



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 (Detailed Clinical Data Operations 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
Supervisor & Number of
Direct Reports (and Staff
Roles (If applicable))

Interview Participants:



Strategic Scoping Questions

Overall Strategic Goals

1. Can you share or provide documents to support the last three years of the Organization's (if defined) Corporate Goals?
2. Where do you see as the greatest areas of potential and Growth for the Company?
3. What Percentage of your business and work is US Centric vs. XUS (outside the US)?
 - In what other countries do you support clients?
4. What is the Organization's History for Achieving Corporate Goals? (ex: Overachieving (exceed goals), Realistic (Regularly Meet Goals), Conservative (Plan and Achieve Steady, Incremental Growth))
5. How does the organization enable and incent business units and professionals to achieve goals.
6. Can you share the Clinical Operations and/or Clinical Data Operations Goals for the last three years?
7. How do the Clinical Operations Goals Align and Support Corporate Goals?
 - What Key Performance Indicators (KPIs) or Critical Success Factors (CSFs) are most important in aligning Clin Ops with Corporate Goals going forward from your perspective?
8. Of the three goals of this engagement 1) – to determine the best place to inject data standards into Clinical Processes and Operations; 2) to clearly understand the expected Return on Investment (ROI) with respect to leveraging standards at Clinical Data pain points; and 3) to realize Clinical Data/Information ROI in the form of: Improved Decision Making, Less effort to produce accurate reports and ability to raise maturity model of clinical trial operations...which is most important (rate by percentage) in your view, and why?

Clinical Data, Information and Operations Goals

1. Can you describe how the leaders of the organization work to acquire access, analyze, use, reuse and optimize Clinical data and information?
2. What are top three challenges with regard to Clinical Data, Information and Operations?
Please provide answers with regard to:
Organizational Structures -
Operational Policies and Procedures -
Technology Operations and Platforms –
3. If you could make one major advance toward the future state in Clinical Data, Information and Operations in 2016 through the near-term future what would it be?
4. In your mind what are the next three business steps to achieving more utility and value out of Clinical Data, Information and Operations?
5. List core business processes of the organization that are expected to be impacted by Clinical Data, Information and Operations Goals from your perspective.



Clinical Leaders and Stakeholders

1. Who are key Leaders (both direct leaders and indirect influencers) of Clinical Data, Information and Operations?
2. Can you provide an organizational View (Org Chart) for the Clinical Organization and provide a cultural overview (using adjectives, telling stories and examples and personal narratives)
3. Can you provide a list of the Key Stakeholders, both internal and external (either providers or consumers) of Clinical Data and Information?
4. How would you rate the Teamwork and Connectedness of Clinical Operations Leaders (both direct and indirect) and stakeholders?
5. Can you associate the key Leaders (Core Clinical Stakeholders/Owners) with the Company's Core Business Processes listed earlier?
6. Who are the key "external" stakeholders of Clinical Operations that need to be kept in mind (if any)?
7. What are the most obvious Strengths and Weaknesses of Clinical Operations Leaders?
Strengths...
Weaknesses...
8. How do these leaders effect and enable Data and Information exchange between and among core Clinical Stakeholders?
9. What broader (internal and external) issues (if any), in your view, affect the productive and effective exchange and use of Clinical Data and Information?
10. What are the KPIs that Core Clinical Stakeholders/Owners are targeting for improvement with this initiative?

Clinical Data Collection, Use, Storage, Governance, Reuse, Harmonization, and Integration

1. How is this done today?
2. Does the Organization track Clinical Data and Information Use across business units and operating environments (Internal and External)?
3. Does the organization maintain any activities or tools to promote Clinical Data and Information Use, Sharing, Optimization, Trending (Analytics) and Storage?
4. What works in the current state of Clinical Operations Data and Information Use, what doesn't?
What's working...?
What isn't working...?
What's missing...?
What's not important going forward...?
5. What broader systems, tools and operations, in your view, are needed and/or necessary for effective Clinical Data and Information Exchange and operations?



Technical Capability and System Performance (Goals are to Increase and Improve)

1. Please provide some detailed information with regard to Clinical Data, Information and Operations:
 - Information/Data Security
 - Special data handling for Private manufacturers?
 - Seamless Encryption at various levels (what levels?)
 - Secure data/information exchange with Customers (via the Web) – or interchanges (explore regulatory compliance and guidelines)
 - Secure Data Portability (data on laptops)
 - System Resiliency/ Redundancy (Enterprise back-up of Clinical Data and Information)
 - Cohesive Technology footprint (any exciting integration of tools) (ex: Enterprise Architecture, Standards)
 - Reference Architecture, Data/Information Model
 - Vendor/ Partner Information and Data Requirements and Rules
 - “Synergies with regard to Clinical Data and Information across other businesses/business units”?
2. What are top three Issues with Regard to Clinical Operations and System Performance and Technical Capability?
3. What is the Long Term Future Vision with Regard to System Performance and Technical Capability (provide a narrative)
4. In your mind what are the next three business steps to achieving advances in technical performance and capability with regard to Clinical Data, Information and Operations?

Other?

1. Are there any other important Administrative, Operational or Technical Goals that affect Clinical Data and Information Exchange and Use?
2. Why are these considerations important?
3. What is required, in your mind, to advance awareness and action on this/these fronts?