BEBPA 2020 Host Cell Protein Conference

26-28 October 2020

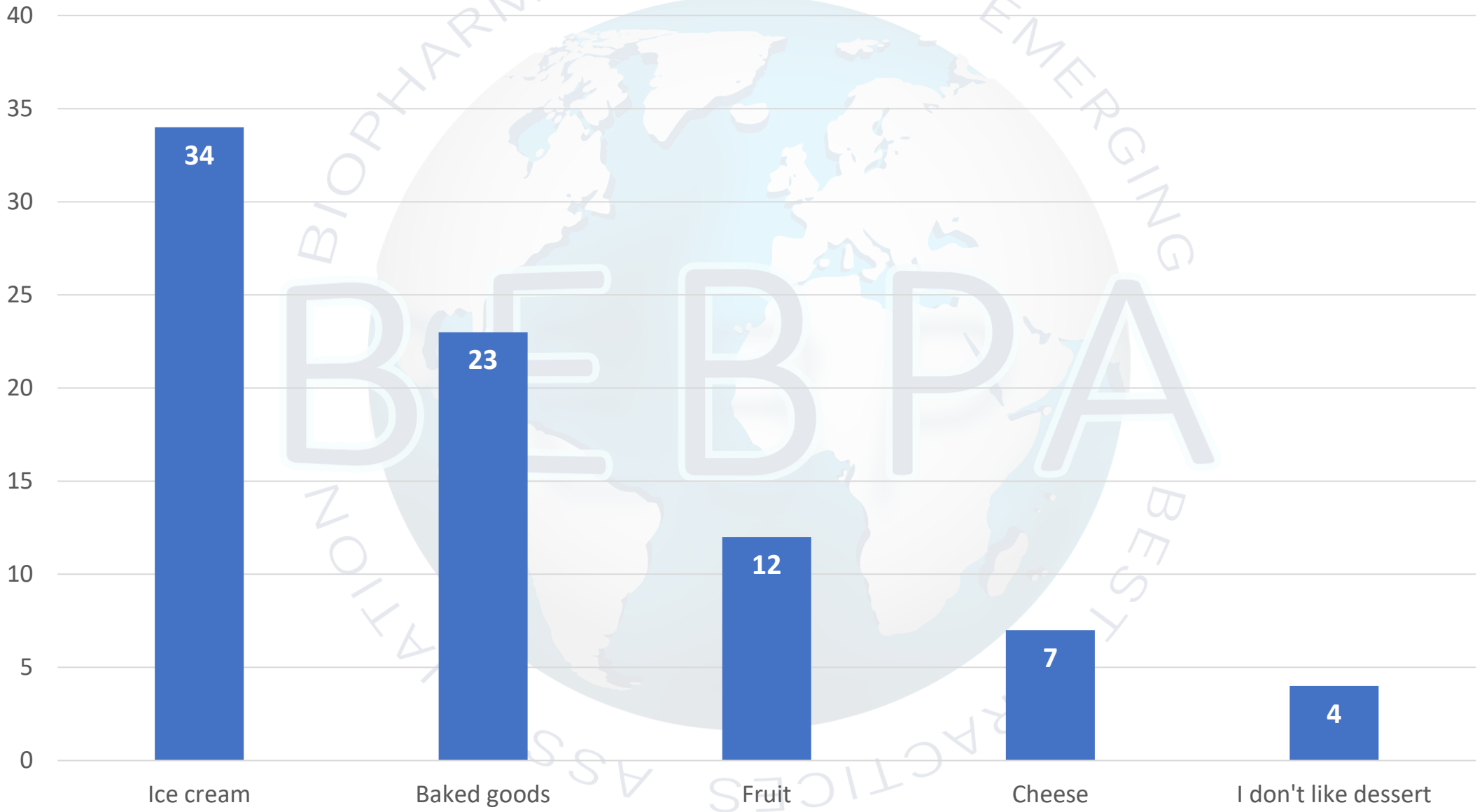
*Our 3rd **VIRTUAL** Conference!*

Audience Survey

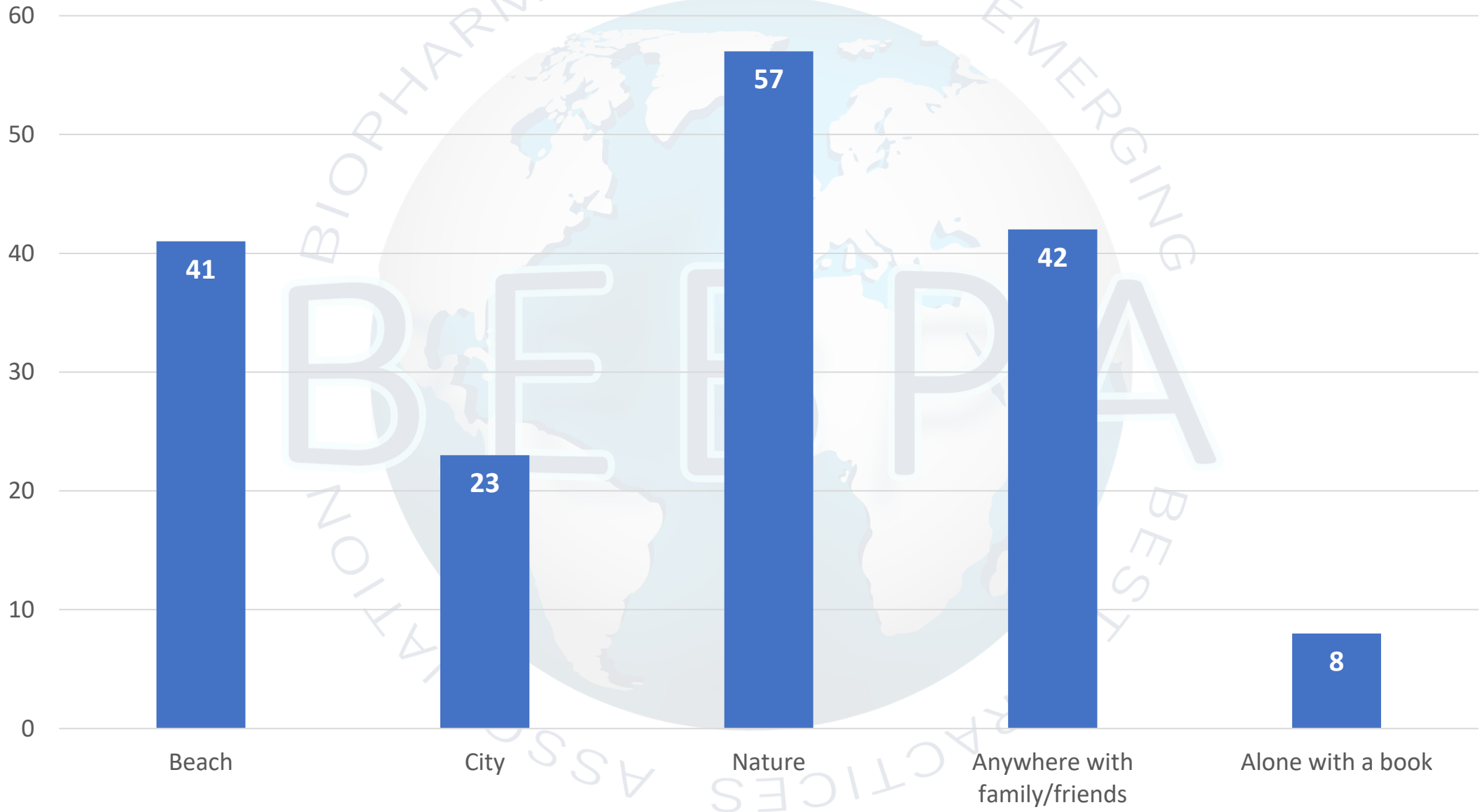
Welcome & Introduction

By: Denise Krawitz

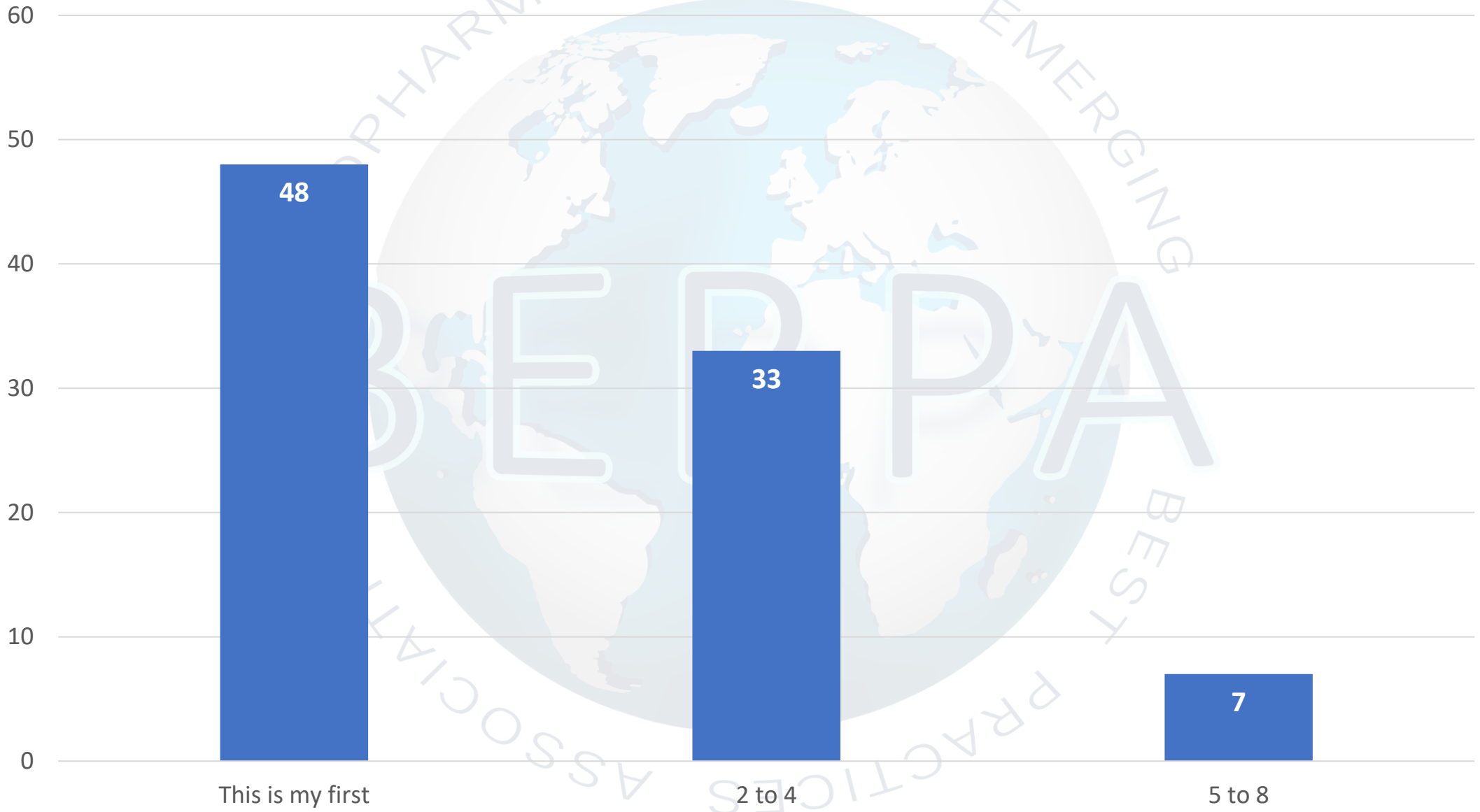
i-1 What is your favorite dessert?



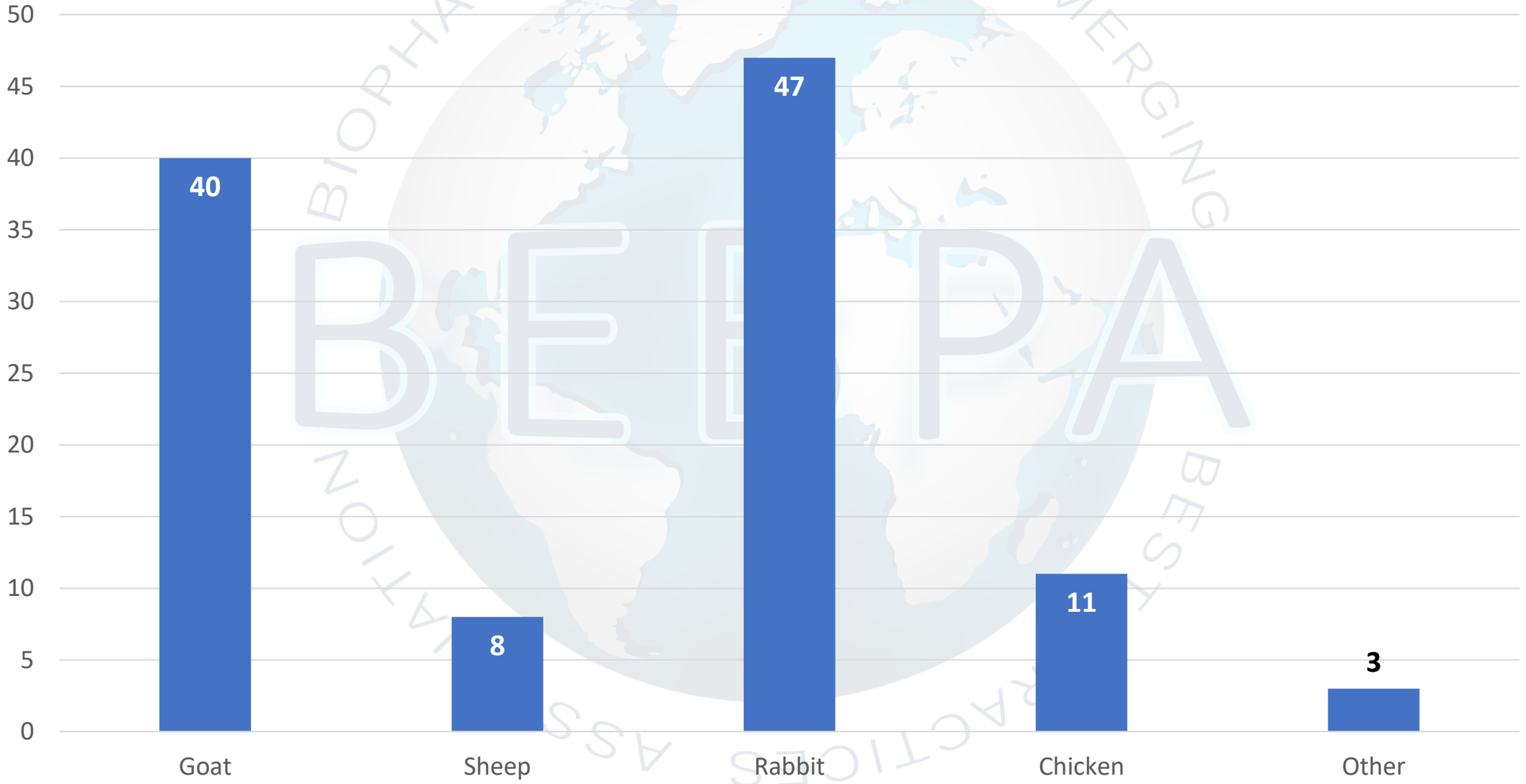
i-2 What is your favorite vacation?



i-3 How many BEBPA HCP Conferences have you attended?



