Clinical Diagnostic Program

Contrived / Surrogate Sample Use Survey Results

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
ALIGN | ACHIEVE | ACCELERATE

April Veoukas, JD, Director Regulatory Affairs | Abbott
MDIC Contrived / Surrogate Samples Work Group Chair

What is Regulatory Science?

The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products

- Benefits patients by speeding the rate of important technologies reaching market
- Reduces time and resources needed for device development, assessment, and review. For example:
  - ➢ Can lead to quicker, more efficient device approvals
  - ➢ Can decrease the size and duration of pre-market clinical trials

Faster, Safer, More Cost-effective

FDA Strategic Plan, August 2011
Advancing Regulatory Science at FDA

FDA Leadership Commitment

"Public-private partnerships have been highly successful in promoting multi-sector dialogue and developing a common view of key issues in medical product development, including the Medical Device Innovation Consortium"

FDA Commissioner
Robert Califf, MD
RAPS Regulatory Focus, January 11, 2016

"What we've lacked is a structure like the Medical Device Innovation Consortium that allows for a larger number of parties to come together to develop these projects on an ongoing basis - a significantly more effective way to do research."

CDRH Center Director
Jeffrey Shuren, MD, JD
MedPage Today, December 4, 2012

MDIC Highlights

- 57 Members
- 6 Projects
- Leading resource on issues important to the Medtech innovation ecosystem
- Congressional testimony on modernizing clinical trials
- $500k funding from FDA for Patient-Centered Benefit Risk Implementation Framework- Project Completed
- $643k funding from FDA for Quality Engagement Forum
- $300k+ of industry funding in addition to member dues

A 501(c)3 - Public-Private Partnership collaborating on Regulatory Science to make patient access to new medical device technologies faster, safer, and more cost-effective

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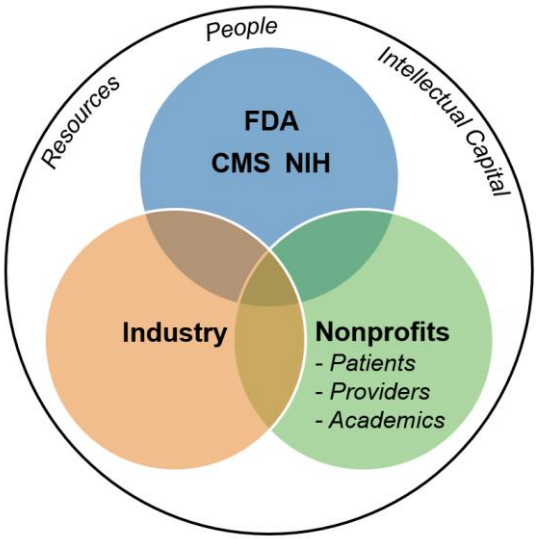

Align Resources

Accelerate Progress

Achieve Results

WORKING COOPERATIVELY
to re-engineer pre-competitive technology innovation

REDUCING TIME
and resources needed for new technology development, assessment, and review

HELPING PATIENTS
gain access to new medical technologies sooner

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Why this initiative?

- ***Issue:***

  The speed at which innovation and improved diagnostics are developed can be hampered by the difficulty in obtaining or retaining clinical specimens.

- ***Goal:***

  Establish a foundation for the use of surrogate samples to support IVD product development and the regulatory process.

What is a contrived / surrogate sample?

A contrived or surrogate sample (CSS) means material used as a substitute for body fluid or tissue taken for examination from a patient.

Examples include, but are not limited to:

- Materials supplemented (spiked) with a measurand of interest
- Pooled specimens of biological origin
- Material created to have functional characteristics of body fluid or tissue taken from a patient

