IQVIA Laboratories

“How To” Guide

How To Interpret and Respond to IQVIA Laboratories Queries?

Aug2025

© 2025. All rights reserved. IQVIA® is a registered trademark of IQVIA Inc. in the United States, the European Union, and various other countries.

About

The purpose of this document is to support Site Coordinators (SCs) in efficiently viewing and responding to queries within the LTMS Portal. It provides a step-by-step overview of the entire query resolution process—from query generation to appropriate response submission.

This guidance includes:

- An explanation of how queries are generated and the rationale behind each query
- The importance of timely and accurate responses
- Instructions for navigating and managing queries in the LTMS Portal
- Examples of common queries with recommended responses and best practices to help avoid recurrence

While the query verbiage may differ based on the database platform used for each protocol, the recommended responses and best practices outlined in this document are applicable across all studies. These practices have been compiled from real-world scenarios and are aimed at enhancing response accuracy, streamlining communication, and minimizing query turnaround time.

Content

- What Are Queries?
- Definition & Common Abbreviation
- Importance of Responding to Queries
- How to View and Respond to Queries in the LTMS Portal
- How to Answer a Query?
- Common Queries, Recommended Response & Best Practices

COMPANY CONFIDENTIAL

Definition & Common Abbreviation

- **LTMS Portal:** An overview of IQVIA Laboratories online central laboratory management system for site staff
- **Administrative Question:** Hereinafter referred to as ‘Question’ in the query text. This is a mandatory question on the requisition form and is directly relevant to the visit.
- **Scheduled Visit:** A visit that occurs within the planned visit structure
- **Unscheduled Visit:** An unexpected visit that occurs out with the planned visit structure.

Accession#	Accession number
CRA	Clinical Research Associates
DOB	Date of Birth
ISS	Investigator Site Support

What Are Queries?

Upon receipt of laboratory samples, IQVIA Laboratories performs a series of edit checks on the patient demographics and visit information. If all data is found to be consistent and correct, the results will be released to the site. However, on occasion, clarification of the data is required by the site to ensure the integrity of the data provided.

The following table provides examples of possible situations that can result in a query being generated to the investigator site.

Query	Example
Demographic Discrepancy	Demographic data provided for the current subject visit does not match the Demographic data provided at a previous subject visit.
Incorrect Shipping Conditions/the state in which the specimen was shipped does not the match the expected specimen state	Frozen samples received in an ambient condition.
Collection Date Matches Date of Birth	Specimen collection date provided matches the DOB provided for the current subject visit.
Duplicate Subject ID	Subject ID provided matches that of another subject in the system.
Missing information on the requisition form	The administrative question has not been answered.
Missing requisition form	The requisition form not received

Importance of Responding to Queries

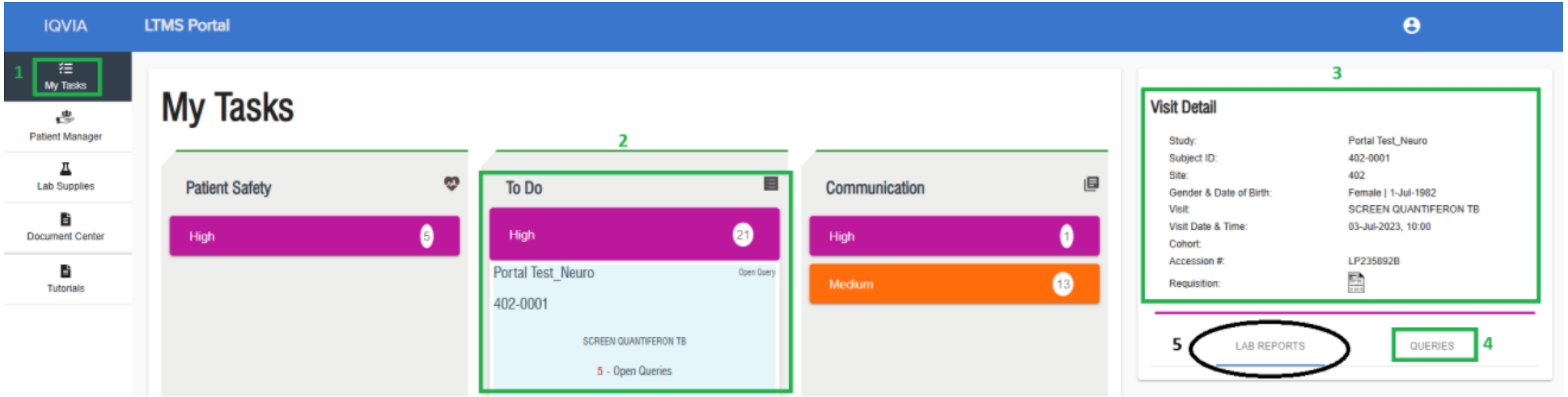
- Accession numbers which have an outstanding unresolved query in IQVIA Laboratories database **MAY** have a **hold** applied on them:
  - Lab report release (including safety reports)
  - Shipment of specimen management samples to other labs
  - Data transfer
- It's therefore very important that the queries are resolved as quickly as possible, particularly when safety data is involved or when your study is approaching a key milestone for data reporting (e.g. interim or final database lock).

