医療機関の治験文書の「何をどこに保管する」を考える
-治験文書管理の標準化・効率化を目指して -

神田 悠社/Yuto Kanda

-A member of J3C(Japan CDISC Coordinating Committee)

-中外製薬株式会社 臨床プロセス戦略部

-CDISC開催webinarの資料の引用について、発表者はCDISCの許可を得ています。
(日本語での補足/レイアウトの修正など、一部改変を加えています)
-本発表について、開示すべきCOI(Conflict Of Interest)はありません。
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自己紹介:神田悠社

Linkedin

- 2012: 中外製薬に新卒入社
- 2012~2014: CRA→Study Manager
- 2014~2019: Process management / Roche CTMSのトレーナー
- 2019~2023: Study Leader
- 2023~1Q 2025: TMF 管理
- 2025~:

  J3C (Japan CDISC Coordinating Committee＝CDISCの日本支部)のメンバー,

  CDISC Steering TMF committeeとの日本リエゾン

(TMF/)ISF, &
ISF Reference Model

TMF&ISF

- **TMF = Trial Master File**
- 臨床試験に関する必須文書・記録を体系的にまとめたもの
- **ICH-E6(R3)GlossaryにおけるEssential Recordsの定義：**

  Documents and data (and relevant metadata), in any format,
  associated with a clinical trial that facilitate the ongoing management
  of the trial and collectively allow the methods used,
  the factors affecting a trial and the actions taken during the trial conduct
  to determine the reliability of the trial results produced and the verification that
  the trial was conducted in accordance with GCP and applicable regulatory requirements.

- **ISF(Investigator Site File)：治験実施医療機関が管理するEssential Records**

First, what is an ISF?

Investigator Site File (ISF)

Your site's collection of records for a study.

It shows what happened at your site, and that it was done the right way.

Good Clinical Practice (GCP) requires your site to keep these records before, during, and after the study.

1

You may call it…

Regulatory binder, study binder, site file, eReg, eISF, or site TMF

2

Who looks at it

Your study team, monitors, auditors, and inspectors. Inspectors use it to confirm the trial was run properly and the results can be trusted.

3

What's inside

Protocol, consent forms, IRB approvals, delegation log, training records, and more

TMF･ISF･標準モデル

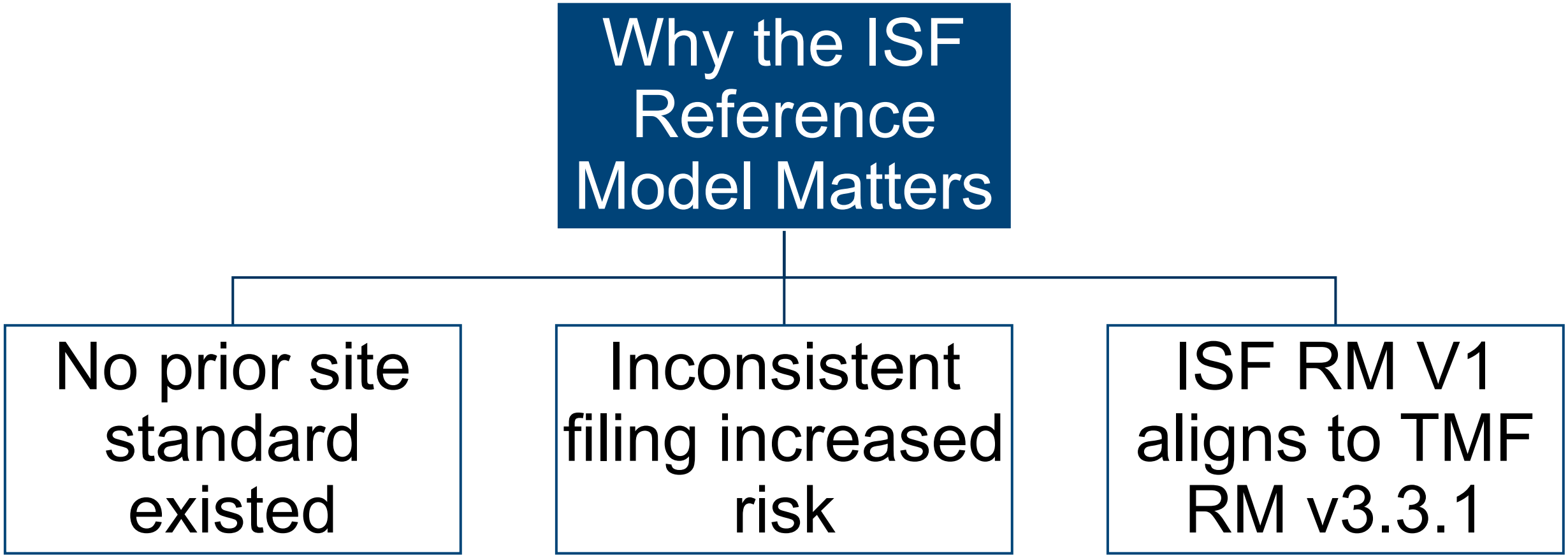
	TMF	ISF
企業主導治験	Sponsor(&CRO)	**実施医療機関**
医師主導治験	アカデミア	**実施医療機関**
標準モデル	TMF Reference Model	**ISF Reference Model**

- 業界における標準モデル
- Ver1が2010年に制定
- CDISCが管理している
- 現在大幅改訂が進行中

- これまでなかった標準モデル
- CDISCが待望の**“Provisional” Ver1を今年Releaseした**

Reference ModelからStandard Modelへ！

Why CDISC Created the ISF RM



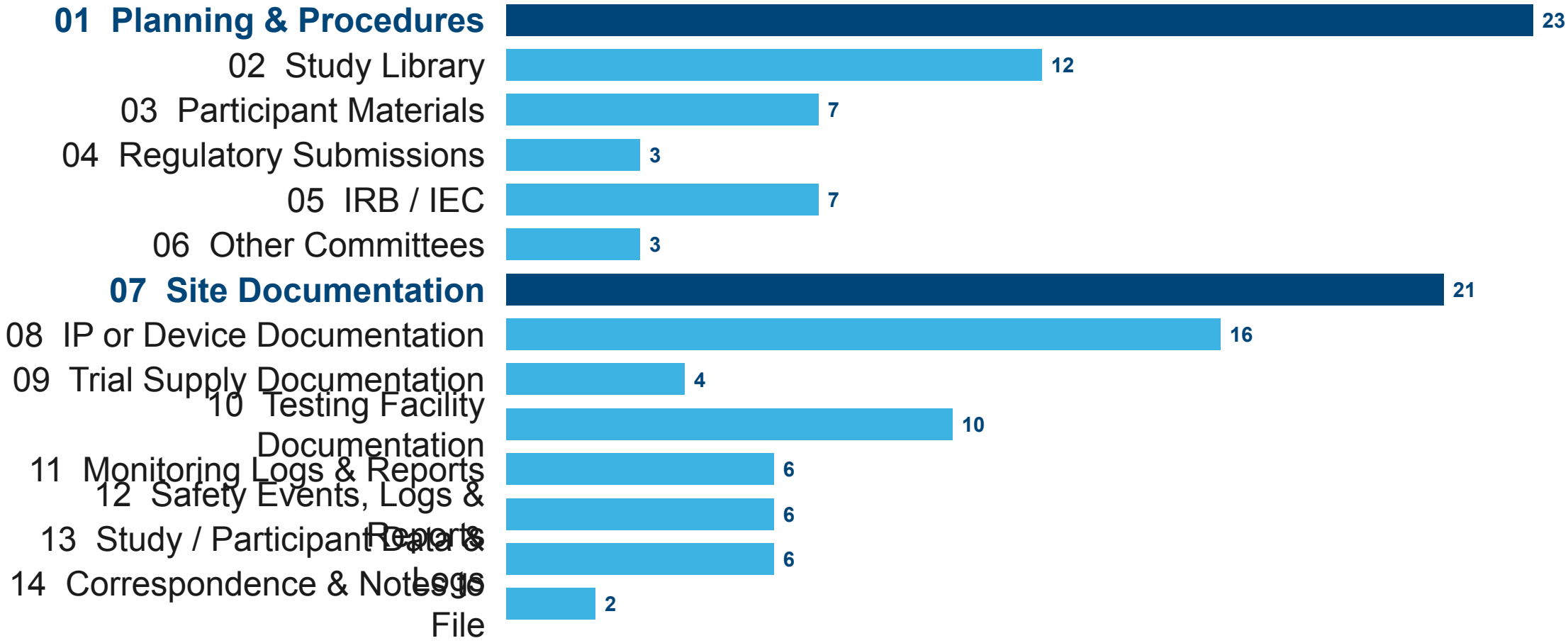
ISF RM Release 1.0 - Overview

	A	B	C	D	E	F	G	H	I
1	ISF Zone Combined #/Name	ISF Zone Number	ISF Zone Name	ISF Section Combined #/Name	ISF Section Number	ISF Section Name	ISF Artifact Combined #/Name	ISF Artifact Number	ISF Artifact Type
2	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.01_ISF Plan	ISF_01.01	ISF Plan	ISF_01.01.01_ISF/eISF Index	ISF_01.01.01	ISF/eISF Index
3	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.02_Feasibility	ISF_01.02	Feasibility	ISF_01.02.01_Feasibility Documentation	ISF_01.02.01	Feasibility Documentation
4	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.03_Site Selection and Activation	ISF_01.03	Site Selection and Activation	ISF_01.03.01_Site Activation Document	ISF_01.03.01	Site Activation Document
5	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.04_Recruitment	ISF_01.04	Recruitment	ISF_01.04.01_Recruitment Plan	ISF_01.04.01	Recruitment Plan
6	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.01_Informed Consent Plan	ISF_01.05.01	Informed Consent Plan
7	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.02_IP or Device Instructions for Handling	ISF_01.05.02	IP or Device Instructions for Handling
8	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.03_IP or Device Labeling Plan	ISF_01.05.03	IP or Device Labeling Plan
9	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.04_IP or Device Transfer Documentation	ISF_01.05.04	IP or Device Transfer Documentation
10	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.05_IP or Device Recall Plan	ISF_01.05.05	IP or Device Recall Plan
