16th Annual EUR Bioassay Conference

27-29 September 2023

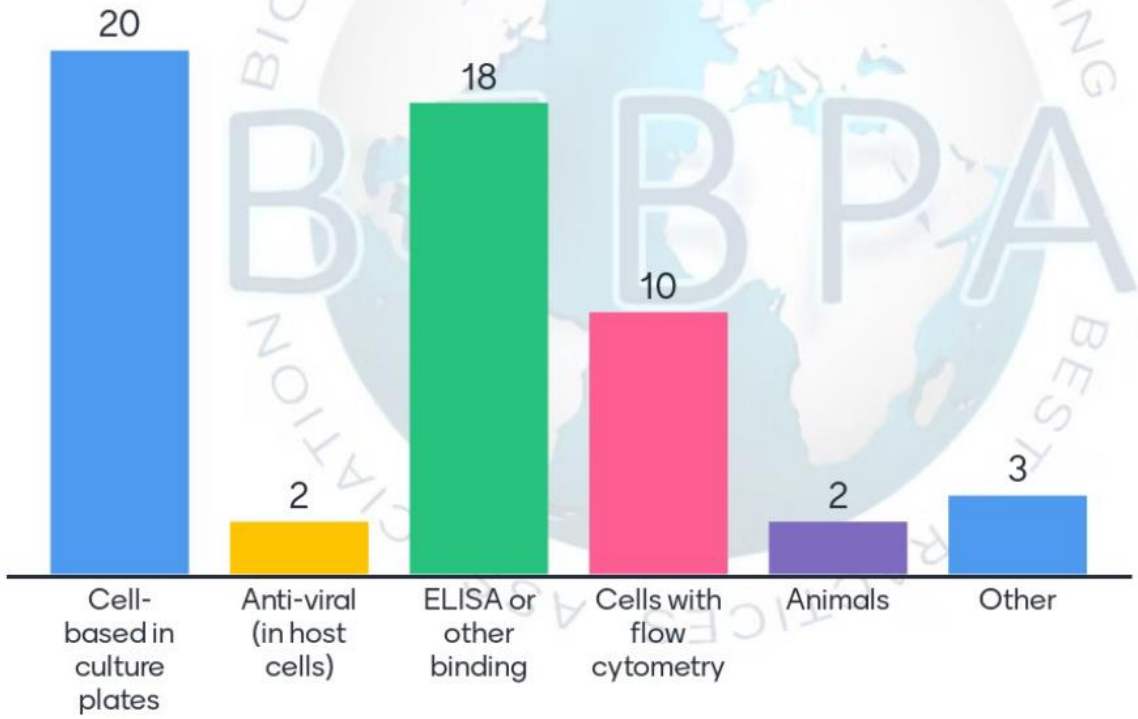
Bled, Slovenia

Workshop 1: Using Mixed Models to Reduce Relative Potency Bias from Allowed Non-Similarity

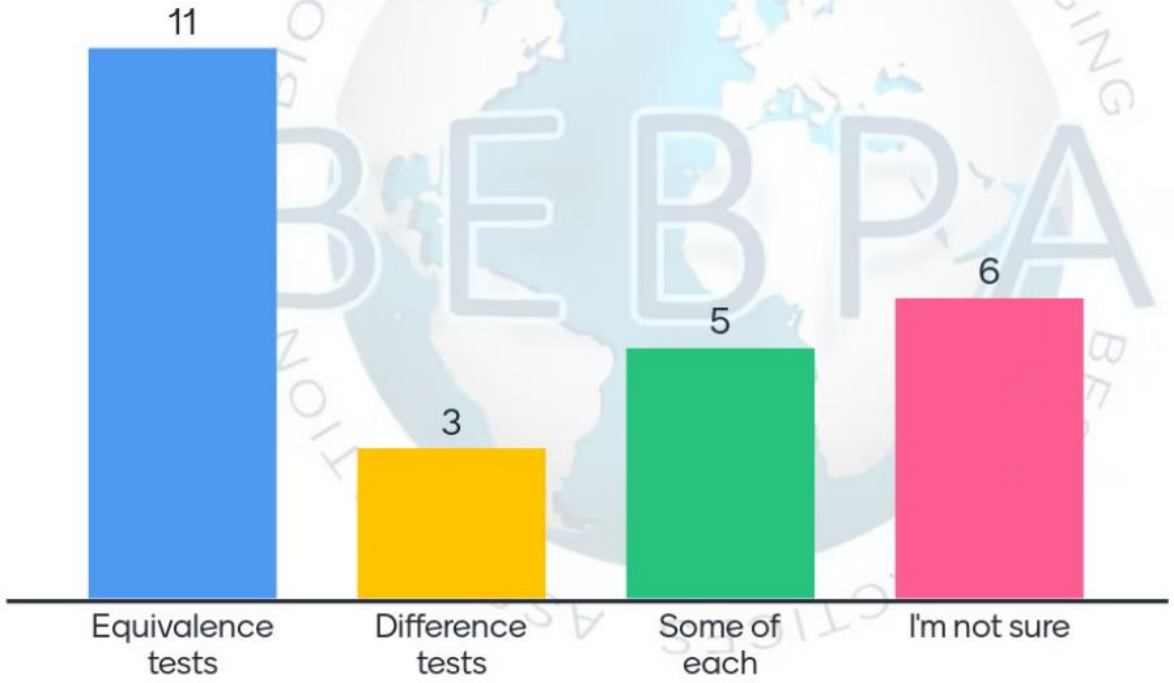
Workshop Leader: David Lansky, President. Precision Bioassays

Audience Surveys

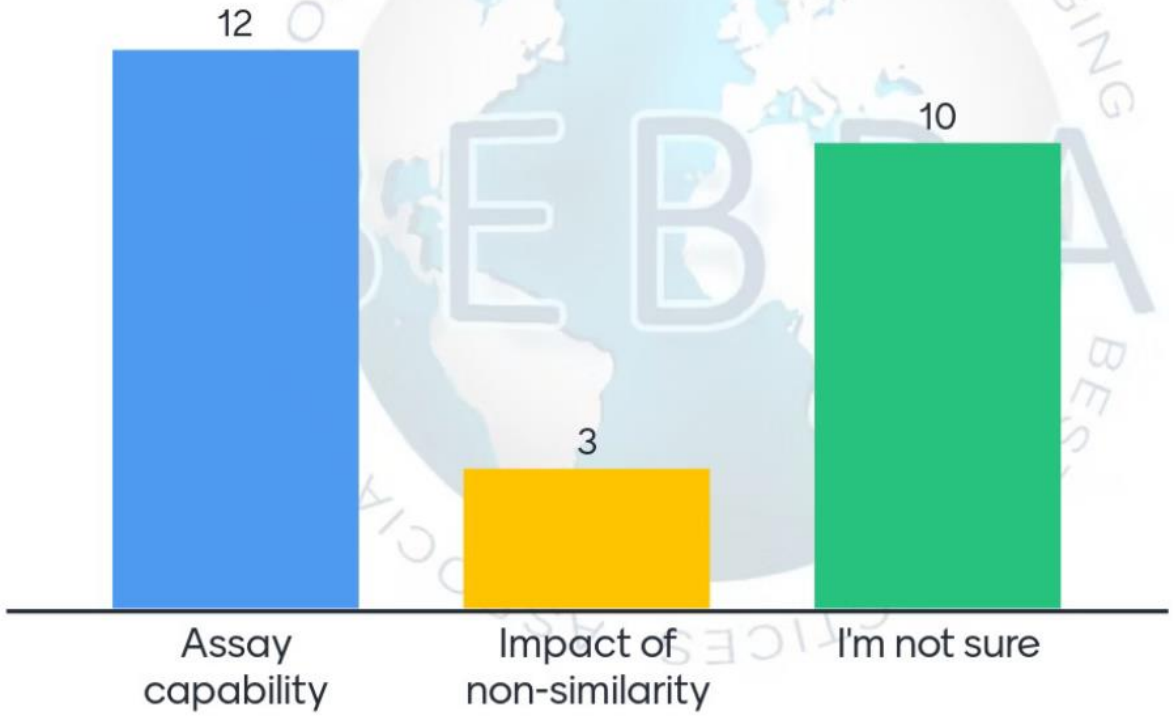
W1.1 What type of bioassay(s) are you running?



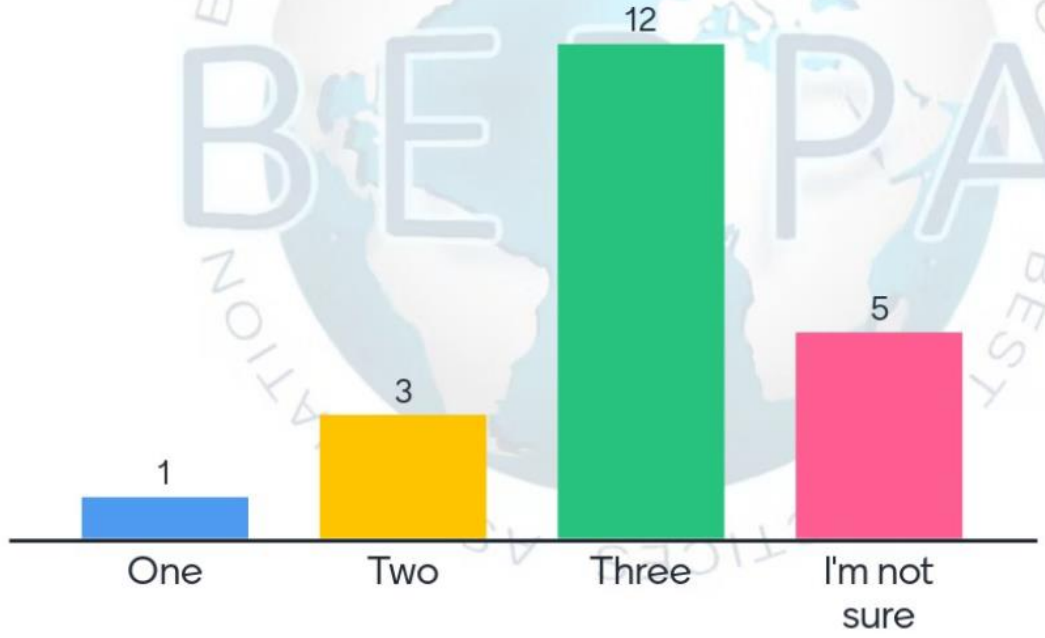
W1.2 Are you using equivalence tests or difference tests for similarity?



