FDA/NIH/NSF Public Workshop on Computer Methods for Medical Devices

Day 1 – Digital Library of Modeling and Simulation Project Discussion
June 11, 2013

This document, prepared by FDA, summarizes the key take-aways and additional comments from Day 1 of the workshop. It is not meeting minutes. For brevity, the term model will refer to both models and simulations. Meeting information is available at: The FDA workshop website

In the months to come, FDA would like to continue to engage panelists, attendees, and the community at large in small groups to hone the project focus and make this Digital Library a valuable resource to the community.

Please contact us at Digital.Library@fda.hhs.gov if you would like to continue to participate in these discussions and small group teleconferences or if you have comments on the development of FDA's Digital Library of Modeling and Simulation.

The Digital Library will be an evolving project. "Big wins" in the short term will emphasize the value added to stakeholders and encourage their participation. Growing the project as a vital resource to the medical device community will achieve long-term goals. To accomplish this, the project must have a clearly defined vision, scope, and goal so that it is as transparent as possible to all participants. It must also have a defined value to participants. The workshop revealed some areas for continued development and several common themes:

Library Content

Data was a highlighted feature identified as easily accessible content. We recognize that collecting data is often time-consuming and expensive and therefore can represent a competitive advantage if others in industry do not have access to the data. There are many instances though, of data collected through academic collaborations, such as NIH- funded research, or industry partnerships that are able to be shared openly. Some examples of data for initial starting points are:

- Data and models that replicate bench tests
- Physiologic boundary conditions for biological systems
- Methods to approach verification and validation for specific types of problems
    - Guidelines for finding limits and boundary conditions
    - Procedural guides to correctly formulate simulations
- Anatomic / geometric data, especially under-represented populations and disease states
- Material properties for biological tissues and other relevant materials

The definition of the original term "pre-competitive" space was the subject of some debate. Competitive interests run through many or all aspects of commercial research. However, there were examples of areas that could fall in a different "shared space":

- Commodity data common to all industry stakeholders
- Research questions posed by consortia of industry, academia, or other partnerships
- Gold standard problems / data that others can use for verification and validation
- Existing open source models and simulations
- A "wanted" section for missing information in key areas

Governing Policies and Scientific Evaluation

Many excellent ideas and suggestions came from discussions about **Categories for entries.** .

- Some would like a more basic tier with no evaluation and an expiration date so all entries are accepted but are removed after inactivity
- In most cases, the entry description should be limited to the applied context of use. The contributor may not have the expertise to know where the model cannot be applied.
- Definitions of the tiers, especially Qualified, need additional clarification.
    - Specify that a qualified model is not required in a regulatory submission.
    - Need to be able to see if a model has been used in a submission

Each user should be able to do **Code Verification** according to their institution's quality control protocols. Stakeholders made several suggestions about how to inform users of these limitations and ensure they verify all code on their systems.

- Treat models as a black box that can be verified without knowledge of the code.
- Provide tutorials on proper verification methods for different types of methods.

Scientific Evaluations are a very important topic that will require further discussion with interested participants in small groups as the Digital Library is developed.

- Open (final) evaluations could have great value to the community.
- Disclose conflicts of interest fully and manage them carefully.
- Subject matter experts will be important in filling knowledge gaps.
- Might be similar to a journal review process.

Licensing and User Experience

Intellectual property protections for the submitter and downloader, assuring their rights to use and license the data, are of paramount concern.

- We plan to use a selection of Open Source Project certified licenses, such as the BSD-Style license or Creative Commons licenses to give stakeholders.
- Expressly convey content with no warranty. The downloader will use the content at his or her own risk.
- Track modifications to models and simulations so that changes can be rolled back if necessary.

User Interaction will help make this an interactive and useful resource. All stakeholders agreed that increasing the amount of descriptive information (metadata) supplied with each upload increases the usefulness of that data moving forward. On the other hand, it creates a barrier to entry, because of the increased demands on time and energy from the submitter.

- Easy to use searching and sorting features will increase utility.
- Varying levels of information are required for different tiers.
- Keep code and file types to open formats wherever possible to ensure usability

Our discussions around commenting brought about a similar relationship. Many saw comments as adding value; however, this has positive and negative implications and may require heavy oversight.

The FDA will use this feedback and continued discussions with interested stakeholders to hone these requirements, in order to strike a positive balance between information and ease of use.