



Leverage Bioanalysis Outsourcing Partnerships to Support Complex Clinical Trials

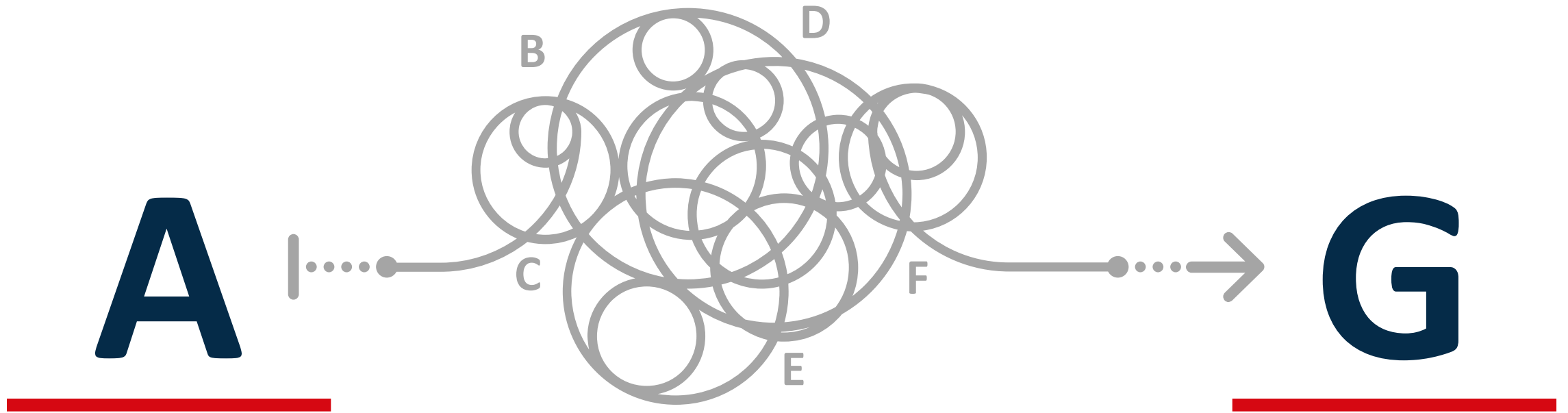
October 24, 2023



Clinical trials used to be simpler



But today's trials are a lot more complex



Lab challenges abound

Multiple ongoing
overlapping trials

Disparate data sources

Loss of data integrity

Increased trial **complexity**

Managing multiple
local labs