COMPANY CONFIDENTIAL

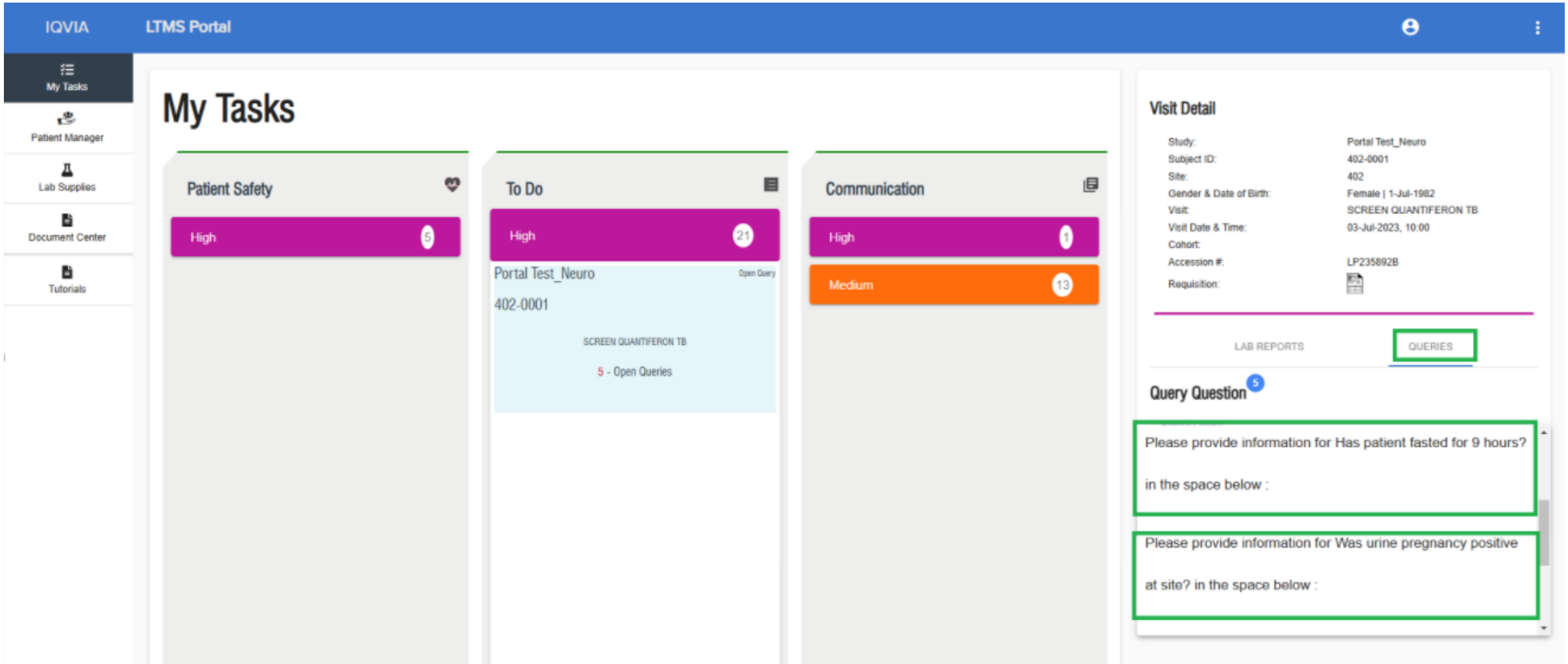
How to View and Respond to Queries in the LTMS Portal

- Sites staff should monitor and respond to queries via LTMS Portal so it can be sent to IQVIA Laboratories for us to resolve the queries and expedite delivery of the lab reports. It allows users to view all open queries in one location when viewing or clarifying queries over phone calls with Investigator Site Support Team.

