

Distributed Queries for Quality Control Checks in Clinical Trials

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Operational Quality Control (QC) checks are standard practice in clinical trials and ensure ongoing compliance with the study protocol, standard operating procedures (SOPs) and Good Clinical Practice (GCP). We present a method for defining QC checks as distributed queries over case report forms (CRF) and clinical imaging data-sources. Our distributed query system can integrate time-sensitive information in order to populate QC checks that can facilitate discrepancy resolution workflow in clinical trials.

Introduction

QC checks are a standard part of the operational workflow of clinical trials that inform project managers (PMs) of protocol, SOP, and GCP violations. They help ensure timely identification and resolution of violations, which can include data discrepancies, inclusion/exclusion criteria errors, adverse events, etc. Many times the information needed to identify these violations, particularly in multi-site clinical trials, is not housed at a single data-source and can only be triggered after monthly or quarterly data-transfers to a central database. Recognizing QC issues in a timely manner can save time and money by identifying errors that can lead to lost data.

QC checks can be managed by a clinical research organization (CRO) for a substantial fee or extracted from a locally administered clinical data management system (CDMS). However, many principle investigators cannot afford a CRO and rely on their PMs to ensure high quality data collection using a CDMS. Maintaining rigorous QC in trials with an imaging component is further complicated, as imaging data is stored in a separate database and protocols generally require imaging to be completed in a small window (e.g., 7 days) with respect to clinical exams. Thus, specifying reusable, standard QC checks based on information from multiple data-sources will enable PMs to actively capture errors and clarify discrepancies with sites in a timely and cost effective manner.

Our Query Manager (QM) application enables users to compose, edit, evaluate, save, share, and discover queries¹, including distributed QC checks. The QM generates unique identifiers for stored queries, and the associated Query Execution Service (QES)

provides a RESTful interface for evaluating QM queries based on those identifiers. We demonstrate the QM's utility for QC checks by defining a distributed XML query (XQuery) that integrates CRF information from the REDCap² electronic data capture system and imaging metadata from the eXtensible Neuroimaging Archive Toolkit³ (XNAT).

Our example query identifies imaging exams that have been labeled as "unusable" in the XNAT database, then checks the REDCap database for the clinical exam date for all patients with unusable imaging exams. An XML summary is returned that informs the PM about the number of days left to perform an action item (i.e., acquire a "useable" quality exam) and remain within the window necessary for a data time point to be valid (figure 1).

```
- <study project="np">
- <image-check>
  <description>xnat:quality = unusable</description>
  <action>request rescans within 7 days of clinical exam</action>
- <participant label="NP001">
  <xnat:quality>unusable</xnat:quality>
  <redcap-date>2009-12-12</redcap-date>
  <rescan-window>4 days</rescan-window>
</participant>
</image-check>
</study>
```

Figure 1. Example query result summarizing the time left to acquire an imaging exam with "useable" quality for the current visit. (Demo query at <http://tinyurl.com/27z2qme>)

Conclusion

The QM supports the definition of QC checks as distributed queries over multiple data-sources that return XML. The QES provides a RESTful interface for evaluating such definitions and provides resolvable unique identifiers (URIs) for the results (potentially usable for QC check report generation). Such queries can be issued against REDCap and XNAT data-sources, providing real-time information about distributed QC check status.

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References

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