

WITH STANDARDS – UNLOCK THE POWER OF DATA



**2022**  
**EUROPE**  
**INTERCHANGE**  
27-28 APRIL | VIRTUAL EVENT

## **CORE: a community-driven solution**

Sam Hume, DSc  
VP, Data Science, CDISC  
2022 Europe Interchange



# Meet the Speaker

Sam Hume

**Title:** VP, Data Science

**Organization:** CDISC

Sam Hume leads the CDISC Data Science team, which collaborates with CDISC staff and stakeholders to develop tools and standards that support clinical and translational data science. Sam directs delivery of the CDISC Library metadata repository that houses all CDISC standards, co-leads the CDISC Data Exchange Standards team, and leads the technical CDISC RWD efforts. He has 25 years' experience in clinical research informatics and has held a number of senior technology positions in the biopharmaceutical industry. He holds a doctorate in information systems.

# Transitioning CORE development to be driven by an open-source development model



How does CORE development happen today?



How is an open-source driven community different?

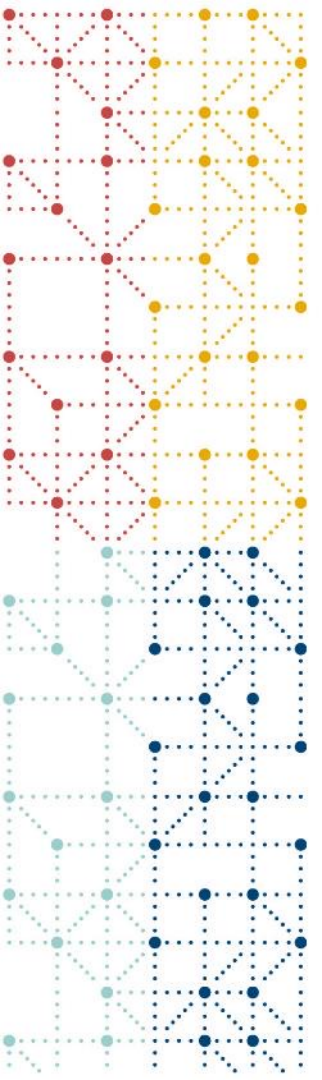


How will we transition from today's development model to an open-source model?



When will we transition to an open-source development model?

