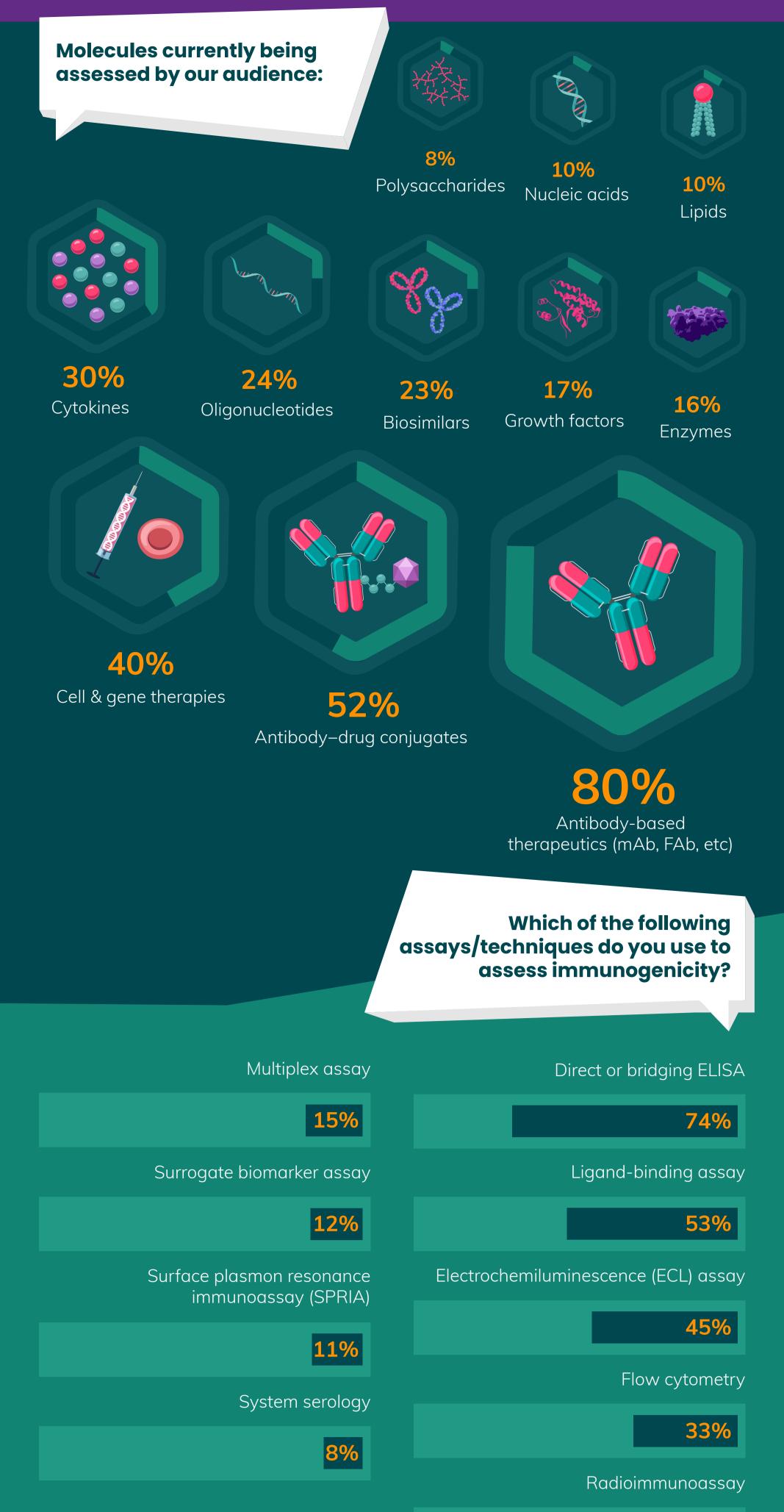




Immunogenicity assessment of therapeutic proteins

Bioanalysis of immunogenicity is critical for the development of therapeutic proteins, as immunogenicity can affect both the safety and efficacy of biological drugs. In this infographic, we explore the current trends in immunogenicity assessment, including the assays used, the challenges involved with particular assays and guidance, and the future trends likely to emerge.

Key trends in immunogenicity



18%

In your opinion, what are the three most important aspects when developing immunogenicity assays?

