# FRAMEWORK FOR THE DESTRUCTION OF PAPER

*Version v2.0*

*18 January 2019*

*Created through the support of the DIA Document and Records Management (DRM) Community*

## Position Statement

The DIA supports the efforts of volunteers of the Document and Records Management Community to advance the purposes of the DIA and provide value to the industry which it serves. Professionals from within the industry volunteer their time and effort to achieve consensus on how their business can be improved. Ideas are shared and improvements developed for implementation within the industry. It is a method of sharing ideas for the benefit of the common good. Through the support of the DIA Document and Records Management Community, an effort was organized in 2018 to review and revise Framework for the Destruction of Paper, which was originally published in 2012.

It continues to be the opinion of the biopharmaceutical industry professionals within this effort that the reduction of the creation of paper is paramount to the process of better content management. Making paper copies and printing electronic records that then get scanned into a digital format results in process redundancy and inefficient use of resources. When only necessary that an original or copy of a paper document be created or collected, this framework recommends the destruction of that paper following a verified conversion of the document into a digital format. This recommendation is conditional on the following:

1) A qualified organizational risk-benefit analysis take place that considers the 5 topic areas (see below) and resultant process is in place and monitored for compliance that ensures the digitized copy is a complete and accurate representation of the paper version;
2) The digitized copy is placed in a validated electronic content management system and an archival process in place to manage the electronic records; and
3) A training plan covering the applicable Policy and SOP(s) have been created, is available within the organization, and users have successfully completed the training before utilizing the process to destroy the paper document.

These general measures are extended and defined in greater depth within the attached version 2.0 of the framework.

Creation of this framework has been accomplished through selfless voluntary contributions of the diverse professionals from a variety of perspective who provided their expertise on what is required for comprehensive regulatory compliance and legally defensible process for the destruction of paper. Recommendations in this revised version continue to be derived following extensive discussions and research in the same 5 topic areas as were explored in version 1.0; namely Technology, Quality, Records Management, Regulatory, and Legal. It continues to be the intention of this framework to

break through the continuing and recurring obstacles that have prevented our Industry to have the confidence in this area for nearly 2 decades. The scope of the initial and this latest effort is on GCP records created in support of a clinical trial in the regions involved with the creation and maintenance of the International Conference on Harmonization (ICH) Good Clinical Practice (GCP). The intent of this framework is not to recommend specific organizational decisions on technology tools or internal processes regarding creation of documents.

## Overview

The DIA, a recognized and highly respected professional association, and their Community for Document and Records Management (DRM), supported an initiative to review and revise the already available version 1.0 of the Framework for the Destruction of Paper; a framework that in 2012 initially provided the process and parameters concerning the destruction of paper documentation that had been digitized and placed in a validated Electronic Content Management System (ECMS). The focus of this current version of the framework as was with the initial effort, was on regions involved with the creation and maintenance of the International Conference on Harmonization (ICH) Good Clinical Practice (GCP). Although perceived to be applicable to other domains of pharmaceutical and device research and development companies and countries and regions of the world, this revised framework has not yet been verified to this extent.

Review and revision of this framework has involved more than 80 professionals from more than 70 biopharmaceutical and device companies, contract research organizations (CROs), consultancy companies, and technical vendors. Contributors on this group, through the DIA DRM Community, have provided their perspective on one or more of the 5 areas of focus within the framework, namely Technology, Quality, Records Management, Regulatory, and Legal. The goal of this group was to revise the 2012, version 1.0, of the Framework for the Destruction of Paper, which is a framework which may be used and adapted by any individual, company, institution, or organization, hereinafter referred to as organization, for their own use. Therefore, the attention of participants on this effort was drawn to the non-commercial nature of this forum. The group who created the version 1.0 of the Framework and this group who reviewed and revised version 2.0 of the Framework has not been a forum for promotion of products, capabilities, or specific companies.

It is acknowledged that the resulting framework will need to be integrated with each organization's own policies and practices. If an organization had utilized v1.0 of the Framework, it is recommended that they review this updated version for continued alignment. The framework will continue to be vetted through many pharmaceutical and device research and development companies, CROs, consultancy companies, and technical vendors, in addition to Regulatory Agencies and other defining bodies who could either be contributors or stakeholders who review GCP documentation. Continuing feedback on this revised Framework is welcomed and encouraged to help it mature and become even more useful. The mechanism for feedback is online on the following website: www.paperdestruction.org. (11JAN19)

The Framework is non-binding in accordance with the DIA's scope and mission. It should be a reference for the industry and should not be considered mandatory or an official standard, but rather as

an opportunity for harmonization across the industry. The framework does not endorse or require any specific technology for implementation.

## Rationale for the Creation of a Framework

Historically, paper documents have been created, used, managed, archived, and destroyed as documentation for support in the conduct of clinical trials. Rapidly, the documentation process has changed from creating and managing paper documents into producing and managing documents in electronic formats. The trend is that the remaining paper documents are scanned into a digital format and uploaded into an ECMS. The process to convert paper to electronic creates redundancy and duplication in the management of documentation in support of the business process as well as the possibility that 2 copies of the same document exist. The destruction of the scanned paper document is a complicated topic and necessitates a thorough examination of the requirements that confirm the electronic version is a complete and accurate representation of the paper that was scanned.

The goal of this framework is to provide a single, unified interpretation of the applicable laws, regulations, guidances, and industry best practices that apply to a complex, legally defensible, and regulatory compliant paper destruction process for the regions in scope. The framework does not provide prescriptive guidance for the detailed processes. This detail will be unique to each organization and the decisions owned by the internal stakeholders that use the framework to establish their own policies and procedures.

## Organization of the Framework

### PARAMETERS

With respect to this framework, the working group considered 5 topic areas.

- TECHNOLOGY: Specific requirements and capabilities of the system
- QUALITY: Capture process & scan quality
- RECORDS MANAGEMENT: Policies, procedures, and practices
- REGULATORY: Established health authority laws & regulations, and GCP standards
- LEGAL: Laws of evidence

Parameters from v1.0 were evaluated or created for each topic. Each working group considered the relevancy of the parameters, their placement in the framework, as well as if additional parameters were required. Each parameter was assessed or new ones created following a thorough assessment of the regulations, laws, guidance, and industry practices currently available. Other industries that have

transitioned to management of electronic content and the elimination of paper have been used as references. Most parameters include: a statement and an interpretation of the statement, and the references used to establish the statement (where available). Note that the writing style of the different parameter topics are unique to the type of the professionals that have reviewed, revised, and finalized the parameters. These styles were retained to allow familiarity of style and vocabulary with the various professionals at the companies that will utilize this framework.

## Technology Parameters

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| **T 1** | **Establish a project scope, project plan, and process for a destruction of paper project.**<br><br>**INTERPRETATION**<br><br>Before embarking on a project involving the destruction of paper, the organization should define the project scope and justify any business needs so that a project plan can be established and communicated throughout the organization. The project scope will ultimately determine the resource and technology needs as well as the project timeline. For example, some organizations may want to convert all paper documents to digitized certified copies and subsequently destroy the paper originals, while others may choose to retain some paper documents indefinitely according to their established procedures. Some organizations may decide to convert and destroy papers in a limited number of departments. It is critical for the organization to identify a project manager, create a project plan, acquire sufficient resources, select and utilize appropriate technologies, and execute the project plan to ensure the project of paper destruction and electronic records archiving will be completed successfully.<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. Project Management Institute (PMI). A Guide to the Project Management Body of Knowledge (PMBOK® Guide). Sixth Edition, 2017. https://www.pmi.org/pmbok-guide-standards/foundational/pmbok (05NOV2018) |
| **T 2** | **Create an inventory of existing and potential systems, technologies, and tools that perform functions in digital transformation and electronic document management and that will facilitate converting paper documents to an electronic format and the destruction of paper.**<br><br>**INTERPRETATION**<br><br>The organization should identify all existing and potential technologies, systems, and tools available to perform functions in facilitating the destruction of paper, converting paper documents to an electronic format, and archiving electronic records. This step is required to complete the following activities for the destruction of paper. Moreover, as technologies advance, the organization must continuously evaluate potential technologies that will facilitate the transformation of the paper document to a digitized copy.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. Industry opinion and practice though not formally cited in the public domain. |
| **T 3** | **Ensure that identified systems, technologies, and tools meet, at a minimum, applicable rules and regulations.**<br><br>**INTERPRETATION**<br><br>Once technologies and systems that can be used to create digitized copies of paper documents have been identified, the organization should ensure those systems meet applicable regulatory requirements which include the following: |

