Trial Master File Reference Model

General Meeting

13th December 2021

Agenda

- TMF Reference Model Community
- The Future of the TMF Reference Model
- Upcoming TMF Meetings
- Next Meeting

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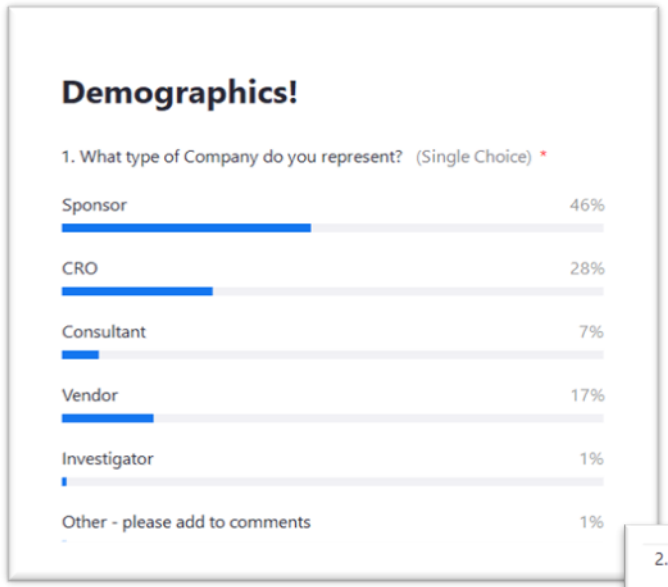
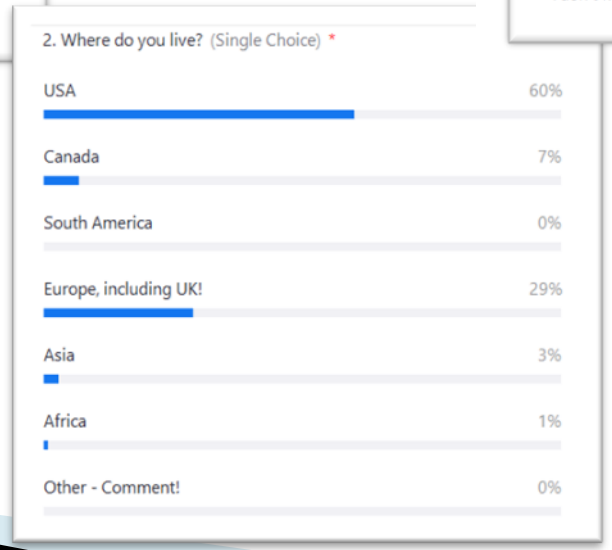
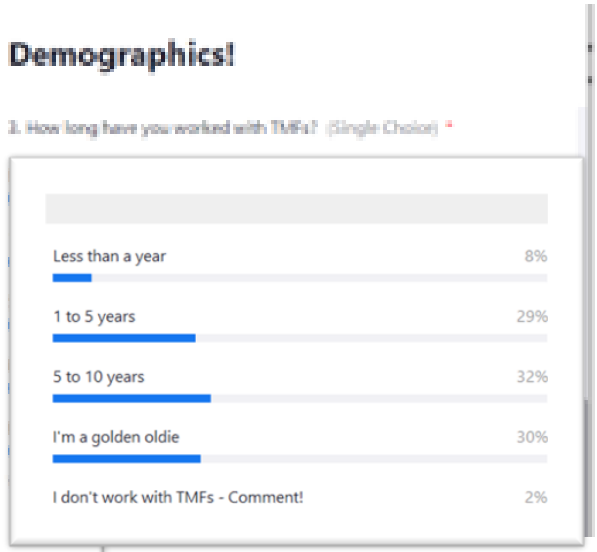
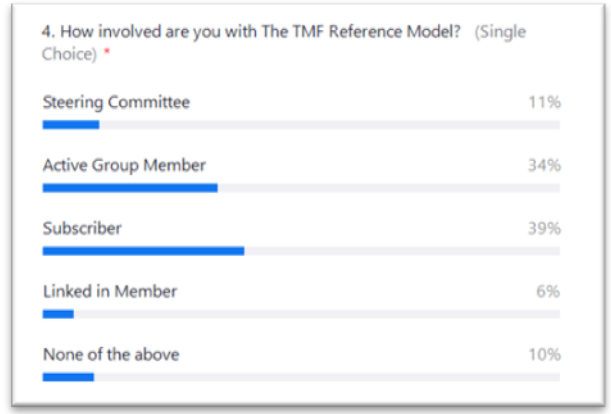
Demographics Polls









