Query Process - Generating, Reviewing, Tracking, and Resolving Queries

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Data Query Process - An Overview

- Generate data discrepancies/queries
- Automatic vs. Manual queries
- Review queries
- Internal resolution
- External resolution - Query processing
- Track queries
- Resolve and receive queries
- Review query responses
- Apply resolution
- Documentation
Query Process - Generating Discrepancies

- Queries or data discrepancies present potential data problems and propose resolutions to those problems.

- Automatic queries

- Manual Queries

- Automatic queries through data cleaning / validation process

- Manual discrepancies from flags during data entry, QA checks etc.
Examples of Automatically Generated Queries

- Missing item values
- Variations from an expected range
- Inconsistencies between values within forms and/or between multiple forms
- Missing or late CRFs
- Duplicate CRFs
- Missing dates.
Automatically Generated Query Example

Family Health International
ID: 7796
Data Problem Summary

- Study: 9725
- Study Title: Sanitary Shedding Study
- Error Type: VALIDATE
- Center: 1515
- PN: 100998
- FSN: 190076

Problem:
For Visit Code: [54] Page 1 of 2
Problem: Item 2a is missing.

Response:
Check the '2a' box.

Automatically Generated

Example of a missing item number 2a
Examples of Manual Queries

- Missing Header Information
- Illegible Data
- Missing Pages
- Blank CRFs
- Invalid Patient Numbers
- Invalid Center Numbers
- Invalid Dates
- Form Sequence Numbers (FSN) that differ on multiple pages of the CRFs
Manual Queries cont...

- Unclear messages written in the body of the CRF by the site
- Information incorrectly crossed out on CRF
- Data that cannot be entered as shown on the CRF
- Items that have two written answers but only one is required
- Queries that were returned without a signature and date, or answered incorrectly at the site
Manual Query Example

Two written answers
Automatic Query vs Manual Query

Automatic

Manual

Site manual query
Reviewing is the process of comparing data on CRFs to data in the database.

- If the problem reported on the query is valid, then the query is sent to the site for resolution.
- If the problem reported on the query is a result of a data entry error or another valid reason, then the query will not be sent to the site.
Reviewing Queries

Before reviewing individual queries

- Confirm that the program or error spec that generated the queries is correct
- Review the frequency distribution of new queries
  - If the same query was generated for each participant, perhaps there is a problem with the query specification or the program code that generated the query
Review Each Individual Query

- Determine if query is correct
- Are there handwritten notes on the CRF that will help resolve the query? – Internal resolution
- Do multiple queries relate to one problem? – Link queries
# Report Examples

## Number of New (N) Queries

**Report: GSS_9726/ Frequency Distribution by All Query Status**

<table>
<thead>
<tr>
<th>STATUS</th>
<th>COUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACD</td>
<td>10</td>
</tr>
<tr>
<td>CU</td>
<td>2</td>
</tr>
<tr>
<td>N</td>
<td>1898</td>
</tr>
</tbody>
</table>
# Frequency Distribution of New Queries

## Report: GSS_9726/ Frequency Distribution by Query

<table>
<thead>
<tr>
<th>Data Table</th>
<th>Name</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>FollowUp</td>
<td>Report1</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Report2</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>Report5</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Report7</td>
<td>5</td>
</tr>
<tr>
<td>Final</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>111</td>
<td></td>
</tr>
<tr>
<td></td>
<td>111</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>
### Report: GSS_9726 / Details New Discrepancies

<table>
<thead>
<tr>
<th>CENTER=1534</th>
<th>PN=102308</th>
<th>STATUS=N</th>
</tr>
</thead>
<tbody>
<tr>
<td>PANEL</td>
<td>ERROR_ID</td>
<td>CT_REGID</td>
</tr>
<tr>
<td>GLR</td>
<td>3159</td>
<td>1,LVENKAT.TEB 6113159.301</td>
</tr>
<tr>
<td>CENTER=1534</td>
<td>PN=102430</td>
<td>STATUS=N</td>
</tr>
<tr>
<td>PANEL</td>
<td>ERROR_ID</td>
<td>CT_REGID</td>
</tr>
<tr>
<td>GLR</td>
<td>4500</td>
<td>1,LVENKAT. TES Ner 0164500.001</td>
</tr>
</tbody>
</table>

**Multiple Queries (3) related to one problem**
Tracking Queries

All queries are tracked through the system database regardless whether they are automatic or manual queries.
Tracking Queries

- Each query has a unique identifier (number)
- Track the following information:
  - Site query is sent to
  - Date sent to site
  - Date received from site
  - Date query is resolved
Example of Tracking Queries

Site query is sent to

Date received from site

Date query is resolved

Date sent to Site
Received Queries From Site

- When queries are received back from the site they are processed and date stamped. They are then forwarded to the Query Manager for resolution through the system. Each query has a unique Discrepancy Id number that is used to locate that discrepancy in the system.

- The query responses received from the data collection site are reviewed.

- If no further clarification is required, the database and the CRFs are updated based on the responses on the DPSFs.
Example of Received Queries
4.9.3 Any change or correction to a CRF should be dated, initialed, and explained and should not obscure the original entry. That is, an audit trail should be maintained. This applies to both written and electronic changes or corrections.
Queries are resolved by updating the database with the information recorded on the DPSF from the site. The query status is updated.

The DPSF from the site, initialed and dated by the Query Manager, is attached to the CRF.
Resolving Queries - DPSF

Initialed and dated by Query manager
5.5.3 (c) When using electronic trial data handling and/or remote electronic trial systems, the sponsor should ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail).