Project Charter

Rationale

- CDISC Conformance Rules are an integral part of the CDISC Standards ("Standards"). They are the specific guidance to Industry ("the Community") for the correct implementation of the Standards in clinical studies.

- Today, the conformance rules in use by the Community have been prepared by CDISC, but they need to be expressed in a common specification in order to be loaded to the CDISC Library. In addition, an executable component must be developed for every conformance rule.

- Governance of the Conformance Rules by CDISC and the Community will provide:
    - One common standard version of the conformance rules
    - Assurance that the rules are correct and complete
    - Assurance that the rules remain current as the Standards emerge and develop

- As a central part of ongoing Standards implementation by the Community, the Conformance Rules must be open, transparent, and available from a single trusted source.

- The Conformance Rules will be applied by the Community within their operational clinical systems. As such, the Community needs a digital (executable) reference form of these rules in addition to the specification.

Mission

- The overall goal of the CDISC Conformance Rules Engine (CORE) Project is for CDISC to provide to the Community a governed set of unambiguous and executable conformance rules for each of the Standards.

- The mission objectives include:

- Ensure consistency in conformance rules implementations across companies and across studies within a company
- Expedite the availability of executable conformance rules for new standards
- Provide the conformance rules to the Community in the CDISC Library
- Provide a minimum viable product version of an open-source execution engine for the executable reference rules
- Publish this engine as open-source, under the CDISC Open-Source Alliance (COSA)
- Provide flexibility to the Community such that they can execute the rules' execution engine from the cloud and from a desktop environment
- Develop the conformance rules in collaboration with the Community; as the conformance rules are an integral part of their day-to-day operations, CDISC needs their expertise in rules development and governance
- It is expected that the Health Authorities will accept and adopt the Conformance Rules as a component of the CDISC Standards that have been mandated for use in electronic submissions

Stakeholders and Leadership Team

- The stakeholder groups are:
  - The Community, who collaborates with the CDISC Standards Team on the creation, governance and maintenance of the conformance rules specification, and leads on the validation of the CORE engine and executable form of the Conformance Rules
  - CDISC, responsible for the specification of the rules (in collaboration with the Community), and provisioning of the rules in the CDISC Library
  - The software engineering partner, responsible for the development of the rules' execution engine and interface

- The Leadership Team is comprised of members of the stakeholder groups, as follows:
  - CDISC: Chief Standards Officer (CORE Product Owner) and Vice President of Data Science (Product Architect)
  - Community: Two to four leaders of the Conformance Rules Industry Interest Group (CRIG); the CRIG is an industry group whose leaders will coordinate the industry collaboration with CDISC on the project
  - Software engineering partner
  - Program Manager

Project Teams

- CORE Leadership:
  - Responsible for leadership on all aspects of project execution
  - Final decision on product backlog and project operational issues
  - Membership:
    - As described above

- CORE Architecture:
  - Responsible for the project DevOps and technical environment, including the Conformance Rules engine and the CDISC Library extensions to store and surface the Conformance Rules.
  - Membership includes:
    - Product Architect: CDISC VP of Data Science
    - Software Engineering partner
    - CDISC IT lead

- CORE Software Engineering Development:
  - Responsible for development of the open-source rules' execution engine
  - Membership includes:
    - Software engineering partner
    - CDISC Data Science team
    - Other CDISC community members with experience and expertise in open-source software development will be considered

- CORE CDISC Library Development:
  - Responsible for committing the conformance rules to the CDISC Library, in both analog (the specification) and digital (the executable rules) form, and for surfacing the executable form of the rules through an API from the CDISC Library to the open-source CORE rules' engine, or to other platforms prepared by Industry that host the CORE engine
  - Membership includes:
    - CDISC VP of Data Science
    - CDISC Data Science Team members

