Part 15 Hearing on Electronic Submissions

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THE DESIRED [REQUIRED] STATE OF ELECTRONIC SUBMISSIONS [eSubmissions]

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TAP's Experience with eSubmissions in the electronic Common Technical Document [eCTD] format:

- More than 700 eCTD submissions have been completed to date
- In September, 2005, TAP completed the conversion of all submissions to the eCTD format
- Conversion included all original NDAs + supplements + amendments
- Conversion also included all Original INDs + amendments
- And the conversion of existing INDs and NDAs to the eCTD format

TAP's Experience with eSubmissions in the electronic Common Technical Document [eCTD] format:

- Overall, while it has taken some time, TAP has electronic systems in place for the eCTD.
- Improvements to those systems are evolving to make the eCTD a better process.
- These improvements involve controlling content and meta-data from authoring to submission to archival.
- The electronic tools are currently available for others to manage information and complete eCTD submissions as well.

General Observations about the State of Electronic Submissions and what is needed moving forward

Observation #1

We [meaning FDA and the industry producing eSubmissions] must work together closely and listen attentively to each others concerns.

- Why: Electronic systems [computers, in general] are fussy entities and information MUST NOT be changed when it is moved from one electronic environment to another, i.e., from the industry system preparing the submission to the FDA system that provides review access.
- Why: FDA reviewers depend on the information submitted to perform their job functions.

Observation #1 cont.

We [meaning FDA and the industry producing eSubmissions] must work together closely and listen attentively to each others concerns.

- Why: Industry depends on the information submitted to initially support and then maintain health care product approvals.
- Why: If electronic systems cannot ‘talk’ to each other successfully to share UNCHANGED information, the process can be compromised.

Observation #2

We must carefully select and closely supervise any third party that may handle electronic systems and any information stored for either FDA or industry [aka, contract organizations that produce, transmit, or otherwise interface with eSubmission information].

- Why: The life-cycle of a health care product, e.g., the development and marketing of a prescription drug is a long term process that could last decades.
- Why: The life-cycle of electronic systems and software is much shorter than a health care product life-cycle. Only third parties with an extensive appreciation for and commitment to managing the disconnect between the long cycle of health care products and the short cycle of systems and software SHOULD BE considered suitable candidates for handling eSubmission information.

Observation #2 cont.

We must carefully select and closely supervise any third party that may handle electronic systems and any information stored for either FDA or industry [aka, contract organizations that produce, transmit, or otherwise interface with eSubmission information].

- Why: Disconnects resulting in information migration or retrofits are costly endeavors. Migration and data retrofits may be likely outcomes when low-bid, inexperienced third party contractors are used.
- Why: This is not only a dollar cost; it is a TIME cost. Delays disadvantage patients or consumers whether the delay has it origins at FDA or within the industry.
- Why: Finally, confidentiality issues may arise due to the incidental or inappropriate release of information. Most of these issues arise NOT from technology but from improper information handling by humans; staff at third party organizations must be of suitable quality and correctly trained. They must be invested in the security of eSubmission information.

Observation #3

We must jointly learn how to handle and access repetitive eSubmission information, e.g., Investigator Forms 1572s and updates MORE EFFICIENTLY and find ways to reduce this workload.

- Why: Current industry submission systems are clogged with this information and easily account for 20 to 50% of each month's submission activities.
- Why: The current, trained labor force for eSubmissions, available within the US, is NOT sufficient to handle the upward spiral of this workload.
- Why: We must turn our attention to and use our limited resources to handle the more difficult and challenging, REPETITIVE submission types, e.g., advertising and promotion submissions. This will require, at a minimum, the integration of three dimensional scanning and viewing into our eSubmission systems.

Observation #3 cont.

We must jointly learn how to handle and access repetitive eSubmission information, e.g., Investigator Forms 1572s and updates MORE EFFICIENTLY and find ways to reduce this workload.

- Why: THE eSUBMISSION PARADIGM SHOULD BE AN ALL INCLUSIVE ONE; we must learn to use our systems and use them repetitively for all submission types if we are to maintain credibility with our external audiences.
- Why: Repetitive use of the same tool set for multiple submission types will drive down our costs and provide positive business cases and incentives for all to participate.

Observation #4

We MUST find common ground to move forward with making eSubmissions a requirement and NOT an option! We must provide incentives to move from the current state where approximately 3-5% of all submissions sent to FDA are eSubmissions to a 95%+ level very soon, e.g., by 2009.

