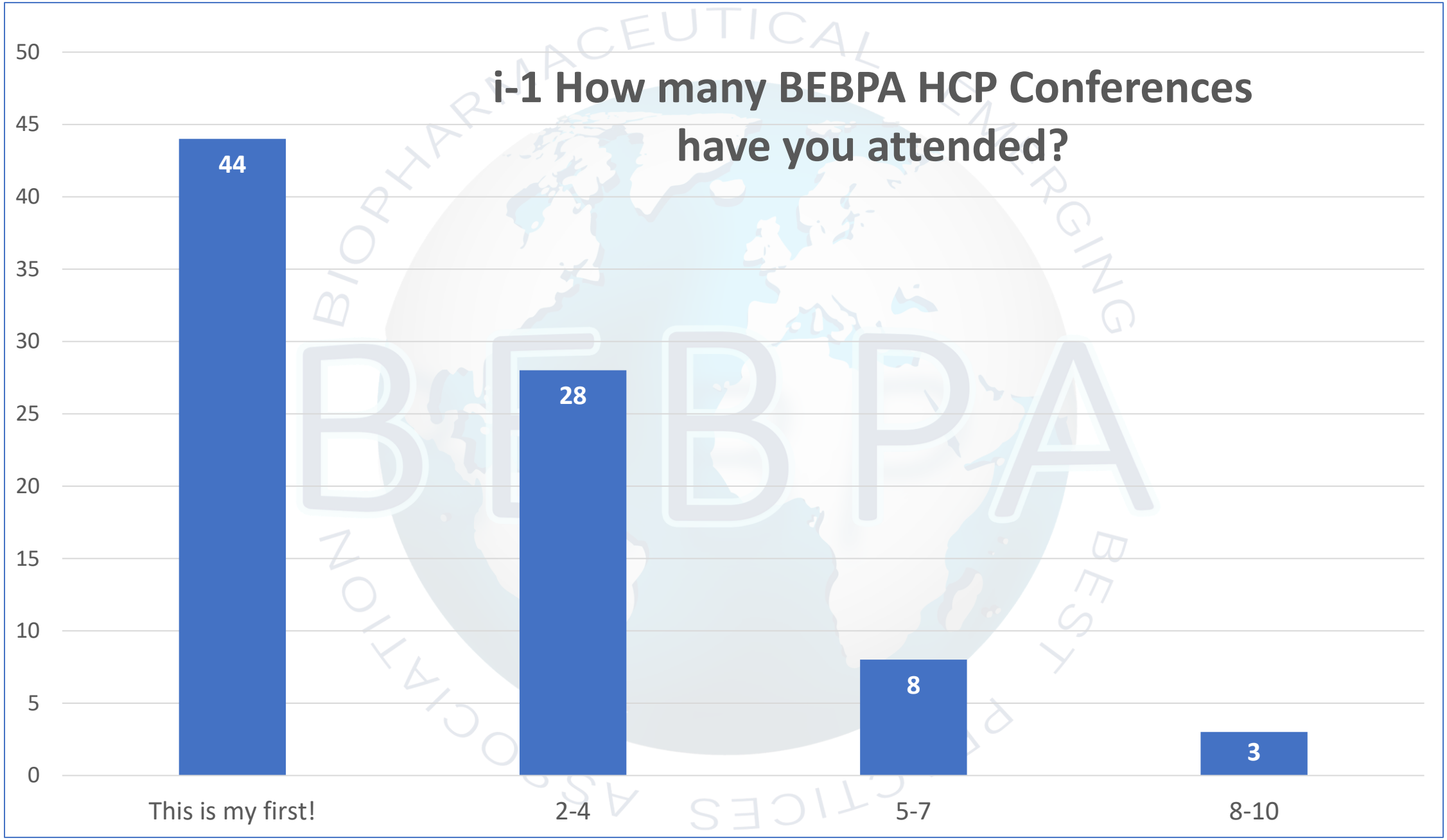
16-19 May 2022

10th Annual Host Cell Protein Conference

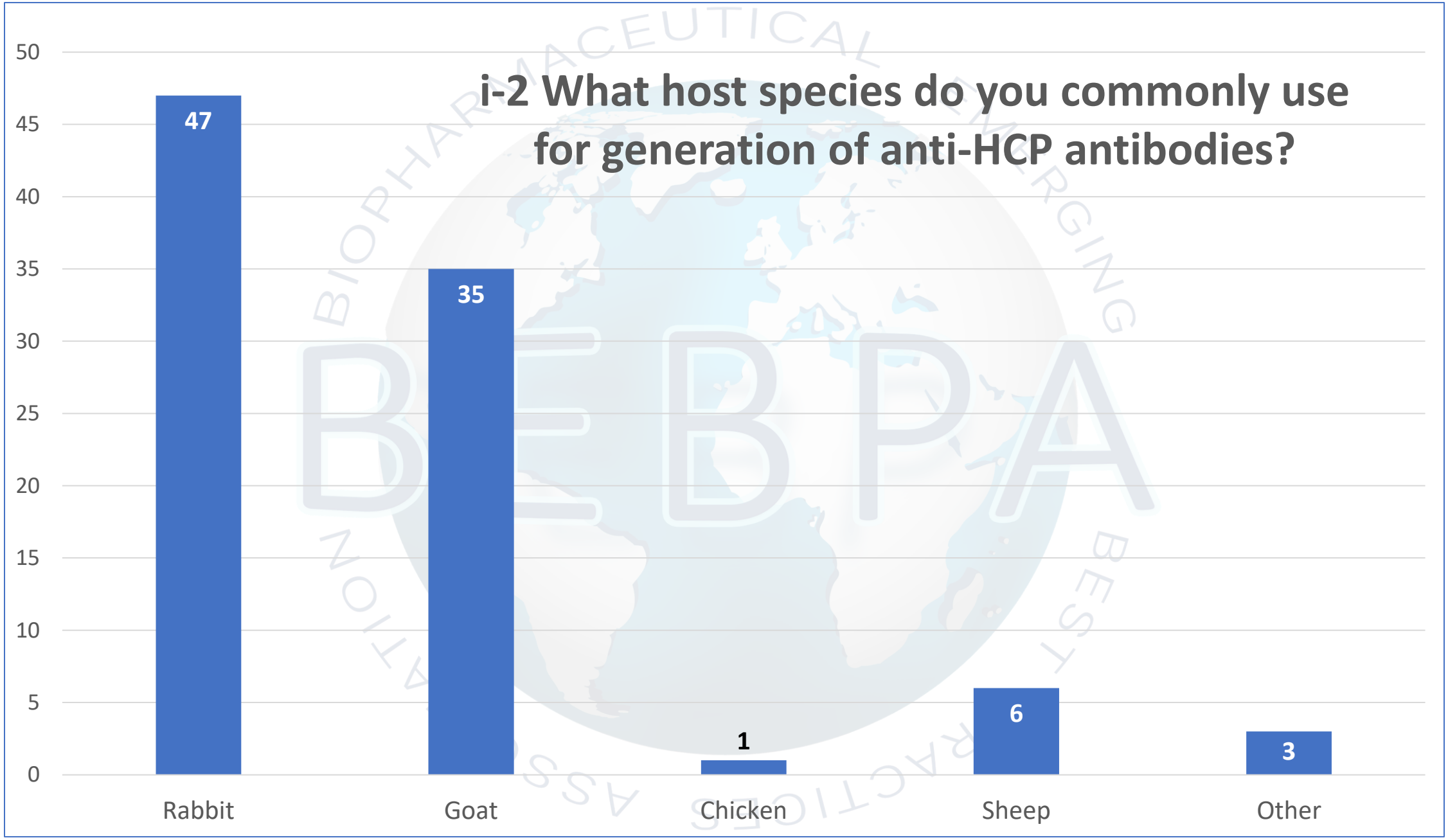
Audience Survey

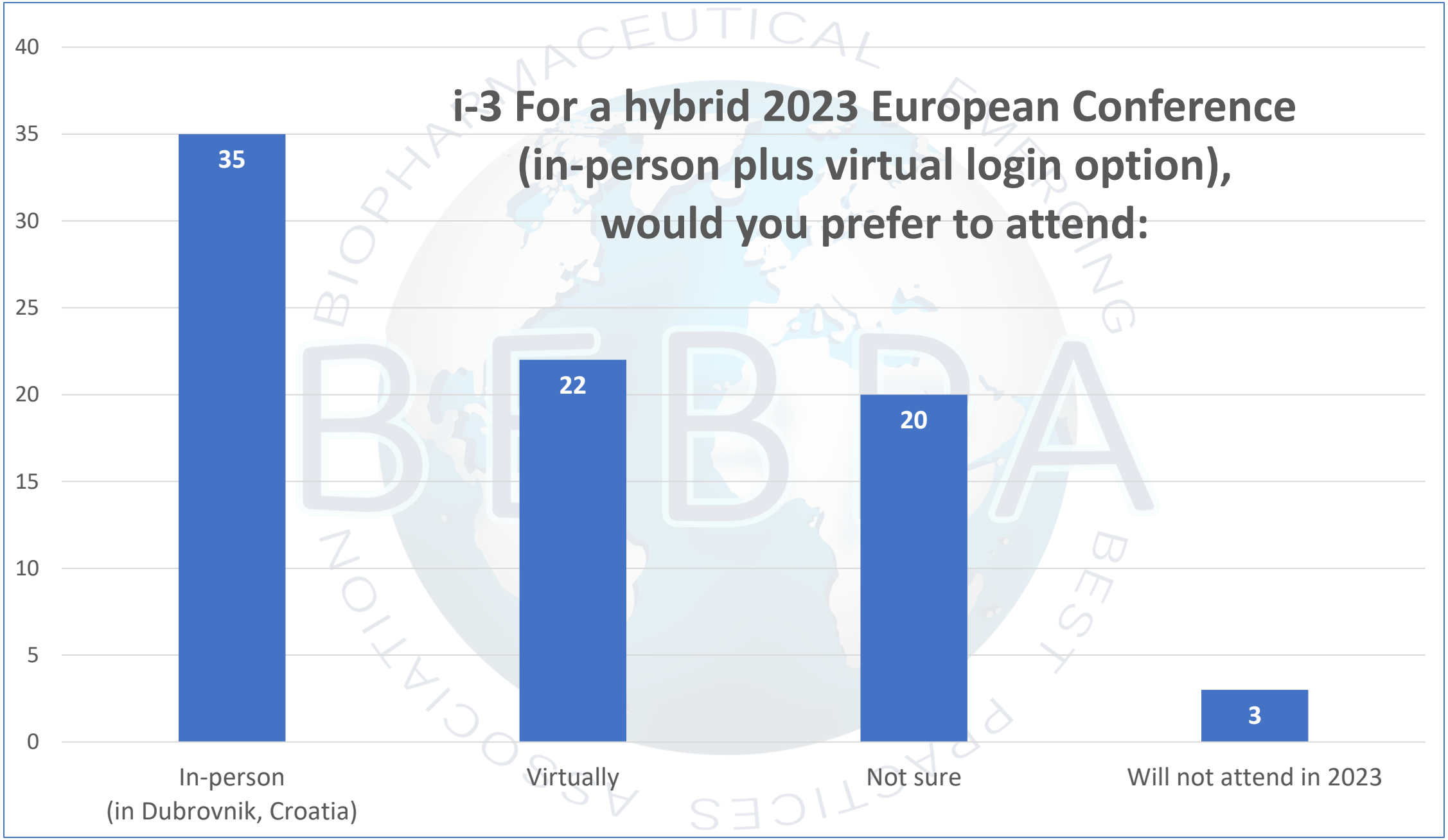
Welcome & Introduction

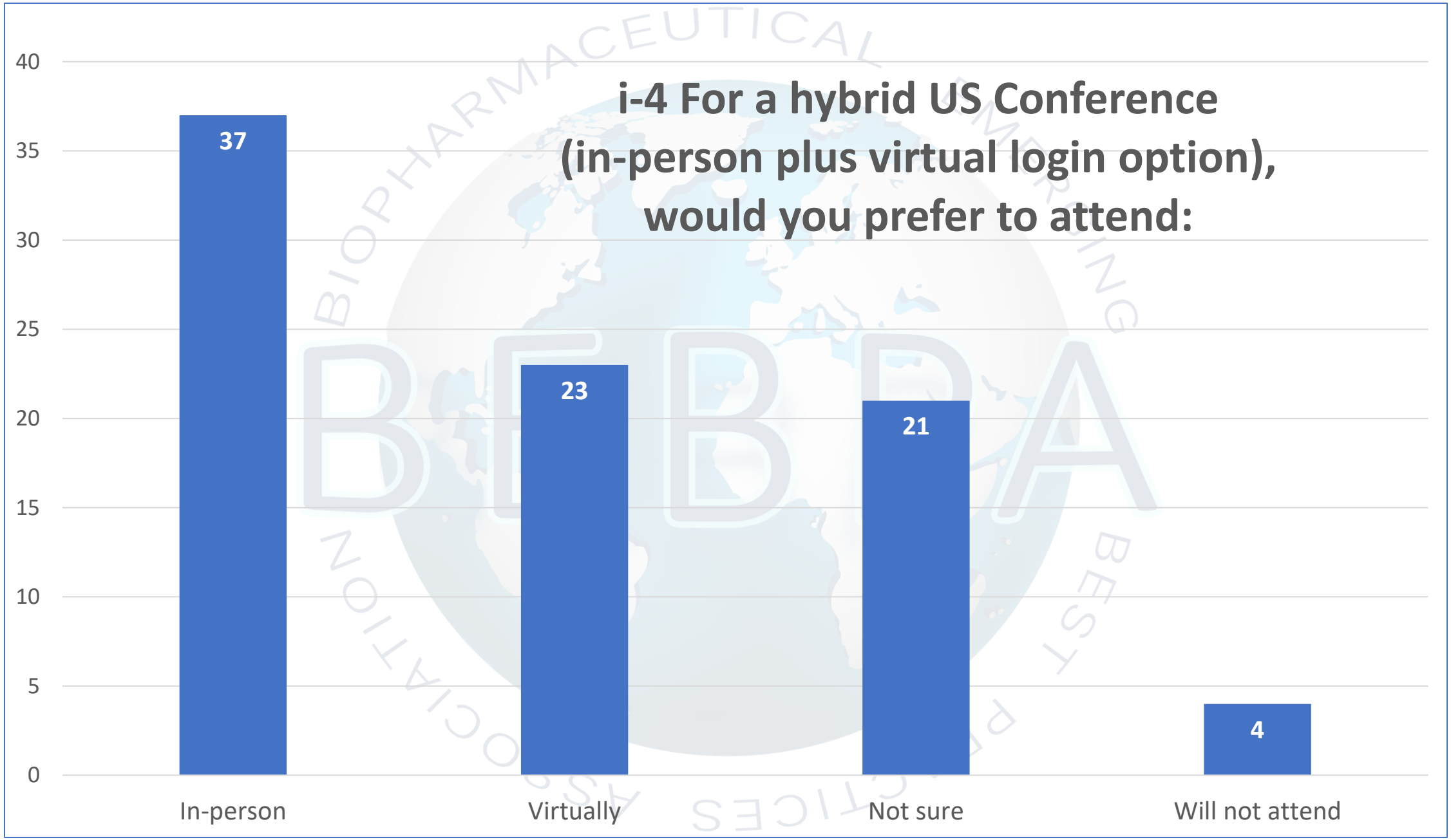
By: Kevin Van Cott


i-1 How many BEBPA HCP Conferences have you attended?
50
45
40
35
30
25
20
15
10
5
0
44
28
8
3
This is my first!
2-4
5-7
8-10

i-2 What host species do you commonly use for generation of anti-HCP antibodies?




