LabConnect

Top Takeaways

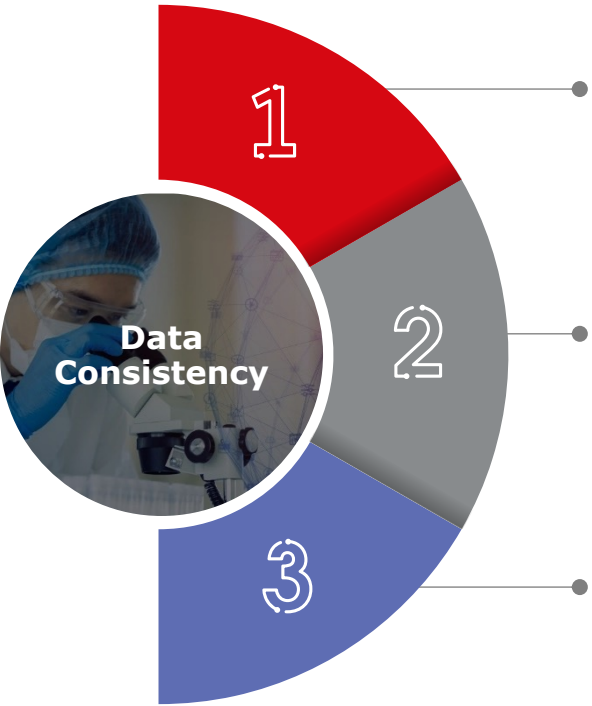
from our webinar series addressing key challenges to reaching clinical trial milestones.

Part 1: Streamlining Sample Collection

Topics

- Translating your complex protocol to the simplest collection kits
- Considerations for streamlining kit designs
- Central lab kits vs. site-procured materials
- Ways to reduce waste

Why do sponsors use a central lab?



Standardized specimen and data collection

Standardized sample analysis

Single lab database for data cleaning and reporting

Why provide specimen collection kits centrally?

Ensures consistent and correct sample collections

- Container types, sizes and additives
- Correct labels

Ensures that sites have all the materials necessary to collect quality specimens

- Inventory assurance
- Lot number/ expiration tracking

Protocol complexity trends

~20

endpoints in Phase II and III trials

263

Procedures per patient

3.6MM

data points generated on average in Phase III trials

75%

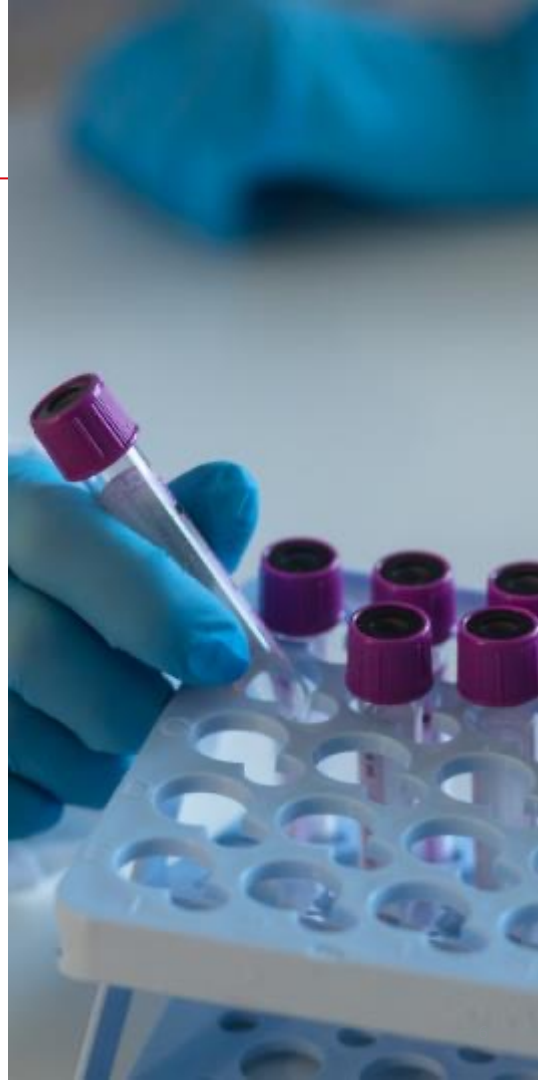
protocols amend more frequently

Tufts Center for Drug Development. *Rising Protocol Design Complexity Is Driving Rapid Growth in Clinical Trial Data Volume.* January/February 2021. Vol. 23 No. 1.