Stringent sample
maintenance requirements

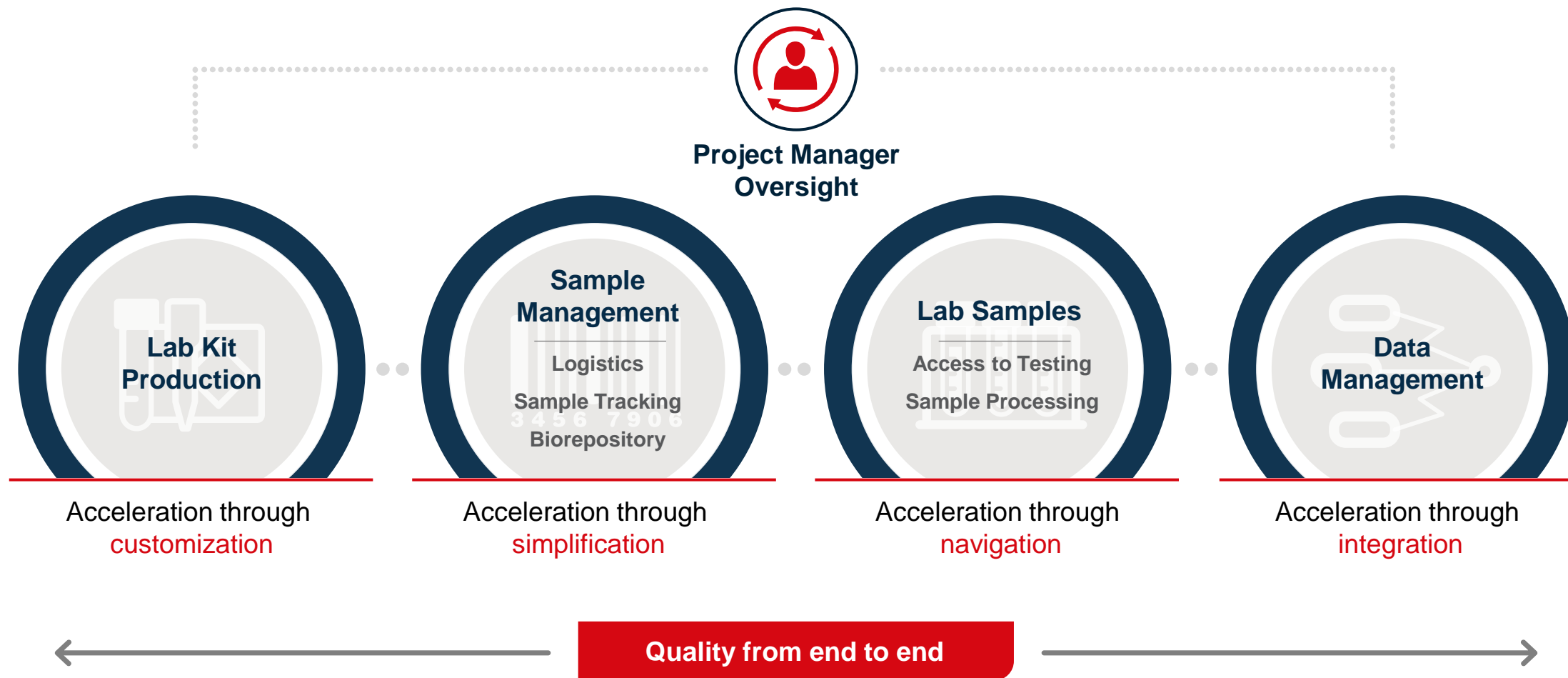
Missed samples

Small sample prep windows

Collection **errors**

Site **burden** and
strict timelines

LabConnect — Central Laboratory Services



A specialized touch for your more specialized needs



LabConnect Enhanced

<24 hours for status
—
Visit/sample forecasting
—
Missed-visit monitoring
—
Subject/sample details

