



CDISC - TMF Plan Template, Version 2.0  
Revisions Made

21-Oct-22

Section #	Section Topic	Page # in Template	Page # in Compare Doc	Revisions Made
0	Instructions	1	1	Updated Instructions for intention and the font written in
0	Table of Contents	2	3	Re-arranged the order for better flow, i.e. Transfer and Archival is now section 11
1	Approvals	3	4	No major changes
2	Document Version History	4	5	No major changes
3	Definitions and Abbreviations	5	6	Added additional instructional text and made all definitions as instructional text examples
4	Introduction	6	7	Reworded section
5	Applicable SOPs	7	8	Added more instructional text. Added tables for both Sponsor and CRO SOPs
5.1	Sponsor Specific	7	8	
5.2	Vendor/CRO Specific	7	8	
6	TMF Training	8	9	Reworded section, added table for type of training by Role
7	TMF Oversight & Access Arrangements	9	10	
7.1	Responsibilities	9	10	Removed the RACI, added an Activity table to state who is doing what at Sponsor or CRO (or other vendor)
7.2	Access arrangements	10	11	Minor text changes
7.3	CRO/Vendor	11	11	Minor text changes, and made all boxes clickable
7.4	For Inspections/Audits	11	12	Reworded all text in this section to be more streamlined.
8	TMF Content	12	13	
8.1	TMF Format, Structure/Content Map/Specifications	12	13	Made all boxes clickable and added additional instructional text and text for what content should be generated with a new table for vendor types. Removed 'Authoritative Sources' as a separate section
8.2	E-Signatures, Originals, Wet Inks, and Raised Seals	15	16	Added additional instructional text. Added description for e-signature process.
8.3	Relevant Correspondence	15	16	Minor text changes.
8.4	Unblinded Records	16	17	Minor text changes.
8.5	Translations	16	17	Major wording changes to instructional text and what is to be entered.
8.6	Living/Fluid Documents	16	17	Section added
9	Conducting TMF Reviews	17	18	Additional instructional text added.
9.1	TMF Review Plan	17	18	Added wording into instructional text and updated table with more details.
9.2	TMF Review Documentation	18	19	Section added.
10	Record and TMF Disposition	19	20	Updated instructional text.
10.1	Archiving	19	20	Sub sections added.
10.1.1	Sponsor TMF at CRO/Vendor	19	20	Sub section added, although text was there in past, cleaned up and made all boxes clickable.
10.1.2	Investigator TMF	19	20	Sub section added, although text was there in past.
10.2	Retention by CRO or Vendor	19	20	Sub section added.
10.3	Legal Hold	20	21	Table added to make clearer.
10.4	Destruction by CRO or Vendor	20	21	Sub section added.
11	Transfer and Archival of TMF	21	22	Added TMF Transfer Agreement info into instructional text; added column to table for type of Documentation.
12	Appendix	22	23	Minor wording.