Why is Kit Design Important?

Poorly designed specimen collection kits can …

- Delay site activation
- Create site challenges for inventory management
- Slow subject screening and enrollment
- Increase queries and re-work at sites
- Result in lost or non-viable samples



How kit design helps reach your objectives faster

Understand all kit strategy options

Consider the needs and capabilities of your stakeholders to identify the best design for your specific project

Identify risks to sample quality and design the kits, labels and forms to mitigate these risks

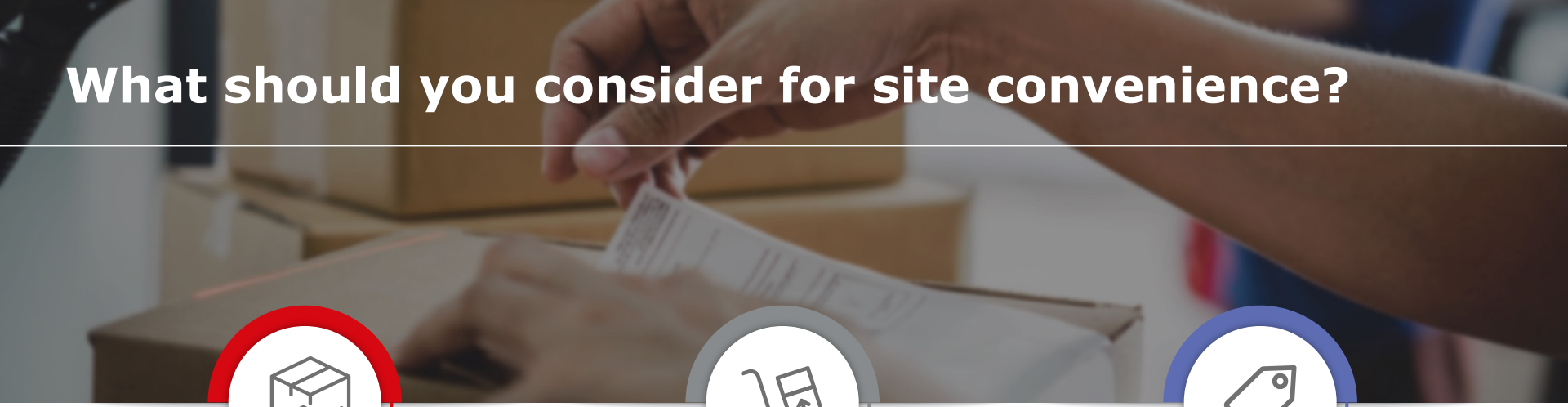
Considerations for Optimal Kit Design – Kit Types

	Pros	Cons
Bulk Supplies	Highly Flexible, rapid start, minimized storage space	Heavy site burden for organizing, selecting correct materials and labeling
Visit Specific Kits	Easy for site use, high quality sample and data collection	Requires storage space, sites must manage kit inventory to expected visits
Sample Specific Kits	Flexible inventory use across many visits or cohorts	Sites must select correct combination of kits for each visit, additional forms to be completed

What are key considerations for optimal kit design?

- Are there special supply types needed and who should procure and supply these?
- How many kits or supplies are needed on site?
- How similar or different are your visits?
- How much space does the site have for storage?

What should you consider for site convenience?



The over-packaging and labeling of shipments to sites impacts inventory reception and management

Customized kits promote correct processing, handling and shipping

Well-labeled and identified kits are easy to locate for subject visits

What should you consider for packaging and shipping?

