An illustration of how quality information can be integrated across organisations

October 13, 2010
What is the Quality Information Exchange (QIX)

The Quality Information Exchange (QIX) is a suite of tools and services to enable research organisations to collaborate effectively with their partners and each other.

- **Quality Information Exchange** is the ability to jointly exchange information about:
  - (Audit) scheduling and planning
  - (Auditor) performance, auditee feedback and service level of service providers
  - Findings, including positive, 'non-findings' to create a quality baseline

- **Exchange of GCP QA information** enables:
  - Better scheduling, planning and targeting of audits
  - Risk baseline specification, benchmarking and objective comparison of performance

- This presentation is an example and illustration of:
  - How operational data for risk management in GCP QA can be captured and shared
  - The example is focussed on transactional and performance data not medical content
  - The principles illustrated here can be applied to a broad set of trial planning activities
QIX software modules complement each other and offer operational flexibility to suit individual organisational needs and extensibility to include new data sources.

The software is available as a hosted service so that users can access it worldwide, eliminate maintenance and enable the coordination of activities and mapping of data.
Collecting and managing audit requests already creates valuable risk information and helps to focus QA resources more effectively.
Packaging audits and creating checklists enables audit planners to specify the focus and details that need to be audited in a structured and standardised way.
Structuring Findings (and ‘non-findings’)

The audit report findings ‘grid’ enables like-for-like comparisons between findings and for organisations to map findings to a common meaning.

This also enables organisations to map their terms to a common environment and report on both negative ‘findings’ & positive ‘non-findings’ to create quality baselines.
Writing reports is facilitated as a large number of the fields are pre-populated and the findings can be published to designated partners.
The findings matrix can be directly linked to CAPAs and mitigation actions with select access for auditees to propose edits for reports and CAPAs during the approval loop.

Create and implement a contingency plan by end of the year.
Setting Trust Levels & Ensuring Confidentiality

Trust levels and role-based access ensure that only anonymous data specifically designated for release can be seen by others and access is actively granted.

- **Level 0**: Use this as the default level if you do not wish to share any information.
  - All information only for internal company users.
  - Data can be used only by i4sm for anonymized aggregated benchmarking and analysis.

- **Level 1**: At Level 1, only the following information will be exposed:
  - Audit Location, Country, & City
  - Audit Category

- **Level 2**: At Level 2, information from lower levels and the following information will be shared:
  - Audit Objective

- **Level 3**: At Level 3, information from lower levels and the following information will be shared:
  - Audit Report Summary
  - Do Findings Exist in the Audit Report

- **Level 4**: At Level 4, information from lower levels and the following information will be shared:
  - Audit Checklist Columns (Type, System, Processes, Deliverables)
  - Audit Report Columns (Findings, Class) Only finding rows where Proprietary = No

- **Level 5**: At Level 5, information from lower levels and the following information will be shared:
  - Audit Report Columns (Comment) Only finding rows where Proprietary = No
Confidentiality concerns can also be addressed by segmenting data into individual activities that do not compromise the auditee or the auditor and by anonymising it.

<table>
<thead>
<tr>
<th>Type of Audit Examples</th>
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<th>Approval</th>
<th>Schedule Planning</th>
<th>Auditor Selection</th>
<th>Prepare</th>
<th>Conduct</th>
<th>Report</th>
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<tbody>
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- **Confidentiality according to preference**
- **Confidentiality agreement required**
- **Confidential**
Why would an organisation participate?

Organisations will actively share information if there are tangible benefits that overcome reservations about confidentiality or company-specific methods.

- All participants can actively benefit from
  - Shared information that provides new perspective on internal data
  - Access to a pool of standardised and 'credentialised' service provider and audit data
  - Analysis of trends, quality heat maps and warning flags for outliers

- This prototype is focused on GCP QA although the same principles apply for
  - Reports from monitoring visits or inspections
  - Pre-inspection visits and other quality data collection processes
  - Any other data source (e.g., QRM, ADAMON, study quality assessment data)

- Smaller organisations can manage their audit process
  - Without paying substantial license fees for COTS software
  - Can benefit from the larger scale of audit activity and share audit packages
  - Can improve the transparency and robustness of their processes