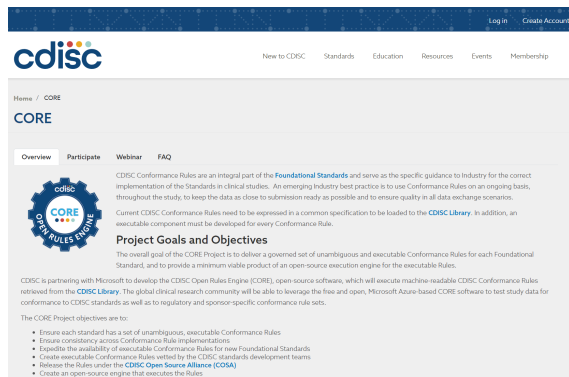




**How does CORE development happen today?**

# CORE Development Today

## Join the Team



<https://www.cdisc.org/core>

## Volunteer for CORE

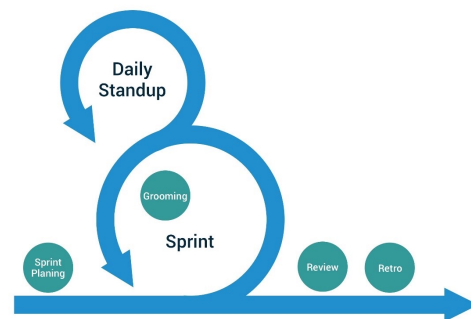


## Environment



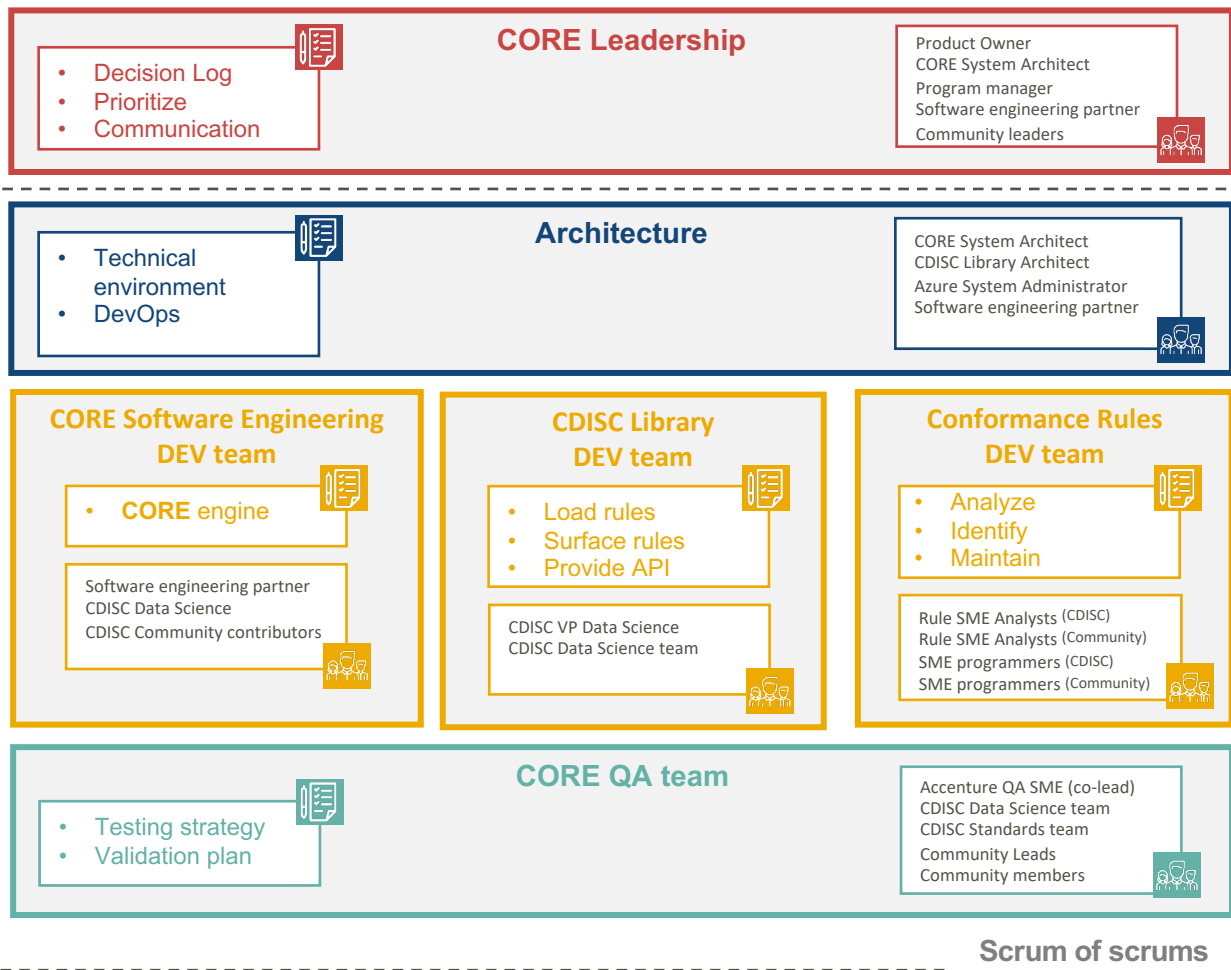
Azure DevOps

## Process

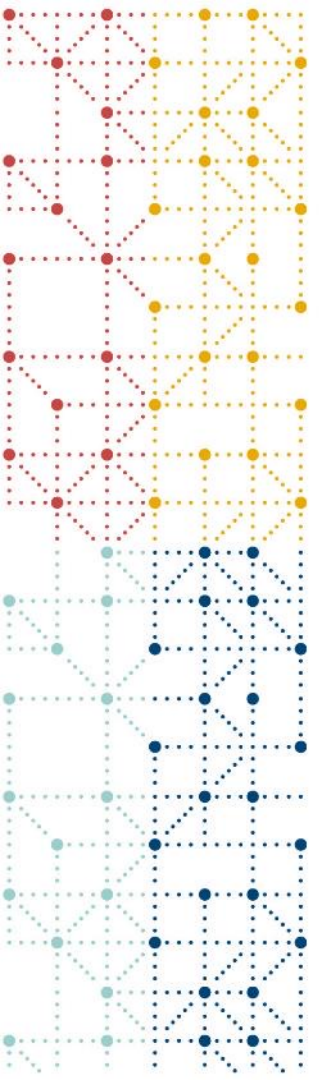


Scrum Framework

# CORE Team Structure



Scrum of scrums  
Agile Methodology



**How is an open-source driven community different?**

# What will make CORE community-driven?

Open-source license

Open-source development model

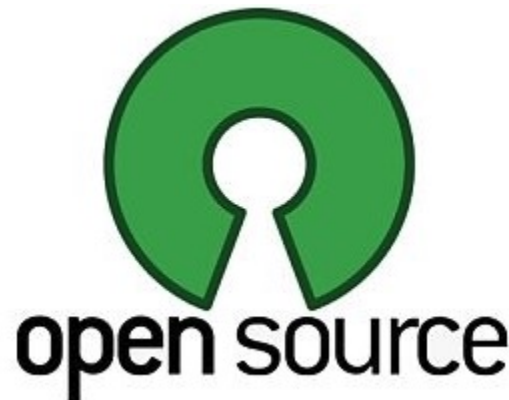
Open-source governance model

GitHub platform



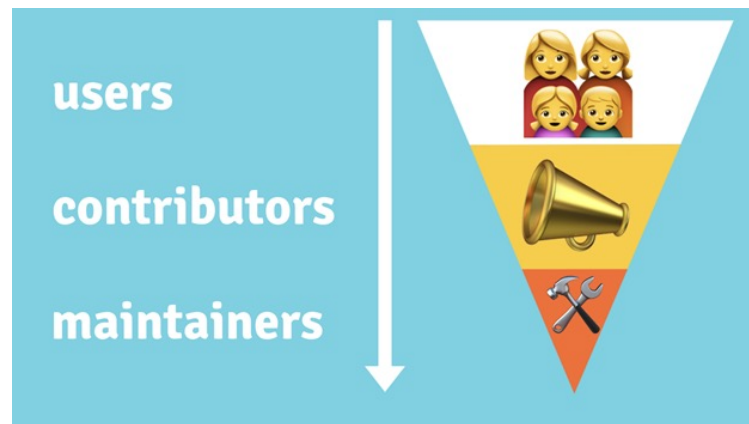
# CORE license

- MIT license
  - Permissive
  - Simple
  - Widely used
  - Low-risk
  - Works for commercial or non-commercial usage
- Contributors License Agreement (CLA)
  - Will not use a CLA
  - Rely on the GitHub inbound = outbound clause in Terms of Service
- Optimize project for ease of participation and deployment
  - The open-source development model helps ensure sustainability



# Meritocratic Governance Model

- CORE is a meritocratic, consensus-based community project
- Based on the Meritocratic Governance Model used by the Apache Software Foundation
- Those with interest in the project can join the community, contribute, and participate in the decision-making process
- Influence and leadership roles favor Contributors over Users
- Active participation is valued



From <https://opensource.guide/building-community/>

# CORE Roles

## Users

- Use the software but aren't submitting code, tests, or documentation

## Contributors

- Submit code, test, or documentation but need to review and commit their work

## Maintainers

- Review and merge contributions and generally run the technical aspects of the project

