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Integrated
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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 *entire trial*.	Site-specific repository of essential documents for *each trial site*.
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

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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.**

☁️ 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 role-based permissions

🧩 Use case:

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

🔒 Key Benefits

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

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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 role-based 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.

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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 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

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

✅ 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**: AI-ready architecture ensures ongoing innovation

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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

🚀 **Benefit:** Unlike competitors, no external workarounds or bolt-ons are needed.
It’s all natively integrated.

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	❌ Requires custom configuration
Unified TMF + ISF Framework	✅ Native structure	❌ Often separate systems
Multi-site ISF Deployment	✅ One instance per trial or hospital	❌ 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