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| | • FDA Quality System Regulations, 21 CFR, Part 820.70. Production and Process Control<br>• FDA Guidance for Industry and FDA Staff: General Principles of Software Validation<br>• Industry guidance such as the GAMP 5 Good Practice Guide (Good Automated Manufacturing Practice)<br>• Personal Information Protection and Electronic Documents Act (PIPEDA)<br>• Uniform Electronic Transactions Act (UETA)<br>• United Nations Commission on International Trade Law (UNCITRAL)<br>• Japanese ERES Guideline (Electromagnetic Records and Electronic Signatures)<br><br>As examples, an Electronic Content Management System (ECMS) may have to be validated according to the FDA guidance on software validation; An international biopharmaceutical company, which has operations in Japan, may have to meet the Japanese ERES Guideline.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. United States Food and Drug Administration. Electronic Code of Federal Regulations. Quality System Regulations. 21 CFR Part 820.70. Production and Process Control. e-CFR data is current as of 30APR2018. https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=e63c2ca02ae54dedc71516f87c1ae2f6&mc=true&n=pt21.8.820&r=PART&ty=HTML - se21.8.820_170 (31OCT2018)<br>2. United States. Food and Drug Administration. General Principles of Software Validation; Final Guidance for Industry and FDA Staff. Issued 11JAN2002. https://www.fda.gov/downloads/medicaldevices/.../ucm085371.pdf (31OCT2018)<br>3. International Society for Pharmaceutical Engineering (ISPE). *GAMP 5:* Good Practice Guides. http://www.ispe.org/cs/gamp_publications_section/gamp_publications_overview. (31OCT2018)<br>4. Department of Justice Canada. Personal Information Protection and Electronic Documents Act (PIPEDA). Act current to 05SEP2018 and last amended 23Jun2015. http://laws-lois.justice.gc.ca/eng/acts/P-8.6/ (31OCT2018)<br>5. National Conference of Commissioners on Uniform State Laws (NCCUSL). Uniform Electronic Transactions Act (UETA). Issued 1999. Approved by the American Bar Association 14FEB2000. http://www.uniformlaws.org/shared/docs/electronic transactions/ueta_final_99.pdf (31OCT2018)<br>6. United Nations Commission on International Trade Law (UNCITRAL). http://www.uncitral.org/uncitral/en/index.html (31OCT2018)<br>7. Japanese ERES Guideline. Using electromagnetic records and electronic signatures for application for approval or licensing of drug. 01APR005. https://ecompliance.co.jp/english/Japanese ERES Guideline.html (31OCT2018) |
| **T 4** | **There are minimum requirements for scanner settings to scan and upload documents into an ECMS.**<br><br>**INTERPRETATION**<br><br>Paper documents should be scanned using the following settings:<br><br>• 300 or 600 dots per inch (dpi).<br>This resolution is recommended to ensure that the pages of the document are legible both on the computer screen and when printed, as well as to minimize the file size.<br><br>The scanning resolution should be determined by the type of document being scanned and its current level of quality. The minimum resolution of 300 dpi is recommended to balance legibility with file size. Documents scanned should provide adequate legibility both on a computer screen and printed copy while at the same time, producing a minimal file size “Paper documents containing handwritten notes should be scanned at 300 dpi. |

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| | Documents with photographs either black and white or color should be scanned at 600dpi.<br>• Simplex (single-sided) or duplex(double-sided) for documents that have information on back pages.<br>• Bi-tonal (Black/White)<br>  ○ If there are attributes to a paper document in color and these attributes are critical to the interpretation of the content of the document, it is recommended that the scan of the paper document be in color.<br>• PDF<br>  ○ For archival purposes, PDF/A should be used which is an ISO-standardized version of the Portable Document Format specialized for use in the archiving and long-term preservation of electronic documents. PDF/A differs from PDF by prohibiting features unsuitable for long-term archiving, such as font linking and encryption.<br><br>The scanning resolution should be determined by the type of document being scanned and its current level of quality. The minimum resolution of 300 dpi as identified under this parameter is recommended to balance legibility with file size. Documents scanned should provide adequate legibility both on a computer screen and printed copy while at the same time, producing a minimal file size.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. United States Food and Drug Administration. FDA Industry Guidance – Portable Document Format Specifications. Special Considerations for Promotional Labeling and Advertising Material.14SEP2016. http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163565.pdf (31OCT2018)<br>2. United States Food and Drug Administration. Guidance for Industry - Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. April 2018. Revision 5. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm333969.pdf (31OCT2018) |
| **T 5** | **Optical Character Recognition (OCR) technology can be utilized for both ease of content identification and increased searchability within ECMS**.<br><br>**INTERPRETATION**<br>When an organization decides to convert paper documents to an electronic format and destroy the paper after the conversion, it would befit the organization to consider utilizing OCR technology so that the content of electronic documents is searchable. This will add value to the new format and provide the ability to search for and identify documents with ease. Moreover, according to FDA guidance, “If you scan a document to create a PDF file, we recommend that you capture text by optical character recognition (OCR) software so that the text of the resulting electronic documents is reasonably accessible and searchable.”<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. United States Food and Drug Administration. FDA Industry Guidance – Portable Document Format Specifications. Special Considerations for Promotional Labeling and Advertising Material.14SEP2016. http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163565.pdf (31OCT2018)<br>2. United States Food and Drug Administration. Guidance for Industry. Providing Regulatory Submissions in Electronic or Paper Format to the Office of Food Additive Safety. Mar. |

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| **T 6** | **There are minimum requirements in electronic document formatting for long-term retention and future document reproduction capabilities.**<br><br>**INTERPRETATION**<br>Organizations require assurances that images of the paper documents which have been scanned along with the resulting original paper destroyed, can be reproduced years later. On September 28, 2005, the International Standards Organization (ISO) approved a new standard governing electronic document archiving, PDF/A. PDF is prevalent in public and private sectors worldwide and is already an accepted archiving format in many markets. The PDF/A Standard will help ensure the long-term availability and reproducibility.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. *ISO. ISO-19005-1 - Document management* - Electronic document file format for long-term preservation - Part 1: Use of PDF 1.4 (PDF/A-1). This ISO document cannot be made available to the public due to the copyright. But if needed, individual can purchase a copy of the document from ISO.<br>2. PDF association. *PDF/A* – A New Standard for Long-Term Archiving. https://www.pdfa.org/pdfa-a-new-standard-for-long-term-archiving/ (31OCT2018) |
| **T 7** | **Address the challenges of long-term archiving.**<br><br>**INTERPRETATION**<br>When using a digital environment, an organization must take steps to ensure long-term integrity and accessibility to electronic documents. The main challenges of long-term digital archiving include 1) authenticity and integrity of data content; 2) viability of information due to technology obsolescence; and 3) reliable, affordable, sustainable and efficient archival media.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. Lu, Maohua and Chiueh, Tzi-cker. Challenges of Long-Term Digital Archiving: A Survey. https://pdfs.semanticscholar.org/494f/cfe2849fcc2b2f79d4ca61b500f8f6caed0d.pdf?_ga=2.61278956.1186691533.1529203474-1706464658.1529203474 (31OCT2018) |
| **T 8** | **Documents scanned or uploaded must be secured in a validated ECMS**.<br><br>**INTERPRETATION**<br>Organizations which are scanning or uploading documents into an ECMS must ensure that the system and repository are fully validated in compliance with 21 CFR Part 11 and GAMP5 standards.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. United States Food and Drug Administration. *Electronic records; electronic signatures – Scope and Application, 21 CFR Part* 11AUG2013. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf (31OCT2018)<br>2. International Society for Pharmaceutical Engineering (ISPE). *GAMP 5. A Risk-Based Approach to Compliant GxP Computerized Systems*. ISPE 2008. http://www.ispe.org/cs/gamp_publications_section/gamp_publications_overview. (31OCT2018) |

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| **T 9** | **When used, time stamps must be implemented with a clear understanding of the applicable time zone**.<br><br>**INTERPRETATION**<br>When using time stamps as part of the information captured on a digitized image, it should be implemented with a clear understanding of the time zone reference used. In such instances, system documentation should explain time zone references as well as time zone acronyms or other naming conventions.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. United States Food and Drug Administration. *Electronic records; electronic signatures, 21 CFR Part 11.* e-CFR. https://www.ecfr.gov/cgi-bin/text-idx?SID=98ba5016feaeb58d0e69d173b6c87ee3&mc=true&node=pt21.1.11&rgn=div5 (31OCT2018)<br>2. United States Food and Drug Administration. *Electronic records; electronic signatures – Scope and Application, 21 CFR Part 11*. 11AUG2003. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf (31OCT2018)<br>3. United States Food and Drug Administration. *Electronic records; electronic signatures, 21 CFR Part 11.* e-CFR. https://www.ecfr.gov/cgi-bin/text-idx?SID=98ba5016feaeb58d0e69d173b6c87ee3&mc=true&node=pt21.1.11&rgn=div5 (31OCT2018) |

## Quality Parameters

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| **Q 1** | **It is critical to perform a risk assessment.**<br>**INTERPRETATION**<br>A risk management and mitigation plan should be established in a Paper Destruction pilot process.<br>• Milestones and considerations throughout the pilot, as well as an overall evaluation at the end of the pilot are recommended to be established to facilitate decisions regarding if and how to proceed with a paper destruction process.<br>This risk management and mitigation plan must align with the organization's risk management policies.<br>**BIBLIOGRAPHY/REFERENCES**<br>1. International Organization for Standardization. ISO 31000:2009. Risk Management-Principles and Guidelines. http://www.iso.org/iso/catalogue_detail?csnumber=43170 (05NOV2018) |
| **Q 2** | **The requirements for the paper destruction process and the certification of destruction needs to be defined by the organization.**<br>**INTERPRETATION**<br>Organizations must develop a destruction policy.<br>• The destruction process should be defined by the organization and should follow all regulatory and local retention guidelines for the type of document being destroyed.<br>• Destruction process should include information on how destruction will be documented (For example, if and when a certificate of destruction should be created, how it will be maintained and at what level: batch level or individual document level, etc.)<br>• Certificates of destruction demonstrate that destruction was conducted as per defined process and related regulations. Note that local regulation and statutory requirements are to also be considered.<br>• The timing of paper destruction needs to be considered in line with country-specific regulations and organization retention policies, including those associated with the hold of records as required for litigation.<br>**BIBLIOGRAPHY/REFERENCES**<br>1. British Standards Institution (BSI). BS EN 15713:2009. Secure Destruction of Confidential Material. Code of Practice. https://shop.bsigroup.com/ProductDetail/?pid=000000000030166950 (19NOV18) |
| **Q 3** | **There should be a controlled, quality-driven process for document scanning and uploading into a validated ECMS.**<br>**INTERPRETATION**<br>**Steps for consideration:**<br>A scanner should be selected that can produce scanned digitized images according to the technology requirements previously identified, including but not limited to scanner settings.<br>The scanning resolution should be determined by the type of document being scanned |

and its current level of quality. The minimum resolution of 300 dpi is recommended to balance legibility with file size. Documents scanned should provide adequate legibility both on a computer screen and printed copy while at the same time, producing minimal file size.