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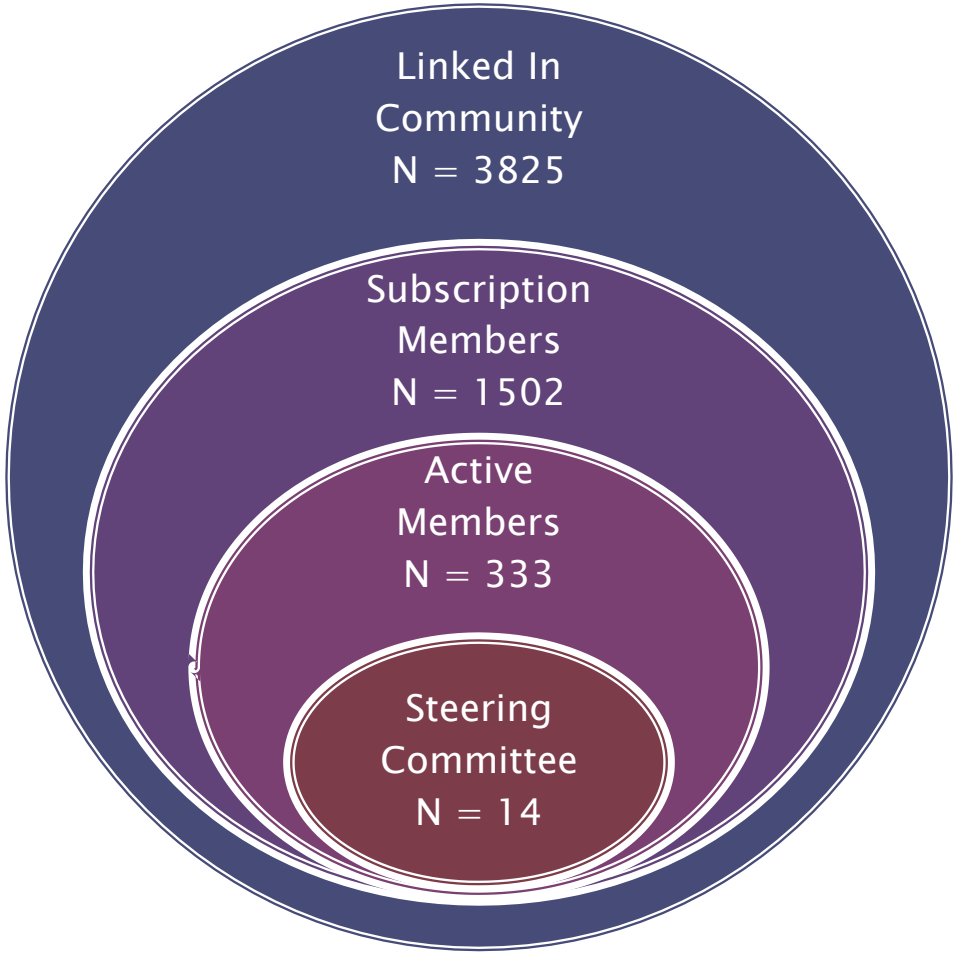
The TMF Reference Model Community



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Trial Master File Reference Model

The Future of the TMF Reference Model

Karen Roy

TMF RM Today

- The TMF RM is owned by the members of the Team
- The TMF RM is freely available
- We are in control of the TMF Reference Model content
- The TMF RM is not a formal standard, has no status or standing with Health Authorities
- We are a volunteer organization with neither funding nor organizational support
- *After more than a decade, we want to ensure the TMF RM is future-proof*

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Situation:	The SC has heard many worthy community goals and potential initiatives ideated in 2020/2021.
Problem:	TMF Reference Model does not have the structure or resources to reasonably complete those goals and initiatives.
Action:	TMF RM Steering Committee completed 'Strategy on a Page' (SOAP) exercise to agree on objectives and success factors
Result:	4 "Pillars" have been identified