Survey Distribution Channels

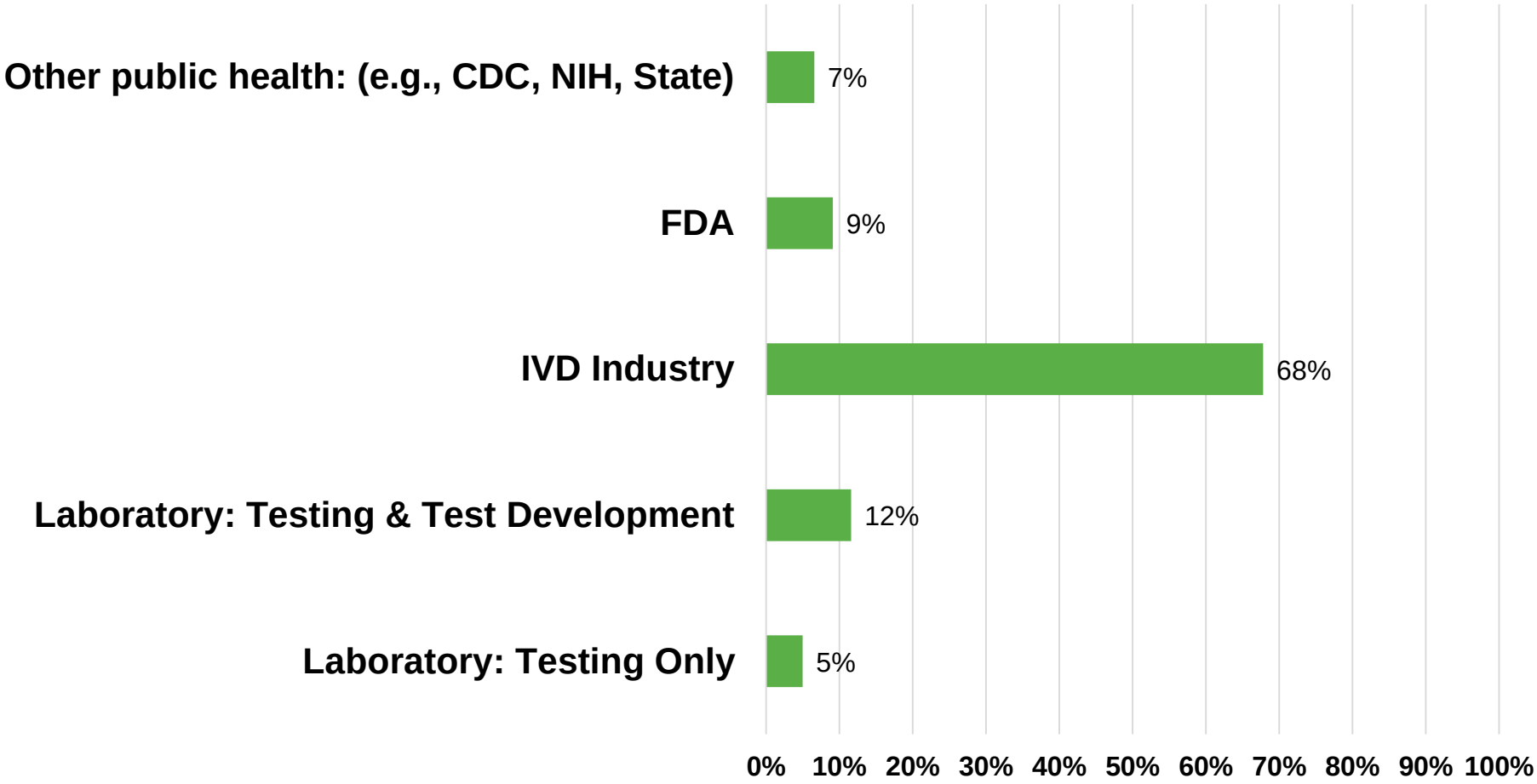
- MDIC Website
- MDIC e-blast communications

Survey distribution assistance by:

- AdvaMed Dx
- Association of Medical Diagnostics Manufacturers
- Clinical Laboratory Standards Institute
- FDA
- Medical Device Manufacturers Association

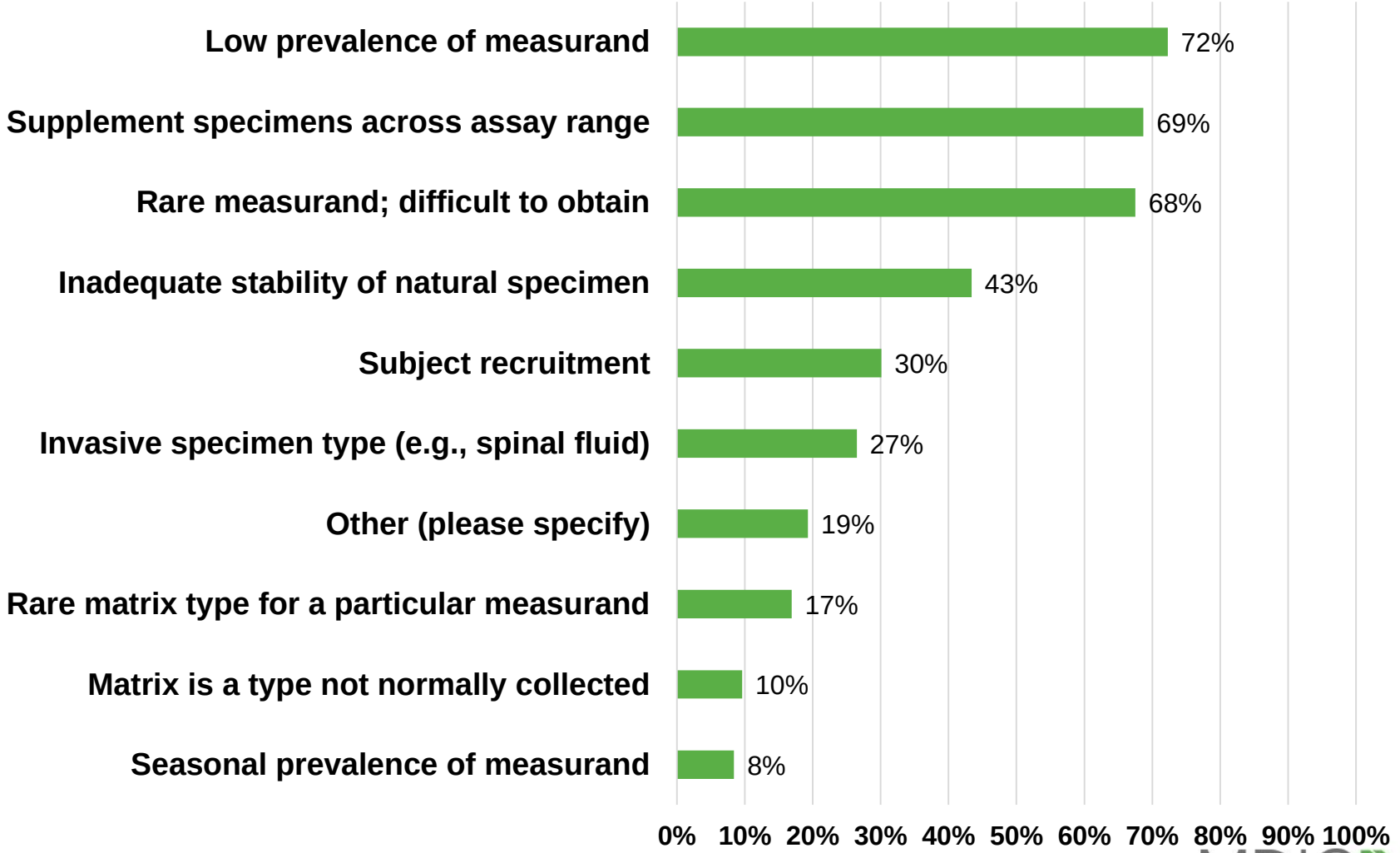
Who took our survey?