- Site staff can respond to data queries by selecting (1) “My Tasks” and then click on “To-Do” (2), select the protocol, refer to subject and visit information populated at (3). Users can further navigate to Queries (4), to view and respond to a query associated with the visit. To access Lab reports, select (5).

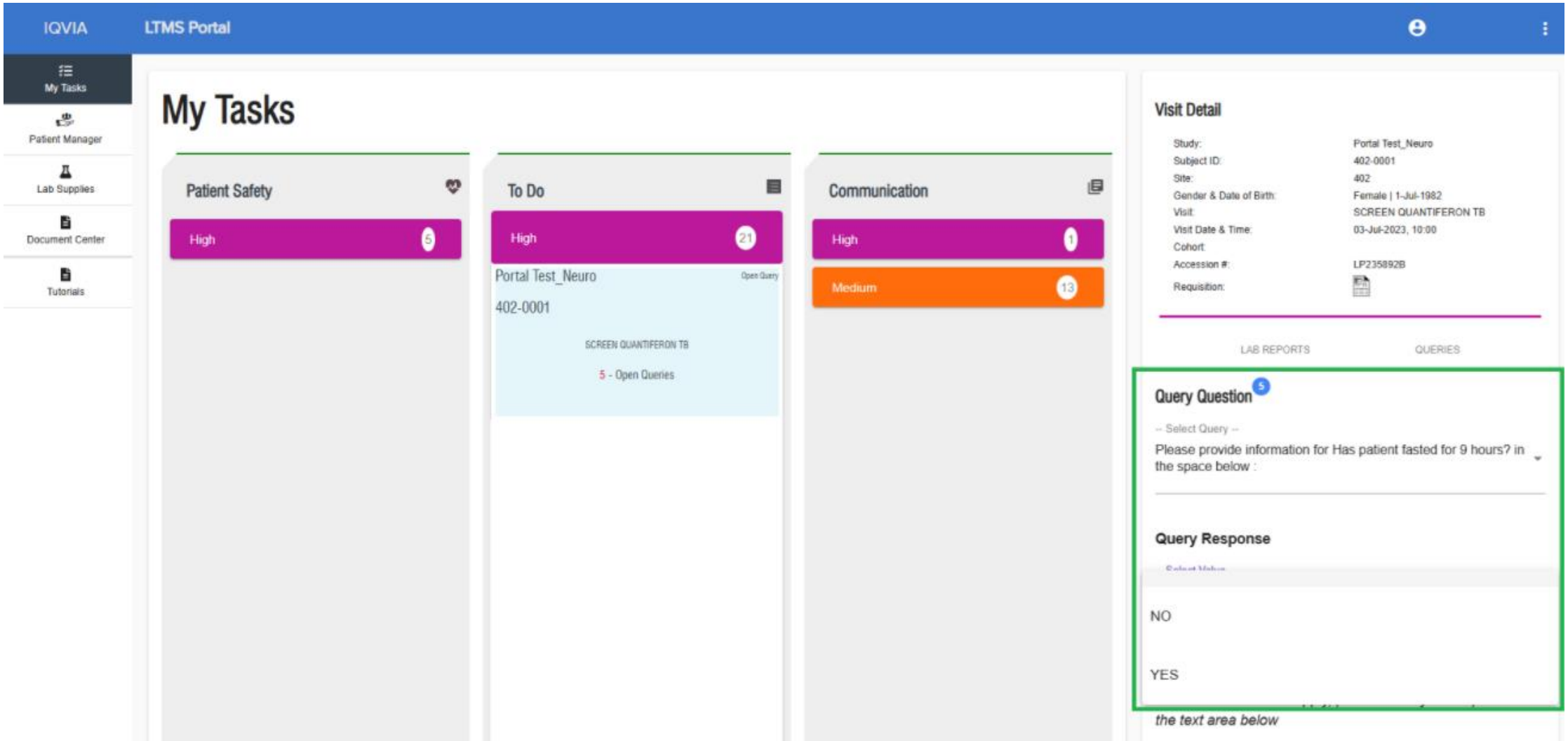


How to View and Respond to Queries in the LTMS Portal



How to View and Respond to Queries in the LTMS Portal

- Click on the query. The query will expand below.