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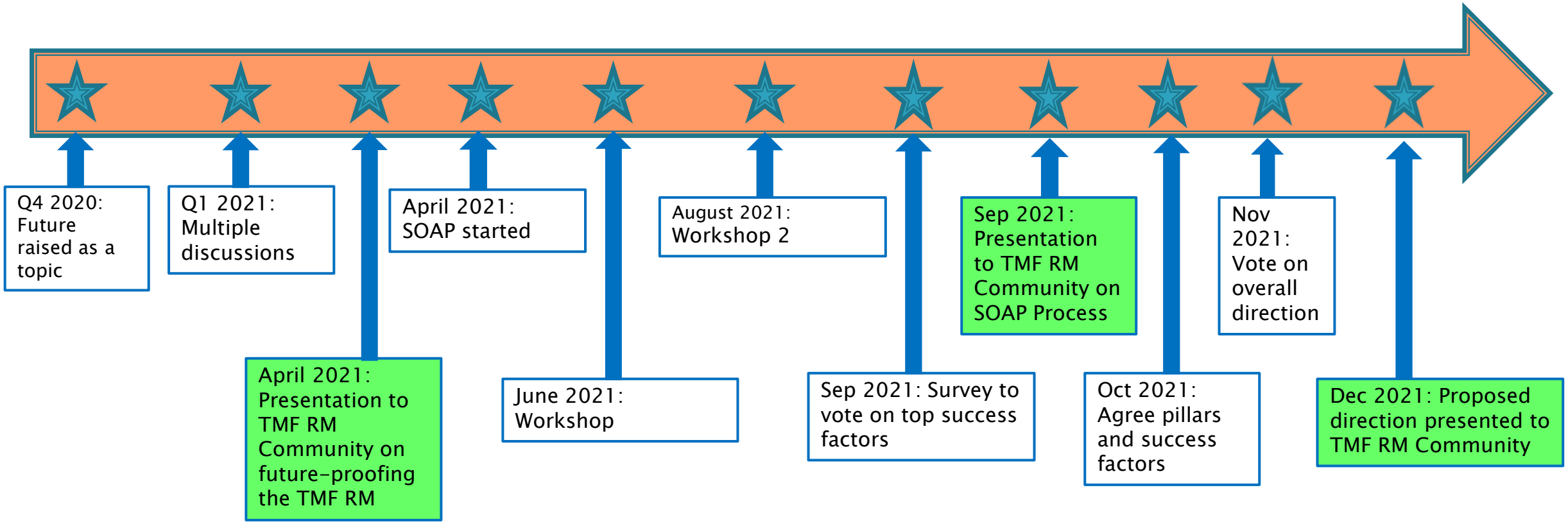
What we as a Steering Committee have been up to!



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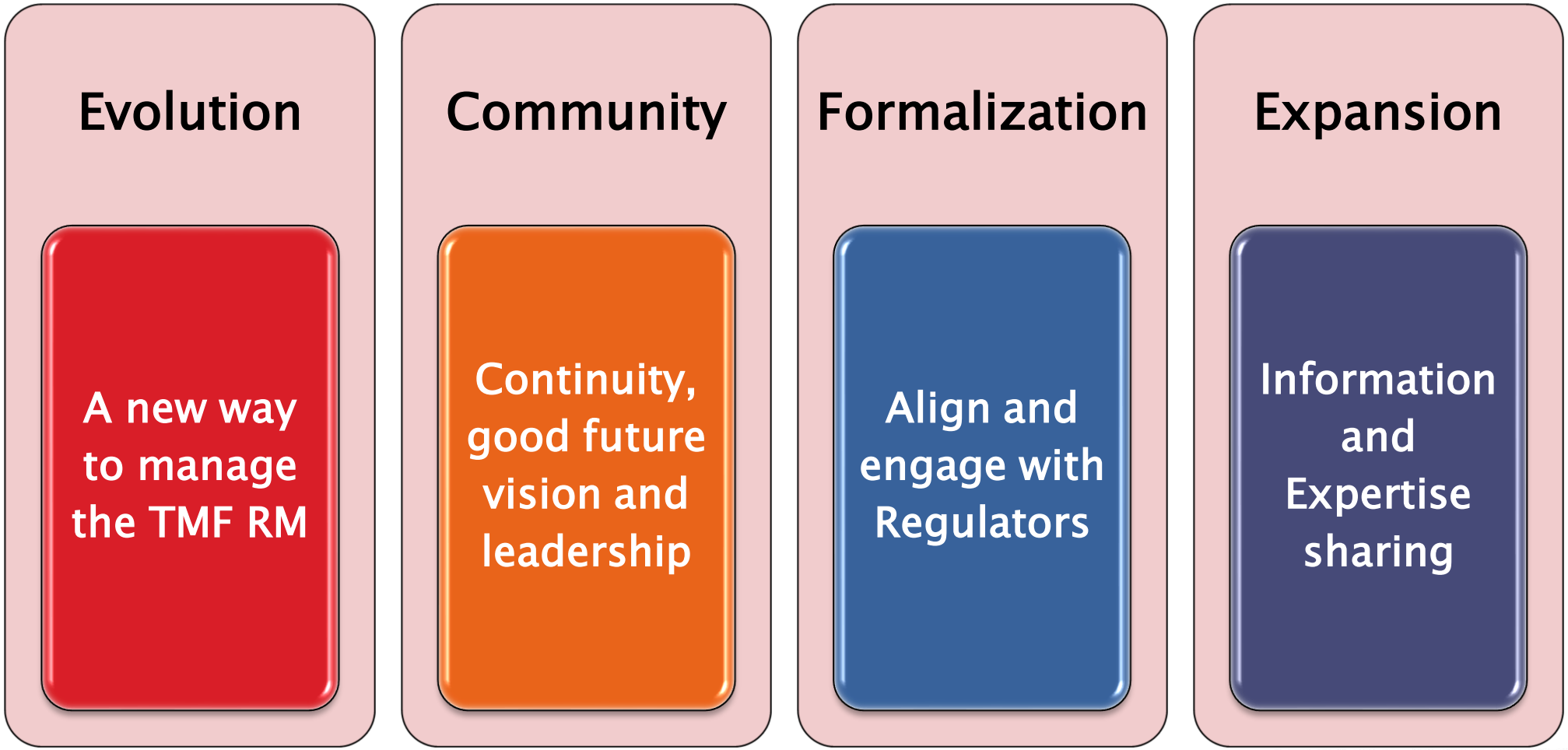
Strategy Pillars for the Future



