LABCORP CENTRAL LABORATORIES & INTERNATIONAL

Labcorp Central Laboratory Services Operating Manual

labcorp

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Labcorp Central Laboratory Services Operating Manual

We Are Your Source For Advancing Health ™

Thank you for choosing Labcorp Central Laboratory Services (Labcorp CLS) to be your clinical trial partner. We're your trusted and experienced partner in the industry. We have worked with >5,000 clinical studies with 1.6 million patients in 103 countries and deliver >2.2 million results yearly, covering all therapeutic areas. This experience and knowledge is used to provide you with consistent and efficient study design.

This operating manual provides a high-level overview of Labcorp CLS, the services that we offer; as well as information on other areas of the Labcorp family that may be involved in the management of your study. The intent is to provide you with a greater understanding regarding key personnel, services, milestones, timelines, and much more that you may experience during the life of your study. This reference document supplements the information that you will receive from your Labcorp CLS study team.

Choose a topic above to begin! We Welcome You!

Labcorp Overview & Your Study Team

Your study team is available to you…in pursuit of answers ™

Our Customer Promise

In the continuum of care, we push the boundaries of modern medicine through cutting-edge science and data insights with passionate people improving patient lives around the world. Each of us deserves to move forward filled with better information, greater knowledge, and more confidence.

We are your source for advancing health: powering clear, confident decisions.

Partners In Development
We will work with you in immersive collaboration alongside experts in science, regulatory and medicine to effectively and compliantly navigate your development journey.

Delivering With Urgency
We will work as a seamless extension of your team to achieve scale, speed and efficiency on your program by leveraging our global network capabilities that are powered by passion and delivered with urgency.

Data & Science For Tomorrow's Breakthroughs
We put patients at the center of everything we do, and together we will smartly develop your next breakthrough with world-class decision data, insights, and technology –purposeful, intelligent science designed for and inspired by patients.

BUSINESS UNIT OVERVIEW

Making Partnership Easy and Effective

We embrace everything that makes your company unique and work to make your job easier.

We will use our scientific and regulatory expertise, combined with advanced digital and data solutions, to disrupt the clinical trial paradigm and simplify our customers' partnership experience.

For drug development pioneers relentlessly progressing life-changing initiatives to the next phase, Labcorp is your science-driven laboratory partner. With a global network of laboratory solutions, unmatched patient data, and scientific expertise, we deliver the insights and clarity you need to confidently advance your programs, on time and with the foresight to anticipate and solve the challenges that inevitably arise. Our continuous investment in science, technology and lab operations provides you access to the latest innovations and actionable data at scale, so you can pursue answers for patients in need across the spectrum of therapeutic areas.

About Labcorp®
Labcorp (NYSE: LH) is a global leader of innovative and comprehensive laboratory services that helps doctors, hospitals, pharmaceutical companies, researchers and patients make clear and confident decisions. We provide insights and advance science to improve health and improve lives through our unparalleled diagnostics and drug development laboratory capabilities. The company's more than 60,000 employees serve clients in over 100 countries, worked on over 80% of the new drugs approved by the FDA in 2022 and performed more than 600 million tests for patients around the world.

Central Laboratory Services
BioAnalytical
Translational Biomarker Solutions (TBS)
Companion Diagnostics (CDx)

The world's largest laboratory and health diagnostics company

Unparalleled scale, breadth and quality in global lab testing

From standard testing to customized assays, you will receive globally consistent, actionable data to drive your studies forward - faster. Labcorp CLS generates more clinical trial data than any other central laboratory in the world.

- More than **97% OF DATA PACKAGES*** delivered on time
- Greater than **98% REPORTABLE TESTS***
- More than **98.4% KITS RECEIVED WITHIN STABILITY***

** Data from ~2022-2023*

Providing the most extensive array of clinical research laboratory services, while generating more than half of all clinical trial data worldwide. Anywhere that our clients need us, we're there. Across our global network of five central laboratory facilities, we employ the highest level of control to minimize variability and enhance data quality.

Each facility has aligned technology platforms and standard global operating procedures to provide clients with consistent and combinable data.

You will receive the most comprehensive menu of scalable solutions, covering the spectrum from large-scale clinical trials testing to custom assay development. Our experts can also support biomarker efforts and manage parallel companion diagnostic development from concept to the clinic. We also continue to develop new testing services to proactively address evolving needs.

- Core Laboratory Testing Services
- Partnering for Protocol Solutions
- Scientific Excellence
- Companion Diagnostics
- Central Labs Resources, Certificates and Accreditations
- Anatomic Pathology and Histology Services

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BUSINESS UNIT OVERVIEW | BIOANALYTICAL

Dedicated scientists armed with the latest technology

Our bioanalytical experts from discovery, nonclinical and clinical can help you anticipate regulatory challenges and offer strategic solutions to guide and enable your study team to make informed decisions faster.

- **THE #1 ranked*** bioanalysis services provider based on an industry survey
- Sample analysis capacity of **340,000*** samples per month
- More than **600 DEDICATED LABORATORY STAFF MEMBERS** and **465 ANALYTICAL INSTRUMENTS*** to support small and large molecule programs

** Data from ~2022-2023*

Drug development programs need regulatory approval to move on to the next milestone. Our scientists are not just familiar with the regulatory process; they are active contributors to key regulatory discussions.

With leadership roles in the Global Bioanalytical Consortium, our scientists participate to help shape today's changing regulatory environment. We have the regulatory expertise you need and can help you ask the right questions to keep your program on track. Specific knowledge of the latest bioanalytical platforms such as AB Sciex, Waters®, Hamilton Star®, Watson Plus™, Gyros™, BioPlex®, MSD and ELISA help inform a molecule's development as we partner with you to generate high-quality results.

Bioanalysis Lab Services for Every Stage of your Molecule Development
You will receive valuable insight and execution no matter when you partner with us along the drug development continuum. We combine strong scientific and regulatory knowledge with the latest technology platforms to drive a small or large molecule forward. The following analytical services are available to you:

- LC-MS and Immuno-Analytical Solutions
- Specialty LC-MS Support
- Discovery Bioanalysis
- Vaccine Analysis
- PK/TK Analysis and Reporting
- Validated Assays
- Organic Synthesis
- Bioanalysis Education Center

Central Laboratory Services
BioAnalytical
Translational Biomarker Solutions (TBS)
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BUSINESS UNIT OVERVIEW | TRANSLATIONAL BIOMARKER SOLUTIONS (TBS)

Advancement in technology to advance your discovery

TBS Immunoassay Capabilities:

- Ultrasensitive immunoassays
- Multiplexed immunoassays
- Biologics Biosimilarity
- Western blotting
- Low sample volume immunoassays
- Gyros immunoassay CD
- Kit based immunoassays
- Custom build immunoassays
- Assay Transfers

TBS is a leader in Auto-Chemistry and Hematology services within multiple species (e.g., human, rat, dog, mouse, rabbit, NHP).

- Hematology and Chemistry
- CBC/differential counts, reticulocyte counts, microscopic morphologic evaluation
- Serum-based assays, urine chemistry assays
- Coagulation Assays
- Standard (APTT, PT, etc.)
- Clotting factor assays
- Intrinsic and extrinsic pathway screening
- Body Fluid Analysis (Cytology)
- Cytospin preparations
- Microscopic examination
- Blood Gas Analysis
- pO2, pCO2, pH, Na, K, Ionized Ca, Cl, Hb, MetHb
- Automated Immunoassays
- Insulin, Bone ALP, Cardiac Troponin I, Myoglobin…

TBS Cell & Flow Cytometry Based Assays

- In Vivo Pharmacology /Tox studies/Global Clinical Trials
- Exploratory Biomarker Work at TBS

Central Laboratory Services
BioAnalytical
Translational Biomarker Solutions (TBS)
Companion Diagnostics (CDx)

Services from Development to Commercialization.

With CDx experience co-development

- Bench to commercialization expertise Rx / CDx co-development:
- Development, validation, testing, regulatory support, and commercialization
- Leaders in both in vitro diagnostic (IVD) and Single Lab PMA approaches
- Experience with 400+ IVD and medical device studies
- Supported more than 75% of all FDA approved companion diagnostics – including recent approvals for HER2, KRAS, EGRF, BRAF, ALK and PD-L1
    - PD-L1 assays for all major anti PD-1 and anti-PD-L1 therapies
    - First liquid biopsy application for EGFR TKI

- Dedicated Lab and staff for ***development, validation and transfer*** of CDx assays
    - Focus on Genomics and Molecular Pathology
    - Associated GMP manufacturing lab

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RESPONSIBILITIES AND COMMUNICATION

Focused on bringing you the power of the combined

Throughout the duration of a study, often multiple parties are involved in managing various aspects. Here is an illustration of each role.

Note: A study specific Client Information List (CIL; previous Communication Plan) will be provided to you, which will document the key contacts on both your side and Labcorp CLS side. This document also details issue management and the escalation processes.

Global Study Manager (GSM) - ***Primary contact point for you***
Acts as primary liaison between you and Labcorp. Ensures that laboratory services are set-up according to your expectations and acted upon. Holds overall responsibility for a study at Labcorp CLS, including study setup and budget management. Manages day-to-day protocol-related activities from setup to closure of the clinical trial. The GSM should be notified first of any concerns that may arise over the course of your study.

Study Design Lead (SDL)
Responsible for the Statement of Work (SOW) and database design for study setup and amendments, which contains the details for services that Labcorp CLS will perform based on your study protocol. Works with the sponsor study team during study setup and amendments and collaborates internally across departments as necessary for feasibility and specific study design matters.

Regional Study Coordinator (RSC)
Provides regional operational support. Manages day-to-day local study activities (e.g., coordination of start-up shipments, logistics import matters, site/CRA information updates, site kit orders) and acts as appointed liaison locally between Labcorp CLS and your study representatives.

RESPONSIBILITIES AND COMMUNICATION

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Global Monitor (GM)
Provides Personalized Study Performance Management (PSPM) monitoring services for study activities based on both standard or customized thresholds and can design customized monitoring solutions as applicable.

Data Manager (DM)
Responsible for defining the format in which data will be transferred and then for executing the transfer of Study Data Files. Works directly with your Clinical Data Management Team.

Data Analyst (DA)
Manages the overall process of resolving discrepant data between you (Sponsor/CRO/Investigator) and our database and takes the appropriate action to update our database if needed. Works closely with the Labcorp Data Manager (DM) and your Clinical Data Management team.

RESPONSIBILITIES AND COMMUNICATION

Focused on bringing you the power of the combined

Throughout the duration of a study, often multiple parties are involved in managing various aspects. Here is an illustration of each role.

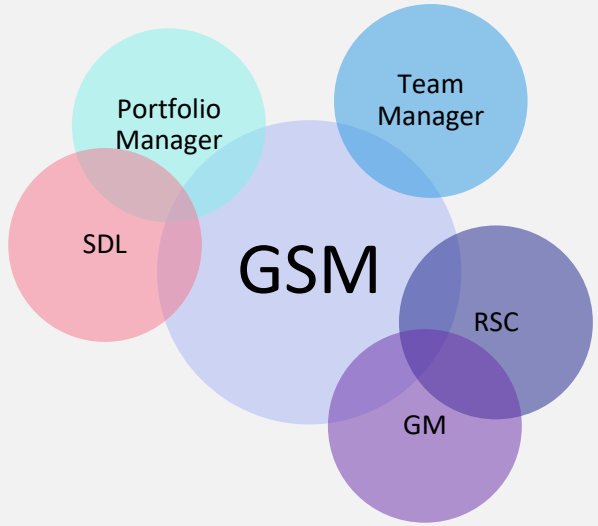
Note: A study specific Client Information List (CIL; previous Communication Plan) will be provided to you, which will document the key contacts on both your side and Labcorp CLS side. This document also details issue management and the escalation processes.

Desktop Publishing (DP)
Responsible for the Investigator Laboratory Manual, Requisitions, Specimen Collection Guides, and any applicable translations.

Global Team Manager (GTM)
Responsible for the performance of our Project Management team members working on study protocols. The Global Team Managers should be contacted when the escalation is related to performance of Project Management team members.

ESCALATION PLAN

A Direct Connection To What Matters



Labcorp CLS has assembled a team with solid experience in clinical trials to ensure that studies run smoothly and are brought to closure on time and on target.

We place a high priority on delivering high-quality service. Your Labcorp CLS study team will closely monitor the delivery of services to ensure that quality is maintained. As a general rule, service delivery issues should initially be addressed with the Global Study Manager before escalation.

However, issues may be handled in several different ways depending on their nature and urgency. Located with your study specific Client Information List (CIL), your study team will share the escalation pathway with you to ensure the communication lines are clearly defined should a need arise. In the event that an escalation relates to personnel performance, please escalate directly at the Team Manager level. We also invite you to use the Escalation Plan to communicate feedback, whether positive or negative.

LABORATORY & OFFICE LOCATIONS

Leverage the expertise, capabilities, and global infrastructure

Note: Refer to your Investigator Laboratory Manual for specific sample shipment details.

Labcorp Central Laboratory Services LP

8211 SciCor Drive
Indianapolis, IN
46214-2985 USA
Tel +1 317 271 1200
Fax +1 317 273 4030

Labcorp Corporation of America Holdings

19750 South Vermont Avenue,
Suite 200
Torrance, CA
90502 USA
Tel +1 310 689 0640
Fax +1 310 689 3418
This is also referred to as the "Los Angeles (LA) Laboratory".

Labcorp Laboratories Japan GK

Harumi Triton Square Office
Tower Y 8F
1-8-11, Harumi, Chuo-ku,
Tokyo 104-6108 Japan
Tel +81-3-6837-9532
Fax +81-3-6220-3667
This is the corporate office address.

CB Lab c/o BML General Laboratory

1361-1 Matoba, Kawagoe-shi
Saitama 350-1101, Japan
Japan Toll Free 0120 123 905
Direct Line +81 3 6837 9536
Fax +81 3 5250 0360
This is the laboratory address normally on the laboratory manual.

Labcorp Central Laboratory Services S.À.R.L.

Rue Moïse-Marcinhes 7
CH - 1217 Meyrin/Genève
Switzerland
Tel +41 58 822 7901
Fax +41 58 822 7521

Labcorp Development (Asia) Pte. Ltd.

1, International Business Park
#02-13 The Synergy
Singapore 609917
Tel +65 6560 8793
Fax +65 6565 5901

Labcorp Pharmaceutical Research and Development (Shanghai) Co., Ltd.

Building 9, No.338 Jialilue Road,
Zhangjiang Hi-Tech Park,
Shanghai 201203, China
Tel: +86 (0) 21 6192 5800
Organization Code of Laboratory or Parent Entity 69582083-X.

RACI INFORMATION

Bringing you innovation, excellence, and maximizing resources.

