

FDA Public Meeting

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Background Information

- Regulatory Affairs professional with responsibility for submission compilation IND and NDA
- Octagon Research Solutions, Inc.
Software and Service provider to the pharmaceutical and biotech industry primarily focused on electronic submissions
- Survey Responders
Numerous emails/voice mails and informal survey participants who could not attend today's meeting

Agenda

- Transition to and implementation of electronic submissions
 - Results of informal survey conducted with 77 responses
- Cost/Time
 - ROI Analysis for two scenarios
 - Actual Time comparisons for paper vs. electronic (including eCTD)

Informal Survey Results

Questions:

1. Have you implemented electronic submissions within your organization?
2. If not, why?
3. What were the major challenges in implementing electronic submissions?
4. What were the major benefits of implementing electronic submissions?
5. Do you feel that costs associated with process and system changes were burdensome?
6. Additional comments

Informal Survey Results

Participants:

77 Responses

Company either:

Tier 1 (Large Pharma) = 16

Tier 2 (Medium Pharma) = 2

Tier 3 (Small Pharma) = 55

Other (CRO/Med Devices/Vet Med) = 4

Revenue:

Tier 3 = <500 Million

Tier 2 = 500 Million to 1 Billion

Tier 1 = 1Billion and up

Informal Survey Results

1. Have you implemented electronic submissions within your organization?

	Yes	No
Tier 1	13%	8%
Tier 2	1%	1%
Tier 3	34%	36%
Other	3%	3%
Total	52%	48%

Informal Survey Results

- If not, why?

	Primary Response Category	% of Response
Tier 1	Lack of internal resources and expertise, lack of upper management support, costs, ingrained processes	100%
Tier 2	Pending acquisition	100%
Tier 3	Time, costs, expertise, & resources	48%
	Assessment Stage	3%
	Implementation Stage	18%
	Mgmt Constraints	3%
	Not Mandated	3%
	No Submission yet	6%
	Other	18%
Other	Implementation Stage	100%

Note: 34 No Response

Informal Survey Results

- What were the major challenges in implementing electronic submissions?

	Primary Response	% of Response
Tier 1	Time, cost, expertise, training, resources, process change	100%
Tier 2	Technology issues (One Company received an RTF)	100%
Tier 3	Time, cost, expertise, training, resources, process change	76%
	Creating compliant documents	11%
	Challenges not perceived as cumbersome	8%
	Legacy study format issues	5%
Other	Time	100%

Note: 22 No Response

Percentages for Tier 1 and Tier 3 are skewed by 1% due to rounding.

Informal Survey Results

- What were the major benefits of implementing electronic submissions?

	Primary Response	% of Response
Tier 1	Ease of use, speed, compatibility, harmonization, reviewer friendliness, re-use	50%
	No paper	14%
	Lifecycle management	14%
	Skeptical of proposed benefits	7%
	Quicker agency approvals	14%
Tier 2	Document Standards/No paper	100%
Tier 3	Ease of use, speed, accuracy, time savings, standard format	80%
	Ease of review	13%
	Lifecycle management	3%
	Expedite foreign translations	3%
Other	Document Standards/No paper	100%

Note: 29 No Response

% Presented in this table are skewed by 1% due to rounding of percentages

Informal Survey Results

- Do you feel that costs associated with process and system changes were burdensome?

	Yes	No
Tier 1	46%	54%
Tier 2	100%	0%
Tier 3	57%	43%
Other	33%	67%

Note: 24 No Response

Informal Survey Results

- Additional Comments
 - 51% of respondents provided additional comments
- Summary
 - Some companies felt that cost was an issue, they also felt that these costs would be worthwhile in the long term
 - Comment from Tier 3 company - “We build and collect things electronically, it makes sense to submit electronically. It is the cost of doing business.”
 - Some companies felt the impact of increased costs would jeopardize their ability to be competitive
 - Most companies felt that finding the correct technology, that is also reliable, is currently, and will continue to be an issue
 - Comment from Tier 3 company - “Available in-house tools are sketchy at best and vendors definitely should be considered for the majority of the processing and publishing.”
 - Some companies felt that eCTD needs to be mandated to obtain buy-in from upper management and to keep sponsors from avoiding submitting in paper
 - Comment from Tier 3 company – “FDA must mandate eCTD for INDs and NDAs/BLAs, or most sponsors will continue to avoid submitting them. eCTD tools are too expensive for small companies.”

Time/Cost Scenario #1

Outsourcing Model – validated software, pressure-tested processes in place and trained staff

Scenario #1 Assumptions:

1. Submission ready documents – content and format reviewed and approved by functional area contributors/sponsor
2. Documents and data provided on a rolling basis – not all at the end
3. Size: 150 Volume NDA (~ 52,000 pages)
4. Approximately half of the submission will be created from paper source documents and all of the paper source documents will need to be scanned

If a paper submission is filed, then it will be full paper – no electronic components

Time and Cost Scenario #1

TOTAL COST	Paper \$218,484	Electronic \$185,750
TOTAL DURATION	75 days	57 days

Time/Cost Scenario #2

Outsourcing Model – validated software, pressure-tested processes in place and trained staff

Scenario #2 Assumptions:

1. Submission ready documents – content and format reviewed and approved by functional area contributors/sponsor
2. Documents and data provided on a rolling basis – not all at the end
3. Size: 450 Volume NDA (~ 157,000 pages)
4. Approximately half of the submission will be created from paper source documents and all of the paper source documents will need to be scanned

If a paper submission is filed, then it will be full paper – no electronic components

Time and Cost Scenario #2

TOTAL COST	Paper \$623,452	Electronic \$557,250
TOTAL DURATION	205 days	172 days

Summary/Conclusions

Major impediments and challenges:

Time, costs, expertise, training, resources,
process change

Major benefits:

Ease of use/review , speed, accuracy,
compatibility, harmonization, document
standards, document reuse

Questions

