CDISC CORE Project
(CDISC Open Rules Engine)

Challenge / Opportunity

- CDISC Conformance Rules are an integral part of the CDISC standards
- CDISC and the Community must govern the Rules
  - Validated by the Community
  - Remain current over time
- Rules must be published in CDISC Library
  - The single source
  - In a common specification
- Executable component must be developed for every Rule
- Open-source solution to ensure Community can run the checks
- Anticipated that Health Authorities will accept and adopt the Rules

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CORE Objectives

1. Each standard has a set of unambiguous, executable conformance rules
2. Ensure consistency across conformance rule implementations
3. Expedite the availability of executable conformance rules for new standards
4. Create executable reference rules blessed by the CDISC standards team
5. Publish these reference rules under COSA as open-source
6. Create an open-source execution engine that works with the reference rules

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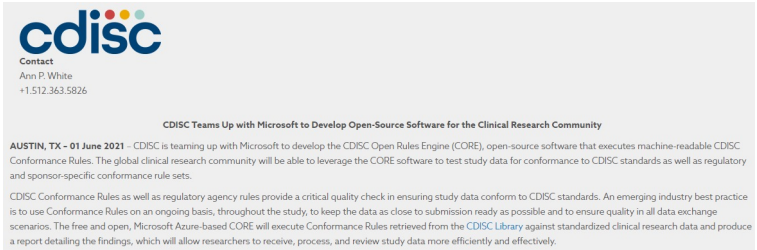
CORE – Further Considerations

- CORE will be released as open source under the MIT license
  - Not offered by CDISC as a commercial product or service
- Executable rules - next step in the evolution of the conformance rules that CDISC publishes with every standard
- Executable rules published by CDISC should make it much easier for rule vendors to adapt these rules for use in their own software
- Existing rule vendors are free to contribute to or use the CORE engine software
- CDISC Core Press Release



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CDISC Teams Up with Microsoft to Develop Open-Source Software for the Clinical Research Community

AUSTIN, TX – 01 June 2021 – CDISC is teaming up with Microsoft to develop the CDISC Open Rules Engine (CORE), open-source software that executes machine-readable CDISC Conformance Rules. The global clinical research community will be able to leverage the CORE software to test study data for conformance to CDISC standards as well as regulatory and sponsor-specific conformance rule sets.

CDISC Conformance Rules as well as regulatory agency rules provide a critical quality check in ensuring study data conform to CDISC standards. An emerging industry best practice is to use Conformance Rules on an ongoing basis, throughout the study, to keep the data as close to submission ready as possible and to ensure quality in all data exchange scenarios. The free and open, Microsoft Azure-based CORE will execute Conformance Rules retrieved from the CDISC Library against standardized clinical research data and produce a report detailing the findings, which will allow researchers to receive, process, and review study data more efficiently and effectively.

