COVID IN NORTH AMERICA:

IMPACT ON THE BIOANALYTICAL AND DRUG DEVELOPMENT COMMUNITY

EBF DAY 4 WORKSHOP 1: COVID-19: CHALLENGES, EXPERIENCES AND IMPACT ON THE BA LAB

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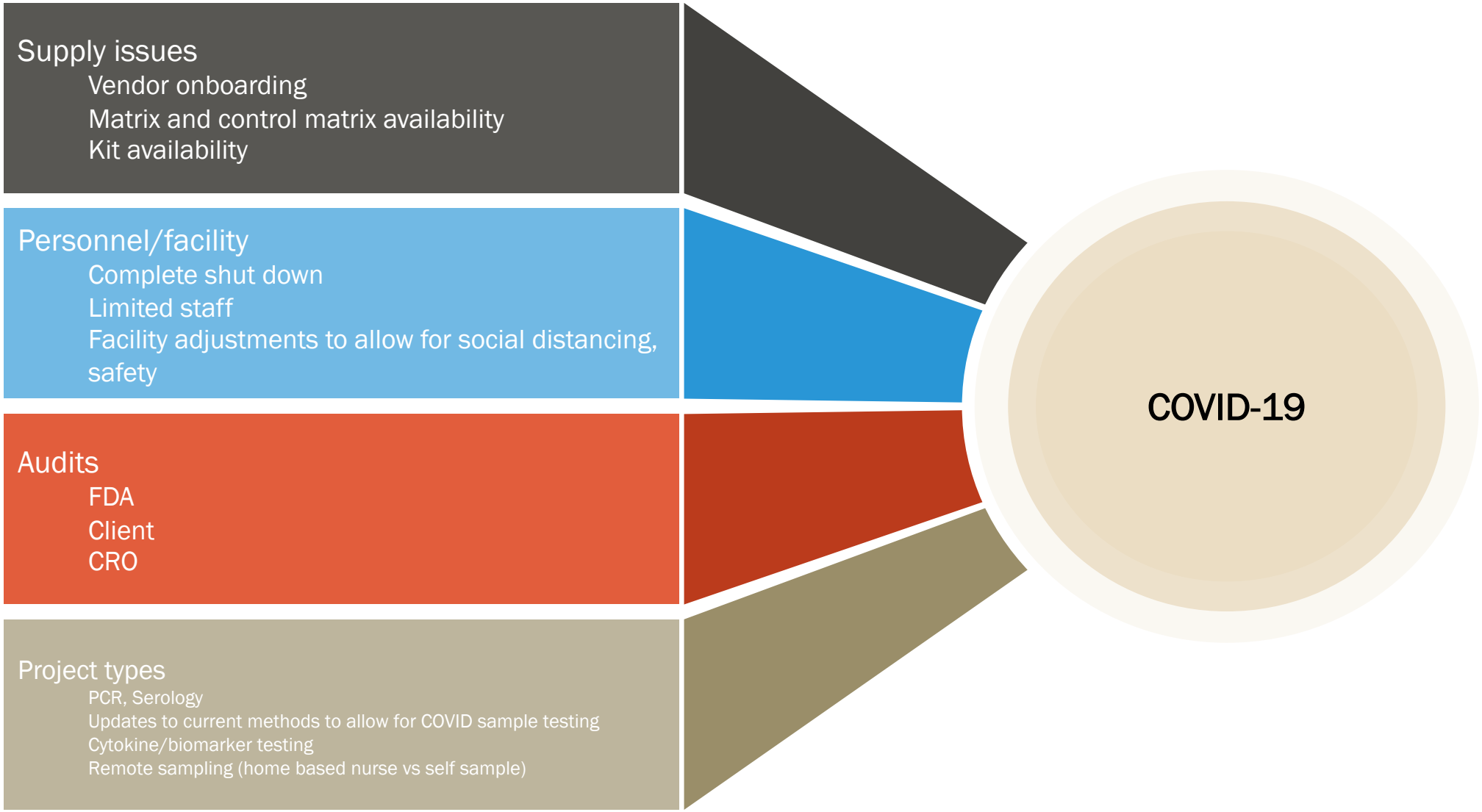
PPD

NORTH AMERICAN SURVEY OF COVID-19 IMPACT

- Survey questions were sent to contacts representing
  - Large pharma
  - Small pharma/biotech (including virtual)
  - CRO
  - Central Labs
- Focused on 4 main areas of impact
- Specific questions centered on impact of shutdowns and reopening, audits and study timelines, project focus, outsourcing and supply chain impact.