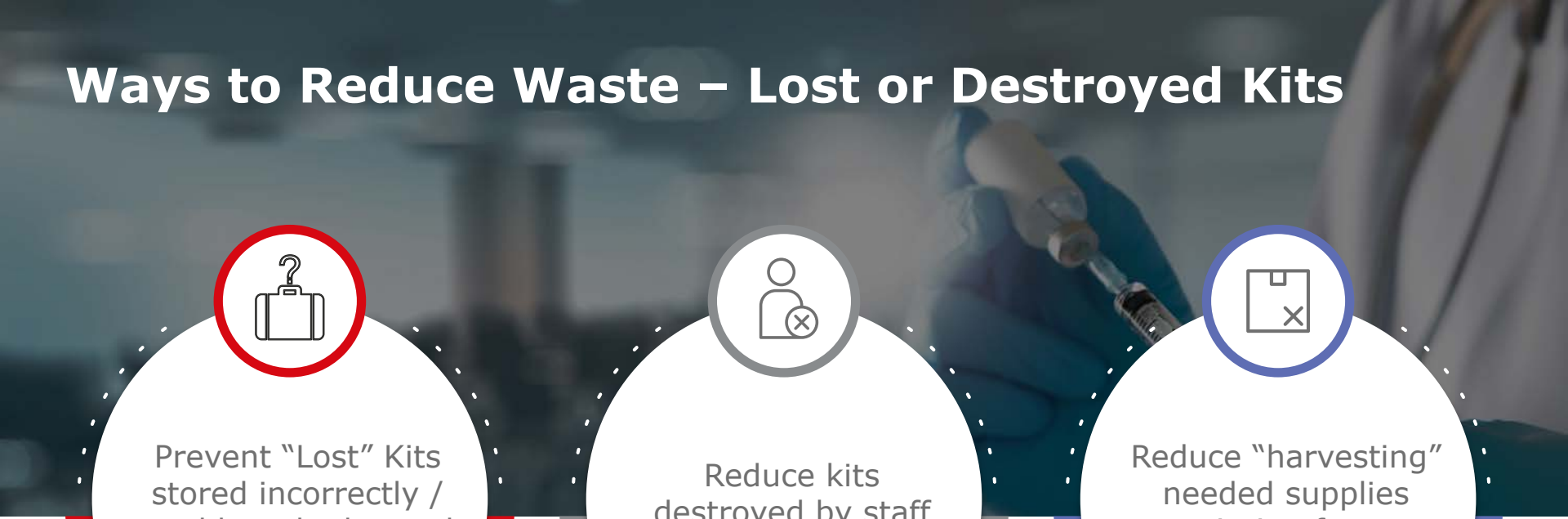
Labeling

Dry Ice/ Regulatory needs

Types of shippers

Verification of correct packaging

Ways to Reduce Waste – Lost or Destroyed Kits

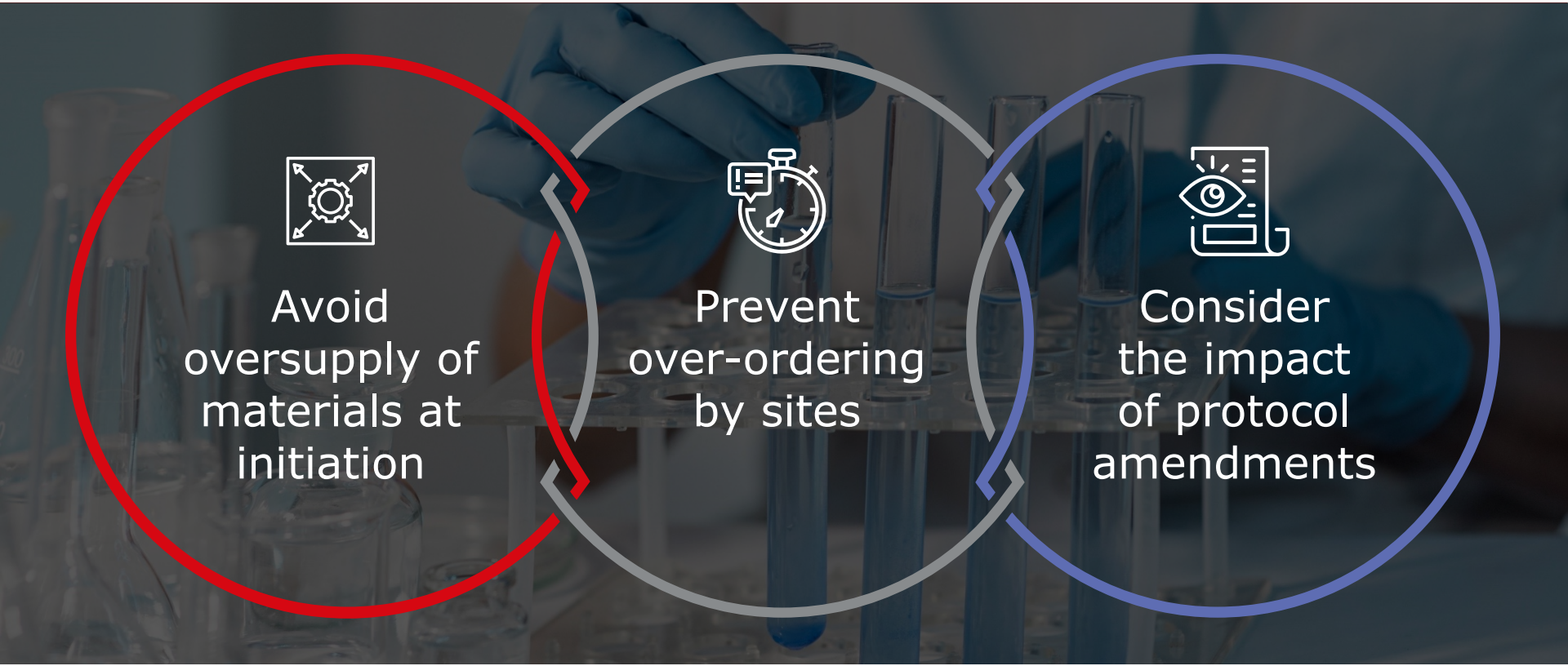


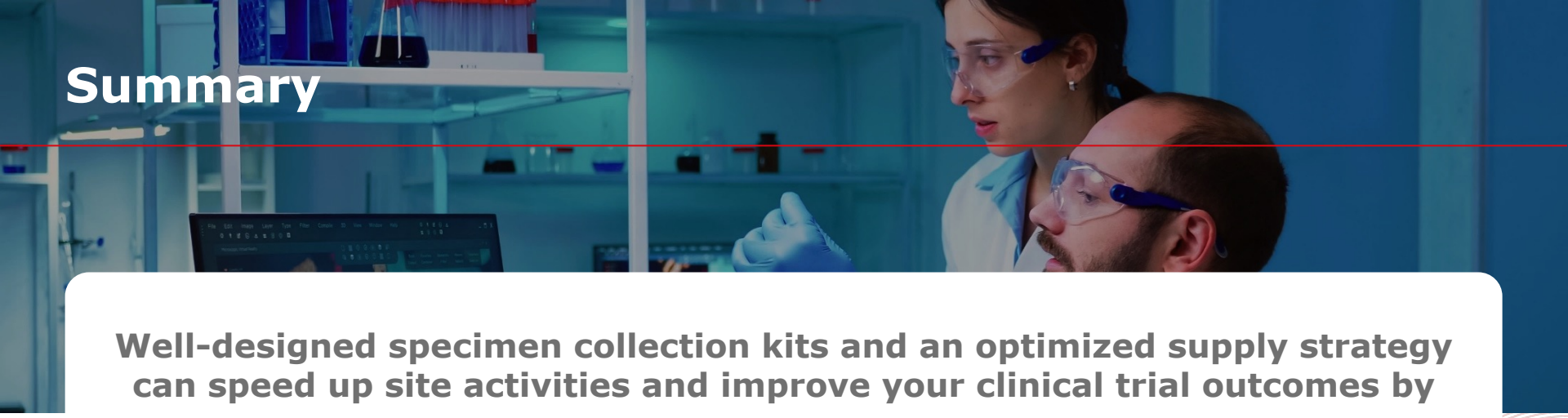
Prevent “Lost” Kits stored incorrectly / unable to be located at site

Reduce kits destroyed by staff due to incorrect use

Reduce “harvesting” needed supplies missing from another kit

Ways to reduce waste – Unused kits and materials





Summary

Well-designed specimen collection kits and an optimized supply strategy can speed up site activities and improve your clinical trial outcomes by

- Reducing time searching for lost or misplaced supplies
- Reducing time for sites to collect, process and ship samples
- Reducing time spent responding to queries and documenting protocol deviations
- Reducing repeated visits/sample collections due to nonviable or mislabeled specimens

Thank You!