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Evolution

A new way to manage the TMF RM

- Extend the granularity of the TMF RM
- Expand the TMF RM to incorporate different types of studies and data
- Implement better tools to manage, map and distribute the TMF RM

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Community

Continuity, good future vision and leadership

- Strengthen community engagement to drive evolution
- Safeguard the continuity of the TMF RM Leadership
- Identify and encourage active working groups to produce deliverables

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Formalization

Align and engage with Regulators

- Establish the TMF RM as a formal standard
- Secure formal recognition from the regulatory authorities as a standard for managing TMF content
- Promote Industry adoption of the Exchange Mechanism Standard

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Expansion

Information and expertise sharing

- Re-brand to reflect the expanded activity
- Produce best practices and documentation
- Agree standardized TMF metrics both internally and externally

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What are the Implications of these Pillars?

- More support is required!
  - Operational
  - Technical
  - Financial
  - Relationships & Influence
- Change in positioning – we are not just a spreadsheet team!

Steering Committee Opinion

- In order to achieve the strategy and its goals and success factors, the TMF Reference Model Steering Committee has unanimously agreed that the TMF Reference Model group should affiliate with a formal organization

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Affiliation search criteria/principles

1. TMF RM content remains under our Team's control
2. TMF RM remains freely available to the public
3. We do not want to be affiliated with a for profit company
4. We want an organization that won't exclude any party involved, including vendors and technologists
5. We want relationships & connections to regulatory authorities
6. We want relationships & connections to standards organizations

What candidate organizations have been identified/were considered?

Considered	Description	Key Consideration
ACRP	Non-profit Organization that focuses on the training and certification of clinical research professionals.	Training centric rather than standards centric.
AVOCA Quality Consortium	AVOCA is now part of the for-profit company WCG, associated with WCG's GCP Quality and Compliance Consulting Solutions.	Membership is open to sponsors, CROs, and Clinical Service providers. This eliminates membership from consulting and vendors. Individuals from these types of organizations have been a key part of the success of the RM. AVOCA is not a standards organization.
DIA	Global association that mobilizes life science professionals from across all areas of expertise to engage with patients, peers and thought leaders in a neutral environment on the issues of today and the possibilities for tomorrow.	The Document and Records Management Community is the original group of likeminded professionals that supported the team to develop the TMF Reference Model and supportive TMF-related materials – providing the platform for document management and meetings. However the TMF RM activities and document management moved from primarily being maintained in the DIA platform to the TMFRefModel.org as the reference model and team grew to be more than those with DIA membership. The "DIA" was dropped from the name of the TMF RM about 7 years ago as the TMF RM is not a product of the DIA or should have been branded as one. The DIA does not "own" the TMF RM as it was created by the industry for the industry. The DIA is not a standards organization nor wants to be one.