- Proposed Incentive #1: Reduce the PDUFA fee, for those submissions requiring fees, by some percentage or amount when completed in eCTD format.
- Proposed Incentive #2: Reduce the PDUFA review clock by some number of days for applicable submissions in eCTD format.

Observation #4 cont.

We MUST find common ground to move forward with making eSubmissions a requirement and NOT an option! We must provide incentives to move from the current state where approximately 3-5% of all submissions sent to FDA are eSubmissions to a 95%+ level very soon, e.g., by 2009.

- Proposed Incentive #3: Grant a tax credit to those industry entities with an on-going eCTD submissions program.
- These incentives are only my opinions based on 10 years of working experience with eSubmissions.
- We must also find ways to enhance the support for FDA offices germane to eSubmissions, e.g., FDA Office of Business Process Support and FDA staff supporting the electronic gateway. This is a requirement on the way to the 95% goal.

Observation #5

The common ground MUST include a Master Plan in which we can all invest. This Master Plan should include the 'what', e.g., items like E2B, SPL, etc, and the 'when', i.e., the order of adoption of new standards for eSubmissions. This investment requires the buy in of the management chain at FDA and within industry.

- Why: Currently the electronic systems deployed are, for the most part, all highly customized and configured to meet individual needs and expectations. We cannot continue to afford this diversity; it is too expensive.
- Why: The electronic silos created by our current approaches will or currently are obsolete due to evolving new technology. There is no better time to make a Master Plan than now.

Observation #5 cont.

The common ground MUST include a Master Plan in which we can all invest. This Master Plan should include the 'what', e.g., items like E2B, SPL, etc, and the 'when', i.e., the order of adoption of new standards for eSubmissions. This investment requires the buy in of the management chain at FDA and within industry.

- Why: Standards Development Organizations [SDOs] are and will continue to produce more and different types of proposed standards for our consideration. We need to select those standards that will yield maximum benefit in an orderly manner.

Observation #6

The Master Plan must include a scheduled and controlled, life cycle development process.

- Why: One merely needs to look at the impact of the Structured Product Labeling requirement, SPL, circa October 2005 to provide justification for this.
- Why: Two additional releases of software corrections and changes were made circa November and December 2005. For those with on-going eCTD programs, this triggered multiple change requests and revalidation steps.

Observation #6 cont.

The Master Plan must include a scheduled and controlled, life cycle development process

- Why: The inclusion of SPL was not compliant with ICH eCTD requirements. Thus, eCTD software providers had to go outside the confines of ICH requirements to produce a fix. This could have been avoided by a Master Plan with a controlled life cycle that included adequate pilot testing. The disconnect between the SPL and ICH eCTD requirements would have become evident during pilot testing and appropriate alternate measures could have been considered.

Observation #7

We must include a 'Plan B' in our Master Plan.

- Why: We must have an alternative, a 'Plan B' when the electricity goes out or a disaster strikes, at either FDA or within the industry to continue with mandatory submissions, e.g., 15–day safety reports.
- Why: We must continue to perform our jobs when the electronic systems are not available, i.e., an outage occurs.
- Why: It is just good business to have a disaster recovery plan for these critical electronic systems. Each party should know when the other party is 'down'.

Observation #8

We must bring the correct focus and attention to the required infrastructure surrounding eSubmissions. We must find a way to get the same level of attention and appreciation for eSubmissions as is currently accorded the content of a New Drug Application, i.e., the submission meta-data and the content must become equally important.

In Conclusion

1. We must work together very closely and understand each other's systems and processes to build and sustain data integrity.
2. We must carefully select and closely supervise any third parties.
3. We must learn how to efficiently handle and access repetitive submission information.
4. We must find common ground to move forward in making eSubmissions a requirement.

In Conclusion cont.

5. The common ground must include a Master Plan.
6. The Master Plan must include a life cycle development process.
7. The Master Plan must include a “Plan B” disaster recovery plan.
8. The importance of eSubmission meta-data and infrastructure must equal the importance of the submission contents.

TO WHOM MUCH IS ENTRUSTED - -

MUCH IS EXPECTED! [author unknown]

We must all hang together lest we all be hung separately. [Benjamin Franklin]

It is truly time to put away our perceived differences and move eSubmissions from the 3-5% participation level to a 95%+ level within the next 2 years. [Al Edwards]