How to View and Respond to Queries in the LTMS Portal

- Site users can enter a response and click submit. Repeat if there is more than one query. When all queries for a visit/accession have been answered, the notification will automatically disappear.

- After the site submits a response, the High Priority banner from “To Do” will disappear. The response is immediately sent to IQVIA Laboratories to review and resolve. If there is an issue with the site response, an IQVIA Laboratories representative will contact the site or re-issue the query back to the LTMS Portal.

- If the site is experiencing delays in receiving reports, they should contact an IQVIA Laboratories representative via the Toll-Free numbers indicated within the Lab manual and Flowchart.

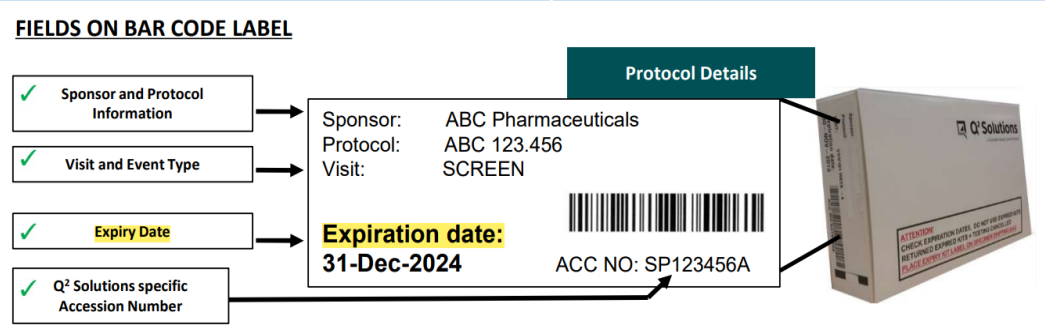
- If site discovers an answer is wrong in site portal after submission, they can contact the ISS team and study PM/PC directly via email/phone to correct the answer.

How to Answer a Query?

- Queries are always communicated to the site via the LTMS Portal, email or by Telephone.
- Queries are available in the LTMS Portal for response.
- If a response is not received for a query, Investigator Site Support will attempt to contact the site directly via telephone to obtain resolution to the query.
- If the Investigator Site Support team is unsuccessful in resolving the query, this will be escalated to the Clinical Research Associates (CRA)/Sponsor via email. The project management team will also escalate these DCQs to the responsible CRA or site monitors.
- It may not be possible to issue the Laboratory Reports for a visit which has one or more queries until any or all queries have been resolved. Delays to patient results could impact patient safety.
- Sites are encouraged to contact Investigator Site Support if it is unclear what information is required to resolve a query.
- Investigator Site Support contact information is available within the Lab manual, Flowchart or *IQVIA Labs Investigator Site Support - IQVIA*

Common Queries, Recommended Response & Best Practices

- *Expired Kits*

Example Query	Reasons	Recommended Responses/Actions	Best Practices
Please confirm if the expired tube(s) for Accession# <ACCESSION#> were replaced with non-expired tubes for sample collection.  	• Expired kits were used • Spare labels were not used	**The expired tube was replaced** • Confirming the replaced tube was taken from Bulk Supplies and providing the new expiration date on label • Providing the new accession number on the replaced tube when possible. **The expired tube was not replaced - Testing will be cancelled** • Confirming the expired tube was not replaced • Providing the disposal plan for the expired tube	• Check expiration date on the label of the kit packaging. This shows the earliest expiration date of all tubes within the kit. • Regularly check the kit storage and the expiration date. Expiry date of individual tubes should be visible on the manufacturers label, where applicable. • We strongly recommend that sites discard kits containing expired tubes. However, if that is the only kit site have at patient visit, the expired tubes should be replaced with non-expired tubes from Bulk Supplies. Ensure that all replacement tubes are properly labeled using the spare labels provided within the lab kit. Before packing tubes for shipping, please check that all tubes have matching accession (barcode) number corresponding to the requisition form in use. • Please remember to conduct regular inventory checks of lab kits and place orders in advance to prevent potential kit shortages.