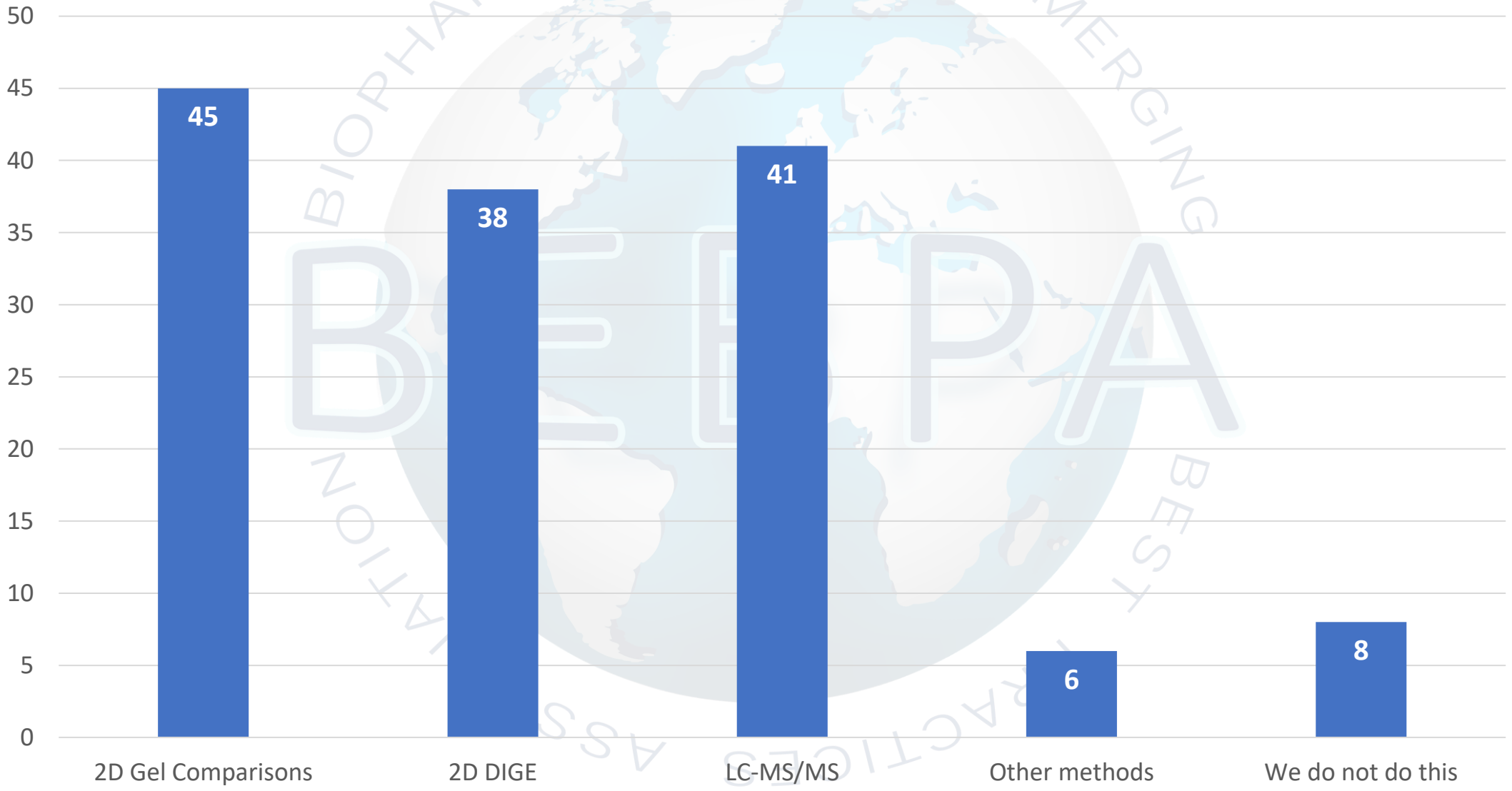
i-4 What host species do you commonly use for generation of anti-HCP antibodies?



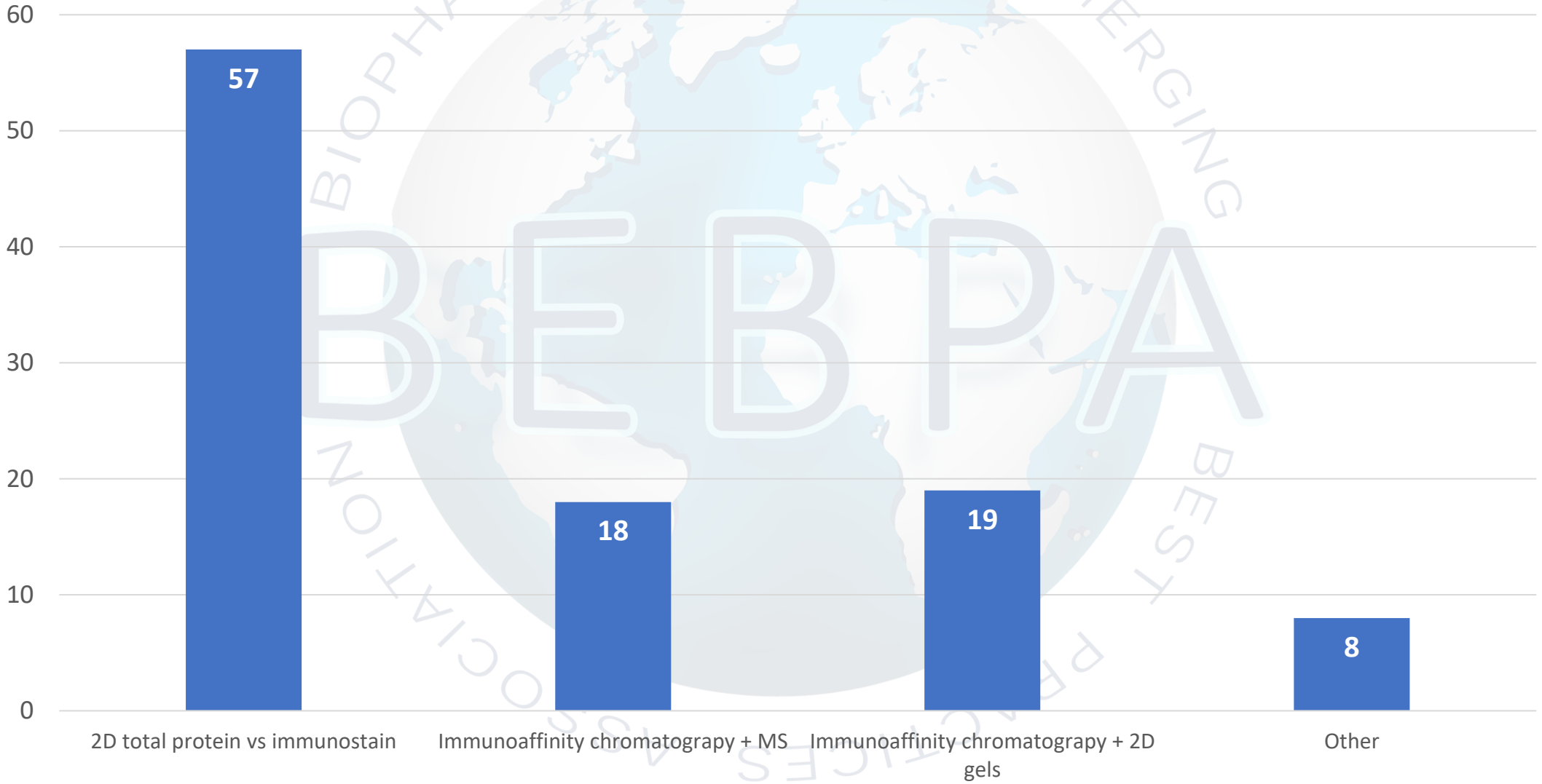
Session 1: Assay and Reagent Development

Session Chair: Stefanie Wohlrab

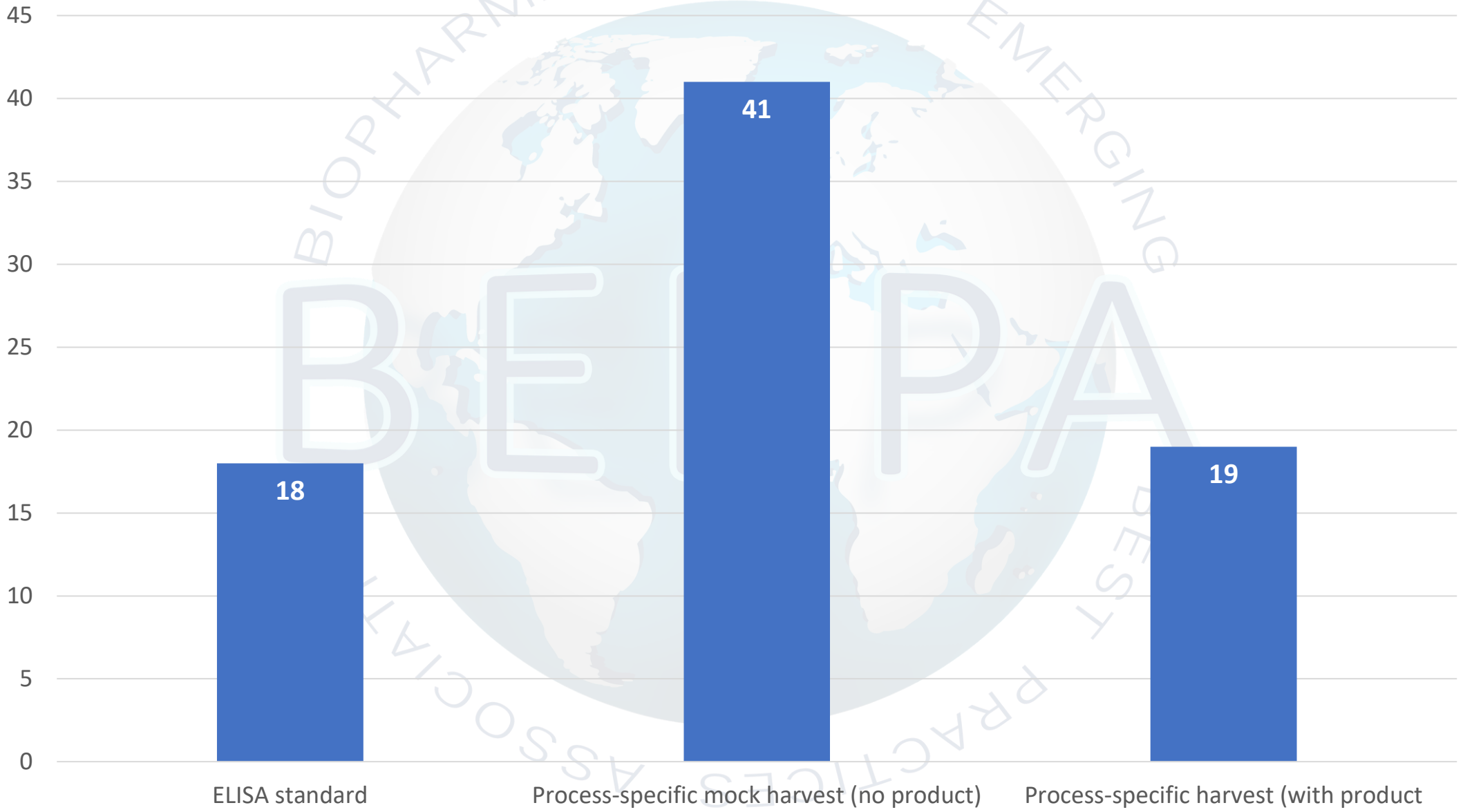
1.1 How do you demonstrate your ELISA standard contains an HCP population representative of your process?



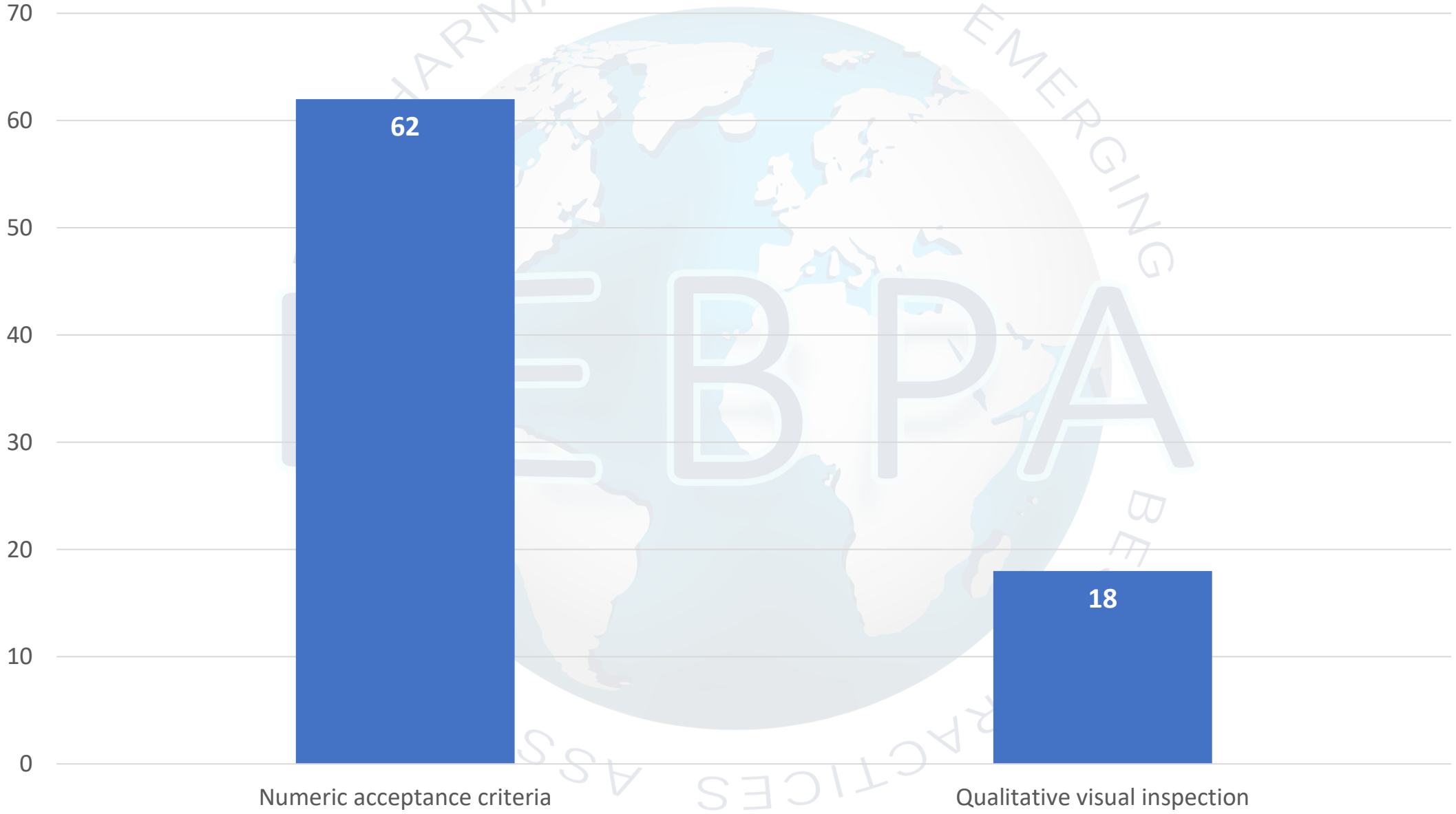
1.2 How do you determine coverage of your anti-HCP antibodies?