121 Survey Responses



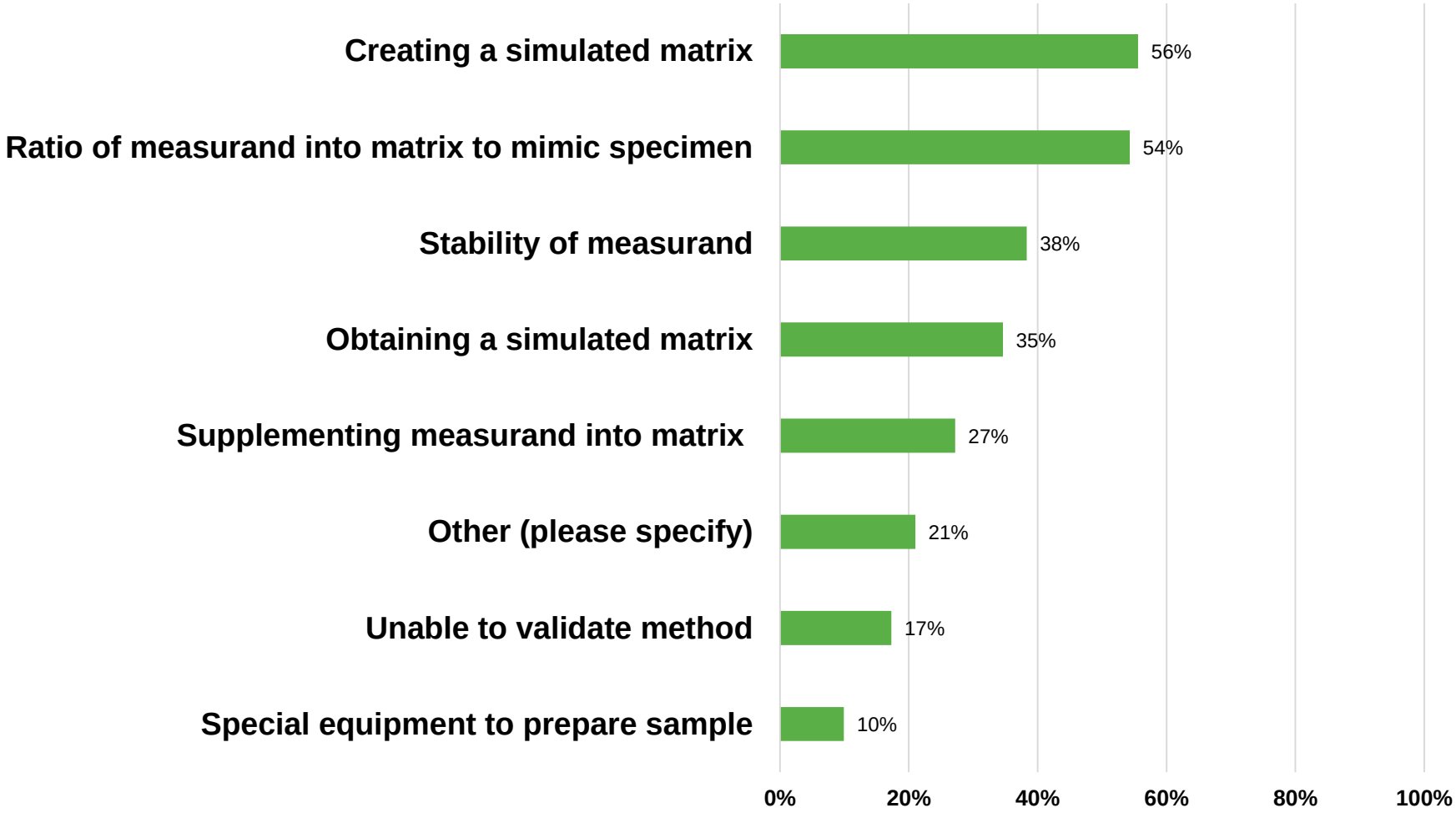
Reasons for using CSS?