Common Queries, Recommended Response & Best Practices

- *Question*

Example Query	Reasons	Recommended Responses/Actions	Best Practices
Please confirm answer for <Question> as data was not indicated on requisition form.	• Site did not provide the required administrative details on the requisition form • Unclear information - handwritten answers/comments are difficult to interpret	• Confirmed that the correct <Question> is _____.	• Each question on the requisition form is required. • All provided information must be clear and legible.
	• The requisition form was not sent with the samples	• Send a scanned copy of the requisition form to ISS team via E-mail. • ISS email address is available within the Flowchart, Lab Manual and IQVIA Labs Investigator Site Support – IQVIA.	• The white copy of requisition form should be sent to IQVIA Laboratories along with the first shipment of samples. • The yellow copy of requisition form should be retained on site.

Common Queries, Recommended Response & Best Practices

- *Question*

Example Query	Reasons	Recommended Responses/Actions	Best Practices
Please confirm answer for <Question> as data was not indicated on requisition form.	Using unscheduled or retest or other scheduled kit for sample collection and the visit name on the requisition form was modified. - In such cases, the sample will be accessioned into the database according to the updated visit name. - Query will be raised if the mandatory question is either missing or not marked on the received requisition form.	**When using an alternative lab kit, please follow the steps below to obtain a new requisition form:** 1. Contact ISS team via email /hotline before the sample collection 2. Provide the original accession# on the requisition form/tube label and request the new created requisition form in the correct visit 3. Download, print and fill in all mandatory fields accurately 4. Ensure the accession# on the requisition form matches the accession# on the tube label 5. Ensure that any change on the requisition form is stated with the signature, date and name of the responsible person to provide traceability 6. Return the printed requisition form with the sample to IQVIA Laboratories	• Ensure all questions are completed to maintain data integrity. • Pending questions may impact sample testing and lab report released. • Regularly monitor kit storage and expiration dates to confirm proper storage conditions and validity of kits. • Destroy the expired kits on site and reorder them as needed to avoid impacting sample collection and testing.

Common Queries, Recommended Response & Best Practices

- *Visit Section*

Example Query	Reasons	Recommended Responses/Actions	Best Practices
Previous non-optional visit (s) not in patient history. This is not the next sequential visit. Please clarify if visit name indicated on the requisition form is correct.	• **Missing next scheduled visit** - Not received Visit 2 before Visit 3	• Please confirm if all scheduled visit samples were collected. • Please refer to the LABORATORY EVENT SCHEDULE shown in the study-specific documentation for the full visit name and select the correct visit name, such as Flowchart or Lab Manual . The visit name in the Protocol may differ from the study-specific documentation. Please ensure the selected visit name matches the one on the Flowchart or Lab Manual.	• If no available visit name can be selected, please contact ISS team via email /hotline to confirm visit name. • Investigator Site Support contact information is available within the Flowchart and IQVIA Labs Investigator Site Support – IQVIA.
Please clarify if visit indicated on the requisition form is correct. This query is raised due to missed visit (s) in patient history.			
Please clarify if visit name indicated on the requisition form is correct. This query is raised because the next scheduled visit for this subject has already been received. The visit history of the subject is out of sequence.	• **Out of Sequence Visit** - Current subject visit provided does not match the expected subject visit (e.g. Visit 3 received before Visit 2)		
Please clarify the correct visit name as the subject has completed this visit before. If this is an Unscheduled/Retest visit, please also clarify tests required.	• **Duplicated Visit** - Current visit already exists in the database under a different accession number.		

Common Queries, Recommended Response & Best Practices

- *Visit Section*

Example Query	Reasons	Recommended Responses/Actions	Best Practices
Please provide visit name as it is missing on the sample label <ACCESSION #> <Tube description>.	• Visit name not indicated on the tube label • The provided visit name was incomplete • Visit name not modified when replacement tube was used	• Please confirm if all scheduled visit samples were collected. • Please refer to the LABORATORY EVENT SCHEDULE shown in the study-specific documentation for the full visit name and select the correct visit name, such as Flowchart or Lab Manual . The visit name in the Protocol may differ from the study-specific documentation. Please ensure the selected visit name matches the one on the Flowchart or Lab Manual.	• If no available visit name can be selected, please contact ISS team via email /hotline to confirm visit name. • Investigator Site Support contact information is available within the Flowchart and IQVIA Labs Investigator Site Support – IQVIA.