1.3 What sample(s) do you use to assess coverage?



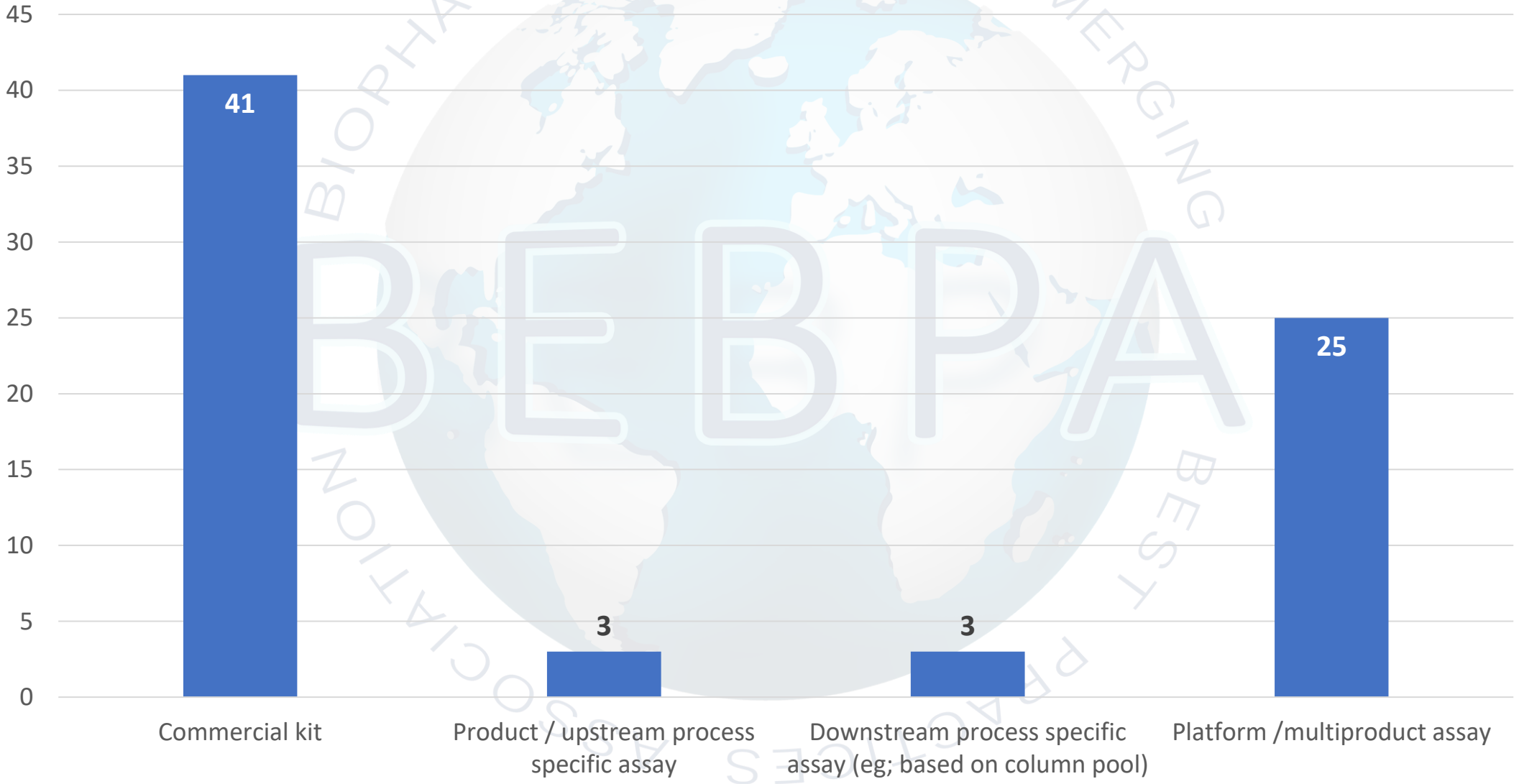
1.4 How do you assess whether you have sufficient coverage?



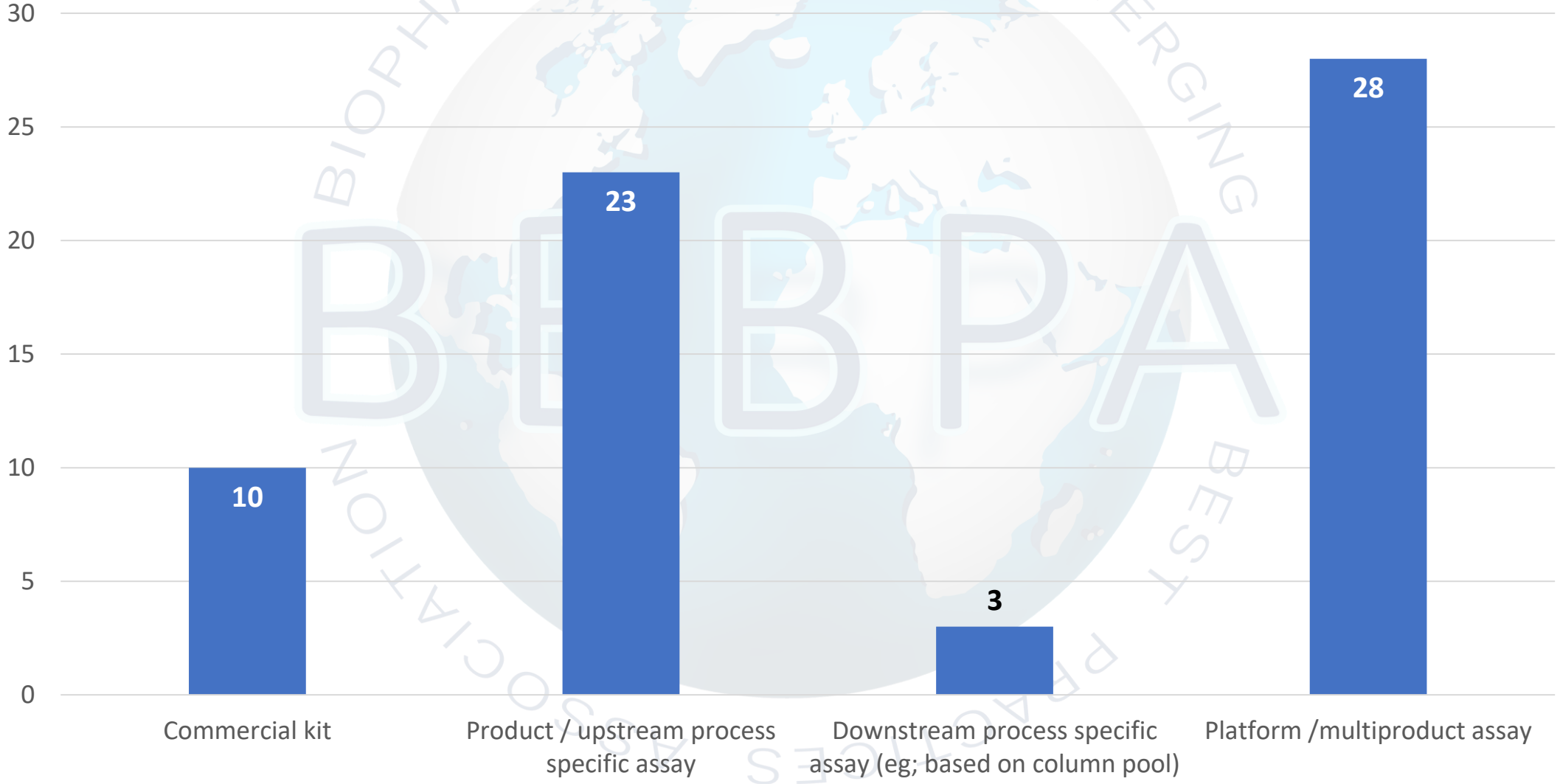
Session 2: Regulatory Trends

Session Chair: Svetlana Bergelson

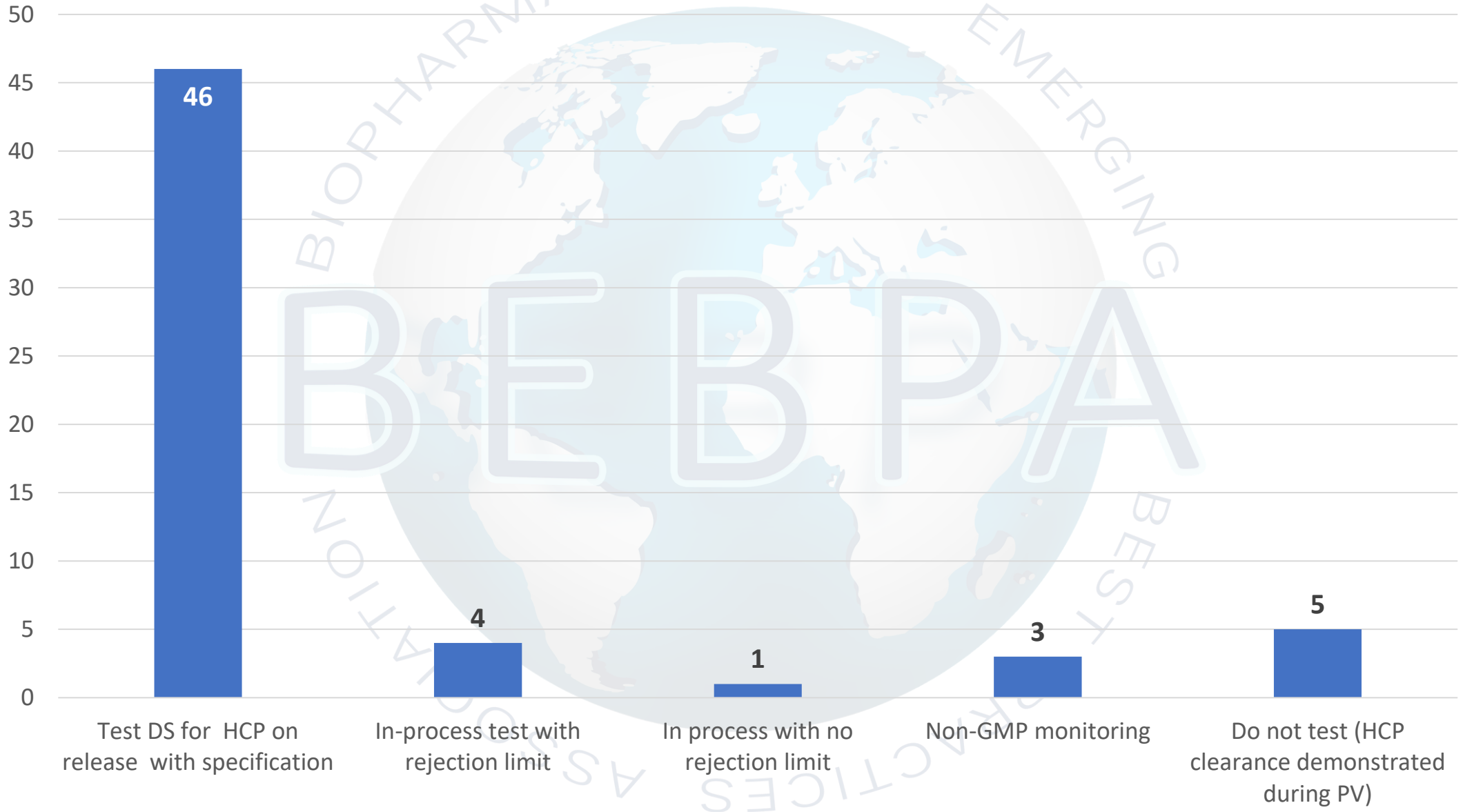
2.1 What type of assay do you typically use for monitoring HCPs during early development (Phase 1)?



2.2 What type of assay do you typically use for monitoring HCPs at the time of commercialization?



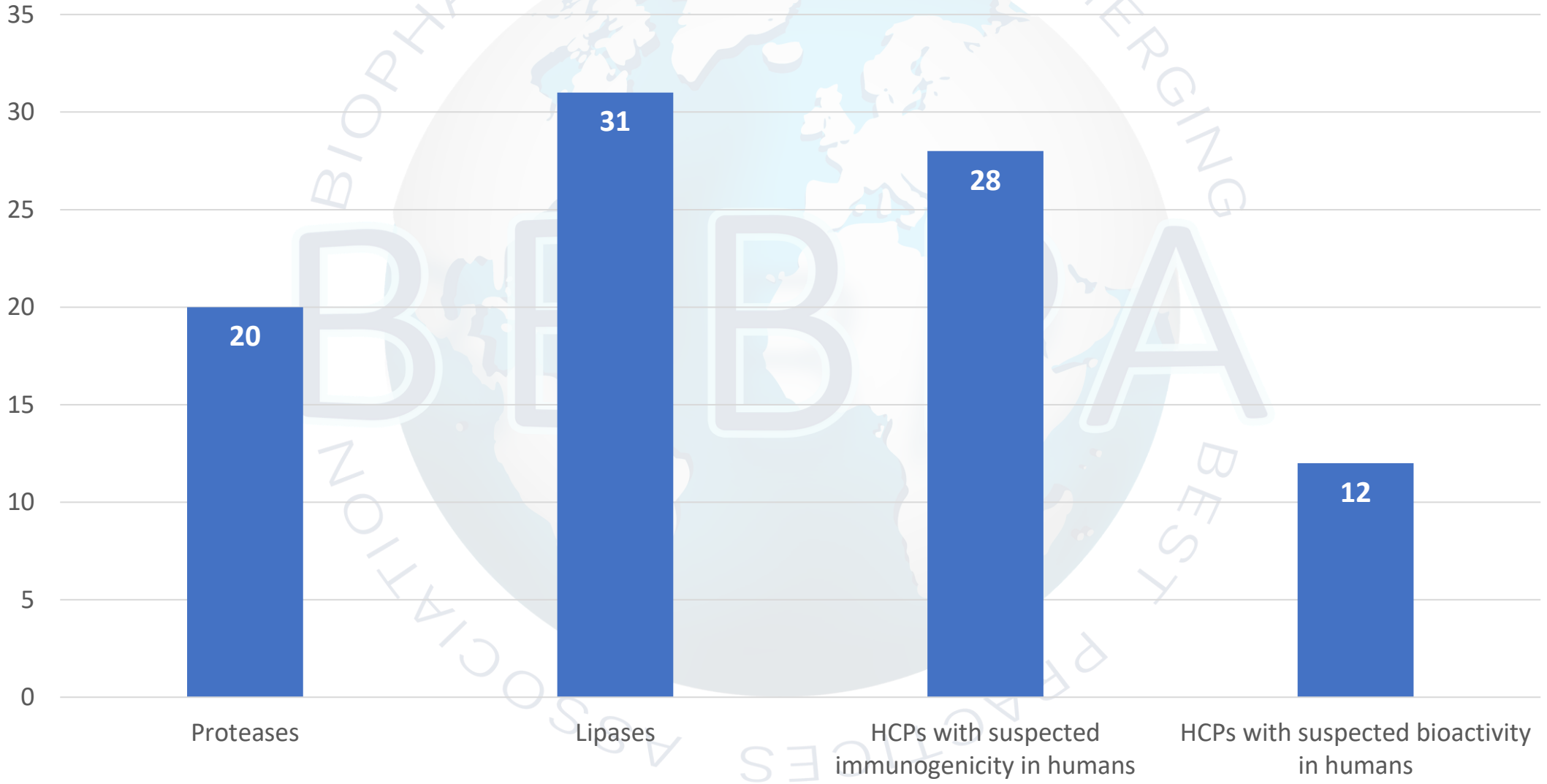
2.3 What was the HCP control strategy for your last successful BLA?



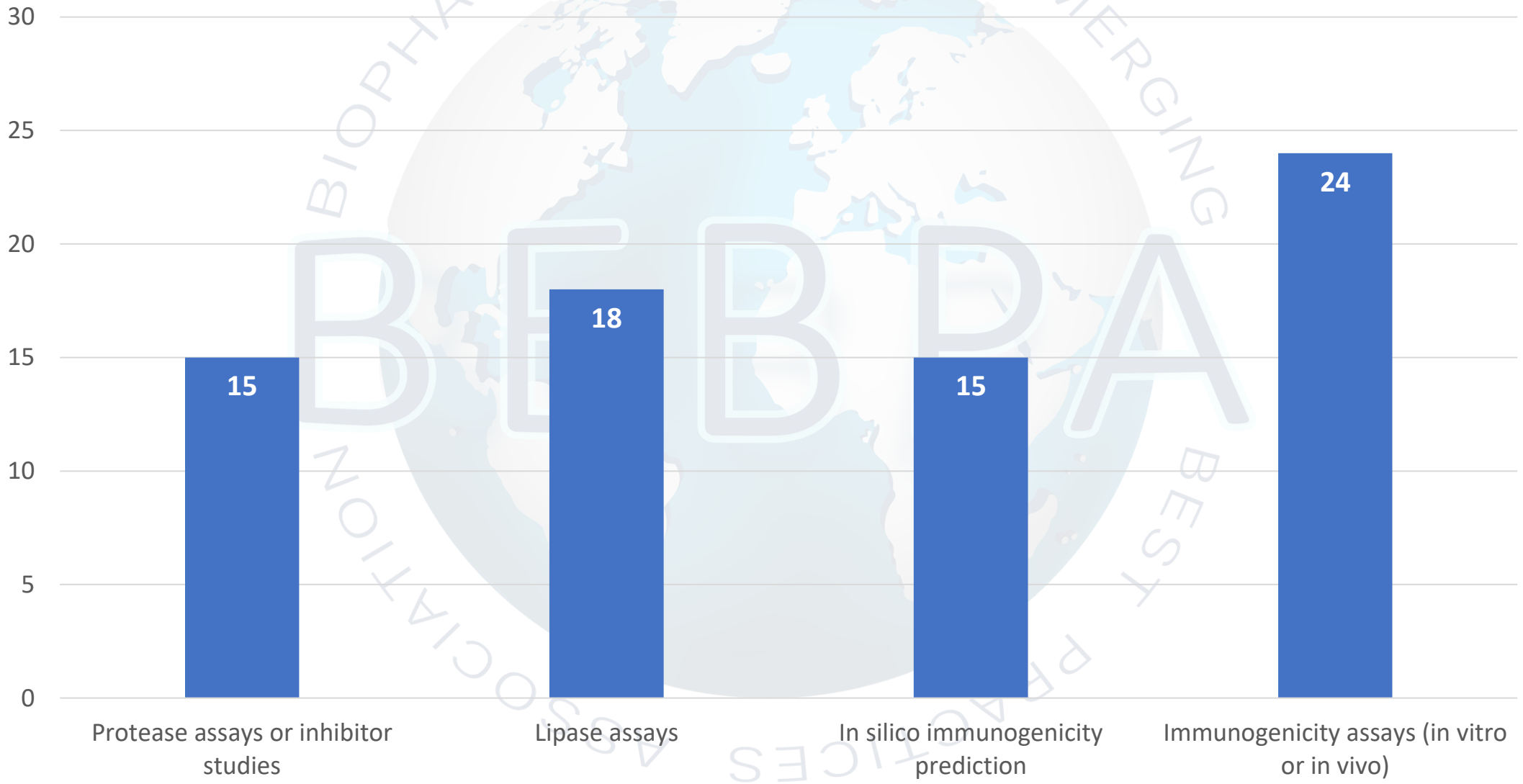
Session 3: ID/Management of ID'd HCP's

Session Chair: Frieder Kroener

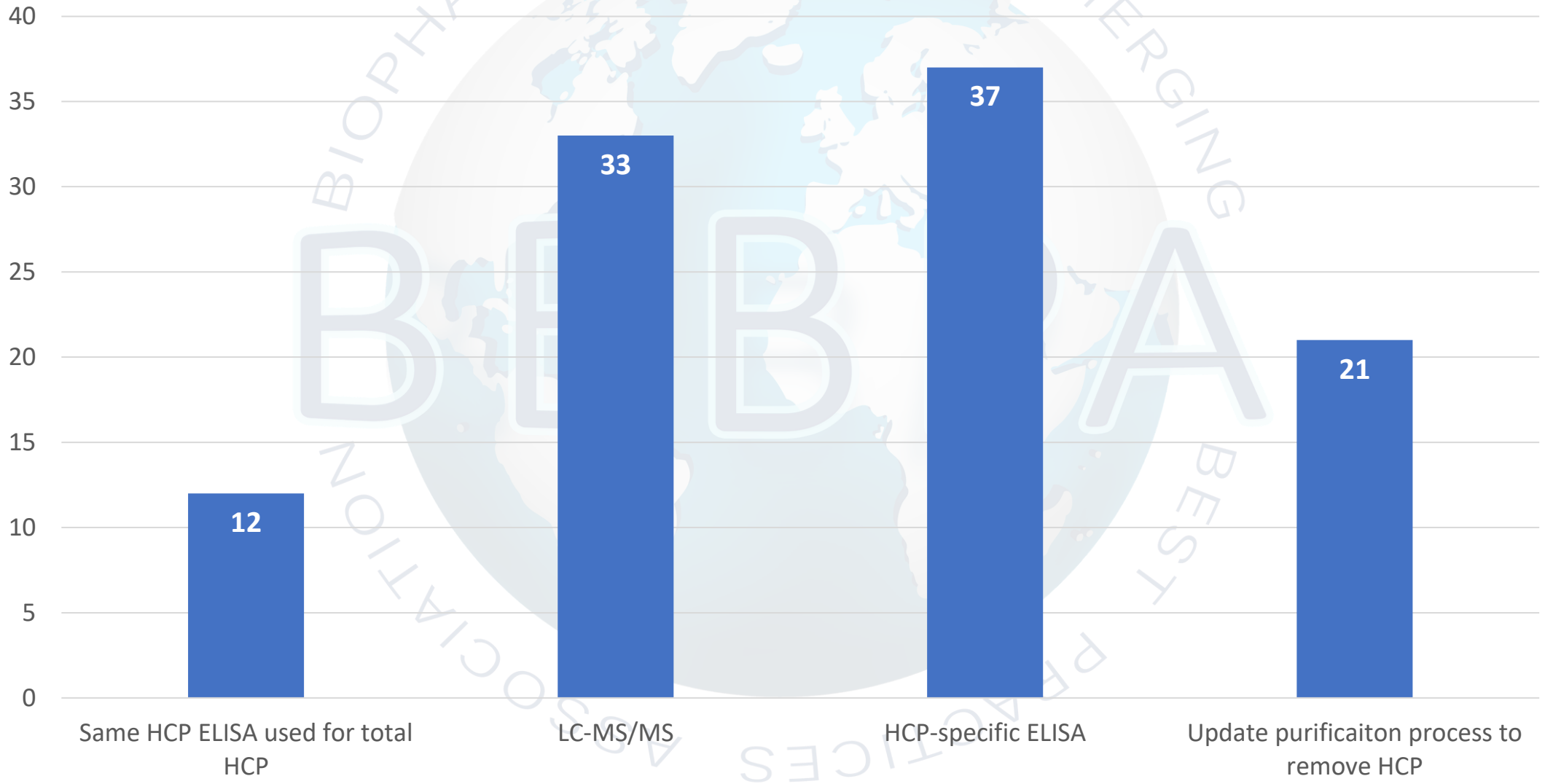
3.1 What category of HCPs have you had trouble with during development?



3.2 What methods do you use to study the impact of HCPs on product quality?



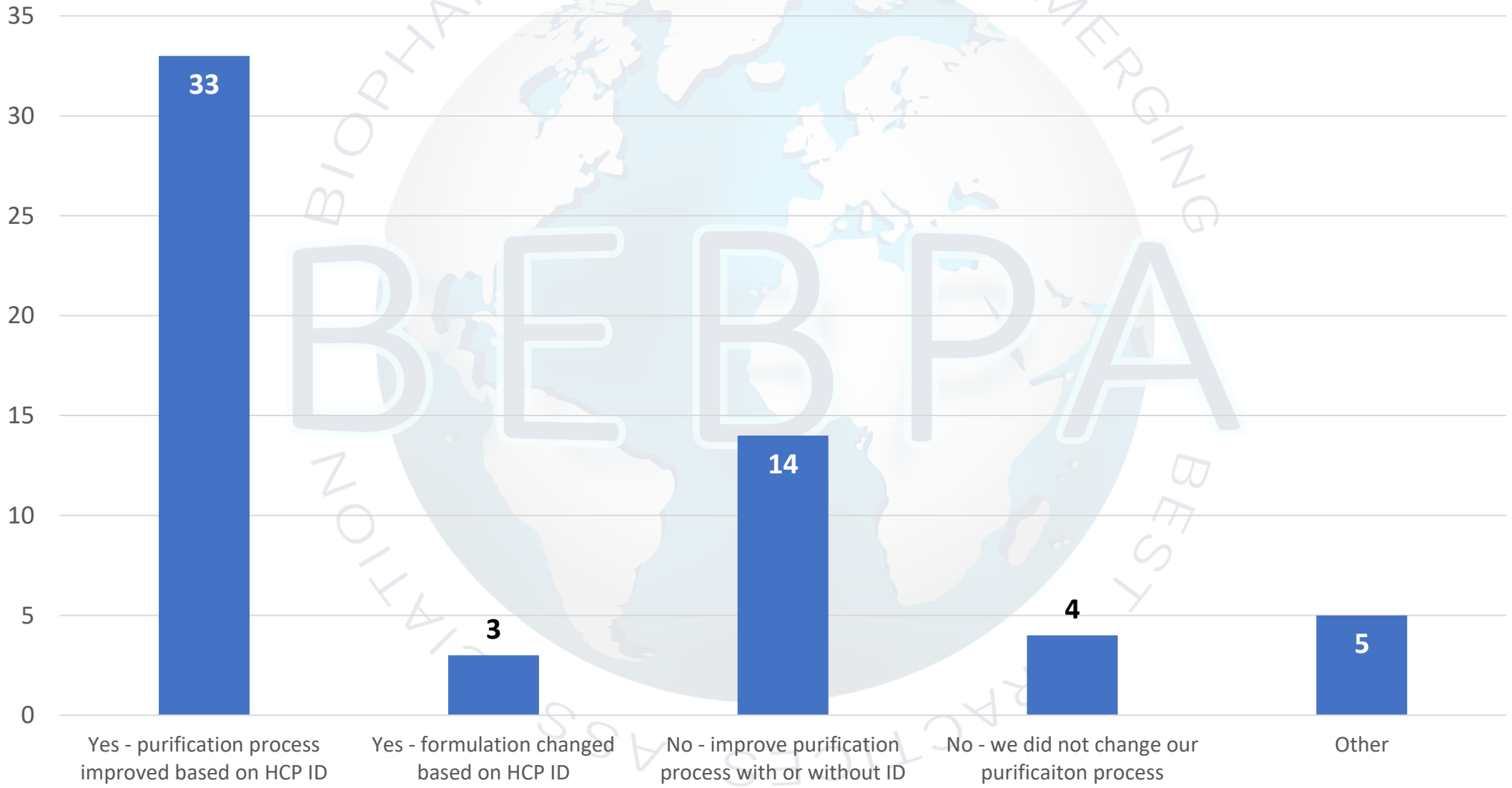
3.3 What is your preferred method to routinely monitor a single HCP?