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What candidate organizations have been identified/were considered?

Considered	Description	Key Consideration
HL7	HL7 (Health Level Seven) is a standard for exchanging health information between medical applications. This standard defines a format for the transmission of health-related information. ... Examples of HL7 messages include patient records, laboratory records and billing information.	Primary standards and other select products are now licensed at no cost.
ISO	ISO is an independent, non-governmental international organization with a membership of 165 national standards bodies. Contains standards for technology and manufacturing.	Requires being a national standard body prior to joining. Access to standards does incur costs.
OASIS	Standards organization with projects for cybersecurity, blockchain, IoT, emergency management, cloud computing, legal data exchange, etc. There was an eTMF technical committee in 2014-15, which was closed on 17NOV17 and is no longer active.	Was not effective in gaining acceptance of a TMF standard in the past; unclear if they would be open to trying again Is Membership Open to all Sponsor, CROs, system vendors, consultants? Access/Relationships with Regulators Focus is more outside our industry

What candidate organizations have been identified/were considered?

Considered	Description	Key Consideration
TransCelerate	TransCelerate BioPharma's mission is to collaborate across the global biopharmaceutical research and development community to identify, prioritize, design, and facilitate the implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines. TransCelerate aspires to create a future state for clinical research where these challenges are no longer roadblocks to success	Membership required to participate; deliverables are available to industry. TransCelerate is not a standards organization
CDISC	An open, non-profit organization that develops and supports global data standards to improve the quality and interoperability of medical research and healthcare. CDISC standards are widely used for study planning and data collection, tabulation, analysis, and submissions to the U.S. Food and Drug Administration (FDA), Japanese Pharmaceuticals and Medical Devices Agency (PMDA), and other regulatory agencies internationally.	Similar structure to current TMF RM, relationships currently established with regulators, implementation would be generally straight forward.

Any other proposals for organizations to be considered?

Who is CDISC (Clinical Data Interchange Standards Consortium)?

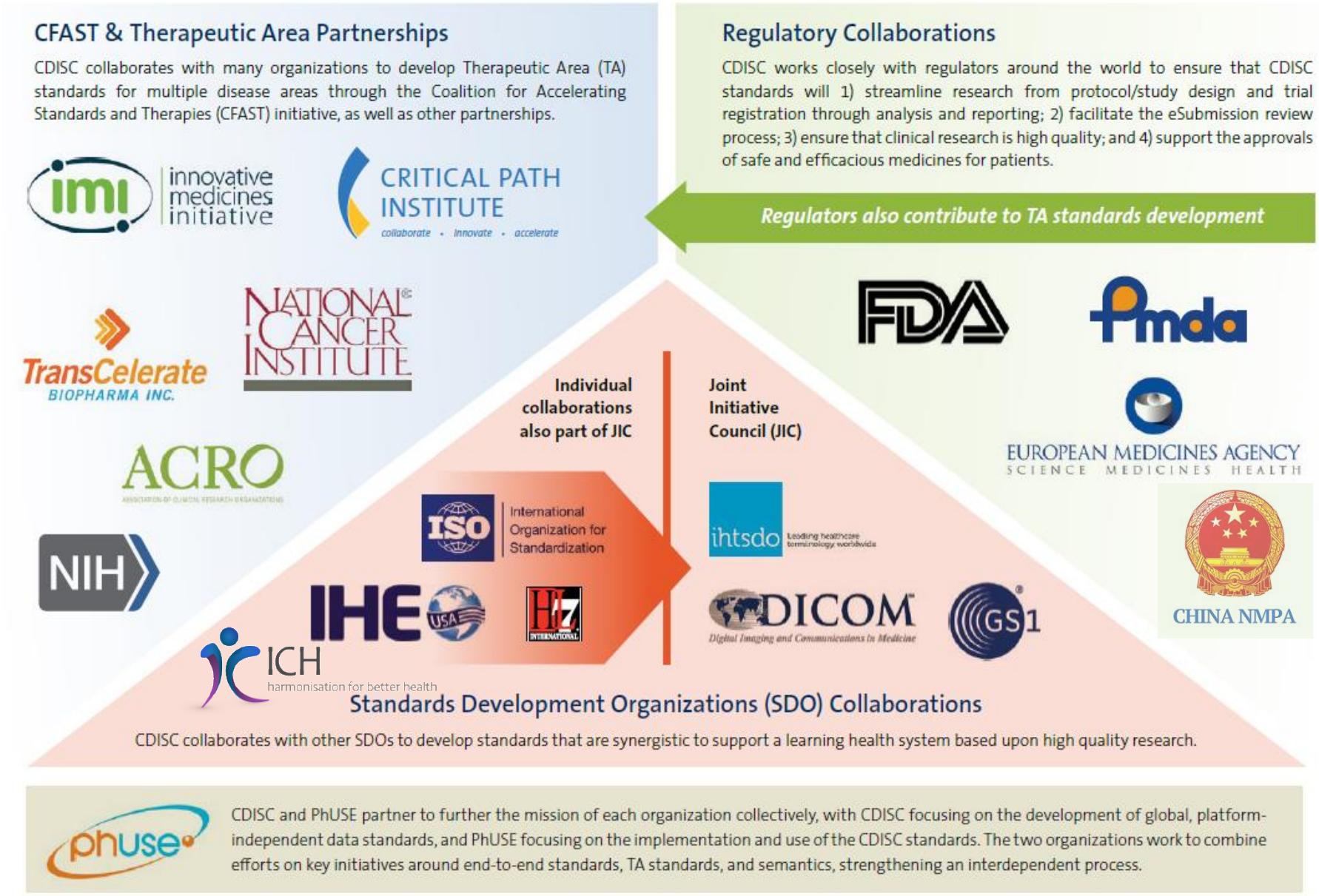
***CDISC's Mission**: To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare*