Responsible **Accountable** **Consulted** **Informed**

		Labcorp CLS	You
Project Start-Up	Provide Study Documentation (e.g., Protocol, Timelines)	C	RA
	Prepare draft Statement of Work	RA	C
	Ad-hoc meetings to review documents	R	C
	Weekly / Bi-weekly meeting	R	I
	Data Management Meetings	R	C
Reports and Alerts	Define the content of laboratory reports to the site	A	R
	Define Blinding Rules (If needed)	A	R
	Provide result reports to sites (e.g., The Portals)	RA	C
Material Preparation and Supply	Prepare labels and requisition forms	RA	C
	Prepare visit kits	RA	I
	Prepare Laboratory Manuals for Sites	RA	I
	Define needs for instructions in local languages	RA	I
	Anticipate custom requirements	R	I
	Provide additional material to sites (as needed)	RA	I
	Anticipate the management of kit expiry dates and needs for resupply	RA	I
	Manage kit expiry dates during the course of the study	ACI	R
	Manage resupply during the course of the study	ACI	R

RACI INFORMATION

Bringing you innovation, excellence, and maximizing resources.

Responsible **Accountable** **Consulted** **Informed**

		Labcorp CLS	You
Sample Management	Organize a back-up solution for sampling if a site is unable to perform blood draw	RA	I
	Propose couriers to transport samples	RA	I
	Propose frequency of shipment and pick-up days	RA	I
	Provide pre-paid airway bills to sites	RA	I
	Manage samples at receipt (e.g., processing, cancellations, shipments)	RA	I
	Ensure long-term storage for applicable samples	RA	C
	Prepare and follow-up on sample destruction documentation	RA	I
	Process requisition forms and queries	RA	I
Data Management	Ensure data security	RA	I
	Set-up process for data validation	RA	I
	Perform data checks and validation	RA	I
	Maintain database with study results	RA	I
	Set-up and perform data transfers	RAC	
	Approve test transfers	A	R
	Manage needs for data changes	RA	C

Study Process

Advancing you through the entire development continuum.

The overall high-level flow of Labcorp CLS processes with the key milestones in the study lifecycle.

NEW PROTOCOL = NEW SOW = SIGNATURE
PROTOCOL AMENDMENT = AMENDED SOW = SIGNATURE

*SOW Signature** (This is a critical milestone for new study setups and amendments to complete before progressing forward.)*

Initiation	Planning	Execution	Monitoring & Control	Closure
Initial Client Call	Budget	Kit Production & Shipping	Pending Test Monitoring	Final Kit Received
Contract Initiated	Protocol Review & SOW / Database Development	First Kit Received	Customized Based on Study Needs	Final Data Lock
	SOW Signature**	Testing & Reporting		Account Reconciliation
		Interim Data Lock		

Your Global Study Manager (GSM) will ask you to provide the main timelines for your study. This includes the necessary Protocol Finalization Date, Kit Delivery Dates (KDD), Site Initiation Visit (SIV), and First Patient First Visit (FPFV) for the initial starting site per geographical region.

Your GSM will in return be able to provide you with a Timeline for Study Startup document describing the targeted time frames and dates for the Labcorp CLS Statement of Work (SOW) and Database Development and Kit Delivery milestones for your study. These milestones will be discussed and agreed upon at the study kick-off meeting.

Throughout the life of the study, your GSM will also review standard agenda items with you, such as:

- Budget / Contract Activity
- Milestone Status
- Risk Management
- Supply Activity

Study Process

Advancing you through the entire development continuum.

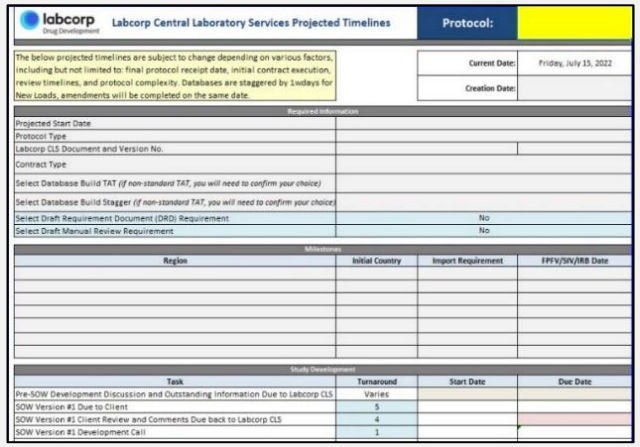
** Dependent upon client*
*** 98% of database designs are accommodated within 10 days. Under standard timelines, each subsequent regional database release will be staggered by 1 business day. A minimum staggered timeline of 3 business days can be accommodated if necessary. If you wish for Labcorp CLS to participate at the Investigator Meeting (Presentation provided or Trainer at the meeting), please advise your Global Study Manager as soon as the location/date/time of the meeting is confirmed. It is recommended to have the presentation prepared after the SOW has been finalized.*

Change of Scope
Please note that timelines to complete an amendment are highly variable depending on the scope of changes. Your GSM will work with you to assess the specific study timelines**. When an amendment to the SOW is requested, the steps below occur to complete the modification:

Update the Statement of Work
- Ensure needed internal reviews have occurred
- Ensure sponsor has reviewed and approved changes
- Sponsor must sign the revised SOW*

Update Budget
- If the amendment has a budget impact, a revised budget will be requested.

Database Modification
- Upon SOW signature or Change Order/Updated PO receipt*, the database modification will be requested


labcorp Drug Development — Labcorp Central Laboratory Services Projected Timelines — Protocol:

The below projected timelines are subject to change depending on various factors, including but not limited to: final protocol receipt date, initial contract execution, review timelines, and protocol complexity. Databases are staggered by 1wdays for New Loads, amendments will be completed on the same date.

Current Date: Friday, July 15, 2022
Creation Date:

Required Information

Projected Start Date	
Protocol Type	
Labcorp CLS Document and Version No.	
Contract Type	
Select Database Build TAT *(if non-standard TAT, you will need to confirm your choice)*	
Select Database Build Stagger *(if non-standard TAT, you will need to confirm your choice)*	
Select Draft Requirement Document (DRD) Requirement	No
Select Draft Manual Review Requirement	No

Milestones

Region	Initial Country	Import Requirement	FPFV/SIV/IRB Date

Study Development

Task	Turnaround	Start Date	Due Date
Pre-SOW Development Discussion and Outstanding Information Due to Labcorp CLS	Varies		
SOW Version #1 Due to Client	5		
SOW Version #1 Client Review and Comments Due back to Labcorp CLS	4		
SOW Version #1 Development Call	1		

PHASE: SET-UP OVERVIEW

Creating Value Through Collaboration

Advancing you through the entire development continuum.

Connected Insights

Begin with a tailored strategy and the right solutions

Difference between a Scope of Work (SOW) and Statement of Work (SOW)

Scope of Work
The Scope of Work is a very detailed and non-protocol specific description of all the services expected from Labcorp CLS as well as from your team during a study. The scope of work is included in the Request for Proposal (RFP) document when applicable. Confirmation of timelines will occur, including a buffer.

Statement of Work
The Statement of Work is a description of your protocol specific services that will be provided by Labcorp CLS and is designed based on your final study protocol. Below are changes/reasons a budget could increase from the initial Request for Proposal (RFP) to the first signed SOW:

- Study design and duration
- Analytic methodology
- Primary, secondary and tertiary city locations
- Number of locations and sites
- Specimen Management services
- Sample storage period
- Number and level of kits
- Number of patients and distribution between regions
- Number of visits
- Shipment frequencies

Statement of Work
Specialty Testing & Services
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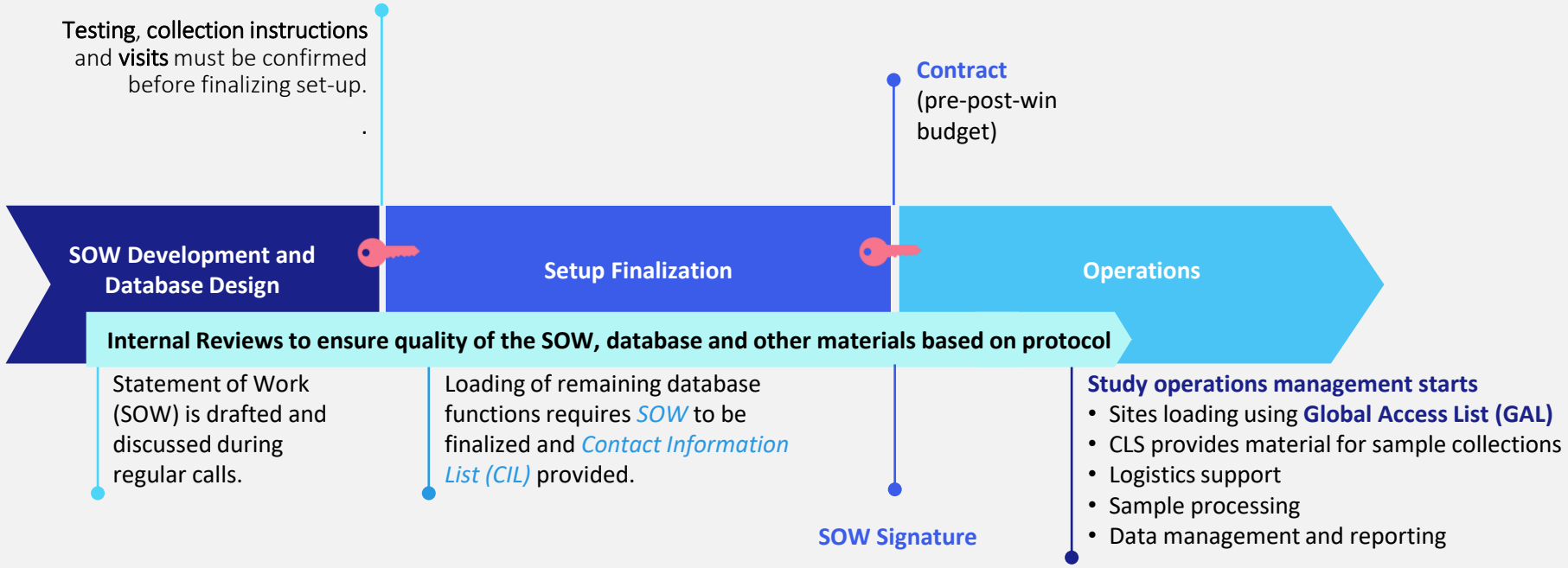
PHASE: SET-UP OVERVIEW | STATEMENT OF WORK

General Process Flow for New Study Setups and Amendments



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PHASE: SET-UP OVERVIEW | STATEMENT OF WORK

Data Blinding

The purpose of blinding results at the Labcorp CLS level is to prevent result recipients from determining which treatment a patient is receiving. Blinding avoids any result from:

- Appearing on laboratory reports.
- Appearing in LabLink and/or Labcorp Sponsor & Investigator Portals. (Online portals that you'll obtain access to)
- Being transferred to your study team.

The blinding of results in our database follows the definition in the Statement of Work. The Labcorp CLS Data Manager also uses this data transfer blinding definition to generate data for your study team. *Blinding should be clearly defined during study set up and who should be blinded: Labcorp CLS, study team, investigators, CRA or data transfer.*

- Define if specimen management samples (i.e., not tested by Labcorp CLS) should be blinded within laboratory reports and/or within any of the online portals (e.g., if a site is shipping back a sample or not may be considered as a blinded information).
- The blinding definition is very technical and must be fully aligned with protocol definition:
  - All the tests to be blinded must be listed.
  - Any exceptions listed must continue to be in agreement with the protocol.
  - The blinding of unscheduled visits must be in agreement with the protocol, especially if the blinding starts after a time event and not only after a specific visit (e.g., after randomization).

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Lab Abnormality Kits

Unfortunately, Adverse Events can occur, but we can prepare with the use of a "lab abnormality follow up" kits, which will be designed in alignment with the study protocol needs:

- Neutropenia
- Thrombocytopenia
- Increase in ALT
- Acute Renal Failure
- Rhabdomyolysis

PHASE: SET-UP OVERVIEW | SPECIALTY TESTING & SERVICES

There are numerous types of specialty testing and services that Labcorp can provide for your study. Here is a bit for information about just a few of them. Click on each of them to learning more.

Anatomic Pathology and Histology (APH) Raw and Source Data Services

Human Genetics Resource Administration of China (HGRAC)

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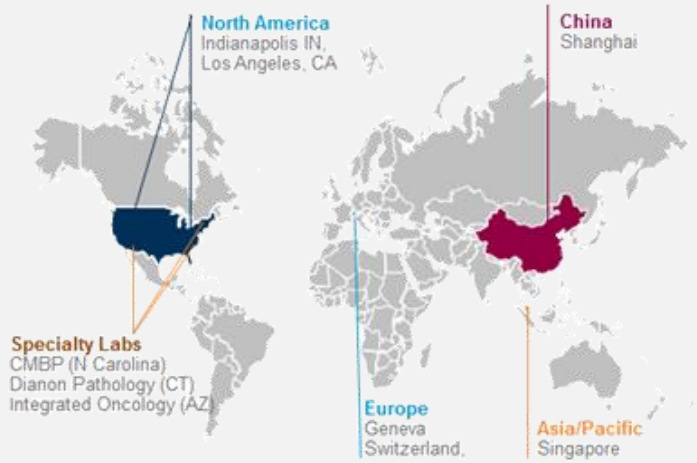
PHASE: SET-UP OVERVIEW | SPECIALTY TESTING & SERVICES

Anatomic Pathology and Histology Raw and Source Data Services

From handling of wet tissue biopsies, paraffin blocks or unstained tissue sections, anatomic pathology laboratory teams follow robust processes and a variety of techniques using the same platforms across the global network of labs to assure consistent data.



Whether it is simple, or complex, APH, we have numerous services.

The following samples types are considered APH…

- Tissue Blocks (Wet Tissue or Embedded), Stained Slides, Unstained Slides, Wet Tissue, Bone Marrow Aspirate Smears, Bone Marrow Core Biopsy, Fine Needle Aspiration Biopsy

And the testing and services that we offer include…

- Simple Types of APH
  - Gross Description / Tissue Processing / Embedding / Re-Embedding, Microtomy / Sectioning, Paraffin Dipping, Image Scanning, Slide and Block Labelling
- Complex Types of APH
  - Central Pathology Read, PDL-1, Staining, Target Lesion Confirmation/Macrodissection, Immuno / Histo / Chemistry (IHC), FISH Analysis

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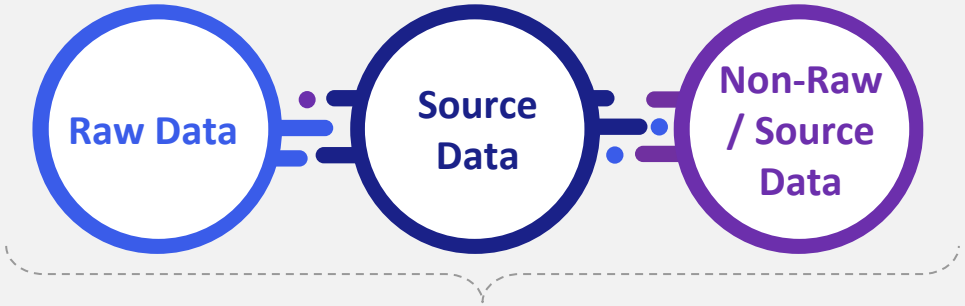
PHASE: SET-UP OVERVIEW | SPECIALTY TESTING & SERVICES

Anatomic Pathology and Histology Raw and Source Data Services



The originating point of subsequent data that requires further measure of interpretation or evaluation to produce a meaningful result.