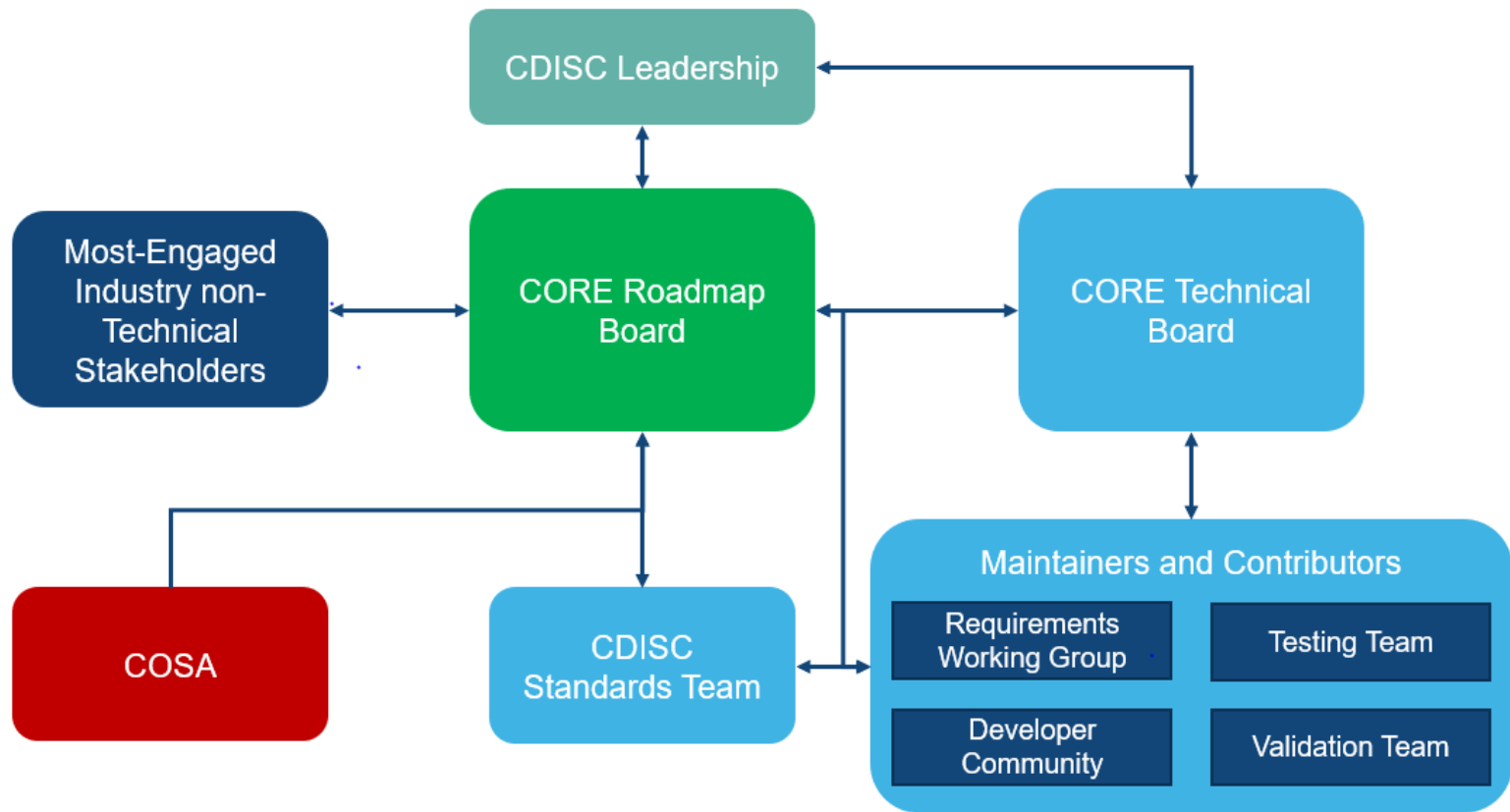
## Governors

- Members of the CORE Roadmap Board or Technical Board

## Rule Developers

- Participate as standards developers creating Conformance Rules

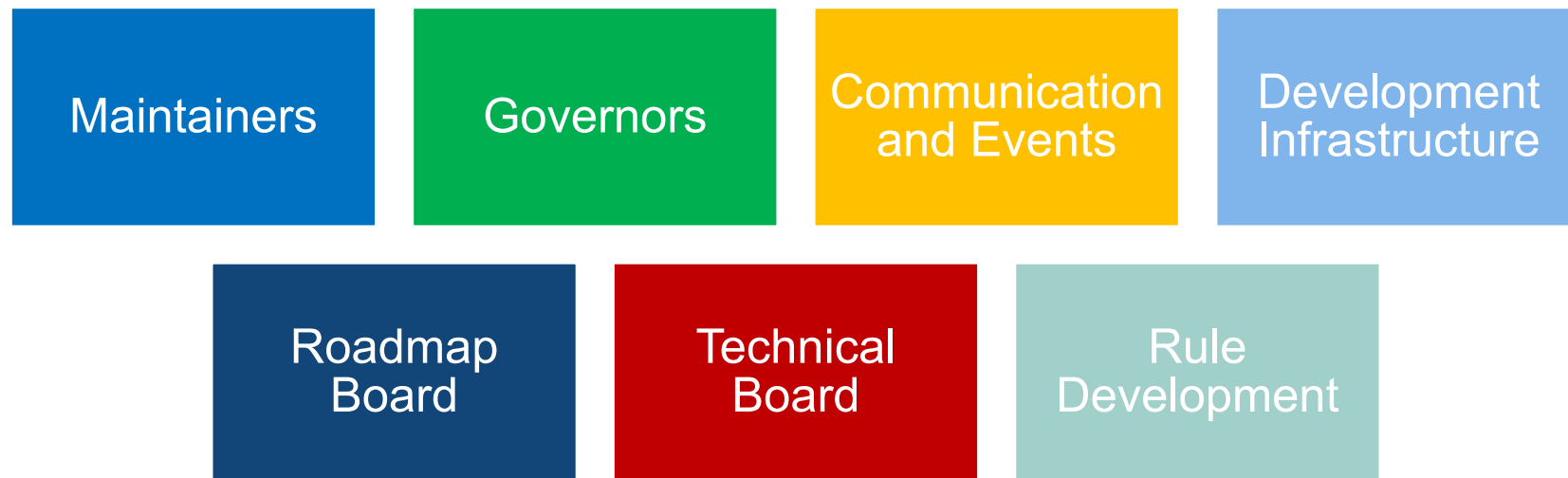
# Governance and Development Organization





**How will we transition from today's  
development model to an open-source  
model?**

# CDISC's Role in the CORE Community



# Content supporting community involvement



User documentation



Developer  
documentation



Contributor's  
documentation and  
on-boarding  
process



Training and  
education



Automated testing  
and test framework



Validation  
documentation



CDISC hosted  
evaluation version



Community-based  
support

# CDISC Library Access for All

## Unlimited Member Access

- Unlimited Library accounts for members available today
- Deprecating Library Archives

## Non-member Access

- Free non-member Library accounts coming for MVP 1.1

## Library EULA

- Updated Library EULA drafted
- Removes vendor costs





# Software Development Process

- Scrum?
- Probably more Kanban style with
  - CDISC developers as team members
  - Volunteer team members
  - External contributors that do not function as part of the team
- Heavy reliance on asynchronous work and messaging
- Decentralized contributions + extensive peer review



# CORE as a COSA Member

**COSA Mission:** The CDISC Open-Source Alliance (COSA) supports, promotes, and sometimes sponsors open-source and free software development projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community.

We anticipate CORE will be a COSA member

COSA support and promotion of CORE:

- CORE workshops and hackathons
- CORE conference sessions & webinars
- CORE community building
- Guidance for CORE governance
- Open-source best practices
- Community of open-source developers



<https://cosa.cdisc.org/>

# CORE Community Tools



GitHub



Slack

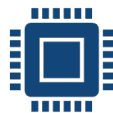


LinkedIn  
Group



Azure

# Commercial vendor involvement



## A variety of commercial alternatives

### Examples:

Software-as-a-Service  
Commercial support  
Embedded in commercial software  
Deployment and implementation services



