White Paper: Resourcing CDISC and CFAST Standards Development

This paper reviews the current state of resource availability on CDISC projects and proposes two new models for expanding resources available to CDISC that should accelerate the pace of development and maintenance of CDISC standards being adopted by industry.

Current State: Volunteers

CDISC depends on volunteers to contribute to the development of new standards and to review and comment on proposed draft standards through the CDISC consensus-based process. Historically, it has been difficult to project and manage to strict timelines for standards developments projects, because the availability of volunteers is uncertain and sporadic, and there is an excessive dependence on key subject matter experts who are in high demand for their time and in very short supply. To make greater progress in standards development and adoption it is necessary to:

- Increase the quantity and quality of participants in the resource pool for standards development
- Develop additional CDISC subject matter experts to guide modeling decisions and ensure the quality and consistency of new standards projects
- Increase the potential to capitalize on learning curve to keep volunteers involved for a longer period of time from project to project
- Develop a broader knowledge of CDISC in the entire research community to review new standards and champion implementation and adoption among stakeholders.

Under the CFAST program, the situation has improved somewhat for two primary reasons:

- New grant funding has allowed CDISC and the Critical Path Institute to engage new staff to provide support to teams with improved training and tools as well as contribute to specific projects
- The support of TransCelerate Biopharma (TCB), which has identified volunteers for new CFAST projects who are empowered by their employers to allocate and prioritize more of their time than under the historical volunteer model.

However, neither of these solutions has been ideal. The new staff members that have been engaged by CDISC and CPath can fulfill only a small portion of the current needs, and need time to build up their skills and knowledge. Meanwhile, TCB has not always been able to fill needs consistently, and TCB volunteers have occasionally had to drop out due to other work commitments, often jeopardizing project timelines as a result.

While CFAST projects also involve volunteers from the broader CDISC community and other groups (such as ACRO), for reasons outlined above, it is difficult to rely on the availability of these volunteers over time, since their day job will almost always take precedence.

To mitigate this concern, CDISC has proposed two new resourcing models.
Proposal: CDISC Fellows Program

In academia, a **fellow** is a member of a group of learned people who work together as **peers** in the pursuit of mutual knowledge or practice. CDISC proposes creation of CDISC Fellows who will actively participate in the development of CDISC standards on a full-time basis for a fixed period of time (targeted as a minimum of one year), with the intent of developing proficiency in the use of standards which can then be leveraged internally by their sponsoring companies, as well as providing ongoing part-time expertise as a reviewer or other participant to the CDISC collaboration community.

Guidelines:

- CDISC will designate a fixed number (initially 6-12) of Fellow positions to be made available 2-3 times per year.
- Candidates must be sponsored by their employer for the period of their rotation, will not be CDISC employees or receive direct funding from CDISC.
- Candidates are expected to have experience in clinical research processes with a passion for contributing to the development of data standards. While past experience with CDISC standards is highly desirable, candidates will be evaluated on their overall potential and will be trained to develop standards-related skills as part of the Fellows program.
- Candidate will apply by submitting an application, letter of intent, CV and evidence of support from sponsoring company.
- Candidates must agree to participate for a full rotation on at least an 80% of full-time basis.
- Candidates will be chosen by a CDISC selection committee (with membership approved by the CDISC Board).
- Candidates must participate in an in-depth training program at the outset of their rotation.
- Rotation will include active development in CDISC and CFAST standards development activities, including involvement in one complete cycle of a CFAST therapeutic area standard (from scoping through public release).
- Rotation will include active participation in multiple standards development participation roles, with a preferred focus area (Project Management, Concept/Metadata modeling, Terminology or Metadata Curation).
- Matriculating fellows will participate in the mentoring of new Fellows appointed in subsequent classes.
- Upon completion of their rotation, Fellows will be honored with a certificate of recognition.

Fellows will be listed on the CDISC website and may refer to themselves or be acknowledged by their employers in public statements, documents, and resumes as "Fellow of the Clinical Data Interchange Standards Consortium", add the
letters FCDISC after other credentials, and receive appropriate recognition by CDISC (including certificate after completion of their rotation). Fellows also must pledge to support the CDISC mission, vision and values, including mentoring new members, and contribute to the advancement and adoption of CDISC Standards.

CDISC also reserves the right to grant honorary Fellows designations to long-standing experts of the CDISC standards community in recognition of past services rendered and ongoing participation.

**Proposal: CDISC SHARE Metadata Curation Collaboration**

CDISC SHARE is a collaborative metadata repository and standards development environment that will eventually house all relevant CDISC standards and serve as the development environment for new standards activities. At present, CDISC SHARE is being managed by a core team of CDISC employees (including two metadata curators) with substantial contributions from a large number of volunteers.

While volunteers have contributed widely to the development of CDISC standards and progress on SHARE historically, it is recognized that the ability to keep pace with new demands for more comprehensive and cohesive standards to support ongoing research needs will require more dedicated and dependable involvement from stakeholders. With the rapidly approaching requirement to use standards for regulatory submissions, most sponsor companies will be assigning staff toward actively managing standards metadata – as well as developing stopgap workarounds for gaps not currently addressed by public standards – individually per company and often per study. These individual custom solutions are not likely to match with future standards, which will increase the burden on each company to convert and transform to maintain conformance with published standards as they evolve.

Rather than solve similar problems individually, and incur a future liability of having to transform to meet evolving requirements, it would be much more economical and expeditious for many companies to work together collectively in SHARE as part of a CDISC collaboration, and to lead the development and curation of CDISC standards (including metadata and terminology) using the interactive capabilities of SHARE workflows to evolve and maintain standards more effectively and rapidly, and capitalize on the advantages of a metadata repository to support consistency, reusability and access.

**Guidelines:**

- Companies who are committed to the ongoing development and use of CDISC standards to support ongoing development programs would each assign a lead curator to join the CDISC curation team on a minimum half-time basis.
- All curators would be required to complete an in-depth training course and mentoring program.
- Companies would retain ability to increase the level of or change participants at any time.

This would become an expert community for implementing new proposals in SHARE and vetting these as candidate standards for use.

This community would support both ongoing new standards development through CDISC and CFAST as well as company-specific needs that could be vetted through the CDISC expert community. Such company-specific solutions would be represented in SHARE, and later become candidates for incorporation in CDISC versioned standards by following the standard CDISC Standards Development process.

Business benefits to participating Companies:
1. Accelerate development and availability of standards
2. Make standards more usable and efficient (concepts, electronic metadata)
3. Enable more rapid terminology assignments to support ongoing projects
4. Develop knowledge and skills that can be transferred internally to improve operational efficiency within each company
5. Develop pre-competitive relationships to cooperate on common challenges regarding standards and build an active peer community to improve the overall efficiency of the research process for all participants.