11	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.06_Unblinding Plan	ISF_01.05.06	Unblinding Plan
12	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.07_IRT User Manual	ISF_01.05.07	IRT User Manual
13	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.08_Trial Supply Plan	ISF_01.05.08	Trial Supply Plan
14	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.09_Operational Procedure Manual	ISF_01.05.09	Operational Procedure Manual
15	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.10_Other Plan	ISF_01.05.10	Other Plan
16	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.11_Safety Manual	ISF_01.05.11	Safety Manual
17	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.12_Site Policies or Procedures	ISF_01.05.12	Site Policies or Procedures
18	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.12_Site Policies or Procedures	ISF_01.05.12	Site Policies or Procedures
19	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.13_Manual	ISF_01.05.13	Manual
20	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.14_Source Data Agreement	ISF_01.05.14	Source Data Agreement
21	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.15_Data Entry Guideline	ISF_01.05.15	Data Entry Guideline
22	ISF_01_Planning and Procedures	ISF_01	Planning and Procedures	ISF_01.05_Guidance Documentation	ISF_01.05	Guidance Documentation	ISF_01.05.16_Sample Case Report Fo	1.05.16	Sample Case Report Form

Saved to this PC

The 14 zones

126 entries in total. Most studies won't use them all. Your ISF Plan and ISF Index go first, in Zone 01.



Where does this record go?

A shortcut from the User Guide for common records. Zones 01, 02, 06, and 09–12 still hold their own records.