i-3 For a hybrid 2023 European Conference (in-person plus virtual login option), would you prefer to attend:
40
35
30
25
20
15
10
5
0
35
22
20
3
In-person (in Dubrovnik, Croatia)
Virtually
Not sure
Will not attend in 2023

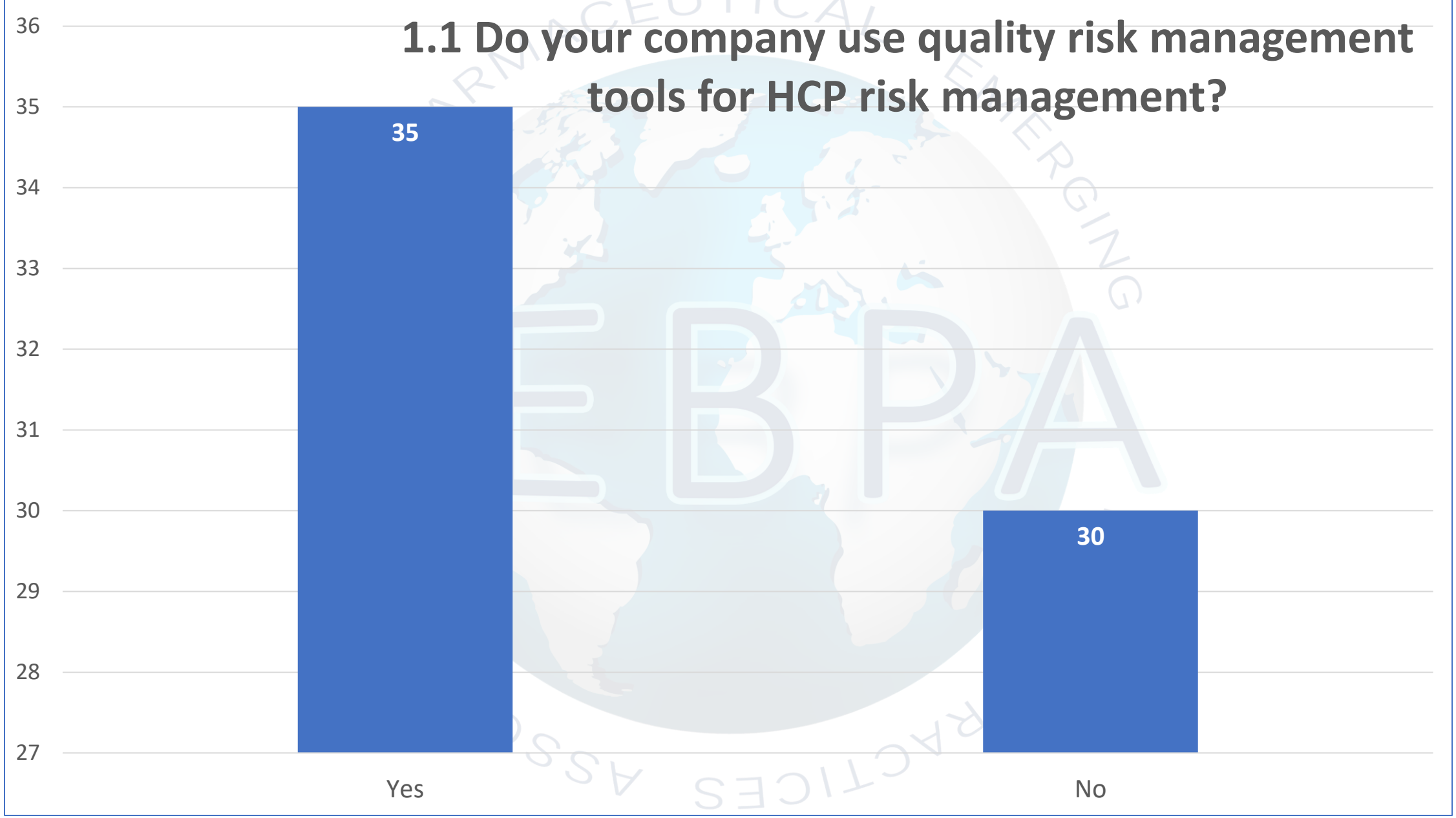

i-4 For a hybrid US Conference (in-person plus virtual login option), would you prefer to attend:
40
35
30
25
20
15
10
5
0
37
23
21
4
In-person
Virtually
Not sure
Will not attend

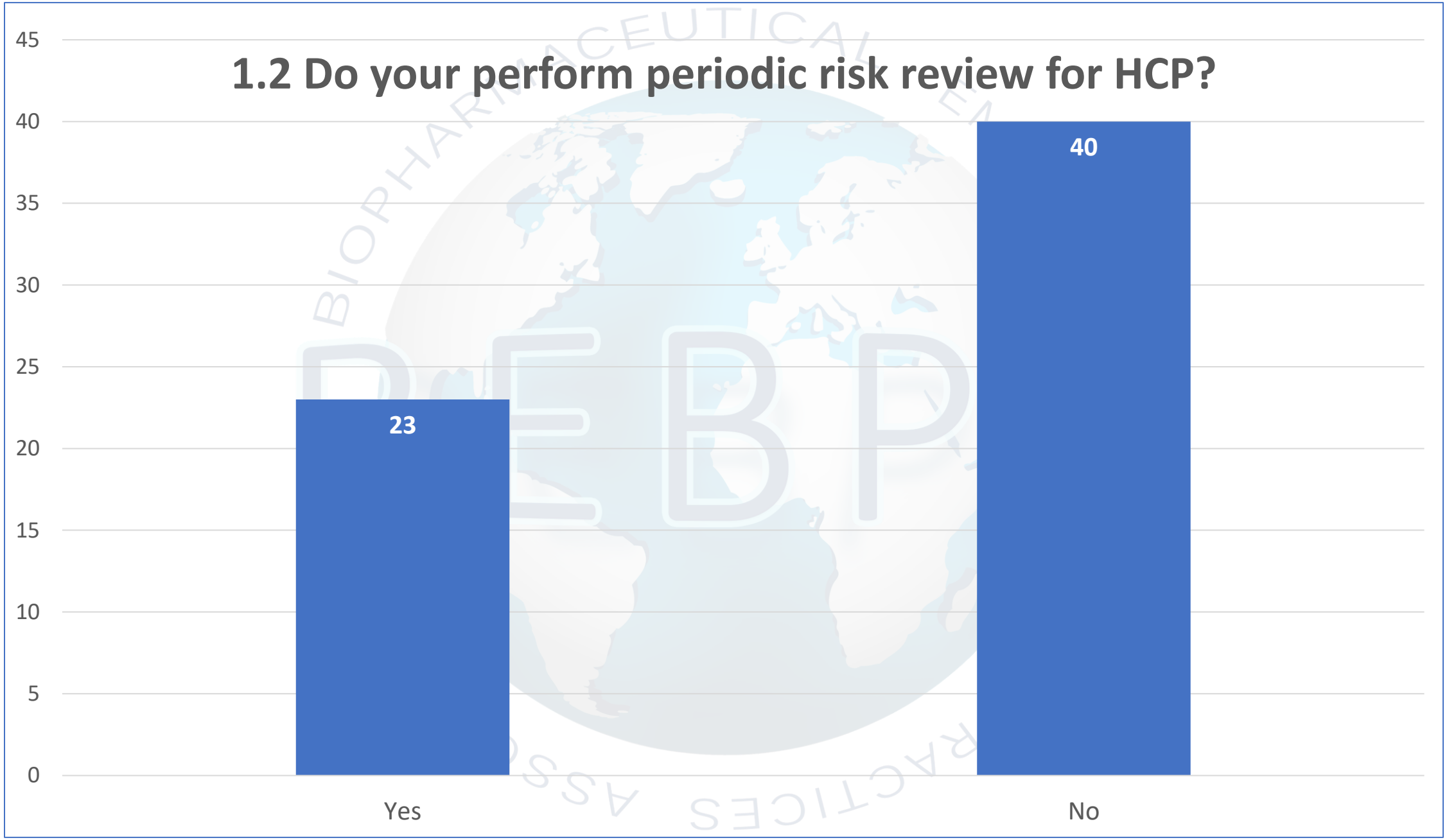
Day 1

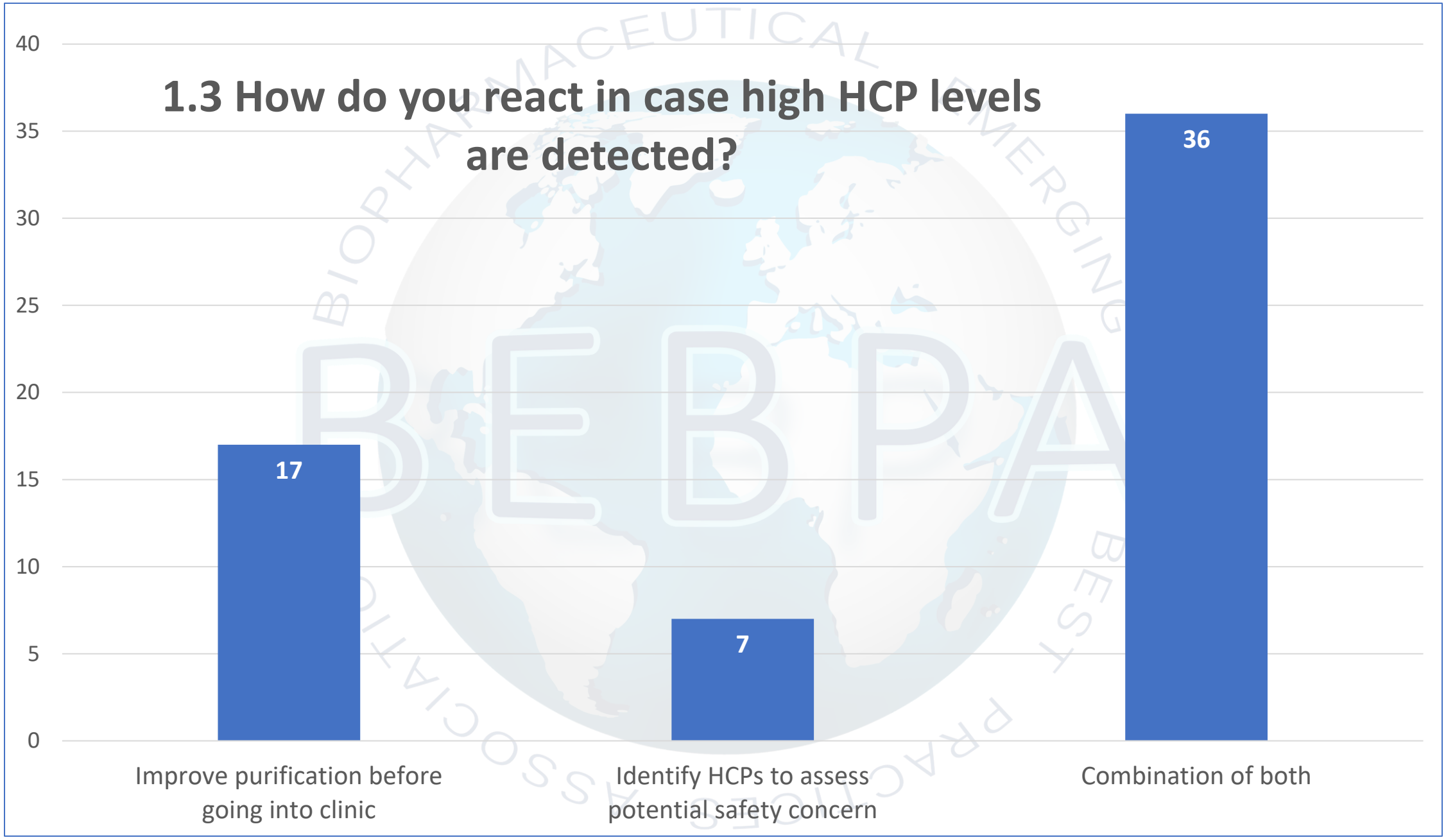
Risk Assessment Session

Session Chair: Christina de Zafra

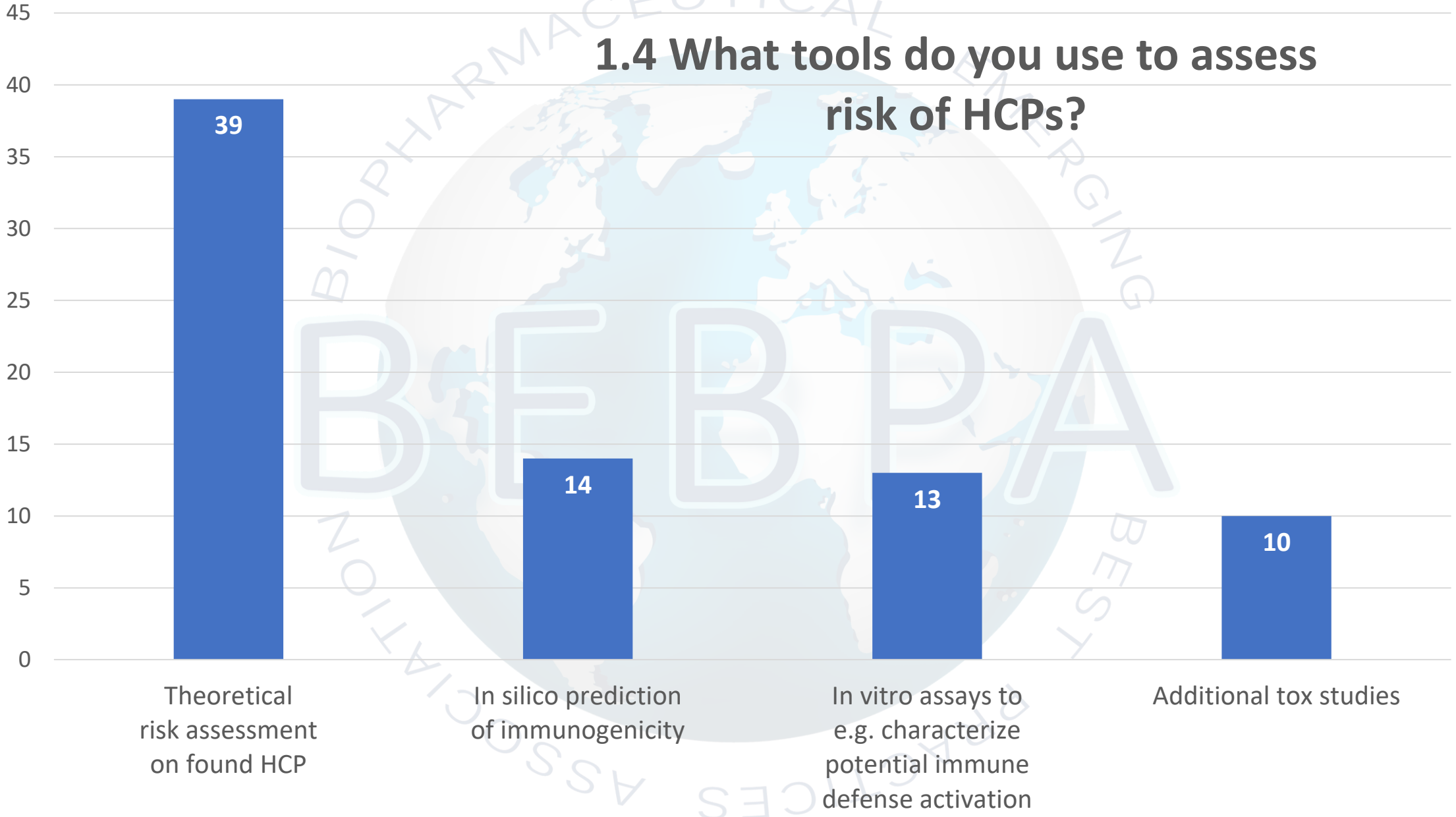
1.1 Do your company use quality risk management tools for HCP risk management?

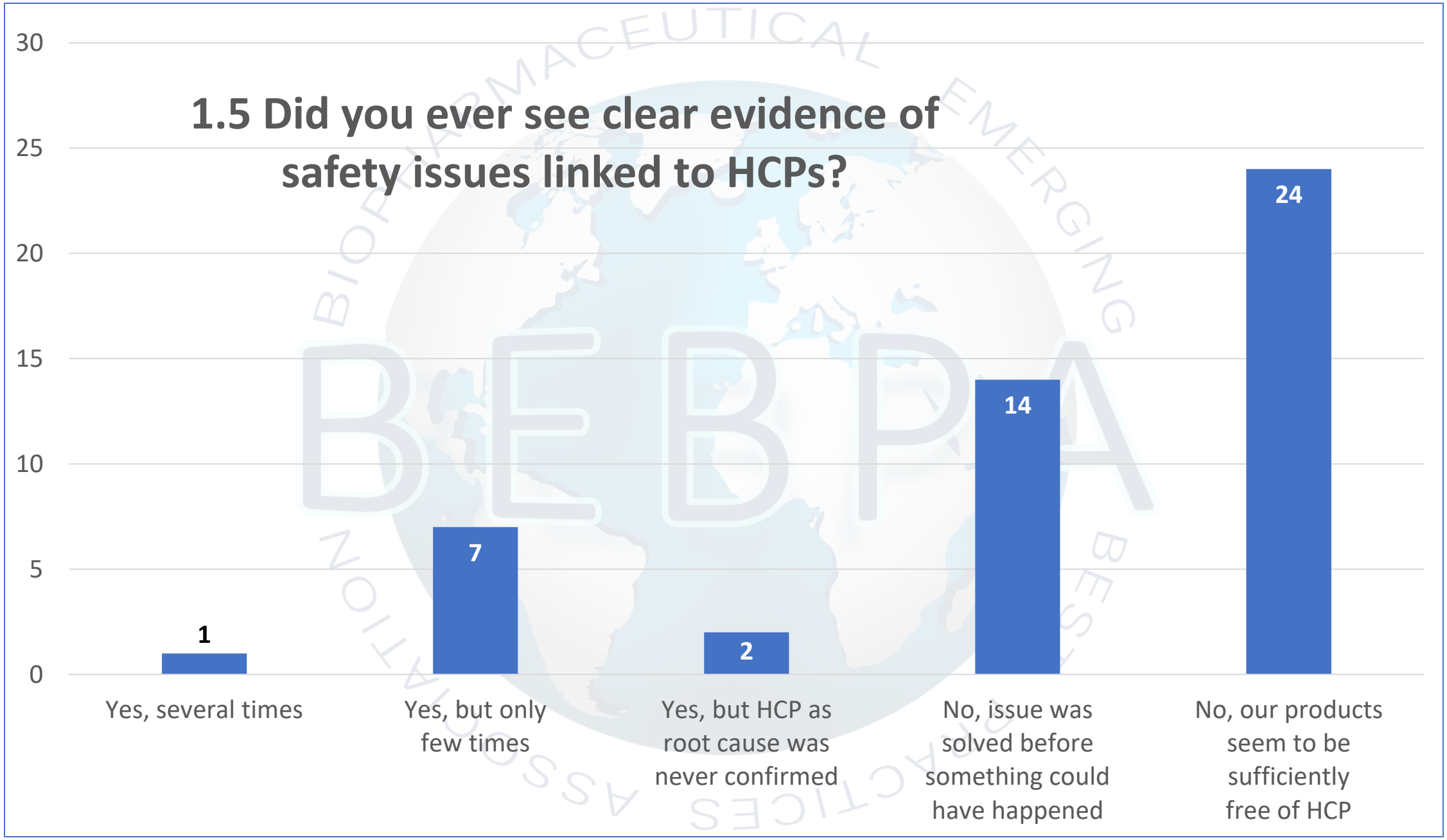


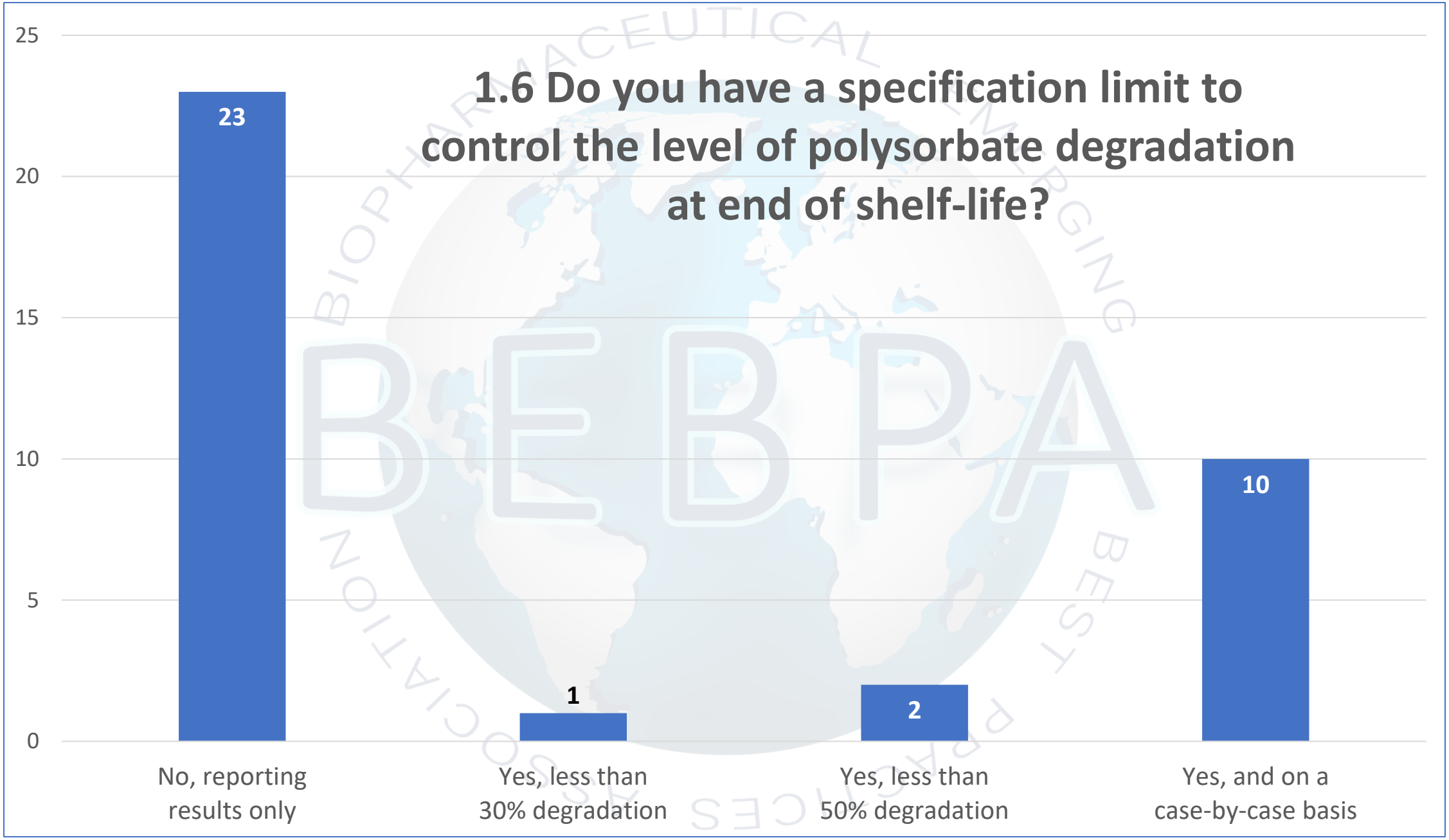

1.2 Do your perform periodic risk review for HCP?
45
40
35
30
25
20
15
10
5
0
23
40
Yes
No


1.3 How do you react in case high HCP levels are detected?
40
35
30
25
20
15
10
5
0
17
7
36
Improve purification before going into clinic
Identify HCPs to assess potential safety concern
Combination of both

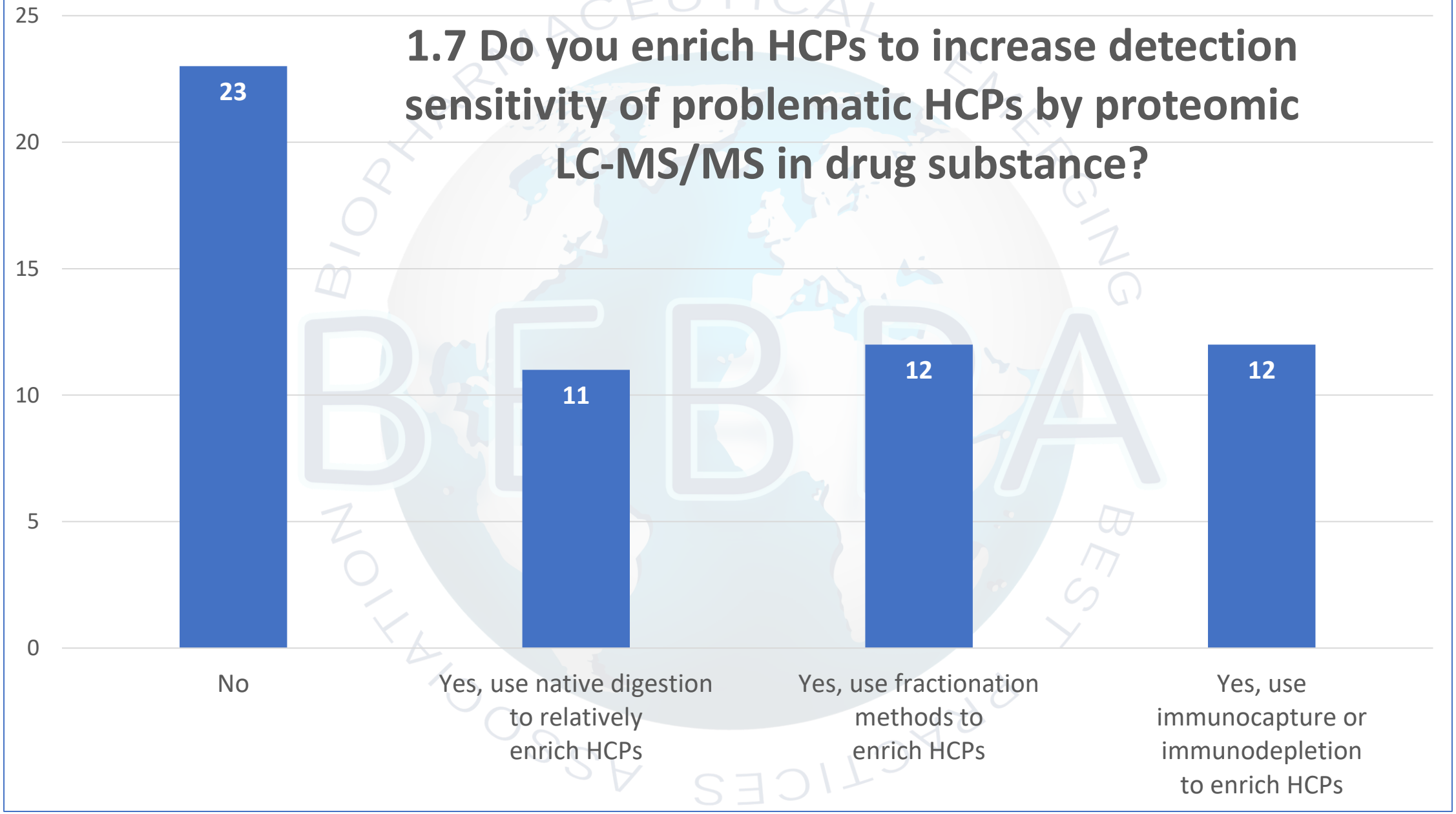
1.4 What tools do you use to assess risk of HCPs?




1.5 Did you ever see clear evidence of safety issues linked to HCPs?
30
25
20
15
10
5
0
1
7
2
14
24
Yes, several times
Yes, but only few times
Yes, but HCP as root cause was never confirmed
No, issue was solved before something could have happened
No, our products seem to be sufficiently free of HCP


1.6 Do you have a specification limit to control the level of polysorbate degradation at end of shelf-life?
25
20
15
10
5
0
23
1
2
10
No, reporting results only
Yes, less than 30% degradation
Yes, less than 50% degradation
Yes, and on a case-by-case basis

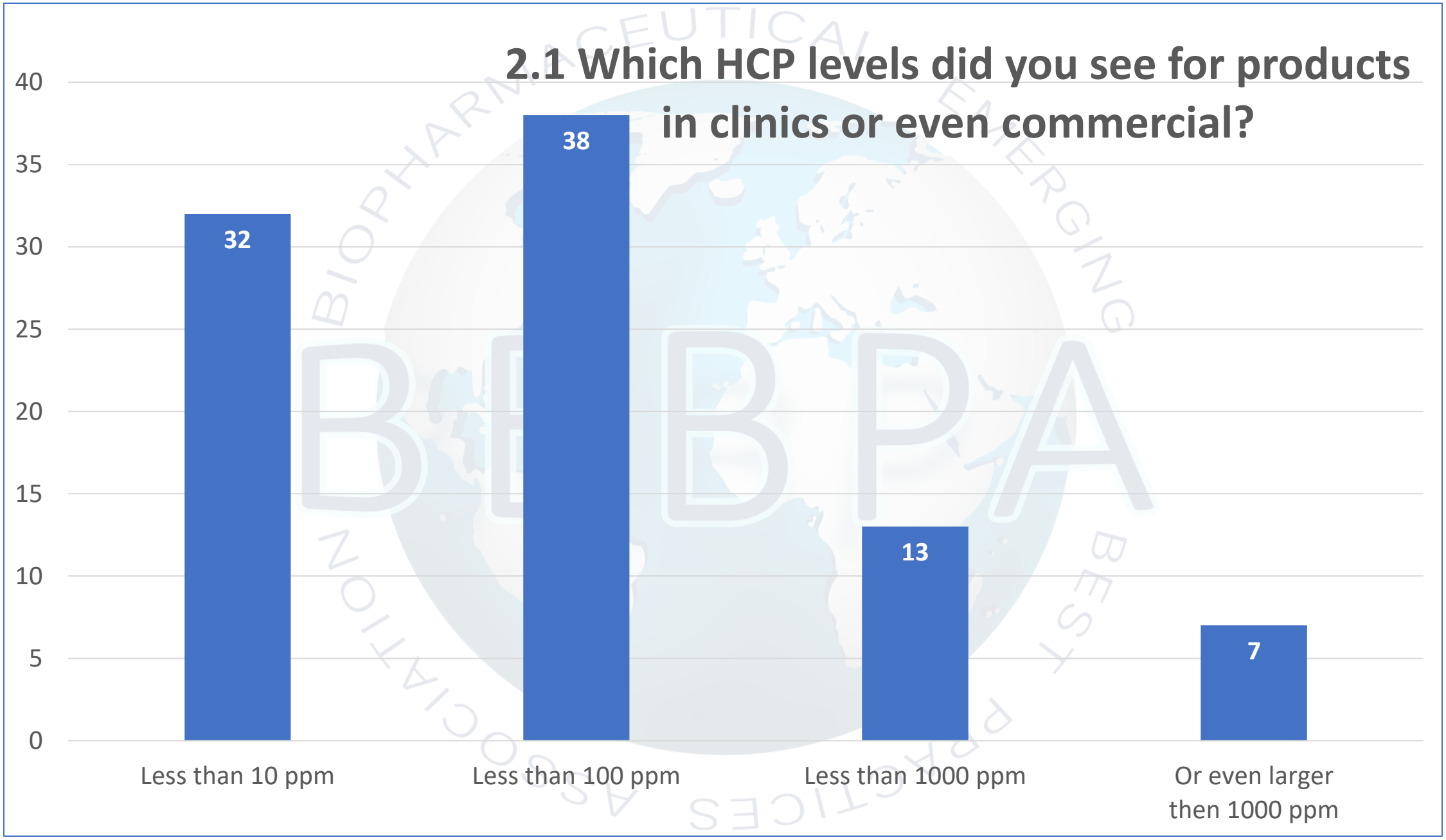
1.7 Do you enrich HCPs to increase detection sensitivity of problematic HCPs by proteomic LC-MS/MS in drug substance?



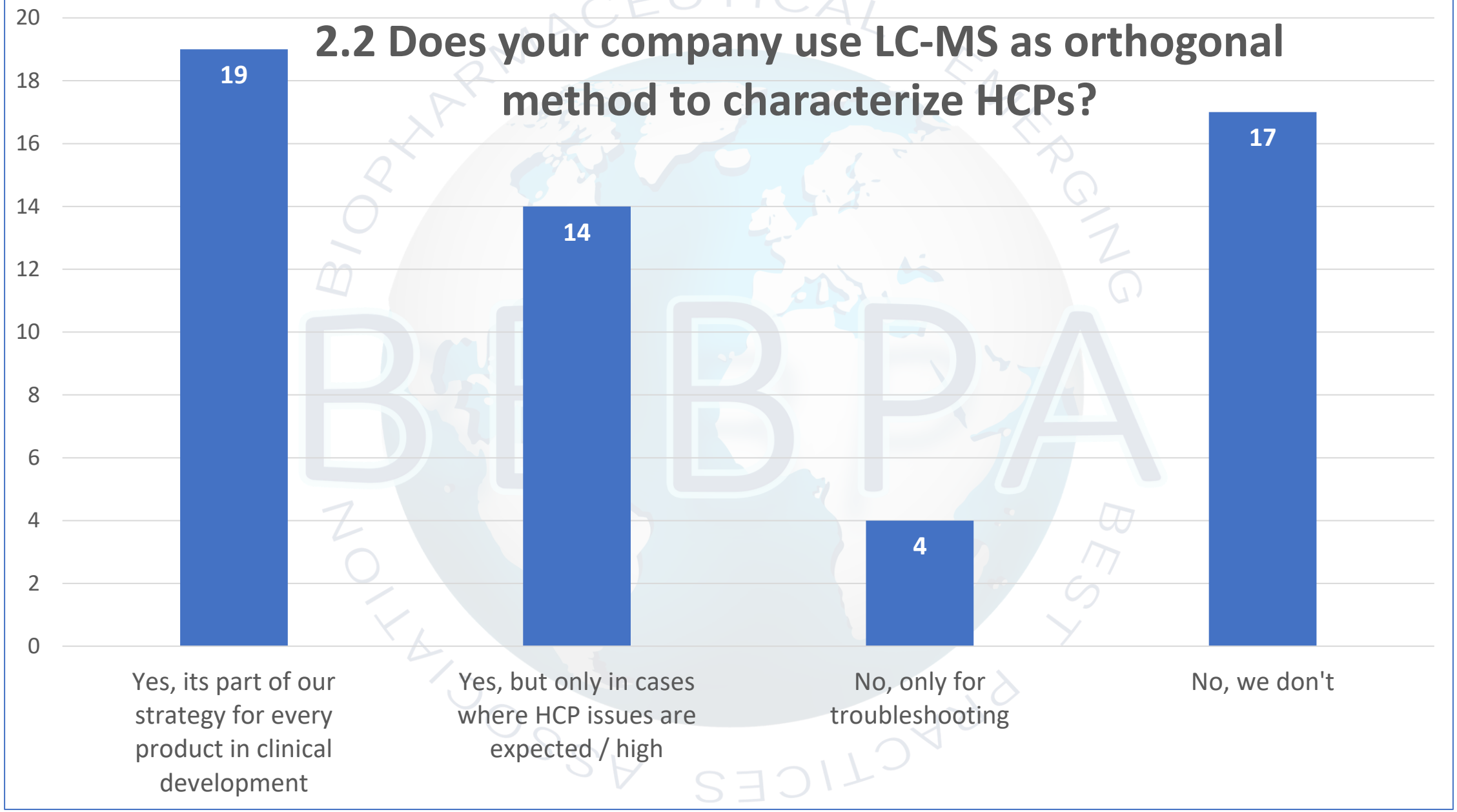
Day 2
Product Specific HCP Profiling Session