- Global Non-profit Consensus-based Standards Development Organization
- 20+ Years of Regulatory Clinical Data Standards Development and Implementation
- Experienced Leadership Team and Dedicated Staff of 40+ Professionals and SMEs
- Volunteer Network of 1000+ Industry Experts
- 500+ Member Organizations

Who is CDISC?

- Regulatory Required, Widely Adopted and Freely Available Clinical Research Data Standards
- Mature Standard Governance Processes
- Innovative Open-Source Technology for Standards Library and Metadata Management
- Involved in a wide range of emerging Industry Initiatives and Projects
- Collaborative Ecosystem of Relationships and Partnerships
  - Members, Regulators, Patient Foundations, Academia, SDOs and Industry

CDISC Alliances and Collaborations



Additional Collaborations

- Academic Institutions
- Accumulus Synergy
- BioPharmaceutical Statistics Leaders Consortium
- Clinical Data Privacy Consortium
- Learning Health Community
- Pharmaceutical Data Standards Leaders
- Clinical Data Sharing Initiatives

What do they offer

- Formal recognition as a Standards Development Organization by Regulatory Agencies (FDA, PMDA, NMPA, EMA)
- A formalized framework for a Standards Development Lifecycle
- Dedicated resources for the management and promotion of Standards
- Technical resources to manage and deploy Standards
- Publication and distribution of Standards documentation and implementation guides
- Formalized Training and Certification on the CDISC Standards
- Dedicated Staff for Events, Education, Membership and Volunteers

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What would this mean for the TMF RM

- We would continue to leverage the community to drive the content and direction of the model
- We would still have a steering committee to govern the model
- We would be part of a formal organization with funding and resources
- We would be better enabled to expand the model (definition of metadata, mapping to other models and standards etc.)
- We would be able to leverage CDISC experience in promoting the use and further development of the eTMF exchange mechanism standard
- We would be part of an organization with formal ties to ICH and the Regulatory Agencies
- We would be part of a clinical standards ecosystem with better interoperability

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What's in it for CDISC?

- CDISC is expanding its scope from clinical data standards to trial design, trial administration and clinical operations
- CDISC is serving as the hub for a number of cross-industry standards initiatives and the TMF RM could be part of that
- Based on CDISC's strategy, there is a natural progression to the development of TMF standards, so why reinvent the wheel when so much work has already been done

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Ask of Community/Next Steps/Timeline

- Request comment on forthcoming position paper available for consultation in February 2022
- TMF RM Steering Committee meets in early March 2022 to ratify decision based on feedback
- Implementation plan agreed by end March 2022

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TMF-related events coming up*

**Events page on website (under Resources menu)*

Conference	When	Location
Hanson Wade Trial Master Files & Inspection Readiness	TBD	Boston, MA, USA
DIA Regulatory Submissions, Information, and Document Management Forum	February 14-16, 2022	North Bethesda, MD, USA
Questex TMF Summit	May 2022	TBD
8th Clinical Trials Strategic Summit	May 4-5, 2022	Boston, MA, USA
Association for GXP Excellence	May 1-4, 2022	San Antonio, TX, USA
HSRAA Conference	September 2022	TBD in UK

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TMF RM General Meetings

- 24th January 2022
- Add to your calendar NOW or download the calendar file (.ics file) from our homepage
- Outlook Meeting Request no longer distributed

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ICH E6R3

- Update on progress report:
- https://ctti-clinicaltrials.org/wp-content/uploads/2021/10/ICH-E6-Public-Web-Conference-May-2021-Final-Report.pdf
- OR: https://www.ich.org/page/ich-public-events#1-2

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QUESTIONS?

