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

Strengthening eTMF Security for Cross Border Clinical Data Protection & Data Re-use

GSK's Model Aligned with CISA and ICH Guidance

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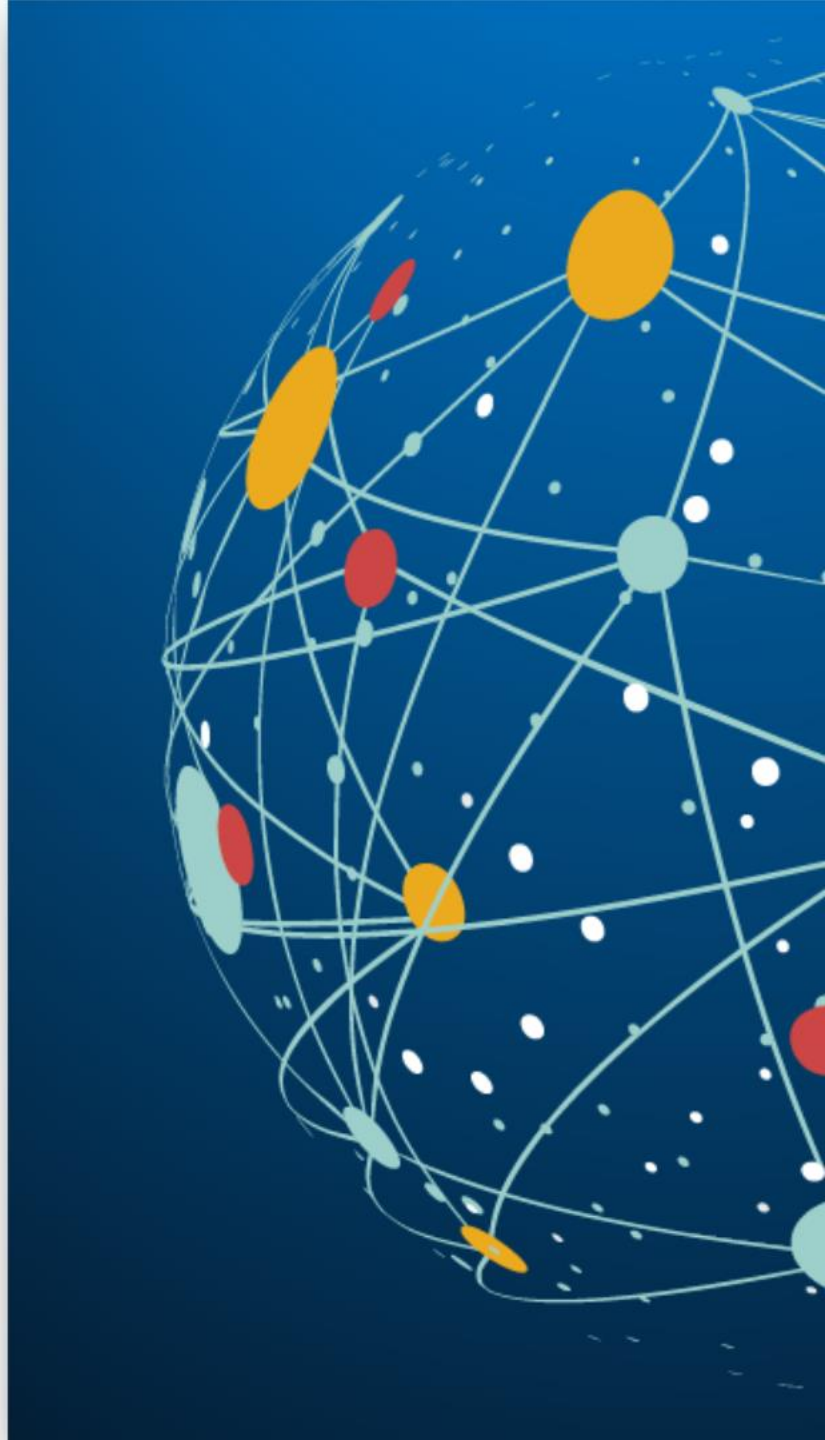
The Context

Global trials and cloud-based eTMF platforms create opportunities for productivity and collaboration — but also raise regulatory, privacy and national security concerns when personal data and regulated documents traverse or are accessible from jurisdictions with differing laws and threat profiles.



