

List of Articles & Other Publications

2024	Risk-Based TMF Management: Considerations to Enhance Quality, Compliance and Efficiency	CDISC	Project Lead
2023	How To Prepare Your Data for a Clinical Trial Site Inspection	Arkivum	Author
2023	Trial Master File Reference Model	TMF Ref Model	Contributor
2022	A Guide to the Archiving of Electronic Records	HSRAA	Project Lead
2022	Impact of the Clinical Trials Regulations on Trial Master Files	TMF Ref Model	Co-Author Presenter
2021	eBook: A Guide to Archiving Laboratory Data	Arkivum	Contributor Reviewer
2021	Regulation EU 536/2014: A Records Manager and Archivist's Perspective	Arkivum	Author
2021	Top 15 EU Regulation 536/2014 Questions –Part 1	Arkivum	Adviser Contributor
2021	Top 15 EU Regulation 536/2014 Questions –Part 2	Arkivum	Adviser Contributor
2021	What Options do CROs and Sponsors Have for Managing Trial Data at the End of a Trial?	Arkivum	Author
2020	Arkivum Report: TMF Futures, Keeping Data Alive	Arkivum	Contributor
2020	I don't need more space; I need less stuff. How defensible destruction ensures that removing is improving.	HSRAA	Author
2020	Real World Evidence Study Master File Index	TMF Ref Model	Project Lead
2020	TMF Digital Archive: Meeting Regulatory Objectives	Arkivum	Author
2020	Trial Master File Essentials	HSRAA	Author
2019	"Real World Evidence" Study Master File Index		Project Lead
2019	Guidance for the Management of e-Mail Communications in Clinical Studies	TMF Ref Model	Project Co-Lead
2019	GxP-Regulated Archives and the GxP Archivist	HSRAA	Author
2018	Guidance for the Destruction of Paper Records in Clinical Research		Co-Author
2017	Guide to the Evaluation and Selection of eTMF Technologies	HSRAA	Project Lead
2017	Guide to the Use of PDF Validators as a Data Integrity Tool	HSRAA	Co-Author
2016	Guidance on the Scanning and Destruction of Original TMF Records	HSRAA	Project Lead
2016	The Real Reason You Should Print in Colour	HSRAA	Author

2016	The Role and Use of PDF in Records Retention	HSRAA	Contributor
2015	Archiving Multimedia (Audio-visual) Files	HSRAA	Co-Author
2015	Review of the Impact of EU Regulation 536/2014 on Clinical RM	HSRAA	Project Lead
2015	Review of the Impact of EU Regulation 536/2014 on Clinical RM	HSRAA	Project Lead
2014	A Guide to the Archiving of Electronic Records	HSRAA	Contributor
2014	Good Clinical Practice: A Guide to Archiving	HSRAA	Co-Author
2012	Guidelines for Selecting a Commercial Records Storage Provider	HSRAA	Project Lead
2012	How to Avoid Being Boxed into a Corner	HSRAA	Co-Author
2010	Guidelines for GCP Clinical Trial Communications	HSRAA	Project Lead
2009	The Myth of Documents Types: Making Records Management Fit for Purpose	HSRAA	Co-Author
