



cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Soft Power in Play – Using Diplomacy in eTMF Management

Karla Navera-Andersen, Senior eTMF Manager, Zealand Pharma A/S

Speaker



Karla Navera-Andersen
Senior eTMF Manager
Zealand Pharma A/S

Karla Navera-Andersen is a Senior eTMF Manager at Zealand Pharma with nearly 18 years of experience in TMFs. She holds a Master of Arts in English and a Pharma Consultant Diploma.

Karla has worked on both the CRO and sponsor sides, across several functional departments. She leverages her broad industry experience to drive stakeholder engagement, foster cross-functional alignment, and simplify the complexities of eTMF.



**How I made
binge-watching billable**



Soft Power in an Unexpected Place

Soft Power



Culture, Influence,
Persuasion

TMF Management



KPIs, Metrics,
Compliance



**What if TMF management
actually works better when we
stop leading with rules?**



Why Hard Power Alone Fails

- Dashboards nobody reads
- Escalations that damage relationships
- “Training” as a punishment
- Compliance that exists only for inspection day

*“The best
propaganda is not
propaganda.”
— Joseph Nye*

Soft Power Pillar 1: Cultural Fluency

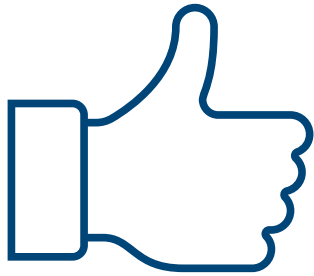


Soft Power Pillar 2: Partnership Over Policing

- eTMF as a service, not a gate
- Hyper-care during pressure moments
- Being *present*, not just correct

Soft Power Pillar 3: Encouragement as Strategy

Normalizing uncertainty



Positive
reinforcement



Visible
appreciation



Soft Power in Play Case 1

The Use of Community in Implementing an eTMF System

- **No internal ownership**

eTMF had always been outsourced → no in-house habits or accountability

- **Comfort with the status quo**

Existing setup “worked” → low motivation to change

- **High resistance to new system**

Perceived as extra work, not added value

- **Cross-functional complexity**

Nearly all departments involved → competing priorities, no shared vision

Soft Power in Play Case 1

Turning Resistance into Ownership





Soft Power in Play Case 2

The EU CTR and the CTIS as (en)Forcing Functions

- **Regulatory change = forced transformation**

EU Clinical Trials Regulation introduced new processes with no opt-out

- **More work, not less**

Additional documents, new timelines, unfamiliar system

- **Poor user experience**

Clinical Trials Information System perceived as complex and unintuitive

- **Stakeholder resistance**

Seen as disruption to already established workflows

Soft Power in Play Case 2

Turning burden into opportunity



Why Soft Power is Not Enough

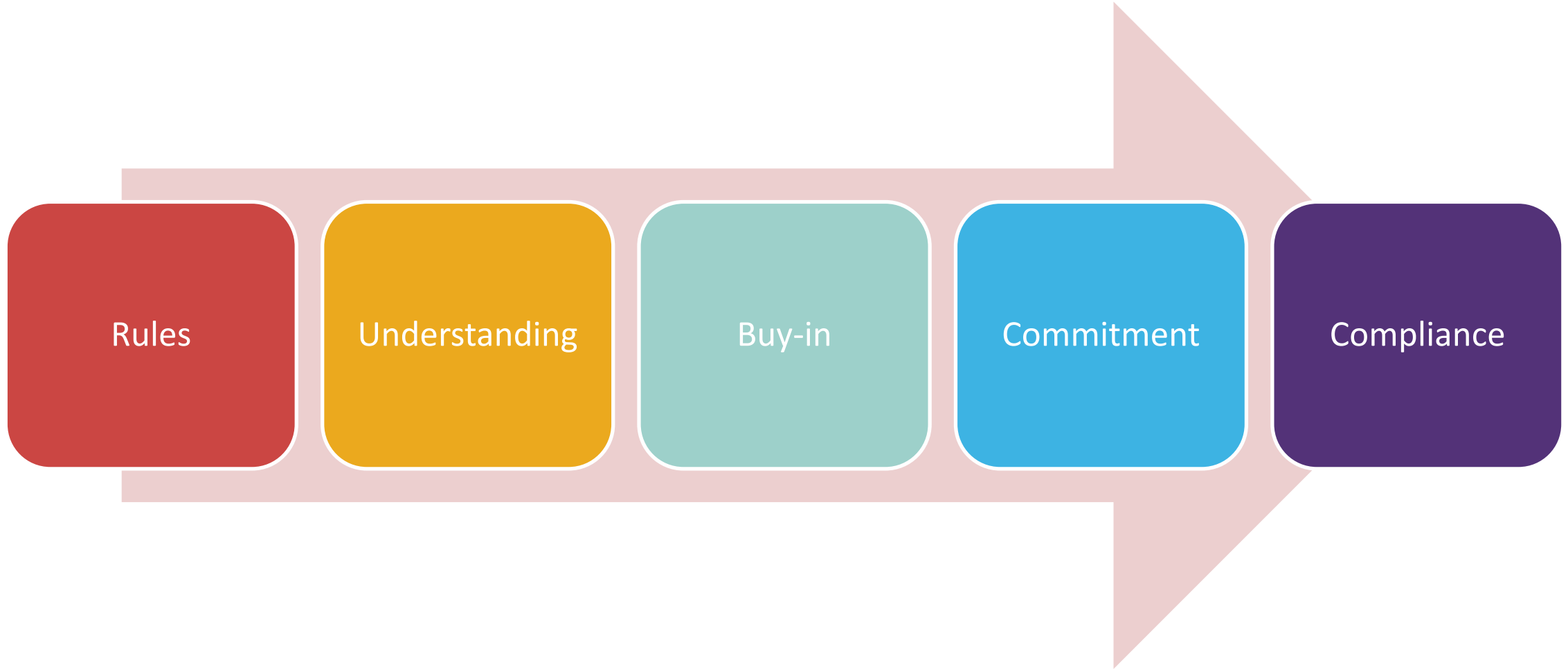


**Hard power is most effective
when it stays in the
background**

Soft Power + Hard Power = Smart Power

Soft power leading the interaction
Hard power anchoring the boundary
Systems doing the enforcing
People preserving the relationships

Redefining Success in eTMF Management



A woman with short blonde hair is seated in a white upholstered chair, looking towards a woman standing on the right. The standing woman has long brown hair and is wearing a dark blazer. They are in a room with wood-paneled walls, bookshelves filled with books, a fireplace with a clock above it, and two lamps with striped shades.

**Influence
comes before compliance**