Agenda

1. The 2025 US Order
2. The ICH Data Governance Framework for data re-use

New National Security Restrictions on International Data Transfers

The U.S. Executive Order 14117 issued by the U.S. Department of Justice (DOJ) regulations (28 C.F.R. Part 202) and Cybersecurity and Infrastructure Security Agency (CISA), effective April 2025

Core concern

Bulk datasets — especially **health, genomic, biometric, geolocation, and government-linked data** — can be re-identified or combined with other data and **used strategically by foreign adversaries**, even when shared indirectly (e.g., via vendors, partners, or cloud services) **regardless of whether it is individualised, anonymised, encrypted, and/or aggregated**.

Source : US Federal Register

Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern

Each company must

- **Identify** where they transfer or allow access to bulk sensitive U.S. personal data and if thresholds are met
- **Assess** whether any access involves Countries of Concern or controlled entities
- **Apply security safeguards** where transactions are permitted
- **Prepare for oversight, licensing, and enforcement**
- Without broadly restricting global data flows, research collaboration, or commercial activity (should be **risk-based and targeted**)

Example of Threshold
Access to > 10,000 US citizens personal Health data over 12 months

Countries of Concern (CoC):
- China (incl.Hong Kong and Macau)
- Cuba
- Iran
- North Korea
- Russia
- Venezuela

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TMF records may contain US citizen data and should therefore be protected from transfer

e.g. Final Subject Data, Database reports, Data Listings, Clinical Study Report, Analysis datasets and outputs, …

Within >500 actives studies, a strong presence in Countries of Concern, simultaneously with the US

⇒ how to comply with the order?

The reflection process

Identify all record types that may contain sensitive data in any form and tailor access for users in CoC

V Strict implementation of the order
X Complex
X Rigid

Implement a new generic security matrix applicable to all the local users

V Anticipate any other national restriction
V Quick to implement
V Keep access to “necessary” records for business continuity such data included in the Regulatory dossier or other submission (e.g., Protocol, Clinical Study Report, Summary report,…) as allowed by order

The new GSK TMF security matrix in practice

Global level roles	Study level role roles	Local level roles
QA, QC reviewers, manager, administrators…	*e.g. Central Study Manager, Data Manager, Statistician, Medical Writer…*	*e.g. Local Study Manager, CRA,…*
Access to the **whole eTMF**, across all studies	Access to the **whole study eTMF** (study and local level records), needed to secure study operations	Access **only to** their **own country** level records **and to all study level** records

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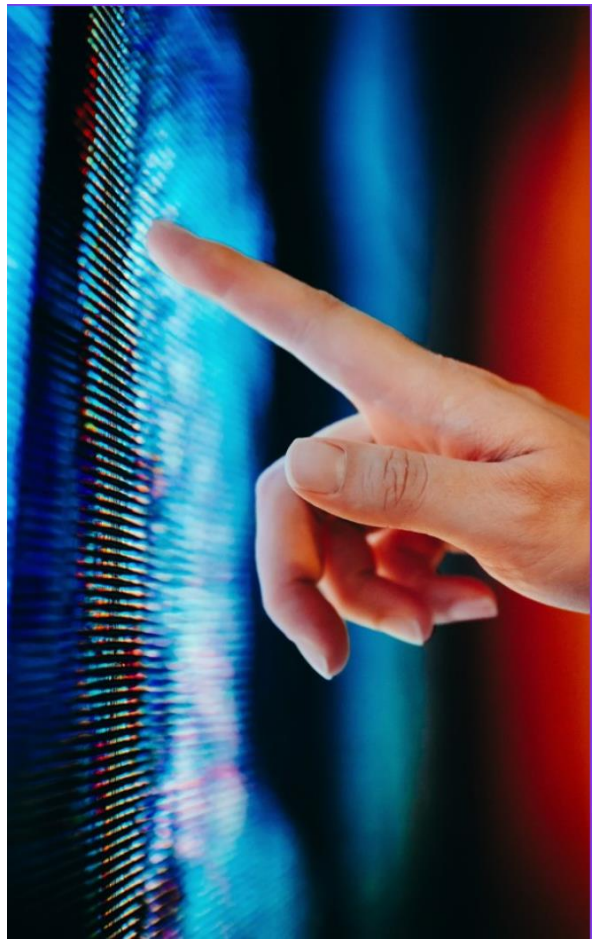
Access to the **whole eTMF**, across all studies	Access to the **whole study eTMF** (study and local level records), needed to secure study operations	Access **only to** their **own country** level records **and to all study level** records
Immediate **revocation of global roles for users in CoC** (change to local level role) Exception is granted for specific roles such as QA,…	Users in **CoC can keep study level roles** but specific local roles are created when possible (e.g. Study Manager, Statisticians).	**Applicable to any local user**, whether in CoC or other country

Remaining constrains/challenges:

- Complex access management process
- Keep monitoring data access by users from CoC through audit trail
- Keep exploring/developing specific local roles
- Remaining uncertainty if more restricted access is needed for some study level records

2. The ICH Data Governance Framework for data re-use

ICH E6 (R3) introduced Data Governance Framework needs, aligning with GDPR



From

"Protect data during the trial"

To

"Protect data across its lifespan, including future uses"

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GSK implemented an IHD re-use Data process

1. Access to any record containing Individual Human Data (IHD) is **restricted** even to those who produced the data

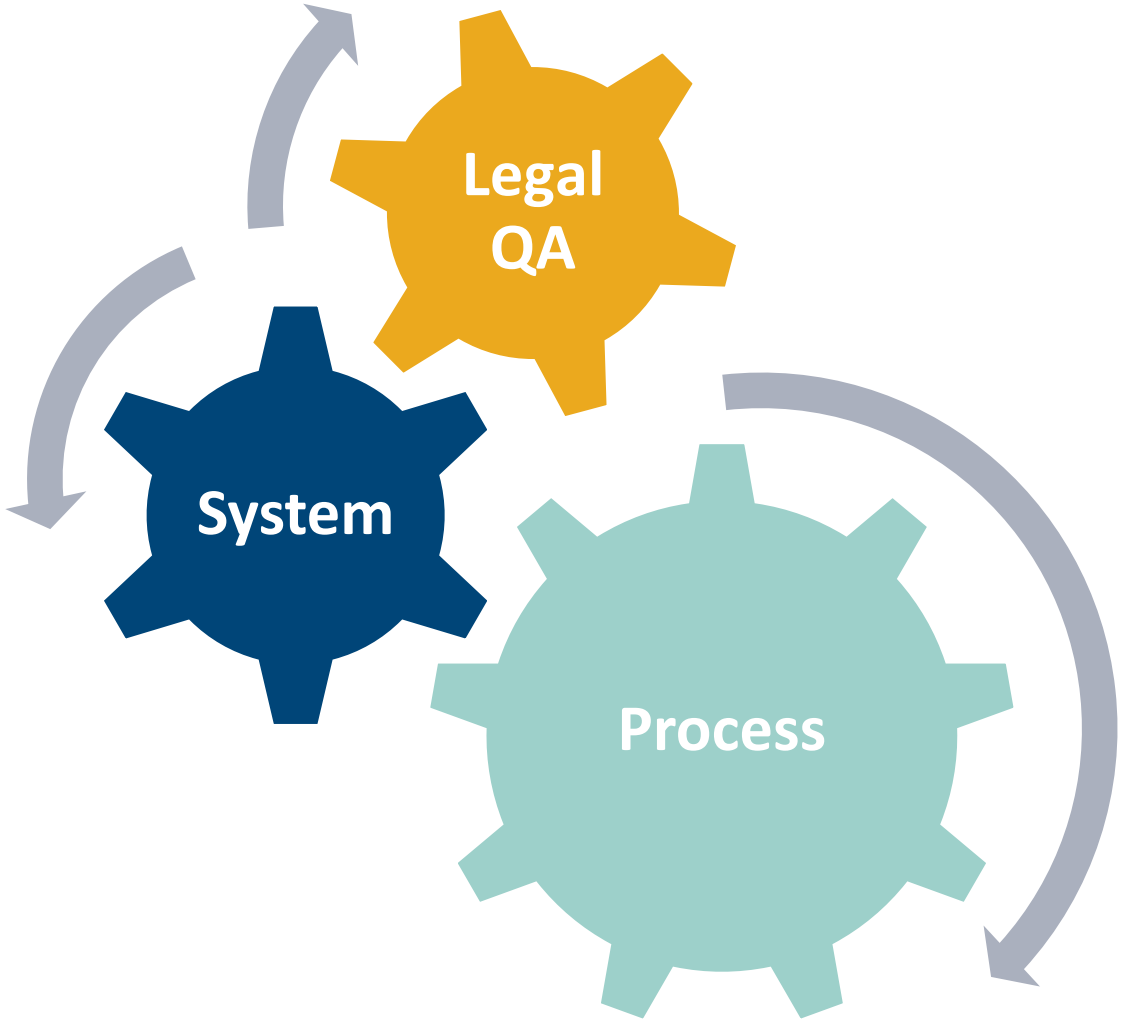
2. Any need for any data re-used is duly documented and goes through a scientific and governance **approval process**

3. Data access is **granted and revoked** once study/analysis is complete

Current challenges

- Operational activities within same ongoing study/project
- Implementation in eTMF
- New AI Initiatives to be fed with historical and new data (training data)

Partnership is key in implementing new guidances



Thank You!

Questions?