Example: A tissue block that is sectioned into subsequent slides.

Data able to be used to provide information for diagnostic purposes in the clinical trial for the individual reviewing the specimen at hand.

Example: Stained H&E slides: The slides are evaluated and interpreted upon pathologist review. The information produced from the H&E slides is recorded in a pathology report. Both the stained slide and the pathology report are needed to produce a meaningful result (data).

Sample types that do not undergo any type of processing, staining, analysis, or sectioning at Labcorp.

Example: A FFPE Tissue Block processed by the site, received & stored as a SM sample, and then shipped to a third-party lab for analysis.

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PHASE: SET-UP OVERVIEW | SPECIALTY TESTING & SERVICES

Anatomic Pathology and Histology Raw and Source Data Services

Retention Requirements

- Retention periods can vary significantly depending on factors such as specimen type, nature of the analysis, regulatory requirements and originating countries.
    - Your Global Study Manager and Regional Study Coordinators are ready to provide the most current timelines. Please reach out to them to understand the specific details tailored to your study.
- If a raw or source data shipment is required, you must have a slide custody agreement or slide transfer agreement in place before releasing the sample.
    - We always ensure that any agreement is thoroughly reviewed by Labcorp QA, Legal and Medical Affairs before it's presented to your team.
- The retention period is an important piece of running a successful clinical trial. In the event an inspection or audit occurs the responsible lab must be able to provision the source from which the data output occurred.

Slide Agreements

There are two types of agreements for tissue sample shipment:

Slide Custody Agreement	Slide Transfer Agreement
For sample(s) that will not be out of Labcorp's possession for more than one year. The custody agreement may receive up to three extension requests but must not exceed the one-year return period.	Must be requested when a sponsor or site requires an indefinite return period for samples.

Responsibilities

Action	Responsible
Maintaining the sample(s) once they are released into their custody.	The party whose custody the sample(s) are released into.
Designate a signee for the agreement.	Client, as dictated by their internal practices and policies. Labcorp does not make that determination on your behalf.
Return of the sample requested for audit or inspection purposes once the request is received from Labcorp.	The party whose custody the sample(s) are released into.

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Human Genetics Resource Administration of China (HGRAC)

Helping you ensure that study operations stay in high compliance with global regulations.

In order to facilitate you with your HGRAC application and ensure the accuracy and integrity of information submitted for your study, we would ask that your study team provide the draft HGRAC application form to your Global Study Manager (GSM) *for review and verification prior to the action of electronic submission*. Your Regional Study Coordinator (RSC) will coordinate a range of tasks related to the application – and if you're able to immediately provide the scheme for the HGRAC application, it will streamline the process.

- *Note: The signature of Labcorp and Labcorp related labs and cooperators will only be provided after the Labcorp CLS RSC has reviewed and confirmed that all Labcorp related information listed in the HGRAC application form is complete and correct based on the signed study contract or service agreement.*

Reminders

- Provide Labcorp CLS with the HGRAC approval letter and approved HGRAC form *after each submission* for documentation purpose as per HGRAC requirements.
- Use the Sample Receipt Report or Specimen Management Report available in LabLink+ to monitor samples sent to Labcorp CLS and ensure the quantity does not exceed the approval scope.
- If data and/or sample(s) are to be destructed at *any point after* study closure according to HGRAC regulations requirement and HGRAC approval (e.g., data/sample to be destructed 5 years after the IP on the Market), notify your Labcorp CLS GSM/RSC.

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PHASE: SET-UP OVERVIEW | SPECIALTY TESTING & SERVICES

Human Genetics Resource Administration of China (HGRAC)

Long Term Storage (LTS) Policy
Process Prior to 2021

- Samples held at the Labcorp CLS during the study and remain at Labcorp Biorepository after the study close.
    - Recommendations for LTS (unless otherwise specified in protocol)
        - *Biofluids (serum/plasma) for Biomarker Future Use = 5 years*
        - *Genetic material (DNA/RNA) = 15 years (current up to Q4 2021)*
- LTS pre-paid at study end for the total samples identified
- PR & PO under Labcorp agreement

Long Term Storage (LTS) Policy
Process 2021 to Current

- Samples kept at Labcorp CLS during the in-life portion of the study and sent to a centralized vendor after the study close (e.g., Azenta).
- Recommendations for LTS should be standard as stated in Informed Consent Form (ICF)
    - *"Up to 15 years" - New Revised ICF contains 25 years retention*
    - *Genetic material (DNA/RNA) = not differentiated from other sample types (serum/plasma/biomarker)*
- LTS not paid-up front, but shipment costs to be considered in Labcorp CLS budget
- Identification of location can be decided on a case-by-case basis, e.g., significant sample storage for a program is already in place, team may not want to move the samples to Azenta.
- Location for storage to be included in the Labcorp CLS Statement of Work:
    - *if origin is Asia-Pac -> Azenta - Indianapolis, Indiana USA*
    - *If origin is USA/Canada/Mexico/South America -> Azenta - Indianapolis, Indiana USA*
    - *If origin is EMEA -> Azenta - Griesheim, Germany*
    - *If origin is China -> Azenta - Beijing, China*

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PHASE: SET-UP OVERVIEW | BUDGET

Initial Contract Signature Workflow Process

Collaborative Efforts for Budget Management

- Working together with you, budget assumptions and study design will be discussed as early as possible to clarify any item that might impact the budget.
- Internally, we use historical data and sister study knowledge to provide robust budgets and reduce variance between RFP and 1st SOW budget.
- We also work with your Clinical team to optimize study design to limit budget changes and work on efficiencies (e.g., identify sites that may be less expensive in terms of transportation).
- Labcorp CLS provides the budget management during the study:
- MONTHLY - Grant Budget Variance Report (eGBV)
  - Compares actual activity with budget estimate
  - Track progress of activity and billings
- QUARTERLY - Budget Review
  - Assesses if a special budget review is required based on specific criteria.
  - If a review is required, a meeting is organized. Based on the eGBV, decisions / actions are agreed upon for items that are over or under budget.
  - Review and decisions are included in the ADI Log and meeting notes.

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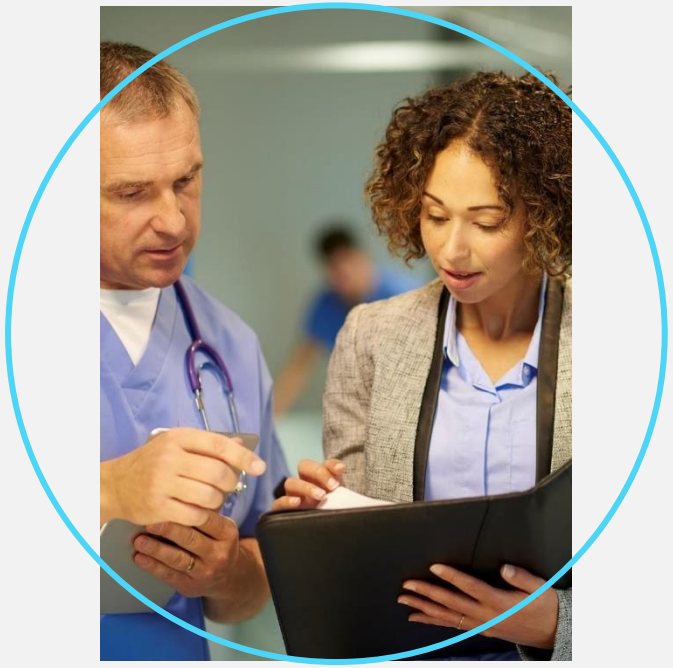
Note: Refer to the "Budget Management" section for additional details.

PHASE: SET-UP OVERVIEW | INVESTIGATOR MANUAL



Based on the Statement of Work design and information, regionally-based Investigator Laboratory Manuals will be created for your study. This document will contain all the needed information for your investigator sites as they work with Labcorp CLS, such as: collection instructions, packaging and shipping information, visit kit reordering information, copies of the requisitions, etc.

- *Note: Study-specific pages are client-customizable; but the standard pages are not.*

The document will be provided electronically to you, within The Portals, in English, but it can also be translated into a few different languages. The Specimen Collection Guides are provided in hardcopy, as well as, being uploaded within The Portals.

All revised versions/translations will be electronically shared with your study team, as they are uploaded automatically in The Portals for site awareness. Translations for the manual are typically available approximately 10 business days after the English version is available.

If you need early access to laboratory information, you might need an ILS or a DRD. Click to the next page for additional information.

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PHASE: SET-UP OVERVIEW | INVESTIGATOR MANUAL

		ILS	DRD
Purpose	Study Conduct		
	Site Effort Determination	✓	✓
	Site Budgetary / Contract Use	✓	✓
	IRB / EC Submission		✓
Timing	Upon Contract Award	✓	
	Upon Statement of Work Signature		✓
Content	Visit Test Schedule (VTS)	✓	✓
	Collection Instructions	✓	✓
	Unscheduled Kit Definition		✓
	Laboratory Certification	✓	✓
	Medical Director CV		✓

ONLY the official, version-controlled Investigator Laboratory Manual may be used for study conduct.

**Please note additional costs will be applied to create these documents.*

Investigator Laboratory Summary (ILS)*

ILS provides a preliminary overview of the VTS, collection supplies / instructions, and laboratory certifications. It can aid in gauging Investigator Site efforts, contracting Investigator Sites, or for your internal reviews. But unfortunately, it cannot be used for regulatory submissions, nor study conduct.

An ILS can be created as early as contract signature, if the following is available: the final protocol is needed with a visit schedule, any applicable blood volumes or collection instructions are required, and Labcorp CLS will require a signature on the ILS indicating acknowledgement of this.

Draft Requirements Document (DRD)*

DRD provides an overview of the VTS, collection supplies / instructions, laboratory certifications, unscheduled kit definitions, and the Medical Director CVs. It can aid in gauging Investigator Site efforts, contracting Investigator Sites, for your internal reviews, or for IRB / EC submissions. But unfortunately, it cannot be used for study conduct.

A DRD can be created after the Statement of Work signature, if the following is available: the final protocol is needed with a visit schedule and any applicable blood volumes or collection instructions are required.

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PHASE: SET-UP OVERVIEW | BEST PRACTICES & LESSON LEARNED

In collaboration with you, we regularly create Best Practices and/or Lessons Learned where applicable.

Kit Delivery Date (KDD)
- If a fast start-up process is required for Labcorp CLS services development (faster than the standard timelines needed by Labcorp CLS), additional fees are applied.

Additional Supplies and Expedited Shipments
- Expedited Shipment and resupply of additional supplies are billable.

Duration of Project for Labcorp CLS
- Study duration impacts budget if storage of samples is needed.

Training Service
- Direct impact on budget

Visit Test Schedule
- Number of visits as well as testing performed in a study has a direct impact on budget. Percentage of Optional or Reflex is an estimation that is used to generate the study budget, but actuals are what is invoiced.

Site and Patient Distribution
- Number of countries, business units, sites primary vs secondary vs tertiary) and visits impact the budget.

Analyte Page
- New group, new test, new requirements (e.g., methodology, specimen type, shipping condition, shipment frequency) impact the budget. Also review the assumptions like shipment efficiencies.

Testing That Requires a Special Turn Around Time
- Expedited testing might impact study budget. Additional fees: Testing fee includes testing and expedited fees.

Additional Testing
- Additional testing fees are included in the database modification fee if a modification of the requisition design is required.

Special Requests for Requisitions and Investigator Manuals
- Costs could be incurred with modifications to customized investigator manuals or if more than 1 hardcopy is provided for additional recipients.

Baggy Kits
- Impacts kit level

Additional Notes for Database Design
- The item or service provided might impact budget.

Sample Transportation Requirements
- Selection of Courier, pass through or direct shipment

Sample Transportation Exceptions
- Direct impact to budget

Calculations
- Lab calculations (except for a short list) and Sponsor requested calculations are billable and charged at the accession level.

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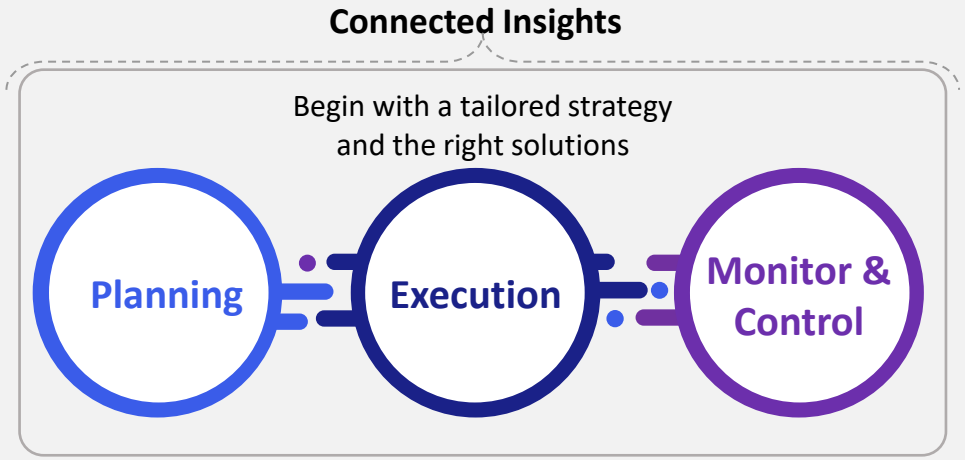
PHASE: STUDY CONDUCT OVERVIEW

Seamless Implementation

Advancing you through the entire development continuum.

The Study Conduct Phase involves a few different steps, click on each of them to learn more



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PHASE: STUDY CONDUCT OVERVIEW | MONITORING

Monitoring risk to ensure a successful trial activity is important to you, so it's important to us. We take risk mitigation seriously and have tools in place to help identify, monitor and mitigate potential risks throughout the life of your study.

Enable custom trial transparency with Personalized Study Performance Management (PSPM) *(Service fees may apply)*

Cancellations Reporting

The goal is to show the trends, define recurrent cancellations root causes, take corrective actions and offer insights to your sites, CRA and local teams for follow up.

If data is blinded, discussions must occur for alternate solutions

Kit Usage Report

The goal is to show the number of kits shipped vs. received vs. expected for each kit/visit type and provide recommendations to mitigate any kit wastage.