Is the record about a participant?	Yes →	**Zone 03 or 13** consent vs. data
No ↓		
Is it about the study drug or device?	Yes →	**Zone 08** drug / device
No ↓		
Is it to or from the IRB / ethics committee?	Yes →	**Zone 05** IRB / IEC
No ↓		
Is it to or from a regulator (e.g., FDA)?	Yes →	**Zone 04** regulatory
No ↓		
Is it about site staff, training, or agreements?	Yes →	**Zone 07** site records
No ↓		
Still unsure?	→	**Zone 14** + rationale in ISF Index

Worked example: consent records

Blank IRB-approved consent form
→ Zone 03 · Blank ICF subsection

ICF summary of changes
→ Zone 03 · Blank ICF subsection

IRB approval of the consent form
→ Zone 05 · IRB or IEC Decision subsection

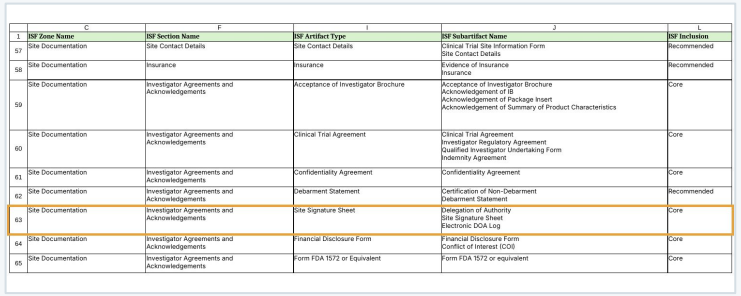
Informed consent log
→ Zone 03 · Participant Log subsection

eConsent final data extract
→ Zone 03 · Source Data subsection (Recommended)

Kept by the sponsor somewhere else? Note where it lives in the ISF Index. Don't file a duplicate.

Three free tools

Created by CDISC, a non-profit standards organization (it also maintains the TMF Reference Model), with

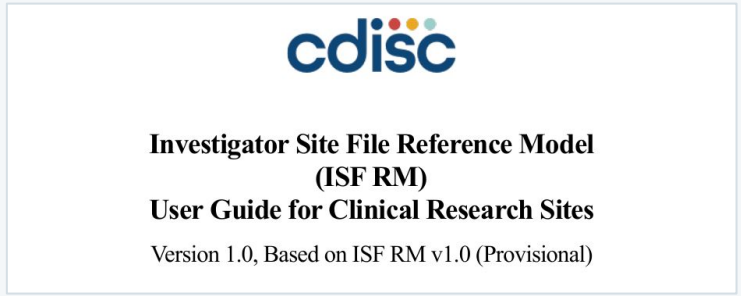


	C	F	I	J	L
1	**ISF Zone Name**	**ISF Section Name**	**ISF Artifact Type**	**ISF Subartifact Name**	**ISF Inclusion**
57	Site Documentation	Site Contact Details	Site Contact Details	Clinical Trial Site Information Form Site Contact Details	Recommended
58	Site Documentation	Insurance	Insurance	Evidence of Insurance Insurance	Recommended
59	Site Documentation	Investigator Agreements and Acknowledgements	Acceptance of Investigator Brochure	Acceptance of Investigator Brochure Acknowledgement of IB Acknowledgement of Package Insert Acknowledgement of Summary of Product Characteristics	Core
60	Site Documentation	Investigator Agreements and Acknowledgements	Clinical Trial Agreement	Clinical Trial Agreement Investigator Regulatory Agreement Qualified Investigator Undertaking Form Indemnity Agreement	Core
61	Site Documentation	Investigator Agreements and Acknowledgements	Confidentiality Agreement	Confidentiality Agreement	Core
62	Site Documentation	Investigator Agreements and Acknowledgements	Debarment Statement	Certification of Non-Debarment Debarment Statement	Recommended
63	Site Documentation	Investigator Agreements and Acknowledgements	Site Signature Sheet	Delegation of Authority Site Signature Sheet Electronic DOA Log	Core
64	Site Documentation	Investigator Agreements and Acknowledgements	Financial Disclosure Form	Financial Disclosure Form Conflict of Interest (COI)	Core
65	Site Documentation	Investigator Agreements and Acknowledgements	Form FDA 1572 or Equivalent	Form FDA 1572 or equivalent	Core