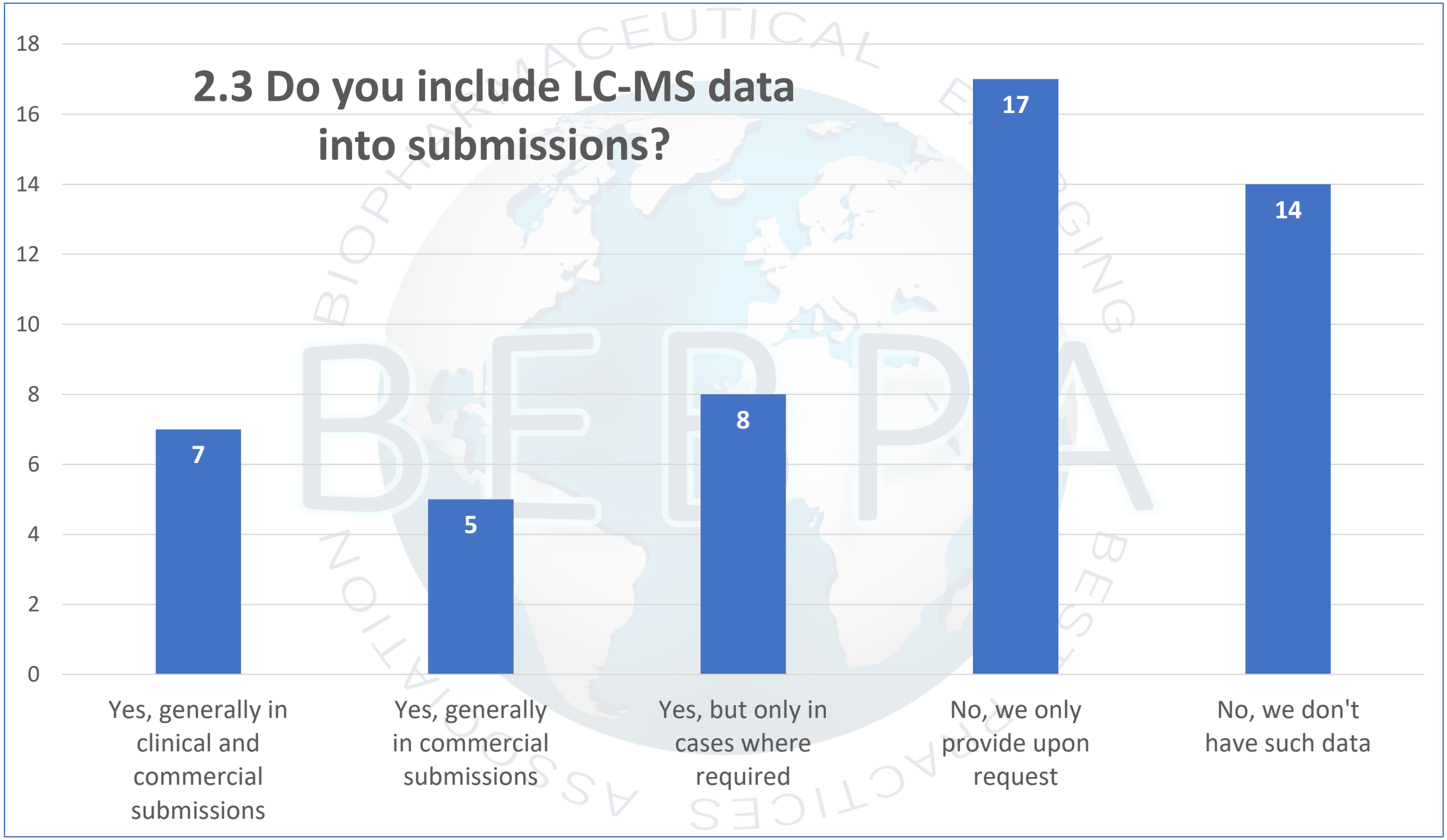
Session Chair: Frieder Kröner

2.1 Which HCP levels did you see for products in clinics or even commercial?

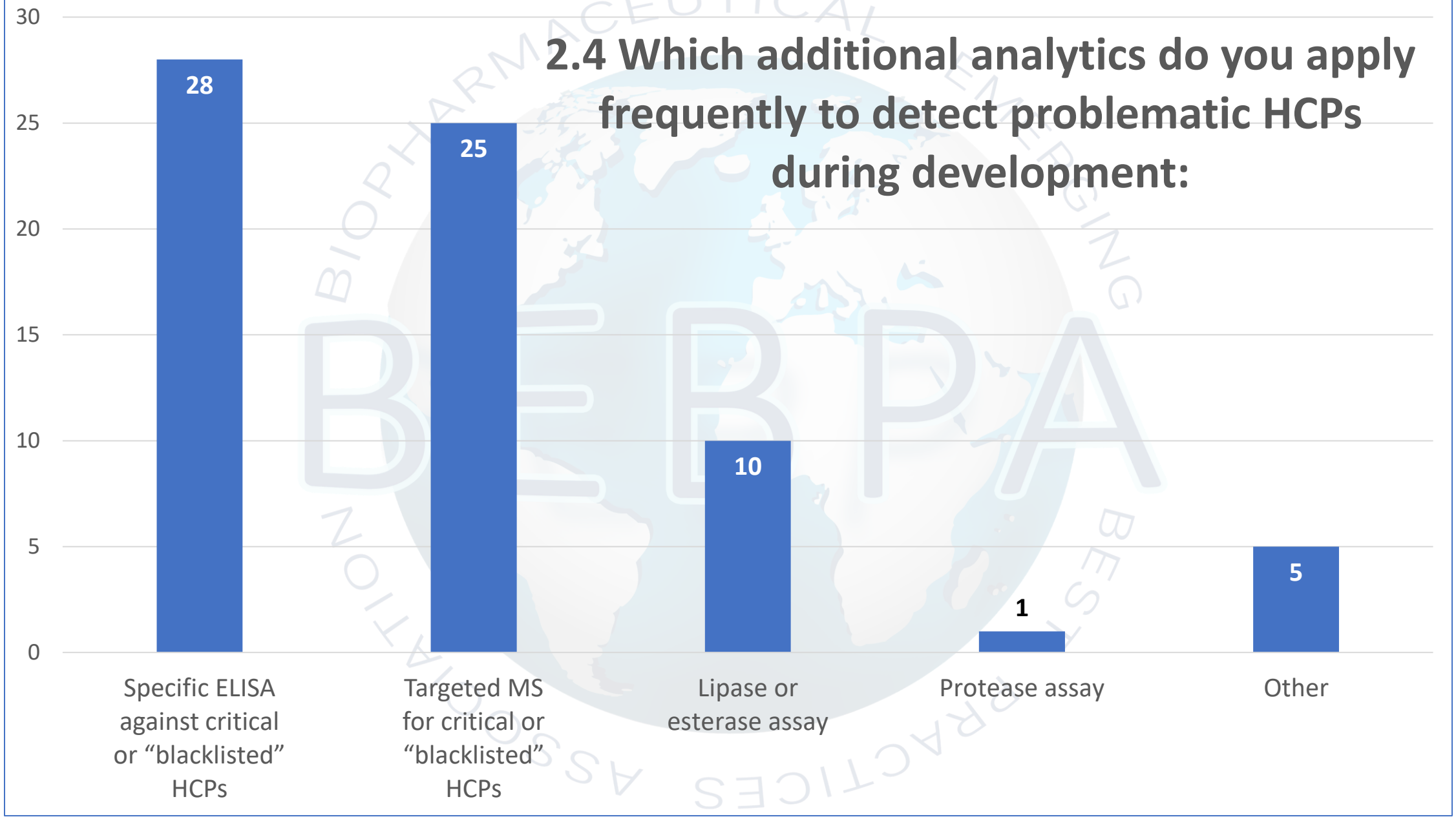


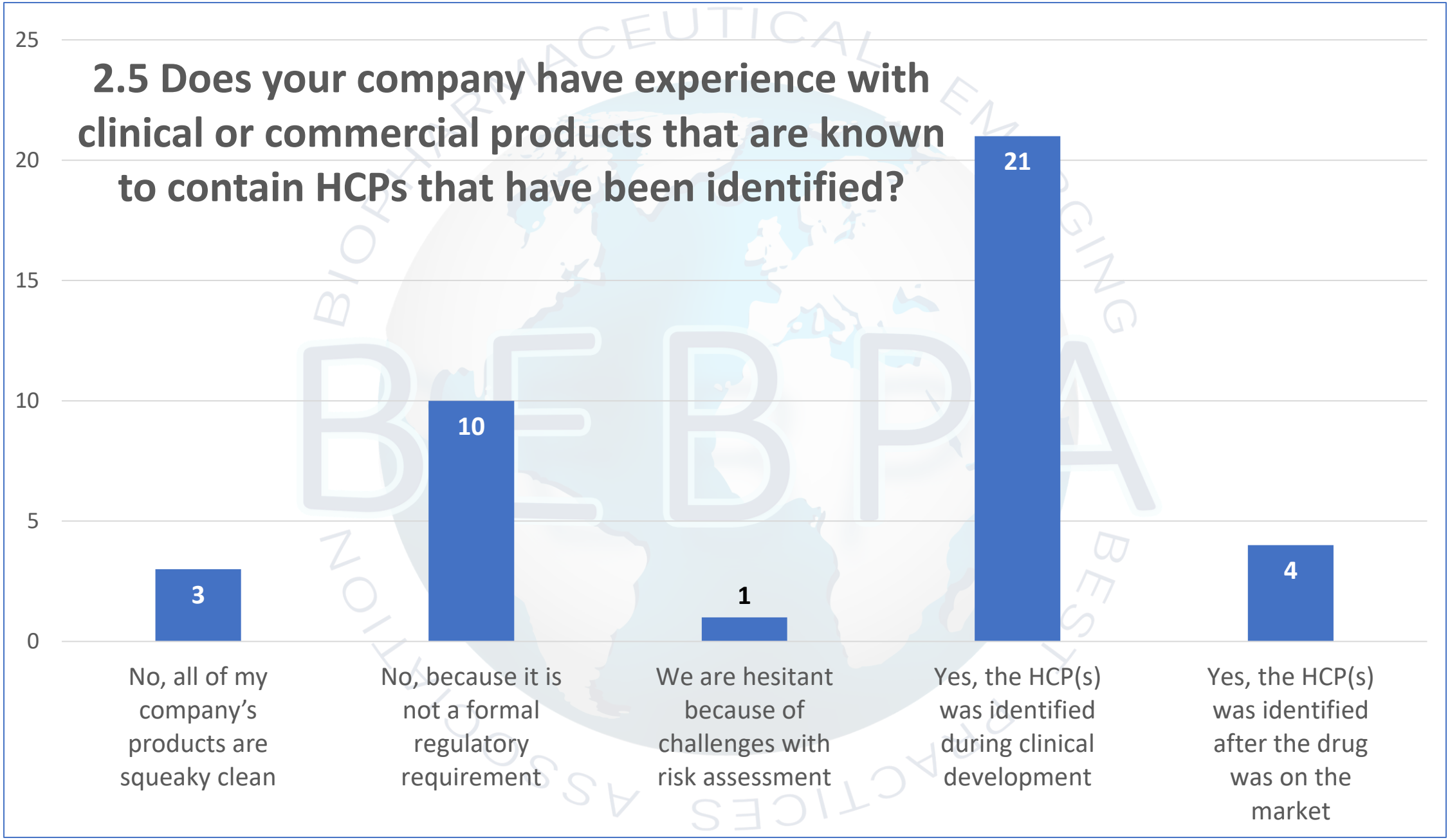
2.2 Does your company use LC-MS as orthogonal method to characterize HCPs?




2.3 Do you include LC-MS data into submissions?
18
16
14
12
10
8
6
4
2
0
7
5
8
17
14
Yes, generally in clinical and commercial submissions
Yes, generally in commercial submissions
Yes, but only in cases where required
No, we only provide upon request
No, we don't have such data

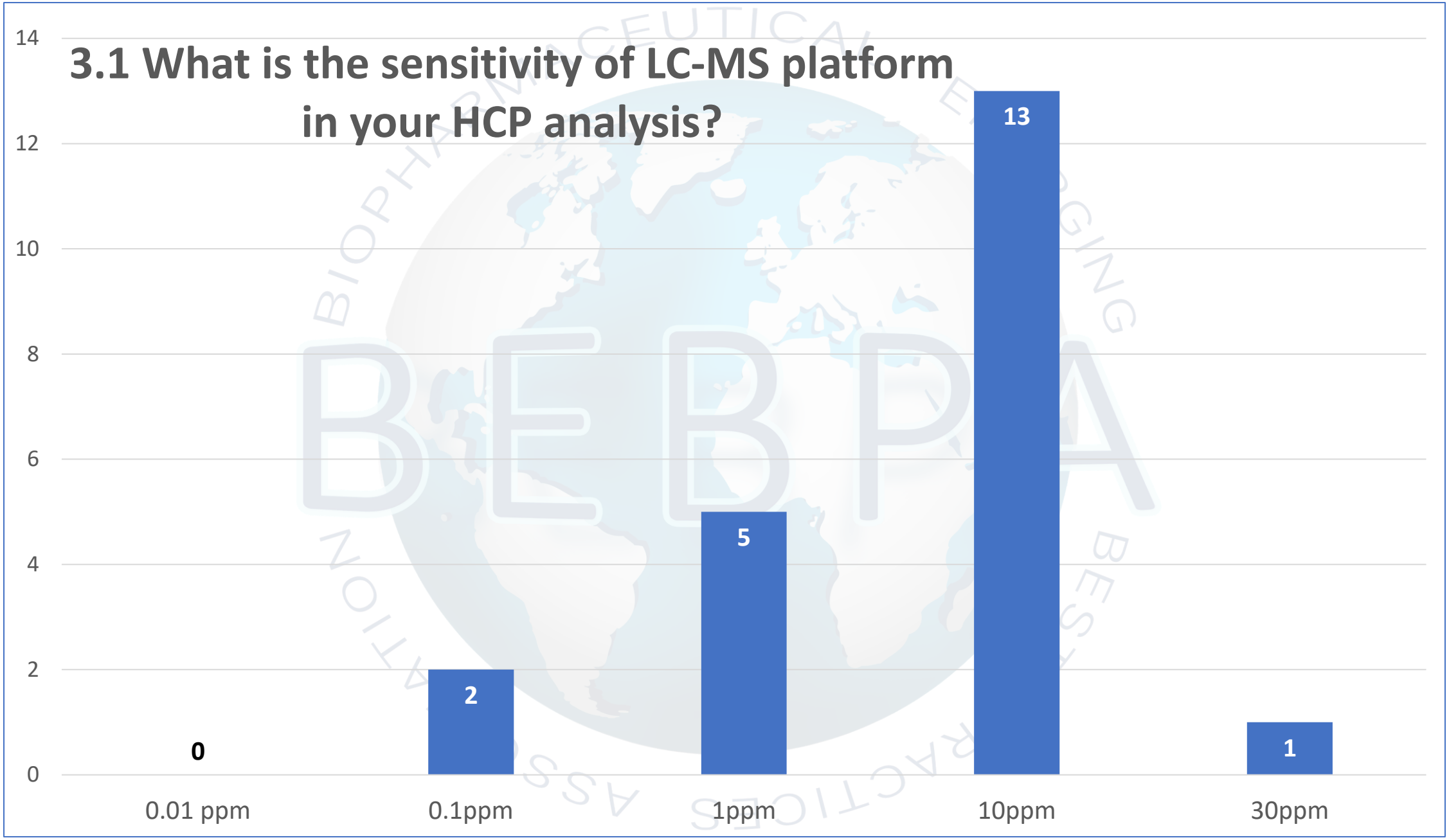
2.4 Which additional analytics do you apply frequently to detect problematic HCPs during development:



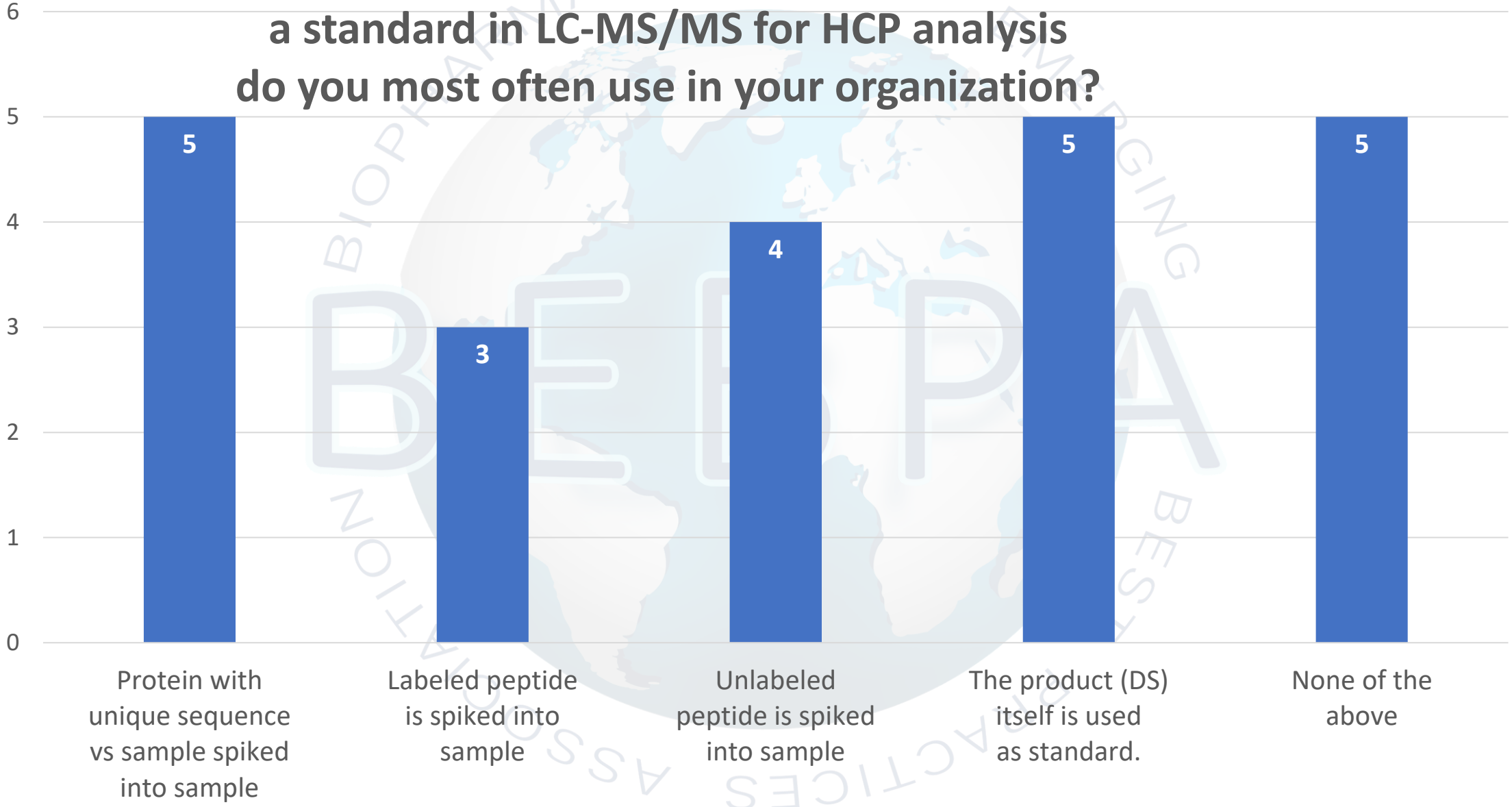

2.5 Does your company have experience with clinical or commercial products that are known to contain HCPs that have been identified?
25
20
15
10
5
0
3
10
1
21
4
No, all of my company's products are squeaky clean
No, because it is not a formal regulatory requirement
We are hesitant because of challenges with risk assessment
Yes, the HCP(s) was identified during clinical development
Yes, the HCP(s) was identified after the drug was on the market