Image Examples of "Schedule of Events"

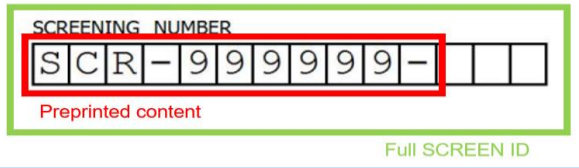
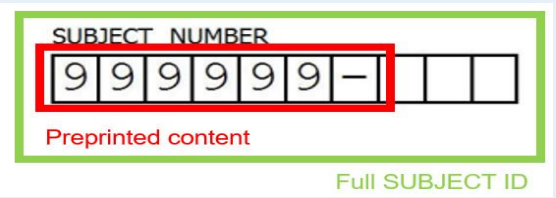
Visit name

SCHEDULE OF TESTING				a					a	b	b	c
		SCREENING	BASELINE	BASELINE TB	WEEK 2	WEEK 4	WEEK 16	WEEK 24	WEEK 24 TB	UNSCH/ RETEST	UNSCH/ RETEST TB	UNSCH STORAGE SAMPLES
	Chemistry	●	●			●	●	●		❍		
	Hematology	●	●			●	●	●		❍		
	Urinalysis	●								❍		
	Lipids	●	●							❍		
	Hepatitis Serology	●								❍		
	Quantiferon TB Plus			●	●				●		●	
	Pharmacokinetic Testing (Primary Samples)					●(4)		●(4)				❍(4)
	Pharmacokinetic Testing (Backup Samples)					●(4)		●(4)				❍(4)
	Blood RNA (Primary Sample)					●		●				❍
	Blood RNA (Backup Sample)					●		●				❍
	OPTIONAL / REFLEX SERVICES											
d	Troponin I	⌘	⌘			⌘	⌘	⌘		❍		
d	CKMB	⌘	⌘			⌘	⌘	⌘		❍		
e	LDL Cholesterol, Direct	⌘	⌘							❍		
f	Direct Bilirubin	⌘	⌘			⌘	⌘	⌘		❍		

Testing/Specimens (Test Name/Panel Name/Specimen Name)	Screening	Visit 1, Visit 2
CBC/DIFF	X	X
BFR	Rf	Rf
HbA1c	X	
Manual Diff (Panel)	Rf	Rf
Chemistry Panel	X	X
Urinalysis (Macro)	X	X
Urinalysis (Micro)	Rf	Rf
Total hCG	O	
TSH	X	
WBC	X	
Ethanol (Urine)	X	
Q-TBNK	X	
PK Sample - Plasma		X