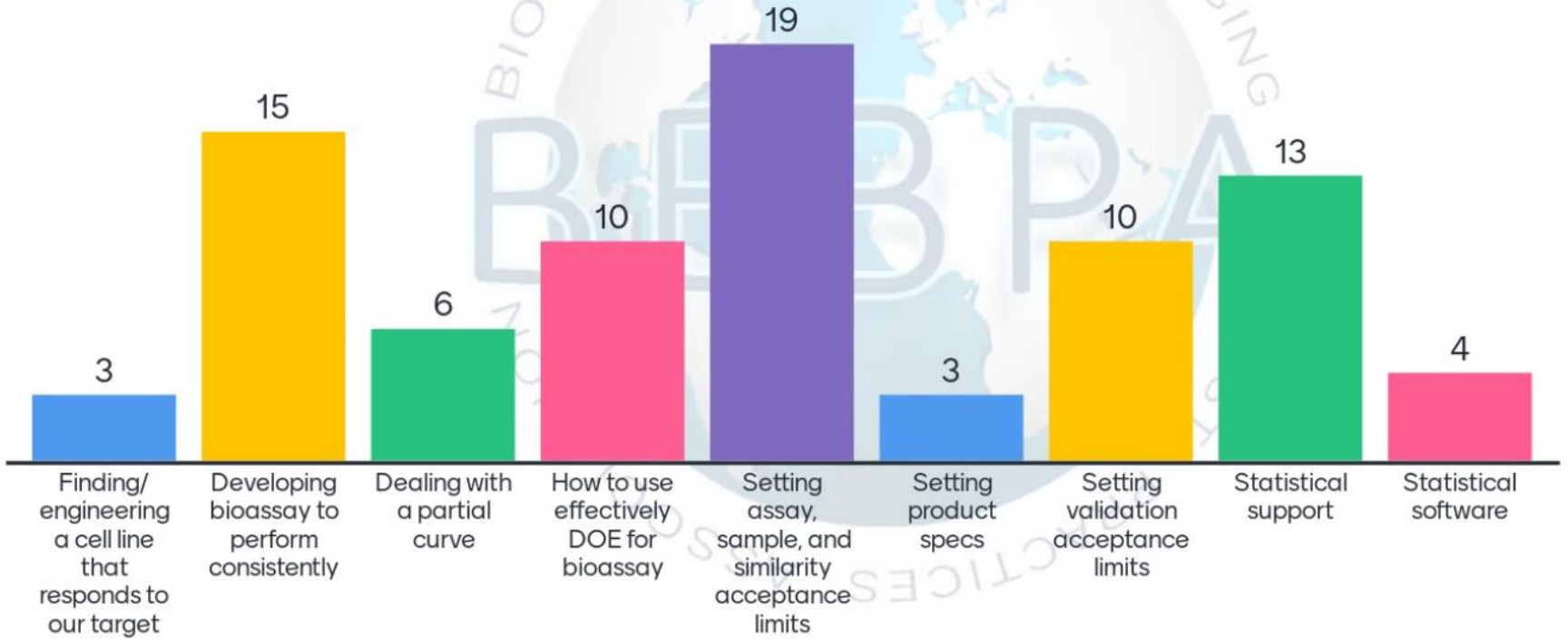
W1.3 How do you set similarity acceptance (or suitability) limits?



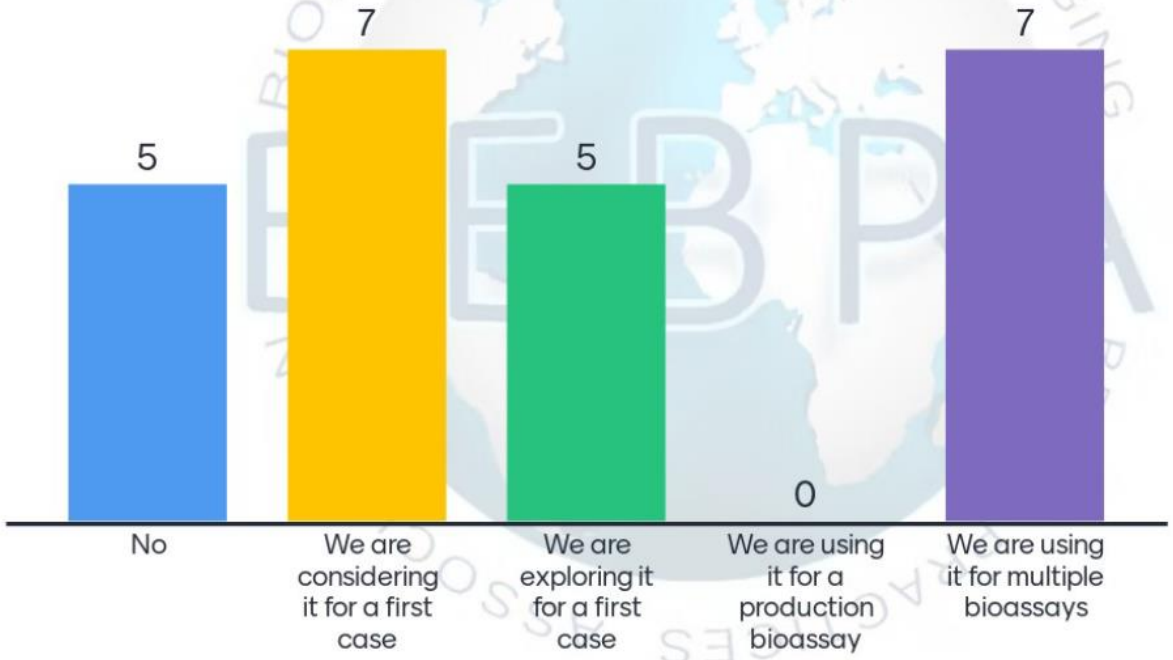
W1.4 Do you consider assay, sample, and similarity acceptance (or suitability) to be one, two, or three separate decisions?



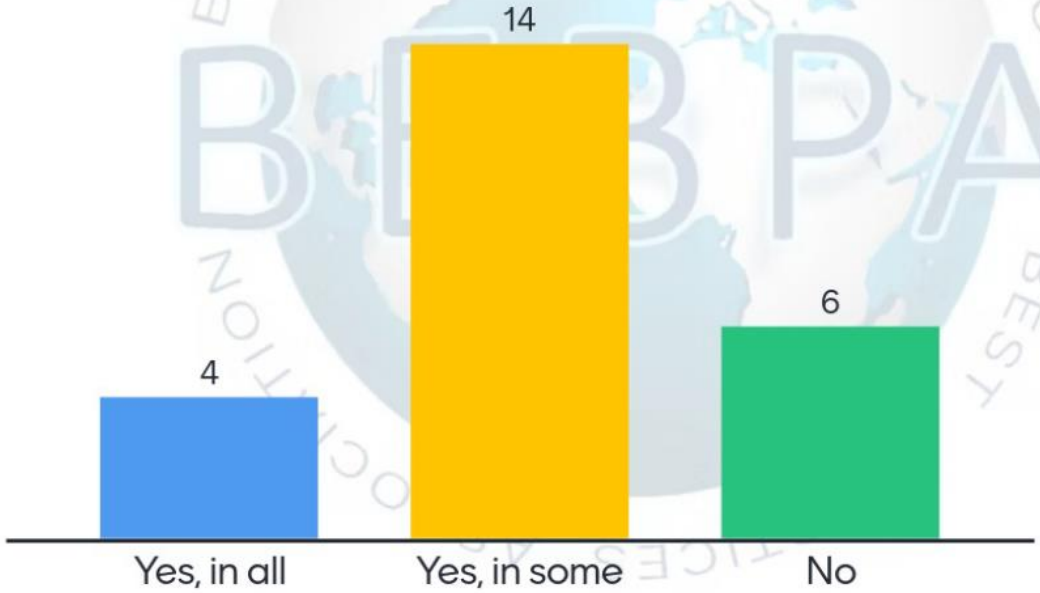
W1.5 What are your biggest bioassay design and/or development challenges?



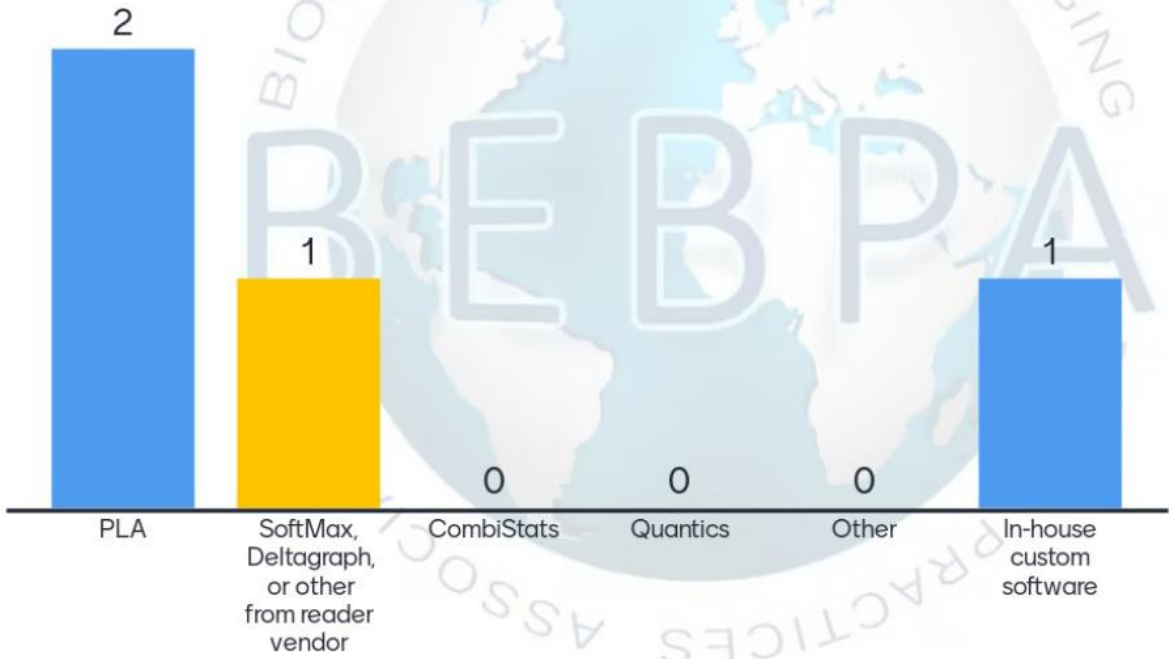
W1.6 Are you using or considering lab automation for bioassay?



W1.7 Is there any randomization of samples or dilutions to cages, rows, columns, plates, or tubes in your bioassay?



W1.8 What software are you using for bioassay analyses?



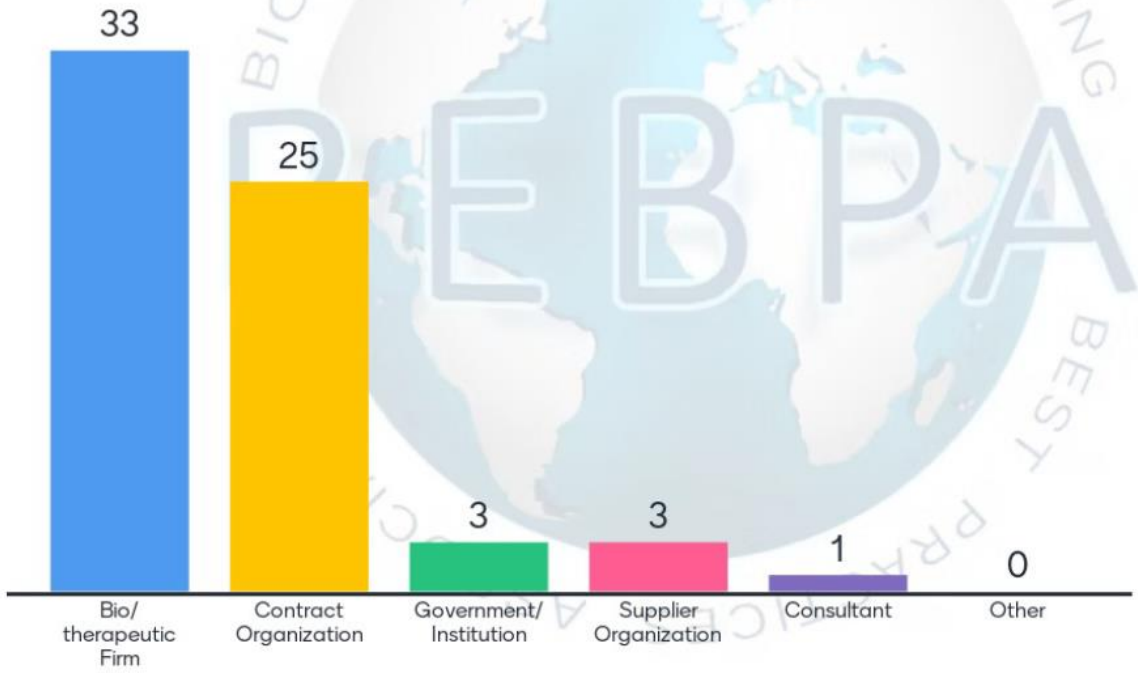
Workshop 2: Care and Feeding of a Late-Stage Potency Assay