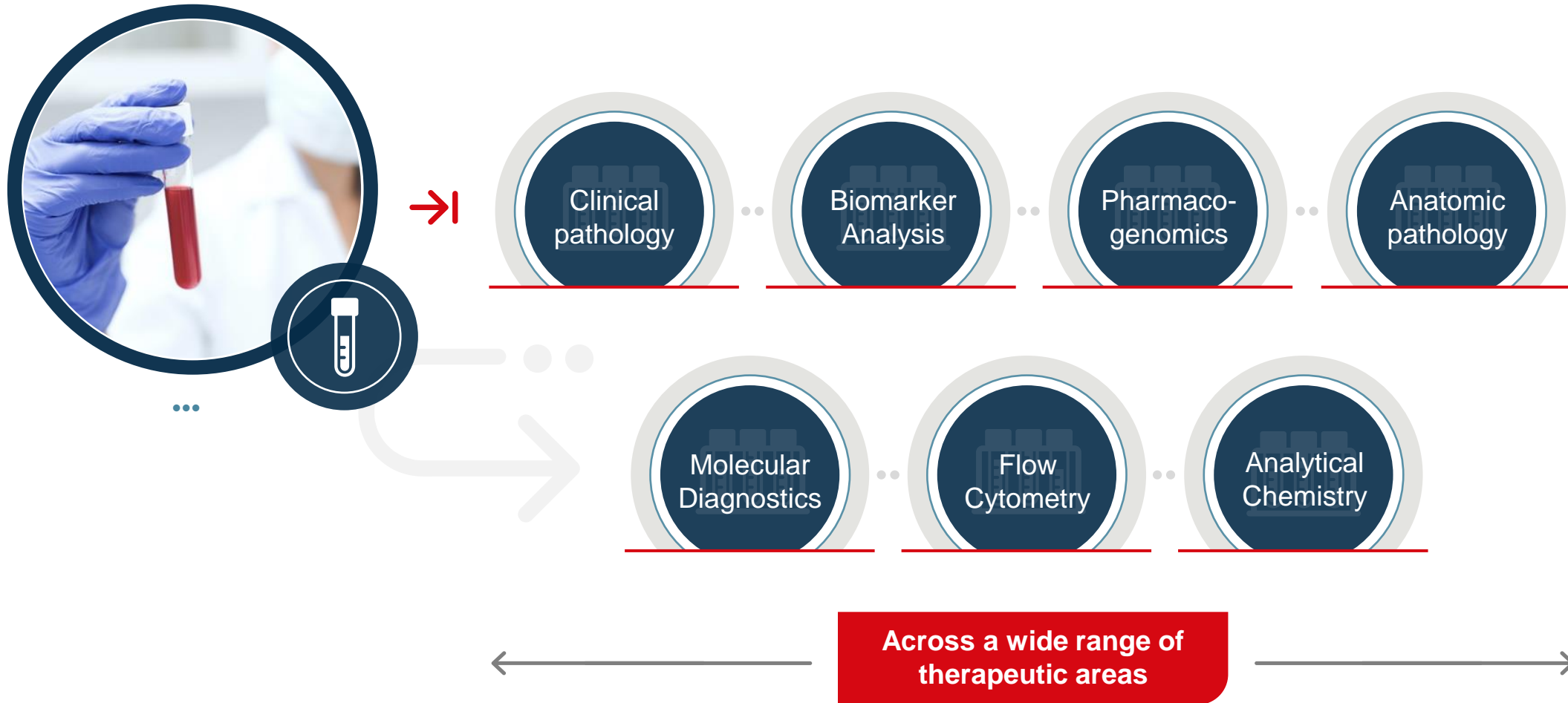
LabConnect Hyper-Tracking

1-2 hours for status
—
Visit scheduling support
—
Visit/sample forecasting
—
Live, real-time monitoring
—
Subject/sample details
—
For complex studies or
higher risk samples

...
..... **>85% compliance**
in getting day-of collection information
compared to 50% industry standard

← Support tools/technology include SampleGISTICS,
electronic accessioning, and more →

The world's #1 most comprehensive testing capabilities



Testing capabilities around the world

- **Five wholly owned operational facilities**, including Johnson City, TN and Cleveland, OH as well as locations in Germany and the Netherlands.

Strategic Alliances

 Cleveland Clinic  Labor Dr. Wisplinghoff

Additional global partners:

