Q² Solutions®

Q^2 Solutions How Do I…? Guides for Site Coordinators

How Do I Interpret and Respond to Q^2 Solutions Data Queries?

Version 1.0 30 Jun 2020

Data Clarification Queries

Upon receipt of laboratory samples, Q² Solutions 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.

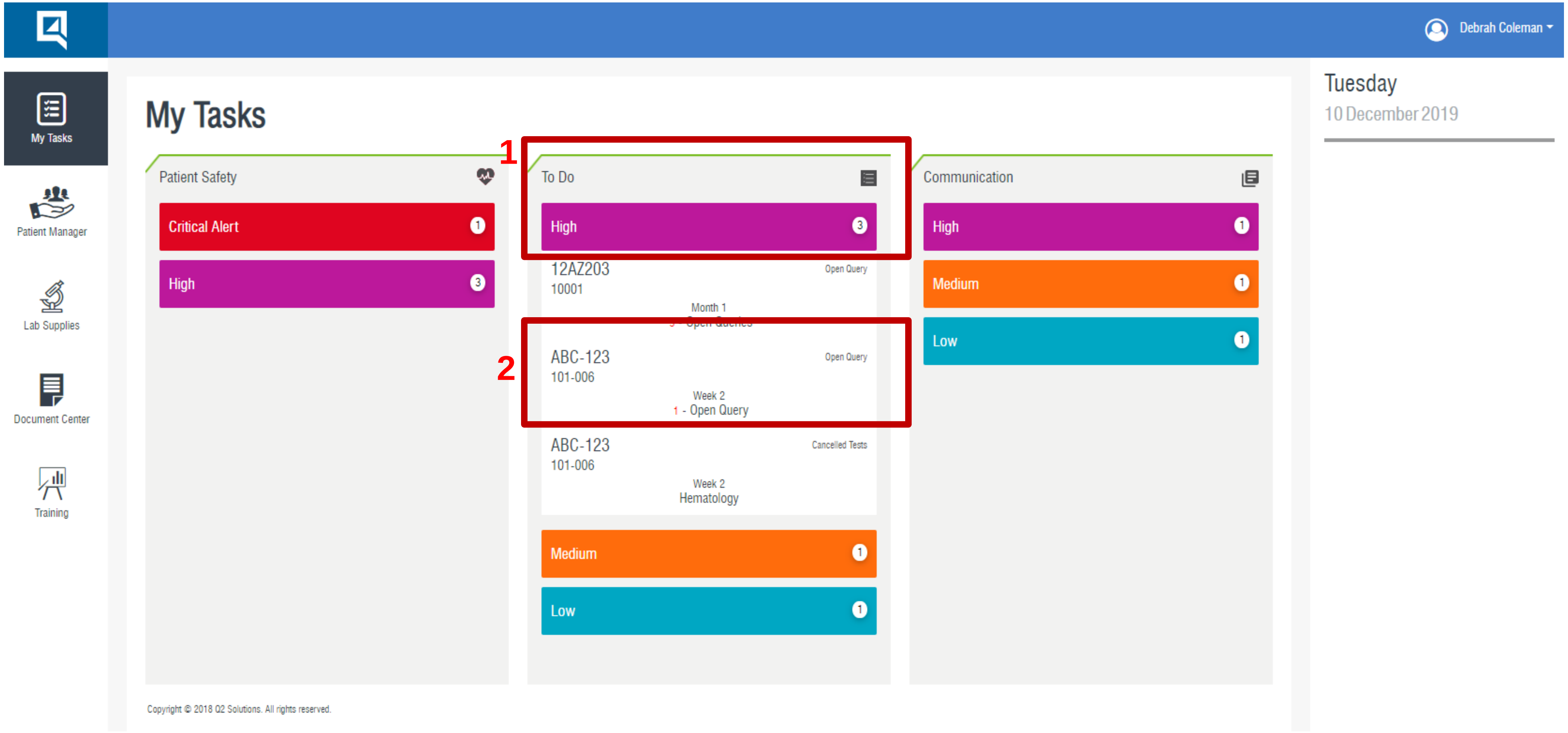
Query	Example
Demographic Discrepancy	Demographic data provided for the current subject visit does not match the Demographic data provided at a previous subject visit.
Out of Sequence Visit	Current subject visit provided does not match the expected subject visit (for example Visit 3 received before Visit 2).
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. This would result in Q² Solutions querying the site for the correct collection date of the frozen sample).
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.

Data Clarification Queries

- Data clarifications 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 CRA/Sponsor via email. The project management team will also escalate these data clarifications to the responsible clinical research associates or site monitors.
- It may not be possible to issue the Laboratory Reports for a visit which has one or more data 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.

How to View and Respond to Data Queries in the LTMS Portal

- Any open Data Query that requires an action will be visible under ‘My Tasks’.
  1 - Click on ‘High’ under ‘To Do’ to view tasks requiring an action.
  2 - Click on Open Queries to view the queries for the associated visit.



How to View and Respond to Data Queries in the LTMS Portal

- In the Visit Detail section, click on the 'Query' tab and review the 'Query' question.
- A response to the question should be entered in the 'Send Your Response' box and any attachments can be provided by selected 'Choose File'. Once all information has been provided click 'Submit'.
- Repeat if there is more than one query.
- When all queries for a visit have been answered, the notification will automatically disappear.