San

Sensitivity 74%	
Specificity 74%	
Drug tolerance 51%	
Regulatory considerations 31%	
Automation & throughput 27%	
ample compatibility with the platform 21%	
Determination of ULOQ, LLOQ & LOD 21%	

The new technical developments in ADA testing being deployed by our audience:

Validation:

30% Singlicate well analysis for ADA testing

24%

Singlicate well analysis for pre-clinical or early clinical phase ADA testing only

Sample analysis:

26% Singlicate well analysis for all ADA testing

16%

Singlicate well analysis for pre-clinical or early clinical phase ADA testing only

Simplified pre-clinical **ADA** analysis:

30% By performing shortened validation

22% By performing single-tier analysis (screening only)

31%

By using the screening (S/N) signal rather than determining the titer

Screening assay signal (or S/N) as a surrogate for:

21% The titer for all ADA testing

21%

The titer for pre-clinical or early clinical phase ADA testing only

We do not apply one of the aforementioned approaches

28%

Challenges of immunogenicity testing

Main challenges in ADA analysis?



40% Drug tolerance leading to false negative results



33% Target interference leading to false positive/negative results



26% Soluble drug target leading to false positive/negative results

21%

Determining cut-points



40% Pre-existing antibodies



31% Sensitivity



25% Lack of clear acceptance criteria in guidances



20% Describing clinical relevance of results

Which stage of immunogenicity assessments is the most challenging?



Neutralization assays Assesses the neutralizing capacity of antibodies present in positive samples.

25%

Screening assays

The first step in immunogenicity evaluation. Detects all clinically relevant antibodies induced against the product.

21%

Characterization assays



37% Selectivity



28% Long term availability of critical assay reagents, including negative control pool

23% Reevaluating clinically relevant cut-points in disease populations

Generally consists of titering testing and isotype analysis. Titering assays characterize the scale of the ADA response and isotype assays detect all relevant immunoglobin isotypes.

10%

Confirmation assay Confirms the positive results eliminates any false positive results following the initial screen

Future thinking

69%

feel immunogenicity testing has increased over the last 5 years

15% say it has stayed the same

11% are not sure

5% say it has decreased

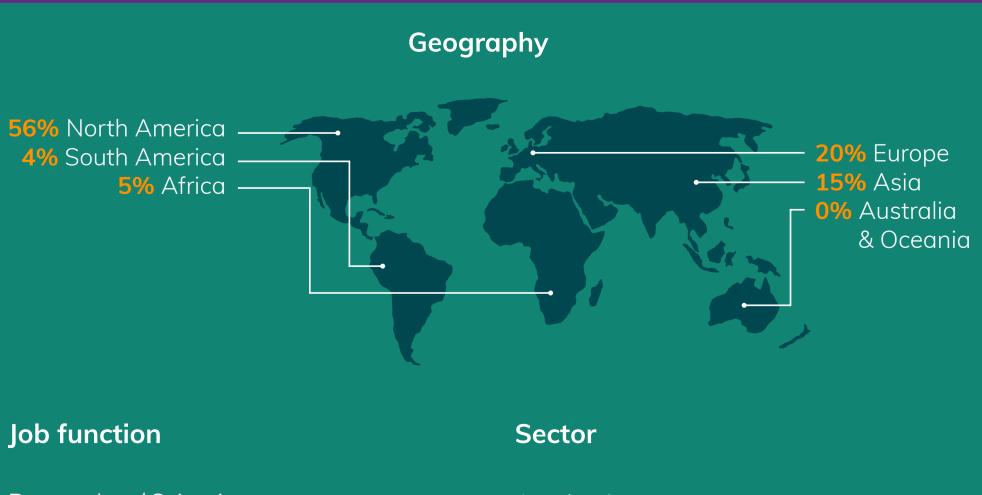
24%

find the FDA's current guidance for ADA cross-validation unclear

27%

are excited by the integration of Al/digital tools to predict immunogenicity and risk

Demographics



Researcher / Scientist
61%
Engineer
3%
Managing Director / Senior Management
21%
Marketing / Sales
2%
Quality assurance
3%
Student
1%
Other healthcare or medical professional
9%

Academia
18%
CRO/CDMO
23%
Diagnostics
8%
Government / NGO
2%
Hospital / Clinic
5%
Pharma / Biotech
39%
Private research foundation
3%
None of the above
2%

This infographic has been created as part of a Bioanalysis Zone feature in association with ICON.



