In the absence of patient-level databases, multi-national, retrospective chart review studies can be implemented to provide valuable real-world data to inform evaluations of treatment patterns, resource utilization, each of care, clinical and economic safety.

Data quality control is challenging both as a result of your potential for human error in the local care medical chart, as an result of data abstraction and data entry processes.

**METHODS**

Table 1 summarizes the core data quality control (QC) mechanisms across the ten recent chart review case studies.

**RESULTS**

Table 1. Summary of Chart Review Design Parameters

<table>
<thead>
<tr>
<th>Countries</th>
<th>Data Variables Collected</th>
<th>Electronic Data Capture (EDC)</th>
<th>CRF QC</th>
<th>Critical Study Variables Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>Advance work (post) and measurement partners</td>
<td>EDC queries</td>
<td>CRF QC</td>
<td>Built into EDC systems.</td>
</tr>
<tr>
<td>Europe (EU)</td>
<td>Clinical characteristics and clinical/safety outcomes</td>
<td>CRF QC</td>
<td>Critical Study Variables Process</td>
<td>CRF QC</td>
</tr>
<tr>
<td>ROW</td>
<td>Clinical characteristics and clinical/safety outcomes</td>
<td>CRF QC</td>
<td>Critical Study Variables Process</td>
<td>CRF QC</td>
</tr>
<tr>
<td>US</td>
<td>Clinical characteristics and clinical/safety outcomes</td>
<td>CRF QC</td>
<td>Critical Study Variables Process</td>
<td>CRF QC</td>
</tr>
<tr>
<td>EU</td>
<td>Clinical characteristics and clinical/safety outcomes</td>
<td>CRF QC</td>
<td>Critical Study Variables Process</td>
<td>CRF QC</td>
</tr>
</tbody>
</table>

**CONCLUSION**

Data QC in the EDC System

It is reported in the EDC system include a robust central platform that enables selection of critical variables (broad or criterion selected) and routing of eligibility screening to reduce latency time (see Figure 3).

**DATA QC IN CASE REPORT FORM (CRF) DEVELOPMENT AND DATA ABSTRACTION**

**REFERENCES**

**STUDY DESIGN**

- **Objectives:**
  - To provide recommendations for improving chart review data quality control mechanisms.

- **Methods:**
  - Case studies included to describe patient demographics and clinical characteristics, treatment patterns, health status, and drug utilization patterns, including all applicable and safety relevant data elements.

- **Results:**
  - Table 1 summarizes the core data quality control (QC) mechanisms across the ten recent chart review case studies.

**DISCUSSION**

- **Soft edits**
  - Soft edits are recommended to reduce additional transcriptions errors that may occur if using paper CRFs for initial data entry from medical charts.

- **Hard edits**
  - Hard edits are required for main data variables not removing unnecessary data points required to fulfill the analysis and that testing of the CRF should occur in at least one medical chart per country prior to finalizing the protocol.

- **Clinical characteristics and clinical/safety outcomes**
  - CRF QC critical study variables to be generated from patient medical charts for cross-validation at the site.

- **Data QC in Case Report Form (CRF) Development and Data Abstraction**
  - Data QC can be performed on the CRF to ensure reliability and reduce the need for target cohort re-definitions.

**CONCLUSION**

- **To provide recommendations for improving chart review data quality control mechanisms.**

**DATA QC IN THE EDC SYSTEM**

- **Sampling Frame Selected by Site Staff**
  - Site staff will have to identify and validate data abstraction and data entry processes.

- **EDC QC in Case Report Form (CRF) Development and Data Abstraction**
  - EDC QC is required pending QC findings.

- **EDC Screening for Eligibility Documentation**
  - EDC QC is required pending QC findings.

- **DM will temporarily remove EDC access to all site staff until QC is complete.**
  - DM will compare re-abstracted data with EDC data to identify and document any discrepancies.

- **DM will perform reconciliation process to be repeated as specified for the study.**
  - DM will review and release the next case to the site once the reconciliation process is complete.