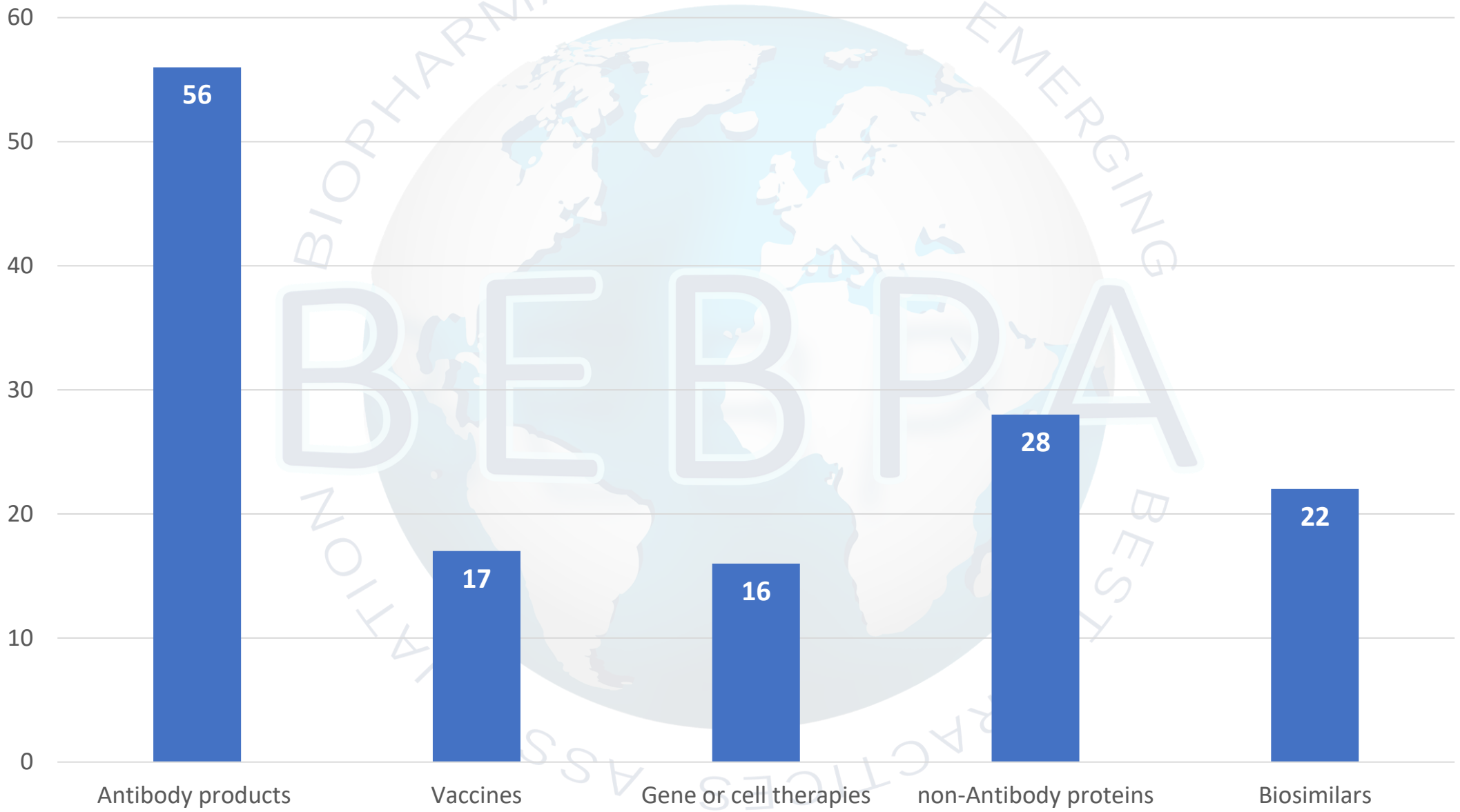
Session 4: Gene Therapy

Session Chair: Denise Krawitz

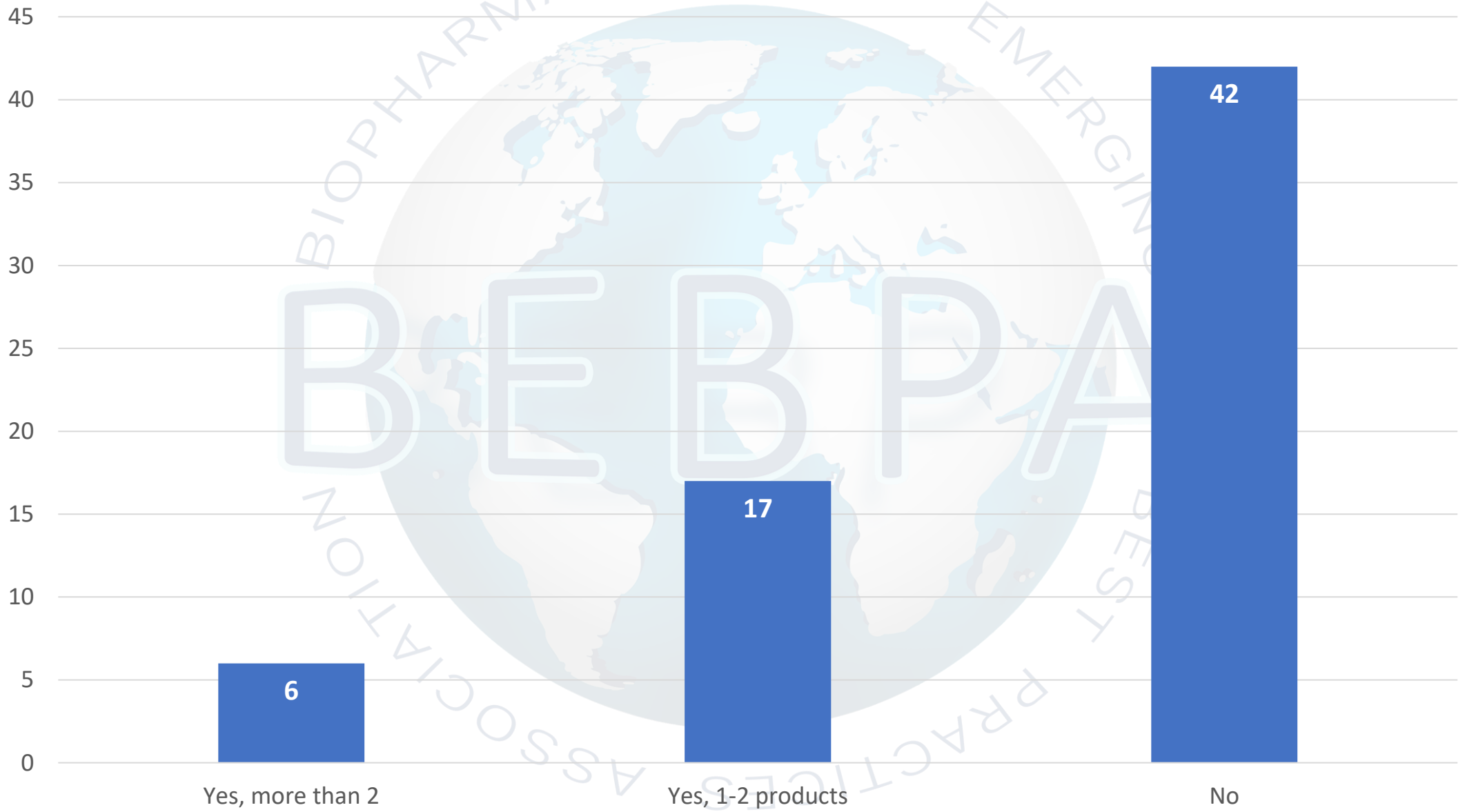
4.1 Has identification of an HCP impurity helped with development?



4.2 What product type(s) do you most frequently work on?



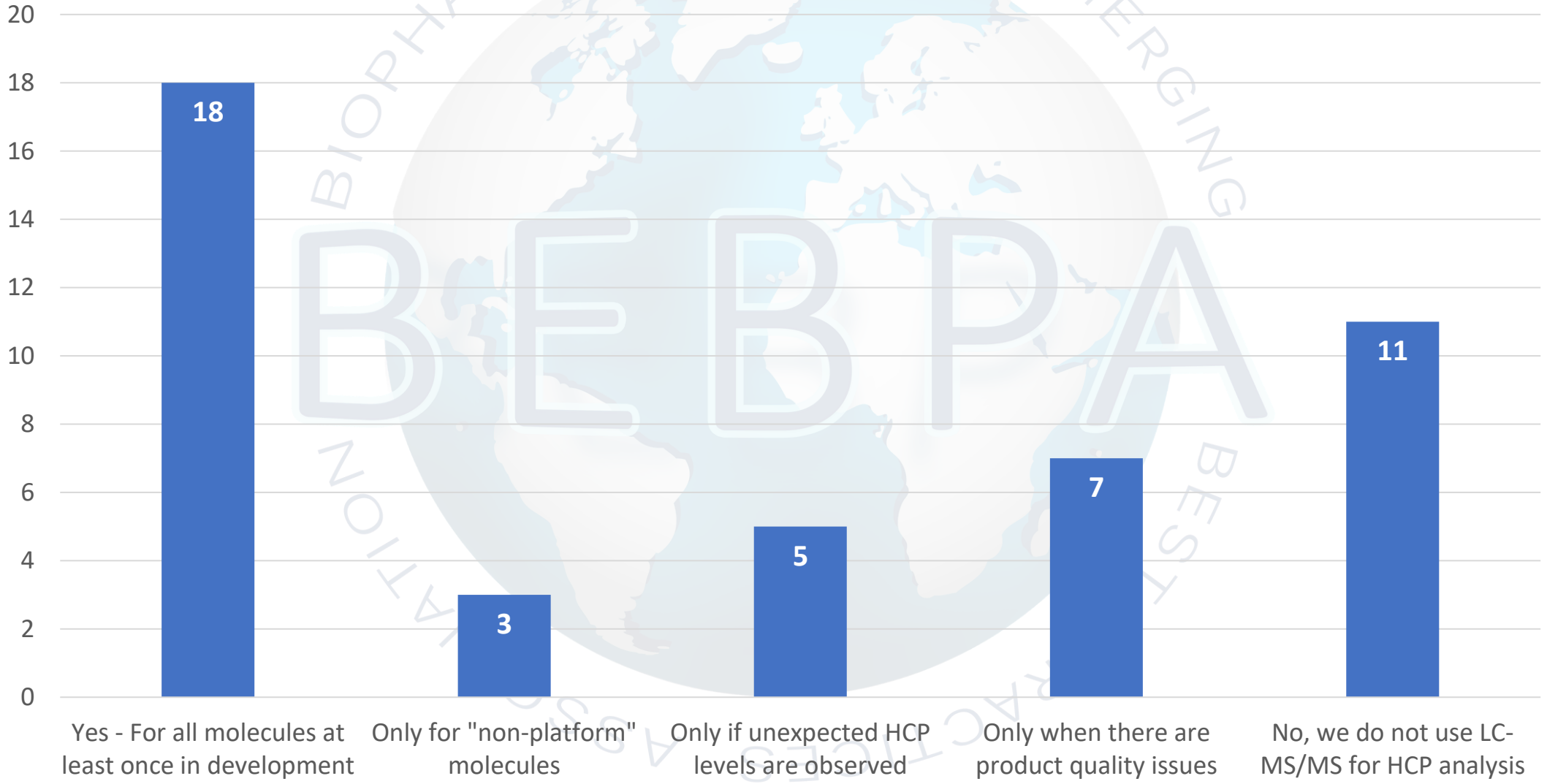
4.3 Does your organization develop gene therapy products?



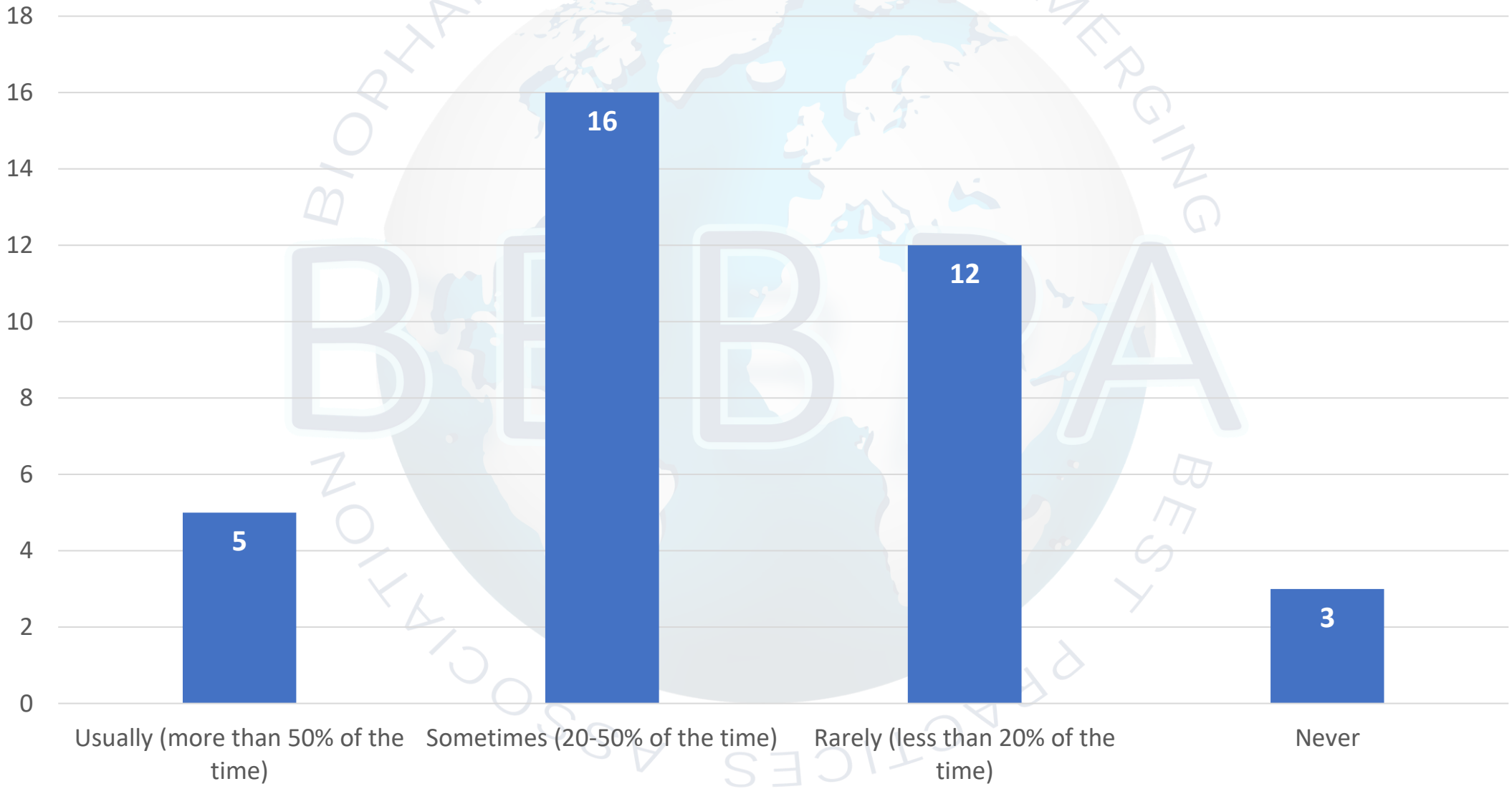
Workshop: LC-MS Workflow for HCP Analysis