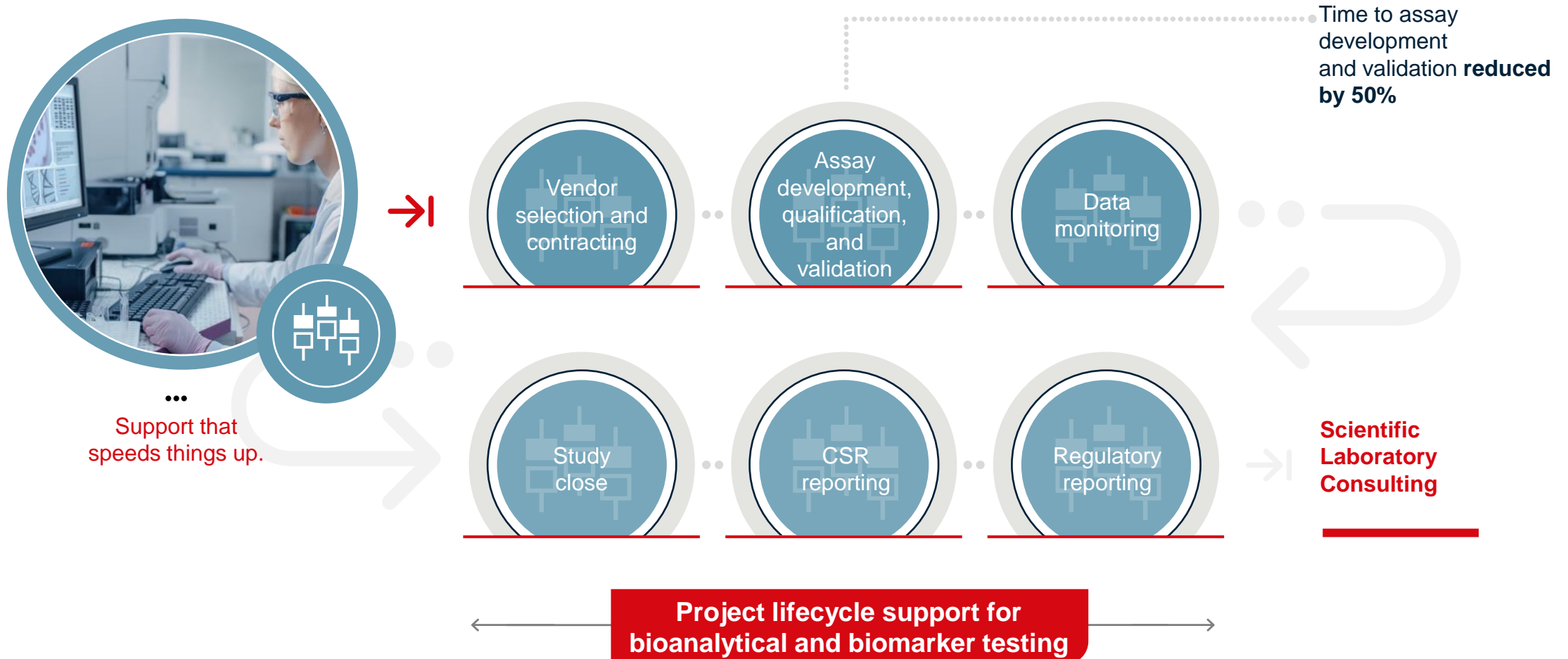
- Regional central lab support (kit building, distribution, regional site support, biorepository, etc.)
- Lab partners in logistically challenged parts of the world
- Lab partners with highly specialized analytical capabilities