Join the TMF Reference Model Discussion Group

https://tmfrefmodel.com/register

- Knowledge sharing
- Networking
- Too Much Fun!

Join the TMF Reference Model Project Team

(be prepared to work! – we can't do this without YOU)

https://tmfrefmodel.groups.io/g/main

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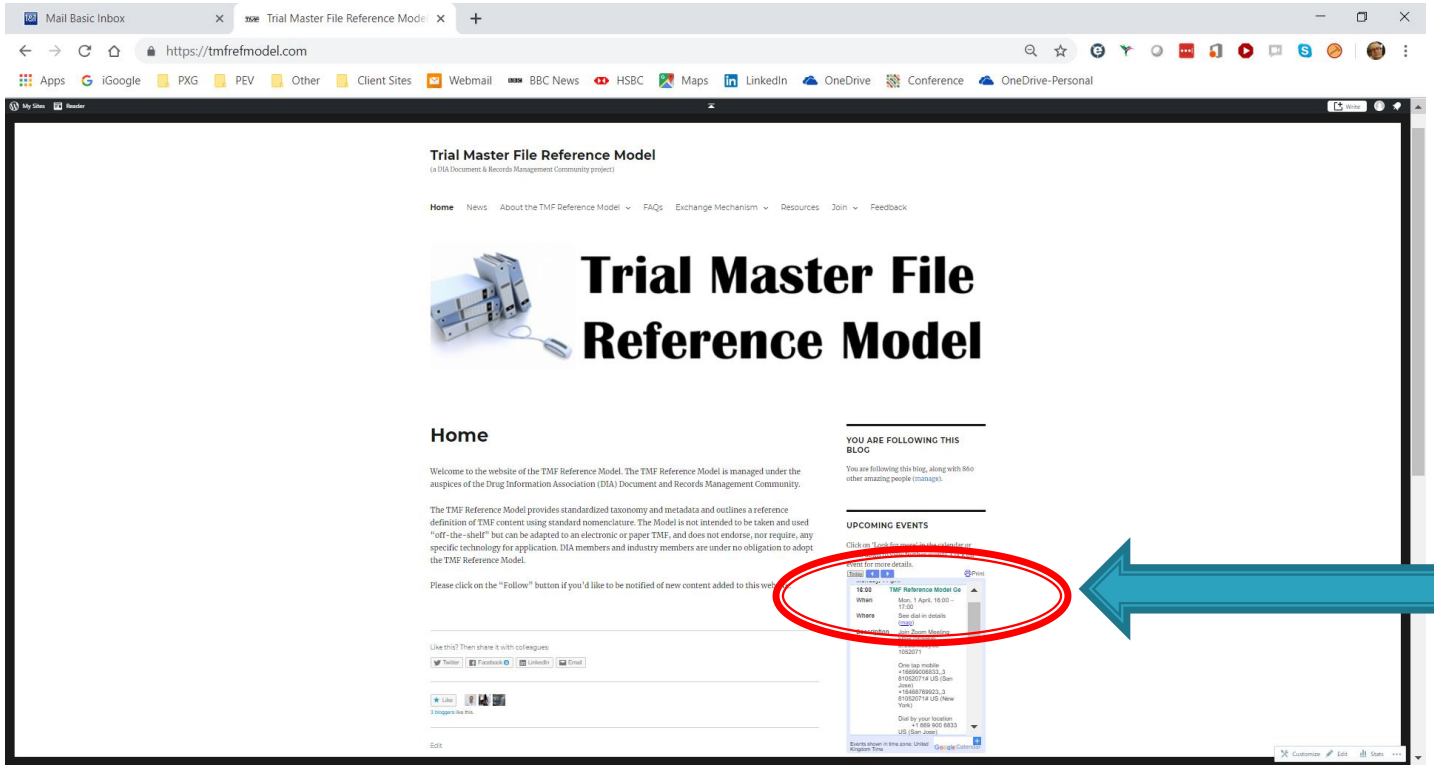
Meeting details

- Wondering where to find details of the next meeting?