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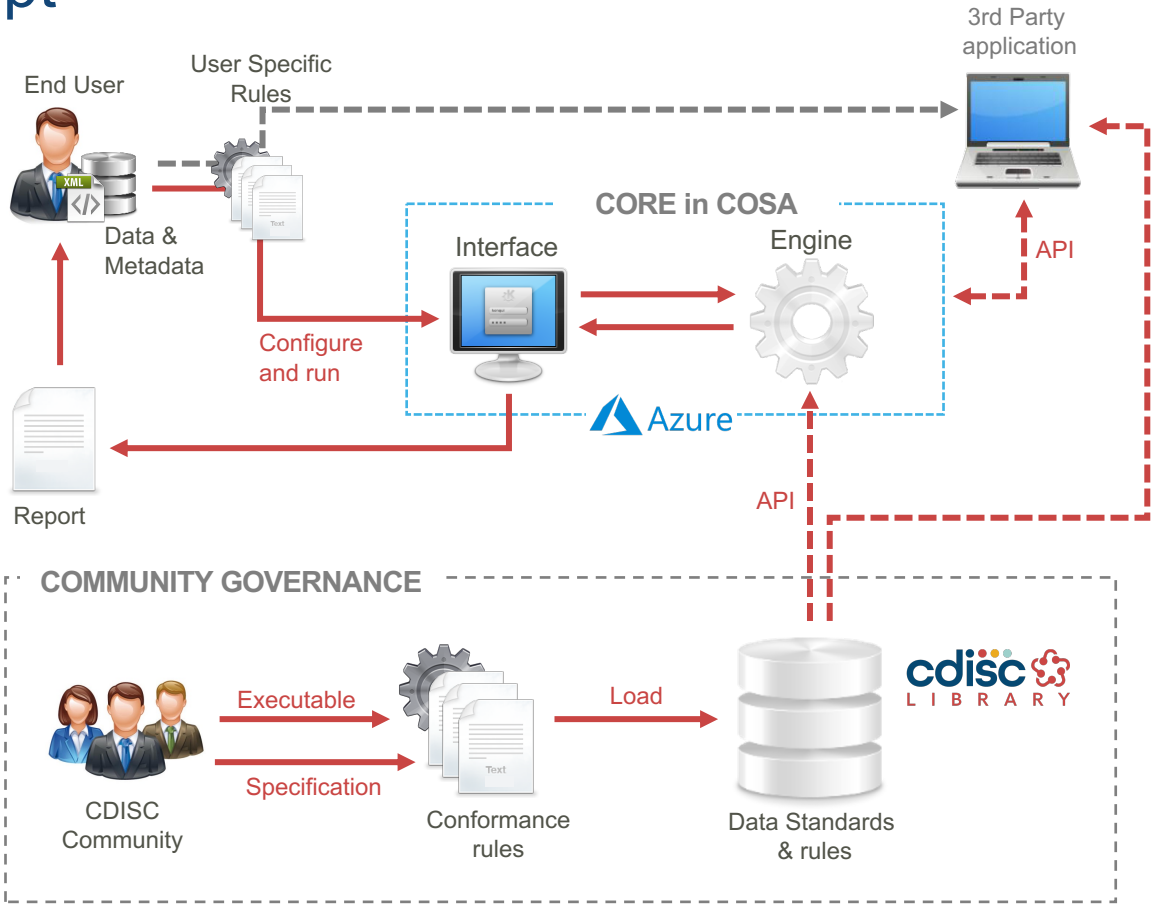
CORE Concept



CORE Business Requirements

- High-level Requirements have been prepared
- Requirements include a plan for 3 releases
- A release package includes
  - Open-source engine
  - Conformance Rules
  - Rules executable component
- The releases are: Minimum Viable Product, Release 1, Release 2
- Minimum Viable Product (MVP)
  - Engine – has enough features to be usable by early users who can then provide feedback for future product development
  - Rules Specification and executable component – focuses on SDTM conformance rules
  - SDTM 2.0 and SDTMIG 3.4 in scope for MVP
  - Does not exclude other (ADaM, SEND, Define.xml) but not critical for MVP

Stakeholders

- **The Community:**
  - Collaborates with CDISC Standards Team on creation, governance and maintenance of conformance rules specification
- **CDISC:**
  - Responsible for specification of the rules (in collaboration with the Community), and provisioning of the rules in the CDISC Library
- **Microsoft: Software Engineering Partner**
  - Responsible for development of the rules' execution engine and interface

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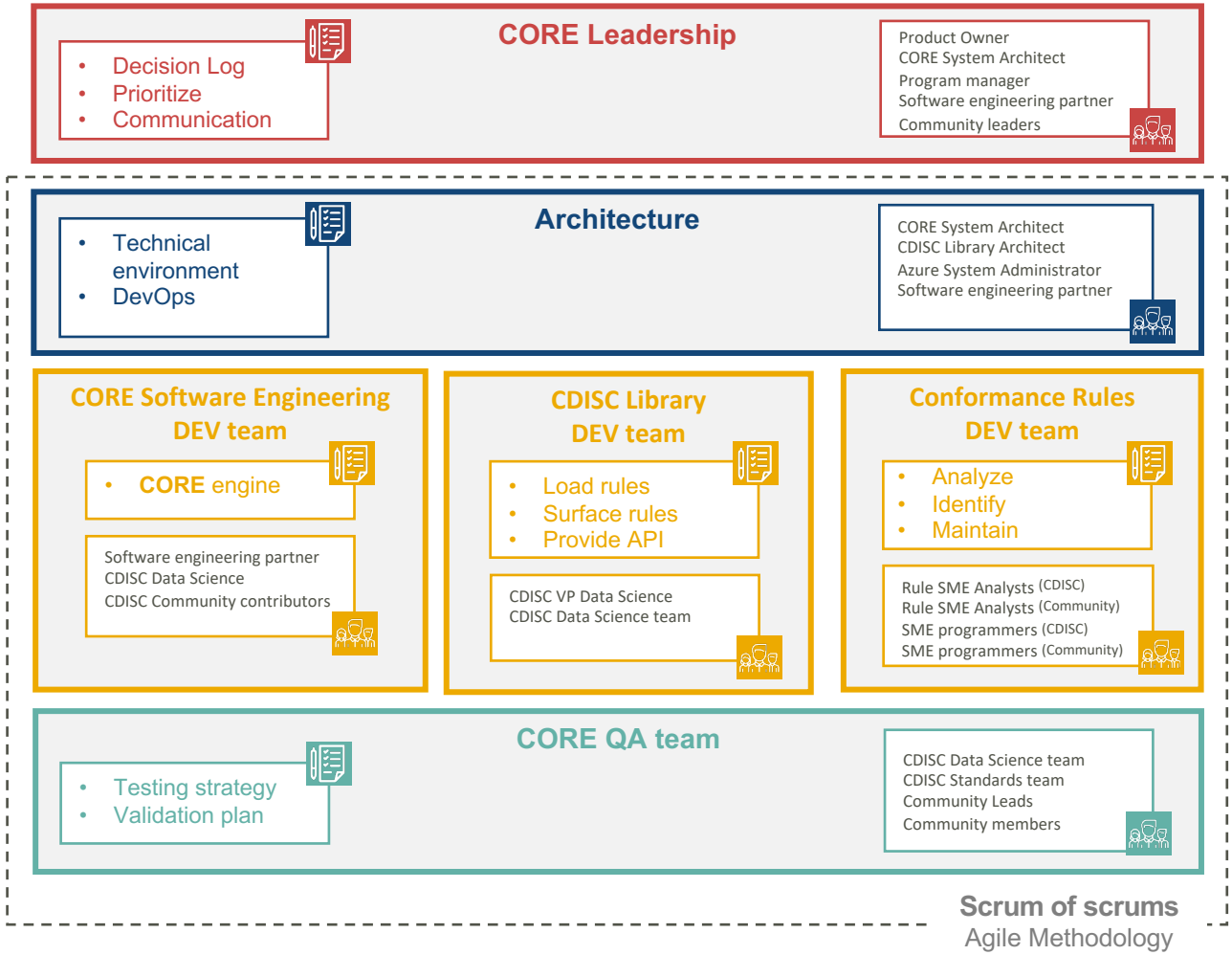
CORE team structure



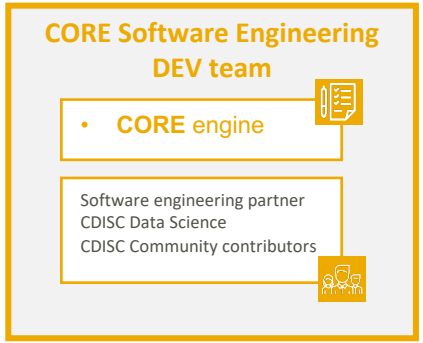
CORE Leadership

- Responsibility:
  - Leadership on all aspects of project execution
  - Project methodology
  - Project structure
  - Project scope
  - Product roadmap
  - Product backlog
  - Release plan
  - Recruitment – volunteers
  - Recruitment – staff
  - MVP scope
  - Groom product backlog
  - Governance