Workshop 1 Leaders:
Sian Estdale, Head of Scientific Affairs, Labcorp
Alex Knorre, Senior Scientific Director, Eurofins BioPharma Product Testing
Bassam Hallis, Deputy Director, UK Health Security Agency

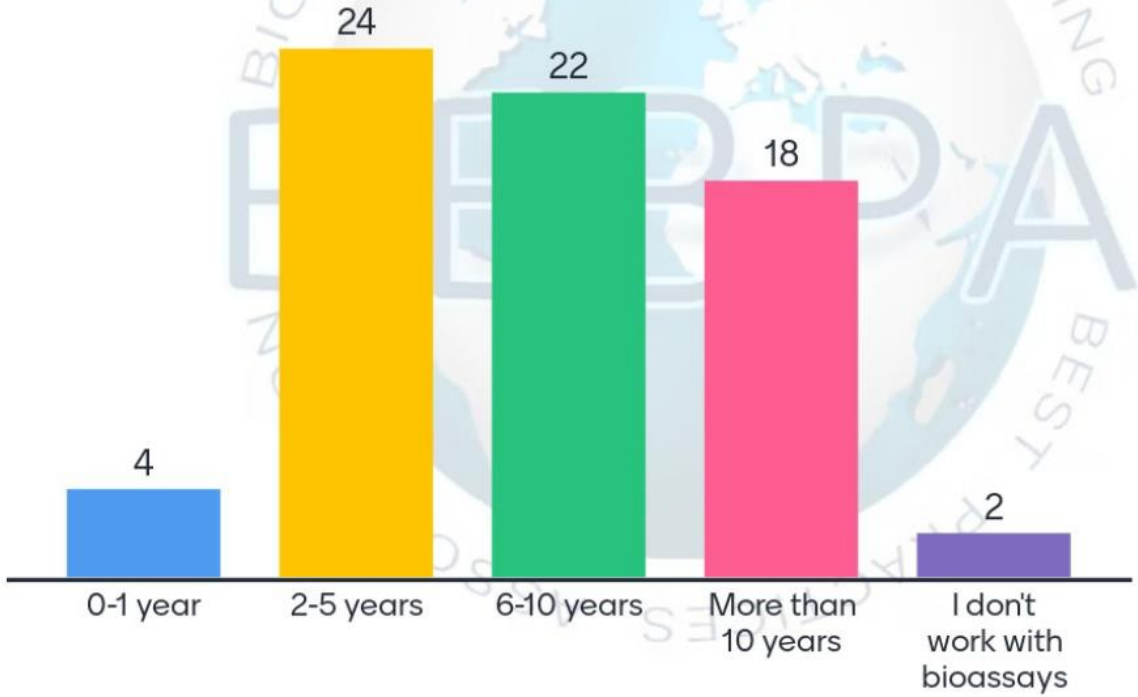
Audience Surveys

Introduction/ Warm-up

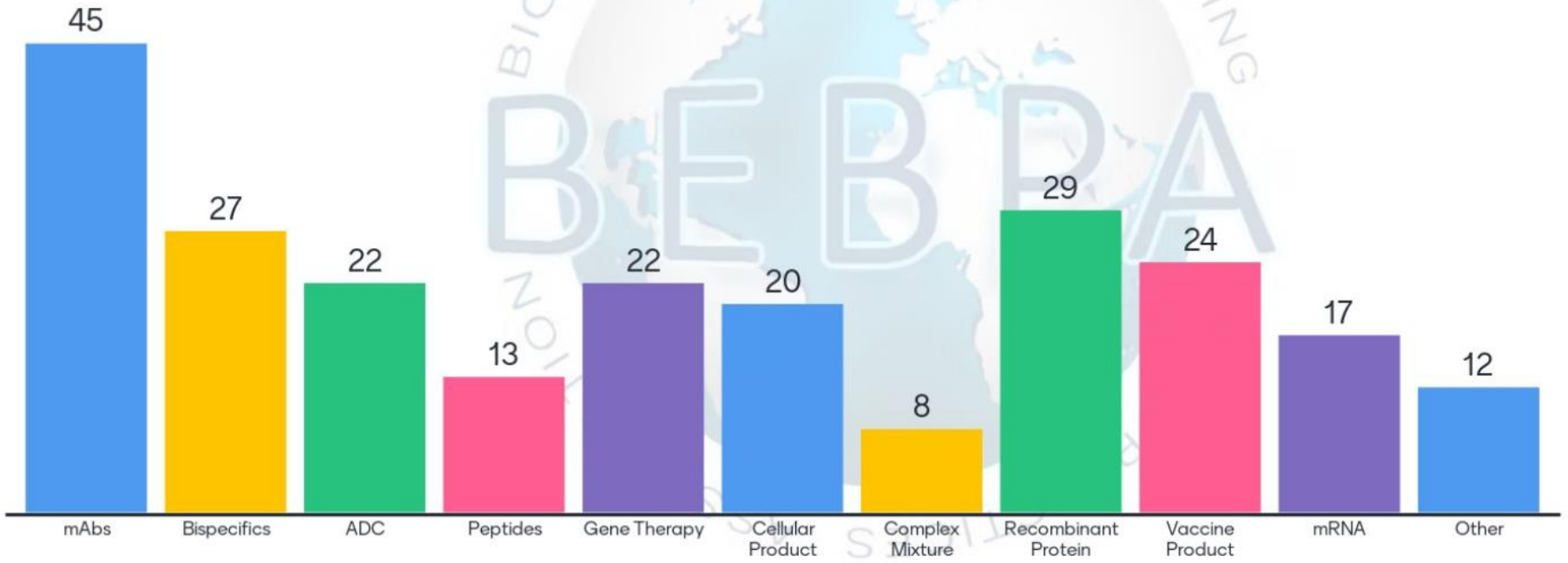
W2.1 What kind of organization do you work with?



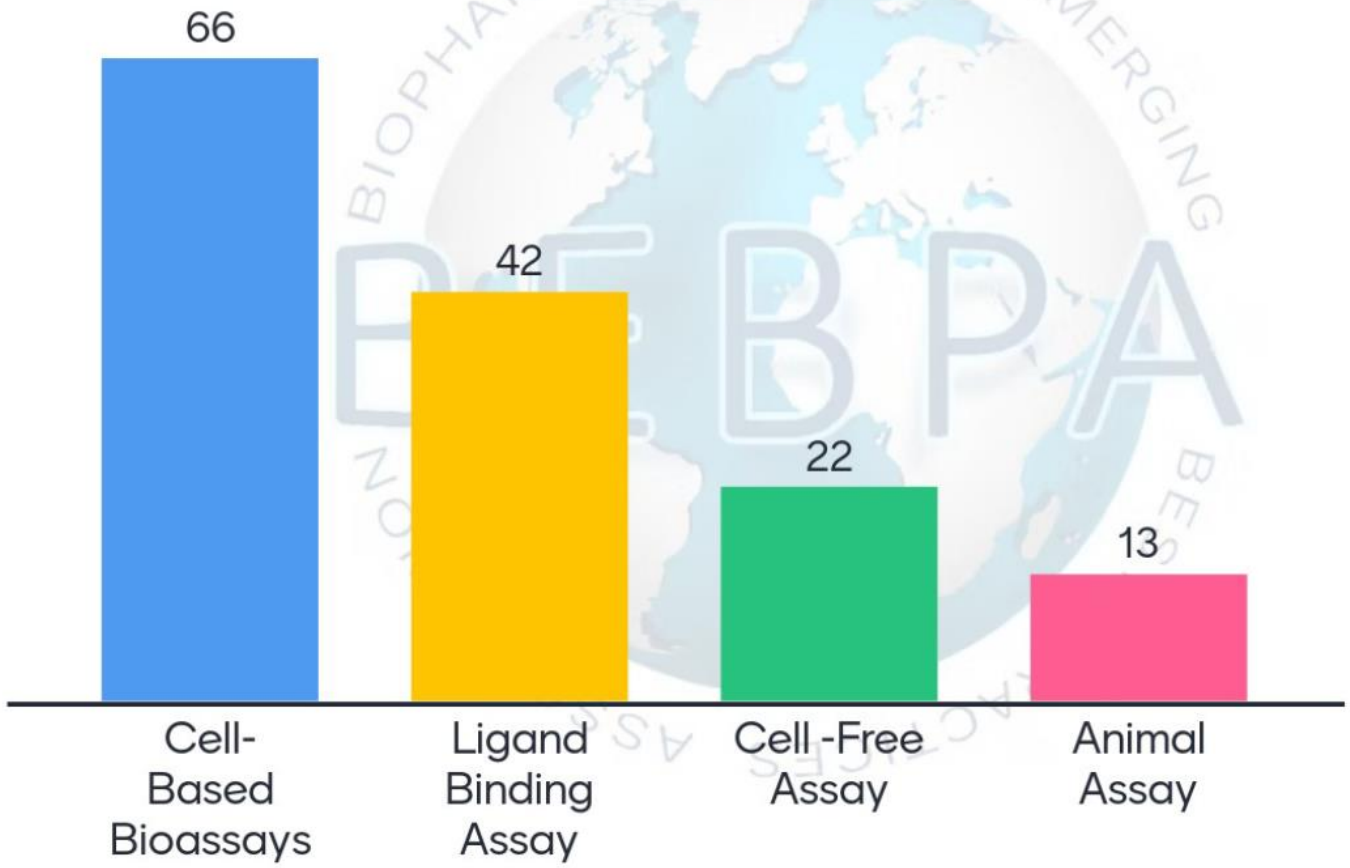
W2.2 How long have you worked with bioassays?



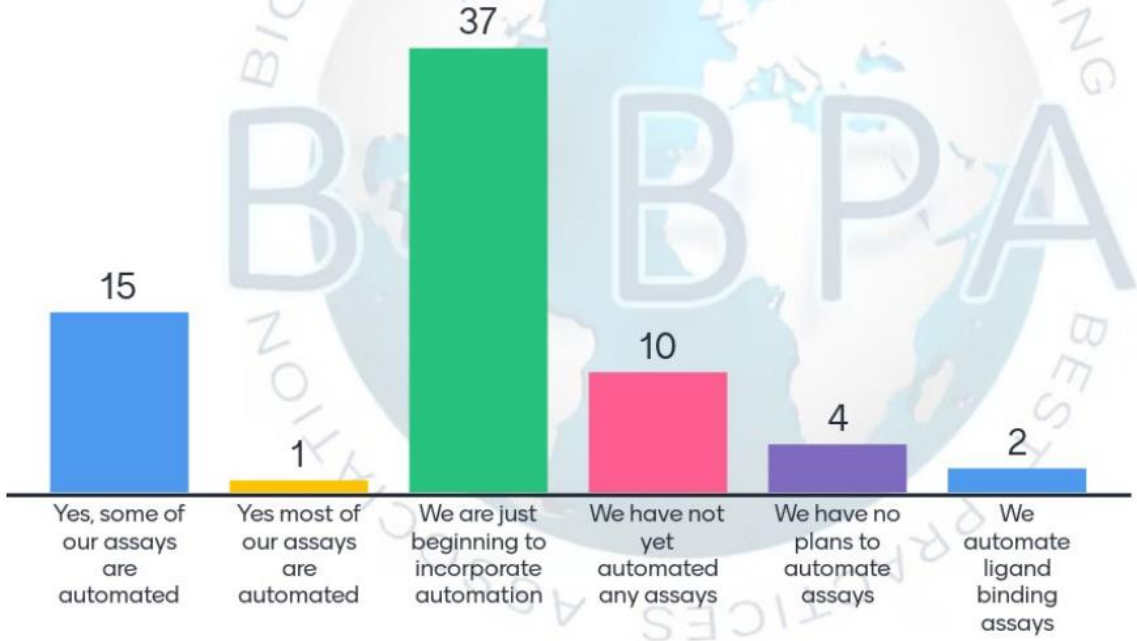
W2.3 What kind of products do you work with?



W2.4 What kind of bioassays do you use?

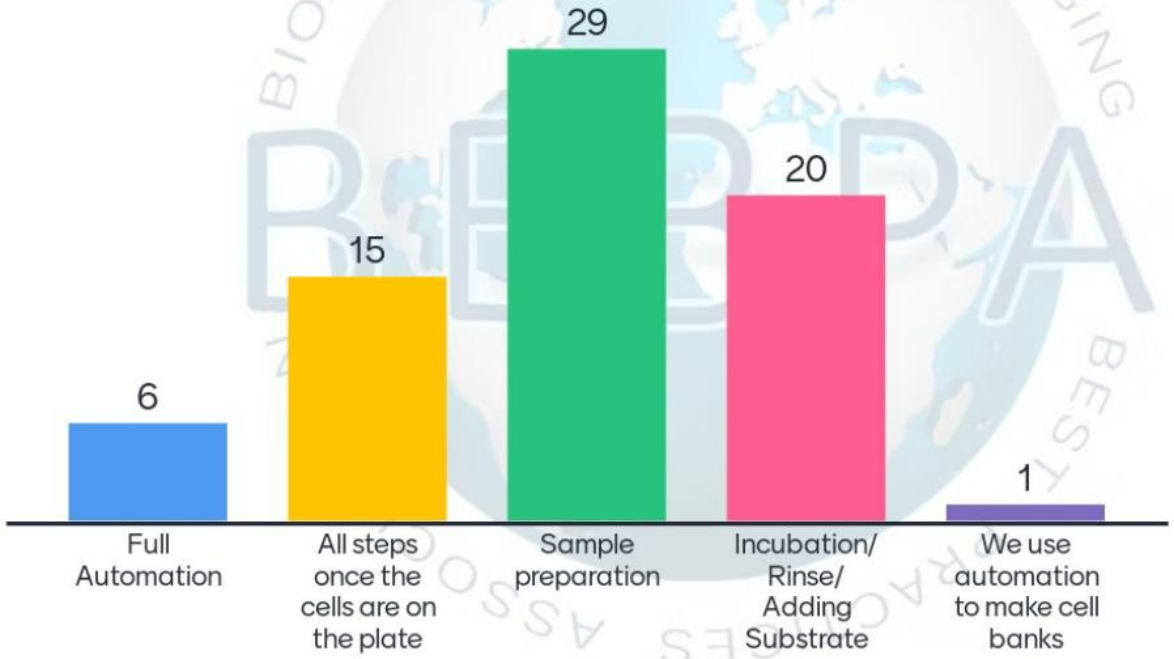


W2.5 Do you use automation in your assays?

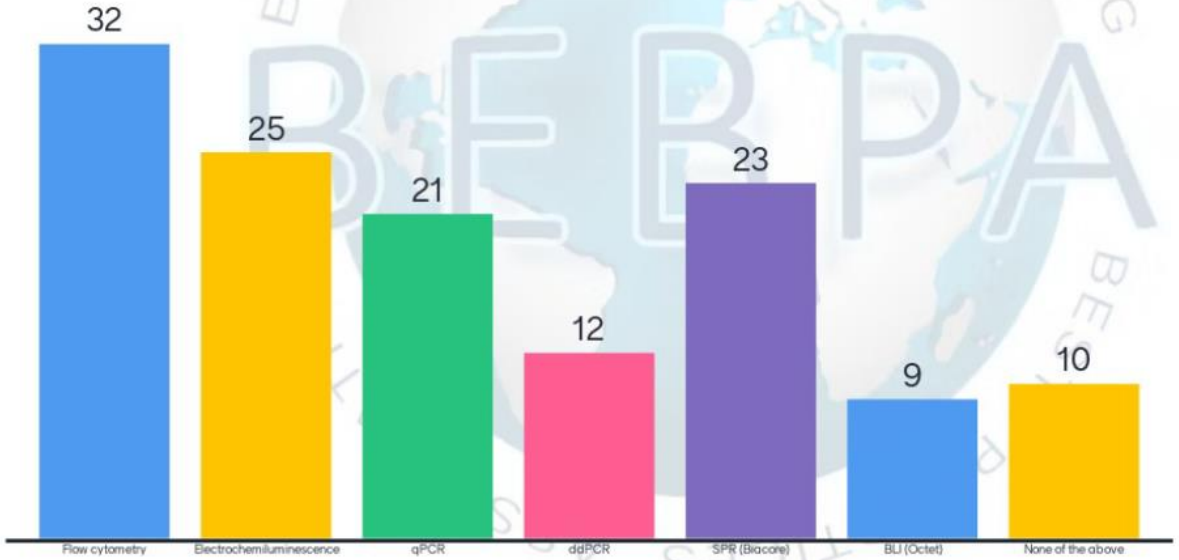


5 69

W2.6 If you automate your assays: what level of automation do you use?

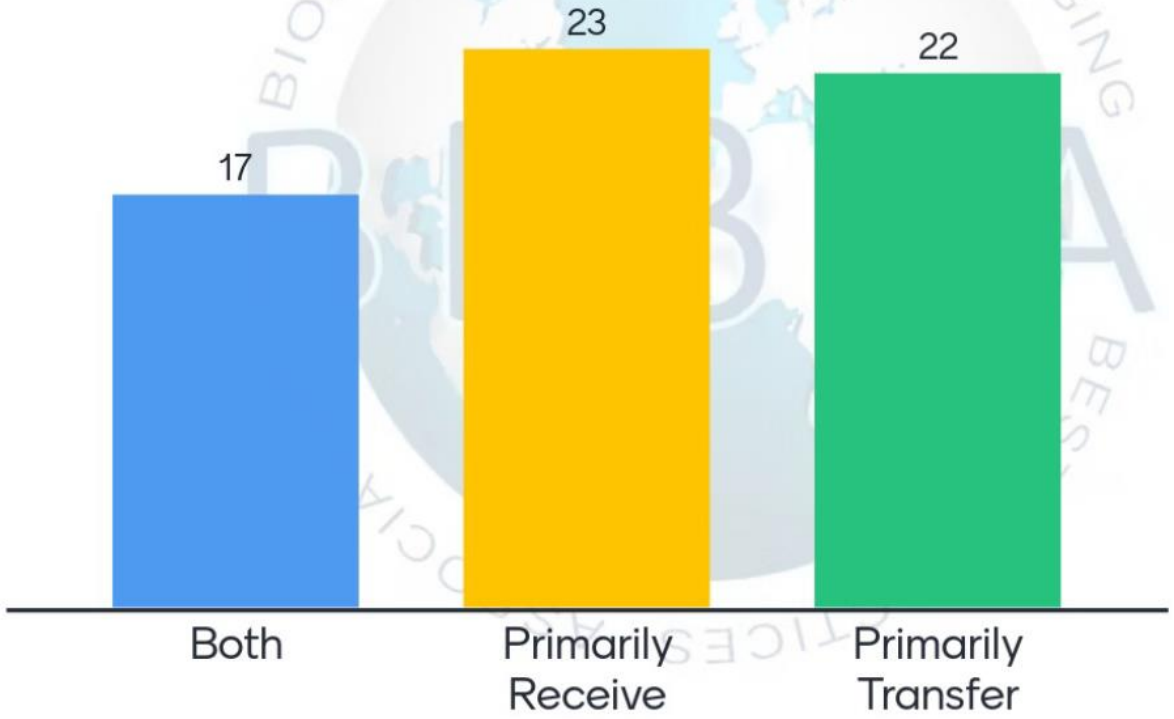


W2.7 What kind of readouts do you use for your bioassays apart from absorbance/luminescence/fluorescence?



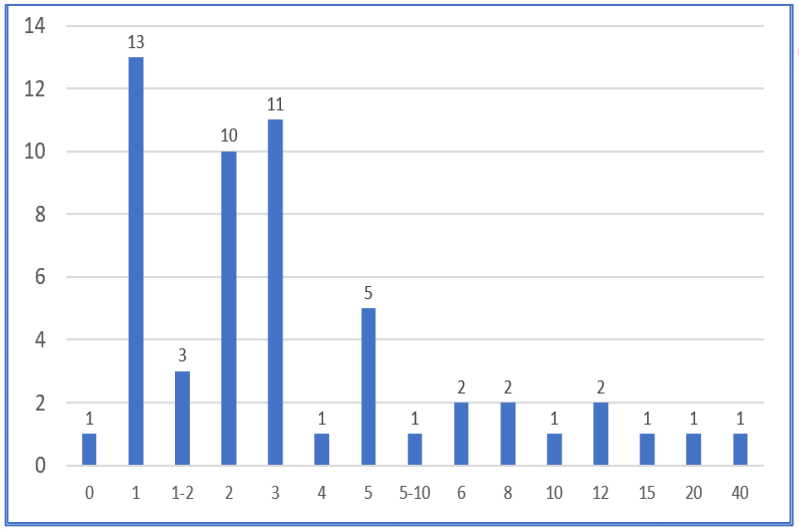
Assay Transfer Intro

W2.8 Are you typically the receiving or the donor laboratory?

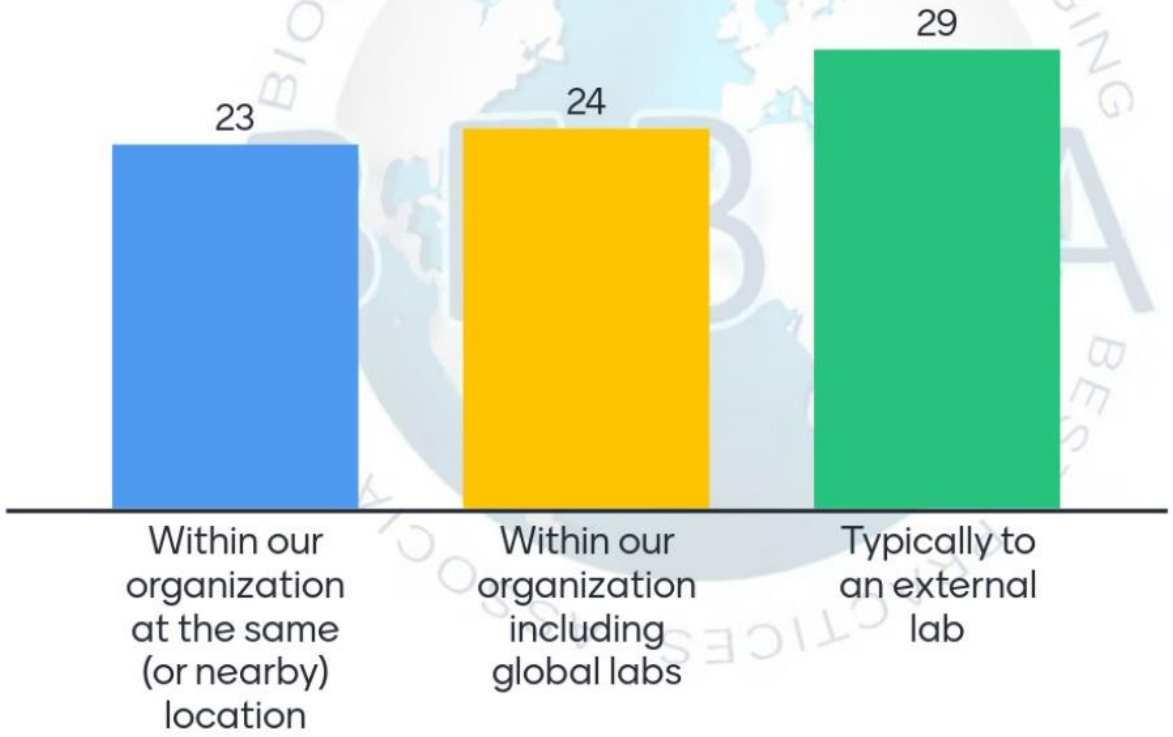


W2.9 How many transfers are you involved with per year?