LABCONNECT



Acceleration through **operation**



Sample Processing – DNA/RNA Isolation



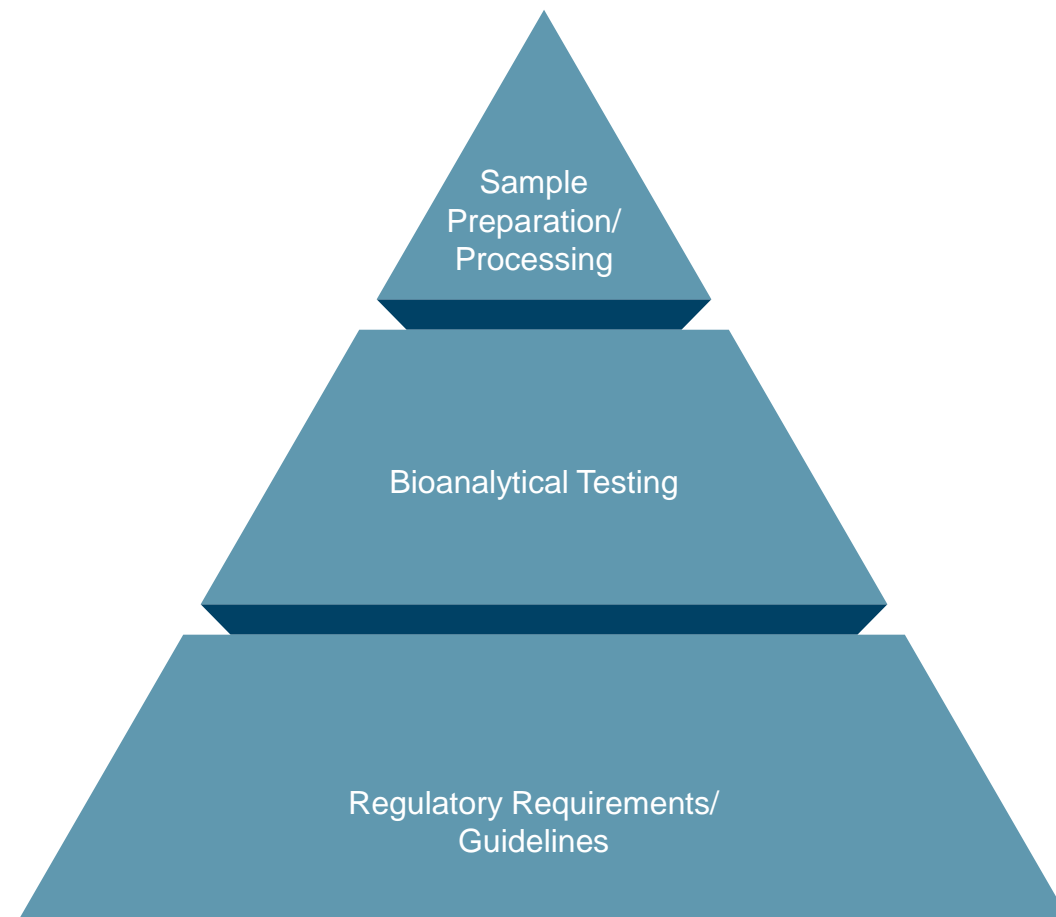
Issue:
Selecting DNA/RNA
isolation method
for downstream
molecular analyses

- Sample type and size
- Dual DNA/RNA extraction
- Isolation kit methodology
 - Solution-based/Column-based/
 - Bead-based
- Technician experience
- QC extracted nucleic acid
- Sample requirements for molecular testing
 - Input (amount and concentration)
 - DNA/RNA purity



Solution:
Scientific Oversight

- Plan approaches to molecular testing
- Selection of technologies and testing algorithms
 - Assay development
 - Assay qualification/validation
 - Sample stability
 - Regulatory requirements/guidance



Molecular Testing Technologies

Molecular Testing Technology	Applications	Benefits and Limitations
qPCR	<ul style="list-style-type: none"> • Gene expression analysis • Verification of NGS results • Copy number variation • Biodistribution 	<ul style="list-style-type: none"> • Known target sequences • Low number of targets • RT-qPCR • Less expensive/technically demanding • More tolerant of variable DNA quality • Requires normalization
ddPCR	<ul style="list-style-type: none"> • Low abundant target detection • SNP detection • Linkage analysis • Biodistribution 	<ul style="list-style-type: none"> • Known target sequences • No standards/references • Higher tolerance of inhibitors than qPCR • Absolute quantitation • Higher sensitivity and precision than qPCR
NGS	<ul style="list-style-type: none"> • Whole genome sequencing • Epigenetic factor analysis • RNA-seq to detect all cellular RNA and identify novel variants • Targeted transcriptome for most common mRNA 	<ul style="list-style-type: none"> • Known and unknown sequences • Many targets • RNA-Seq and targeted transcriptome • More expensive/technically demanding • Less tolerant of variable DNA quality

Flow Cytometry Challenges



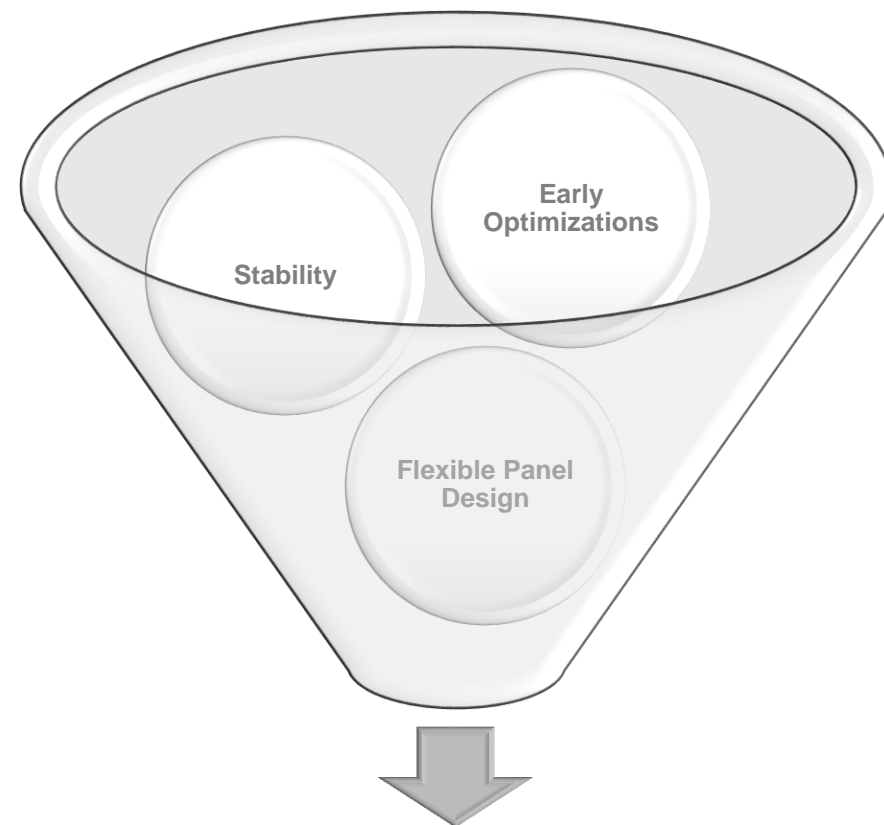
Issue: Complexity

- Vendor selection/contracting
- Method transfer
- Method development
- Method validation/qualification
- Vendor database configuration



Solution: Defined Strategy

- Identify patterns to evaluate cell subsets and ID biomarkers
- Early optimization/matrix assessments
- Early Stability Assessments
- Flexible core with additional marker groups
- Strategic placement of open channels i.e., PE to allow for quick panel customization & optimization



Acceleration through **communication**



Efficiencies

- Real-time sample status reduces time locating samples and reported data
- Enables early intervention
 - Proactively identify and address discrepancies, missing samples, and samples collected in error
- Automated statistics for streamlined tracking
- Eliminates need for clinical team to track samples

Complex Biomarker Plans & Sample Challenges



Issue: Complex Biomarker Plans

- Clinical sample analysis plans with many bioanalytical assessments
- Multiple testing laboratories (international)
- Components of single sample to undergo different analyses at multiple labs
- Sample requirements for downstream testing
 - Collection procedure
 - Transport conditions
 - Sample processing procedure