THE MAP

ISF Reference Model

An Excel spreadsheet listing every ISF section, subsection, and record name



Investigator Site File Reference Model (ISF RM)
User Guide for Clinical Research Sites

Version 1.0, Based on ISF RM v1.0 (Provisional)

THE HOW-TO

User Guide

Written for site teams. Explains the model, how to set it up, and how to fill in the Plan Template



INVESTIGATOR SITE FILE (ISF) PLAN

[ENTER Site Name]

Protocol number or study identifier	*[ENTER]*
Date	*[ENTER ISF Plan date or state Date of Final Approval]*
Version	*[ENTER version number of the ISF Plan; e.g., 1.0, 2.0]*
ISF format	*[Select one: Paper/electronic (eISF)/hybrid]*

YOUR RULES

ISF Plan Template

A fill-in-the-blanks Word document for how your ISF will be maintained

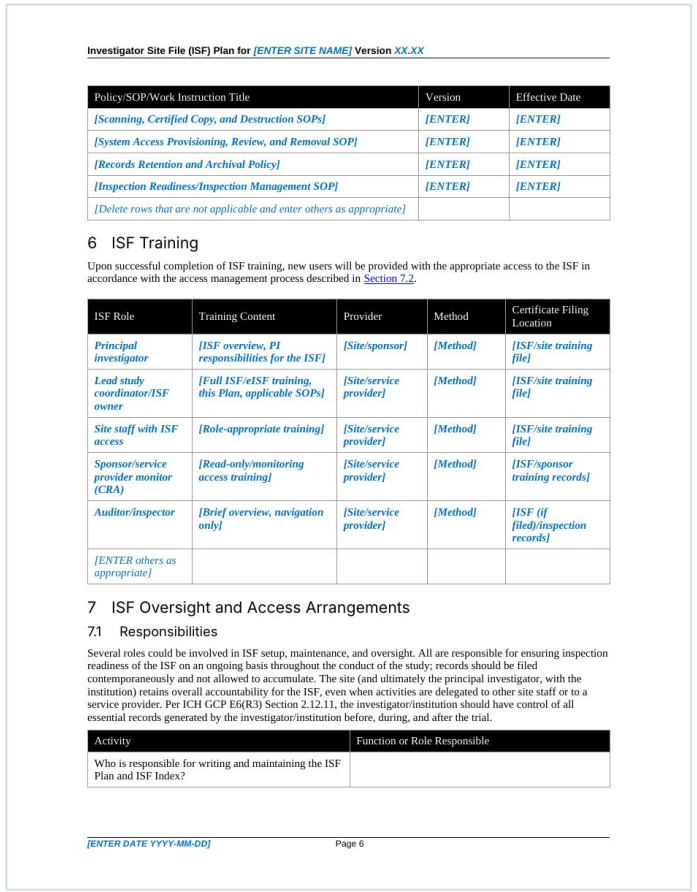
From these, you create one more thing for each study:
your ISF Index, the table of contents for the ISF.

ISF Plan vs. ISF Index

	ISF Plan: the “how”	ISF Index: the “what”
Question	How will we maintain this ISF?	What goes in this ISF?
What it is	The written rules for this study’s file	The table of contents for this study
Examples	Who files, who reviews, who has access, how long we keep it	Each subsection marked Applicable, Not Applicable, or Provided by Sponsor
Who uses it	Site team and anyone delegated	Filers, reviewers, monitors, auditors
Start from	ISF Plan Template (Word)	ISF RM spreadsheet (Excel), filtered by Zone

For the Site Signature Sheet: the Plan says who keeps it current; the Index says whether it applies and where its records are.