CORE Architecture

- Responsibility:
  - Project DevOps environment
  - High-level requirements
  - Recruitment - staff
  - Tool selection
  - Deliver Non-Functional Requirements
  - System architecture
  - Data architecture
  - Deliver Product Backlog Items
- Membership:
  - System Architect: CDISC VP Data Science
  - Rules execution engine developer leads
  - CDISC IT lead

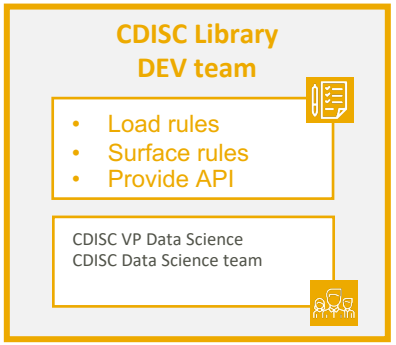
Software Engineering DEV Team



- Responsibility:
  - Development of the open-source rules' execution engine
  - Beta release package definition
  - Deliver Product Backlog Items
  - MVP release deployment

- Membership:
  - Software engineering partner
  - Software engineer (x2)

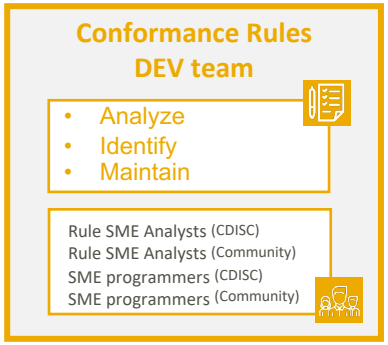
CDISC Library DEV Team



- Responsibility:
  - Load conformance rules to the Library, both the specification and its executable form
  - Surface the rules from the Library
  - Library rules analysis
  - Library architecture updates
  - Beta release package definition

- Membership:
  - Software engineering Library
  - CDISC Library Architect
  - Software engineer (x2)

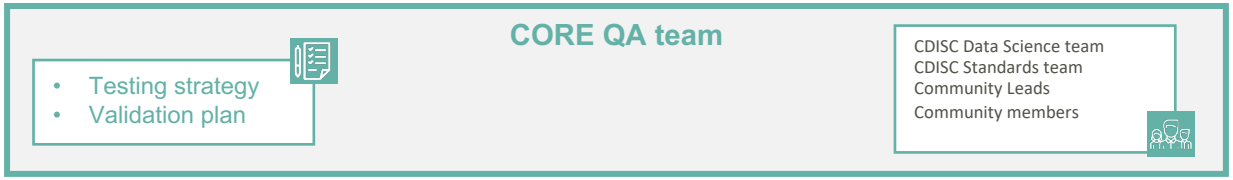
Conformance Rules DEV Team



- Responsibility:
  - The rules' specification and the executable form of the rules
  - Executable rules development
    - Includes testing
    - Test Documentation
  - Deliver Product Backlog Items
  - User stories / input in Interface
  - Input in High-level requirements
  - Conformance Rules Governance process

- Membership:
  - SDTM/SDTMIG SMEs
  - Rule Developer
  - Rule Programmers

QA Team



- Responsibility:
  - Analysis and development of validation plan
  - Analysis and development of test data
  - Execution of validation plan
  - Execute CORE engine for executable rules and test data
  - Report and analyze test results
  - Coordinate with Software Engineering DEV team on test results

- Membership:
  - Validation Lead
  - Validation SMEs
  - Technical Writers
  - Security Engineer (3rd party)