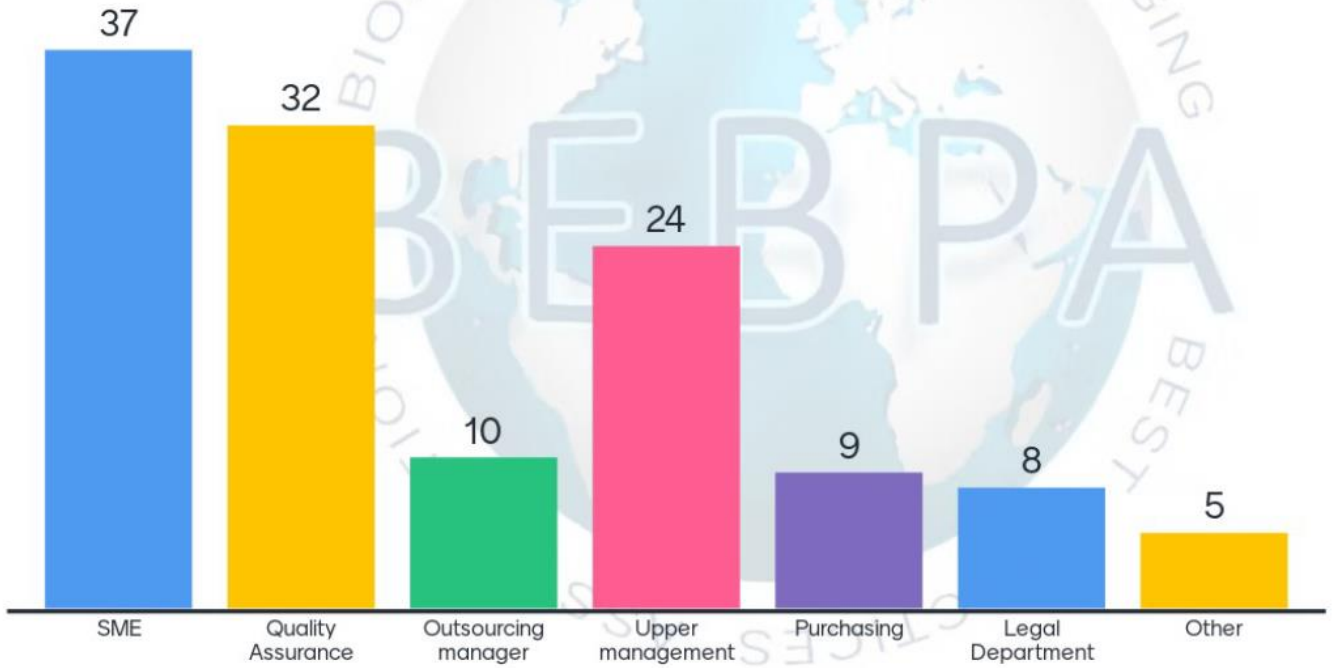
57 responses



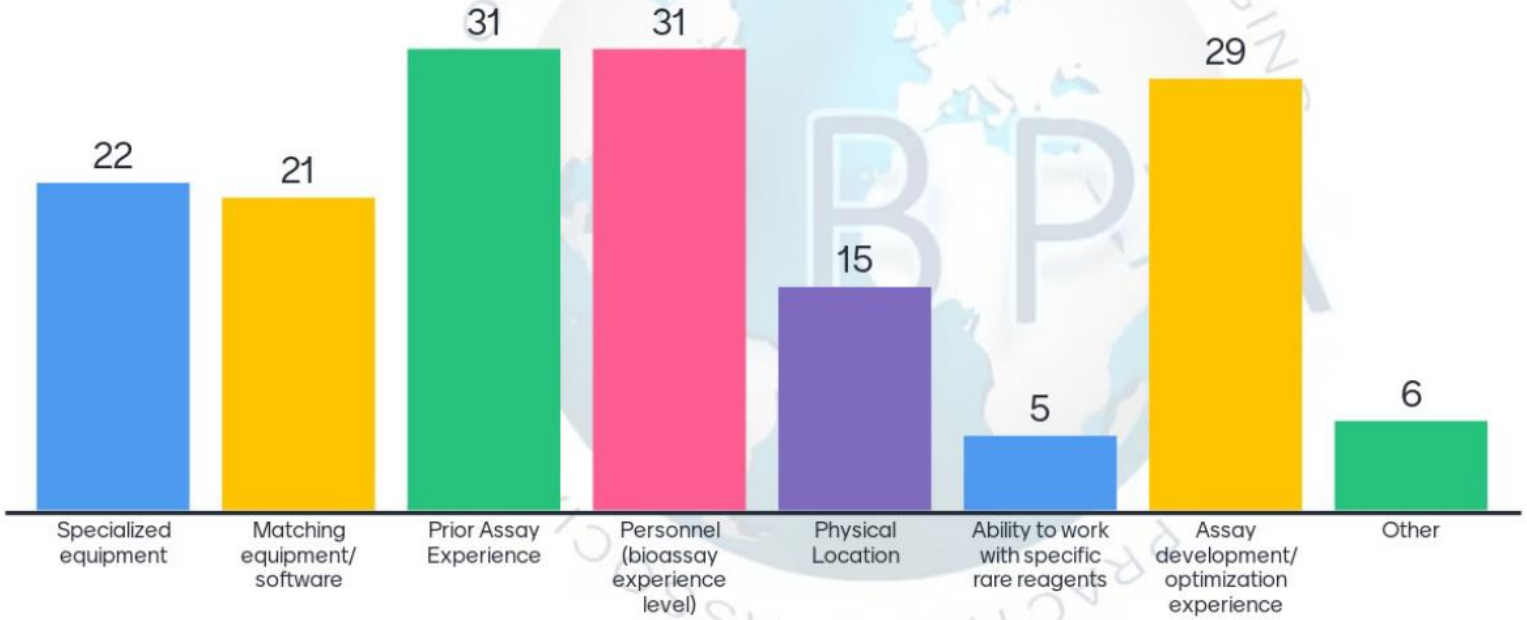
W2.10 Do you typically transfer within your organization or to an external lab?



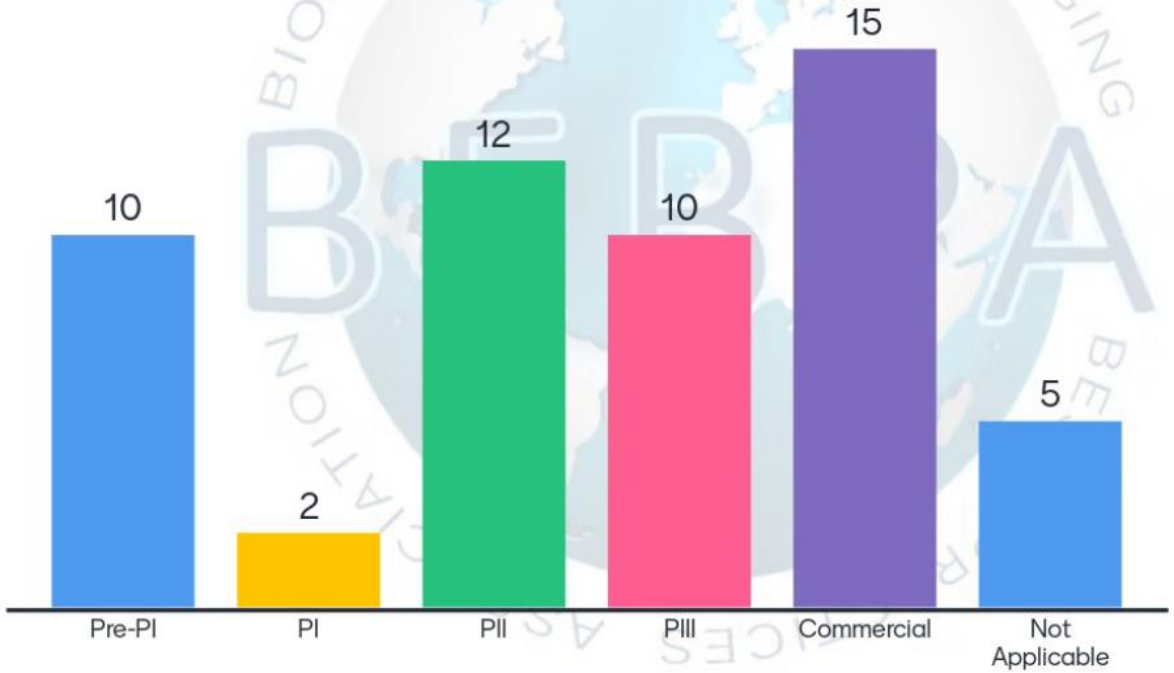
W2.11 Who is included from your team when selecting an external lab?



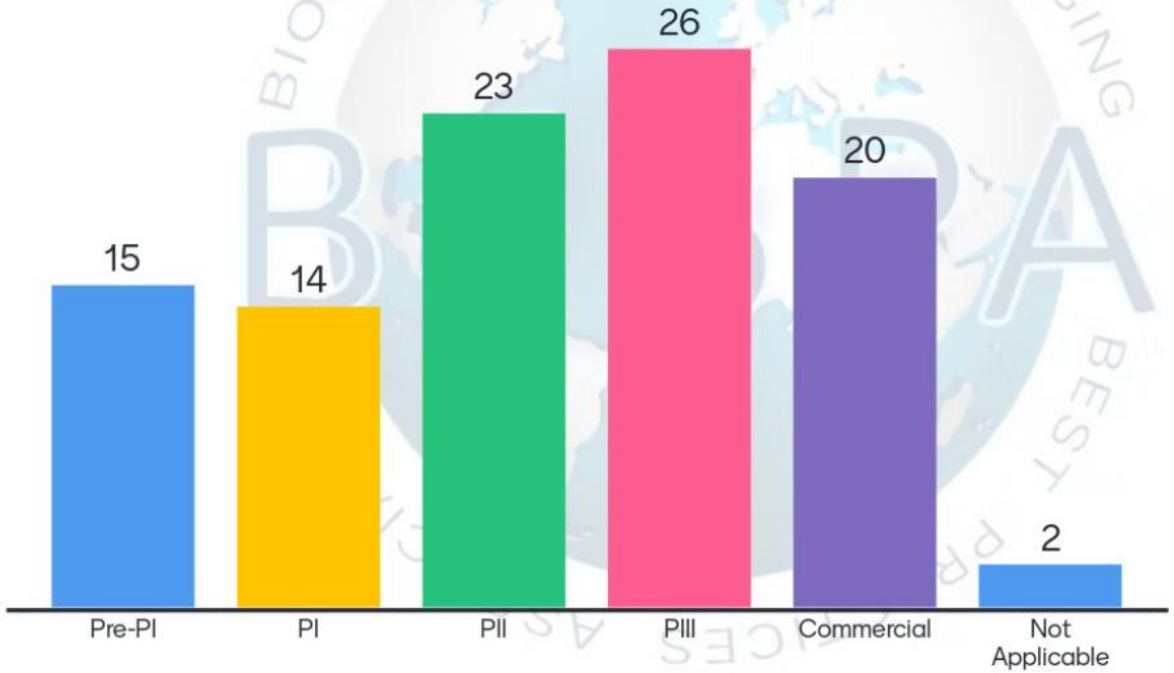
W2.12 What are the top three criteria for selection?