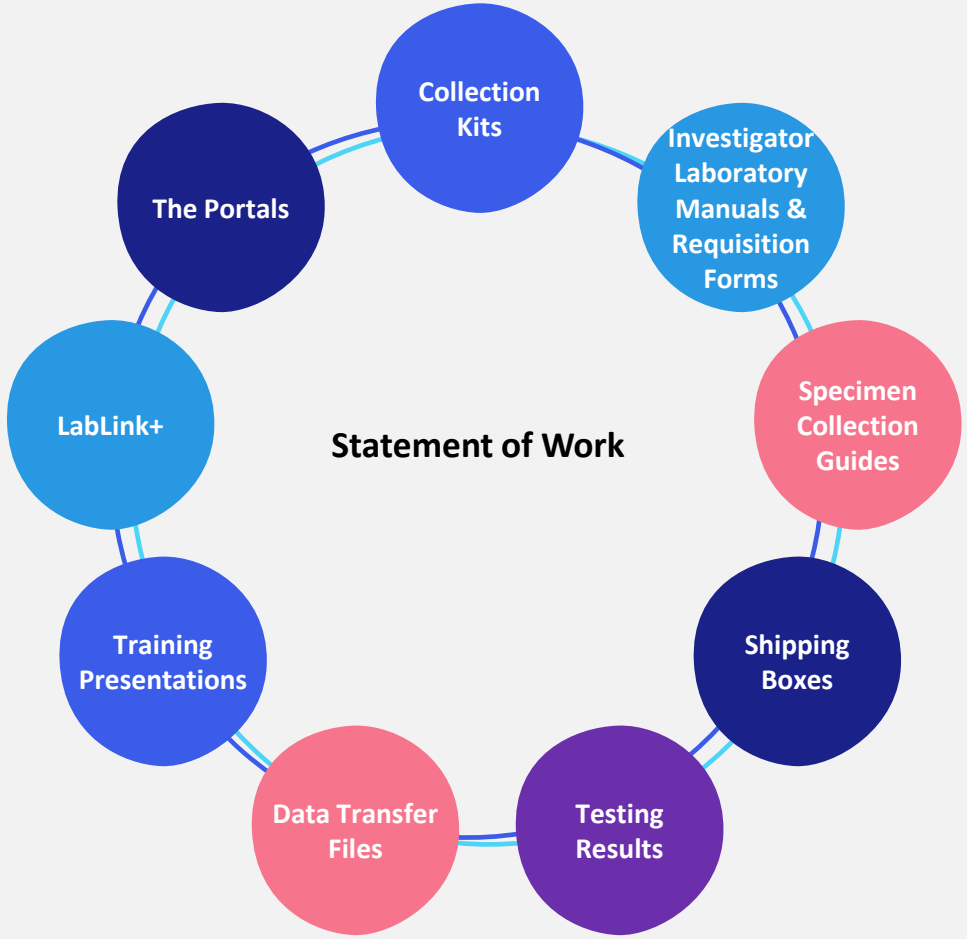
Sites with a high kit wastage are highlighted so that you can follow up with them on the root cause and implement corrective actions.

Missing Specimen Management Samples

The goal is to provide a list of missing samples per Specimen Management collection.

PHASE: STUDY CONDUCT OVERVIEW | SYSTEMS / DELIVERABLES

Your Labcorp CLS study team has a variety of study deliverables based upon the activities noted in your study. Some of the common deliverables are as follows:



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PHASE: STUDY CONDUCT OVERVIEW | KIT MANAGEMENT

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PHASE: STUDY CONDUCT OVERVIEW | KIT MANAGEMENT

Each of our kits is specific to you, your protocol, your investigator and your visit.

For tracking purposes, a unique bar code, otherwise known as an accession number, is assigned to each kit, its contents, tubes and requisition forms. Therefore, one accession number corresponds to a single specific patient-visit. Each kit is also given an expiration date, which must be checked before the kit is used by the site.

We are not able to report results for specimens collected in expired containers. We also ***do not*** track kit expiration dates and expired kits should be reported back to us by the investigator site so adjustments to the site's inventory levels can be made. Furthermore, kit expiration information is available in LabLink+ and The Portals.

Kits and Accession Numbers

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PHASE: STUDY CONDUCT OVERVIEW | KIT MANAGEMENT

Guidelines for Kit Inventory Management

The Kit Inventory Management guidelines are designed to reduce kit wastage at your investigator sites.

- **Study Setup**
  Some factors (e.g., kit level unit prices and quantity billed based on study design) may influence the study budget. Below are some points to consider while setting up or modifying your study design.

- **Kit Levels** are calculated based on the number of items in each kit and their impact on the study budget.
  Note: Customizing a kit with "baggies" can increase the Kit Level to a 4 or 5.

- **Visit Definition**
  How kits are used at a visit, whether required, optional or unscheduled.

- **Site and Subject Distribution**
  When discussing the subject and site numbers, it is important to consider the estimated screen failure and enrollment rates. This information is a key factor to define the correct start-up content for sites and to limit kit wastage or extra kit ordering.

- **Protocol Amendments Impacting Kit Content**
  For database updates related to a protocol amendment, it is important to review with your GSM/SDL how any changes impact the kit contents. This ensures implementation of a suitable solution that minimizes both site confusion and the number of discarded kits.

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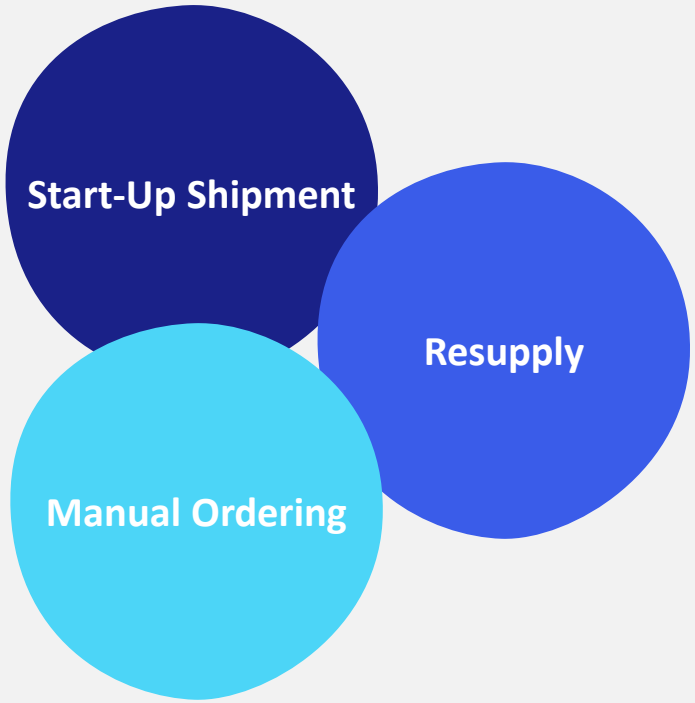
Click on each area to learn more.



Material Supply: Definition and Recommendations

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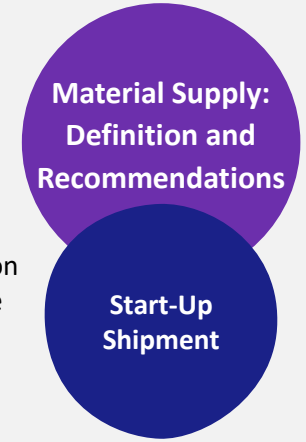

Start-Up Shipment
This is sent to the investigator/affiliates (in some countries) upon sponsor request and can even be sent prior to the first visit, if needed for SIV. The start-up package includes visit-specific lab kits, bulk supplies, an Investigator Manual, Specimen Collection Guide (optional), airway-bills and commercial invoices and shipping boxes when applicable based on the sites location. These supplies are meant to cover a site's anticipated needs for the first 3 to 4 weeks of the study. Site information is loaded into Labcorp CLS' system based off of the Global Access List (GAL) Template. Refer to Other > Quick Links for more details.

Start-Up Package Content

- To reduce kit wastage, the content of the start-up package can be customized based on your estimated enrollment rate per site or per country.

Import/Export License Requirements

- In countries such as Russia and the Ukraine, and regions such as Latin America and Asia-Pacific, we recommend that your study team orders a higher number of kits to cover the first few months of your study. This step helps avoid repeated customs clearance activities for the local affiliates and sites where the kits are actually delivered. Though there is also a risk of kits becoming expired without being used if a high number of kits are ordered in advance. Some import licenses could limit the number of kits shipped through customs. We highly advise that you work closely with the local affiliates to ensure the ordered quantity matches the figures listed in the license and avoids custom clearance issues.

Start-Up Supply Delivery: Site Initiation Visit (SIV) versus First Subject Visit (FSV)

- During study setup, it is important to clarify whether you need kits delivered in time for SIV or FSV. In addition to SIV or FSV, investigator meetings can also require kits to be delivered. ***If SIV is scheduled more than two weeks prior to FSV, we do not recommend ordering a full start-up supply. This minimizes the impact on kit shelf-life***. We suggest you order a limited number of kits or we can provide a "demo" kit (standard kit with mock documentation or study demo kit). ***If we are shipping in time for FSV, the recommended delivery time frame is about five days prior to the visit. For either the SIV or FSV option, you must determine the logistics for triggering all start-up shipments.***
- We do not recommend having a study with countries having Import License/request for approval in place to start first in the clinical trial, due to custom clearing time and internal shipment time.

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Resupply
For most countries, kit resupply can be sent automatically. The following are the two automatic processes:

- Min-Max Resupply
  - Used for the first visit (screening), unscheduled visits (such as retest and early withdrawal) and optional visits (not required but time-linked visits).
  - ***Number of kits at each site is pre-defined during setup based on planned subject numbers throughout the study***. When site inventory for a specific kit drops below the minimum pre-defined quantity, the system triggers a resupply of kits to replenish the site with the maximum value.

Note: Site inventory is determined either by kits being returned or if we are advised to adjust the numbers based on expired kits.

Automatic Resupply for Required Visits
This process triggers the exact amount of kits needed for a specific patient after receipt of the first required visit. Each time the system receives a patient scheduled visit, it looks ahead five to nine weeks to determine what other kits are needed within that time frame. If needed, a kit order is triggered automatically.

The project is set to have kits triggered 21 days (34 for Japan Kit Production) in advance of a patient visit: this indicates the number of days preceding the patient's visit (including Saturdays and Sundays) kits should be ordered to be received at site approximately 7 days in advance.

This can also be customized. This is to help control expiring of kits and to help with storage problems at sites. If a scheduled visit is not received at Labcorp CLS 42 days after it is expected - per the patient delivery schedule - our system will put that patient's delivery schedule on hold.

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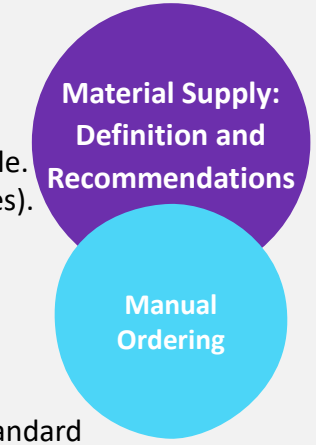

Manual Ordering

The investigator or you may also place an order directly with us, even if the automatic ordering process is available. Manual orders are the only method for ordering bulk items (e.g., Urine Pregnancy Kits, airway bills, shipping boxes). Orders can be placed via our website [Click Here; (preferred)], phone, or via The Portals.

If a member of your study team manually places an order via phone, ***we recommend that they check the site inventory status first via LabLink+ to avoid ordering in duplicate with the automatic resupply***.

To limit the amount of expedited fees for shipment or production when you place an order, please consult the standard delivery timelines available on the resupply website. Additionally, we can advise you about the standard delivery timelines when an order needs to be placed.

In countries that require import/export licenses, automatic resupply is not available. Manual orders must be made in these areas as the start-up package is non-standard and customized with the help of the Regional Study Coordinator (RSC) assigned to your study. We recommend that you consolidate re-ordering kits needed for all the sites and place one order that will avoid several customs clearance processes.

It is important to review the definition of kit resupply when your study reaches any important milestone. This will help you assess whether you need to increase, decrease or even disable kits which are no longer needed. Additionally, we recommend that you review transportation costs in order to limit site resupply requests which may increase the global budget.

Note: Shipping timelines are dependent on country and local regulatory needs. For country specific resupply timelines, refer to our website listed above.

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Expired Kits

Our Automatic Resupply system ***does not*** monitor expired kits. For the system to work properly, you or your sites must notify us via phone, web order or fax each time a kit is discarded, so that inventory can be adjusted.

Kit inventory, as well as expired kit listing, can be reviewed within LabLink+ or within The Portals.

We recommend that your study monitors review the requests made by sites to ensure they are not over-ordering and that sites use their kits following the First-In/First-Out concept.

For orders placed via phone, our Site Support Team will verify that there is a real need, to help limit kit over-ordering.

It is possible to disable the resupply for a specific visit/kit if it has been completed for all patients at a specific site. We recommend you apply this option when a study reaches a critical milestone.

We will work with you throughout the life of your study to help ensure that you are fully optimizing the kits for your study.

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Kit Wastage Control Best Practices

Kit Wastage Control Best Practices
Special attention must be spent at the beginning of the study. Most of the kit wastage typically happens during the enrollment period.

The start-up supplies should cover site needs for the first 3 to 4 weeks of the study.

Clarify whether the site needs kits delivered in time for SIV or FPV.

Once confirmed that a site is a high, medium or low recruiter, inform your Global Study Manager or Regional Study Coordinator so automatic resupply levels can be adjusted.

Always keep us informed of site enrollment statuses.

Before placing a manual order, check the kit inventory at the site, and update Labcorp on any expired / damaged kits. Consolidate orders whenever possible.

Manual ordering in excess is a high contributor to kit wastage. It is recommended for you to have periodic checks to ensure sites are not ordering in excess.

For countries that do not have automatic resupply like Russia, Ukraine, Latin America and Asia-Pacific: initially order enough kits to cover 4-5 months of the study.

Be careful not to overestimate the number of kits needed.

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Specimen Management FAQ

Who should I address my ad-Hoc shipment request to?

Sample shipment requests should be made to all Regional Study Coordinators (RSC).

- These shipments can be sent to a defined location listed in the SOW or to a different one/not listed in the SOW.
- If the address is not listed in the SOW, it might take longer as Labcorp CLS needs to create the SM class (could take up to 48 hours). No SOW amendment is needed, however if more than one shipment is expected, it is recommended to amend the SOW and database accordingly.

For urgent requests, please make sure the Global Study Manager is on copy in addition to the RSCs. Please be aware that the cut-off time for processing ad-hoc shipment requests is 12:00 PM (noon) at the regional SM Location. After that time, the email is processed the next business day.

What is the process for pass through shipments?

Pass through shipments are shipped to/between the regional Labcorp CLS facilities prior to be shipped onto the specific Referral/Third Party Lab. Pass through shipments are not consolidated by default, unless this is documented in the SOW or requested for ad-hoc shipments. The lab might receive several packages.

How can we ship our samples to the Referral/Third Party Lab?

Most of the shipments pass through via another SM Location for cost efficiency, as Labcorp CLS already has samples being shipped across the different platforms.

- If the referral lab wants one package, Labcorp CLS can consolidate the shipment on the SM Location within the same region as the Referral/Third Party Lab.
- If multiple specimen classes (e.g., one PK class per time point) must be shipped and packaged together, this should be specified in the SM section of the SOW.
- In case of urgent shipments, Labcorp CLS can organize direct shipment to the Referral/Third Party Lab without passing through.

What is the process for consolidated shipments?

