Liquent

Information Technology Strategic Planning; Public Meeting

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Caveats

- Focused on questions asked that impact areas where Liquent interacts with stakeholders

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What would help improve the quality of electronic submissions to the agency?

- Areas where FDA has influence on quality
  - Standards definition
  - Consistency of standards within FDA
  - Communication with stakeholders
- Standards Definition
  - Global standards desired
  - Submission validation criteria
  - SPL
    - Clarification on FDA's thoughts on PLR and MedDRA and SNOMED coding
    - Improved feedback mechanism communicating non-critical technical issues and formal process for correcting

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What would help improve the quality of electronic submissions to the agency? continued

- Consistency of standards within FDA
  - Standard rules for electronic submissions across FDA centers
  - Incorporation of DDMAC and APLS submissions into eCTD submissions
  - Increased communication between Reviewers and Office of Business Process
    - Provide instructions on how to handle requests for information outside of typical eCTD specification
      - Example: Received requests for dataset programs

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What would help improve the quality of electronic submissions to the agency? continued

- Communication with stakeholders
  - Guidance clarification
    - Study Tagging Files
    - Cross application references
    - Hyperlinking
    - INDs in eCTD format
  - Lessons learned from submissions received
  - Understanding of validation criteria
  - Expectations regarding documentation
    - Inter and intra-document links (including lifecycle)
    - Document level tables of contents
  - LCM operator usage
  - Reviewer training

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What would help increase the quantity of electronic submissions to the agency?

- Provide temporary incentives for electronic submissions
  - Reduced fees
  - Faster action dates
- Increase acceptance with FDA
  - DDMAC and APLS submissions
    - Provide graphical representation with request option for physical sample?
    - Provide text portions as separate PDF for easier review?

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How would you prioritize these quality and quantity improvements?

Improvement Area	Priority
Standards Definition	3
Consistency of standards within FDA	1
Communication with stakeholders	2
Provide temporary incentives for electronic submissions	5
Increase acceptance with FDA	4

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What data standards are needed to implement these improvements?

- Standard for exchange of promotional materials
- Communication Exchange
- SDTM and SEND implementation
- Considerations for XML document exchange
  - Protocol
  - Case Report Forms
  - Stability
  - Others?

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How should FDA engage stakeholders while developing, testing, and implementing these solutions?

- Public Meetings
- Ability to comment
- Workgroup/Testing Teams
- Post Mortem Teams for ongoing improvement

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What lead time is needed for stakeholders to respond to and be in alignment with FDA initiatives?

- Depends on complexity of change
  - Minor
    - Example: change to allowable values for STF attributes, additions to dictionary lists for SPL, electronic signature
    - 3 – 9 months from final standard
  - Moderate
    - Example: Structured Product Labeling, move to eCTD v3.3 specification
    - 1 year from final standard
  - Major
    - Example: move to Regulated Product Submission, CDISC standards
    - 2 years from final standard

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What data standards areas provide the greatest challenge?

- Standards associated with unstructured content
  - Protocol Representation
  - Structured Product Labeling
  - Etc.
- Standards associated with content that will have a continual lifecycle over many years
- Most difficult for industry to implement and for the agency to manage

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What approaches will facilitate the most effective & efficient adoption & implementation of data standards?

- Early involvement from agency, industry and software vendors
- Global input early in standards development
- Commitment to harmonized standards
- Assignment of business process manager to sponsors to assist with questions on development and maintenance of eCTDs.

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What key areas require new or expanded electronic submissions guidance?

- eCTD
  - Clarification on corresponding actions for appending leaf elements when parent leaf is deleted or replaced
  - Recommendations for migrating to V3.3.3 of eCTD specification
  - Clarification on STF files when a study is referenced in multiple sections of an application
  - Clarification on how to perform cross-application references
  - Clarification of INDs in eCTD format
  - Clarification on LCM
  - Clarification on EDC CRFs
- RPS
  - Current agency thinking on usage and implementation
- CDRH? CVM?

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What lessons learned & best practices should FDA consider as we transition from program-specific to enterprise IT solutions using a reusable and modular model?

- Need to look for revision to EU telematics strategy to see if possible recommendations
- Other possibilities
  - Enterprise standards
  - Consistent processes across centers
  - Training
  - Scalable and open technology

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What specific concerns (i.e., security, confidentiality, etc.) exist for a third party entity or entities providing services related to electronic submissions and review and how can they be addressed?

- Not sure this is an issue. Would expect all 3rd parties used by FDA to have to abide by confidentiality agreements
- Security perhaps
  - Secure access and transfer of information
  - Ensuring 3rd party computers are secure

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