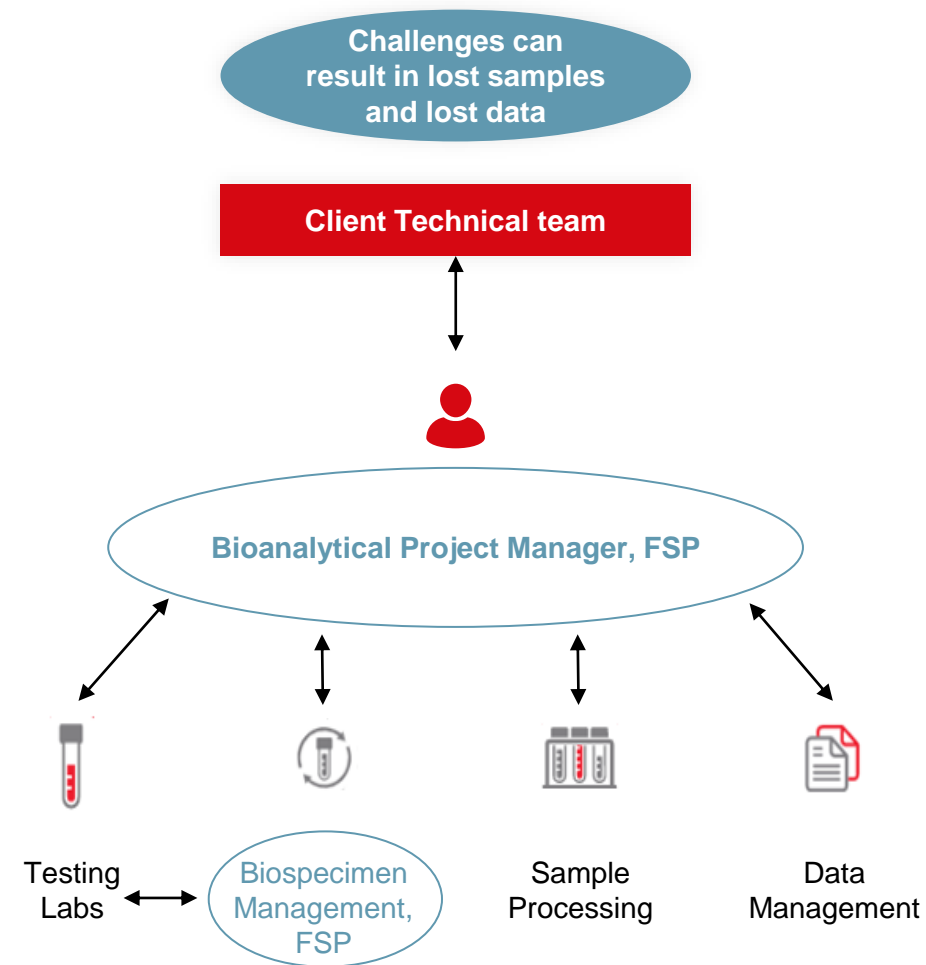
Issue: Global Clinical Sample Challenges

- Strained clinical site and testing lab resources
- International sample shipments
 - Delays at Customs
 - Sample stability
- Selecting sample processing methods
- Selecting downstream testing methods and technologies
- Maximizing data generated from samples collected



Solution: Scientific and Technical Expertise

- Study Director, Scientific Project Managers, Biospecimen Managers
- Plan, manage, and oversee specimen handling to mitigate risk of lost samples
- Specimen collection (tubes/stabilizers)
 - Sample transport conditions and logistics
 - Sample preparation and processing method
 - Coordinate analyses at testing laboratories



The world is our laboratory

20+

Years of global
clinical trial experience

1,570

Studies supported
(548 Global)

93

Countries supported
on 6 continents

50+

FDA drug
approvals supported

5000+

Laboratory
testing menu

>

More points of
service than any other
Central Lab

Clinical Trial Ecosystem



- BSM provides real-time oversight and tracking of:
 - Missed visits
 - Data Discrepancies
 - Missing Samples
- BSM creates and maintains consolidated specimen dashboards, with consistency across studies and programs



Partner labs



3rd-Party labs



Local labs



- Customized kits are created for the need of each collection, and come prelabelled, separated, and in sequence of draw.
- Access to past kit orders allows for management of kit inventory at each site

- Lab Vendor management team to advise selection of lab from LabConnect's comprehensive network of safety labs, specialty labs, and CROs or facilitate testing at Sponsor's preferred laboratories.
- BSM ensures timely shipment and assures proper labeling requirements are met for successful testing across laboratory portfolio



Standardized, normalized, and harmonized data from multiple data sources worldwide



Unified dataset to CRO/Sponsor

- LabConnect's Data Management teams provides standardized, normalized, and harmonized data from all laboratories
- Unified data set provided to Client/CRO at client-defined intervals
- BSM oversight reduces errors in data file and accelerates final data transfers during critical data milestones





Labs



Lives

Thank You!