If we take for example a consolidation shipment in Geneva, all the other SM Locations prepare their samples, based on the standard timelines, and ship to Geneva. Upon receipt of samples, Geneva samples are added, and one consolidated shipment is made to the Referral/Third Party Lab. Each SM Location must be given sufficient time to prepare samples before shipping to the consolidating site so this may add additional TAT relative to a standard pass-through shipment. The electronic packing lists (EPL) per platform are sent by the consolidating platform once they ship to the Referral/Third Party Lab.

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Specimen Management FAQ

What happens if samples are received at Labcorp CLS in the incorrect condition? (i.e., Temperature)

Upon receipt at Labcorp CLS, Specimen Management (SM) samples will be inspected and registered into the system. Unless specified otherwise in the Statement of Work the below standard procedure will apply:

- If sample received at higher temperature (e.g. ambient instead of refrigerated/frozen): SM will change condition upon receipt to preserve sample stability and move to an IC (Incorrect Condition) Specimen Class.
- If sample received at lower temperature (e.g. frozen instead of refrigerated/ambient): SM will not change condition upon receipt and will store in an IC (Incorrect Condition) Specimen Class.

Note: These classifications are viewable within LabLink+.

Can I track required frozen samples where testing is blinded or there is no laboratory report going back to site?

Discuss with your Global Study Manager options to receive a Sample Pending Arrival Report (SPAR).

- The report is auto-generated on the third business day of the month and goes ***only to*** *the designated Report Recipient at the Investigator Site*. Monitors and other study personnel can monitor sample receipt using the LabLink Sample Receipt Report.
- *If the SPAR is initiated mid study, only visits received after report initiation will show missing containers on the report*.
- Each expected but unreceived container on the day of the report generation will appear if the requisition has been received and the container falls into one of the following categories: *Elapsed time from collection date is 15 to 30 days; Elapsed time from collection date is greater than 30 days; Container has been autocanceled (greater than 62 days)*
- In the absence of a collection date, the requisition receipt date will be used to track elapsed time.
- Depending on the interval between collection and the report date, it is possible that a container may appear on only two reports; it will not appear on more than three monthly reports unless it was canceled and then the cancellation removed.
- Only cancellations that occur through the autocancel routine will appear on the report as cancellations. Manually canceled containers will not appear on the report.
- Optional containers will only appear on the report if there are storage or testing groups ordered on the containers. Orders may occur due to site request (on requisition) or due to database changes for a variety of reasons.
- Site use of incorrect visit kits or reassignment of visits may result in additional containers and/or expected containers not received. Added containers will not always have label lines or label lines may match the original visit and not the reassigned visit.
- If a cancellation is removed from a container, it will appear on the report once again, if not received before subsequent cancellation.
- Back-up containers retained at the site may appear on the report despite instructions for the site to retain for a specific period before shipping. Care with the initial design of the studies can prevent this, if desired.

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Specimen Management FAQ

What should be done if the total TAT from sample collection until delivery at referral laboratory exceeds sample stability?

In case ***sample stability*** requires it, Labcorp can investigate the possibility of direct shipment from Investigator Sites to referral laboratories. It is important to note that these types of shipments are usually more expensive and allow for less visibility/traceability of samples, as these will not be registered within the Labcorp CLS database. If traceability is important, a premium courier service may be used to ensure appropriate sponsor contacts are copied on shipment confirmation notifications. Of course, premium courier use will further increase the budget.

PHASE: STUDY CONDUCT OVERVIEW | LOGISTICS

Logistics

Courier Arrangements

Courier, dry ice information and contact details are clearly provided in the Investigator Manual, except in EMEA, where courier information is provided electronically. Courier vendors may vary depending on the country and site location. We produce and ship collection kits specific to a study after the database is completed. All collection kits are produced at our facilities in Indianapolis, Indiana (USA) and Mechelen, Belgium. The kits are shipped globally to participating investigator sites. Except for China and Japan, due to importation requirements and to meet client needs, kits are produced for each country individually within China at our facility in Suzhou New District and within Japan at the BML Kawagoe City facility unless mentioned otherwise.

Dry Ice Capabilities in the European Union, Switzerland, UK, Norway, and Iceland

In clinical trials, quality data begins with consistent sample collection. Dry ice is a vital component of clinical trial studies whenever the samples need to be shipped to the central lab in a frozen condition to ensure the stability and preservation of the sample. Instead of relying on a third-party vendor to create and deliver dry ice to your investigator sites our European Operations Center (EOC) in Mechelen, Belgium, can accommodate your dry ice needs.

Holidays

When scheduling patient visits, and prior to shipping samples, investigator sites should pay particular attention to the local country holidays. These dates are provided in the Investigator Manual and our Site Communications sends quarterly email reminders to all active sites. Investigator sites should not ship samples the day before a holiday. If a pick-up needs to be done on a bank holiday day, this is done using a Premium courier, which will impact the study budget. If transit time is 48 hours, allow more than 2 days for shipping. Our Investigator Services staff can be contacted by sites and Sponsors during public holidays. Contact information and listing of global holidays can be found [Click Here].

Import and Export Licenses

Either you or a designated Importer/CRO that you specify must obtain the necessary import/export licenses required by a given country. However, we can assist by providing the needed expertise as well as a set of demo shipping documents specific to the study (Proforma invoice and packing list) required by specific countries for the purpose of importing kits.

Kit Import and Global Logistics in China

Labcorp CLS Shanghai is responsible for importing kits to China.
Labcorp CLS Shanghai takes care of the customs clearance and final delivery to sites.

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Ad-Hoc Sample Shipment Process

How quickly can Labcorp CLS turn around an ad-hoc shipment request?

This depends on the availability of the samples that need to be shipped along with the number of samples requested to be shipped. Typically, Labcorp CLS cannot ship samples the same day they are received. The earliest is next available shipment when the courier can be booked.

- *Note: Ad-hoc shipments being sent to a country that is not defined in the Statement of Work will incur additional fees.*

Sample Preparation and Shipment Timelines

As a general guide, the standard sample preparation turnaround times (TAT) depend on the quantity of samples to prepare. TAT applies for one SM class and destination. If several shipments are required, TAT for each shipment starts once the previous shipment for the same SM class and destination has been completed.

Timelines need to be confirmed with the Labcorp CLS team, especially for samples requiring the application of mini-labels as these are applied at the time samples are prepared for shipment. Sorting of samples does not impact TAT but removing it may allow to gain time. Specimen Management package and shipping timelines are completely dependent on the number of samples being shipped (ranging from 2-10+ business days).

Please take into consideration TAT is defined in business days, no preparation or shipment is done on public holidays. Once a shipment is initiated, no sample can be added to a shipping list and/or package. If shipment is required, a separate shipment request must be submitted.

Expedited sample preparation and retrieval fees for up to 200 samples per day apply (2.25 USD/3.30 CHF per container or per contracted agreement). Premium couriers can also be used, however extra costs apply depending on the shipment definition (e.g., destination, condition, weight) and Labcorp CLS needs to be informed 48 hours in advance.

Datalock or Critical Ad-Hoc Shipment Requests

Check with your Global Study Manager in case of critical shipments and data locks:

- Expedited sample preparation and retrieval fee might apply.
- Consolidated shipments can be bypassed for direct to the Referral/Third Party Lab as Labcorp CLS can save 2-3 days in the transit time.
- We can also use premium couriers, however extra costs apply depending on the shipment definition (e.g., destination, condition, weight) and Labcorp CLS needs to be informed 48+ hours in advance.
- If your referral lab is open on Saturdays, Labcorp CLS can arrange a delivery with a premium courier.

PHASE: STUDY CONDUCT OVERVIEW | SCHEDULED SAMPLE SHIPMENTS

Scheduled Sample Shipments

What is the timing for monthly shipments?
If specified in the SOW, the monthly shipment is shipped on the specified day (e.g., first Tuesday of the month). If the SOW does not specify any day of the month, shipments are scheduled to be shipped on a monthly basis once the first sample for any given specimen class is received. Following shipments are not scheduled any earlier than 29-30 days from the last shipment date. Shipments may be shifted between 1 and 3 business days depending on workload and shipping instructions to Referral/Third Party Lab (e.g., only ship Mondays to Wednesdays).

Shipments may be cancelled upon request if not needed. Please make sure the Global Study Manager is on copy in addition to RSCs.

Shipment of primary vs. back-up samples?
How can I be sure that primary samples are shipped according to the specified schedule and back-up samples are stored until the end of the study? This should be specified in the SM section of the SOW (i.e., different shipping frequencies for each aliquot). Labcorp CLS creates 2 different specimen classes in order to differentiate primary vs. back-up samples.

How do ad-hoc shipment requests affect the regular shipment schedule?
Ad-hoc shipment requests are processed alongside the regular shipment schedule. If a selected group of samples is requested to ship (but not all available samples), a “SP” Specimen Class is used for the ad-hoc request. Ad-hoc shipment is organized in addition to the normal shipment day.

The next scheduled shipment is performed as per the SOW defined frequency after an ad-hoc shipment.

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PHASE: STUDY CONDUCT OVERVIEW | SHIPPING TIMELINES

Collection Kit Shipping Timelines

Refer to the table below for approximate shipping timelines for global regions. For country specific resupply timelines, refer to our website [Click Here].

Region	Manufacturing & Shipping	
	Start - Up Request *(Business Days)*	Resupply Request *(Business Days)*
North America	6 - 10	9 – 13
Latin America**	6 - 24	9 – 24
China	10 - 13	11 – 15
Asia Pacific**	7 - 11	10 – 14
Japan *(Kit built in US)*	7 - 11	10 – 14
Japan *(Kit built in Japan)*	17 - 19	17 – 19
EMEA *(without import license)*	8 - 12	11 – 15
EMEA *(with import license)* **	12 - 18	15 - 21

Sample Shipping Timelines

- *TAT indicated for pass through is for samples to arrive at SM location. Count an additional 24-48hr transit time to final destination. Premium courier could be used for non-standard days of shipments (i.e., those where above boxes are empty) with SM approval.
- Due to export limitation in China, we need to ensure the export permit and China Inspection and Quarantine Bureau (CIQ) permit is on hand, then we can ship samples out. Domestic shipment, TAT is 48hr.
- If storage is required prior to shipping to Referral/Third Party Lab, samples are stored in Singapore and shipped from this SM location.

GVA SM SHIPMENTS	MON			TUE			WED			THU			FRI			SAT		
24-48hr Transit Time	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M
Europe Ref Lab	•	•	•	•	•	•	•	•	•									
Direct - US Ref Lab	•	•	•	•	•	•	•	•	•									
Pass-Through (Indy CLS)	•	•	•	•	•	•	•	•	•	•								

INDY SM SHIPMENTS	MON			TUE			WED			THU			FRI			SAT		
48hr Transit Time	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M
US Ref Lab (24-48hr)	•	•	•	•	•	•	•	•	•	•	•	•	**	**	***			
Direct - Europe Ref Lab	•	•	•	•	•	•							•	•	•			
Pass-Through (Geneva CLS)	•	•	•	•	•	•	•	•	•				•	•	•			

**Domestic shipments to Lab opened for Saturday delivery only
***Domestic shipments to Lab opened for Saturday or Monday delivery

SINGAPORE SM SHIPMENTS	MON			TUE			WED			THU			FRI			SAT		
72hr Transit Time	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M
Direct - Europe Ref Lab	•	•	•	•	•	•							•	•	•			
Direct - US Ref Lab	•	•	•	•	•	•							•	•	•			
Pass-Through (Geneva CLS)	•	•	•	•	•	•	•	•	•				•	•	•	•	•	•
Pass-Through (Indy CLS)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

CHINA SM SHIPMENTS	MON			TUE			WED			THU			FRI			SAT		
144hr Transit Time	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M
Direct - Europe Ref Lab	•	•	•	•	•	•	•	•	•	•	•	•						
Direct - US Ref Lab	•	•	•	•	•	•	•	•	•	•	•	•						
Pass-Through (Geneva CLS)	•	•	•	•	•	•	•	•	•	•	•	•						
Pass-Through (Indy CLS)	•	•	•	•	•	•	•	•	•	•	•	•						
Pass-Through (Singapore CLS) (96hr)	•	•	•	•	•	•	•	•	•	•	•	•						

Due to export limitation in China, we need to ensure the export permit and China Inspection and Quarantine Bureau (CIQ) permit is on hand, then we can ship samples out. Domestic shipment, TAT is 48hr.

JAPAN SM SHIPMENTS	TUE			WED			THU			FRI			SAT			SUN		
72hr Transit Time	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M	F	R	M
Direct - Europe Ref Lab	•	•	•	•	•	•	•	•	•	•	•	•						
Direct - US Ref Lab	•	•	•	•	•	•	•	•	•	•	•	•						
Pass-Through (Geneva CLS)	•	•	•	•	•	•							•	•	•	•	•	•
Pass-Through (Indy CLS)	•	•	•	•	•	•	•	•	•				•	•	•	•	•	•
Pass-Through (Singapore CLS) (24hr)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

If storage is required prior to shipping to Referral/Third Party Lab, samples are stored in Singapore and shipped from this SM location.

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PHASE: STUDY CONDUCT OVERVIEW | SAMPLE DISPOSAL

Sample Disposal

SM samples can be discarded only after a Sample Disposal Form has been signed.

Blanket approval listed in the SOW:

- For example, if the sample is received at an incorrect temperature and is out of stability, it can be discarded without a signed sample disposal.
- In case of a protocol amendment, tests may be removed from a study. Then samples received after the amendment implementation can be discarded as well, if approved.

If a SM sample has a doubtful identification, you are contacted to define the actions to be taken on the sample (e.g., discard, confirm the sample identification).

For the samples tested by Labcorp CLS, SOPs are followed to define when a sample should be discarded. Your authorization is not needed.

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PHASE: STUDY CONDUCT OVERVIEW | RISK MANAGEMENT

Risk Management

Labcorp CLS has a process to build consistent Risk Registers to best manage risk consistently across the portfolio.

Risks are ranked by probability and each risk contains a prevention strategy.

Below are some definitions for the risk strategies:

- **AVOID**: Risk avoidance involves changing the project management plan to eliminate the threat entirely (e.g., modify the SOW set-up to avoid the risk).
- **TRANSFER**: Risk transfer requires shifting some or all the negative impact of a threat along with ownership of the response to a third party.
- **MITIGATE**: Risk mitigation implies reduction in the probability and/or impact of an adverse risk event to be within acceptable threshold limits.
- **ACCEPT**: This strategy is adopted because it is seldom possible to eliminate all threats from a project. This strategy indicates that the project team has decided not to change the project management to deal with a risk or is unable to identify any other suitable response strategy.

Review/Revision

- End of enrollment
- 90 days before interim or final locks
- Protocol amendments
- Technical SOW amendments

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PHASE: STUDY CONDUCT OVERVIEW | INTERNAL DATABASE LOCKS

Internal / Interim* Database Lock

We need you to provide milestone dates for interim database locks. As interim datalock approaches, it is highly recommended to alert your Global Study Manager at least 3 months prior to the lock date. Early notification will aid in you, us, and any additional vendors having ample time to ensure a clean database.