The ISF Plan Template



Investigator Site File (ISF) Plan for *[ENTER SITE NAME]* Version *XX.XX*

Policy/SOP/Work Instruction Title	Version	Effective Date
[Scanning, Certified Copy, and Destruction SOPs]	*[ENTER]*	*[ENTER]*
[System Access Provisioning, Review, and Removal SOP]	*[ENTER]*	*[ENTER]*
[Records Retention and Archival Policy]	*[ENTER]*	*[ENTER]*
[Inspection Readiness/Inspection Management SOP]	*[ENTER]*	*[ENTER]*
[Delete rows that are not applicable and enter others as appropriate]		

6 ISF Training

Upon successful completion of ISF training, new users will be provided with the appropriate access to the ISF in accordance with the access management process described in Section 7.2.

ISF Role	Training Content	Provider	Method	Certificate Filing Location
Principal investigator	*[ISF overview, PI responsibilities for the ISF]*	*[Site/sponsor]*	*[Method]*	*[ISF/site training file]*
Lead study coordinator/ISF owner	*[Full ISF/eISF training, this Plan, applicable SOPs]*	*[Site/service provider]*	*[Method]*	*[ISF/site training file]*
Site staff with ISF access	*[Role-appropriate training]*	*[Site/service provider]*	*[Method]*	*[ISF/site training file]*
Sponsor/service provider monitor (CRA)	*[Read-only/monitoring access training]*	*[Site/service provider]*	*[Method]*	*[ISF/sponsor training records]*
Auditor/inspector	*[Brief overview, navigation only]*	*[Site/service provider]*	*[Method]*	*[ISF (if filed)/inspection records]*
[ENTER others as appropriate]				

7 ISF Oversight and Access Arrangements

7.1 Responsibilities

Several roles could be involved in ISF setup, maintenance, and oversight. All are responsible for ensuring inspection readiness of the ISF on an ongoing basis throughout the conduct of the study; records should be filed contemporaneously and not allowed to accumulate. The site (and ultimately the principal investigator, with the institution) retains overall accountability for the ISF, even when activities are delegated to other site staff or to a service provider. Per ICH GCP E6(R3) Section 2.12.11, the investigator/institution should have control of all essential records generated by the investigator/institution before, during, and after the trial.

Activity	Function or Role Responsible
Who is responsible for writing and maintaining the ISF Plan and ISF Index?	

[ENTER DATE YYYY-MM-DD] Page 6

Page 6 of the real template

Govern — Cover page, sign-offs, your SOPs and training (§1–6)

Organize — Your ISF Index, what doesn't apply, records kept by others (§8)

Control access — Who does what, who sees what, originals and copies (§7, §8.2)

Review — How often you review or audit the ISF (§9)

Close & retain — Who keeps the records after the study, and for how long (§10–11)

Reference your SOPs instead of repeating them. The template is meant to be adapted, not copied.

Naming your records

*A suggested pattern from the **User Guide (Section 3.1)**, not a requirement. Set your own convention in the*

Element	What it identifies	Example
StudyID	The sponsor's protocol or study number	ABC123
SiteID	Your site number for this study	S014
Zone	The ISF Zone the record is filed in	07
Artifact	The subsection, using the ISF RM name	SiteSignatureSheet
Subartifact	The specific type of record	DelegationOfAuthority
Version	Which version of the record this is	v03
Date	The record's date, as YYYY-MM-DD (same as the TMF Standard Model)	2026-10-15