Co-Organizers: Martha Stapels & Kevin Van Cott

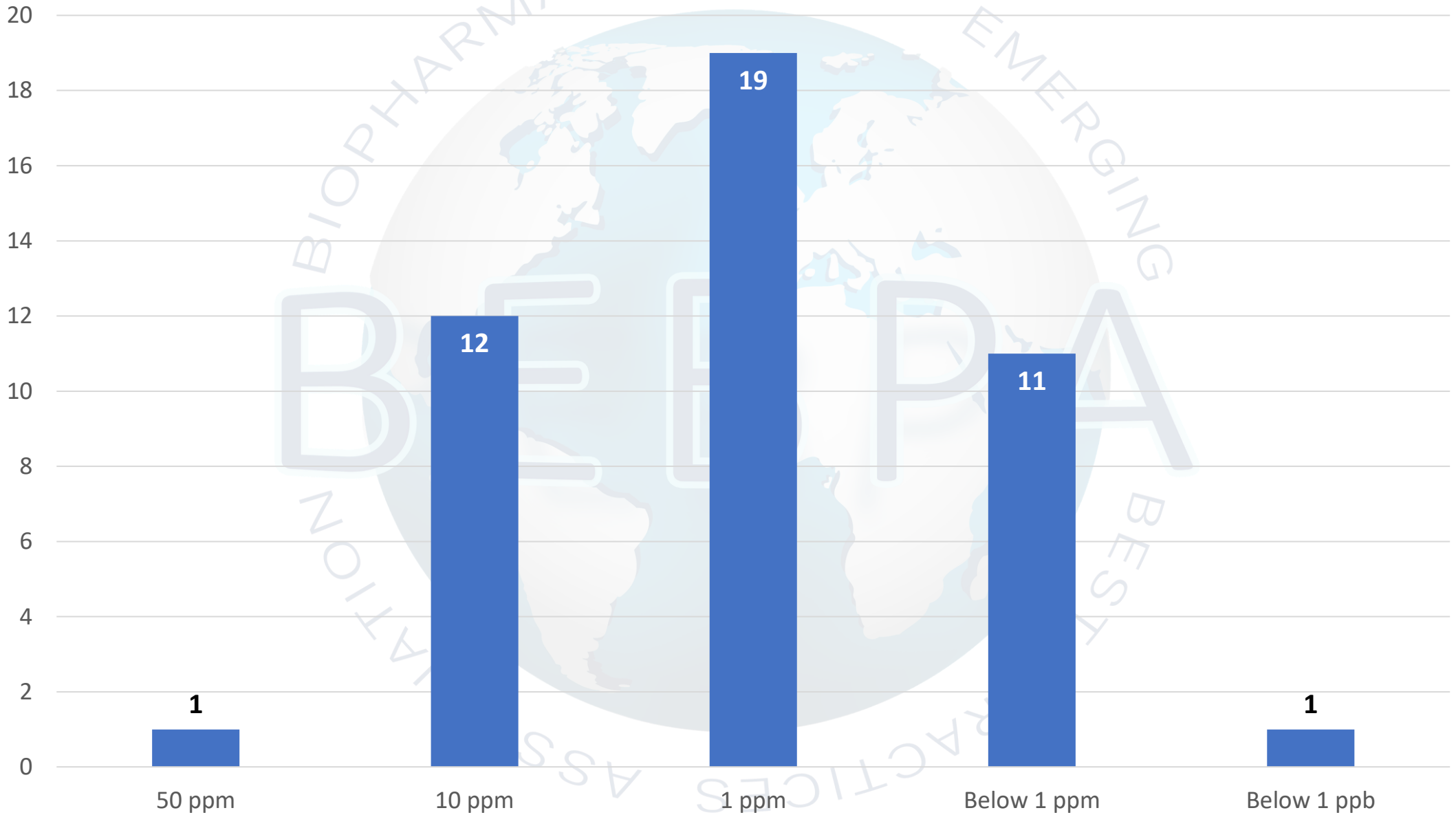
W-1 Do you routinely use LC-MS/MS to monitor HCPs during development?



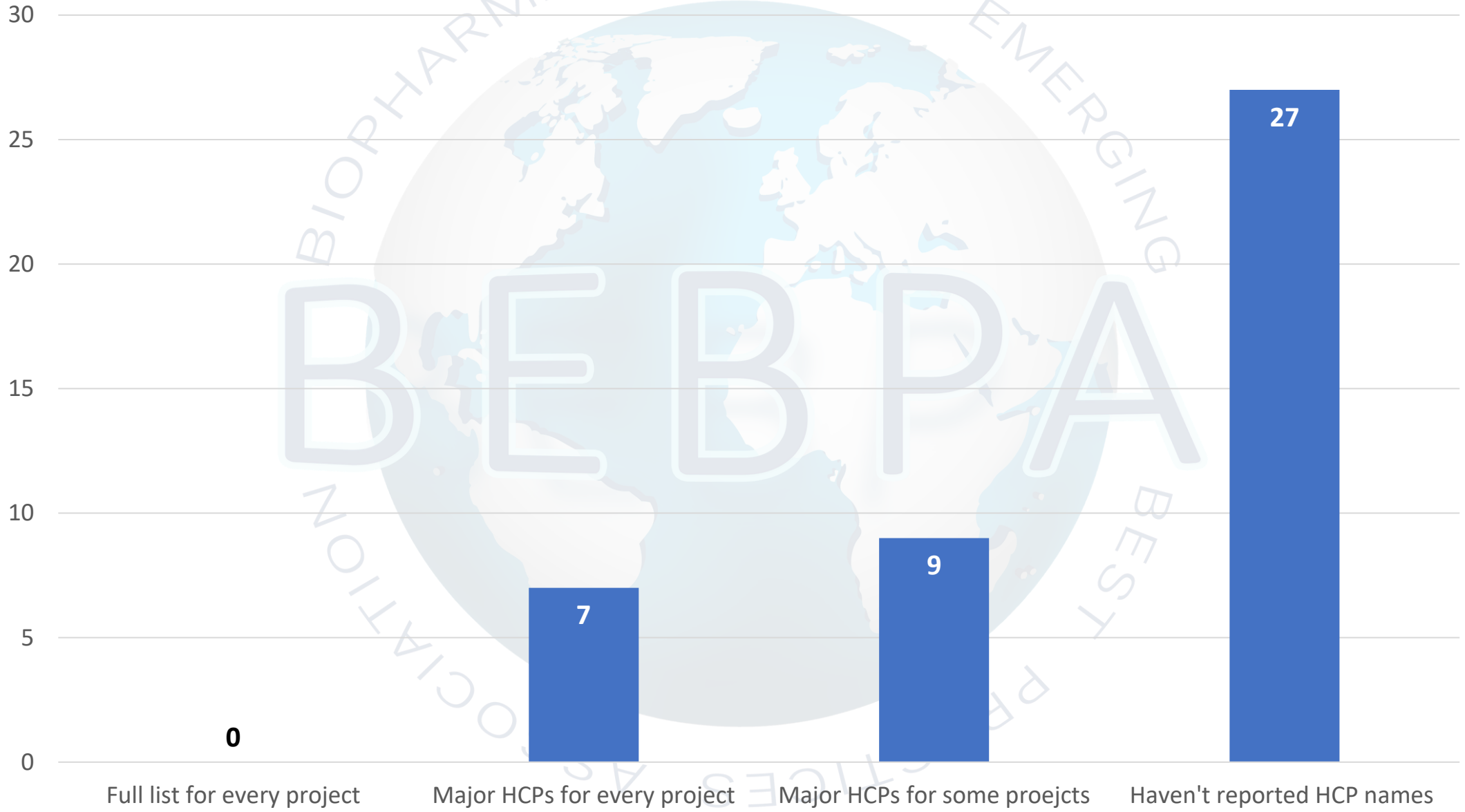
W-2 When degradation is a problem (product or excipient), can you definitively identify the culprit as an HCP with MS?



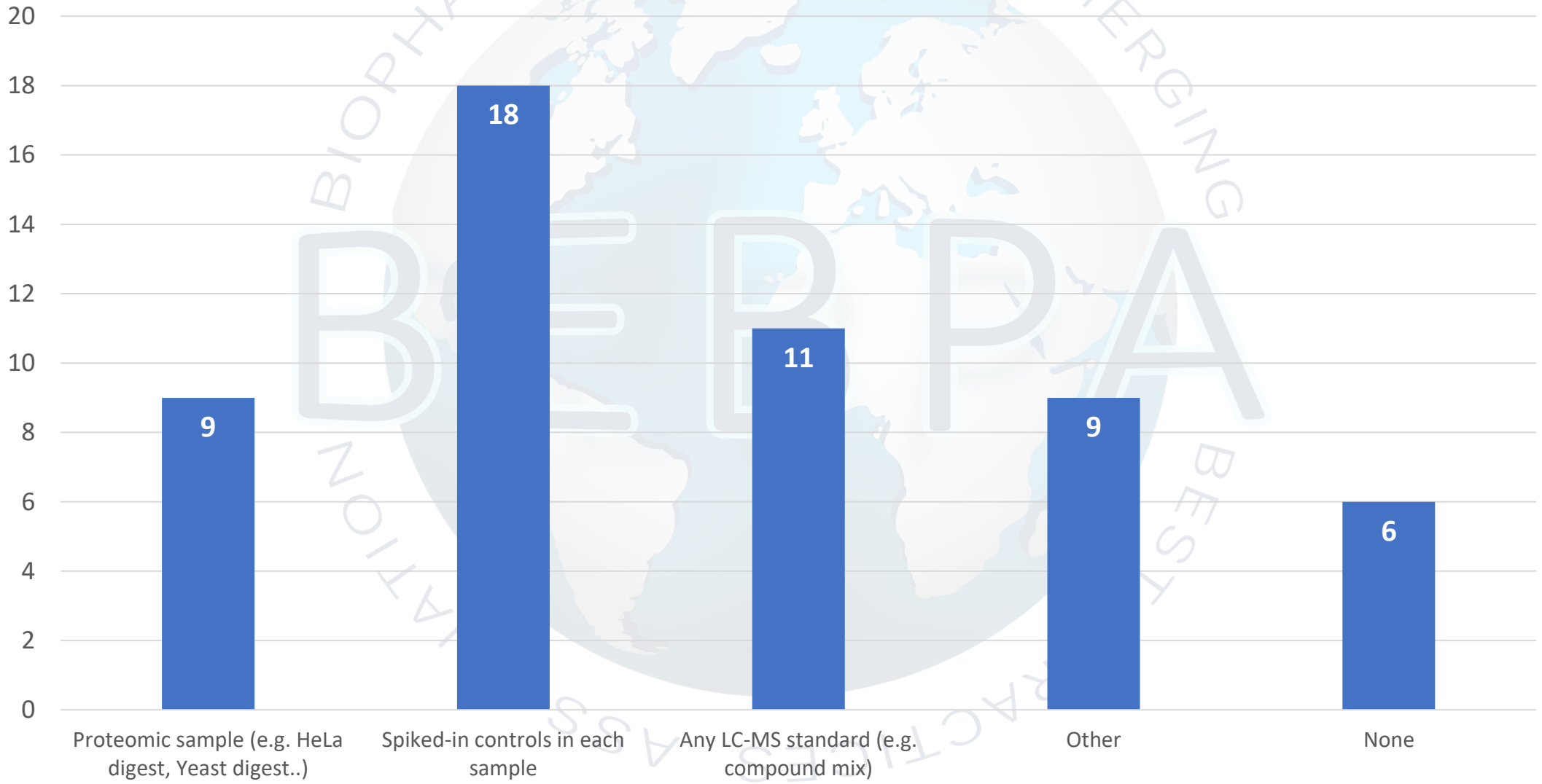
W-3 How low do we need to go to detect individual HCPs?



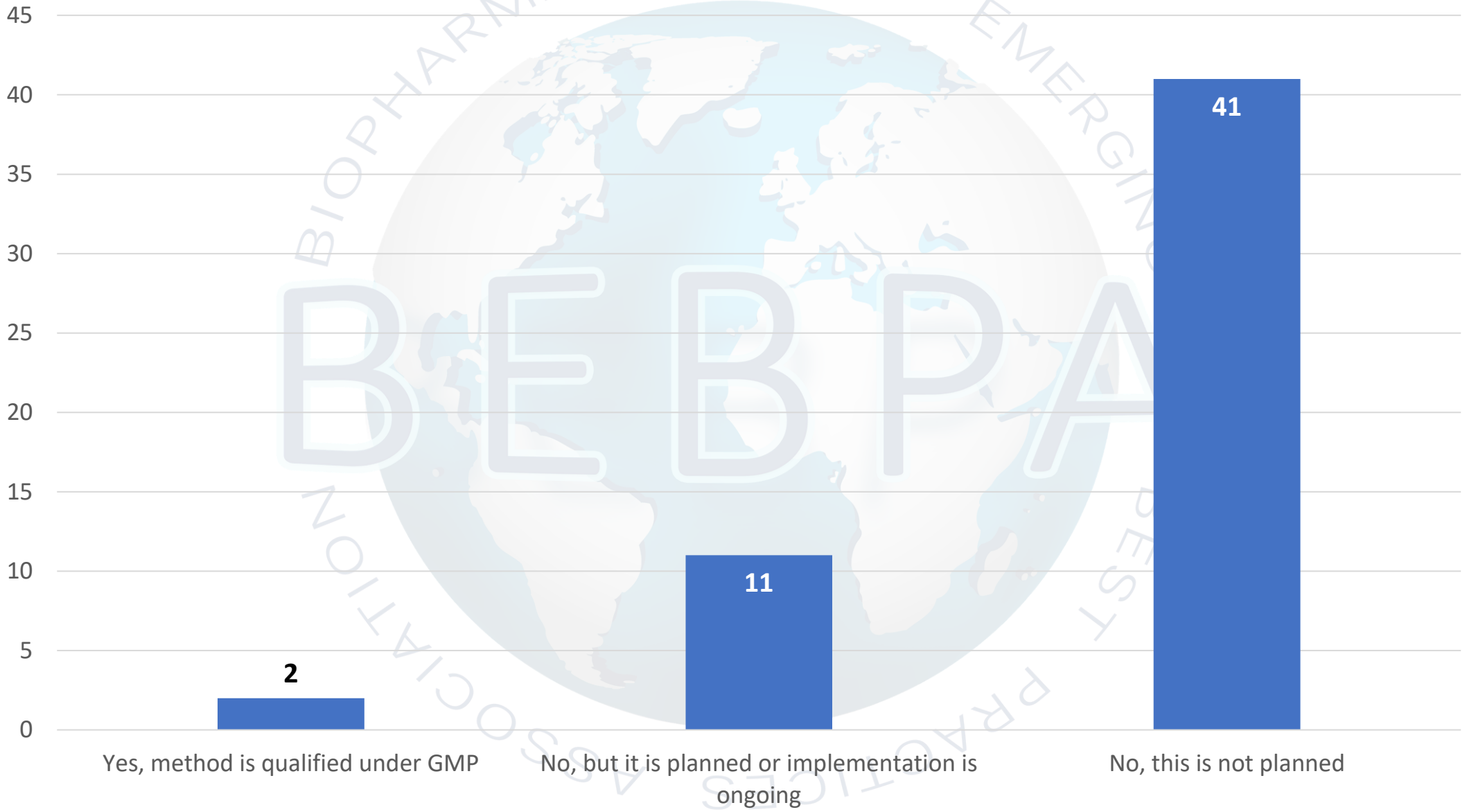
W-4 Do you report HCP names to regulatory agencies?