Scrum of Scrums

- Responsibility:
  - Ongoing scrum of scrums for the agile methodology used in the project
  - Sprint Planning meeting
  - Daily stand-ups
  - Sprint Review meeting
  - Sprint Retrospective meeting
  - Release Plan updates
  - Governance
- Membership:
  - CDISC Scrum Master
  - CDISC VP of Data Science
  - Workstream team leads

Project Governance

- CDISC will provide
  - The Product Owner
  - The CORE System Architect
  - A Program Manager
  - A Project Manager / Scrum Master
- These CDISC roles will manage and prioritize the product backlog and deliverables developed in partnership with the software engineering partner
- Project teams report on progress & issues at Scrum of Scrums, Sprint Planning, and Sprint Review meetings
- Unresolved issues will be addressed at CORE Leadership Team meetings
  - Leadership Team will maintain a log of project issues and their resolution

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Project Governance: Activities

CORE Leadership

CORE Leadership Governance Activities
- *Establish governance plan*
- *Resolve escalated issues*
- *Maintain decision log*
- *Communicate to stakeholders*

Scrum Master / Program Manager (Scrum of Scrums)

Scrum Master / Program Manager Governance Activities
- *Maintain Product backlog*
- *Identify and resolve issues*
- *Escalate unresolved issues to CORE Leadership*

CORE System Architect

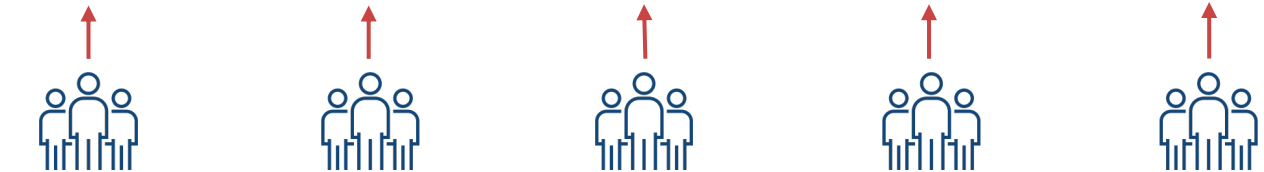
Software engineering team operational lead

Library team operational lead

Conformance Rules team operational lead

QA team operational lead

Team Leads Governance Activities
- *Maintain Team backlog*
- *Identify and resolve issues*
- *Escalate unresolved issues to Scrum Master*