Common Queries, Recommended Response & Best Practices

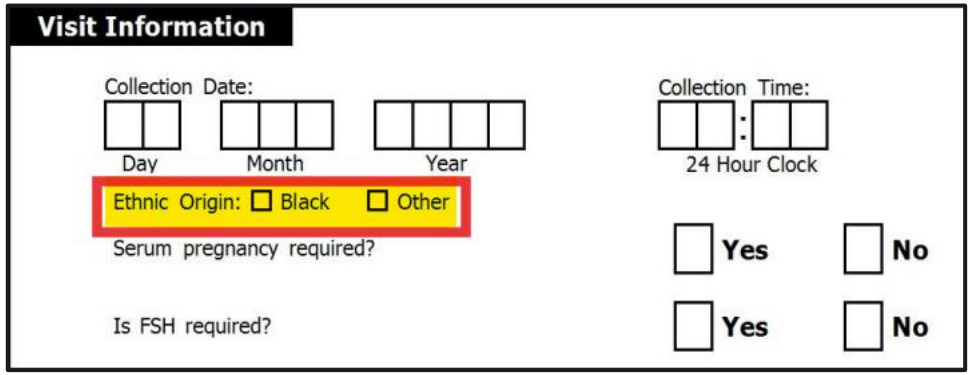
- *Subject Section*

Example Query	Reasons	Recommended Responses/Actions	Best Practices
<SCREEN_ID> is already assigned to another subject at site. Please clarify correct SCREEN ID.	• The lab kit was used from other sites, but the pre-printed site number on the requisition form was not modified. • The subject demographic information on the requisition form does not match the database.	 • **Correct Examples** SCR-999999-999 ✓ • **Avoid** 999999-999 ✗ 999 ✗	• If using kits from other sites, please revise the preprinted content on the requisition form to reflect accurate and consistent information. • Screen ID / Patient ID should be provided in the format specified on the requisition form, including the preprinted content. • The screen ID/patient ID on the tube label must match the ID provided on the requisition form.
<PATIENTID> is already assigned to another subject at site. Please clarify correct Patient ID.		 • **Correct Examples** 999999-999 ✓ • **Avoid** 999 ✗	

Common Queries, Recommended Response & Best Practices

- *Subject Section*

Example Query	Reasons	Recommended Responses/Actions	Best Practices
Subject's Ethnic Origin was not indicated on Lab requisition. Please clarify subject's Ethnic Origin.	• Subject's ethnic origin not indicated on the requisition form (e.g. site uses other visit kit) • Font and checkbox for Ethnic origin is small and is easily missed out	• Indicated that the subject's ethnic origin is OTHER, BLACK or provide in free text.	• Ethnic Origin question is mandatory, and the answer need to be provided for laboratory test calculation.



Common Queries, Recommended Response & Best Practices

- *Sample Section*

Example Query	Reasons	Recommended Responses/Actions	Best Practices
Please confirm correct collection date (DD/MMM/YYYY). Date written on requisition form is significantly earlier than date received at IQVIA Laboratories. Stability of specimen may be in question.	• **Warning notification** - The sample stability exceeded based on the collection date provided on the requisition.	• Fill in date of sample collection in the format of **DD** (Day)/**MMM** (Month)/**YYYY** (Year). • Use uppercase letters for the month. **Example:** 	• All provided information must be clear and legible. • Complete the requisition form during the subject visit - do not prefill it. • Ensure the provided information match the site records. • Ensure that any change on requisition form is stated with the signature, date and name of the responsible person to provide traceability. • Refer to Flowchart or Lab Manual for shipping frequency and courier last call by/last pick up time for courier availability. • During public holidays, refer to holiday memo to ensure courier availability.
Please clarify collection date (DD/MMM/YYYY) as data on requisition form is unclear.	• **Illegible Handwriting** - The handwritten information are nonstandard and difficult to interpret. • **Unauthorized Modification** - Collection date was changed without proper documentation, including the signature, date and name of the responsible person.		
Please provide collection date (DD/MMM/YYYY) as date on requisition form is not provided.	• **Information Not Provided** - The question was overlooked.		

Revision Log

The purpose of this revision log is to document changes made to the version of the data clarification queries guideline for site coordinators provided by IQVIA Laboratories.

Section updated	IQVIA Laboratories Document Version & Date		Revision(s)
	Current	Amended	
N/A	V01 30Jun2020	N/A	N/A
• Cover page • Contents • List of Common Abbreviations • Importance of Responding to Queries • How to View and Respond to Queries in the LTMS Portal • How to Answer a Query? • Common Queries, Recommended Response & Best Practices	V01 30Jun2020	V02 03Jul2025	• Update file name and Logo • Add contents page • Add 'List of Common Abbreviations' • Add 'Importance of Responding to Queries' • Update 'How to View and Respond to Queries in the LTMS Portal' • Update the instructional steps for viewing and responding to Queries in the LTMS Portal • Add instructions for locating contact information for the Investigator Services Support (ISS) team. • Add 'Common Queries, Recommended Response & Best Practices'

Revision Log

The purpose of this revision log is to document changes made to the version of the data clarification queries guideline for site coordinators provided by IQVIA Laboratories.

Section updated	IQVIA Laboratories Document Version & Date		Revision(s)
	Current	Amended	
• Cover Page • Before the main content • Throughout document • Common Queries, Recommended Response & Best Practices	V02 03Jul2025	V03 Aug2025	• Update the title of document to “How To…” • Add ‘About’ section at the beginning to outline the purpose of this document • Add ‘Definition’ of key terms to enhance clarity and avoid confusion. Combine ‘Definition’ and ‘Common Abbreviation’ in the one page. • Substitute some wording to improve readability • Add image examples of ‘Schedule of Events’ • Remove AP queries