## Vendors contribute to the open-source community

### Examples:

Contributors  
Maintainers  
Board members



## API and Plugin architecture promote tool development

### Examples:

Issue Management  
Define-XML Authoring  
Workflow



## CORE Deployment Alternatives

### Examples:

Alternative User Interface  
On-premises version  
Multi-cloud version  
Embedded deployment  
Alternative rule engine

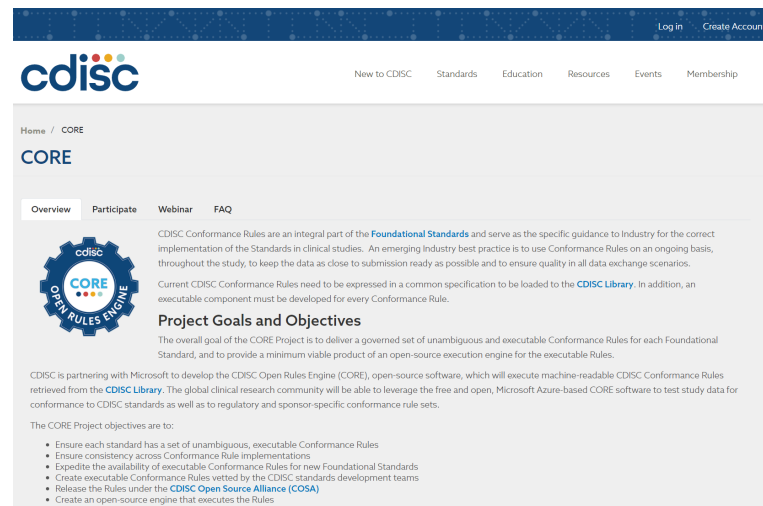


**When will we transition to an open-source development model?**

# When will CORE be released as open-source?

- Currently planning to release CORE as open-source after the MVP 1.1 release
- CDISC will provide an update after we finalize our MVP 1.1 plans
- Tasks prior to releasing as open-source:
  - Code refactoring
  - Technical documentation
  - Move to GitHub
  - CORE community
- Until then volunteer for the team!

Get Involved!



The screenshot shows the CDISC CORE project website. At the top is a dark blue header with the CDISC logo and navigation links: Home, CORE, New to CDISC, Standards, Education, Resources, Events, and Membership. Below the header, the page title is "CORE". There are tabs for Overview, Participate, Webinar, and FAQ. The "Overview" tab is selected. The main content area features a large gear icon with "CDISC CORE OPEN RULES ENGINE" inside. The text explains that CDISC Conformance Rules are an integral part of the Foundational Standards and serve as specific guidance for the correct implementation of the Standards in clinical studies. It mentions that 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. It also states that current CDISC Conformance Rules need to be expressed in a common specification to be loaded to the CDISC Library. In addition, an executable component must be developed for every Conformance Rule. The "Project Goals and Objectives" section states that the overall goal of the CORE Project is to deliver a governed set of unambiguous and executable Conformance Rules for each Foundational Standard, and to provide a minimum viable product of an open-source execution engine for the executable Rules. A paragraph mentions that CDISC is partnering with Microsoft to develop the CDISC Open Rules Engine (CORE), open-source software, which will execute machine-readable CDISC Conformance Rules retrieved from the CDISC Library. The global clinical research community will be able to leverage the free and open, Microsoft Azure-based CORE software to test study data for conformance to CDISC standards as well as to regulatory and sponsor-specific conformance rule sets. The "The CORE Project objectives are to:" section lists five bullet points: Ensure each standard has a set of unambiguous, executable Conformance Rules; Ensure consistency across Conformance Rule implementations; Expedite the availability of executable Conformance Rules for new Foundational Standards; Create executable Conformance Rules vetted by the CDISC standards development teams; Release the Rules under the CDISC Open Source Alliance (COSA); and Create an open-source engine that executes the Rules.

<https://www.cdisc.org/core>



# Thank You!

Sam Hume  
[shume@cdisc.org](mailto:shume@cdisc.org)