(could select more than one answer)

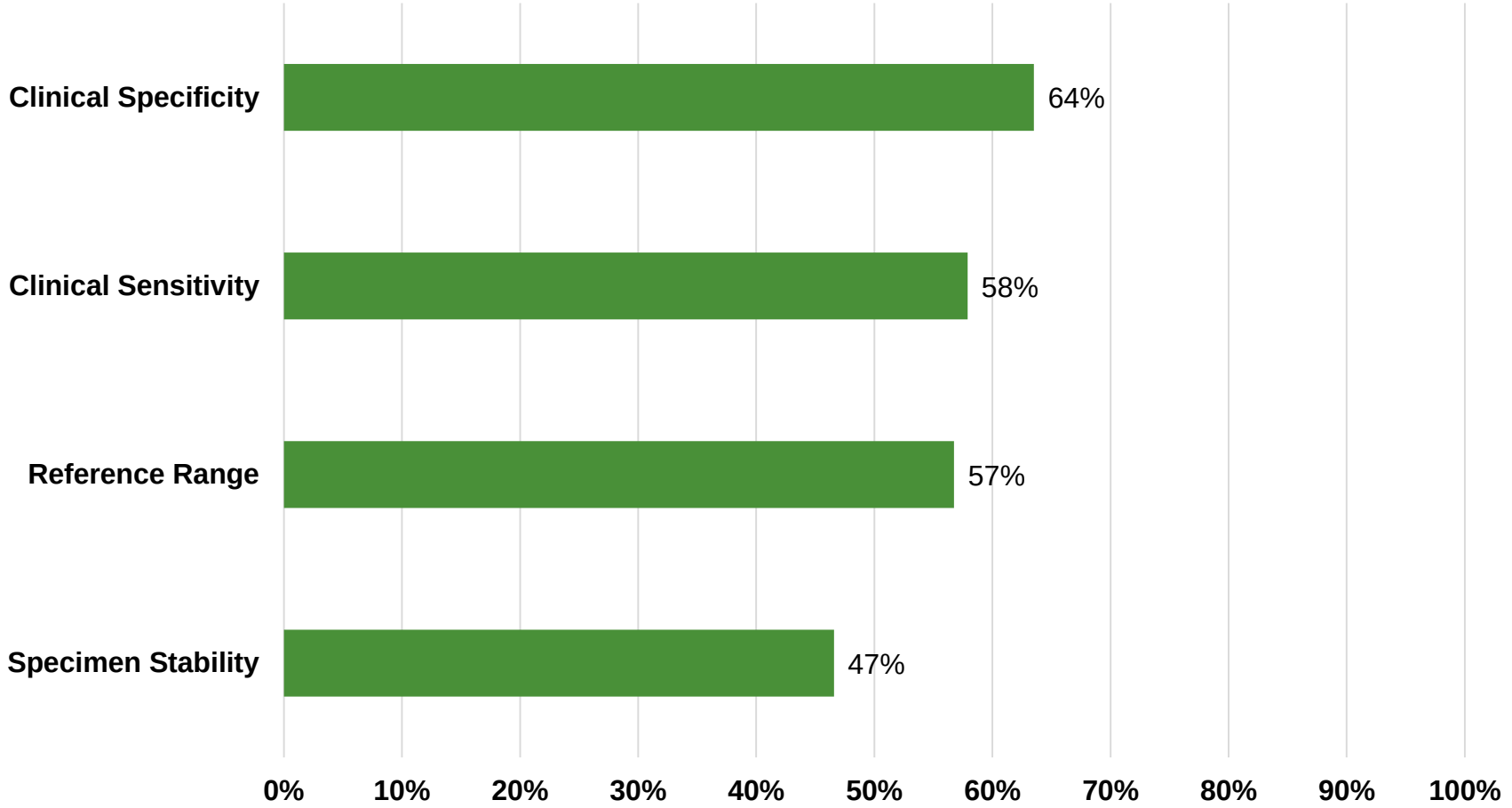


What technical challenges have they encountered when using CSS?