Labcorp CLS does not have a fee for interim data locks explicitly, but may charge for additional data transfers if more transfers or file types are required per month than standard, as per Commercial Policies and/or client-specific Master Service Agreements (MSA).

For Labcorp CLS a clean database means: no pending tests, no accessions on hold, no open sponsor queries, and no Specimen Management (SM) samples in storage (unless specifically requested), no SM samples remain in a Hold status, nor in a Resolution Pending class. Upon notification of an upcoming lock we will then take the following actions:

Note that you may not use the interim verbiage, but if you need a clean data snapshot at any moment during the study, such as for a "Safety Review Committee" meeting, a data "snapshot", "interim analysis", "Data Monitoring meeting", etc. Labcorp CLS would follow the interim database lock process for any sort of data cut-off moment you need during the study.

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PHASE: STUDY CONDUCT OVERVIEW | EXTERNAL LABORATORY MANAGEMENT SOLUTIONS (ELMS)

External Laboratory Management Solutions (ELMS)

What is an external lab?

Any laboratory outside of Labcorp CLS that performs testing for your trial, and which returns result data back to Labcorp CLS.

ELMS offers comprehensive solutions to assist with lab selection and management services, and aid in study-to-study consistency for all your trials, large and small. The assays involved will be maintained by an Electronic Laboratory Worksheets (ELW) containing the assay specifics and the details are then included within your Statement of Work. We make it easy for you with a core package of services - ELMS solves the external lab problem with:

- Vendor Management
- Quality Services
- Contract Management
- Data Services

Our solutions become a scalable One-Vendor solution that simplifies relationships by standardizing quality agreements, audit procedures, and regulatory documentation, reducing the burden of management transfers to central lab for efficiency and negotiating power, and standardizing vendor and data management.

Contract Services	Vendor Management	Quality Services	Data Management
• Unique trials deserve unique management • Confidentiality agreements • MSA/CDA • Individual project agreements	• We manage performance so you don't have to • Turn-around time monitoring • Change management • Vendor performance monitoring and contingency planning	• Avoid uncertainty in your trial's results • Quality issue management • Audits and monitoring • Audit report review	• More results…Fewer hassles • Data entry • Data transfer • Data cleaning and resolution

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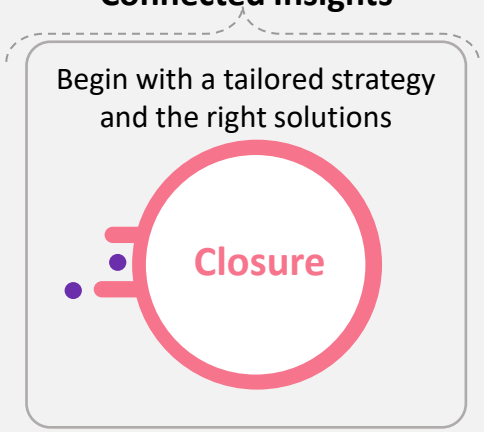
PHASE: STUDY CLOSE OUT OVERVIEW

Trusted Insights Smarter Decisions Added Value

Advancing you through the entire development continuum.

Connected Insights



Once you and your team have confirmed study closure, Labcorp CLS will begin the study closure process.

During this important milestone, we will work to ensure all data has been reconciled, final data transfers are complete and confirm samples still in storage are sent either for destruction and/or shipped to an external laboratory.

Untested human biological samples cannot be discarded by Labcorp CLS, they must be returned to a site or to another location that you appoint.

At this time the final reconciliation with finance will occur.

Please see some key components in the study closure phase.

- Final Database Lock
- Long Term Storage (LTS)
- Final Sample Reconciliation
- Budget Reconciliation

PHASE: STUDY CLOSE OUT OVERVIEW | FINAL DATABASE LOCK

Data is Reconciled | **Samples are Shipped** | **Queries are Resolved**

Final Database Lock
The final database lock date is extremely important. In order to properly prepare of the events that occur (e.g., samples shipments, test resulting, end of study batch testing) advanced notice of the final database lock date is critical.

Even though the final database lock date is discussed from the very beginning of the study, if / when the date is adjusted throughout the life of the study, always inform your Global Study Manager.

Final Database Lock
Long Term Storage (LTS)
Final Sample Reconciliation
Budget Reconciliation

PHASE: STUDY CLOSE OUT OVERVIEW | LONG TERM STORAGE (LTS)

Long Term Storage Samples

Our biorepository services, also known as, long term storage (LTS), can be used globally - whether centralized or de-centralized.

WE ARE FLEXIBLE AND READY TO WORK TO MEET YOUR NEEDS.
THE PEACE OF MIND YOU NEED TO FOCUS ON WHAT MATTERS MOST.

Biorepository Capabilities

- Sample Storage
  - Wide Range of Sample Types
  - Plasma, Serum, Whole Blood, DNA, PBMC, Tissue, others
  - Wide Range of Storage Conditions
  - Ambient, 2 to 8°C, -20°C, -70°C, -80°C, -150°C Vapor Phase Liquid Nitrogen
- Advanced Sample Processing
  - Anatomic Pathology and Histology
  - Genomics: DNA/RNA Extraction
  - PBMC
- Testing Services
  - Central Laboratories: Over 4500 different tests
  - Translational Biomarker Solutions
  - Companion Diagnostics

Protection - A Robust System You Can Trust

- Continuity
  - Secured Facilities
    - Monitored, controlled access areas
    - F5 tornado rated facility in Greenfield, Indiana
  - Business Continuity Plans
    - Redundant backup storage units
    - Diversified backup power sources
  - Business Stability
    - 25+ years of experience
    - Diversified drug development services
- Preservation
  - Temperature Control & Monitoring
    - Continuous automated monitoring system
    - Redundant local temperature monitoring
  - Freezer Validation & Management
    - Temperature mapping
    - Probe calibration

Final Database Lock
Long Term Storage (LTS)
Final Sample Reconciliation
Budget Reconciliation

PHASE: STUDY CLOSE OUT OVERVIEW | FINAL SAMPLE RECONCILIATION

Final Sample Reconciliation
During study closure the Global Study Manager (GSM) will provide you with a full inventory of all samples currently stored at Labcorp CLS.

At this time, you will be able to confirm any actions needed for the samples.

For example, samples may be discarded, shipped to another laboratory or housed in the Labcorp Biorepository.

Once actions are confirmed, the GSM will implement your request(s).

Final Database Lock
Long Term Storage (LTS)
Final Sample Reconciliation
Budget Reconciliation

PHASE: STUDY CLOSE OUT OVERVIEW | BUDGET RECONCILIATION

Budget Reconciliation
As a part of the study closure, the final budget reconciliation will be completed once the final sample reconciliation is confirmed by you.

Finance will reconcile all study expenses and initiates the final invoice to fully close all activity.

Once the final invoice is generated, the GSM can review the details with you.

Final Database Lock
Long Term Storage (LTS)
Final Sample Reconciliation
Budget Reconciliation

Supplies, Materials, Logistics

Seamless Delivery, Smarter Trials, Engaged Patients

When it comes to managing the different supplies and materials produced for your study and the corresponding transportation arrangements and costs - it is critical that there is precise and proactive communication between you, your sites and your Labcorp CLS study team.

Click on one of the three main area for additional details.

Note: You'll be redirected to the "Phase: Study Conduct Overview | Kit Management" or "Phase: Study Conduct Overview | Logistics" section.

- Some factors (e.g. kit level unit prices and quantity billed based on study design) may influence the study budget. Below are some points to consider while setting up or modifying your study design.
- Kit Levels are calculated based on the number of items in each kit and their impact on the study budget:

Kit Level 1	A kit configuration with requisition only
Kit Level 2	A kit configuration with 1-13 items
Kit Level 3	A kit configuration with 14-27 items
Kit Level 4	A kit configuration with 28-70 items and/or manually produced kits
Kit Level 5	A kit configuration with more than 70 items

- Customizing a kit with "baggies" can increase the Kit Level to a 4 or 5.
- Visit Definition: how kits are used at a visit, whether required, optional or unscheduled)
- Site and Subject Distribution: When discussing the subject and site numbers, it is important to consider the estimated screen failure and enrollment rates. This information is a key factor to define the correct start-up content for sites and to limit kit wastage or extra kit ordering.
- Protocol Amendments Impacting Kit Content: For database updates related to a protocol amendment, it is important to review with your GSM/SDL how any changes will impact the kit contents. This will ensure implementation of a suitable solution that minimizes both site confusion and the number of discarded kits.

Materials, Kit Supplies, Manufacturing, Shipping

Logistics

Guidelines for Kit Inventory Management

Reporting and Study Monitoring
Personalized Study Performance Management (PSPM)
LabLink+
Data & Reporting Permissions
Labcorp Sponsor & Investigator Portals (The Portals)

Data & Reporting

Unrivaled global patient data, clinical trial data and analytics.

We are investing to accelerate your development goals and enhancing data delivery and quality. Data reconciliation occurs in real time, improving quality and reducing timelines with fewer data streams to manage.

REPORTING AND STUDY MONITORING

Laboratory Reports

Results for most safety assays will be available 24 hours after the sample is received by Labcorp CLS. Results for non-safety assays may have longer turnaround times. Results will not be released if the requisition form has inaccurate or incomplete information. The testing will be performed, but the results will be held until we receive the required information.

As soon as the result of a test or a group of tests is available, the corresponding laboratory report is made available in the Labcorp Investigator Portal (The Portal) or released by email / fax to the investigator site. Investigator sites may receive laboratory reports at different times depending on the turnaround time of the tests.

Subject Age & Surrogate Date of Birth (DOB) Options

- If using Age: Labcorp CLS will not collect a DOB and will not be able to provide DOB format for downstream laboratories / data transfers. ***It is the sponsor responsibility to verify that all sponsor selected external labs/vendors are able to accept Age format if necessary***. To establish and appropriately apply Reference Ranges throughout the total duration of the study, Labcorp CLS will always collect the main subject identifier (i.e. Subject Number), Age and Sex at every visit.
- If using DOB: Labcorp CLS will always collect all subject identifiers (i.e. Subject Number), Age, and Sex at every visit unless indicated.

Queries

Upon kit receipt, the requisition form is reviewed for any inaccurate or incomplete information during the data entry process. If discrepancies are found, the patient visit is put on hold in the system and our Investigator Site Support Team contacts the site to clarify the missing or discrepant data. The test results will be released only when the missing or inaccurate information is confirmed as accurate. You are able to review accessions on hold within LabLink and/or the Labcorp Investigator Portal [Click Here].

If a site and CRA cannot be successfully contacted, the query will then be escalated to your RSC and yourself.

- eQuery and the Labcorp Investigator Portal
    - eQuery or electronic query notification and resolution is available via The Portal for investigators. This tool supports the resolution of missing or discrepant specimen information with investigator sites, which is a critical part of generating high quality data for clinical trials. eQuery enhances the overall investigator site experience by:
    - Simplifying and streamlining site operations by consolidating queries into the same platform as other lab data, such as study documents and test results
    - Providing a faster, more convenient resolution of queries within the Labcorp Investigator Portal
    - Applying a consistent process for escalation and resolution of unanswered queries, leading to faster release of test results
- Reference guides are available within the Labcorp Investigator Portals to provide details about the features and use of eQuery.

REPORTING AND STUDY MONITORING

Site Support & Queries

Our Investigator Site Support team is available to provide continued support and performance monitoring 24/7 from our multilingual Investigator Site Support Team, which is dedicated to answering investigator inquiries and resolving issues in the most appropriate and efficient manner. Our website is another useful resource where sites can easily find training material [Click Here].

Cancellations

A test can be cancelled for various reasons. The most common reasons are hemolysis, insufficient quantity of blood, tube expirations, inappropriate transport conditions (temperature), or no specimen received. In these cases, the tests are cancelled and a cancellation message will appear on the laboratory report. You are able to review accession cancellations within LabLink and/or the Labcorp Sponsor & Investigator Portals [Client Here].

Additional Testing

Additional testing by Labcorp CLS that is requested by sites must be authorized by you. This should be discussed in detail with the Global Study Manager if it begins to occur, as the budget will be impacted.

Alerts

For patient safety (chemistry, urine, etc.), standard reference ranges will be reported within the Investigator Manuals. Study flagging will be designed and agreed upon so it can be fully documented within the Statement of Work. If there are special requests for special patient populations or existing client guidance documents, this will need to be discussed and agreed upon for feasibility.

Data Blinding

Blinding refers to withholding of test results that may provide insight into the study medication assignment. To determine if test results should be blinded, it must be confirmed that knowledge of any of the test results would make the study team or investigators aware of a subject's treatment arm. Test results can be blinded at the visit and/or recipient level, and will result in:

- No communication or reporting of test results and flags
- No access to results in LabLink+ and Labcorp Sponsor & Investigator Portals

- The following items can affect how blinding is conducted in the study:
  - Addition, removal or changes to visit or laboratory test
  - Changes to visit Protocol Visit Codes (PVC)

Blinded data may be provided by electronic data transfer to individuals who are eligible to receive results.
The blinding definition is defined in the SOW during the study setup.

REPORTING AND STUDY MONITORING

Permanently Detached Accession (PDA)

For data monitoring needs, it may be applicable to PDA certain accessions with a study. This involves removing an accession and its results from a protocol, project, site and patient number. Once the PDA process is completed, the accessions and results will no longer be visible to you, as the sponsor team. It can be requested from either: the study team leader, a member of the sponsor's clinical team (safety, medical monitor or biomarker lead), or your Labcorp CLS study team.

If you need to request a PDA, ensure that you include the following information for your GSM/RSC: accession number, site number, protocol/project number, patient/subject number, a detailed description as to why the PDA is required for the patient visit, and the sponsor final approver.

Note: PDAs for accessions that contain Sample Management (SM) storage samples will be requested using the sample disposal process and must be on a separate sample disposal form from any accession(s) not being permanently detached.