Day 3
Uses of LC-MS/MS for HCP Profiling Session

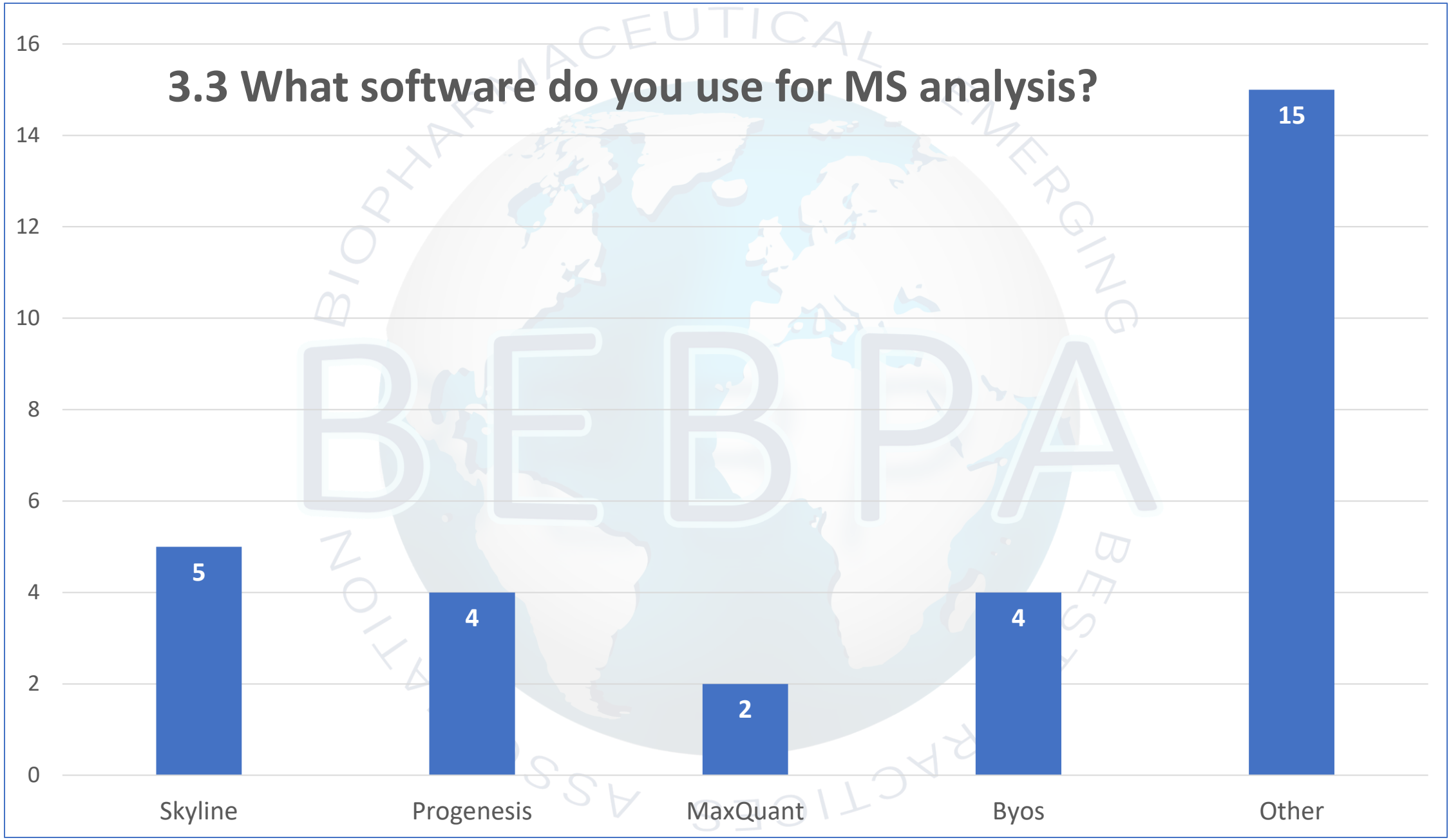
Session Chair: Martha Stapels


3.1 What is the sensitivity of LC-MS platform in your HCP analysis?
14
12
10
8
6
4
2
0
0
2
5
13
1
0.01 ppm
0.1ppm
1ppm
10ppm
30ppm

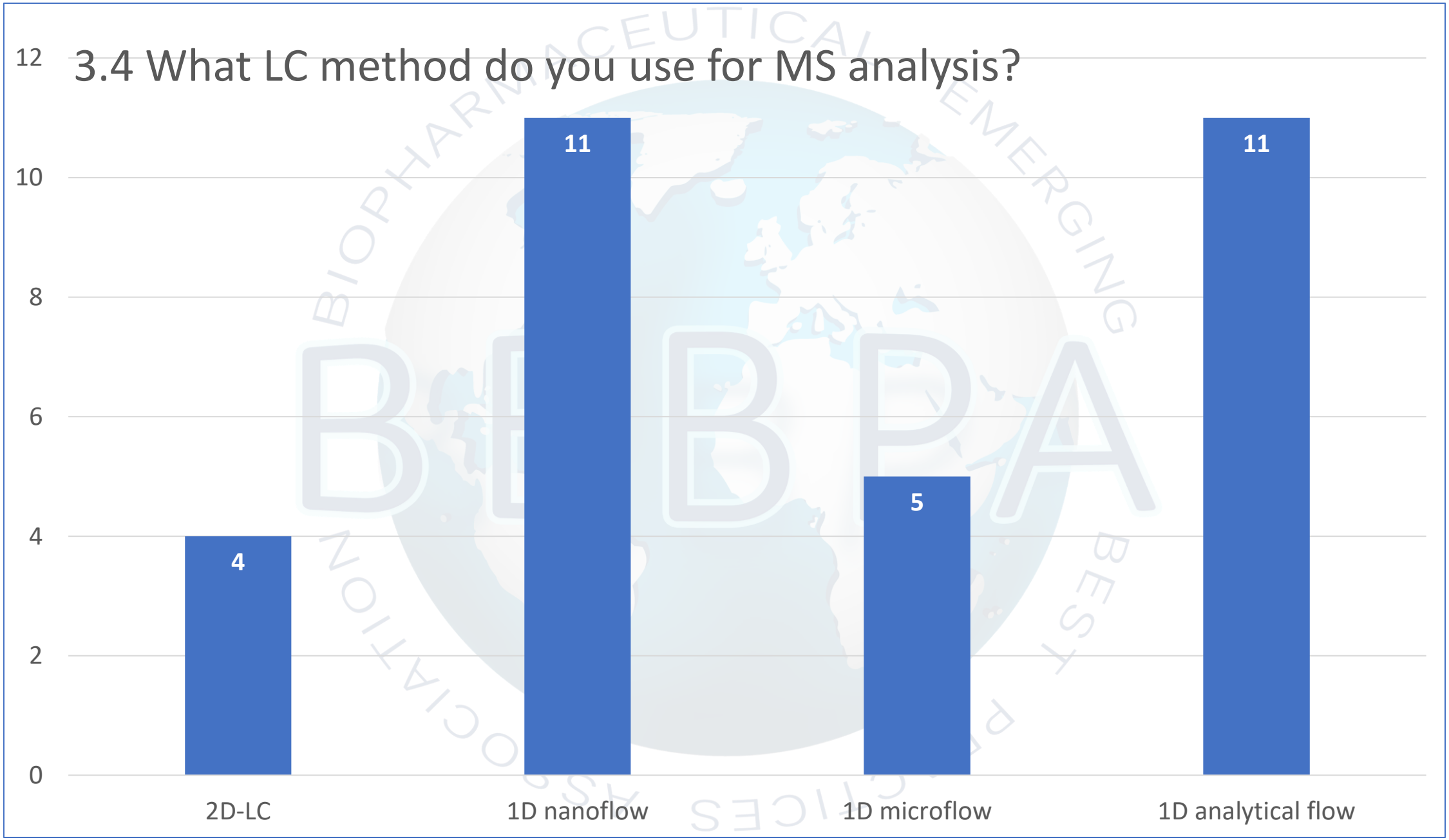
3.2 Which of these approaches for use of a standard in LC-MS/MS for HCP analysis do you most often use in your organization?



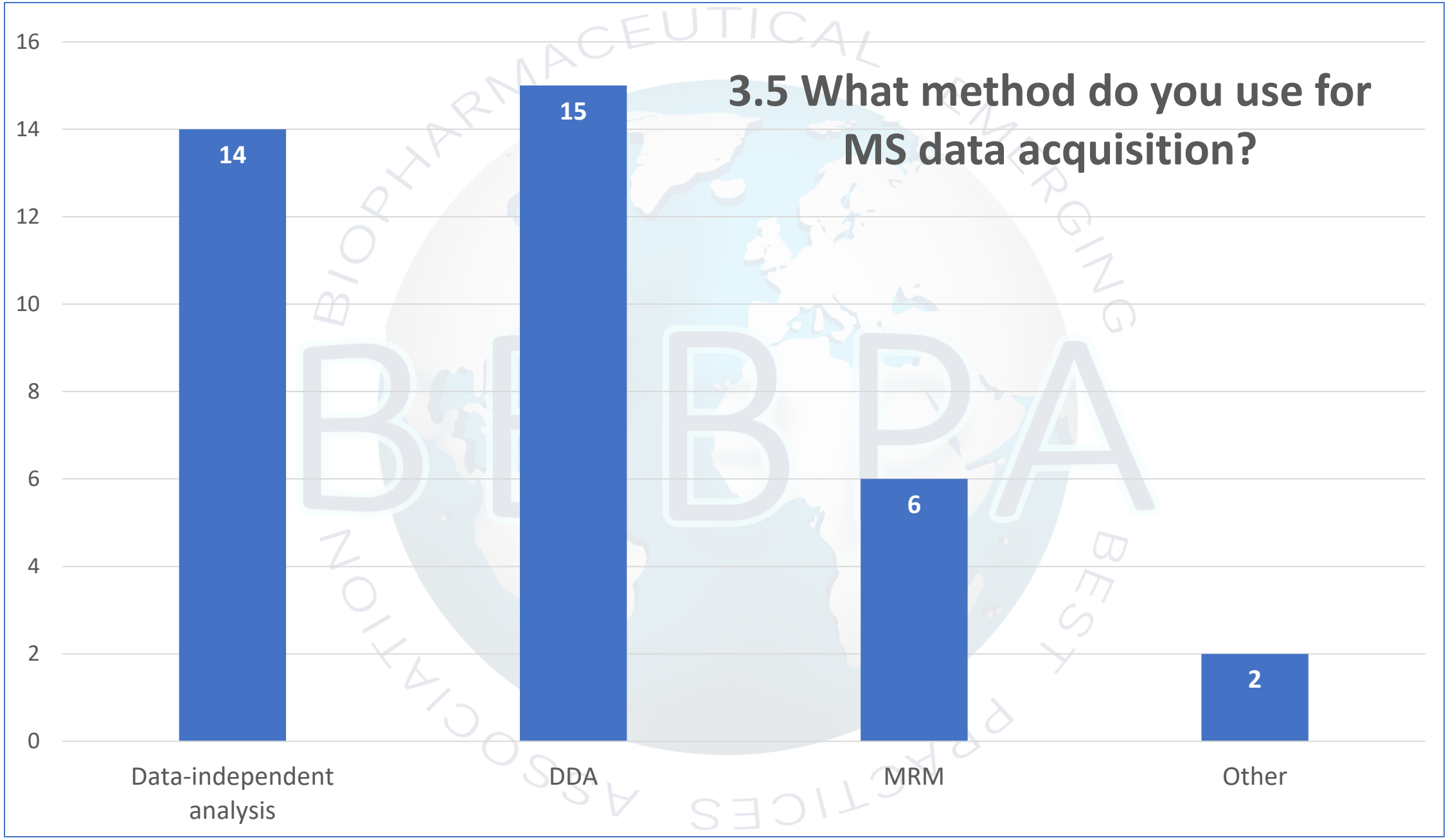
3.3 What software do you use for MS analysis?