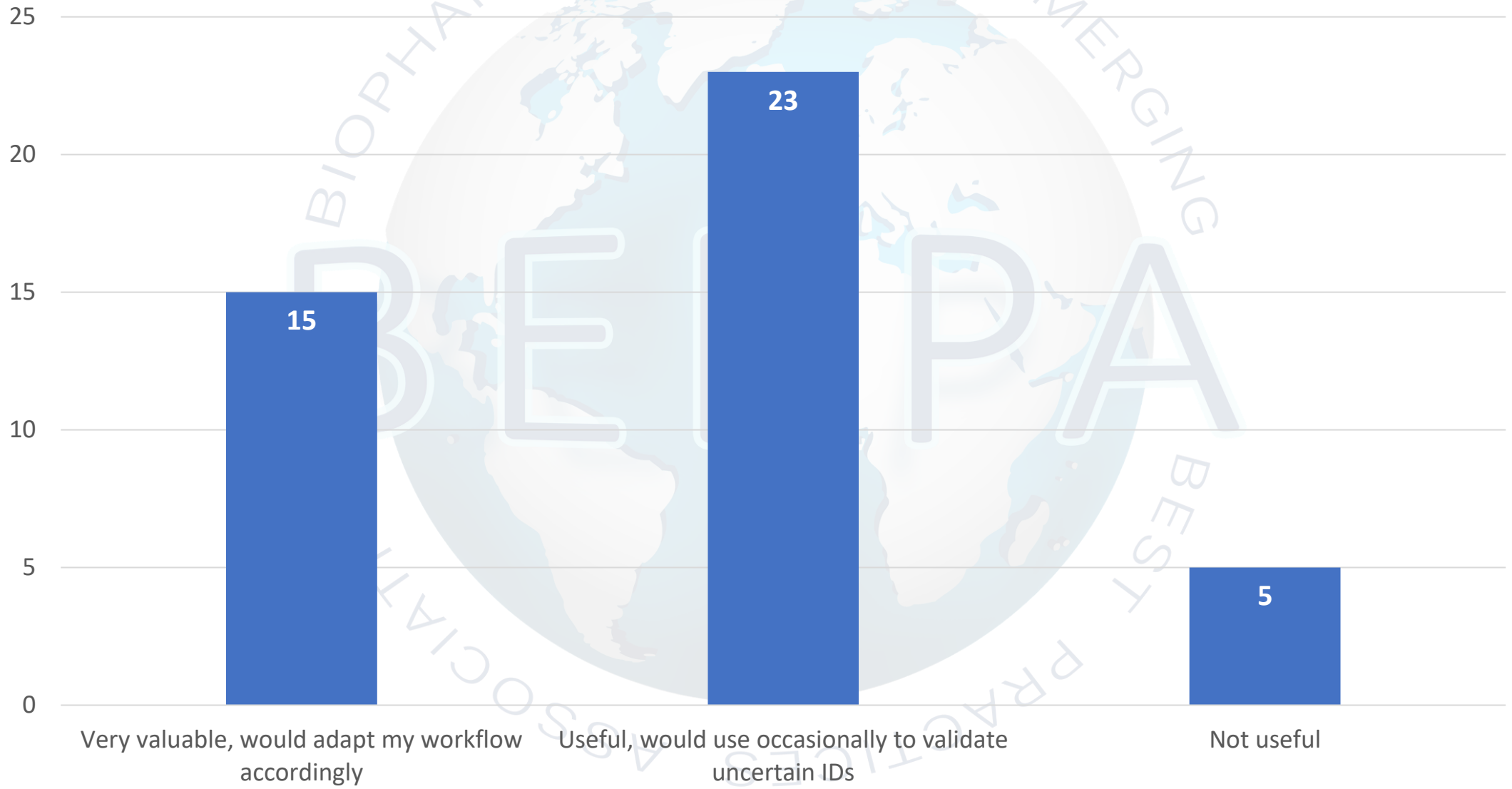
W-5 What kind of routine LC-MS System check do you use for HCP profiling?



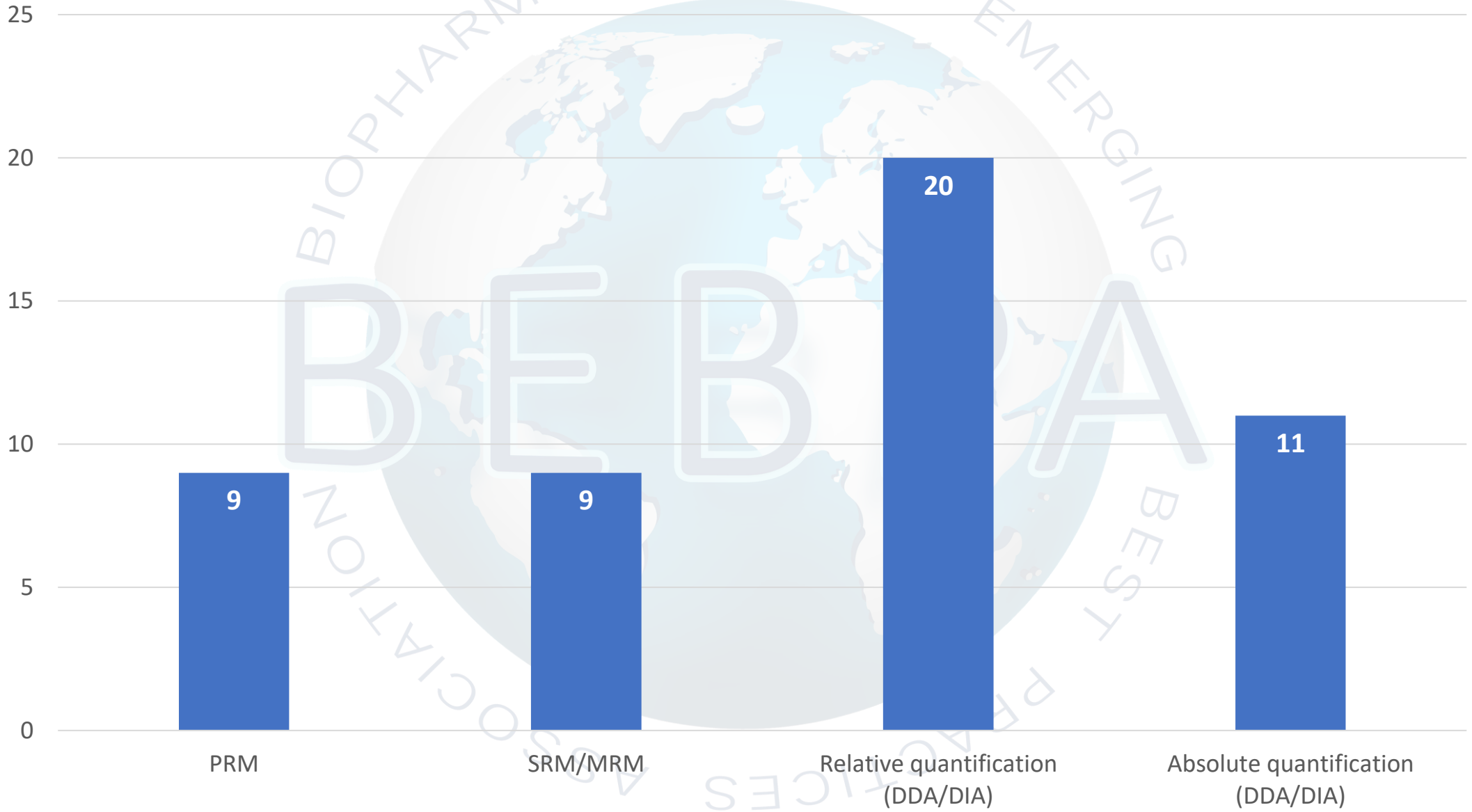
W-6 Do you use any MS-based HCP analysis under GMP?



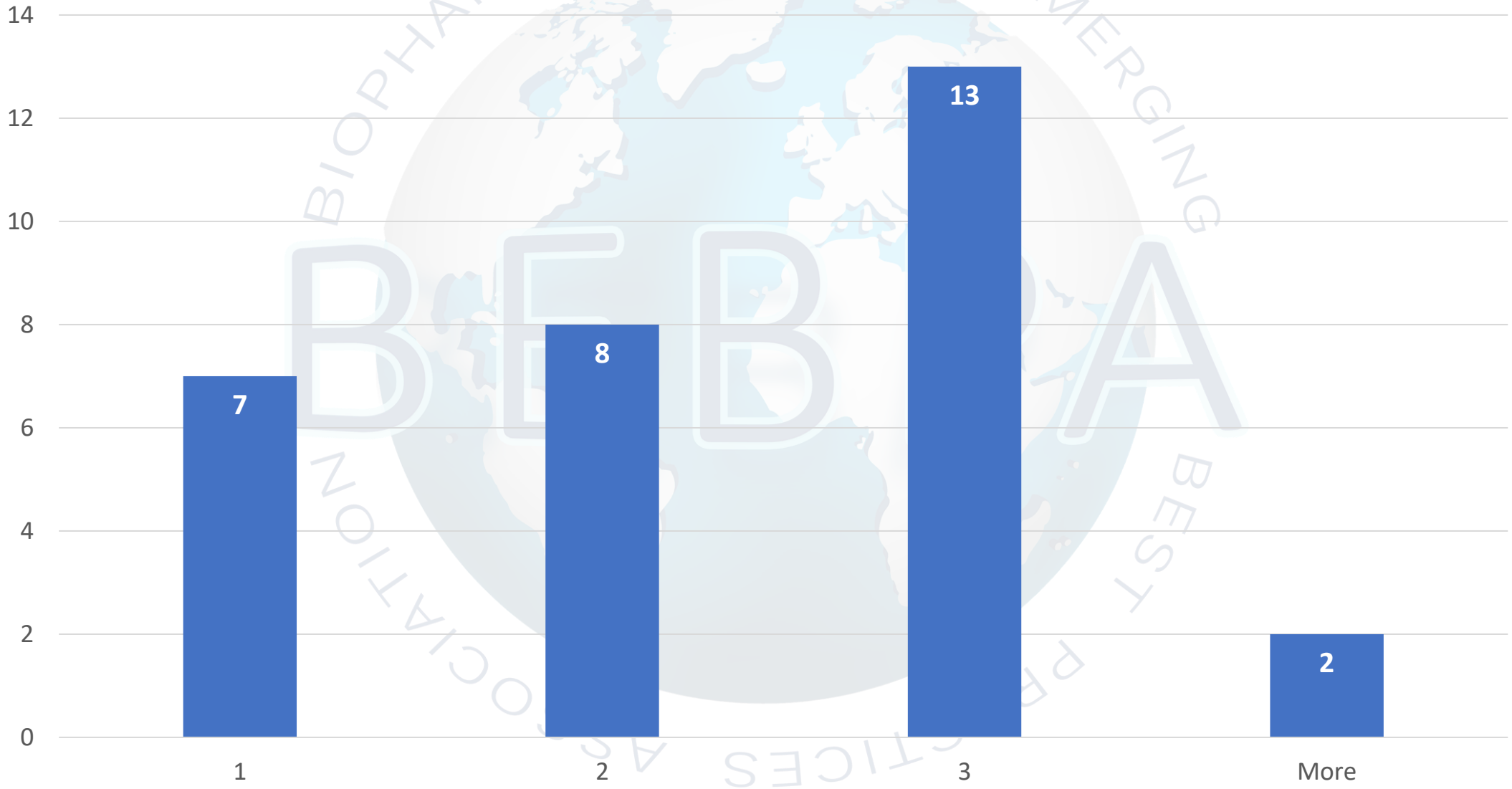
W-7 Would a commercial library for popular cell lines with MS, MS/MS and peptide collisional cross section be valuable to you?



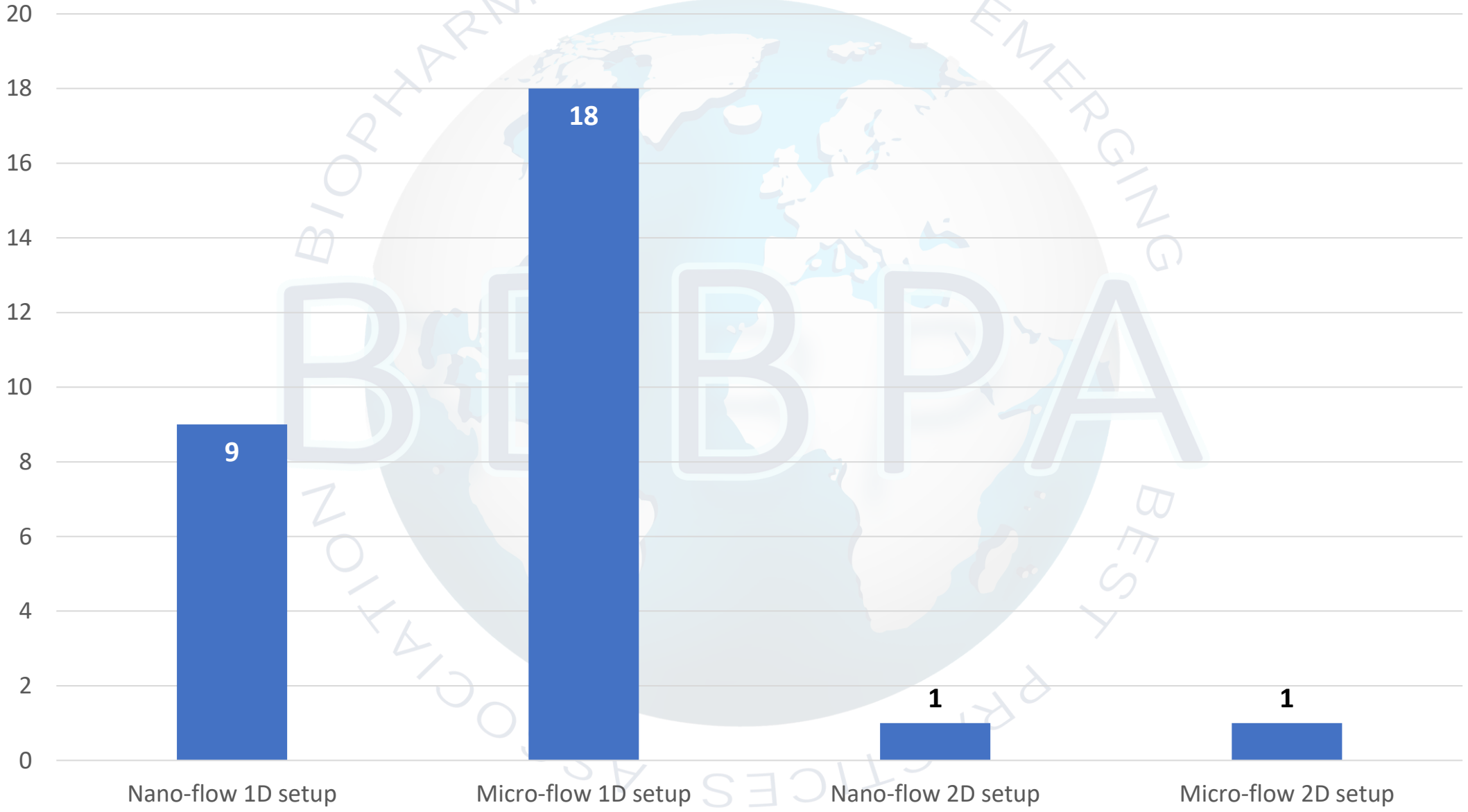
W-8 What is your quantification strategy?