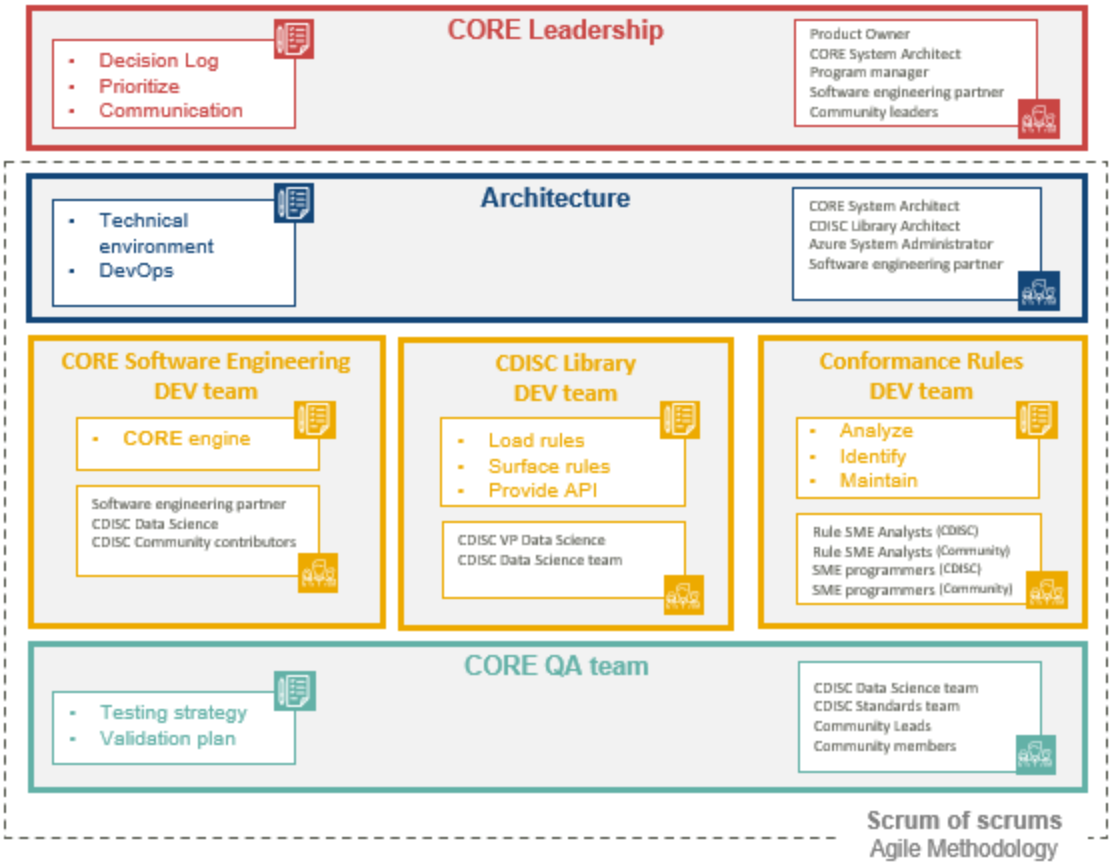
- CORE Conformance Rules Development:
  - Responsible for development of the rules' specification (analog) and the digital (executable) form of the rules

    - Responsible for formalizing the analog and digital conformance rule sets as CDISC Intellectual Property, described in CDISC Policy 003, the CDISC Intellectual Property Policy
    - Membership includes:
        - Conformance Rules SME analysts from CDISC Data Standards
        - Conformance Rules SME analysts from Industry, organized/coordinated by the CRIG leadership
        - Conformance Rules SME programmers from among CDISC Data Standards and CRIG

- CORE QA:
    - Responsible for validation testing of the rules' executable engine, (i.e., testing beyond the unit testing done by the Engine Software Engineering Team)
    - Responsible for validation testing of the digital (executable) reference form of the rules
    - Membership includes:
        - CDISC Data Science team members
        - CDISC Standards team members
        - Community leads (i.e., CRIG leadership)
        - Community members

- CORE Scrum of Scrums:
    - The project methodology is Agile Scrum. This team is responsible for the ongoing Scrums of the project team leads
    - Membership includes:
        - Scrum Master
        - CDISC VP of Data Science
        - Project Team leads

- The following diagram is a summary picture of the project team structure:



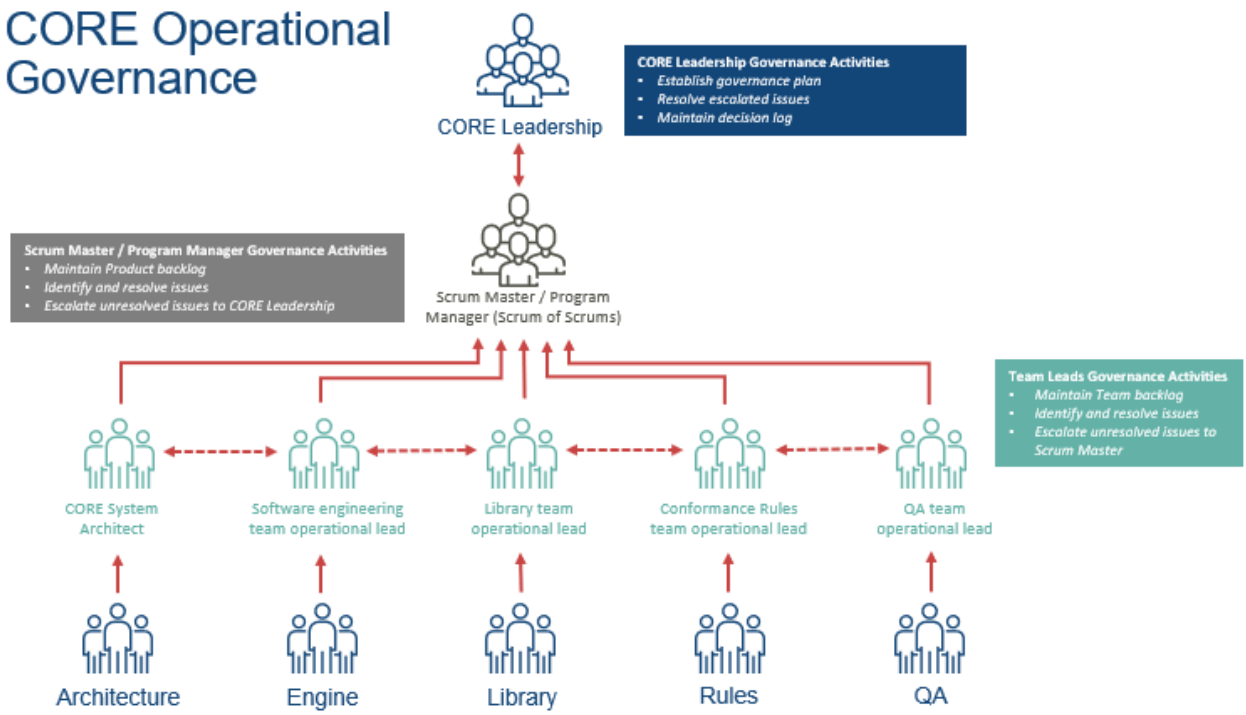
Project Operational Governance

- CDISC will provide the Product Owner, an Architect, a Program Manager, and a Project Manager / Scrum Master to manage and prioritize the product backlog and deliverables developed in partnership with the software engineering partner technical team.
- The CORE Leadership Team will function as the CORE Executive Governance Board. CDISC Chief Standards Officer is the CORE Product Owner with responsibility for the

backlog and project priorities. CDISC VP of Data Science will provide CDISC leadership on the CORE Architectural Review Board.

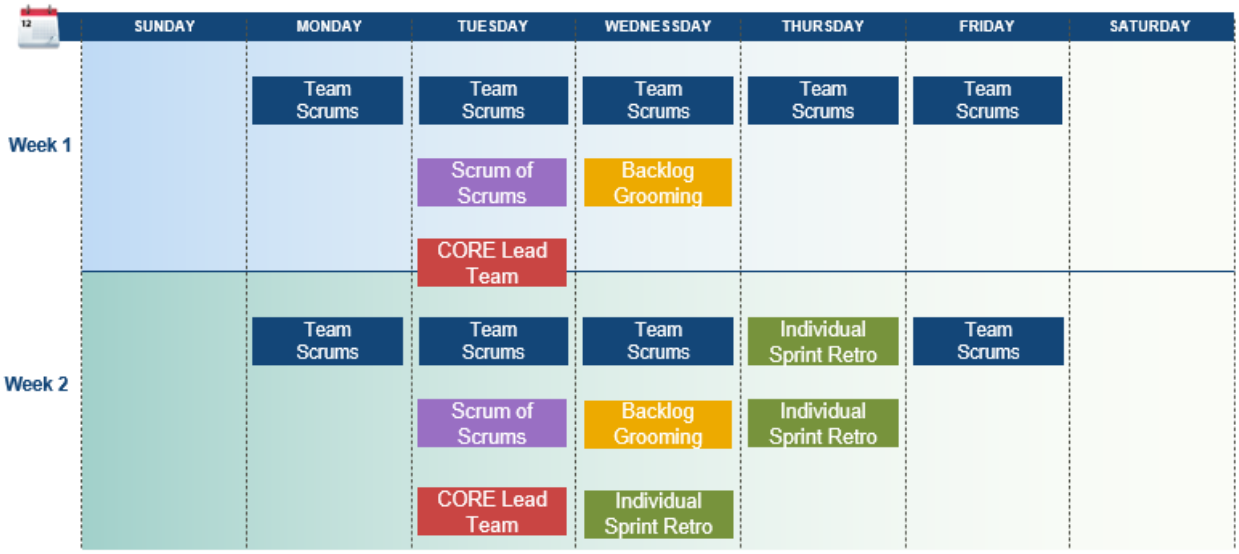
- **Backlog Grooming** (Refining) – team leads will meet weekly with Product Owner to align and refine product backlog.
- **Sprint Planning** – Each team's near-term work effort (sprint backlog) will be established in a Sprint Planning meeting
- Regular Meetings will be held to address team progress, dependencies, and issues (blockers)
    - Daily - Most teams minimally meet in a daily standup meeting (**DSU**) aka **Scrum**
    - Weekly - Volunteer teams will minimally meet weekly
- **Scrum-of-Scrums** - Team leads will meet weekly to discuss progress, dependencies, and issues (blockers) with the goal of alignment and issue resolution
- **Sprint Review** - Teams' will demonstrate progress in a Sprint Review meeting
- Unresolved issues will be addressed at the CORE Leadership Team meetings. The Leadership Team will maintain a log of project issues and their resolution

- The following diagram is a summary picture of the project operational governance:



<u>Project Meetings and Cadence</u>

- The following diagram describes the planned meeting cadence for the project, based upon 2-week agile sprints:



Conformance Rules Governance

- The Conformance Rules Specification and the executable form of the Specification will be part of the CDISC Standards and will thus be governed by the CDISC Operating Procedures (COP001) for standards development.

Timeline

- For the minimum viable product
  - Initiation: 2021 Q2
  - Planning: 2021 Q2
  - Execution: 2021 Q3 - 2022 Q1
  - Closure: 2022 Q1