



2025 CDISC + TMF
EUROPE INTERCHANGE

GENEVA

CONFERENCE & EXPO: 14-15 MAY | TRAININGS: 12, 13, 16 MAY

The Danish TMF Network

Presented by Karla Navera-Andersen, Clinical Trial Manager,
Clinical Operations, Ascendis Pharma



Meet the Speaker

Karla Navera-Andersen

Title: Clinical Trial Manager

Organization: Ascendis Pharma A/S

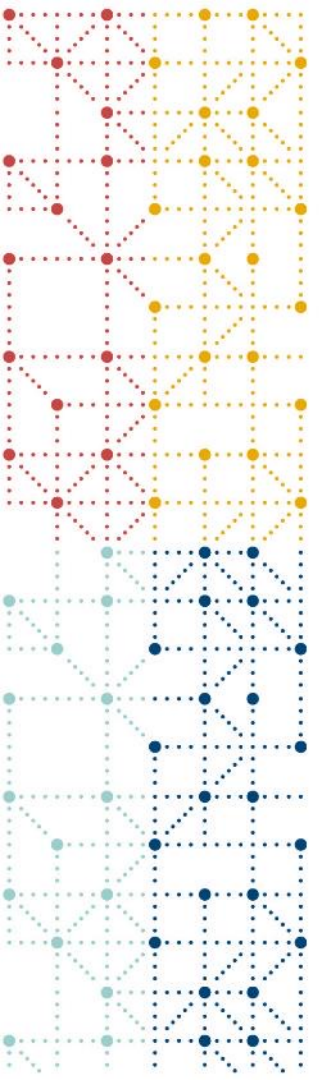
Karla Navera-Andersen is an eTMF Manager turned Clinical Trial Manager at Ascendis Pharma A/S.

Karla holds a Master of Arts in English and a Pharma Consultant Diploma. She has spent over 15 years working with TMFs, starting her TMF career as a student in the paper TMF archive in a large pharmaceutical company.

Since then, Karla has worked on both the CRO and Sponsor side and within Clinical Operations and Regulatory Affairs. Currently, Karla is working as a Clinical Trial Manager, focusing on improving the quality and processes of TMF management within Clinical Operations and between Sponsor and CRO.

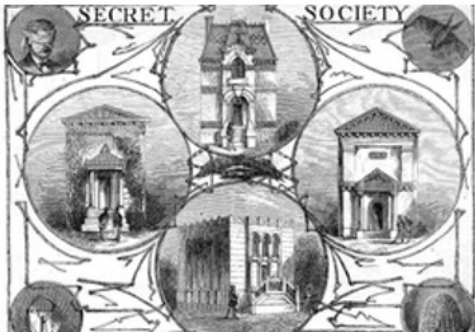
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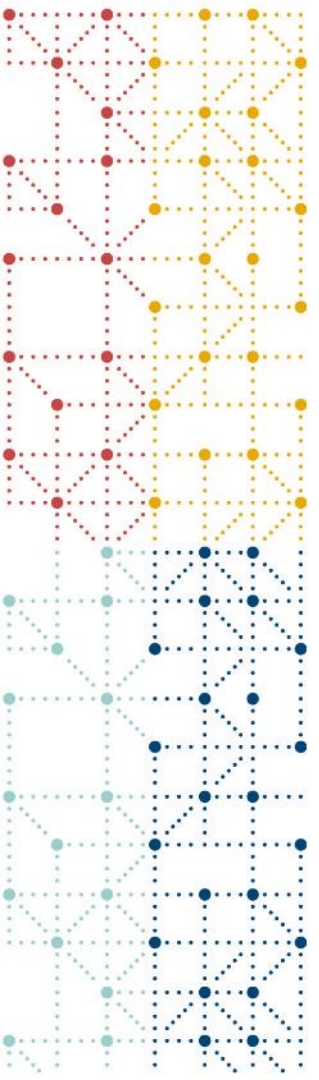
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The Secret TMF Society