The use of grayscale and color significantly increases the file size and it is only recommended when these features improve the readability of the material. It is recommended that documents with color also be scanned in color (e.g. color seal, color-coded data outputs, etc.). Avoid re-sampling to a lower resolution.

A captured image should not be subjected to non-uniform scaling (i.e. sizing).

Digitized images should be saved in the PDF format and should be readable using Adobe Reader without the need of additional software.

**Preparation Steps for Scanning Documents:**

- Remove the documents from plastic wallets and binders
- Check original paper documents to determine whether simplex or duplex scanning settings are required. Duplex scanning settings are required if the scanning process will automatically process documents with information on back pages; otherwise, double-sided documents might have to be manually scanned in a simplex setting.
- Remove the document from its binder or folder or separate it from its binding. To avoid removing the binding from a valuable document, a book scanner can be used.
- Flatten bent pages
- Ensure the proper orientation of all pages
- Remove paper clips, staples, binder clips, sticky notes, and other items attached to the document.
- If applicable for an automated process:
    - Insert separator sheets, with barcodes, between document sections for indexing purposes.
    - Group by size to lessen the time needed to re-calibrate scanners (for document collections containing multiple sizes).

**There Are Two Scenarios for Consideration Depending on the Scanning Process:**

- Individual document scanning
- Batch scanning - Documents can be batched according to specific scanner limits for ease of scanning and to facilitate scanning in bulk.
    - If scanning in batches, document separator/cover sheets can be used to distinguish each document within the batch.

For the capture of metadata along with the indexing of the electronic records, an ECMS should be considered as part of the process.

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| **Q 4** | **The authenticity of scanned or digitized images as certified copies must be established.**<br><br>**INTERPRETATION**<br><br>A quality check (QC) process should be defined to review the scanned paper document(s). The quality driven validated process should be established for image quality, indexing quality, metadata accuracy, and the establishment of the certified copy. Monitoring of the validated process needs to be documented. If completion of QC steps is being documented electronically, an audit trail and/or electronic signature functionality is to be implemented as part of the overall validation of the ECMS. All QC may be done at individual document level or a batch level, as per the organization process.<br><br>**Criteria For QC: Image Quality (not in Order of Priority)**<br><br>The following are considerations for organizations to assess and to best define their organization-specific requirements for establishing image quality:<br>• Are all of the pages present? Are all of the pages in the correct sequence? If pages are numbered, are all pages in order?<br>• Are there any double feeds, i.e. skipped pages noted in the scan due to pages sticking together?<br>• If scanning duplex, does the image contain all of the information from both sides of the document? If scanner settings are duplex, are true blank pages removed?<br>• Is the document the right size and orientation (e.g., US Letter, A4; landscape)?<br>• Are all pages in the correct orientation?<br>• Is the scanned image too light/too dark? If the original paper document has content that is too light to produce a quality readable digitized copy, retention of the paper document should be considered.<br>• Are pages skewed?<br>• Have any sticky notes been inadvertently scanned and may block content on the paper document?<br>• Is all content legible?<br>• Are all characteristics and content of the original document seen in the digitized image?<br>  ○ There are no bent corners blocking document content<br>  ○ De-speckling capabilities are not used<br>  ○ Removal of hole punches on images is not recommended<br>  ○ Removal of any content from the original document is not permitted (e.g. fax header information).<br>  ○ Pages with only header and footer information are not to be considered as blank pages. |

The quality of the image should be a true reproduction of the quality of the original. It is not recommended that images be enhanced. If an image is too light/dark, retention of the paper original should be considered.

**Criteria For QC: Indexing Quality**
Indexing document attributes or metadata may be completed before or after scanning, depending on organization processes and the technology used. All attributes should be checked for accuracy before QC process is considered complete and the images are uploaded into an ECMS.

**Considerations for QC to Create A Certified Copy: Process to be defined or approved by the organization and should include:**

- QC process to document the chain of custody and document processing through the life of the original and digitized copy.
- Track chain of custody
- Track quantity regarding the number of pages and resulting image quality.
- Track who has uploaded and approved the document.
- The process for certifying a copy must be documented in Standard Operating Procedures. If an electronic method is going to be used as part of the certification process, then it must be validated.
- If organizations wish to use scanned or digitized image instead of the original paper document and destroy the original paper, the scanned copies must meet the definition of a certified copy.
- Organization records management policies must be followed.
- Any legally protected documents not to be destroyed should be defined, listed, and maintained according to the organization's established processes. *(Refer to Glossary for the definition of legally "protected document")*
- It is recommended but not required that QC steps be performed by a different person than the person that performed the scanning and indexing.

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| | 7. Industry opinion and practice though not formally cited in the public domain. |
| **Q 5** | **There must be a documented, quality-driven process for destruction of paper documents and for maintaining certified copies in an ECMS; in compliance with regulations and legal requirements.**<br><br>**INTERPRETATION**<br>If organizations wish to retain the electronic copies in an ECMS in place of paper, the ECMS must comply with FDA 21 CFR part 11 and Section 5.5 of the Note for Guidance on Good Clinical Practice (CPMP/ICH/GCP/135/95)1. These references include the following additional requirements:<br>• Computerized system validation<br>• Maintenance of SOPs for the use of the system<br>• A defined process for granting access to the ECMS as well as periodic review of user access lists.<br>• Maintenance of an audit trail of data changes ensuring that there is no deletion of entered data or scanned documents<br>• Maintenance of a security system to protect against unauthorized access<br>• Maintenance of a list of the individuals authorized to make data changes<br>• Maintenance of adequate backup of the data and archiving of any source data (i.e. hard copy and electronic). Minimum standards for back up should be organization specific.<br>• Appropriate training records for those involved in the scanning and uploading processes.<br>• Documents being easily located and traceable in the system<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. British Standards Institution (BSI). BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically. https://shop.bsigroup.com/upload/269461/BIP_0008_2_Chapter_sample.pdf (19NOV18)<br>2. European Medicines Agency Q&A: Good Clinical Practice (GCP). Expectations of EU competent authorities on the use of electronic Trial Master Files. https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice/qa-good-clinical-practice-gcp (19NOV18)<br>3. United States Food and Drug Administration. FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations Guidance for Industry: Part 11; Electronic Records; Electronic Signatures- Scope and Application https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070266.pdf (19NOV18) and https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm125125.pdf (19NOV18) |

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| **Q 6** | **All training must be completed and documented.**<br><br>**INTERPRETATION**<br>All personnel involved in the scanning, uploading, and QC processes should have appropriate training to enable these individuals to perform their assigned functions. All training and must be documented, and training records must be maintained per institutional procedure.<br><br>**BIBLIOGRAPHY/REFERENCES:**<br>1. United States Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 4. Revised as of April 1, 2011. Sec. 211.25 Personnel qualifications.<br>2. European Commission. Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use Eudralex, Vol 4, *Chapter 2 Personnel.* https://eur-ex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF (19NOV18) |
| **Q 7** | **Third party requirements must be specified for when activities are transferred to consultants and vendors.**<br><br>**INTERPRETATION**<br>Any duty or function that is transferred to a third party (e.g., CRO, consultants, contractors, vendors) must be specified in writing. Third parties must be qualified to provide advice on the subject for which they are retained. Records must be maintained stating the name, address, and qualifications of any third parties and the type of service they provide. It is recommended that the standards described and included in vendor contracts, agreements, oversight plans, etc., will be confirmed as appropriate.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. International Council for Harmonization (ICH). Guideline for Good Clinical Practice E6. ICH Harmonized Tripartite. Section 5.2, Contract Research Organization<br>2. United States Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 4. Revised as of 01APR2011. Sec. 211.34 Consultants. |
| **Q 8** | **Change management programs facilitate the successful migration from a paper format to electronic format in the ECMS.**<br><br>**INTERPRETATION**<br>Changing from a paper-based system to an electronic system has numerous advantages including accessibility and searchability as well as allowing for better control of documentation through audit trails and controlled versioning. When an organization decides to convert paper documents to an electronic format and destroy the paper document, before, during and after the conversion, the organization needs to facilitate the change management activity and manage the changes appropriately. Part of the change management process could include preparing a value proposition with appropriate communication pieces and establishing change champions to facilitate process implementation.<br><br>When transferring from paper documents to electronic copies, both the systems being utilized and the process to perform the transfer need to be validated. In addition to utilizing a |

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| | validated system, system considerations are to include security/access controls, the availability of logs as well as training of system users.<br><br>How original paper documents are handled following the creation of the certified electronic copy along with a process for handling certified copies needs to be considered. In addition, a Business Continuity Plan could also be helpful, in the event of system failure.<br><br>Process validation should include verification that appropriate metadata content along with complete, accurate, and legible documents are effectively transferred. Adopting these other related technologies are critical to the success of migrating documents from paper to electronic format.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. European Medicines Agency Guideline: Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) 06DEC2018<br>2. Medical and Healthcare Products Regulatory Agency (MHRA). Good Clinical Practice Guide. SEP2012<br>3. International Society for Pharmaceutical Engineering (ISPE). GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems. http://www.ispe.org/cs/gamp_publications_section/gamp_publications_overview. (05NOV2018)<br>4. Jones, John, Aquirre, DeAnne, and Calderone, Matthew. Ten principles of Change Management, Strategy + Business.15APR2004 http://www.strategy-business.com/article/rr00006?gko=643d0 05NOV2018<br>5. ADKAR Change Management Model. Change Management Learning Center.1996-2007. SEP2011. |
| **Q 9** | **Monitoring of quality must take place.**<br><br>**INTERPRETATION**<br><br>It is recommended that continuous review, routine monitoring, and/or audits of process and systems by the organization occur to ensure established validated process and specified requirements are being met, followed, and maintained. It is prudent that evidence of the monitoring be created and maintained by the organization.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. United States Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 4. Revised as of 01APR2011. Sec. 21 CFR 820.22 Quality Systems.<br>2. United States Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 4. *Revised as* of 01APR2011. Sec. 21 CFR 820.75b Process Validation.<br>3. European Medicines Agency Guideline: Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) 06DEC2018<br>4. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) – specifically section 5.5.3. |