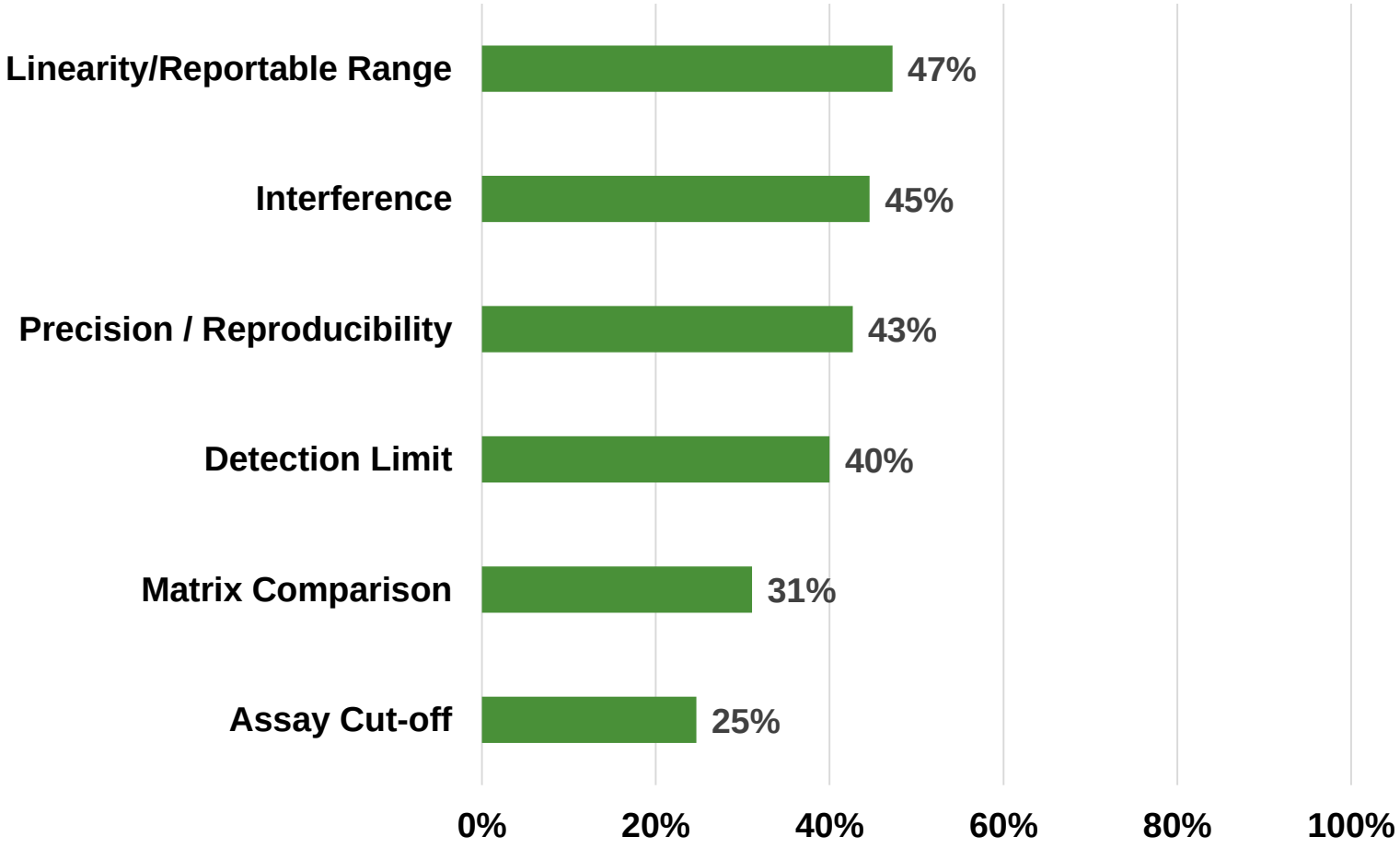
(could select more than one answer)