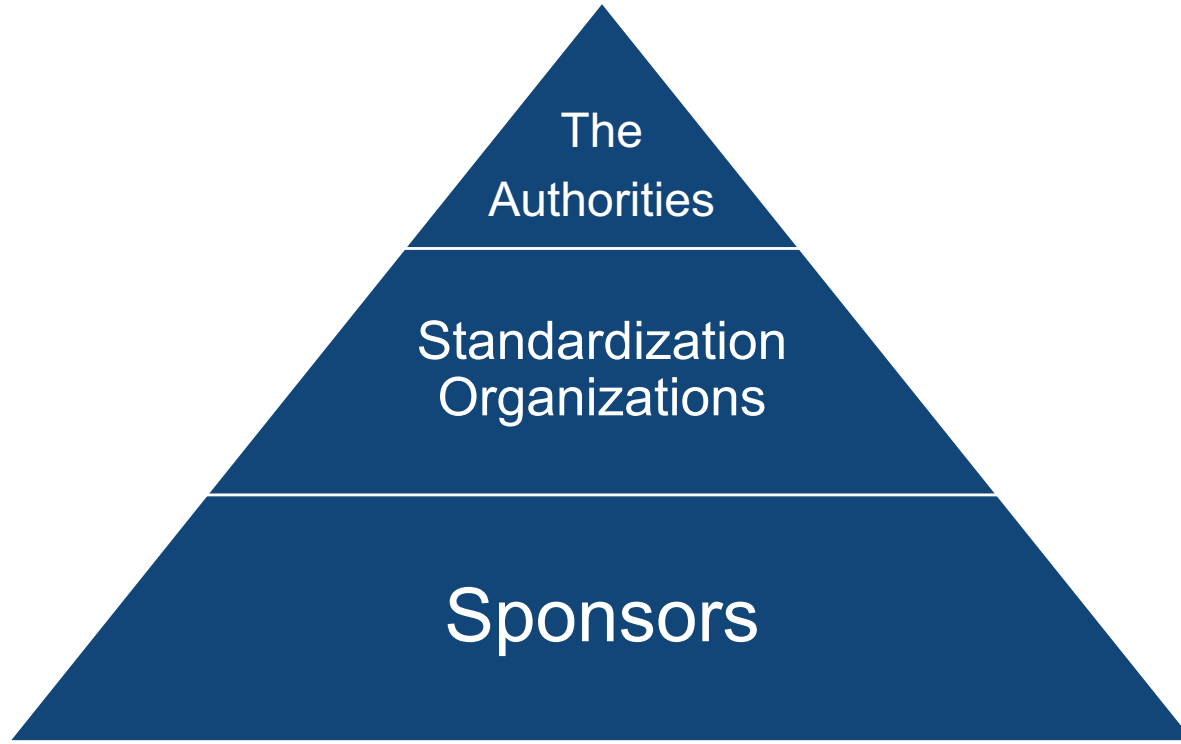
Secret Societies



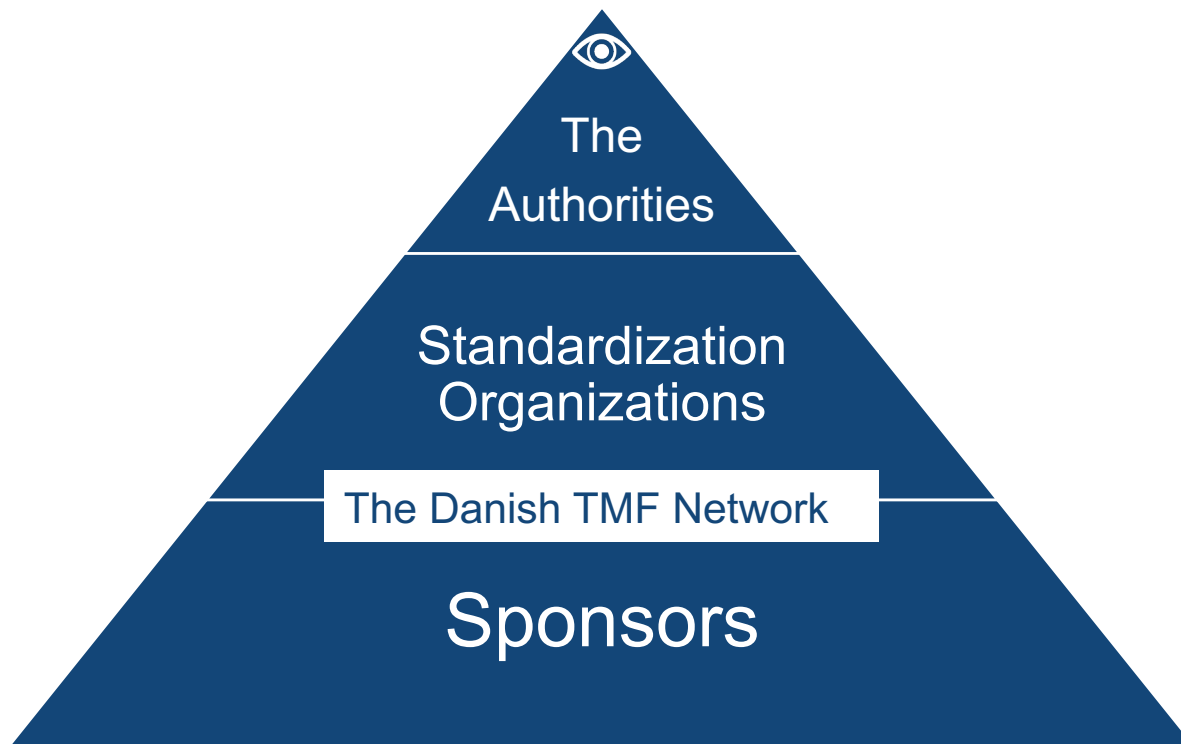


YOU CAN'T SIT WITH US!