## Regulatory Parameters

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| **R 1** | **A general definition of taking a "risk-based approach" is that the methods used to assure and control quality are: proportionate to the importance of the information collected and the quality risks associated with that information; uses reliable, reproducible, data-backed evidence to diagnose risks; deliberately focuses energy and budget to ensure operational feasibility; and avoids unnecessary complexity.**<br><br>**INTERPRETATION**<br>When creating a process for the destruction of paper documents following a validated process for creating an electronic copy/digitized image of the paper document, the organization is encouraged to determine which parameters and suggestions are meaningful for the organization. Each organization faces specific challenges. This framework is designed to be applied in the context of one's organizational challenges and priorities.<br><br>The references below are among industry's most comprehensive applications of taking a risk-based approached, as defined by ICH. The industry is encouraged by the regulatory agencies themselves to take risk-based approaches, in part, to encourage more efficient and meaningful use of research and development budgets and maximize the ultimate quality of patient care.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, E6(R2), Current Step 4 version. 09NOV2016.<br>2. United States Food and Drug Administration. FDA Guidance for Industry: Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring. AUG2013. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf (05NOV2018) |
| **R 2** | **Ensure adequate preparation for potential inspections by health authorities with respect to paper destruction.**<br><br>**INTERPRETATION**<br>A primary activity of any inspection is a request on the part of the inspector to review records. With respect to answering inspector inquiries regarding paper documents that have been destroyed, consider the following:<br>• Document and be prepared to present the organization's decision-making process around destroying paper such as organizational policy, standard operating procedures, work practices, best practices, etc.<br>• Be prepared to show documentation of every step of destroying the paper document including scanning logs (if bulk scanning), audit trails, evidence of monitoring the established processes, certificates of destruction, etc. (See Quality parameters.)<br>• Have evidence of your validation process available, such as any results of process testing.<br>• Stay apprised and informed of industry events and published findings with respect to inspections of paper and electronic records. Use this information to drive process improvements. Where possible, document and reference where real life experiences have impacted your process. |

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| | Please note this parameter is specific to the destruction of paper documents, and not meant to detail the much broader topic of inspection readiness in general.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. European Medicines Agency Guideline: Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) 06DEC2018<br>2. Framework for the Destruction of Paper Workbook Tool www.paperdestruction.org (11JAN19) |
| **R 3** | **Ensure compliance with U.S. Food and Drug Administration rule on Electronic Records/Electronic Signatures (21 CFR Part 11) and European Medicine Agency Good Manufacturing Practice guideline on Computerized Systems (Annex 11).**<br><br>**INTERPRETATION**<br>Part 11 establishes the requirements for the technical and procedural controls that must be met by the organization if the organization chooses to maintain regulated records electronically; Annex 11 covers the interpretation of the principles and guidelines of GxP-regulated activities to computer systems.<br><br>Both Part 11 and Annex 11 permit the use of electronic signatures provided they have following features:<br>• Have the same impact as handwritten signatures within the boundaries of the organization<br>• Be permanently linked to their respective record(s)<br>• Include the time and date of signature<br><br>Part 11 and Annex 11 also describes the controls that must be designed by the organization to ensure the integrity of the computer system operations and the information stored.<br><br>Limited areas of Part 11 are dissimilar to Annex 11; these, for the most part, are limited to the verification of identity and accountability of actions by authorized individuals, as well as to the reporting to authorities.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. United States Food and Drug Administration. Electronic Records; Electronic Signatures. 21 C.F.R. § 11 (2017) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11 (05NOV2018)<br>2. United States Food and Drug Administration. Guidance for Industry: Part 11, Electronic Records; Electronic Signatures — Scope and Application. AUG2003. https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm125125.pdf (05NOV2018)<br>3. The Rules Governing Medicinal Products in the European Union; Volume 4 Good Manufacturing Practice; Medicinal Products for Human and Veterinary Use; Annex 11: Computerised Systems. European Commission. JUN2011. https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/annex11_01-2011_en.pdf (19NOV18) |
| **R 4** | **Address the concern for Japanese raised seals**<br><br>**INTERPRETATION**<br>It is recommended that a document with a raised seal be considered a “protected document” and be maintained in its original form until technology solutions and guidance for authentic |

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| | preservation is more feasible. In Japan, Hanko (or Inkan) or a Japanese seal, is often required as proof of verification of a transaction or as an official acknowledgment of a situation or event, instead of using a hand-written signature. In addition, the Jitsu-In (corporate signature) stamp and electronic signatures are used during official activities. Until electronic versions of Japanese raised seals are developed, such protected documents should be maintained in their original form.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. J-JCP defines Record Keeping at Article 26-12 and Article 41: Ministerial Ordinance on Good Clinical Practice for Drugs Ordinance of the Ministry of Health and Welfare No. 28 of 27MAR1997 (As last amended by the Ordinance of Ministry of Health, Labour and Welfare No. 161 of 28DEC2012) https://www.pmda.go.jp/files/000152996.pdf (05NOV18)<br>2. Japan Law Concerning Electronic Signatures and Certification Services. MAY2000, http://www.cas.go.jp/jp/seisaku/hourei/data/aescb.pdf (05NOV18) |

# Records Management Parameters

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| **RM 1** | **Records Management best practices are to be followed**<br>**INTERPRETATION**<br>Records management best practices are recommended for the archiving, retrieval, and retention processes involving electronic records, often referred as **e-archive**. These are necessary to ensure authenticity, reliability, integrity, and usability of the electronic records over the long-term.<br>Characteristics of paper and electronic archiving are not very different; the same overall steps need to be followed. However, in order to destroy paper document/records and use only electronic records, there must be an understanding of what it takes to safeguard an e-record versus paper throughout the retention time. In addition, before deciding to digitalize records that originate as paper documents and store them in electronic format, organizations must do a cost/benefit assessment of the necessary processes ensuring appropriate and comprehensive archiving of the electronic record using a validated archiving process. Some high-level definitions and requirements are listed below.<br>**Definitions:**<br>**Transformation** – This is the process of preparing records for e-archive by converting them from their native form (in this case paper) to a preferred preservation format (archival electronic format). The paper to electronic conversion process must be validated and mechanisms provided to ensure that the context, content, and structure of the original paper document are preserved. e-Archiving ready formats may include DOCX, XLSX, PPTX, PDF, PDF/A, XML, HTML, PNG, JP2000 and TIFF.<br>**Transfer to Archive** – This is the process of moving the records from an operational system into the e-archive. The process should be fully validated. Transmittal records such as migration report/summary, validation report/summary should be created to verify successful transfer of the records for audit-trail/chain-of-custody requirements.<br>**Migration** – This is the automated or semi-automated process of transferring electronic records from a previously used system to a new one and includes the transfer of existing metadata and audit trail, applying any required additional metadata and assigning classification for storage within the receiving system, such as the e-archive. During migration, electronic records should be verified by the originator and the receiver to ensure the preservation of context, content, and structure of the record, audit trail and associated metadata.<br>**Records Management Process Requirements:**<br>**Establish Records Retention Schedules** – Organizations must ascertain which records are required to be retained and for how long, taking into consideration all regulatory, legal and business aspects. Electronic records must be able to fulfill these requirements.<br>**Storage** – The e-archive must have the appropriate security controls in place to prohibit changes to the final records. This e-archive must also be valid for the associated metadata, unless otherwise specified in internal processes and procedures for role-specific privileges.<br>**Retention** – Authorized users of an e-archive must have permission to assign retention rules to records. |

**Legal Hold** – Retention rules must allow authorized users to suspend (hold) records for the time imposed by legal requirements.

**Search and Retrieval** – Unique identifiers should be assigned to records. The e-archive should allow authorized users to browse or search using a variety of metadata and if possible, the content of the records. Search results and viewing rights must be limited according to privileges assigned to the authorized user.

**Monitoring and Reporting** – Storage space should be monitored so that appropriate action can be taken should the storage space reach a critical level. There should be a capability for authorized users to execute reports from the system.

**Preservation and Maintenance** – The e-archive must be able to maintain the authenticity of an electronic record during access and maintenance. An audit trail must be maintained of all archived record preservation processing and any resulting changes or updates. There should be sufficient safeguards to protect against archive media degradation or technology obsolescence. The e-archive must maintain the authenticity of corresponding electronic signatures associated with the record during ingest and throughout the lifespan of the record, according to organization policy.

**Disposition and Destruction** – Authorized users of the e-archive should be able to generate a destruction report to list records from within the e-archive that are eligible for destruction. There must be a mechanism to ensure electronic records destroyed are not recoverable. The e-archive must retain an audit trail of all destroyed records including the dates of destruction.

**Business Requirements Include:**

**Regulatory compliance** – The e-archive process must comply with applicable government regulations and guidelines. The requirements must ensure GxP compliance, specifically address the 21 CFR Part 11 regulations on electronic records, and also consider additional regional regulations as applicable. Sufficient audit trail information should be available.