3.4 What LC method do you use for MS analysis?

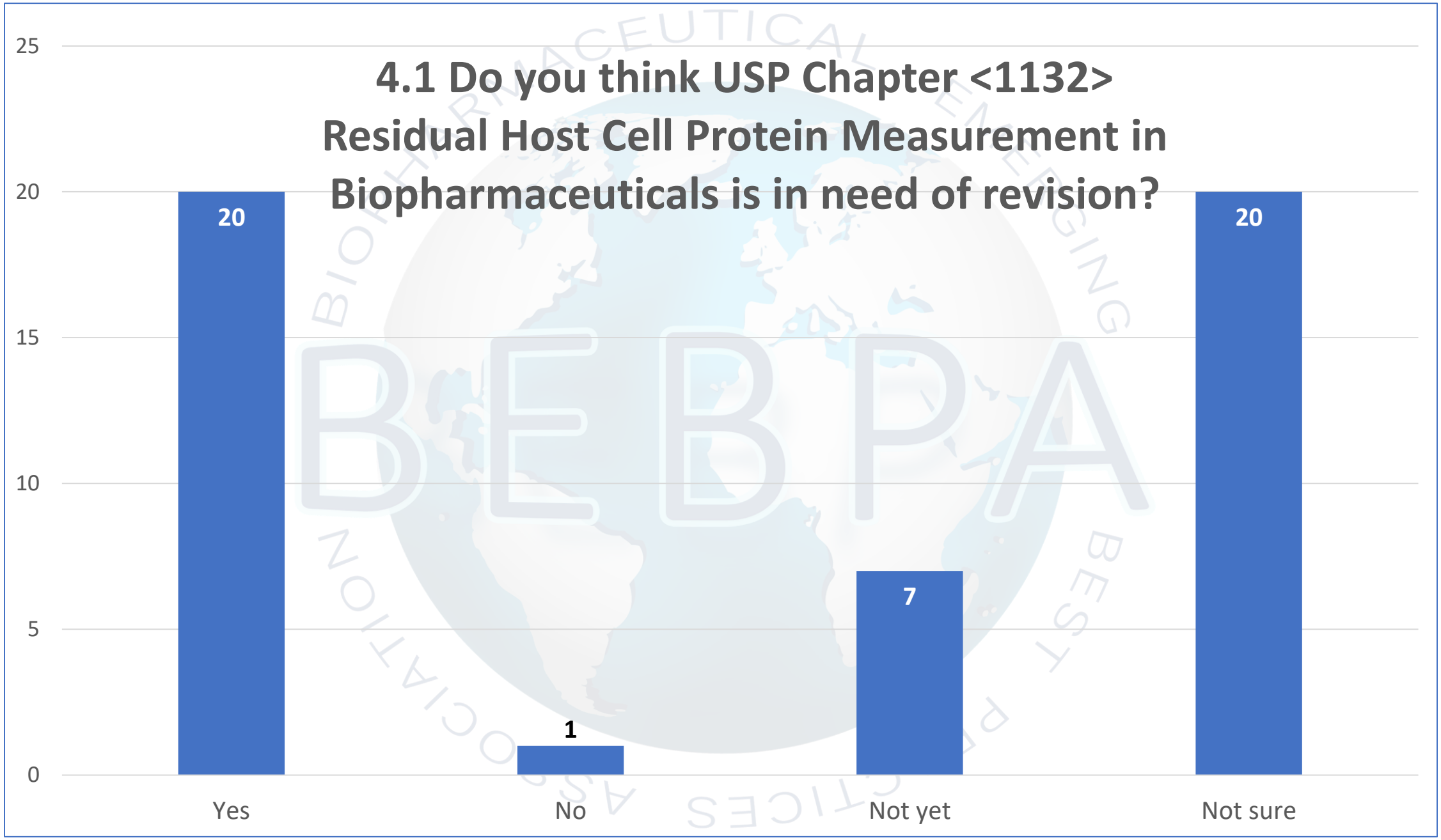


3.5 What method do you use for MS data acquisition?

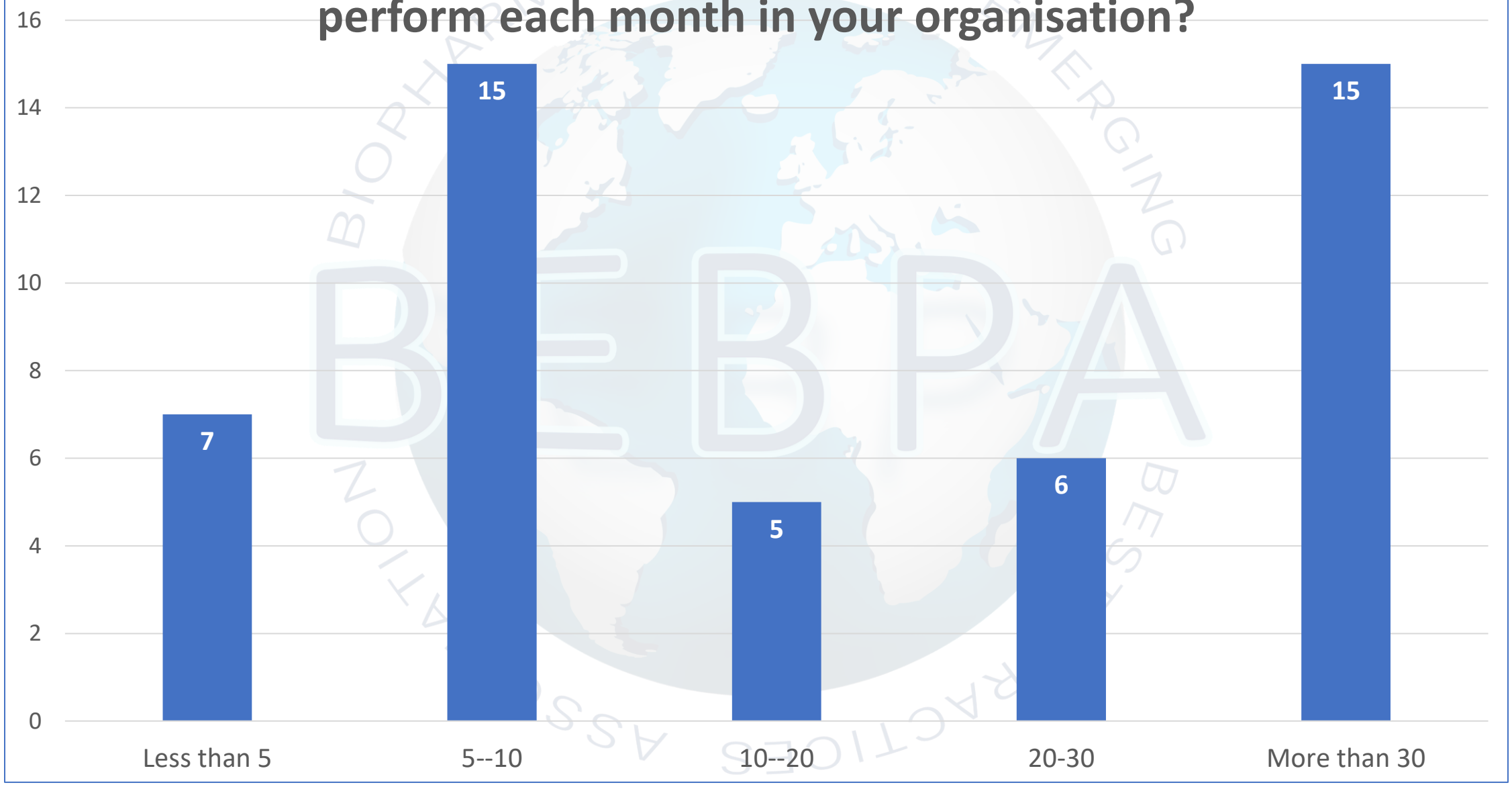


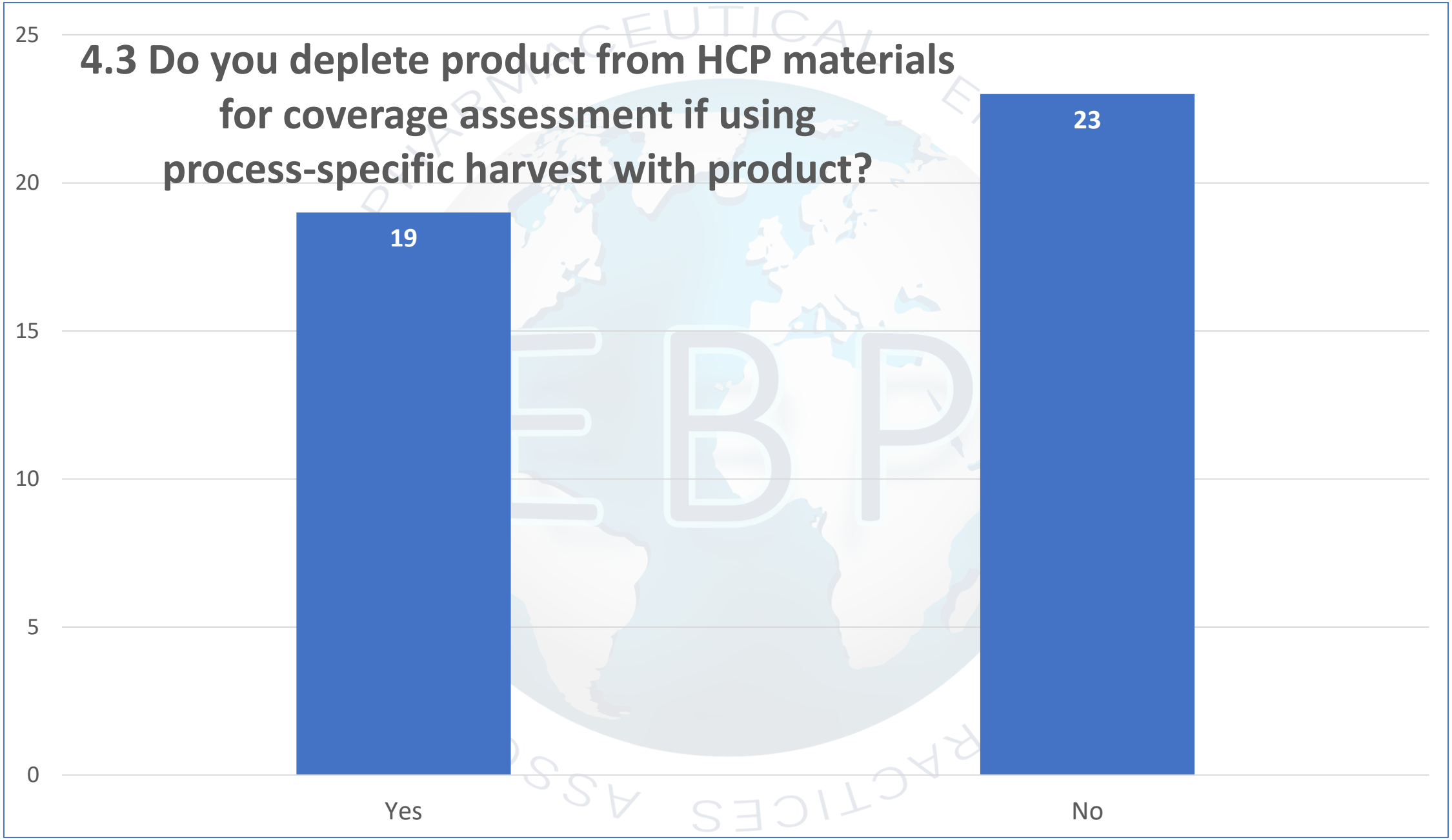
Day 4
ELISA Method Development Session

Session Chair: Stefanie Wohlrab

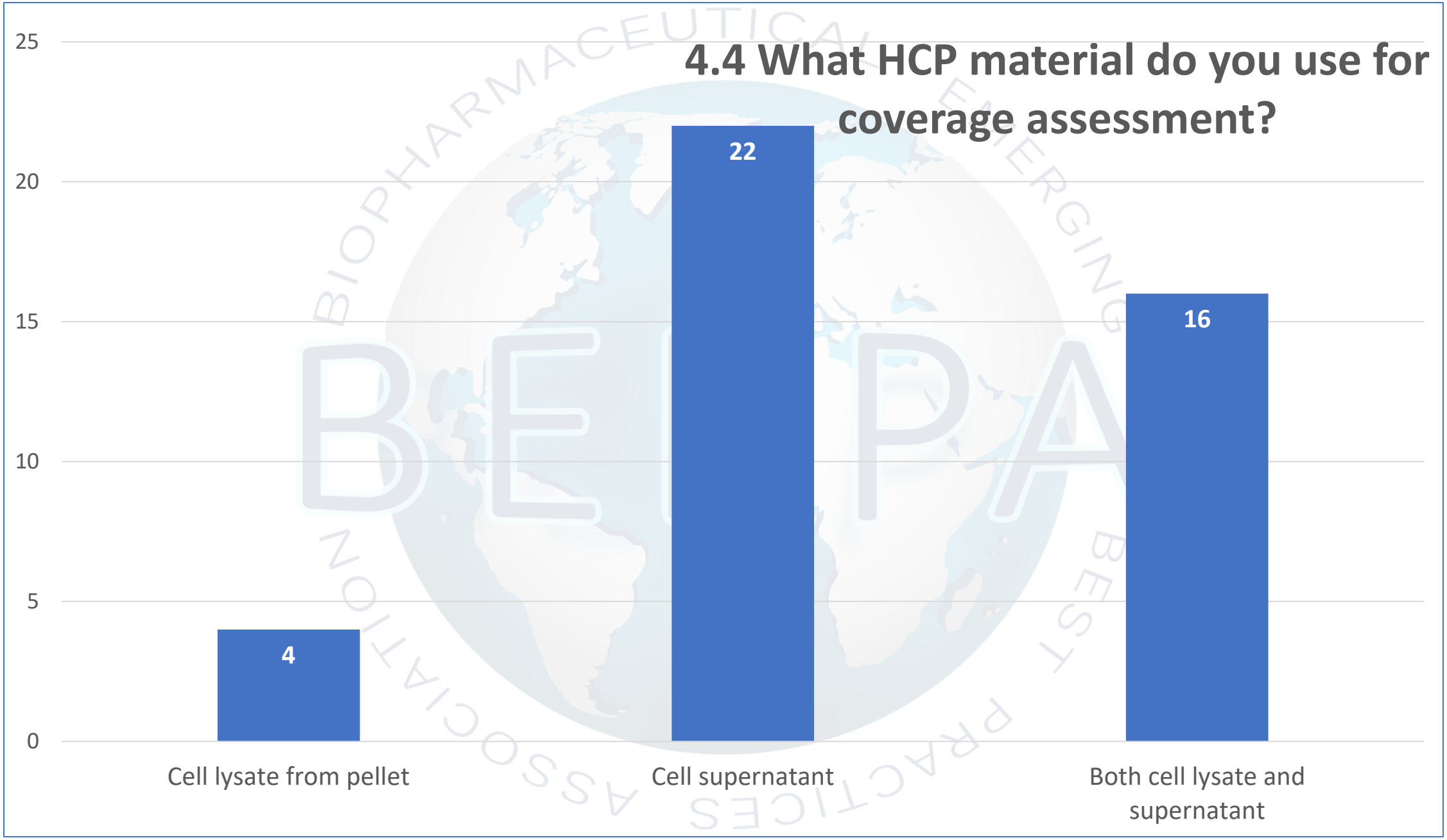

4.1 Do you think USP Chapter <1132> Residual Host Cell Protein Measurement in Biopharmaceuticals is in need of revision?
25
20
15
10
5
0
20
1
7
20
Yes
No
Not yet
Not sure

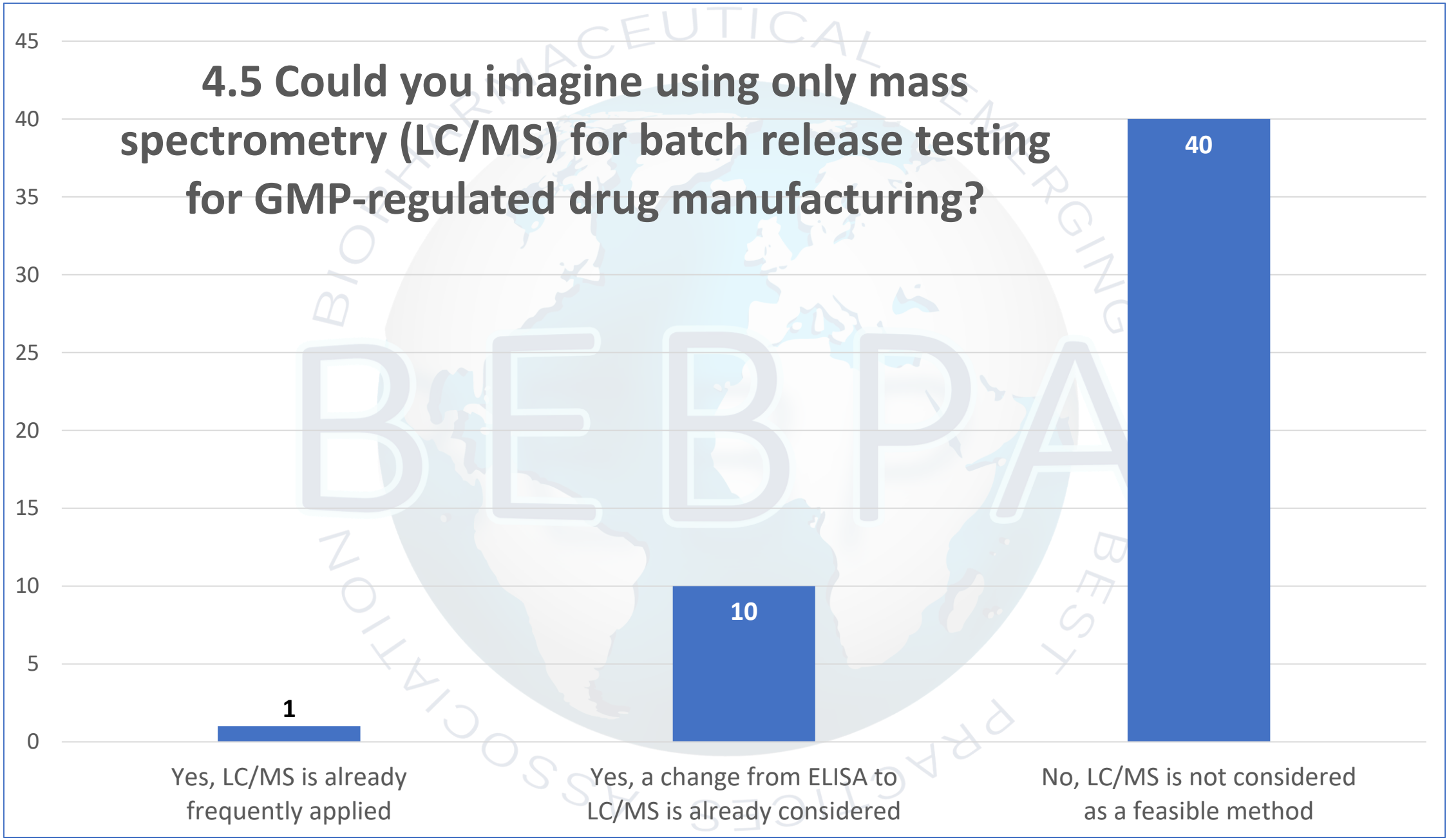
4.2 How many HCP ELISAs (plates) do you perform each month in your organisation?