Architecture

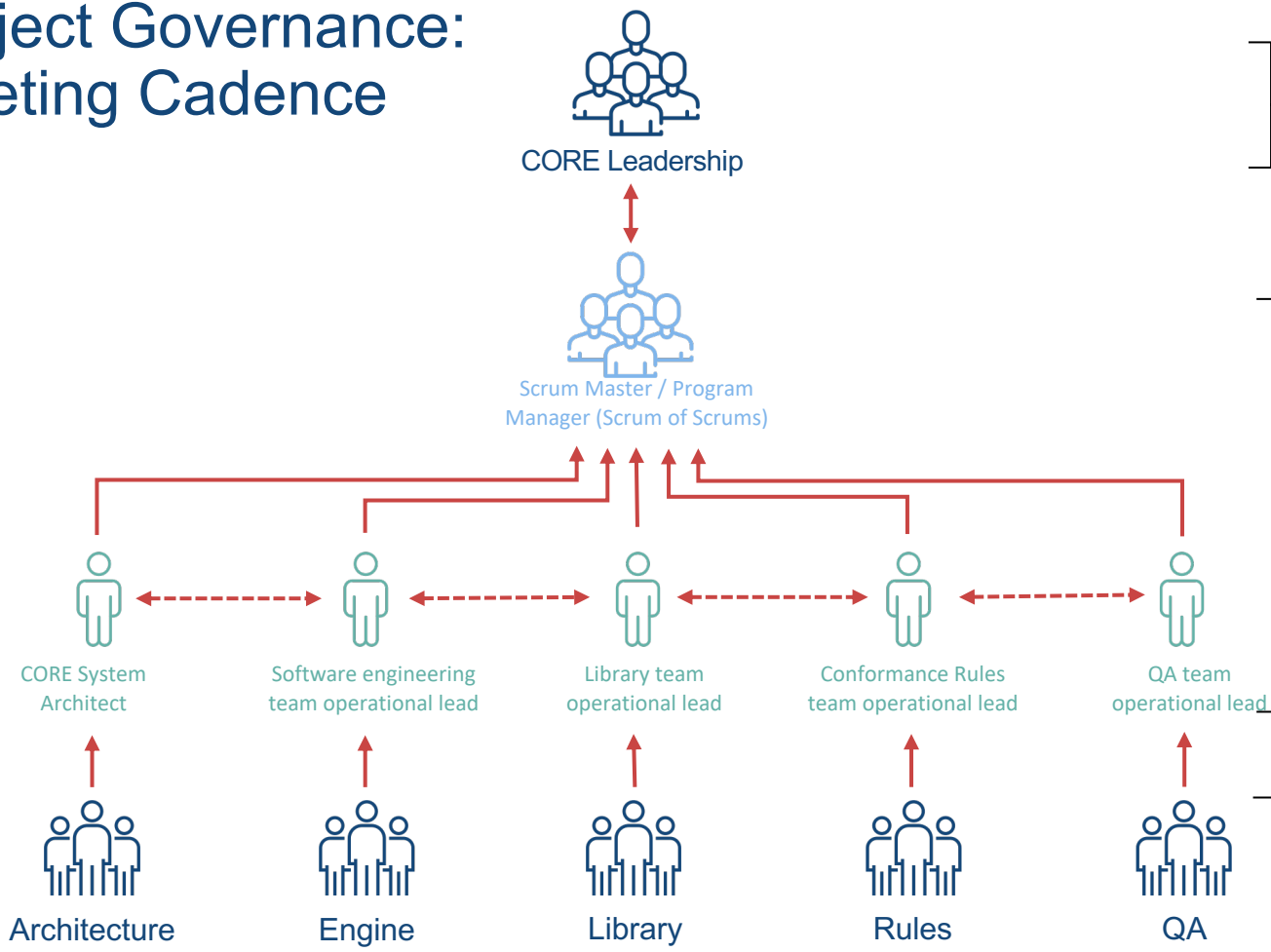
Engine

Library

Rules

QA

Project Governance: Meeting Cadence



CORE Leadership Meeting Cadence
- *Weekly*

Team Lead Meeting Cadence*
- *Backlog Grooming - weekly*
- *Scrum of Scrums – weekly*