NOTABLE AREAS OF IMPACT

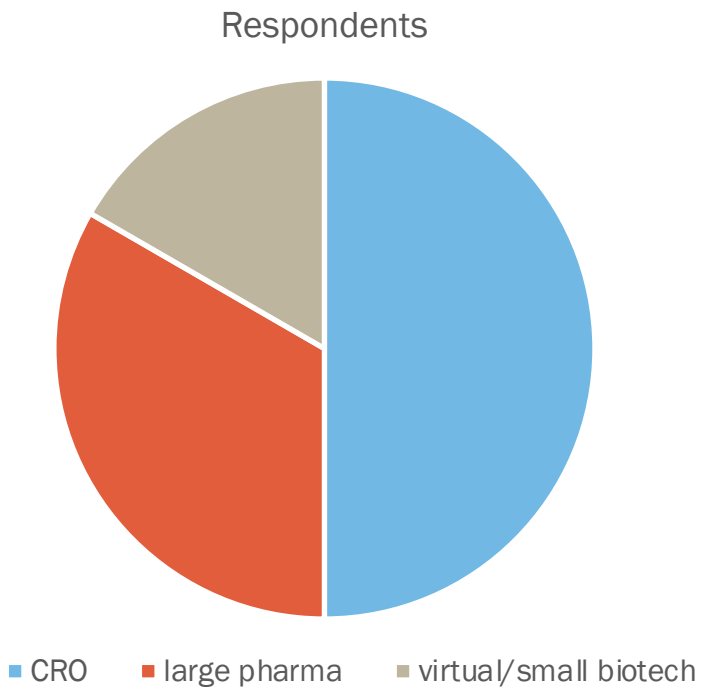


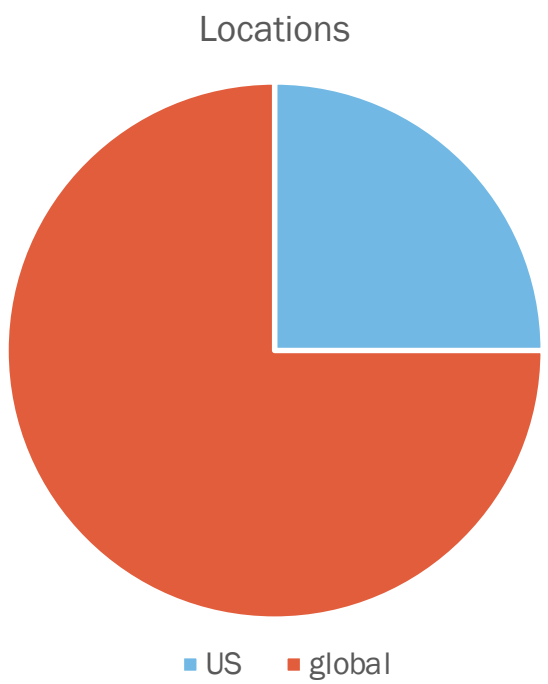
SURVEY QUESTIONS

1. Did you shut down? If so, for how long? What did shut down and then reopening look like (limited staff, etc.)?
2. How have your audits changed? All virtual? Delayed? How has this impacted study or submission timelines? Has focus of audits changed significantly? If so, in what way?
3. How has your project focus shifted? How has outsourcing changed?
4. How has supply chain been affected and how has this affected studies?
5. If you are a global lab, what are differences you've seen between North American operations and worldwide sites?