The TMF Universe: Simplified



The TMF Universe and the Danish TMF Network





The Danish TMF Network: The Deets

- Professional group consisting of eTMF managers, clinical trial administrators, business analysts and system specialists
- Over 15 Danish (and 1 Norwegian) pharmaceutical companies
- Bi-yearly 3-4 hour meetings with an agenda
- Mailing list and LinkedIn group
- Only sponsors and CROs, no vendors
- Main objective: knowledge exchange and alignment

The Origin Story: Strength in Proximity

- Established by the 6 founding members in 2015 during a TMF conference in London
- 6 TMF'ers from Ferring, Lundbeck, Leo Pharma and Novo Nordisk
- Common challenge: *"The Newfangled Electronic Trial Master File"*
- Able to meet F2F after the conference due to the proximity of the companies in Denmark



The Danish TMF Network: The Evolution

Then

- 6 members
- 4 companies
- System-based discussions
- Presentations

Now

- 60 people on the invitation list
- +15 companies
- Process-based discussions
- Discussions about the “softer” side of TMF management
- Collaborations and round-table format

The Meeting Format



Discussion Topics



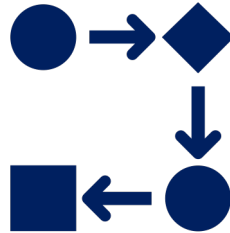
Inspections



Stakeholders



Requirements



Processes



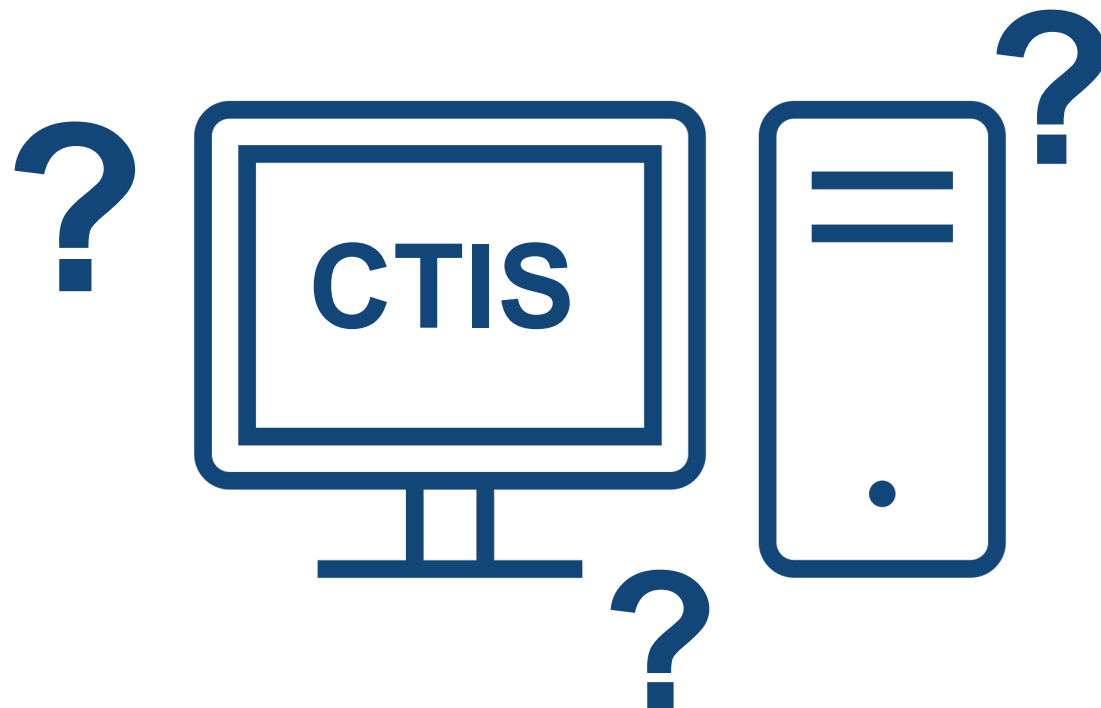
Conferences

Discussion Example 1



- Metrics and EDLs have been a source of many discussions
- One sponsor suggested a solution to improve subpar eTMF metrics to management
- Solution well received by the TMF network during a 2024 meeting
- Sponsor's management is still discussing the implementation
- Begs the question: who are the metrics for?

Discussion Example 2



Discussion Example 3



Why It's so Important

- Tunnel vision
- Representative from different areas
- Knowledge sharing from a vault of over 350 years of experience
- Understanding authority requirements
- Strength in numbers
- Information overload; averted
- Safe space





Main Gains

- Demystification of inspections
- Diversity fuels rich discussions and practical solutions
- Alignment and challenging authorities
- The feeling of belonging and worth
- Due to judgement free zone; real issues are discussed

Takeaway Messages



Talking inspections = Better preparedness



It's about the process, not the platform



Round table discussions reveal real industry struggles



Higher stakeholder engagement because TMF is everyone's business

Takeaway Messages – The Softer Ones



Helps fight burnout and isolation, especially for niche roles like TMF professionals



Safe spaces create shared growth



Real human insight > Guidelines alone



Community makes the challenge worthwhile



you CAN
sit with us