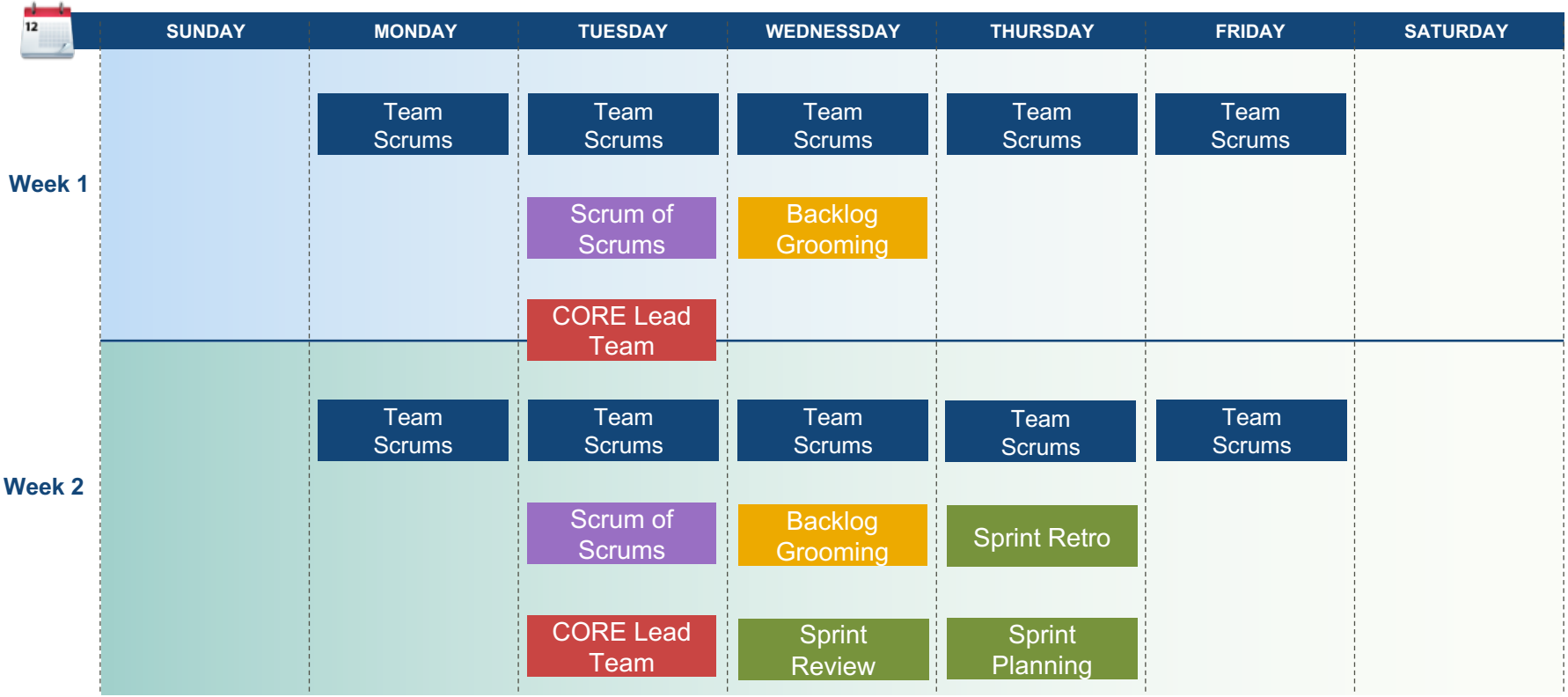
** Plus Team Member meetings*

Team Member Meeting Cadence

Architecture, Engineering & Library:
- *Scrum meeting - daily*
- *Sprint Review - fortnightly*

Rules & QA:
- *Team meeting - weekly*
- *Sprint Review - fortnightly*

Meeting Cadence



* Some Teams will scrum less than daily; actual cadence TBD

Ask for Industry Participation (1)

- Focal teams:
  - Conformance Rules DEV team
  - QA team
- Conformance Rules DEV team
  - Develop the rules Specification and the executable form of the rules
  - Work areas:
    - Specification structure and content
    - Executable rules content
  - Team members:
    - SDTM/SDTMIG SMEs
    - Rule Developer
    - Rule Programmers

Ask for Industry Participation (2)

- QA team
  - Develop and execute validation plan for rules Specification and executable form of rules
  - Work areas:
    - Analysis and development of validation plan
    - Analysis and development of test data
    - Execution of validation plan
      - Execute CORE engine for executable rules and test data
      - Report and analyze test results
      - Coordinate with Software Engineering DEV team on test results
  - Team members:
    - Validation Lead
    - Validation SMEs
    - Technical Writers
    - Security Engineer (3rd party)

Ask for Industry Participation (3)

- Project execution period
  - 2021 Q3 – 2022 Q1 (about 9 months)
- Expected FTE level
  - Minimum 20%
- Meeting types and cadence
  - Based upon agile Kanban methodology
  - Meetings
    - Team meeting once or more per week, as determined by team
    - Attend other DEV teams' Sprint Review once fortnightly (every other week)

