Document Overview

The purpose of this document is to capture information needed to assist key leaders:

1 – Determine best place to inject data standards into Clinical Processes and Operations
2 – Clearly understand the expected Return on Investment (ROI) with respect to leveraging standards at Clinical
    Data pain points
3 – Realize Clinical Data/Information ROI in the form of:
      - Improved Decision Making
      - Less effort to produce accurate reports
      - Ability to raise maturity model of clinical trial operations

The questions contained in this questionnaire will help the Project Team gain an understanding of the current state of Clinical Business and Technical Capability and Operations as well as Insights into the Future Vision for how the organization intends to advance current capabilities, operational effectiveness and key business outcomes in these areas to realize growth.

Two Sections

The Questionnaire is segmented into two sections: 1) Higher Level, Broader, More Strategic Scoping Questions and 2) Lower Level, More Tactical and Specific Technical and Operational questions (Strategic Scoping Questions are provided in a separate document)

Intangibles

Questions are also posed to develop key insights and Identify some of the unstructured processes and gaps in data, information and system use which combined, provide Leaders and the Project Team an understanding of the operational nuances in the operating and computing environments.

Artifacts in 4 Core Areas

The Project Team, through the process of completing the questionnaire, also plans to gather key artifacts, review current state content with regard to: 1) Clinical Data and Information Acquisition and Use, 2) Organizational Structures and Roles/Responsibilities with regard to Clinical Data, Information and Operations, 3) Clinical Operating Procedures, Policies and Process and 4) Key Clinical Technical Systems, Applications and Tools.

Interviewee Profile and Date/Time Stamp

The following information is to be completed at the time of the interview:

Date, Time and Location
of the Interview:

_____

Interviewee or Group
Organization and Role:

_____

Name of Immediate
Supervision& Number of
Direct Reports (and Staff
Roles (If applicable))

_____

_____

_____

Interview Participants:

_____

_____

_____

Detailed Technical and Operational Questions

Clinical Data, Information and Operations

- By what means (tools, processes, communication forums etc.)does the Clinical Organization:
  - Obtain Data (how many data sources/feeds)
    - Formats of all data sources? / File/ Data Types? (Numbers of Each)
    - Indicate any industry standards being followed for each data source.
  - Use Data (How many systems and people use Clinical Data and Information)
  - How data is reused and/or harmonized – who does this reuse/harmonization? When, when, for what purpose and how? Any data/information governance in place or planned?
  - Where is Clinical Data Stored (how many places/forms)
    - How often is clinical data backed-up, archived
    - What data redundancy mechanisms and tools are in place?
- What processes are in place that support Clinical Data, Information and Operations? What SOPs (names, numbers and owners)
- What is the Current Volume, Mix of Clinical Data?
- How does the Clinical Consumer obtain clinical data/information? (Please provide existing High Level Data/ Information Flow and Value Maps)
  - Are they any derivative processes (other organizations and processes etc.) that use and modify Clinical Data (name occurrences, uses, stakeholders, purpose etc.)
  - How are these processes similar/different for the Core Clinical Data/Information Processes?
- Are there key performance indicators or metrics that relate to Clinical Data and Information?
- How often do leaders and staff and line professionals of the organization meet and talk about shared Clinical Data/Information, common definitions, data quality targets, supporting goals, plans and operations?
- Do the leaders of these organizations currently collaborate, plan or share common goals with respect to Clinical Data, Information and Operations?

Clinical Data and Information Sharing

Administration

- Current metrics or performance (business or tech) issues
- Vision for future process, system, integrations with other systems, and how the information is organized
- What does success look like and how to measure it

Clinical Data Architecture

Describe Current business processes; highlight any pain points and systems used throughout the process

- Obtaining Clinical Data and Information
- Creating /importing Clinical Data and Information
- Clinical Data and Information Data Structures, Models and Meta Data (Documentation, Processes?)
- Clinical Data and Information Data Governance (Roles :Data Steward? Compliance Lead? Archivist?, Business Rules, Data Quality, Documentation, Processes?)
- Clinical Data and Information Data Classification (Existing Data Classification Schemes?, Different Types, Care and Maintenance? Security considerations)
- Periodic Review/ Cleansing of Data? (Any MDM Efforts, Data Quality improvement efforts, Activities, Rules, Standards?)

Clinical Data and Information Sharing

What are the systems, Tools and Touch points for Clinical Data and Information? Please provide any diagrams or documentation regarding the current state of clinical data and information sharing, data flows.

- ETMF? (existing or planned)?
- CTMS? (existing or planned)?
- EDMS (existing or planned)?
- Operational Data Stores? (existing or planned)?
- Data warehouses? (existing or planned)?
- Clinical Data Exchange via Health Information Exchanges (existing or planned)?
- Linkages to/ Use of Hospital/Provider EHRs? (existing or planned)?