A PDA might be needed if:

- A visit or collection is performed without patient consent
  - *E.g., An optional DNA test requiring informed consent is in the study. The patient did not give consent, but the collection is made*
- A visit kit is returned with incorrect identifiers for the protocol and sponsor
  - *E.g., Site 123 returns a visit kit but there is no record of that patient at the site or in the study and the correct study cannot be identified by the site*
- A visit kit is returned without a requisition and the site is unable to confirm which study and patient the visit kit belongs to

A PDA might not be possible if:

- Analytical results have been reported out in the Labcorp database
  - A separate Medical Affairs approval request can be sent in the event a visit or sample should not have been collected
- Container status is available, *pre-scanned* or *on-hold*
- No clear reason for the PDA request is provided

Some exceptions:

- *If any laboratory reports with NON-analytical results have been reported (e.g.,: No specimen received, Container received empty)*
- *Accession with analytical results without Medical Affairs approval after accession has been combined*

LABLINK+

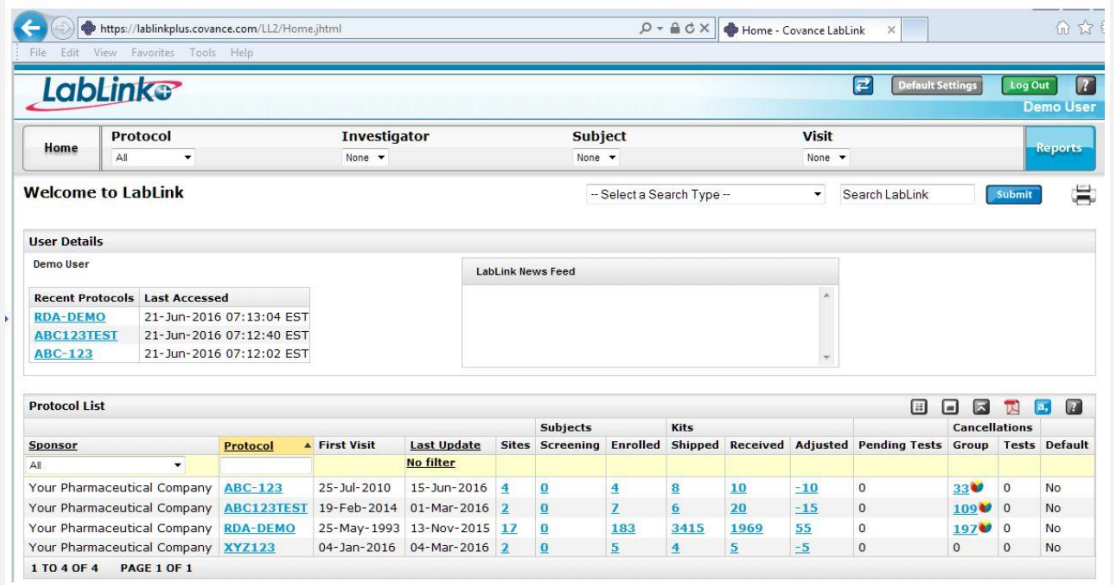
Helping you make operational pivots with integrated data

LabLink+ is a near-real time web-based monitoring tool for clinical trial laboratory results.

Results can easily be reviewed by site and/or by patient. Custom reports can be created using the ad-hoc reporting tools. LabLink+ is provided at no additional cost and does not require any additional computer hardware or software. LabLink+ is available to sponsors and monitors only. Your Global Study Manager will assist you with obtaining access.

LabLink+ is a secure web-based portal that allows sponsors to monitor the progress of time-sensitive lab kit inventory information and clinical trial laboratory test results from anywhere in the world.

To access LabLink+ [Click Here].
For details on permission levels [Click Here].



LABCORP SPONSOR & INVESTIGATOR PORTALS

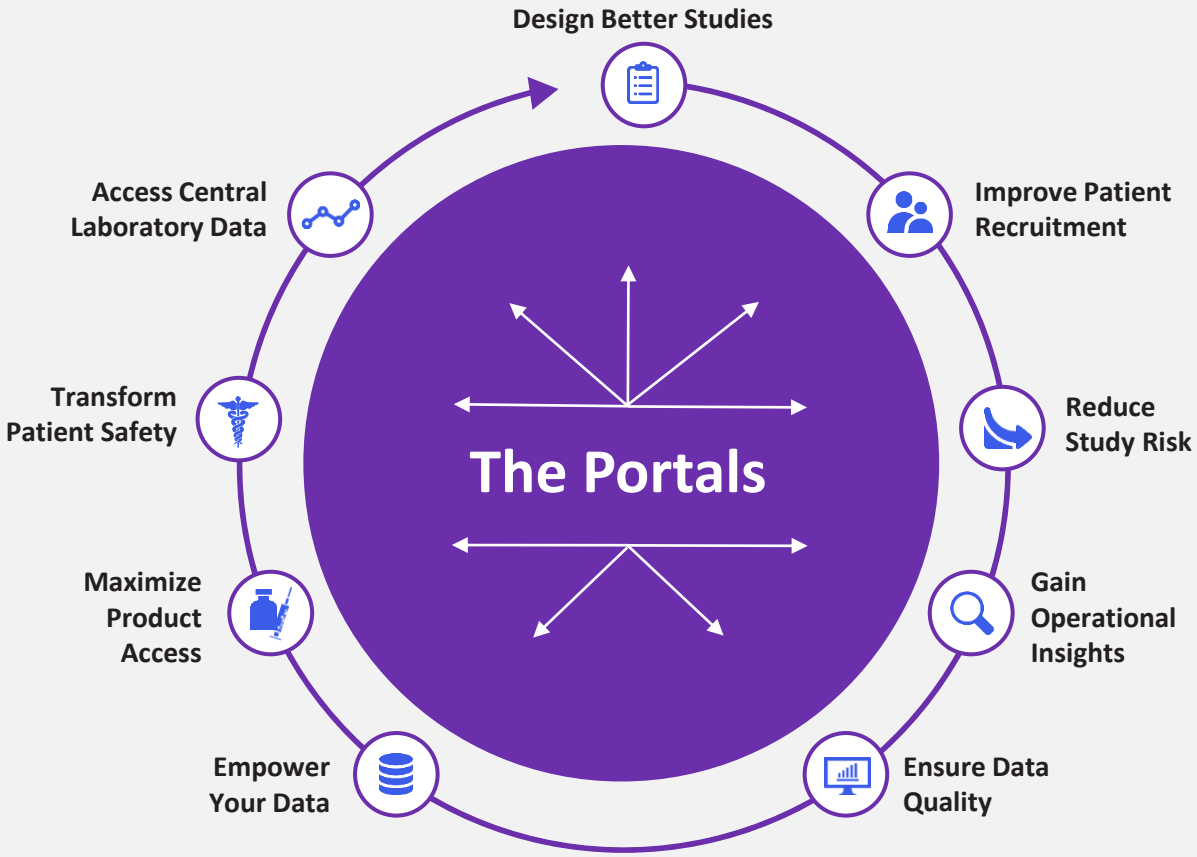
Reduces study risk and ensures that the whole study team stays on track.

Labcorp Sponsor & Investigator Portals (The Portals)

Timely access to your central laboratory testing data is essential. By providing near real-time information, the Labcorp Sponsor Portal helps to reduce the risk of rework at sites, increase efficiency with up-to-date, version-controlled documents and improve collaboration between the study team and investigators. With secure online access, you can view all relevant laboratory information at any time in order to see trends at a site or subject level, download and print multiple documents, view study documents and communications, kit inventory, and enable more timely follow-up with investigators.

The Labcorp Sponsor Portal also allows you to track your study and keep tabs on user access and read/ unread documents by running reports directly.

To access the Lab Portals [Click Here].
For details on permission levels [Click Here].



Sample Tracking and Site Shipping Applications

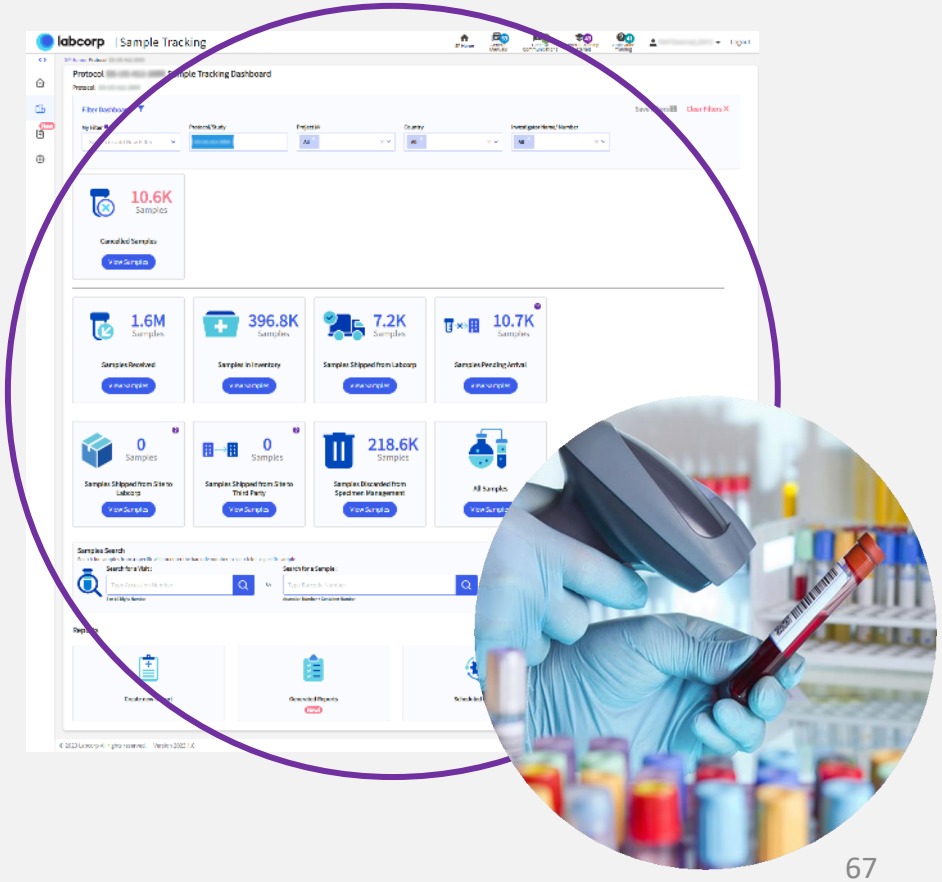
Enhanced Visibility of Specimens within the Central Lab

Sample Tracking allows users of the *Labcorp Sponsor Portal* to view key events in the journey of central lab samples for each assigned protocol. It provides you with enhanced, near real-time visibility of specimens within the central lab. You will be able to:

- *See the information that matters to you* through configurable study groupings with aggregated sample counts, customizable filters, aggregations and fields.
- *Quickly find samples of interest* with accession level or sample level identifiers.
- *Understand sample dependencies* by providing visibility on the parent and child aliquot relationships.
- *Save time through* on-demand and scheduled report generation with replicable report designs.

There is no additional charge for use of the **Sample Tracking** for Labcorp Central Laboratory Services studies.

Site Shipping allows sites to enter shipment date and time as well as tracking information for every Labcorp CLS sample shipment they send out. The tool provides the opportunity of an initial quality check by the sites, as it will identify visit and sample data discrepancies. When investigator sites use the Site Shipping Tool, aggregated counts of samples shipped from sites to Labcorp and sites to a third-party are available for Sponsors in the **Sample Tracking**.



DATA & REPORTING PERMISSIONS

Global Access List (GAL) Template Instructions

The Global Access List is the Labcorp CLS standard template to gather the correct contact details for Investigator Site contacts, shipping addresses, reporting information and access rights to Labcorp systems. Guidelines for using the template can be found directly within the tool itself. Here are a few key points to keep in mind upon receiving a blank copy of the GAL:

- The Blinding Roles are defined by YOU and included Labcorp CLS Statement of Work. You will only want to use the Blinding Roles that are applicable to your study.
- The site, CRO, and/or sponsor information included in the template will be used to load primary users into the Labcorp CLS database and to grant primary and secondary users access to the Labcorp Sponsor Portal, Labcorp Investigator Portal, and/or LabLink+.
    - The Labcorp CLS database accepts only ONE primary user per role and per site:
        - Principle Investigator, Supplies Recipient, Lab Report Recipient, Study Nurse/Coordinator, Additional Site Role, and one Monitor/CRA
        - First and Last name, Email, full address, phone number and fax number are required fields for primary roles.
    - Secondary users will have Web Portal Access only (they are not loaded into the Labcorp CLS database)
        - Multiple site users can have Portal Access to the Labcorp Investigator Portal:
            - Lab Report Recipient, Study Nurse/Coordinator, and Additional Site Role
        - Multiple Site Monitors, CRAs, Sponsors, Additional Sponsors Role and Third-Party users can have access to the Labcorp Sponsor Portal and/or LabLink+.
        - First and Last name and email address are the only required fields for secondary roles.

If contact information needs to be revised during the life of the study, please send an updated “Global Access List” template to your Regional Study Coordinator. Ensure that the “Action” column is highlighted per the indicated Action type!

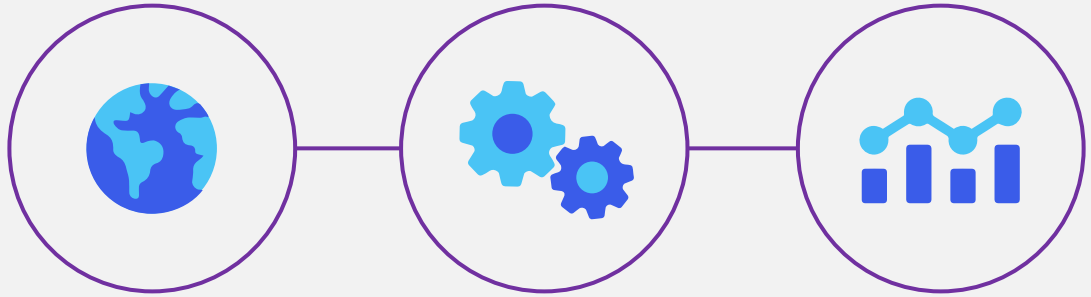
Labcorp would like to remind Sponsor users that a periodic review of the users assigned to your protocol is highly recommended. You have access to review the user access information via the Reports page within The Portals. Under the Reports section, you will find the Protocol Access tab that lists all users assigned to your protocol. You can review the information on screen or export to CSV or Excel. After reviewing the user access report for your protocol, if any changes are required, please contact your Global Study Manager and/or Regional Study Coordinator. They will make the appropriate user access requests if needed.

PERSONALIZED STUDY PERFORMANCE MANAGEMENT (PSPM)

Customizable monitoring options for your needs.

Personalized Study Performance Management (PSPM) offers you different options. Here is a high-level description of each.

If it is necessary to have a more customized report for your study, our Global Monitors will assess the feasibility based on your requests. Please note additional costs will be applied for customized reports. To understand the different monitoring services and how they could best meet your study-specific requirements, contact your GSM for further details and cost assessments.



Standard Monitoring

Performed free of charge for your protocol and, a few data points, are even monitored regularly with analysis provided to the GSM.

Tier 1 Services

Tier 1 Add-ons

Client Customized Labcorp CLS Result Analytics, Study Health, and Kit Management Monitoring and can include up to 9 different add on services.

Tier 2 Services

Tier 2 Add-ons

Client Customized Labcorp CLS Result Analytics, Study Health, and Kit Management Action-Based Monitoring or increased reporting and can include up to 6 different add on services.

Additional Services

Leverage the expertise, capabilities, and infrastructure of Labcorp

No matter the size of your organization, or trial…

We have unique solutions from start to finish that enable the trial will operate efficiently and yield high-quality data. Nobody else can match our experience, testing volume, or breadth of service. In addition, as a complete provider, we enable efficiencies on the client side that translate to tangible savings for our clients.

INVESTIGATOR MEETINGS

Labcorp CLS provides dedicated investigator training professionals and tools to increase the protocol compliance of your study sites and maximize the viability of every specimen collected. Our investigator training services offer enhanced personal and technology-based options that consistently meet the needs of your investigator site, foster productive relationships throughout the life of your study and ensure patient safety.

You can choose between two interactive training options. Each plan is customized to your protocol for the successful initiation of your study sites and/or ongoing studies.