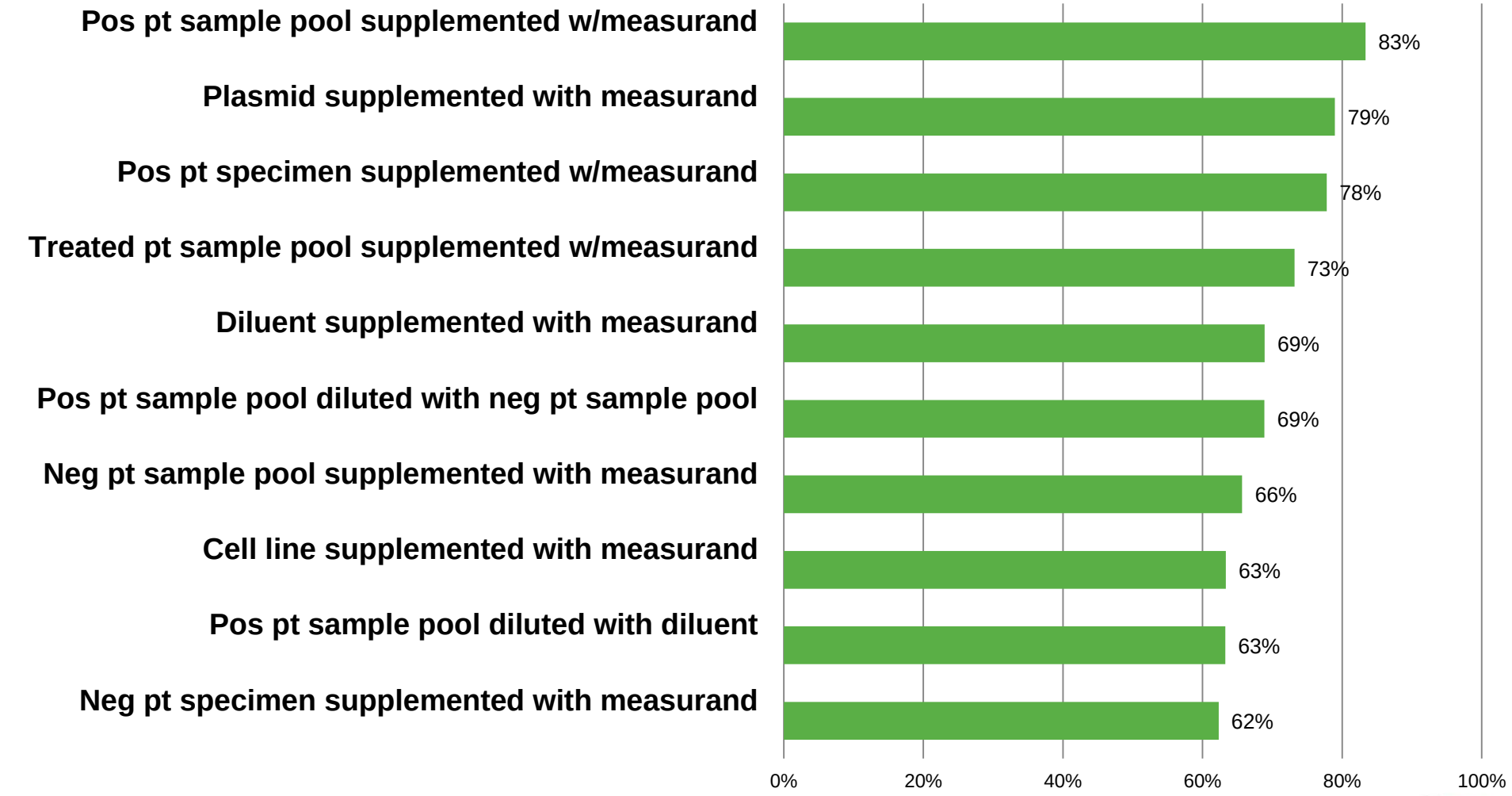
When has it been *not* routinely acceptable to use CSS when working with a regulatory body (or as a regulatory body)?



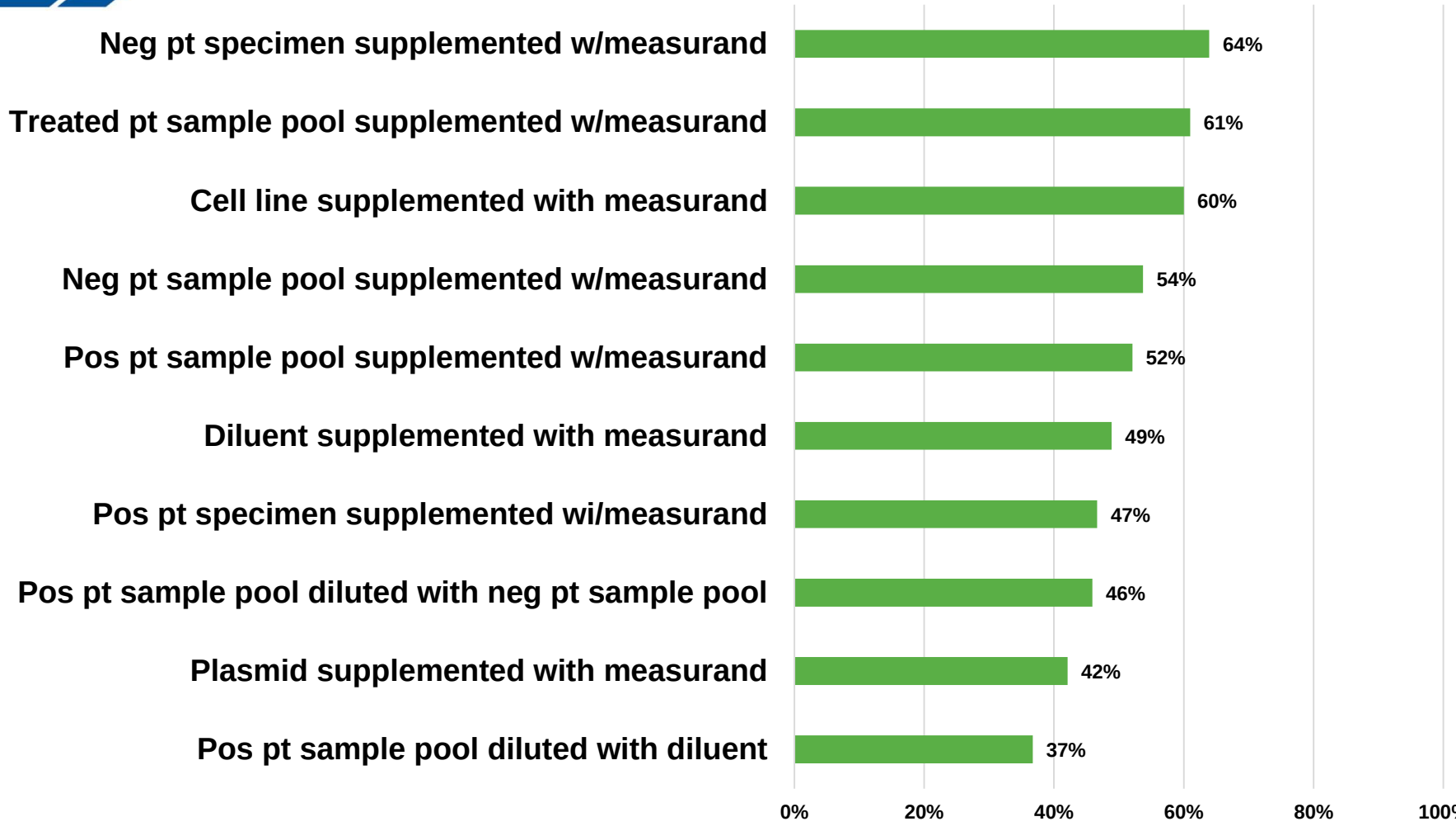
When has it been routinely acceptable to use CSS when working with a regulatory body (or as a regulatory body)?