**Security/Privacy** – The e-archive should limit system access to authorized users with access levels based on job responsibility. An access control list must be maintained.

**Interfaces** – The e-archive should have the capability to interface with appropriate operational systems and supporting tools.

**Infrastructure and Technical** – Technical and infrastructure requirements of the e-archive system should be documented.

**Training and Support** – Training and maintenance documentation should be created and maintained.

**System Management/Serviceability** – Procedures covering disaster recovery, contingency plans, back-up and restoration of the system, change control, etc. should be in place.

**BIBLIOGRAPHY/REFERENCES**


1. ISO 14721:2003: Space data and information transfer systems -- Open archival information system -- Reference model. 2003 Print.
2. United States. National Archives and Records Administration. Electronic Records Archive (ERA), ERA Requirements. College Park, M.D., 2010. Web. 16SEP2011
3. United States Food and Drug Administration. Electronic records; electronic signatures, 21 CFR, Part 11. 2003. Web. 16SEP2011
4. International Council for Harmonization (ICH). Integrated Addendum to ICH E6: Guideline for Good Clinical Practice E6[R2]. NOV2017.

5. Integrated Addendum to ICH E6: Guideline for Good Clinical Practice E6(R2) (05NOV2018)

## RM 2

## Risk Assessment of e-Records-Only Retention

Take risk parameters into account before deciding on a procedure to destroy paper (also, see RM5, RM7).

**INTERPRETATION**

Analyze the risks and follow appropriate procedures to mitigate those risks.

| Lack of or incomplete: | Possible Mitigation(s) |
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| Authenticity of the Electronic Record | Establish clear policies and procedures for quality and accuracy of electronic duplication and file process. |
| Reliability of Duplication | Demonstrate that quality control process/system is periodically evaluated and continues to be consistent with established policies and procedures. |
| Trustworthiness | Include proper controls over the management of electronic records in policies and procedures and routinely evaluate compliance. |
| Records Management Infrastructure | Policies and procedures to include a reliable process for ensuring that there are no duplicate records. |
| Retention of Audit Logs | Create automatic audit trails that will be retained by the system for an agreed period. |
| Technology Capabilities | Evaluate the longevity of technology solutions and migration plans for technology changes. |
| Legal Input | Ensure that policies and procedures comply with legal requirements in all applicable countries. |

**BIBLIOGRAPHY/REFERENCES**


1. The Uniform Rules of Evidence (US 128-0060-00 to 0170-00) has been adopted by the United States federal courts and 34 states.
2. The use of electronic evidence in civil and administrative law proceedings and its effect on the rules of evidence and modes of proof. A comparative study and analysis. European Committee on Legal Co-Operation (CDCJ) https://rm.coe.int/1680700298 (05NOV2108)


## RM 3

## Business requirements for creating a viable electronic archiving program.

**INTERPRETATION**

When deciding about paper versus electronic archiving, it is recommended to perform a risk evaluation in addition to a cost/benefit assessment. The assessment may favor the electronic archives process with characteristics such as:

- Immediate accessibility across geographies
- Availability in inspections
- Reusability by downstream processes and data mining

**The trustworthiness of the retained records** must be ensured throughout the required retention time. Source data should be attributable, legible, contemporaneous, original, and accurate (ALCOA) and must meet the regulatory requirements for recordkeeping.

Procedures detailing how this will be achieved (including roles and responsibilities) and applicable controls need to be in place.

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| | **Records retention schedules -** Reviewing (or defining) records retention schedules is part of building a viable e-archiving program. Retention of electronic records should follow the predicate rule: the type of records to retain and the length of retention should not change because of the change of physical nature from paper to electronic. The timing for the destruction of paper is a good opportunity to review and complete (or create) retention schedules according to the regulations applicable to each record type.<br><br>**Archiving records** electronically may be the preferred solution when:<br>• Records are generated and delivered to the ECMS in electronic format<br>• A "Certify Copy" process has been established<br>• A high access/retrieval rate is expected including re-use in down-stream processes (e.g. in submissions). The documents that are captured earlier into the ECMS will have a higher access rate.<br>• Accessibility across geographies is required.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. International Council for Harmonization (ICH). Integrated Addendum to ICH E6: Guideline for Good Clinical Practice E6[R2]. NOV2017. (05NOV2018) https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf (19NOV18) |
| **RM 4** | **Assessing the timing for destruction of paper documents**<br><br>A timeline for the discarding of the paper document is dependent on following the appropriate procedures.<br><br>**INTERPRETATION:**<br>Once the verification processes have been completed for: (1) the scanning and upload of images to a repository, and (2) the document is "Approved" in the repository, then the electronic version may be considered as the authoritative source. Any documents that are categorized as "Protected" must not be destroyed.<br><br>The paper document should be destroyed once the electronic image is "approved" so that the potential conflict of use is eliminated. The actual destruction of the paper should follow internal organization policies on destruction, taking into account confidentiality levels and issuing of certificates of destruction where required. Before destruction, it is important for the organization to determine if there are any requirements per country local laws and regulations that would dictate extended retention for the paper document.<br><br>**BIBLIOGRAPHY/REFERENCES:**<br>1. Industry opinion and practice though not formally cited in the public domain |
| **RM 5** | **Assessment of the reliability of electronic versus paper document archiving**<br><br>**INTERPRETATION:**<br><br>**Introduction**<br>A reliable record is one whose contents can be trusted as a full and accurate representation of the transactions, activities or facts to which they attest and can be depended upon in the course of subsequent transactions or activities. Records should be created at the time of the transaction or incident to which they relate, or soon afterward, by individuals who have direct knowledge of the facts or by instruments routinely used within the business to conduct the transaction. Issues (those pertaining to records management |

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| | process (RM) and those to quality check (QC) and technical (T)) could arise if documents are:<br>• Not captured (RM)<br>• Not complete (QC)<br>• Not representing all relevant information (QC)<br>• Illegible (QC)<br>• Incorrect; not what they should be (QC)<br>• Without context (RM)<br>• Altered/manipulated (QC, T)<br>• Deleted (Technical)<br>• Vanished (RM, T)<br>• Insufficiently or inconsistently indexed (RM, QC)<br>• Not retrievable (RM, QC, T)<br>• Not accessible (RM, T)<br>• Hidden for relevant usage (RM, QC, T)<br>• "Forgotten" knowledge for retrieval not available (RM)<br><br>In addition, reliability could potentially be harmed by human error, environmental conditions, poorly set up processes and systems, or fraud.<br><br>**Guiding Principles**<br>In most aspects, electronically handled documents can be considered to be more reliable because:<br>• Alteration/deletion is prevented or controlled by system controls<br>• Access is independent of physical location<br>• Indexing and filing can be multi-dimensional<br>• Transfer, quality assurance (QA), and retention are independent of media<br><br>**Requirements**<br>Underlying records management principles are largely identical for paper documents and electronic records. Situations where a hybrid approach (both the paper document and electronic record being created) is utilized, then one of the two must be designated as the official or authoritative source.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. ISO-15489 standard set of definitions<br>2. Industry opinion and practice though not formally cited in the public domain |
| **RM 6** | **Continuous access to electronic records**<br><br>**INTERPRETATION**<br><br>**Introduction**<br><br>The records retention times vary considerably and may span several decades. As a result, preservation and access to electronic records over long periods must be addressed before transforming paper records into electronic and destroying the paper.<br><br>Electronic records management systems typically require significant upgrades or replacement every 3 to 5 years and migration of records and associated metadata held within the older system to the new system is required to ensure retention over long periods of time. Furthermore, records may be migrated for business-related reasons. |

There is a high probability that more than one migration will be needed over the entire lifetime of an electronic record, and these may impact ownership, meta-data and even content.

**Guiding Principles**

- The records created today will be the legacy records of the future.
- Any ECMS in use should be seen as a “temporary shelter” for the records.
- Beyond the technical solutions, appropriate organizational commitment and control must be in place to ensure long-term access and retrieval of electronic records.
- Strategies for the migration of records should be part of any system planning and be fit for purpose.
- Taxonomies, metadata, and indexing practices may change over time. Appropriate functionality must be built in the system and associated processes to account for that change.
- Multiple formats increase the complexity of validation and the risk during migration. The variety of content structures and formats should be limited as much as possible by following industry best practices and standards.

**Requirements**

The following requirements provide the foundation for long-term continuous access:

**1. Setting up a new system (design specifications):**

- Migration functionality should be stated as a business requirement.
- System design should include readiness for batch export/transfer of content, metadata and audit trail into readable format in reasonable time (as the number of records increases, performance may become an issue).
- The method for migrating electronically signed documents without compromising the validity of the signatures should be clarified. Particularly as a technical alteration of the files could be required in the course of future migrati**ons.**

**2. System Operations:**

- Long-term preservation should be considered at the time of records creation, including plans to migrate records without losing critical information.
- The number of formats should be limited by using widely accepted standard formats whenever possible (e.g. PDF/A)
- Consistency and quality of metadata should be checked continuously.
- The data model should be adjusted on an ongoing basis to keep all records up-to-date with regular system usage.

**3. Migrating of electronic records:**

- Each migration offers the opportunity for harmonizing file formats.
- Data model requirements for the new system should consider the legacy documents from the beginning including retrieval functions and usability that may not be available with the successor system.
- Moving legacy documents into special areas outside the regular system is not recommended as it will create silos of neglect and pose a risk for retrieval and access.

**BIBLIOGRAPHY/REFERENCES**

1. ISO 15489-1:2001: Information and documentation -- Records management – Part 1: General. 2001.
2. ISO 15489-2:2001: Information and documentation -- Records management – Part 2: Guidelines. 2001.

| RM 7 | **Requirements for retaining both wet ink and electronic signatures** |
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An evaluation of which signatures are required by regulations is important for the organization to conduct. It is recommended that corresponding organizational procedures indicate where exactly wet-ink signatures are required.