Training Plans 1 and 2 both feature protocol-specific e-Learning training designed to provide individually paced computer instruction. Video demonstrations reinforce the process steps in your protocol, and assessment questions throughout the training establish comprehension and understanding of the material. The e-Learning also serves as a valuable site reference tool.

In addition to the training plans, the Labcorp Investigator Training Center provides a full spectrum of ancillary services to support your study at every milestone. Available upon request, these services include:

- Additional face-to-face training sessions
- Additional live remote training sessions
- Simple or complex training modification
- Detailed, study-specific training calls

In collaboration with your GSM, site performance can be optimized through our training or issue-driven retraining, as necessary.

Training Plan 1

- Face-to-face customized training session with e-Learning provides customized, study-specific training for your investigator sites
- On-site customized training during your investigator meetings or site visits
- Investigator trainer Q&A sessions and 1:1 assistance
- Demonstration kits, shipping supplies and all training materials are provided e-Learning formats include flash for placement on your web portals, or industry standardized Learning Management Systems (LMS) modules.

Training Plan 2

- A single training session in any of the following formats:
- Webinars
- Teleconferences
- Presentation recordings
- Train-the-trainer virtual sessions interactive e-Learning provides the same customized training features and choice of formats as Training Plan 1

ADDITIONAL SERVICES

In collaboration with your GSM and Labcorp Study Team, as applicable, don't hesitate to request more information on any additional services that may be needed. We are here to creatively work through solutions with you.

- Personalized Study Performance Management (PSPM) reporting and monitoring solutions
- Special Handling services
  - Re-labeling / Labeling of non-Labcorp CLS samples with Labcorp CLS barcodes
  - Blinding of Patient Identification
  - De-Identification of samples
  - Special Aliquot and Centrifugation services
  - Special Sample Inspections

Budget Management

Together, we're exceptional

The initial quote provided to you by Labcorp CLS for your protocol is based on information provided by you via study protocol, request for proposal (RFP), etc. and is subject to change based on various elements as the Statement of Work is developed for your study.

BUDGET DRIVERS

What will influence your budget?

Listed here are some main opportunities for budget review for you to take into consideration. These budget drivers can significantly impact the study budget.

Driver	Considerations
Transportation	○ Specimen shipping (ambient, refrigerated, frozen) from the investigator site to Labcorp CLS or direct shipments from the investigator sites to a referral laboratory significantly affects the budget. ○ This cost is billed directly to you through Labcorp's courier account allowing contingencies to be implemented and early morning delivery when possible. ○ Transportation efficiencies may be gained or lost depending on how well your sites are consolidating samples for shipping to Labcorp CLS for testing. Sample consolidation is the practice of sending all used visit collection kits for all Labcorp CLS studies back from the investigator site to Labcorp CLS within the same shipment. ***The greater the sample consolidation, the lower the transportation costs.*** ○ Site location [primary vs. secondary or tertiary location(s)*] directly impacts the transportation costs as well as serviceability for your trial. Secondary and tertiary locations may require the use of premium couriers, resulting in higher costs. ○ Country and subject allocation will affect the overall transportation costs. This is mainly due to site location and courier requirements. ○ The number of subjects per site and the total number of overall sites will also impact the budget. A greater number of sites and subjects enrolled per site increases the overall transportation costs.

What is a primary city?

All capital cities are considered Primary and large metropolitan areas also fall under this category. Typically, a Primary city will have an international airport from which samples can be directly exported to a major regional hub or to the final destination. This varies per country, as an example, in China only Shanghai is a Primary city.

What is a secondary city?

Secondary cities are typically locations that need to go through a Primary city for international departure to a major regional hub or to the final destination. These destinations may lack a large and effective transportation/logistics network or may be somehow difficult to reach.

What is a tertiary city?

Tertiary cities are rare in the Labcorp network. These destinations lack a large and effective network and are difficult to reach. Packages originating from these areas not only need to go through a combination of domestic transfers, but may also combine several modes of transportation (ground, train, air). Transit time is not always guaranteed and the price is high.

BUDGET DRIVERS

What will influence your budget?

Listed here are some key budget drivers for you to take into consideration. These budget drivers can significantly impact the study budget.

Driver	Considerations
Collection Supplies	○ Collection Supplies include visit collection kits and any additional bulk or custom supplies utilized for your trial. ○ Kit design and overall complexity affects the overall cost of collection supplies. ○ *The kit complexity is based on the number of containers and/or special design requirements for your study.*
Number of Subject Visits and Screen Failure Rates	○ The total number of subjects, subject visits and screen failure rates largely influences the cost of your trial.

Visit Requirements and Patient Testing	○ In your Visit Test Schedule, you may have testing that is optional. Your GSM will ask you to provide estimates on the percentage of subjects that may need to have this optional testing performed so that Labcorp CLS can best provide you a budget fitting your estimations.
	  ○ *Be aware that if you have more subjects than planned having optional testing performed, it will increase your budget.*
	○ Overestimating the optional testing in the SOW will increase your budget. However, only the testing performed will be billed in the end.
	  ○ *Be sure to discuss the best options with your GSM to capture this correctly in your Visit test schedule.*

Project Modification	○ Some modifications are billable, consult with your GSM for any cost analysis. ○ Any project modification due to protocol amendments or otherwise, should be discussed with your GSM. Usually, modifications require the SOW to be amended and signed before implementation. The database will be updated after the SOW is signed. If the modification involves changes to the requisitions, kits or manuals, new versions may need to be sent to the sites. ○ Coordination of post modification activity should be arranged with your GSM.

BUDGET MILESTONE MANAGEMENT

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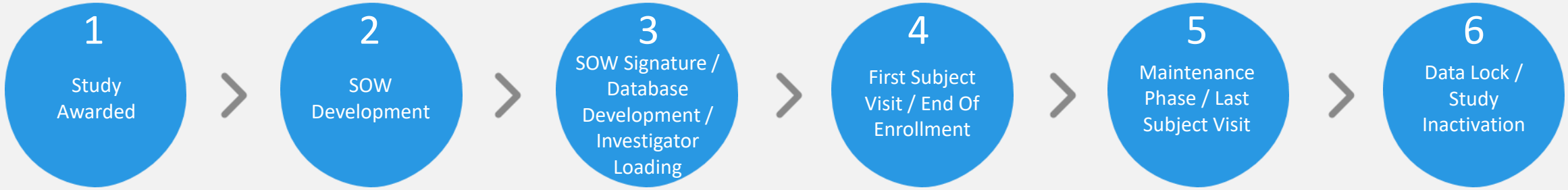
Click on the circles to learn more!



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Study Awarded

- The Global Study Manager and Study Design Lead will review the initial quote and any assumptions before developing your study's Statement of Work (Study Specifications).

BUDGET MILESTONE MANAGEMENT

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Statement of Work (SOW) Development

- Your GSM will discuss the budget drivers in relation to the Statement of Work with you and provide follow-up documentation for reference.
- This will assist you in making more informed decisions, ultimately reducing unnecessary or unexpected costs throughout the life of your study.

BUDGET MILESTONE MANAGEMENT

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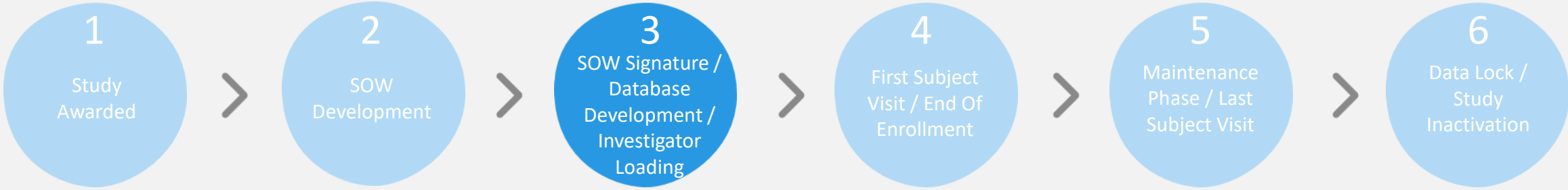
SOW Signature / Database Development / Investigator Loading

- New budgets are created after the SOW is finalized for the initial SOW Development and for any SOW Amendments which will impact the study budget.
- A transportation analysis can be performed after all investigator sites are loaded into the Labcorp CLS system.
- Your budget will more accurately reflects transportation assumption costs due to site location as more remote site locations may require more expensive transportation services.



BUDGET MILESTONE MANAGEMENT

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First Subject Visit / End Of Enrollment

- Your GSM will be reviewing your study's budget variances (eGBV) report regularly to monitor your study's budget performance.
- The enrollment period is critical for your study budget, as this is where site efficiencies, kit usage and logistics costs will become more refined as all sites will come on-board.
- A 50% enrollment budget review is performed, which can include a secondary/tertiary city transportation analysis. Budgets will be updated as needed to reflect actual study design.
- The End of Study Enrollment review is performed, which can include a transportation analysis. Subject numbers are updated to reflect actual subject allocation per country and per site and budgets are updated. Proactive budget management during enrollment allows your study managers to modify enrollment strategies and approaches for better cost management. After End of Enrollment, budgets more accurately reflect trial costs, including transportation. You will receive eGBV reports to assist with analyzing the study budget details which have been billed to date versus the estimated budget. ***Remember, your GSM is here to support you through the entire process***.

1 Study Awarded > 2 SOW Development > 3 SOW Signature / Database Development / Investigator Loading > 4 First Subject Visit / End Of Enrollment > 5 Maintenance Phase / Last Subject Visit > 6 Data Lock / Study Inactivation

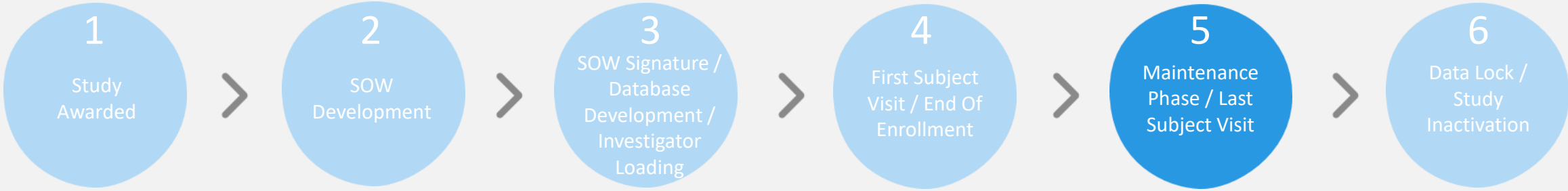
BUDGET MILESTONE MANAGEMENT

Together, we're exceptional

The initial quote provided to you by Labcorp CLS for your protocol is based on information provided by you via study protocol, request for proposal (RFP), etc. and is subject to change based on various elements as the Statement of Work is developed for your study.

Maintenance Phase / Last Subject Visit

- Your GSM reviews your study's eGBV report regularly to monitor your study's budget performance. If your budget is not on track, an assessment is performed to determine why the budget is not on target and your GSM will work with you on steps which may need to be taken to get your budget back within target.



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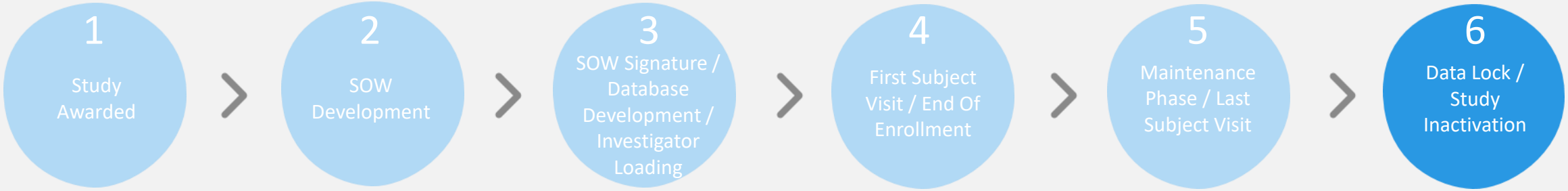
Data Lock / Study Inactivation

- Your study becomes inactive after data lock or the last subject visit has occurred. Final account reconciliation is performed, and study budget monitoring is concluded.
- Your final invoices are created so study budgets can be closed out.



BUDGET MANAGEMENT EXPECTATIONS

Labcorp CLS Global Study Managers

- Consult and communicate to your unique study budget needs
- Proactively monitor and manage study budgets from setup through execution and closure, including regular budget reviews and updates
- Ensure that contract and budgets are aligned with the SOW and your needs
- Keep your Labcorp CLS GSM informed of any changes to site and subject assumptions or to the protocol throughout the study

Recommended Budget Update Milestones

- Initial signed SOW
- After site loading and/or 50% enrollment
- End of enrollment
- SOW/Budget Amendments

Other

Stay connected and informed.

QUICK LINKS

Stay Connected

Quick Links to commonly used resources.

Link	Service / Application
[Click Here]	Labcorp Central Laboratories & International
[Click Here]	Labcorp Central Laboratory Services
[Click Here]	Current Investigator & Study Staff Information
[Click Here]	Need to order more inventory of Collection Kits and/or Bulk Supplies?
[Click Here]	Holiday Schedule Information
[Click Here]	Labcorp Investigator Portal Login
[Click Here]	Labcorp Sponsor Portal Login
[Click Here]	LabLink+ Portal Login
[Click Here]	Global Access List (GAL) Template Instructions

GLOSSARY

**Part of your Labcorp CLS Study Team within Global Project Management*
***Part of your Labcorp CLS Study Team within Clinical Data Management*

Terminology / Acronyms	Definition
APAC	Asia Pacific Region
BioA	The bioanalytical experts starting from discovery in both nonclinical and clinical study needs.
CAPA	Corrective and Prevention Action
CIL	Client Information List
Clinical-BioTech	The clinical-biotech experts in a full-service CRO.
CLS	Central Laboratory Services
CRA	Clinical Research Associate
CRO	Clinical Research Organization
DA**	Data Analyst
DM**	Data Manager
DP*	Desktop Publisher
ECG	Electrocardiogram
EDC	Electronic Data Capture
eGBV	Electronic Grant Budget Variance Report
EMEA	Europe, Middle East, Africa
EOC	European Operations Center; which is our Kit Production facility in Mechelen, Belgium
EPL	Electronic Packing List / An EPL accompanies Specimen Management shipments.
FSFV	First Subject First Visit
FSV	First Subject Visit
GAL	Global Access List
GM*	Global Monitor
GSM*	Global Study Manager / *Your primary contact!*
GTM*	Global Team Manager
IM	Investigator Meeting
IVRS	Interactive Voice Response Systems
KDD	Kit Delivery Date
KOM	Kick-Off Meeting
LMS	Learning Management System
Min-Max	Minimum and Maximum
PO	Purchase Order
PSPM	Personalized Study Performance Management
PVC	Protocol Visit Code
Q&A	Questions and Answers
QC	Quality Control
RFP	Request for Proposal
RSC*	Regional Study Coordinator
SDL*	Study Design Lead
SIV	Site Initiation Visit
SOW	Statement of Work
The Portals	Labcorp Sponsor Portal and Labcorp Investigator Portal

NAVIGATION OVERVIEW