W2.13 What is the current phase of your project you want to transfer?

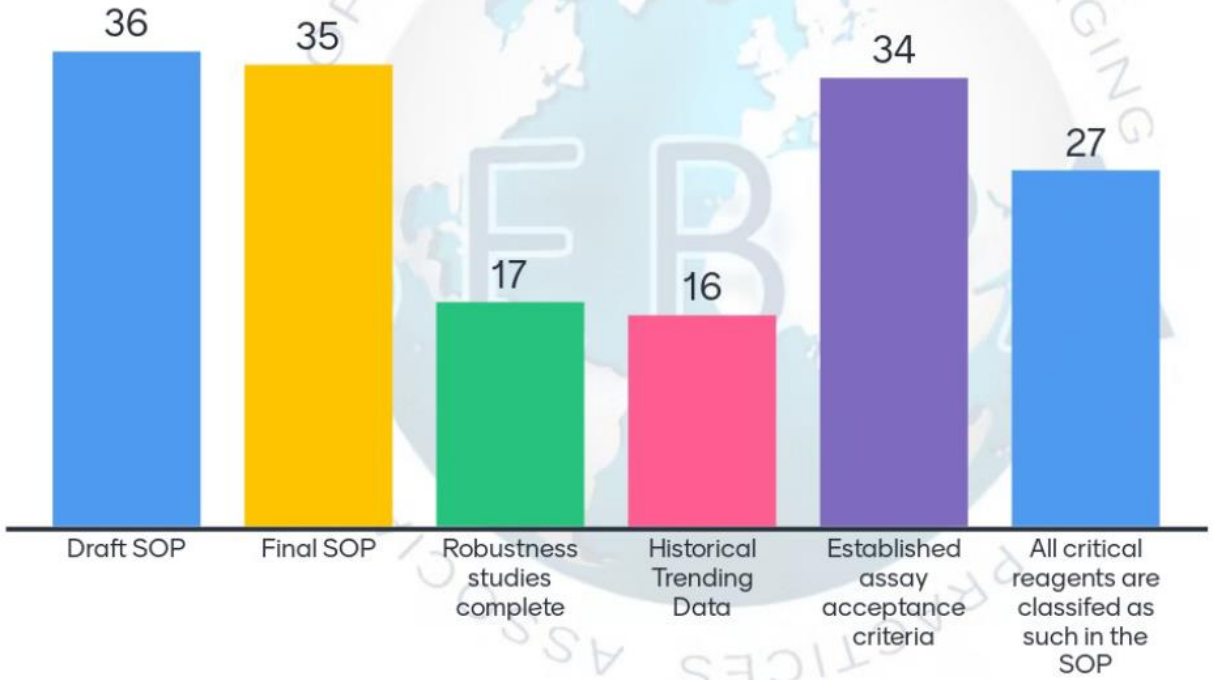


W2.14 At what phase do you typically transfer your assays?

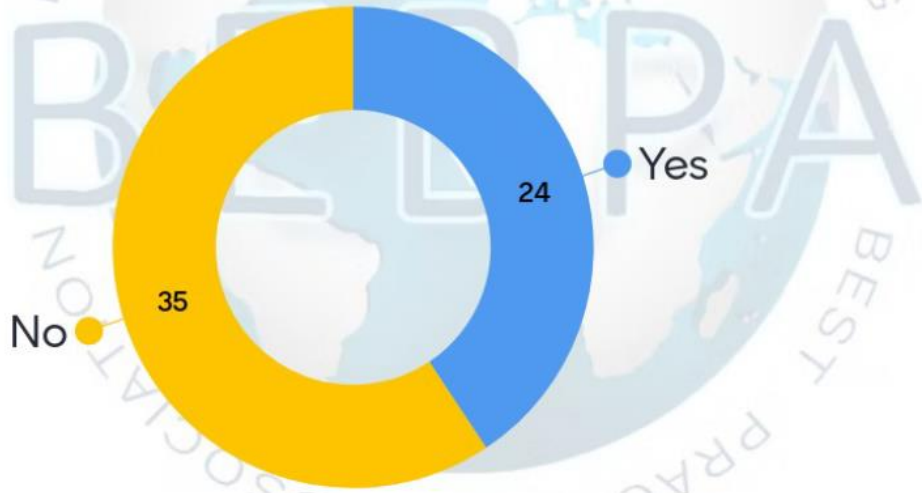


Assay Transfer-Specific

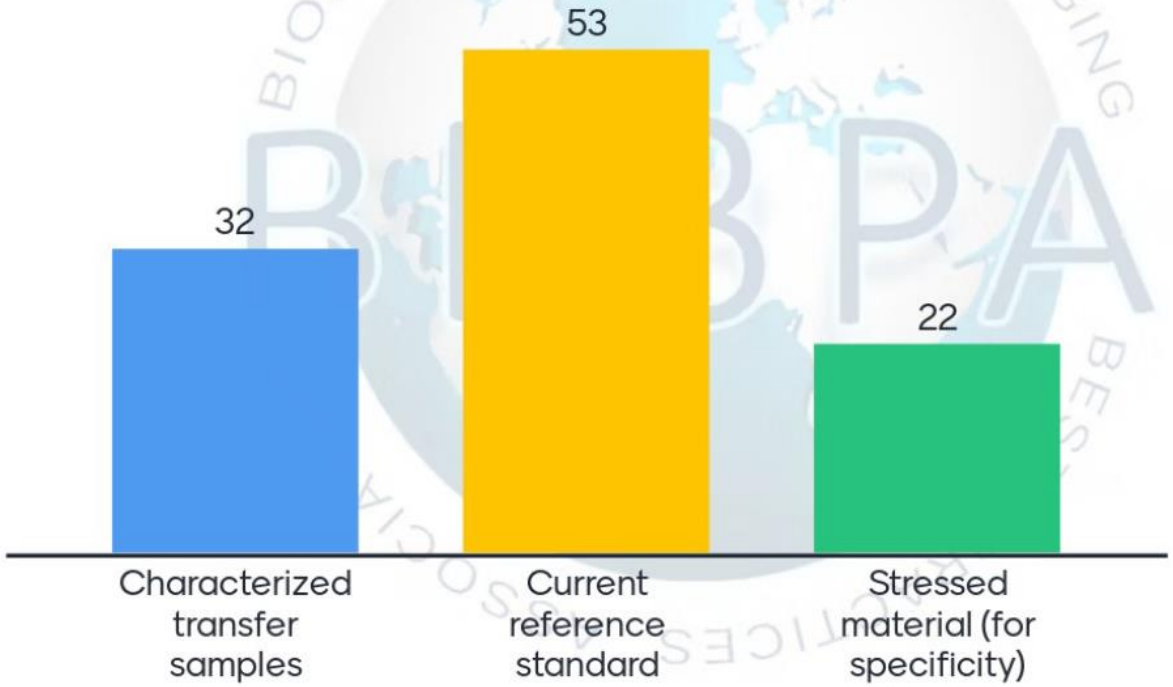
W2.15 When you transfer an assay what information do you usually have available? Choose all that apply.



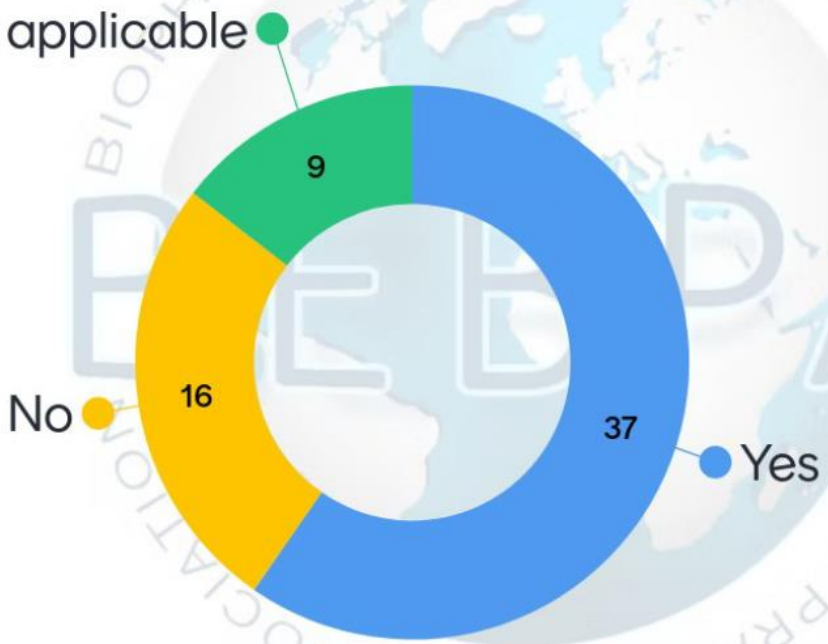
W2.16 Do you make all critical reagents or request the receiving lab (e.g. cells, ligands)



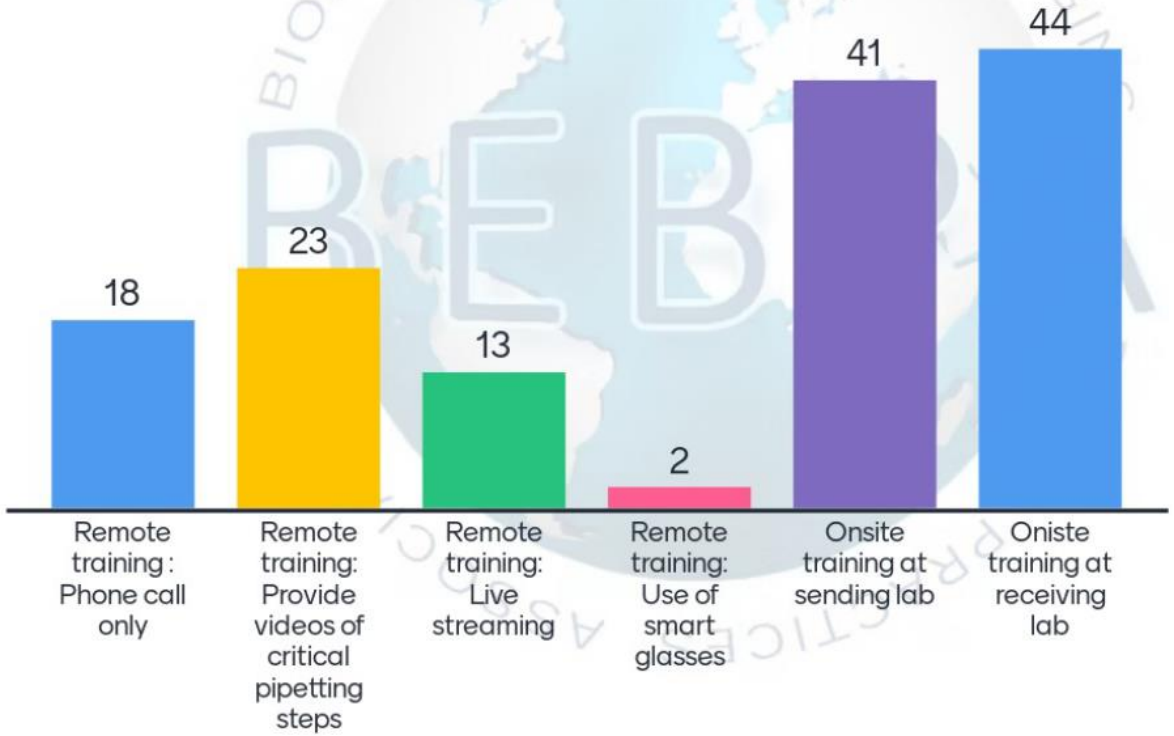
W2.17 What kind of samples would you use for transfer?