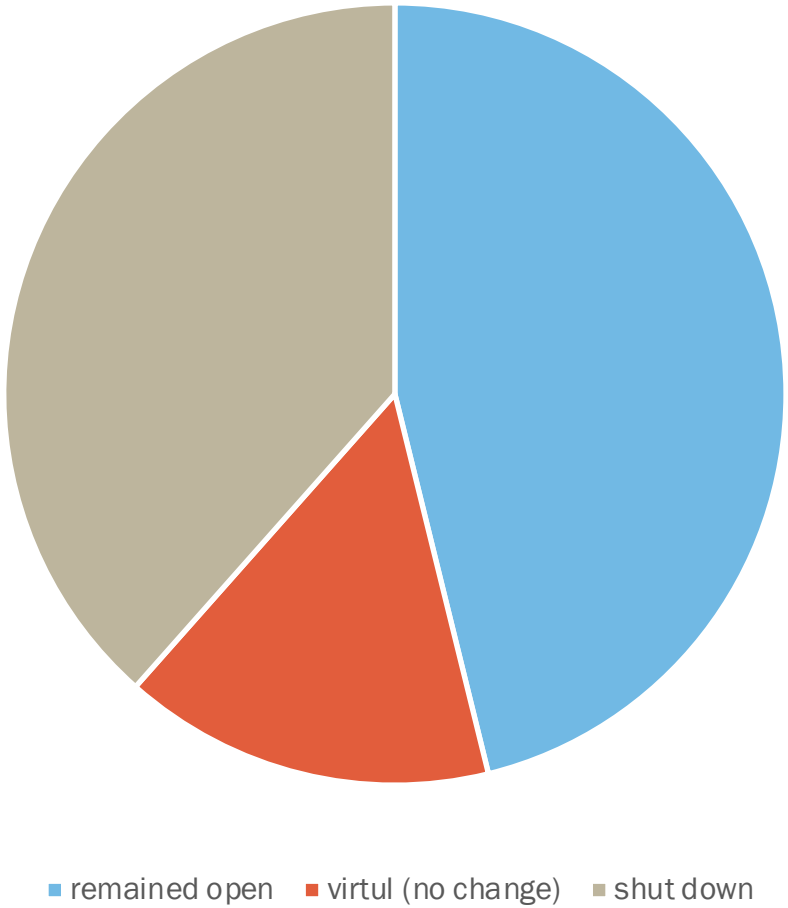
SURVEY PARTICIPANTS

- 6 CRO (include central labs)
- 4 large pharma
- 2 virtual/biotech





SURVEY QUESTION 1: DID YOU SHUT DOWN? IF SO, FOR HOW LONG? WHAT DID SHUT DOWN AND THEN REOPENING LOOK LIKE (LIMITED STAFF, ETC.)?



- All CRO remained open as essential business
- 3 large pharma shut down, 1 shut down but kept personnel on site to handle samples
- 1 large pharma stayed open
- 1 CRO/CL clinic shut down, labs stayed open
- Shut down through June

- All implemented safety protocols
  - Study participants tested for COVID at check-in
  - Clinical staff tested every other week
  - Clinics running at 70% capacity

ON-SITE COVID PROCEDURES

- “We added a Business Continuity Plan to our Disaster Recovery Plan in order to identify engineering controls and how operations management could limit operations to critical staff if the situation arose. We also added additional work areas in order to allow our employees to socially distance; we added daily disinfecting procedures to critical laboratory and office areas; and we added an employee self-health check-in procedure prior to starting a shift. We are also in the process of installing Plexiglas dividers to provide more protection for the laboratory work stations. We continue to access the situation and make further adjustments as needed.”

  -CRO

ON-SITE COVID PROCEDURES

- “Prior to the widespread exposure and company wide essential personnel only shutdown, we anticipated the spread of the pandemic and incorporated enhanced protective equipment in our lab and outsourced a very large study based in a high prevalence Asia COVID location to a CRO.”

  -Large Pharma

SURVEY QUESTION 2: HOW HAVE YOUR AUDITS CHANGED? ALL VIRTUAL? DELAYED? HOW HAS THIS IMPACTED STUDY OR SUBMISSION TIMELINES? HAS FOCUS OF AUDITS CHANGED SIGNIFICANTLY? IF SO, IN WHAT WAY?

- Sponsor audits
  - "mostly" virtual
  - ~70/30 for one respondent
- FDA audits
  - all virtual

