An Industry Perspective on Information Technology Strategic Planning

PhRMA ERS and BIO IT Working Groups

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Who we represent

- **BIO**
  - The Biotechnology Industry Organization (BIO) represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

- **PhRMA**
  - The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures.

1. What Would Help Improve the Quality of eSubmissions to the Agency?

- Better communication to stakeholder community (not just individual sponsors)
  - Post common errors on the FDA website and include preferred solutions or acceptable options
  - Work with industry to identify and publish best practices: we know quality problems start with sponsor misinterpretation
- Strongly promote the use of technical discussions aligned with pre-application meeting
- Align globally as much as is practical. After a decade on this, we are drifting away from it. Let's re-engage.
- Establish specific endpoint for legacy electronic formats
- Collaborate with stakeholders to apply best practices to implementation planning and execution

2. What Would Help Increase the Quantity of eSubmissions to the Agency?

- Facilitate business processes: Make it easy to do daily work electronically
  - Significant efficiency gains are possible in lifecycle (daily) processes
  - Re-engineer processes to benefit multiple constituents
    - Do not simply automate legacy paper-based processes
    - Electronic standards can be either an incentive or an added burden
- Show benefits for eSubmissions versus paper
  - Powerful metric: illustrates resources saved for scientific review
  - Access to eSubs is faster: providing scientist greater review efficiency
- Harmonize standards with EU and Japan: speeds new therapies to patients and minimizes costs
- Implement consistent approaches across all Centers
- Fully engage vendor community throughout development and implementation: we need their tools and support

4. What Data Standards are Needed to Implement These Improvements?

- A broad program (Roadmap) of activity that looks at the end-to-end business process holistically is a critical first step
  - This roadmap has been advocated by PhRMA in public at DIA meetings in 2006 and 2007
- Limited resources require that we target change to business processes with high-value return
- To elucidate our industry's priorities, we are surveying PhRMA and BIO members to identify business processes that each deems critical
  - While data are still being analyzed, we can share preliminary information from this survey

Preliminary Survey Results

- As expected with large & small pharma and biotech companies, there is much diversity in individual responses
- Industry shares FDA's desire to leverage automation to redesign our end-to-end business processes
  - Industry recognizes and prioritizes development of terminologies and global standards as key enablers of automation. As such, use cases need to represent multiple stakeholders' business processes and dev/maintenance processes need to be open.
  - Shared service models such as a public private partnership are also prioritized as a key enabler
  - The challenges of replacing an existing electronic standard with a completely new electronic format weigh heavily on industry unless there is clear value in the change

Preliminary Survey Results

	Process-Specific Results	Cross-Functional Results
High	eClinical	Terminologies Public-Private Partnerships (CRIX) Data Aggregation
Medium	eCTD Investigator Portal SPL	eGateway eSignature
Low	Stability Financial Disclosure	

Note – this page presents an initial cursory review of the survey results which are still being assessed. Further details and interpretation will be provided in a written response to the docket.

5. How Should FDA Engage Stakeholders While Developing, Testing, and Implementing These Solutions?

- Make sure business problems we're resolving are well-defined. Align with industry leadership on biz process changes before IT development
  - Enables opportunity for win-win & alignment of resources and timelines
- Promote broad constituency participation and efficient solutions
  - Always use implementation working groups
  - Leverage trade groups
- Work with SDOs to create open standards
- Develop lifecycle policy for versioning standards

6. What Topics Are Most Useful to Include in IT Plans?

- **IT Plans are one element of change: they must include broader elements to provide the external community the information needed to align with Agency programs and goals**
  - Business process drivers
  - IT capability that satisfies the business needs
  - Standards or technology that enable a solution
  - Clear lifecycle progression over time
  - Ranked prioritization
  - Where FDA will engage SDOs for solutions

12. What Lessons Learned and Best Practices Should FDA Consider as We Transition from Program-specific to Enterprise IT Solutions Using a Reusable and Modular Model?

- **Focus initially on capabilities of highest cross-functional value**
- **Involve all stakeholders in all aspects**
- **Develop and implement in phases that emphasize commonality: focus on core capabilities**
- **Engineer a new vision: do not do not automate antiquated paper-based processes**
- **Enterprise solutions require compromise on the part of individual business units, but offer efficiencies from greater overall transparency**
- **Promote effective & efficient solutions to all parties through public-private venues**
- **Use CRADAs only when other options have been exhausted**
- **Lead-time for Sponsors to implement a change require a case-by-case evaluation: expect at least 18-months for change**

13. What Specific Concerns (i.e., security, confidentiality, etc.) Exist for a Third Party Entity or Entities Providing Services Related to eSubmissions and Review and How Can They be Addressed?

- Protection of Intellectual Property
  - Access control management, security, confidentiality
- Reliability and accountability
- Availability and affordability for all constituents
- Fully integrated capability to avoid multiple point solutions that are cost inefficient and burdensome
- Limiting accessibility
- Governance participation
- Change Management Process
- Maintain incentive for capital investment by innovators

Conclusion

- We fully support FDA's commitment to publish and maintain a rolling 5-year IT plan
  - Believe the transparency resulting from this action will better align FDA, industry and vendor implementation plans and enable us to be more effective and efficient implementing business process change enabled by information technology than we have been previously
  - BIO & PhRMA will provide additional feedback on industry's priorities coming out of our survey in written response to this docket