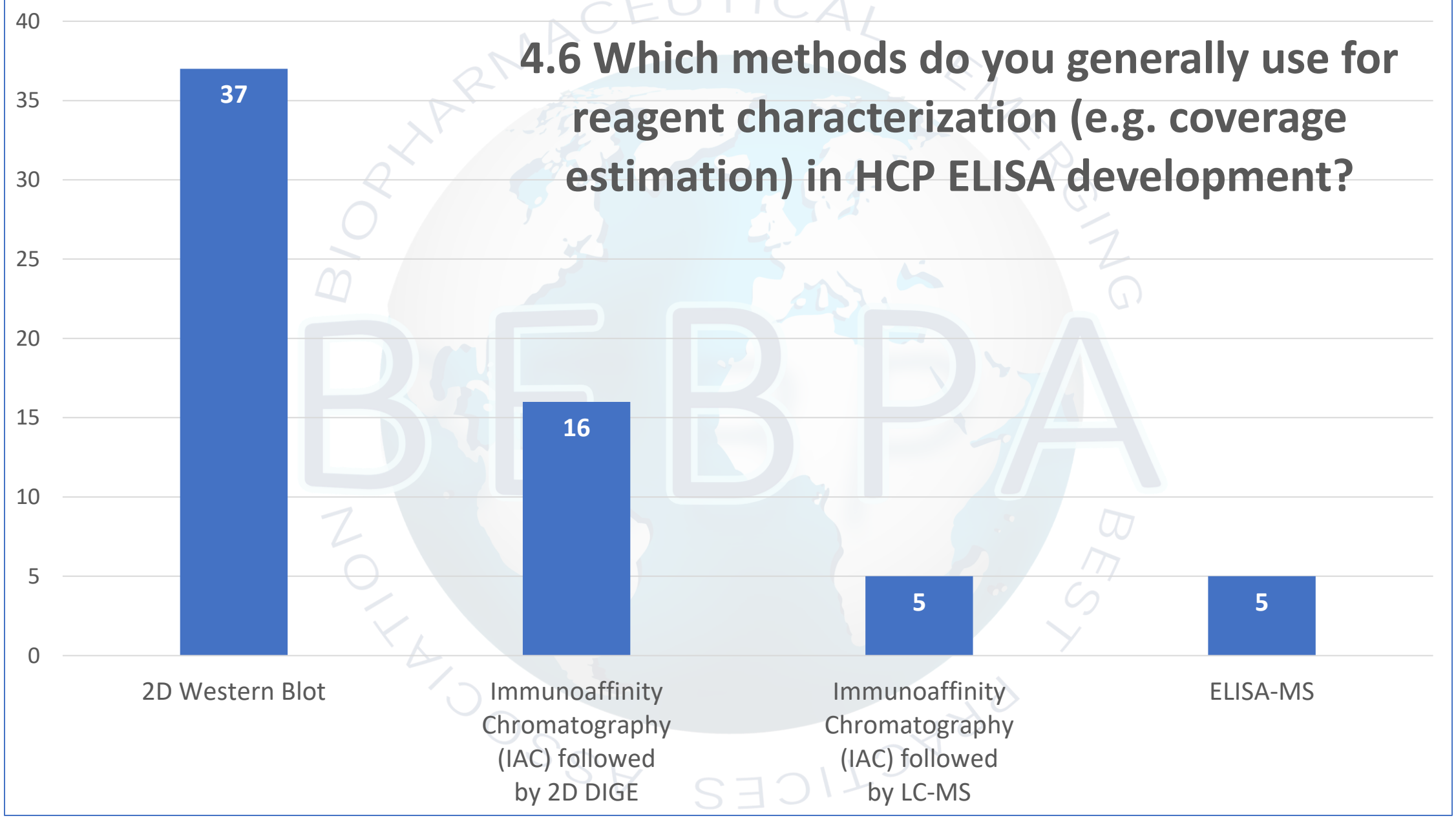

4.3 Do you deplete product from HCP materials for coverage assessment if using process-specific harvest with product?
25
20
15
10
5
0
19
23
Yes
No

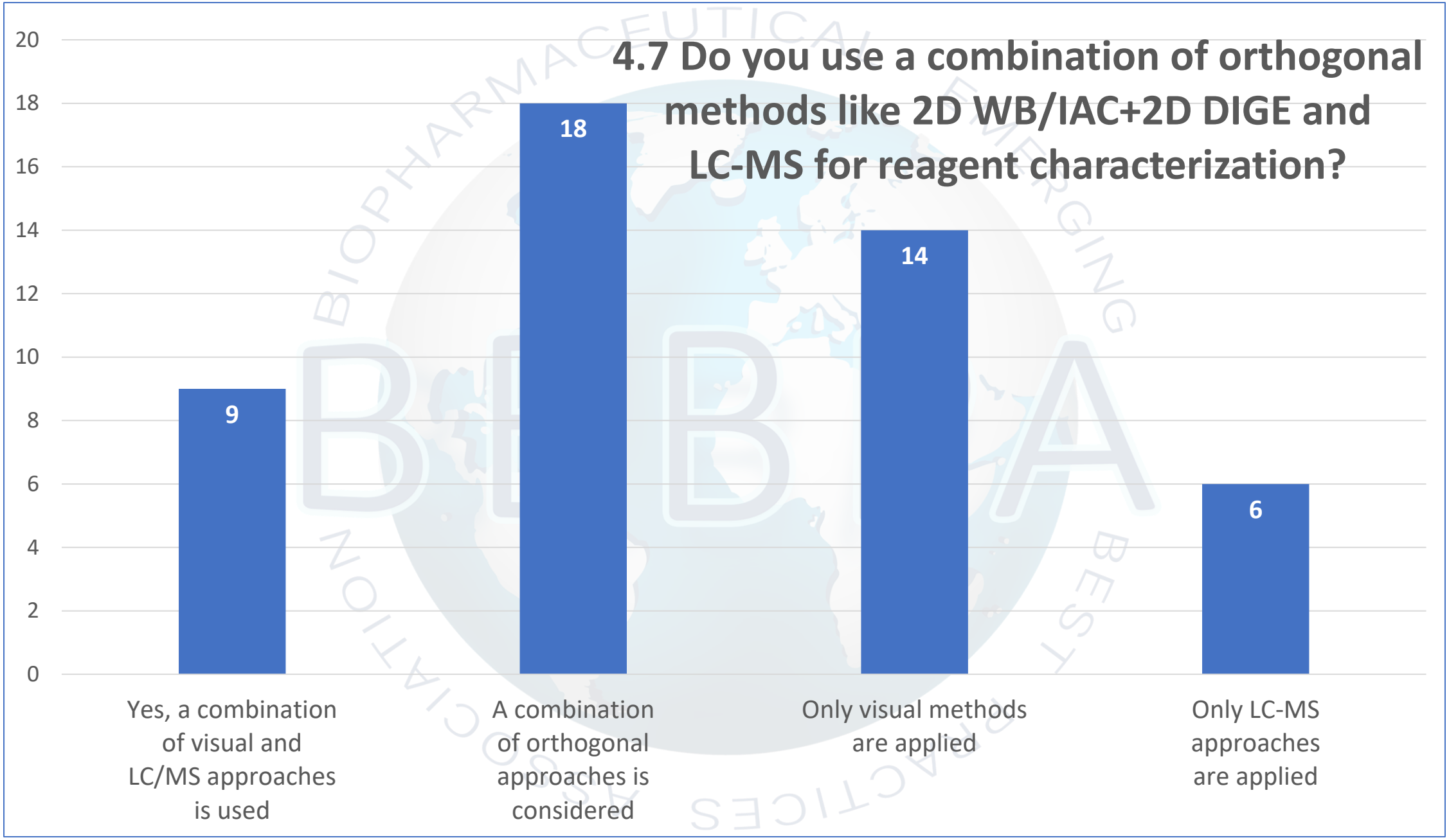
4.4 What HCP material do you use for coverage assessment?

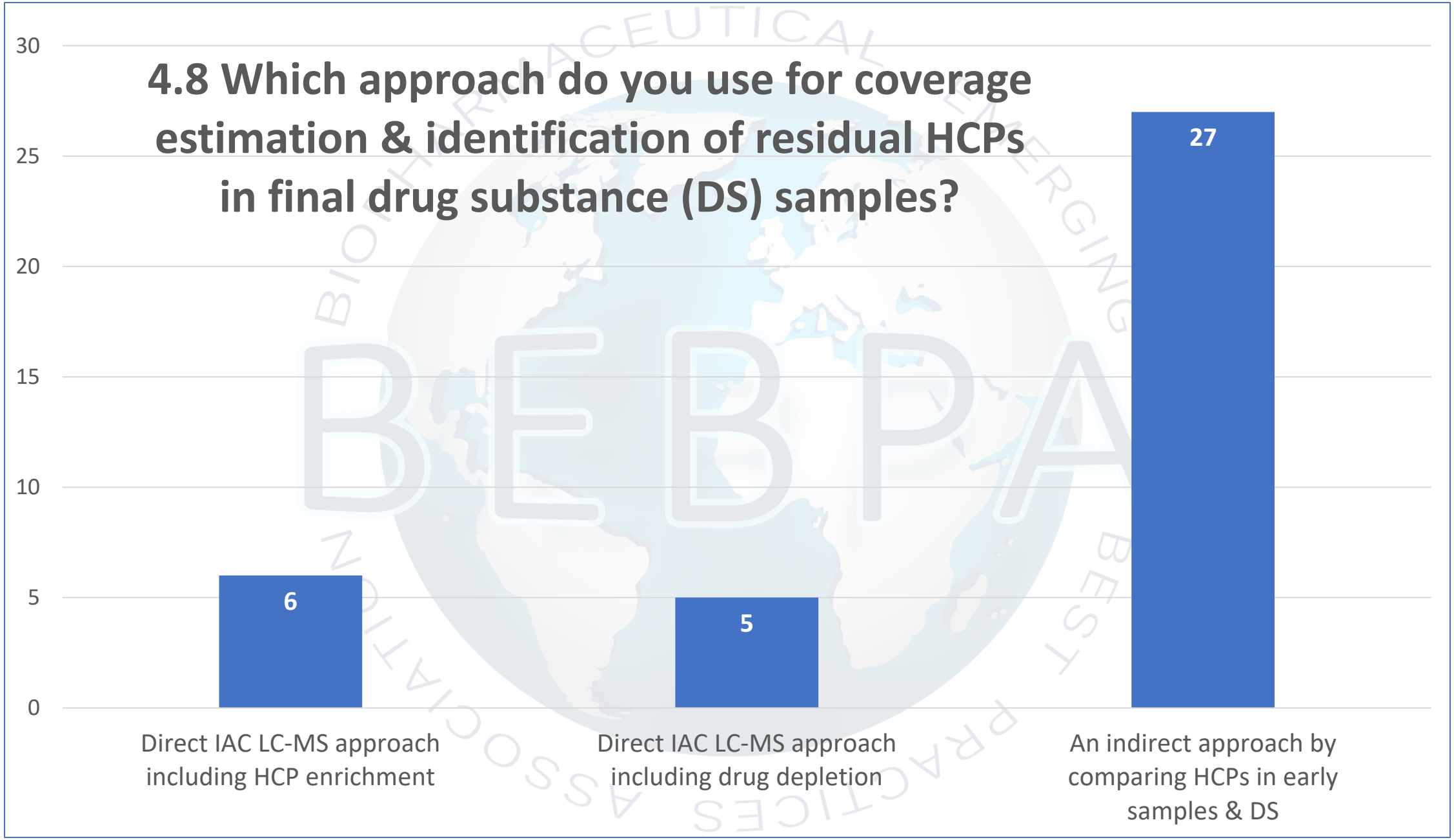



4.5 Could you imagine using only mass spectrometry (LC/MS) for batch release testing for GMP-regulated drug manufacturing?
45
40
35
30
25
20
15
10
5
0
1
10
40
Yes, LC/MS is already frequently applied
Yes, a change from ELISA to LC/MS is already considered
No, LC/MS is not considered as a feasible method

4.6 Which methods do you generally use for reagent characterization (e.g. coverage estimation) in HCP ELISA development?




4.7 Do you use a combination of orthogonal methods like 2D WB/IAC+2D DIGE and LC-MS for reagent characterization?
20
18
16
14
12
10
8
6
4
2
0
9
18
14
6
Yes, a combination of visual and LC/MS approaches is used
A combination of orthogonal approaches is considered
Only visual methods are applied
Only LC-MS approaches are applied


4.8 Which approach do you use for coverage estimation & identification of residual HCPs in final drug substance (DS) samples?
30
25
20
15
10
5
0
6
5
27
Direct IAC LC-MS approach including HCP enrichment
Direct IAC LC-MS approach including drug depletion
An indirect approach by comparing HCPs in early samples & DS

THANK YOU

for attending BEBPA's 2022 Host Cell Protein Conference

We could not have done this without YOU!