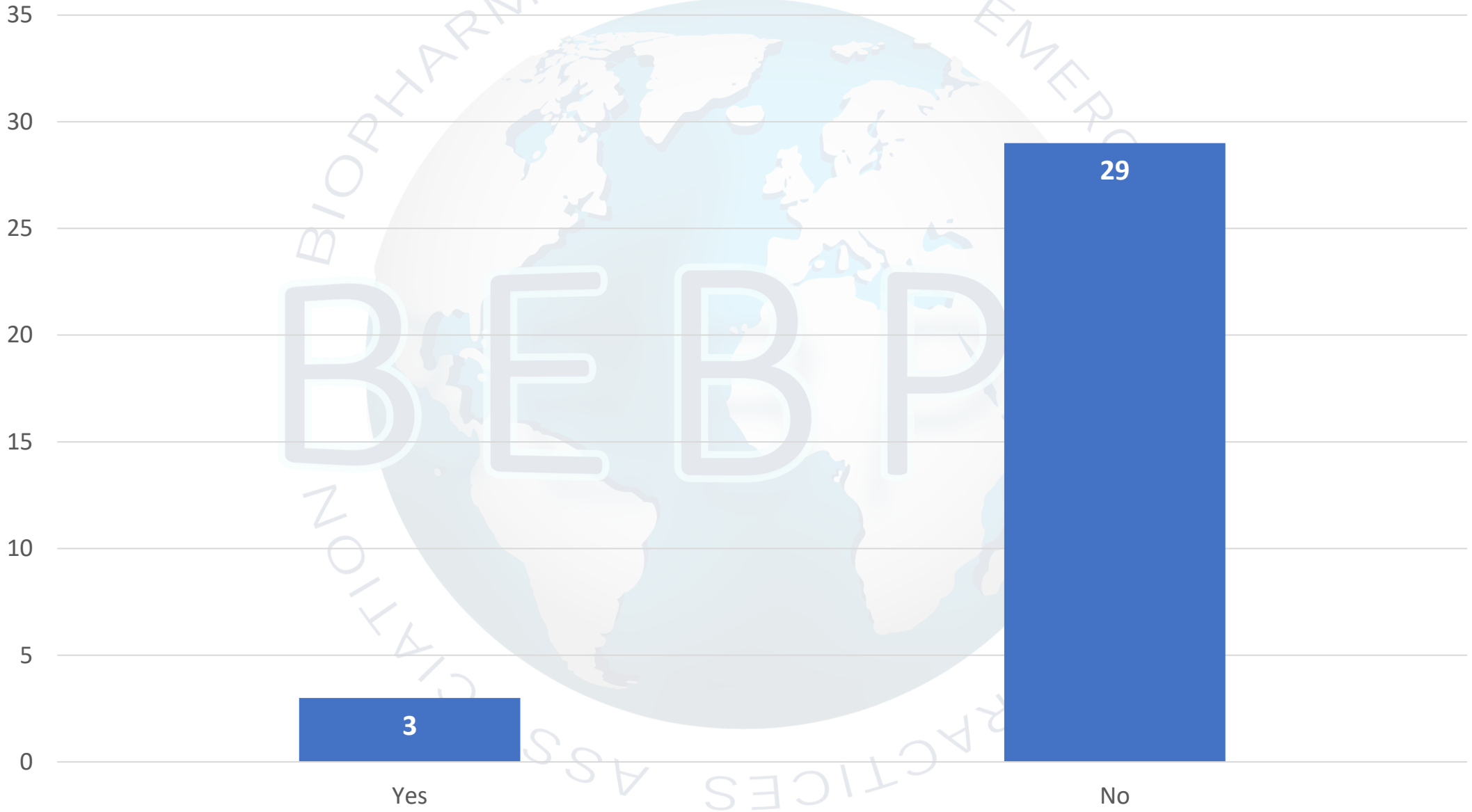
W-9 How many experimental replicates (excluding injection replicates) for validation of HCPs?



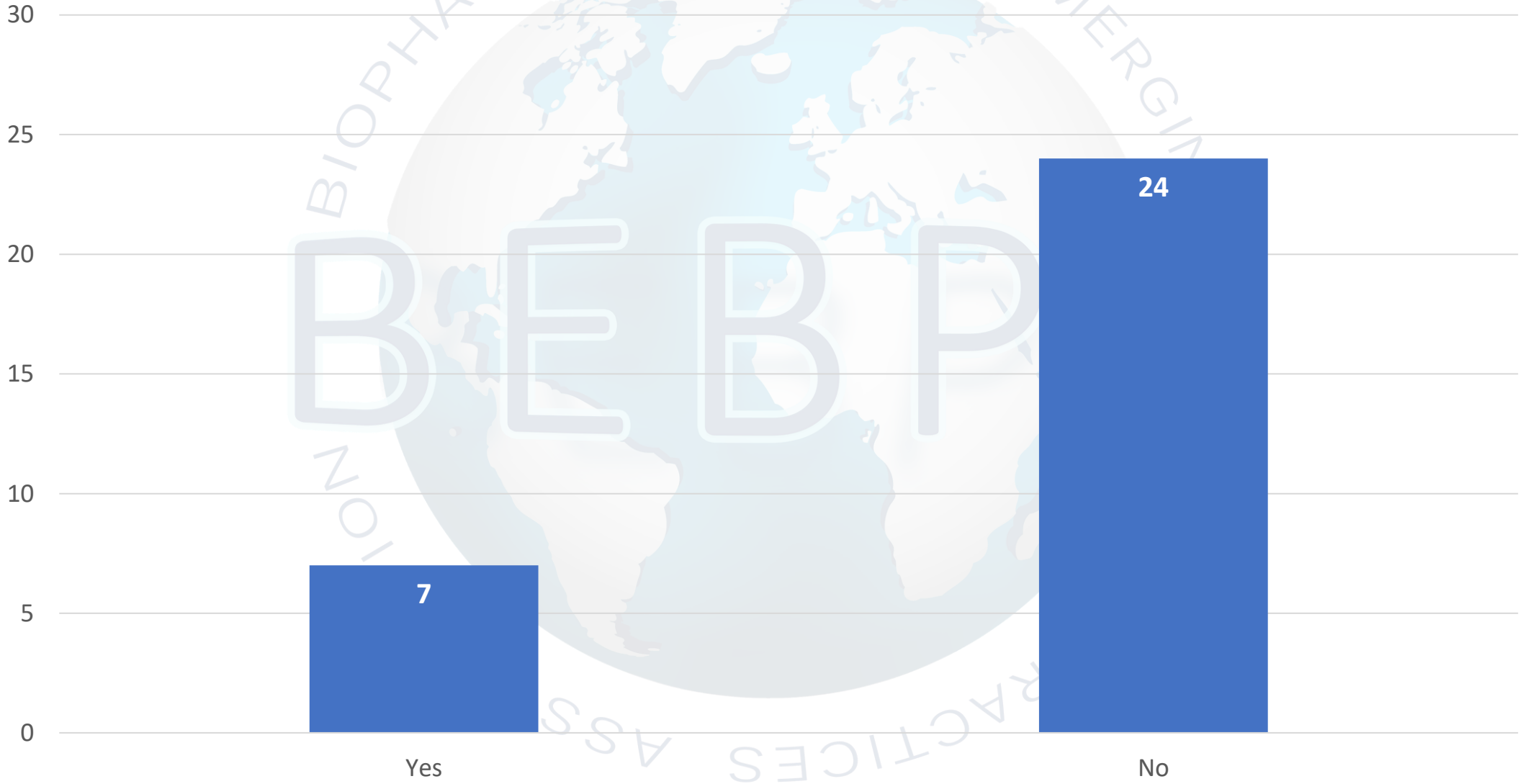
W-10 What LC setup are you using?



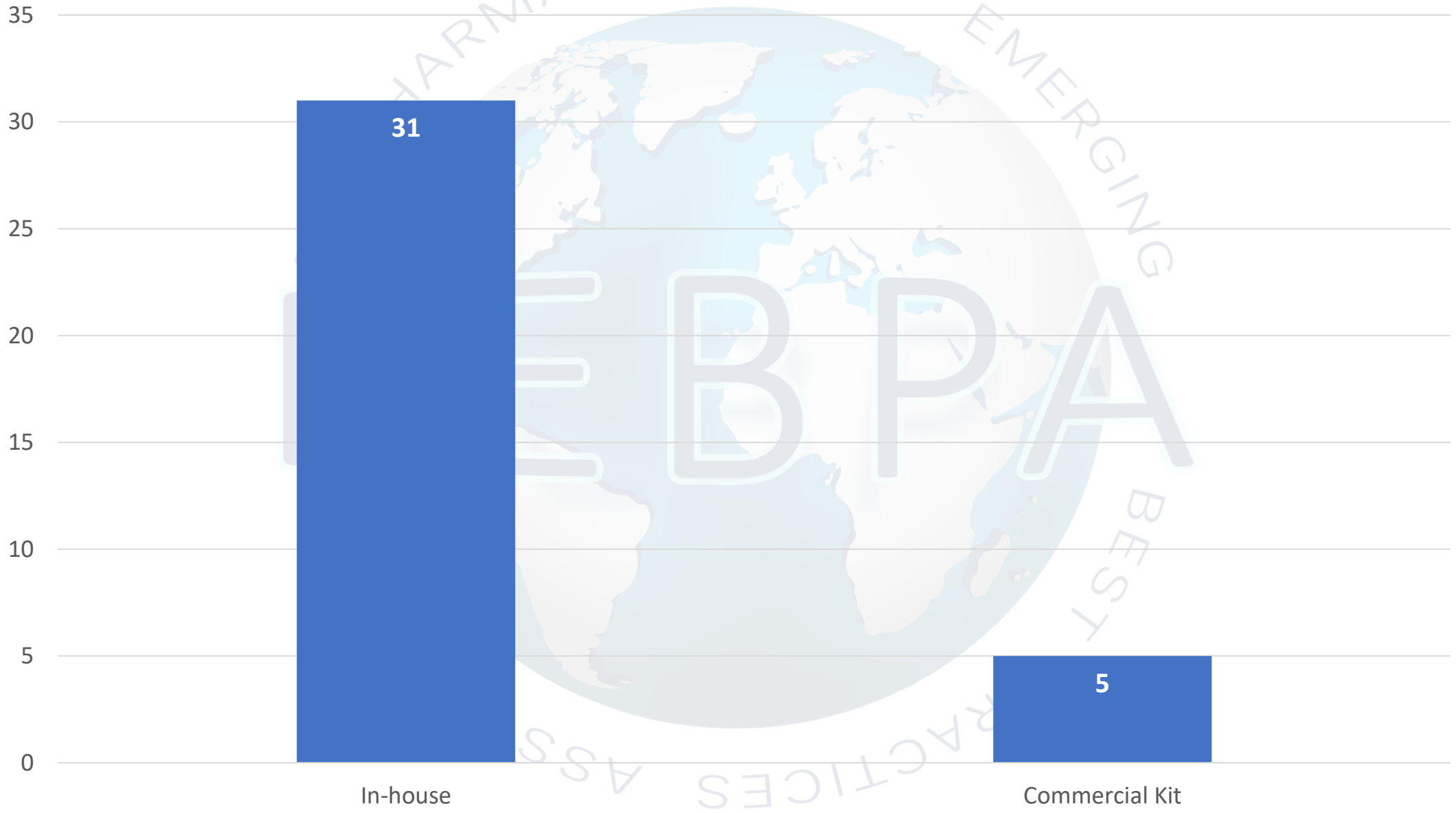
W-11 Are you using de novo sequencing?



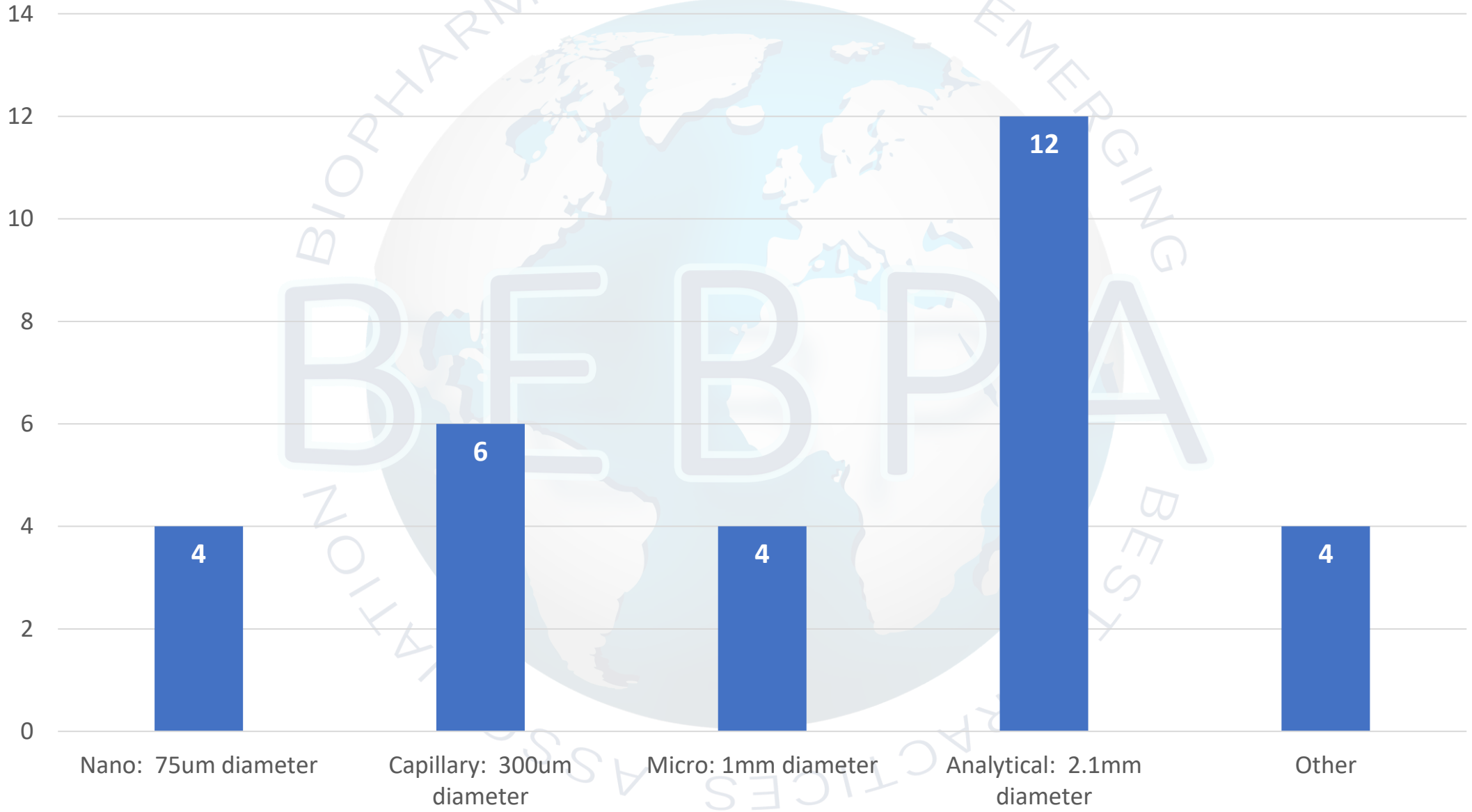
W-12 Is your sample preparation for HCPs valid for another characterization workflow (e.g. peptide mapping)?



W-13 Is your sample preparation in-house or commercial kit?



W-14 Which method do you prefer for HCP analysis?



THANK YOU

for attending BEBPA's 2020 Host Cell Protein Conference

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We could not have done this without YOU!