On TMF Reference Model website, click on calendar to see meeting details. Click 'Copy to my calendar' to add to your Outlook / Google calendar.

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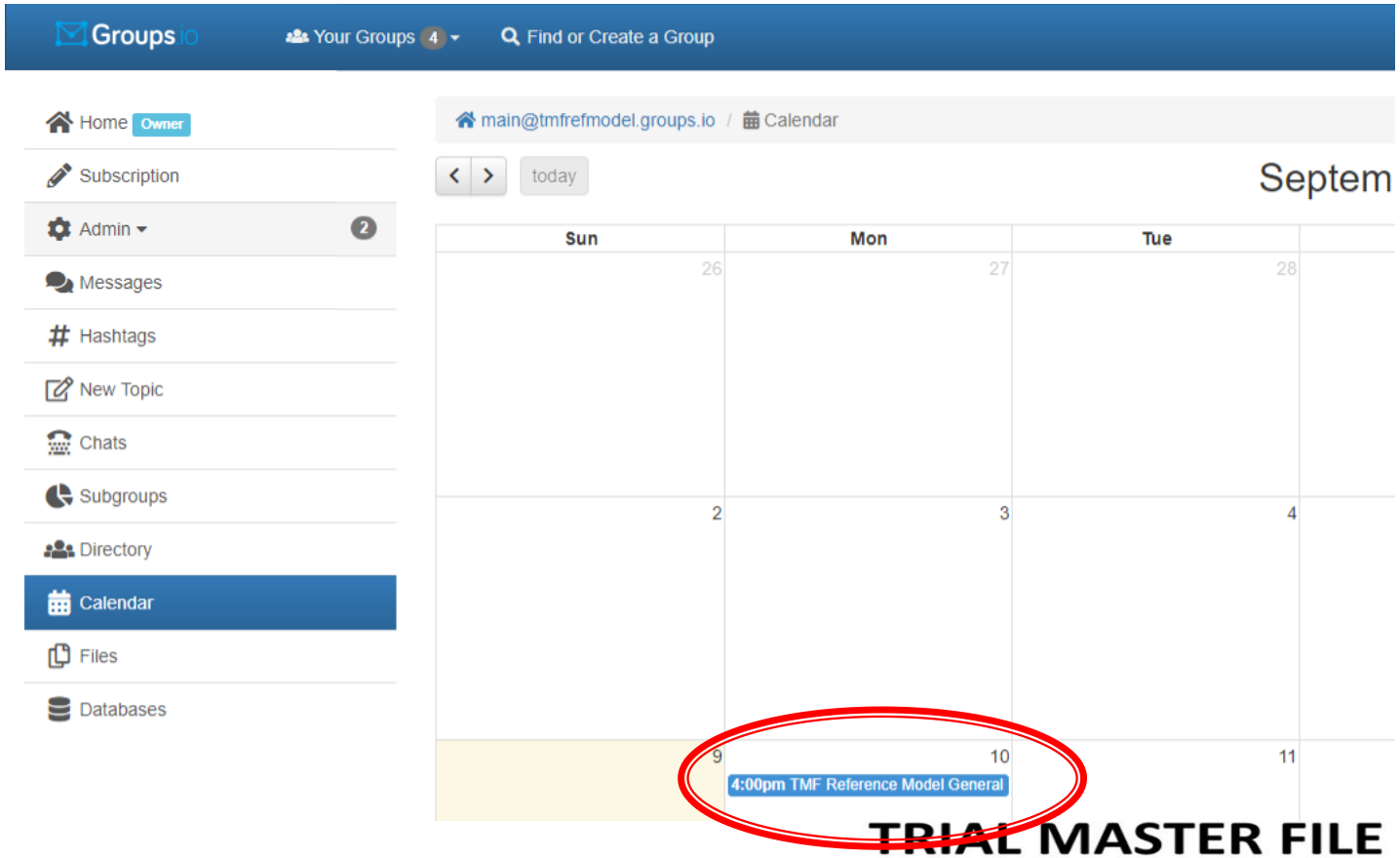
Meeting details

- Wondering where to find details of the next meeting?

On Groups.io, click on Calendar to show group calendar. Click on an event to see dial-in details

https://tmfrefmodel.groups.io/g/**main**/



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