**INTERPRETATION**

Signatures are generally used for the following four purposes:

- Document agreements between parties (e.g. contract)
- Confirm the correctness of statements made or data entered
- Verify procedural requirements (e.g. confirmation of steps in workflows, signatures on shipment records or dispensing logs)
- Indicate verification that a copy of an original record has the same information including data that describe the context, content, and structure as the original

The cited regulations below do not specify the required format (wet ink or electronic). Some countries may not accept electronic signatures on documents such as contracts. Requirements should be verified on a country-by-country basis.

When paper documents with signatures are scanned and a digitized copy/ electronic records is created, it is not necessary to apply an additional electronic signature to the record. Therefore, the rule shall be that electronic signatures should apply only to records electronically generated and maintained in validated electronic environments.

Signatures on paper documents are considered wet-ink signatures. However, the definition of wet-ink signatures should also include official seals and stamps to original documents. Additionally, some governmental bodies now use seals with holographic images. While these may be digitalized, the electronic version of the original document at this time cannot be exact representations of the original documents. The documents that do not meet the identified purposes as stated above or have unique regional requirements (i.e. raised seal) should be maintained in original paper format. The former expectation that wet ink signatures should be issued in non-black ink to differentiate from copies is no longer a requirement in this time of color copiers/printers/scanners. Blue or black ink are typical choices.

Electronic signatures must be maintained in the source system for the entire retention time of the signed document or migrated (including signature manifestation) to an ECMS guaranteeing their integrity and usability over time. In the event an electronically signed document must be removed from the source system and the audit trail of the electronic signature not be able to travel with the document, the signature and date page should be included on the printed copy or on a signature sheet that identifies the version and date of the signed document as well as the signatory name(s) and date/time of the signature(s).

In the event of a legal hold, organizations are required to maintain both electronic records and paper documents with signatures per their organization policies and legal requirements.

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1. International Conference on Harmonization: Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2):. 2016. Web. 9NOV2016
2. United States Food and Drug Administration. Electronic records; electronic signatures, 21 CFR, Part 11. 2003.

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| | 3. Medicines and Healthcare Products Regulatory Agency (MHRA). TSO 2012 (Seventh impression 2017. |
| **RM 8** | **Exceptions, e.g. legally protected documents**<br><br>Some paper document types must be identified as legally "protected" to prevent the destruction of those paper documents.<br><br>**INTERPRETATION**<br>The electronic rendition is authoritative and immediately effective upon approval. To manage the application of paper destruction rules, a risk-based approach should be used to identify each document type within the ECMS on how to apply those rules, based on the following:<br>• **Protected** - The paper document must be retained for reference according to an effective document retention policy.<br>• **Retain Until Established Period** - The paper document must be preserved during an established timeframe but may be destroyed at a determined point in time. Often, a Certificate of Destruction will be required upon completion for a bulk destruction effort (see also Q8).<br>• **Non-Protected** - Able to destroy the paper document during established and communicated timeframe<br><br>It is possible to have exceptions to these definitions. Particular regions or markets may require special handling for a specific document type or characteristic (e.g. Japanese seals). Legal analysis will likely be required within an organization to understand the extent of these exceptions.<br><br>A method should be devised to track changes to this Protected Document Types map so that inspections and audits can reference when a specific condition or policy on a document type is changed or determine what rule was in effect at the time of inquiry.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. Industry opinion and practice though not formally cited in the public domain |
| **RM 9** | **Oversight and management of stakeholders**<br><br>**INTERPRETATION**<br><br>Numerous functional stakeholders are surrounding the management and oversight of paper content. A plan to anticipate questions and address the concerns of the stakeholders through communications and education should be prepared as part of a transformation project. Change management and oversight of the functional stakeholders is crucial to the successful implementation of the process stream(s).<br><br>Communication of expectations and oversight of the stakeholders involved in the creation, management, use, archival, and destruction (if applicable) of paper documentation is essential. Stakeholders would include representatives from (but not limited to) Clinical Operations e.g. Trial and Site Management, Pharmacovigilance, Regulatory, Clinical Supplies, Medical Writing, Legal and Contracts, Biostatistics, Data Management, Records Management, Laboratories, and Quality Assurance.<br><br>A clearly defined process and procedure, identifying roles and responsibilities, should be communicated cross-functionally to the stakeholders and other relevant parties impacted. Oversight and/or management plan should be created to perform ongoing assessments of gaps, trends, risk, and process viability in addition to confirming functional and/or external |

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| | vendor compliance with the process stream(s). To encourage and support functional stakeholder engagement, ad-hoc educational and Q & A forums may be beneficial.<br><br>If external vendors manage paper documentation, a clear directive on process and expectations needs to be communicated in a vendor oversight and/or management plan to ensure alignment with the process stream(s). If an external vendor has an established paper destruction process in place, the organization needs to review and assure alignment with their own processes and philosophy.<br><br>**BIBLIOGRAPHY/REFERENCES**<br>1. Industry opinion and practice though not formally cited in the public domain |

## Legal Parameters:

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| **L 1** | **Once records exist, they may be sought as evidence in government inquiries, civil litigation, or criminal prosecution**.<br><br>**INTERPRETATION**<br><br>When information or a business record is created, regardless of its medium it is discoverable in a legal proceeding. In short, a record is a record.<br><br>During discovery, records must be produced in the manner as they were kept in the usual course of business or they must be organized and labeled to correspond to the discovery request.<br><br>When a record is placed on hold per one of these requests the record must be retained in the format that it was used during the normal course of business, whether that medium is paper or electronic. Business needs generally drive the process and therefore, it is interpreted and recommended that an organization's business practice for managing records should include written procedures for the creation, electronic capture, use, preservation, and destruction. As long as the normal business process is to (1) transfer information captured on paper, (2) ensure that the electronic format is an exact duplicate of the paper format with the same attributes, (3) discard the paper format and (4) retain only the electronic format, then such a process may be allowed to continue.<br><br>Legal Hold SOPs often require suspending records retention policies for any records subject to hold. In this regard, it is important to include organization legal and regulatory representatives in determining whether mid-process and transitory paper formats as proposed in this framework would be subject to holds. Depending on an organization's risk threshold, this agreement may need to be revisited for each Legal Hold. If there is agreement that the documented business practice, i.e. normal course of business, would not keep interim paper formats once scanned, an organization may wish to revise Legal Hold policies and procedures to allow for these defined and quality driven business processes to continue without the requirement to keep both copies and to ensure that official records are declared and managed properly, particularly with respect to Legal Holds.<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. Federal Rule of Civil Procedure 34, "a party must produce documents as they are kept in the usual course of business". |
| **L 2** | **If an organization maintains ECMS and scans documents and certifies them as the authoritative source, the discovery of these documents stand on equal footing with discovery of paper documents**.<br><br>**INTERPRETATION**<br><br>Building on the first parameter, there is a precedent for the use of and reliance on scanned digitized images for legal discovery and proceedings in the organization and thus for establishing written procedures for declaring the scanned record as the original. The advisory committee's note to the 2006 amendments to the Federal Rules of Civil Procedure states that "Rule 34(a) is amended to confirm that discovery of electronically stored information stands on equal footing with discovery of paper documents." |

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| | Also, in two litigated cases, the electronic copy of a record was considered "same as" the hardcopy and the authoritative source can certainly be the electronic one.<br><br>An organization's computerized data will be subject to discovery even if hard copies of documents have been produced. As such, ensure the corporate glossary includes terms such as certification, authoritative source, and that any process and procedures allow for or mandate the use of the electronic format for this purpose.<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. International Council for Harmonization (ICH). Integrated Addendum to ICH E6: Guideline for Good Clinical Practice E6[R2]. NOV2017.<br>2. FED. R. CIV. P. 34(a)(1)(A)-(B) and accompanying advisory committee's note.<br>3. Linnen versus A.H. Robins Co., the ruling from the court was as follows: "A discovery request aimed at the production of records retained in some electronic form is no different in principle, from a request for documents contained in any office file cabinet." The court continued, "To permit a corporation such as Wyeth to reap the business benefits of such [computer] technology and simultaneously use that technology as a shield in litigation would lead to incongruous and unfair results."<br>4. Anti-Monopoly, Inc. v. Hasbro, Inc., 1995 WL 649934 (S.D.N.Y. Nov. 3, 1995).<br>5. World IP Contacts Handbook 14th edition |
| **L 3** | **The duty to preserve evidence in support of litigation holds extends to data compilations, computerized data, and other electronically recorded information, including copies of original records**.<br><br>**INTERPRETATION**<br><br>Federal Rule of Civil Procedure 26 specifically includes "electronically stored information" within its purview of discoverable documents: (ii) a copy - or a description by category and location - of all documents (except drafts of expert reports), electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control and may be used to support its claims or defenses, unless the use would be solely for impeachment.<br><br>UK Civil Procedure Rules 31.4 describes a document as "anything in which information of any description is recorded; and 'copy' in relation to a document, means anything onto which information recorded in the document has been copied, by whatever means and whether directly or indirectly." UK Civil Procedure Rules Practice Direction Part 31B confirms that "documents" includes "electronic documents" and that this includes "for example, e-mail and other electronic communications such as text messages and voicemail, word-processed documents and databases, and documents stored on portable devices such as memory sticks and mobile phones." It also includes "electronic images" which are defined as "an electronic representation of a paper document."<br><br>Ensure the corporate glossary includes the terms "electronically recorded information" and "computerized data."<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. USA Federal Rule of Civil Procedure 26. Duty to Disclose; General Provisions Governing Discovery Rule 26(a)(1)(A)(ii)<br>2. UK Civil Procedure Rules<br>3. UK Civil Procedure Rules Practice Direction Part 31B |

