

EASYTMF[®] Integrated **EASYISF**

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Key Differences: Investigator Site File (ISF) vs Trial Master File (TMF)

Feature	Trial Master File (TMF)	Investigator Site File (ISF)	
Purpose	Central repository of essential documents for the <i>entire trial</i> .	Site-specific repository of essential documents for <i>each trial site</i> .	
Owner	Typically managed by the sponsor or CRO	Managed by the Principal Investigator and site staff	
Contents	All regulatory, ethics, trial-level documents including protocol, IB, contracts, monitoring plans, etc.	Site-specific documents: delegation logs, site CVs, training logs, drug accountability logs, etc.	
Regulatory Role	Proves the sponsor conducted the trial per GCP & regulations.	Proves the site conducted the trial per GCP.	
Structure	Complex, often categorized using DIA TMF Reference Model.	Simpler, often mirrors TMF but only for site-relevant docs.	
Number per Study	One per trial	One per site (e.g., 50 sites = 50 ISFs)	
Inspection Ready	Always needs to be inspection-ready	Must also be inspection-ready at each	
		site SYNAP © ON	

Unified Platform Strategy vs. "Investigator-Only ISF"

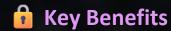




Unified Platform Strategy

One cloud-based system, two tailored interfaces:

- •Sponsor/CRO view: Full TMF control & oversight
- •Site view: ISF module with access to site-specific docs only
- → Single platform reduces duplication, increases compliance, and simplifies monitoring.



- Scalability Easily onboard new sites in minutes
- 11 Transparency Real-time access, reduced document loss
- **Inspection-ready** Built-in compliance features
- **Innovation-ready** Future-proof foundation for AI-supported monitoring, eSource integration

Cloud-Based "Investigator-Only ISF"

- •Multi-site deployment: A centralized cloud ISF instance usable by dozens or hundreds of sites
- •Access-controlled: Each investigator sees only their site's data
- •No sponsor oversight required (ideal for academic trials or investigator-initiated studies)
- •Fully GCP-compliant with audit trail, e-signatures, and rolebased permissions



W Use case:

Perfect for hospital networks, academic research groups, or early-phase biotech trials

Cloud-Based ISF – Use Cases and Integration Roadmap



Overview

The Investigator Site File (ISF) module is designed to operate as a secure, scalable, and cloud-hosted system tailored for site-specific compliance in clinical trials. It supports multiple use cases ranging from decentralized research to enterprise hospital deployments.

Use Cases for Multi-Site Cloud-Based ISF

Academic Research Networks

- •Designed for trials managed by universities or research consortia.
- •Allows centralized sponsor-free deployment with strict rolebased access per site.
- •Ensures compliance with GCP and institutional SOPs.

Early Phase Biotech Trials

- •Supports lean startups with fast-paced, international site activations.
- •Requires minimal local infrastructure reducing setup and training costs.
- •Facilitates inspection-readiness from day one.

Hospital Systems & Multi-Department Research

- •Allows shared ISF instances across hospital departments.
- Encourages unified documentation standards across therapeutic areas.
- •Enables quality assurance teams to oversee multiple active trials centrally.



Integration Roadmap



To support evolving regulatory, technological, and operational needs, the cloud ISF system is designed with a multi-phase integration roadmap.

Phase 1: Unified Document Architecture

- Modular templates for TMF and ISF
- •Compliance with DIA Reference Model (V3.0 and newer)
- •Harmonized metadata tagging for easier retrieval and audit trail logging

Phase 3: Intelligent Automation (AI-Enhanced)

- •ML-supported monitoring of documentation completeness and timeliness
- •Predictive compliance alerts based on site behavior and submission patterns
- •Deviation detection and auto-notification for missing essential documents

Phase 2: API-Based Ecosystem Connectivity

- •Integration with eSource, EDC, CTMS, and IRB portals
- Automatic document ingestion from certified systems
- •Secure outbound data transfer with real-time status syncing

Key Benefits

- •Inspection-Ready: Always compliant and auditable
- •Scalable: Supports trials with 1 to 1000+ sites
- •Interoperable: Built to connect and evolve with modern e-clinical ecosystems
- •Future-Proof: Al-ready architecture ensures ongoing innovation SYNAP₩ON





SynapCon's TMF/ISF – Built for Flexibility by Design

Smart by Structure – Integrated TMF & ISF Architecture

- Designed from Day One for Investigator-Specific Access
- •Each site is automatically assigned to a project group within the study TMF
- •Role-based permissions allow sites to access only their own documents
- •No duplication full audit traceability within unified eTMF
- ISF Options for Every Trial Type
- Single ISF Instance per Trial
- → Sites access only their documents via shared platform
- → Ideal for large multicentre clinical trials
- •Single ISF Instance per Institution
- → E.g., one hospital runs all studies via one secure ISF hub
- → Reduces onboarding, maximizes standardization

Competitive Advantage – Built-In ISF Flexibility



Why SynapCon's Architecture Beats the Patchwork Solutions

Feature	SynapCon	Typical Competitors
Site-Specific Access in TMF	Built-in via project groups	X Requires custom configuration
Unified TMF + ISF Framework	✓ Native structure	X Often separate systems
Multi-site ISF Deployment	One instance per trial or hospital	X Typically one ISF per site
Role-Based Document Access	✓ Default	▲ Add-on or limited
Audit & GCP Compliance	✓ Full traceability	Manual effort required

Faster onboarding, lower cost, simplified oversight – and full inspection readiness from day one.

Manual Section: ISF & TMF Integration Model



Integrated TMF/ISF Deployment Architecture

- 1. Project Group-Based Access Design Each investigator site is assigned a dedicated project group within the sponsor's Trial Master File (TMF). This ensures:
- Access to only their assigned documentation
- Role-based controls defined per study protocol
- Central audit trail with local site visibility

This eliminates the need for document duplication or multiple system instances to comply with GCP or GDPR.

2. Cloud-Based ISF Deployment Models

The SynapCon ISF module supports flexible deployment:

Option A: One ISF Instance per Trial

- All participating sites access a common ISF platform
- Site-specific access limits visibility to their own documents
- Ideal for commercial multicenter clinical trials

 Option B: One ISF Instance per Institution
- A single ISF installation serves all trials managed by one academic centre or hospital
- Each department or study team is segmented by permissions
- Streamlines management for investigator-initiated studies or hospital research units

Both models are fully integrated with the overarching TMF structure and benefit from:

- Centralized compliance monitoring
- Seamless e-signature and audit logging
- Veridat-backed data immutability (if enabled