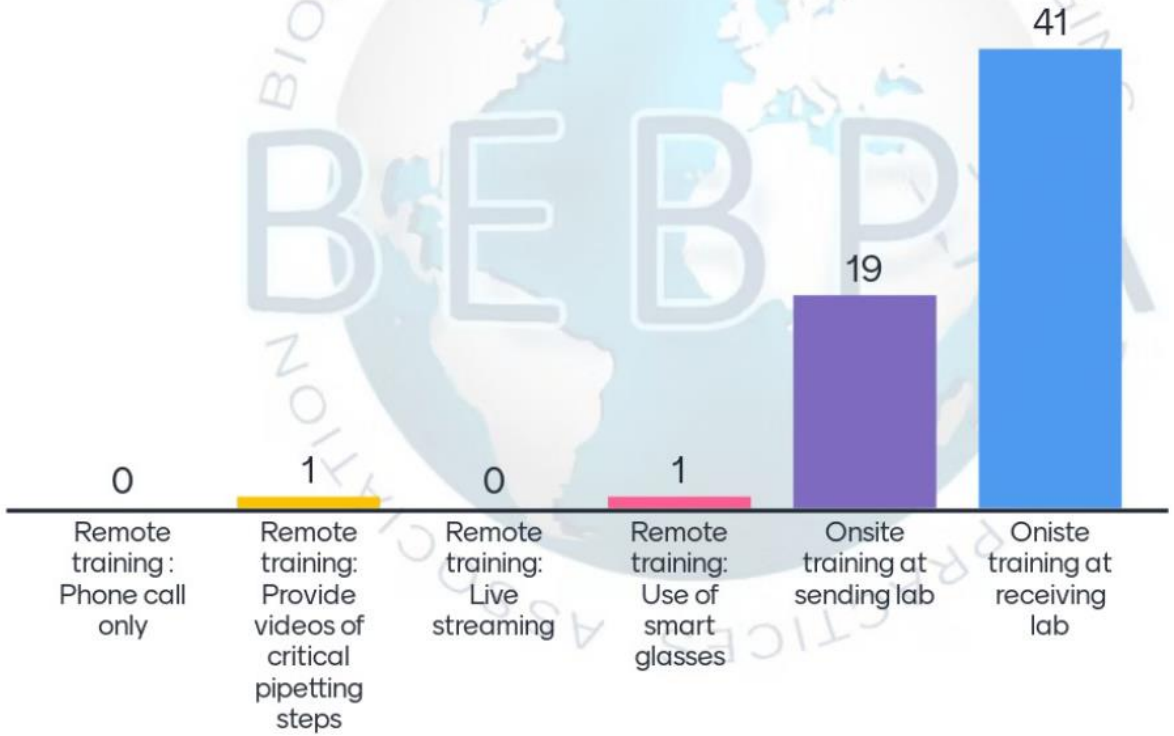
W2.18 Do you perform a gap analysis?



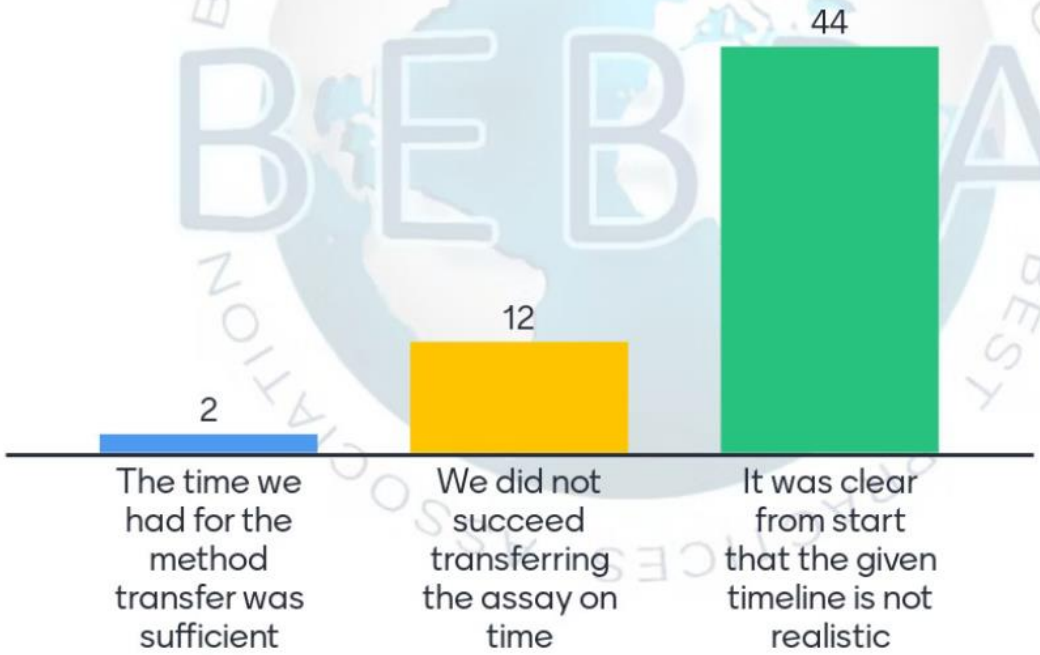
W2.19 What training approaches have been successful for you when transferring assays?



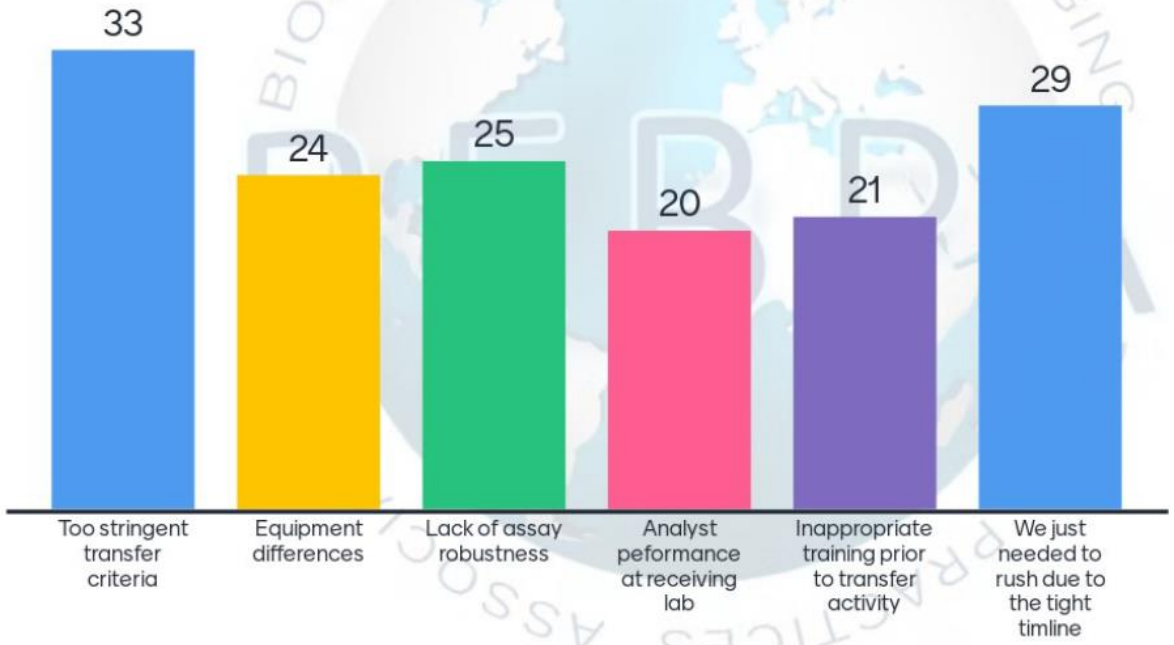
W2.20 What is your favorite training approach for assay transfer (select one) ?



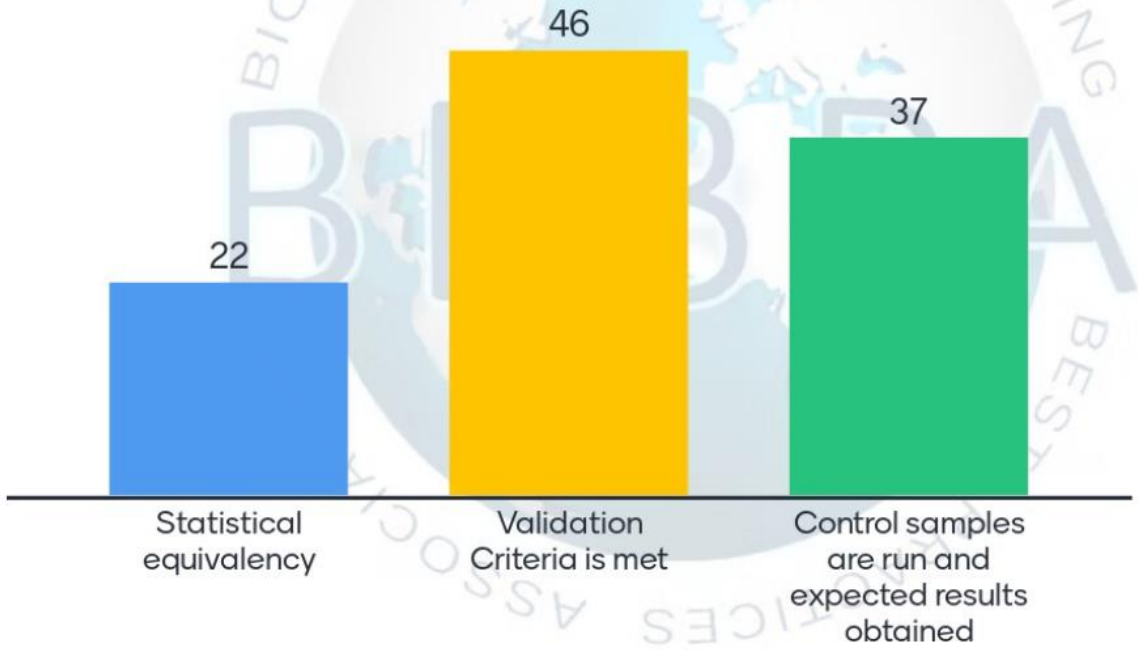
W2.21 Availabe time for method transfer: Which of the following sentences fits most according to your experience?