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| **L 4** | **Electronic signatures and records are equivalent to paper signatures and records, and therefore are subject to the same legal scrutiny to determine authenticity**.<br><br>**INTERPRETATION**<br>Signatures are not solely determinative in the courts' appreciation of whether paper or electronic is defined as the original, provided the record be authenticated. Where electronic signatures and their associated electronic records meet the requirements of CFR 21, Part11, the FDA will consider the electronic signatures to be equivalent to full handwritten signatures.<br><br>eIDAS (electronic IDentification, Authentication and trust Services) qualified electronic signature shall have the equivalent legal effect of a handwritten signature.<br><br>"A signature in digital form […] that represents the signatory […] should be equivalent in legal terms to the handwritten signature of the signatory."<br><br>Japan recognizes simple electronic signatures as legal and enforceable and includes conditions for the presumption of legal authenticity. Electronic signature means an electronic data compilation of a series of symbols created, adopted, confirmed or authorized by an individual or organization to electromagnetic records to be equivalent of the handwritten signature or seal.<br><br>The use of signatures, whether electronic, digital, or via wet ink, does not change the requirements for ensuring authenticity throughout the record lifecycle, regardless of how the record is stored, used and managed.<br><br>Ensure the corporate glossary includes the terms "digital signatures", "electronic records "electronic signatures" and "authenticity" and those process elements are captured to ensure a record's signature remains authentic and verified as appropriate.<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. Electronic Signatures in Global and National Commerce Act ("ESIGN")<br>2. FDA Code of Federal Regulations Title 21 Sec.11.1c (US)<br>3. Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (eIDAS) Sec 4 Article 25 (EU)<br>4. MHRA GXP Data Integrity Guidance and Definitions; Revision 1: March 2018 (6.14) (UK)<br>5. Law Concerning Electronic Signatures and Certification Services 2000 (JP) |
| **L 5** | **A process that accurately reproduces or forms a durable medium for reproducing the original [paper] enables the destruction of the original [paper]… so long as the process is used in the regular course of business [Business as Usual] and that the process is auditable**.<br><br>**INTERPRETATION**<br>Reproductions, i.e. complete and accurate copies of records, have the same legal significance as the original and may be used in place of the original for all purposes including evidence. Complete and accurate includes a review of the following characteristics: authenticity, integrity, and reliability of the document.<br><br>For such a process to be acceptable, a standard operating procedure must stipulate that, where original paper documents are filed in an electronic document management system, electronic documents shall be treated as the original; this procedure shall also describe the |

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| | conversion process and its conditions. An official at the Japanese competent authorities notably recommended that original paper documents be scanned to create a digitized record rather than retyped. Copies generated before the process is put into the usual course of business may require additional requirements during certification as these were generally created as convenience copies, not as replacements for the original in the context of the legal records.<br><br>The process must be documented and auditable in order for both trust and verification conditions to be met.<br><br>Ensure the corporate glossary includes the terms “complete,” “accurate,” “authenticity,” “copies,” “integrity,” “reliability,” “document management system,” “original,” and “scanning” as a method of reproduction. Define process elements that capture the conversion (scanning) process and its conditions, including requirements for determining reliability, authenticity, completeness, and accuracy. Define in the corporate records management policies any requirements for ensuring copies are complete and accurate.<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. Uniform Photographic Copies of Business and Public Records as Evidence Act (UPA)<br>2. Civil Evidence Act 1995 CHAPTER 38<br>3. Industry opinion and practice though not formally cited in the public domain<br>4. World IP Contacts Handbook 14th edition<br>5. The Japanese Ordinance regarding Standards for the Clinical Trial of Drugs (MH Ordinance No. 72 of 1997, as amended) (the “Ordinance”)<br>• Article 26<br>• Article 41<br>6. Japanese PFAD Circulars No. 1001001 01OCT2008<br>7. Japanese PFAD Circulars No. 0401022, 01APR2005<br>8. MHRA GXP Data Integrity Guidance and Definitions; Revision 1: March 2018 (6.14) (UK) [Validated Process] |
| **L 6** | **Original paper records may be destroyed once a true copy is made unless regulation or legislation specifically state otherwise**.<br><br>**INTERPRETATION**<br>Even though German legislation covering clinical trials does not expressly prohibit the destruction of original paper documents after these are put in electronic format, it is the prevailing view among legal scholars that the destruction of original paper documents would not be permissible in clinical trials if and to the extent such original documents are subject to record retention obligations.<br><br>Ensure the corporate glossary includes the terms "destruction" and "rendition." Also, be sure to define process elements that capture any changes in records retention requirements for the paper medium. In light of specific views by German Legal scholars, clear statements are needed in corporate records management policies to ensure retention of paper medium is not required above complete and accurate renditions.<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. The Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 as amended (“the Clinical Trials Regulations”) Regulation 31A (7)<br>2. International Council for Harmonization (ICH). Integrated Addendum to ICH E6: Guideline for Good Clinical Practice ICH GCP (E6) R2 8.1 "When a copy is used to replace an original document, the copy should fulfil the requirements for certified copies". |

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| **L 7** | **Sponsors of a clinical trial must keep records of the essential documents of that clinical trial. Records may be kept on magnetic or other media, thus including ECMS. Most importantly, these guidelines set out that electronic records must be complete, accurate, certifiable (to the approved protocol for which they are governed) and reliable, and the individuals responsible for the production, amendment, and deletion of those records must be identified.**<br><br>**The implementation of a process whereby (i) original paper documents are converted to electronic documents and (ii) original paper documents are destroyed once converted would only be acceptable provided the above conditions are met. In order to verify that the electronic documents are the same as the original paper documents, Japanese competent authorities indicated that a standard operating procedure must stipulate that, where original paper documents are filed in an ECMS, electronic documents shall be treated as the original; this procedure also must describe the conversion process and its conditions**.<br><br>**INTERPRETATION**<br>There must be evidence for the destruction of the paper record in this process. This evidence must include the individual responsible for that destruction action (4). Similar requirements exist for the electronic counterparts.<br><br>Ensure corporate glossary includes the terms “record lifecycle phases,” “audit trail,” and “metadata.” Define process elements that capture individual staff names during record lifecycle changes, i.e., destruction, certification of the electronic original. Changes to corporate records management policies may be required to state the requirements and conditions of the conversion and verification process.<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. The Japanese Ordinance regarding Standards for the Clinical Trial of Drugs (MH Ordinance No. 72 of 1997, as amended) (the “Ordinance”)<br>• Article 26<br>• Article 41<br>2. Japanese PFAD Circulars No. 1001001, 01OCT2008<br>3. Japanese PFAD Circulars No. 0401022, 01APR2005<br>4. MHRA GXP Data Integrity Guidance and Definitions; Revision 1: March 2018 (6.14) (UK)<br>5. Law Concerning Electronic Signatures and Certification Services 2000 (JP)<br>6. Industry opinion and practice though not formally cited in the public domain |
| **L 8** | **Policies, procedures, and other quality and compliance documentation, including partner agreements, developed or modified to support the paper destruction process must be reviewed in light of applicable legal requirements. The implementation of a paper destruction process may entail the review of documentation beyond records management policies (e.g. vendor oversight SOP)**.<br><br>**INTERPRETATION**<br>New governance documentation must align or include revisions to existing documentation to ensure alignment with enterprise records management principles and policies and to ensure such policies extend beyond the enterprise to any contracted parties and organizations conducting activities on behalf of the organization, including but not limited to CROs. Contracts and agreements must align with record keeping requirements of the |

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| | enterprise to ensure that an equivalent or higher standard is applied throughout the process regardless of which party is responsible for a particular activity in the paper destruction process.<br><br>**BIBLIOGRAPHY/REFERENCES**<br><br>1. Industry opinion and practice, though not formally cited in the public domain |

## Last Words: Glossary, Feedback, Team Membership, Acknowledgements

The Framework for the Destruction of Paper is free and available through the following links on the DIA website and on the website that has been established for the paper and all supportive tools developed to facilitate its use:

- https://www.diaglobal.org/en/resources/tools-and-downloads#Destruction-of-Paper
- www.PaperDestruction.org (11JAN19)

### Glossary

A glossary has been provided as part of this framework so that readers are able to reference the same definitions that the work groups did in its development. If the work groups found that no standard definition of a term was available, yet necessary to be established as foundation, a definition was created to ensure common understanding. The glossary directly follows this section.

### Feedback on the Framework

The ultimate goal of this framework is to become regarded as a truly valuable reference for our industry. Provision of a mechanism and acceptance of feedback is core to this goal. The mechanism for feedback will be possible through a submission process posted on the website: www.PaperDestruction.org (11JAN19)

### Team Membership

This team welcomes new members, in whatever capacity they can contribute. To become involved with the continued enhancement and maintenance of this framework, contact the DIA DRM Community Chair or DIA Community membership coordinator, located on the DIA website or join the LinkedIn Group called “TMF Reference Model” and request assistance to connect with this work group.

In accordance with the DIA Volunteer Code of Conduct, no volunteer shall use any information provided by the Association or acquired as a consequence of volunteer's services to the Association in any manner other than in furtherance of his or her volunteer duties with DIA. Volunteers are expected to act at all times in the best interests of the organization and not for personal or third-party gain or financial enrichment. DIA does not own the Framework for the Destruction of Paper. It does reserve the right to reproduce, display, and distribute

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## Acknowledgements

Finally, as with the development of v1.0 of this Framework, it would be a very significant misstep if the amount of time and professional expertise that was contributed selflessly to the revision and creation of v2.0 of the Framework were not acknowledged. This Framework is the product of thousands of hours from devoted volunteers associated with companies, large and small, who supported the effort.