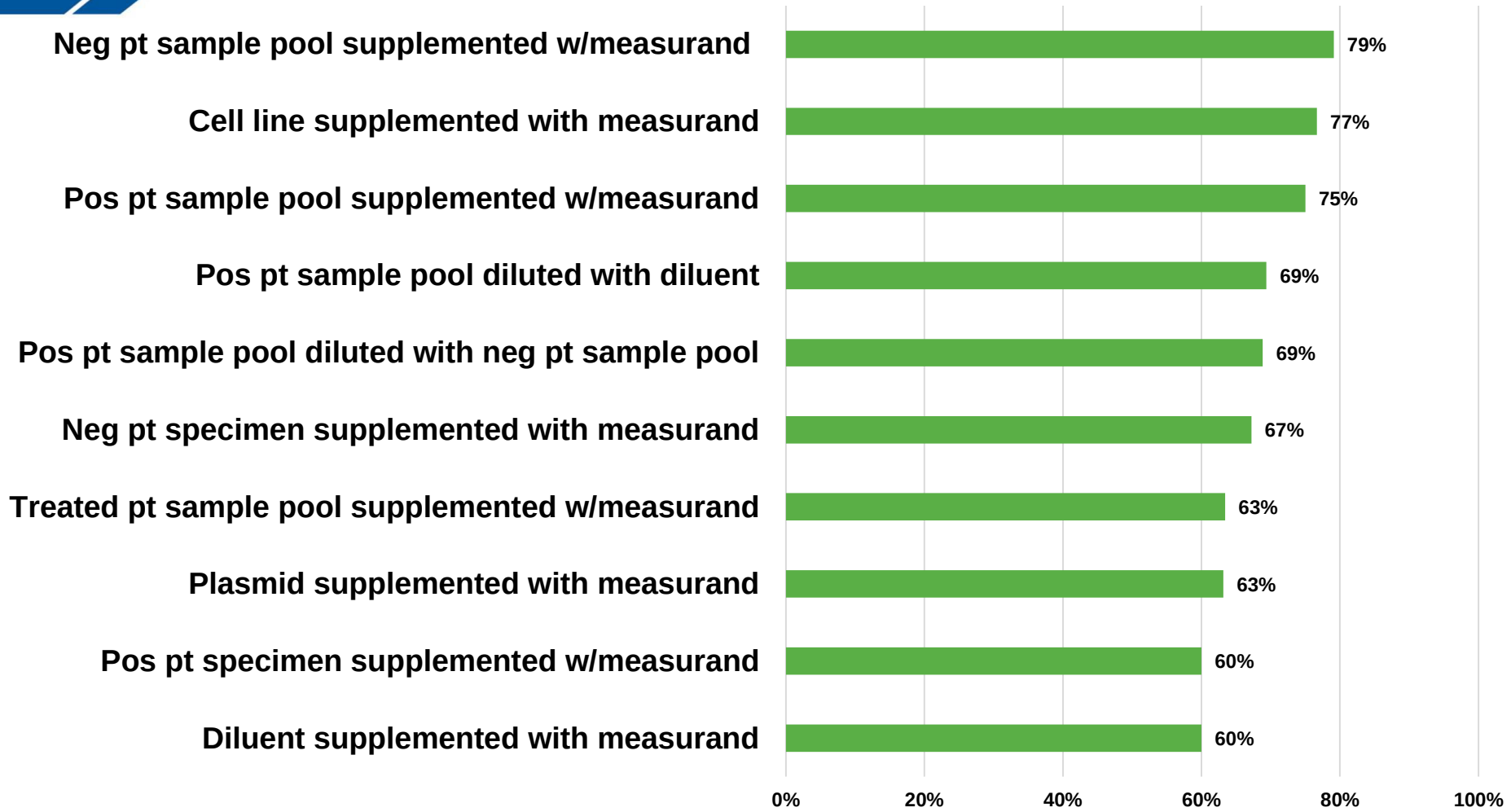
When would you most frequently use the specified CSS to complete Linearity / Reportable Range?



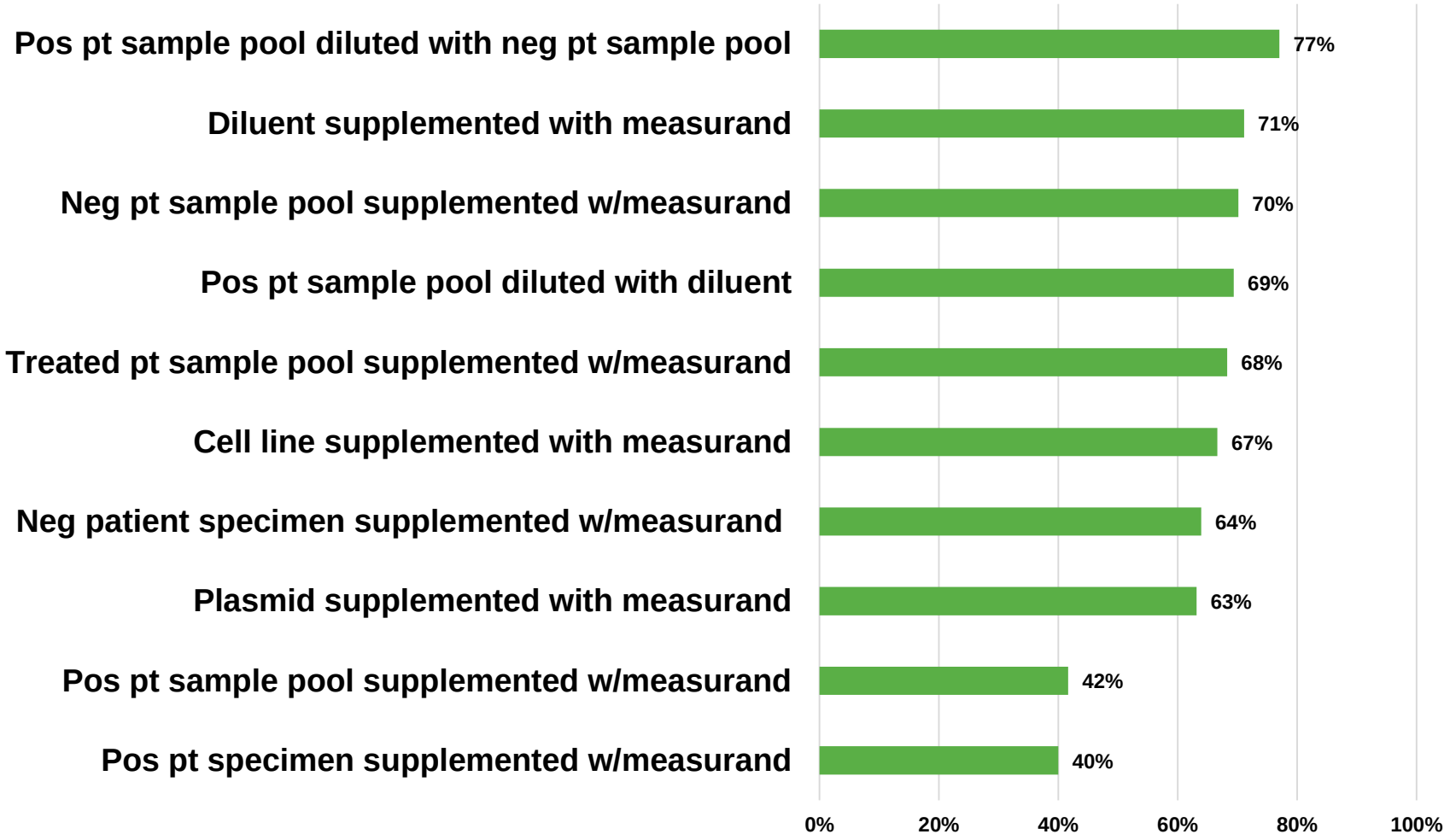
When would you most frequently use the specified CSS to complete Interference?



When would you most frequently use the specified CSS to complete Precision / Reproducibility?



When would you most frequently use the specified CSS to complete Detection Limit?



Next Steps

- Summarize survey results
- Summarize analysis collected from 510(k) and PMA summaries and literature
- Outline framework
- Public comment on framework
- Deliver white paper

Who is working on this project?

MDIC has assembled a work group comprised of member organizations and other subject matter experts to guide work on this project.

Industry:

Khatereh Calleja, JD, AdvaMed
Ronald Freeze, PhD, Abbott
Patrick O'Donnell, Roche
Pamela Frank, Abbott
Ian Giles, MD, Sysmex
Brad Spring, BD

April Veoukas, JD, Abbott (Working Group Chair)

Program Manager:

Carolyn Hiller, MDIC

FDA:

Marina Kondratovich, PhD, CDRH | OIR
Zivana Tezak, PhD, CDRH | OIR
Yun-Fu Hu, PhD, CDRH | OIR

Expert Advisors:

Susan Alpert, MD, PhD
Constantine Gatsonis, PhD
Fred Lasky, PhD

For Additional Information
Visit the Clinical Diagnostic Program Website:

http://mdic.org/ClinicalDx/

Or contact:

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