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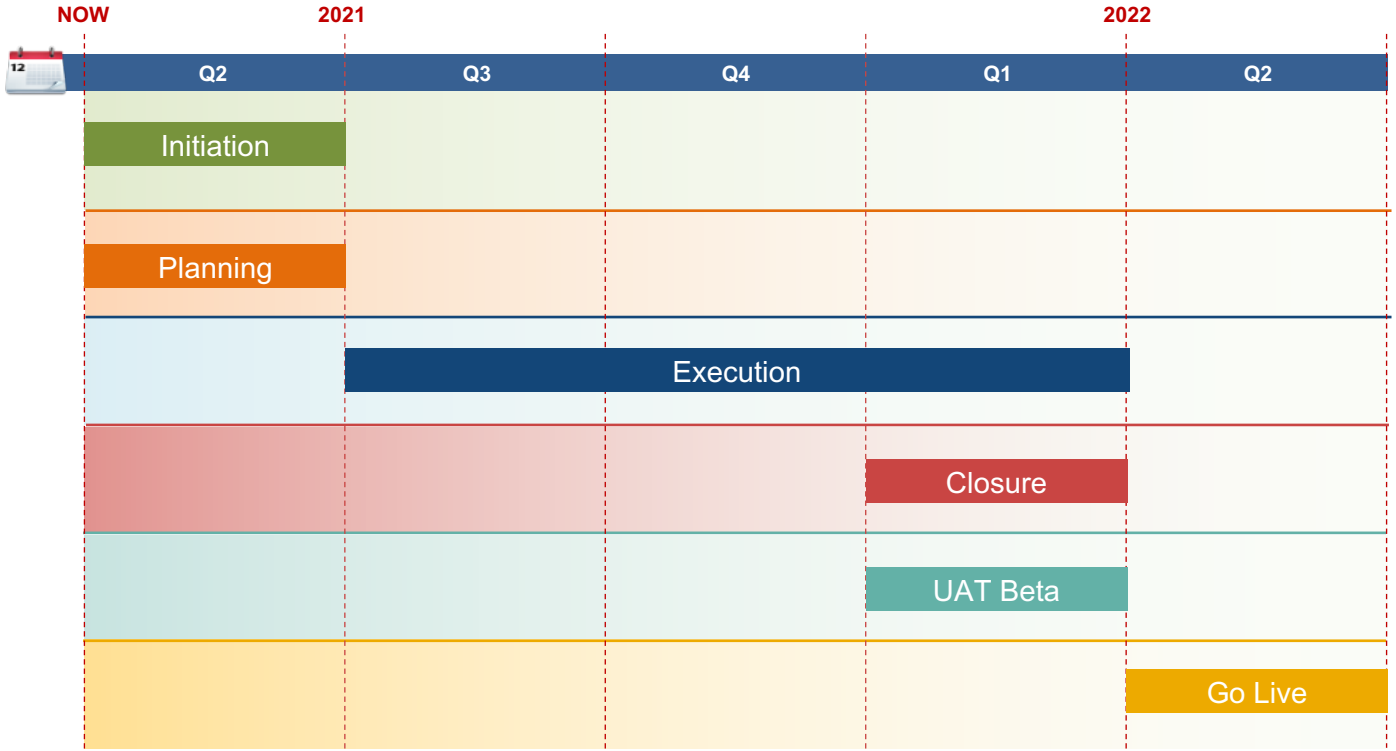
Timeline

For the minimum viable product:

- Initiation: 2021 Q2
- Planning: 2021 Q2
- Execution: 2021 Q3 - 2022 Q1
- Closure: 2022 Q1

Timeline


NOW
2021
2022
Q2
Q3
Q4
Q1
Q2
Initiation
Planning
Execution
Closure
UAT Beta
Go Live

Thank You!

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