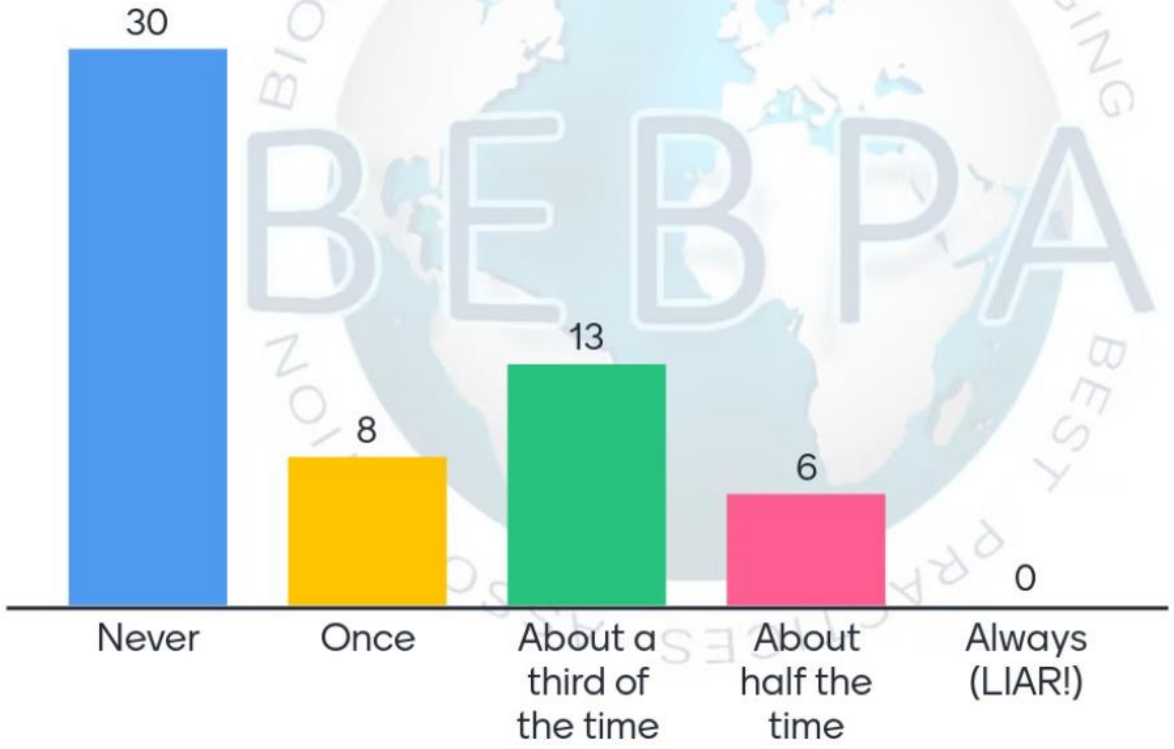
W2.22 What are the main reasons for an unsuccessful transfer?



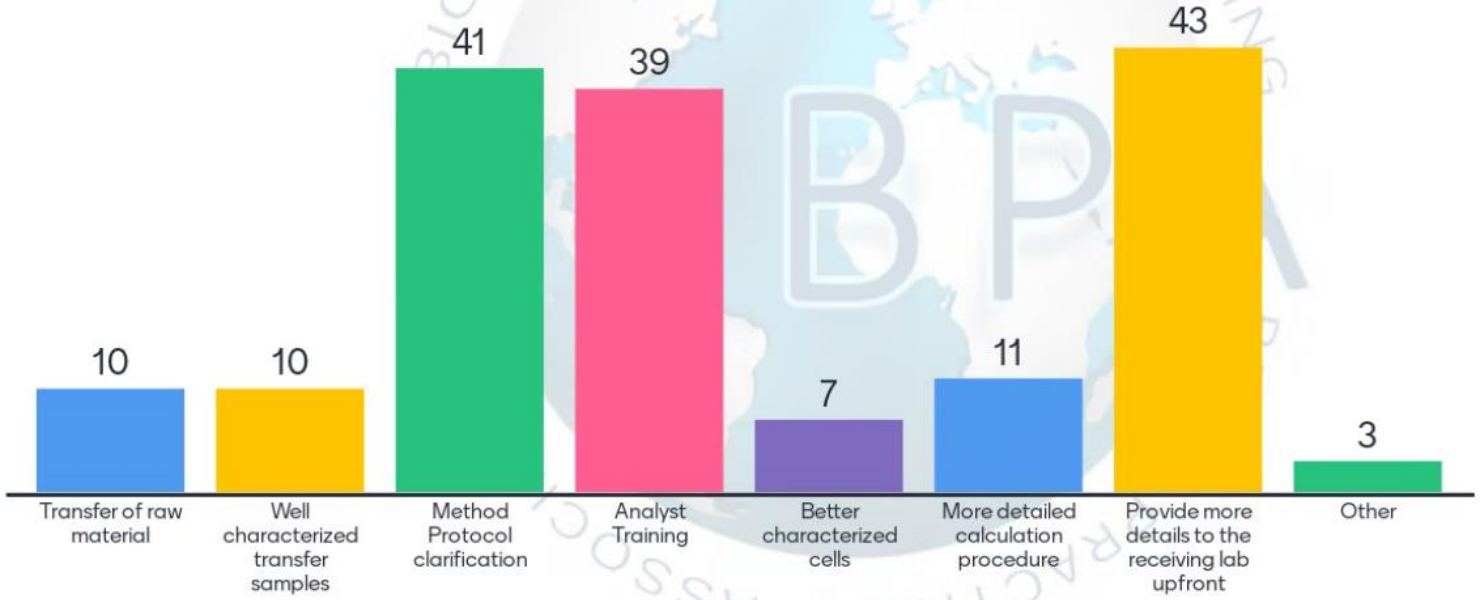
W2.23 How do you judge a successful transfer?



W2.24 How many times have you had a transfer succeed without any problems?

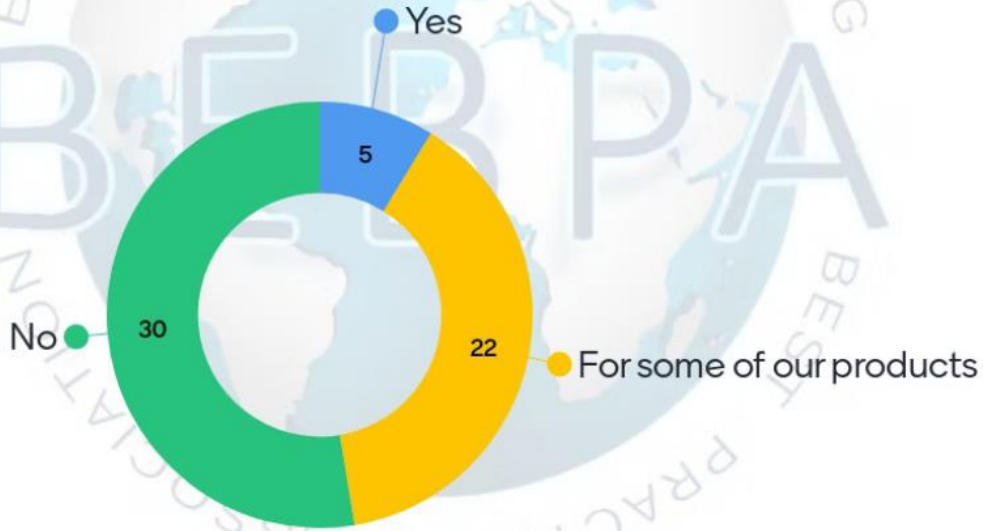


W2.25 In hindsight what could have been improved?

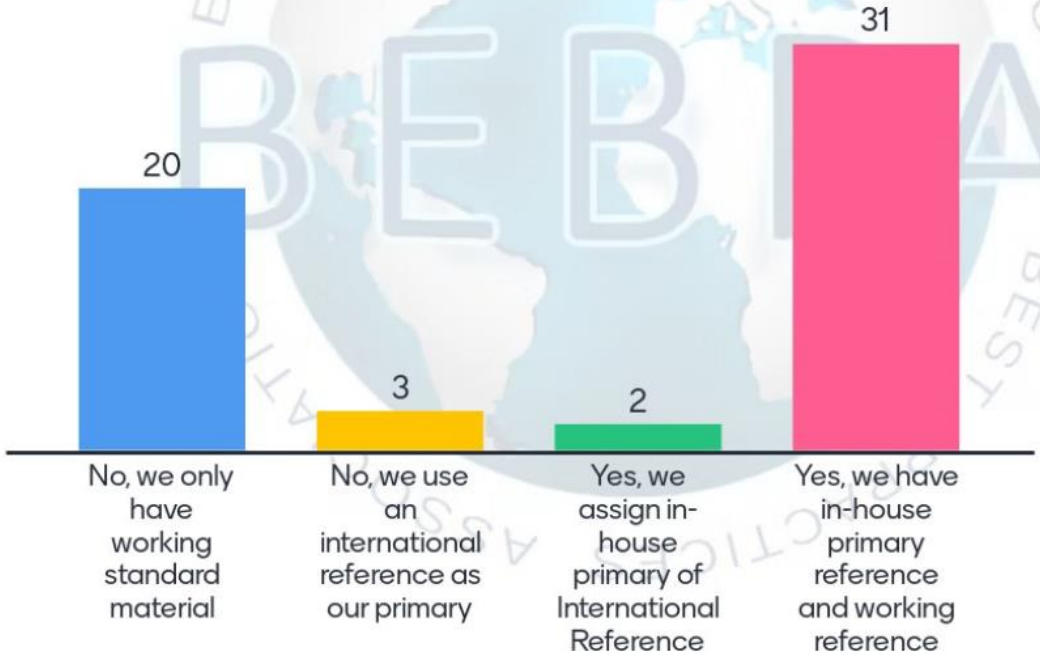


Reference Standard Intro

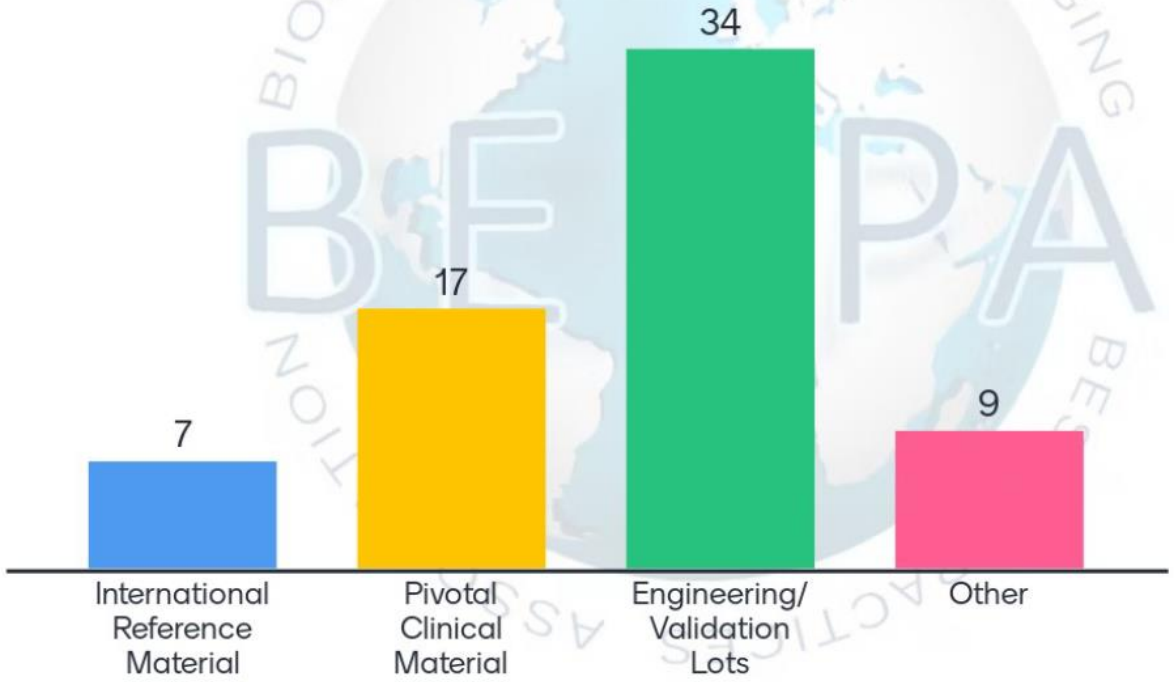
W2.26 Is an international or recognized Reference Standard (e.g. WHO, USP, EDQM) availabe for your product(s) ?



W2.28 Do you have a two- tiered reference sytem (one with primary and secondary reference material)?



W2.27 What is the typical source of your primary reference material?




BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION
BEBPA

Thank You!!