Full name ABC123_S014_07_SiteSignatureSheet_DelegationOfAuthority_v03_2026-10-15

Where to find the ISF reference model

1 Go to **www.cdisc.org/tmf**

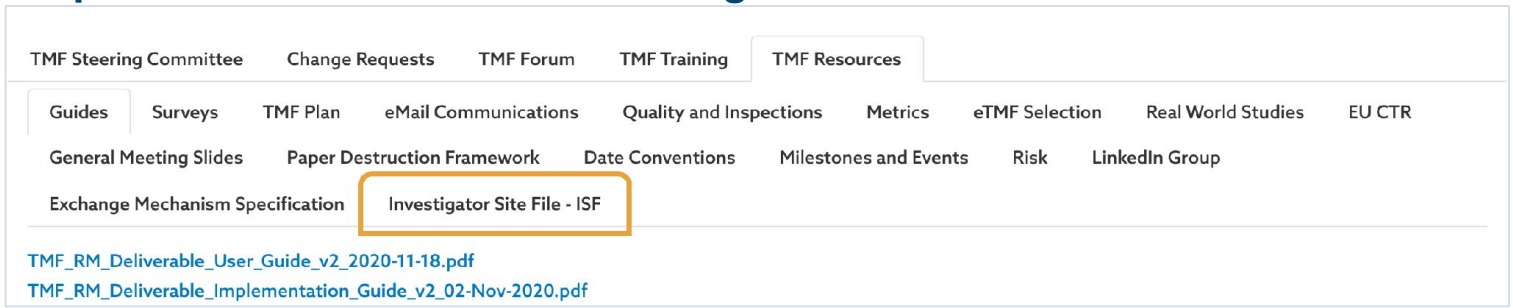
2 Scroll down to the tabs and click TMF Resources

3 Click Investigator Site File - ISF

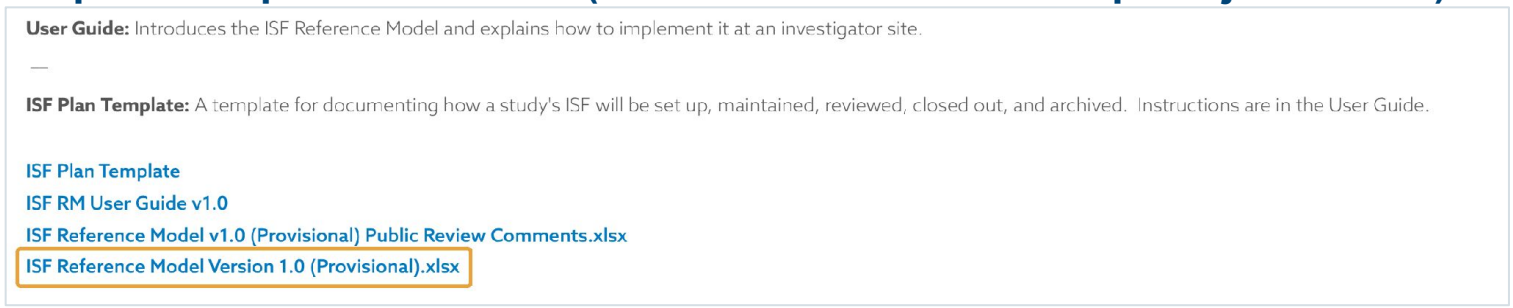
4 Download ISF Reference Model Version 1.0 (Provisional).xlsx

The User Guide and ISF Plan Template are linked just above it. All free.

Steps 2–3: TMF Resources › Investigator Site File - ISF



Step 4: the spreadsheet link (User Guide and Plan Template just above)



Where the standard is heading

ISF reference modelは
TMF standard modelに統合されます！

Today: version 1.0

- Provisional, but ready to use now
- User Guide and ISF Plan Template available
- Built by ~45 industry volunteers

Next: part of the standard

- **Joins the TMF Standard Model** (v1 draft now in review)
- Your ISF stays site-focused
- Timing to be confirmed

Then: final

- Moves from provisional to final once it joins the standard
- Your feedback shapes what changes
- ISF names become CDISC Controlled Terminology that systems can read

How it fits current GCP (ICH E6(R3))

Paper or electronic, with the right controls

Paper, electronic, or a mix are all acceptable

Fit it to your study

You decide which records apply and write down why in your ISF Index

Under E6(R3)