Data Management

- In a narrative form, can you describe the core data flows, uses and applications of Clinical Data and Information?
- Are there any capabilities that you currently need that current systems and Tools don't provide?
- What categories of data does the Clinical Organization generate?
    – What are the volumes of each kind of data/information
- What are various applications and uses associated with (processes/departments/drugs/trials/etc.) core clinical data/information?
- Where do gaps exist (if any) between necessary business processes and the data and information needed to support them?
- What are the most effective and streamlined Clinical Data/Information Process Flows? What works best currently?
- What is the most cumbersome/difficult aspect of Clinical Data/Information Process Flows?(Include data/information flow &use).
- Are there any variations of the clinical data/information process flow driven by customer/partner requirements?

Data Management (con't)

- What tools do you use to generate data and information reports (Word/Excel/other)?
  - Are any templates used for Data/Information Management? Data Security, Data Quality? (Please provide sample documents for review)
    - How Many? For What Purpose?
    - Is there one person or team responsible for managing data flows/ stores/ records?
- How is Clinical Data/Information(overall – and as a library) Quality checked?
  - Are Data/ Information stores ever replicated (why and for what purpose)?
- Is any of the Clinical Data/Information restricted or regulated in any way? If so, how? Country specific regulatory aspects?
- Are any of aspects of your current clinical data/information (or parts of data/information) re-purposed or re-used? (Why? how? when? by whom?)
- Is any of the Clinical Data/Information translated into other languages?
- Is any of the Clinical Data/Information subject to legal hold?
- Is any of the Clinical Data/Information subject to unique security and/or compliance requirements?
- Is your Clinical Data/Information required to be reviewed on a regular basis?
- Are any of your data/information management processes governed by documented rules?
- What works well concerning Clinical Data/Information processes?
  - What process changes need to be made?
- Are Clinical Data and Information Management system metrics tracked? And is this of any concern?

Collaboration

- How, When and Why do you share Clinical Data/Information (what are the most frequent/ common instances)
  - How do you communicate to collaborators that action is required from them?
- Do you have standard processes for capturing Clinical Data and Information? What are they (list all)
- What means are used to share Clinical Data/Information with internal and external stakeholders(list all data stores, exchanges and touch points)?
- Which teams need to share clinical data/information? Why?
- How could data/information sharing between teams be improved?
- What works best in terms of data sharing currently? How?
- What aspects of data sharing could be improved? Why?

Search Capability

- How do you go about finding specific clinical information and data?

- How easy is it to find the information needed?

- What are the key properties or metadata used in clinical data management?

- How does your information search vary by date type or information category?

- What data security is used to allow or restrict access to specific datasets or repositories?

- What means of finding information work well?

- What would make your life easier in terms of trying finding and storing clinical data and information?

- Is there a desire to move to more self service oriented reporting? Why and in what areas?

Reporting and Printing

- Do you currently use any reports around clinical data/information management?

    - List any and all sources and uses of Clinical Data and Information Reporting

    - If yes, how do you create them?

    - If yes, where do you store them?

    - If yes, who are they distributed to? How? Why? When?

- Are there additional reports or reporting capabilities you would like to have access to?

- Do you have special Clinical Data/Information printing requirements?

- How is Clinical Data updated? Archived and stored?

- How do you know which version of a data source is the most accurate or current if there is more than one instance and/or source of the data/information?

- Do you currently submit any clinical data/information to regulatory or public health authorities, or use data that has been approved by the health authorities? (How?, When?, Why? To Whom?)

- How do you manage data/information sources that are approved by regulatory, health authorities or that need to be maintained for auditing purposes?

Data Management Systems

- What Data Management Systems do you currently use to manage clinical data and information?
    - What are the challenges you face in managing data in your current operating environment?
    - What functionality would you expect to add the most value with regard to future state data management systems, applications or tools?
- Do different working teams within the organization require specialized clinical data/information? (Who? What? Why? When?)
- What is the process for handling data queries and reconciling / requesting missing data? Please provide any SOPs or high level diagrams.
- What do you dislike about the current systems, tools and process for working with clinical data and operations? What, if anything, do you see as the biggest barriers to user adoption of new and/or advanced data/information management technology?

Technical Capability and System Performance

- Does the IT Organization have a strategic planning process for acquisition and maintenance of clinical data and information? Please provide a sample/example.
- Did the CIO coordinate the development of the IT strategic plan with stakeholders in Clinical Operations?
- Do you know and believe in the organization's IT strategy? Is it realistic?
- Are IT projects prioritized based on the needs of Clinical Operations? What criteria are used in decision making?
- Does the Organization's IT architecture reflect the organization's strategic goals? And the Goals of Clinical Operations?
- Have implementations of the organization's IT strategies and plans produced tangible improvements in Clinical Business Capability and Practices overall?
- What are the biggest IT Challenges facing Clinical Operations?
- What words would you use to describe the IT Infrastructure and Support of Clinical Operations?
- What are three specific and immediate Technological Changes you would recommend for Clinical Operations?
    - And for the Organization as a whole?