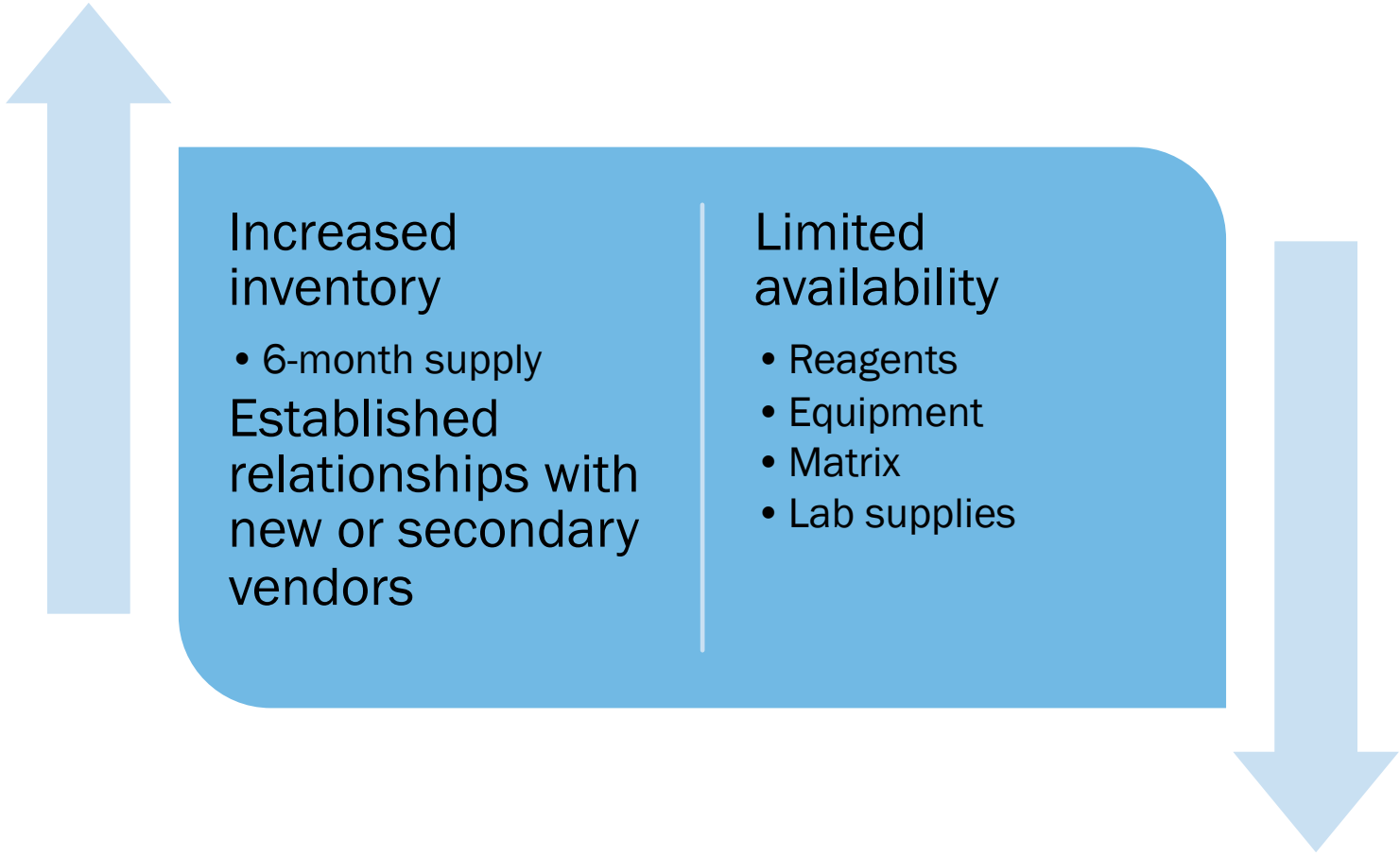
- Minimal to no impact on pipeline, milestones, submission timelines
- Scope of audits relatively unchanged since information can be shared securely with virtual face-to-face interactions
- One respondent saw more detail-oriented audit from FDA focused entirely on BioA (to support regulatory submission)

SURVEY QUESTION 3: HOW HAS YOUR PROJECT FOCUS SHIFTED? HOW HAS OUTSOURCING CHANGED?

- Reprioritization of COVID-19 programs
  - Delays in new discovery/early development programs
  - Delays in pre-clinical programs
  - Some reported delays in clinical sample analysis, enrollment delays
  - Increase in COVID testing – due to development of assays for testing SARS-CoV-2

- Increase in outsourcing
  - Due to shut down
  - Need for safety precautions and restrictions for personnel

SURVEY QUESTION 4: HOW HAS SUPPLY CHAIN BEEN AFFECTED AND HOW HAS THIS AFFECTED STUDIES?



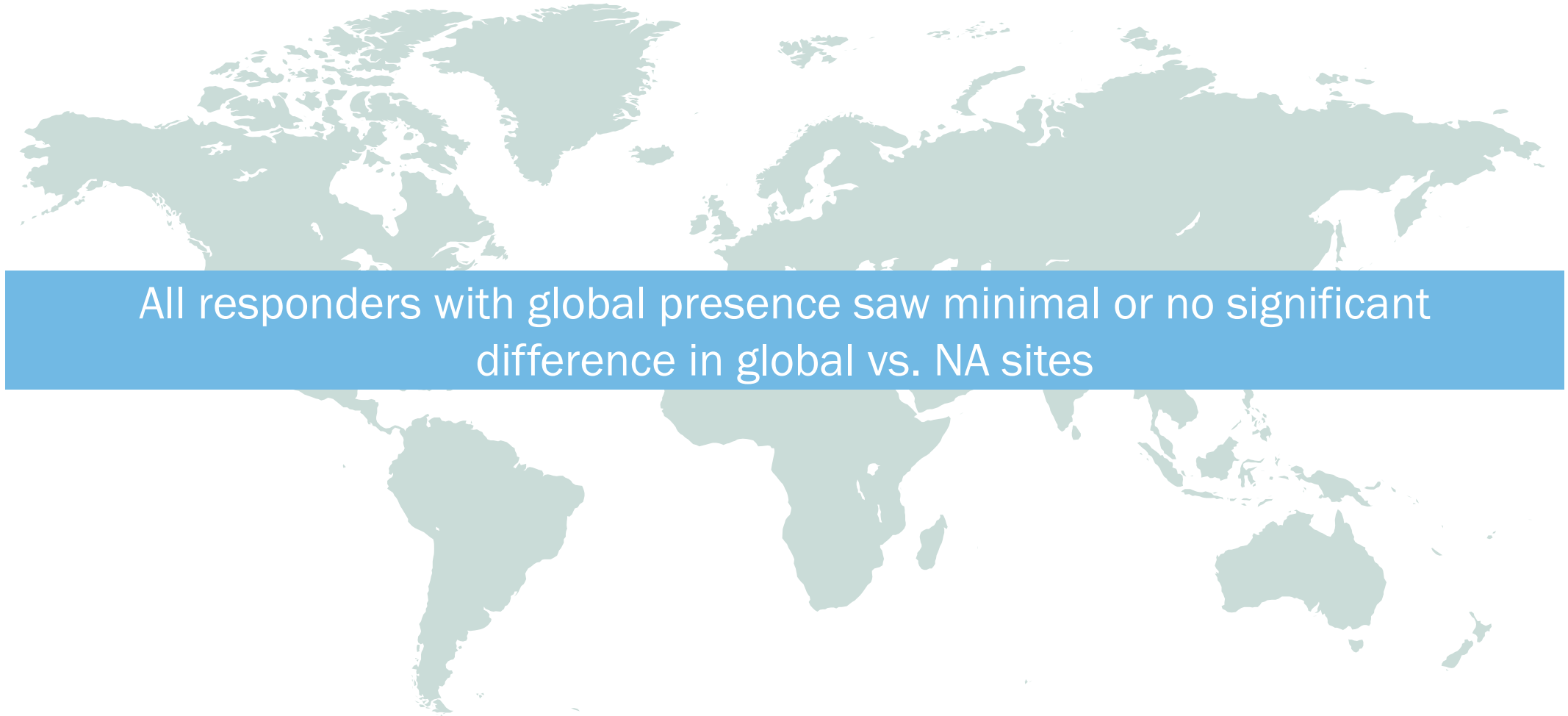
Minimal Study Delays

- border restrictions
- custody flow

SURVEY QUESTION 4: HOW HAS SUPPLY CHAIN BEEN AFFECTED AND HOW HAS THIS AFFECTED STUDIES?

- “We worked with our vendors early on to identify materials and supplies that could become limited due to capacity related issues. We increased our inventory to cover possible delays so that we could remain in operation should such capacity issues arise. We have established relationships with secondary vendors in the event of supply chain related delays.”

SURVEY QUESTION 5: IF YOU ARE A GLOBAL LAB, WHAT ARE DIFFERENCES YOU'VE SEEN BETWEEN NORTH AMERICAN OPERATIONS AND WORLDWIDE SITES?



All responders with global presence saw minimal or no significant difference in global vs. NA sites

ACKNOWLEDGEMENTS

- Pat Bennett and Heather Myler
- Those who responded to the survey, names have been kept confidential.