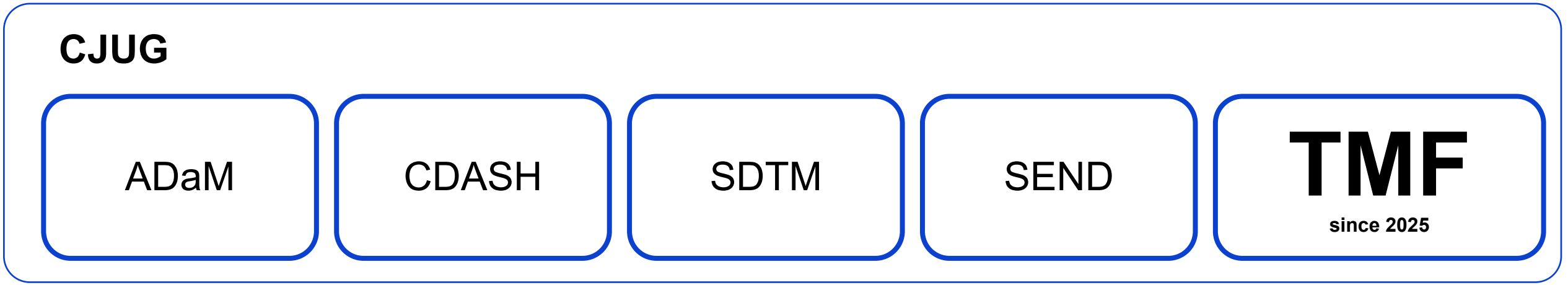
Tell the sponsor who will keep your records after the study ends

CJUG TMF teamのご紹介

CJUG:CDISC Japan User Group

- CDISCユーザーネットワークは、アメリカ/ヨーロッパ/アジアなどで
  それぞれ設立されている組織です。
- CJUGは日本のCDISCユーザーネットワークであり、2002年に設立されました。
- 規制当局/製薬会社/CRO/アカデミア/ITベンダーなどのメンバーが
  各CDISC標準のワーキンググループに参加し、
  日本でのCDISC標準の普及へ向け活動しています。

https://wiki.cdisc.org/spaces/J3C/pages/32812990/What+CJUG （一部改変）



CJUG TMF team

< Mission>
CDISC TMF HQから最新情報を入手して国内への展開を推進　&
国内の意見を CDISC TMF HQにFeedback

組織タイプ	組織名 (英語名のA-Z)	人数
Pharma	旭化成セラピューティクス, 中外製薬, メルク, KMバイオロジクス, ノバルティス, 大塚製薬工場, SinoCellTech & 住友ファーマ	10
CRO	A2ヘルスケア, CMIC, リニカル& PPD-SNBL	8
Service Provider	アガサ, クリンクラウド, CRSキューブ, Medidata, TransPerfect and Veeva	9
Academia	国立健康危機管理研究機構, 順天堂大学, 慶應義塾大学病院, 神戸大学医学部付属病院, 名古屋大学医学部付属病院, 三重大学医学部付属病院, TRI, 横浜市立大学付属病院, 長崎大学病院	24
Consulting	inSeption Group	1

4つのサブチーム:

- **TMF RM/SM**
- **ICH E6(R3) vs TMF**
- **Record management in academia**
- **Sponsor-CRO collaboration**

ISF Reference Modelの読み込みや
各施設のMapping試行を行っています。

最近よく思っていること

文書管理に求められているのは、
守りから攻めの mindset change

文書管理業務は決して backyard業務ではない .
むしろregulation 遵守の最前線

標準化 vs カスタムのバランスは難しいが、
<u>まずは</u>標準化の目的･背景を理解すべき ！

業務効率化 | 脱属人化 | 記録移転 効率化 | タイパ | 自動化 | 品質向上 | 被験者対応 時間UP | etc.

References

ICH E6(R3)	https://www.pmda.go.jp/files/000281699.pdf
CDISC TMF website	https://www.cdisc.org/tmf
CDISC Webinar (recording, 10/28) “From Reference Model to Working ISF: Getting Started with the CDISC ISF Reference Model”	https://www.cdisc.org/events/webinar/reference-model-working-isf-getting-started-cdisc-isf-reference-model-japanasia
TMF Standard model	https://www.cdisc.org/public-review/cdisc-tmf-standard-model-v1-community-review

Thank you!
Let's have
Too Much Fun in Japan !