# Glossary

| Term | Archive |
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| Alternate Name(s) | |
| Definition | Action to deposit a record into a storage medium and location which will enable long-term preservation, minimize deterioration, ensure long-term viability for the entire retention period, and ensure restricted and controlled access |
| Black's Legal Dictionary | 1. Backing up files on a computer. Refer to archives. 2. To store documents for long term use. 3. The archives building. |
| ARMA | 1. To transfer records from the individual or office of creation to a repository authorized to appraise, preserve, and provide access to those records. – 2. Computing · To store data offline. – n. ~ 3. An archive.1,2,3,5 – 4. Computing · Data stored offline. – 5. Computing · A backup. – 6. Computing · An attribute in some file systems, typically used to indicate that a file has changed since it was backed up. |
| North American Legislation | |
| EU/MS Legislation | |
| Harmonized Guidelines | |
| Japanese Legislation | "Archive(s)" as stated in paragraph (4) means designated areas, facilities or equipment (cabinets, rooms, buildings, or computer systems, etc.) that enable secure storage and retrieval of study-related materials and protection of contents from untimely deterioration. Study-related materials should be retained in principle in the archive(s) of the test facility. However, this does not preclude the use of contract archive facilities. In the case of using contract archive facilities, the facilities must be in compliance with the provisions of the GLP Ordinance for Drugs, etc., and the test facility management should be responsible for ensuring the GLP compliance status thereof. Guidance on the Implementation of the Ministerial Ordinance on the Good Laboratory Practice for Nonclinical Safety Studies of Drugs as Revised by the Ministerial Ordinance for Partial Revision of the Ministerial Ordinance on the Good Laboratory Practice for Nonclinical Safety Studies of Drugs PMDA-Japan |

| Term | Certified Copy |
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| Alternate Name(s) | Attested copy, Exemplified copy, Verified copy, Confirmed true copy, Confirmed exact replica |
| Definition | A certified copy is a copy of original information that has been verified as an exact (accurate and complete) copy having all of the same attributes and information as the original. The copy may be verified by dated signature or by a validated electronic process. |
| Black's Legal Dictionary | A copy of a document. signed and certified as a true copy by the officer to whose custody the original Is entrusted. |
| ARMA | A duplicate that has been verified as an accurate reproduction of the original by an authorized official, typically the individual responsible for creating or maintaining the original. |

| Term | Certified Copy |
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| North American Legislation | • “A Certified Copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original”.<br>FDA's Guidance for Industry Computerized Systems Used in Clinical Investigations (May 2007)<br>• “a duplicate is a counterpart produced by the same impression as the original, or from the same matrix, or by means of photography, including enlargements and miniatures, or by mechanical or electronic re-recording, or by chemical reproduction, or by other equivalent techniques which accurately reproduces the original”.<br>Fed. R. Evid. 1001(4)<br>A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original. |
| EU/MS Legislation | "Originals or copies certified after verification as being accurate copies"<br>• EMA, ICH Topic E6 (R1) - Guideline for Good Clinical Practice, CPMP/ICH/135/95 |
| Harmonized Guidelines | • “A certified copy is a copy of original information that has been verified as an exact (accurate and complete) copy having all of the same attributes and information as the original. The copy may be verified by dated signature or by a validated electronic process”<br>• “An eCertified copy is a copy that is created through application of a validated process that is certified to preserve the information in the original. NOTE: an eCertified copy of an eSource document can also serve as a source document”.<br>CDISC Clinical Research Glossary Version 8.0, (Dec. 2009) |
| Japanese Legislation | Although the term of “duplicate” is not defined under the Japanese legislation, the Legal Terminology Dictionary (9th Edition) is stating as follows with respect to “duplicate”:<br>If a person prepares a document having the identical contents as the authenticated copy in addition to the authenticated copy in order to use it for purposes other than its primary purpose, the document is called a “duplicate.”<br>We could not find the definition of the term “certified copy” neither in the Japanese legislation nor the Legal Terminology Dictionary (9th edition).<br>We could not find the definition of the term “record copy” neither in the Japanese legislation nor the Legal Terminology Dictionary (9th edition).<br>“Authenticated copy” is one kind of a copy and means a copy which is prepared based on the original by an authorized person and which has the same effect as the original externally. Hiroshi Kaneko et al., horitsugaku-sho-jiten [The Dictionary of Law] (4th edition, comprehensively revised) (2008) at 320. |

| Term | Electronic Record |
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| Alternate Name(s) | eRecord, Electronic Document |
| Definition | An electronic record is a record created in an electronic format (i.e., born digital) or a digital copy of a record that originated in paper. |
| Black’s Legal Dictionary | A collection of data, managed and processed to become information. It is collection by electronic processes. Known also as machine readable record. |
| ARMA | Data or information that has been captured and fixed for storage and manipulation in an automated system and that requires the use of the system to render it intelligible by a person. |

| Term | Electronic Record |
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| **North American Legislation** | • “Electronic record is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system”.<br><br>FDA's Guidance for Industry Computerized Systems Used in Clinical Investigations (May 2007)<br><br>• “Document means a draft or other demand, document of title, […]or other record, statement, or representation of fact, law, right, or opinion (i) which is presented in a written or other medium permitted by the letter of credit or, unless prohibited by the letter of credit, by the standard practice referred to in Section 5-108(e) and (ii) which is capable of being examined for compliance with the terms and conditions of the letter of credit. A document may not be oral.<br><br>“Record means information that is inscribed on a tangible medium, or that is stored in an electronic or other medium and is retrievable in perceivable form”<br><br>Uniform Commercial Code para. 5-102 (6) and (14)<br><br>An electronic record is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. |
| **EU/MS Legislation** | • “Document means anything in which information of any description is recorded”.<br><br>England Civil procedure Rules, Part 31, Rule 31.4<br><br>• “Electronic Document means any document held in electronic form. It includes, for example, e-mail and other electronic communications such as text messages and voicemail, word processed documents and databases, and documents stored on portable devices such as memory sticks and mobile phones. In addition to documents that are readily accessible from computer systems and other electronic devices and media, it includes documents that are stored on servers and back-up systems and documents that have been deleted. It also includes Metadata and other embedded data which is not typically visible on screen or a print out”.<br><br>England Civil procedure Rules Practice Direction Part 31 B, para. 5(3)<br><br>• “Electronic Image means an electronic representation of a paper document”.<br><br>England Civil procedure Rules Practice Direction Part 31 B, para. 5(4)<br><br>• “Records: provide evidence of various actions taken to demonstrate compliance with instructions, e.g. activities, events, investigations, and in the case of manufactured batches a history of each batch of product, including its distribution. Records include the raw data which is used to generate other records. For electronic records regulated users should define which data are to be used as raw data. At least, all data on which quality decisions are based should be defined as raw data”<br><br>Rules Governing Medicinal Products in the EU, Vol. 4, Good Manufacturing Practice, Chap. 4 Documentation. |
| **Harmonized Guidelines** | • “A document is an ordered presentation of XML elements, possibly including text and tabular analyses, description, and figures. Descriptors for HL7 documents include type, class, and element. NOTE: In HL7, a document can be either physical (referring to the paper) or logical (referring to the content) with the following characteristics: 1) Stewardship; 2) Potential for authentication; 3) Wholeness; 4) Human readability; 5) Persistence; 6) Global vs. local context.<br><br>CDISC Clinical Research Glossary Version 8.0, (Dec. 2009)<br><br>• “Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken”.<br><br>ICH Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance |

| Term | Electronic Record |
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| Japanese Legislation | Trueness of an electronic record - “Trueness” means that an electronic record is complete, accurate and reliable, and at the same time, it is clear where responsibilities for the creation, modifications and deletions lie.<br><br>In order to secure trueness, the following requirements must be met:<br><br>(1) Rules and procedures for maintaining security of the system are documented and performed appropriately.<br><br>(2) The creator of stored information is clearly identifiable. When modifying<br><br>information that has been stored, the original information before the modification must also be retained and the modifier must be clearly identifiable. To achieve this, it is preferable if audit trails are recorded automatically and it is possible to check the recorded audit trails using a predetermined procedure.<br><br>(3) A procedure for making a back-up of electronic records is documented and performed appropriately.<br><br>3.1.2. Readability of an electronic record<br><br>“Readability” means that the contents of an electronic record can be generated into a format which a human can read (e.g. displayed on a device, printed on papers, copied to other electronic recording media.)<br><br>3.1.3. Keepability of an electronic record<br><br>“Keepability” means an electronic record can be retained for a period while reserving its trueness and readability.<br><br>In order to secure keepability, the following requirements need to be met:<br><br>(1) Procedures for securing keepability, for example management of electronic recording media, are documented and performed appropriately.<br><br>(2) When transferring the stored electronic records to another electronic recording medium or format, trueness, readability and keepability of the transferred electronic records are also secured.<br><br>“Electromagnetic Record” means a record that is prepared by means of an electronic method, a magnetic method or any other not perceivable by human senses and that is used for information processing by computers.<br><br>Article 2, Paragraph 10 of the Act on Utilization of Telecommunications Technology in Document Preservation, etc. Conducted by Private Business Operators, etc. (Act No. 49, December 1, 2004)<br><br>[SAN comment: This English translation is taken from the Japanese Law Translation website operated by Ministry of Justice, Japan. http://www.japaneselawtranslation.go.jp/?re=02] (5NOV18)<br><br>(Note)<br><br>With regard to documents which must be retained or prepared pursuant to provisions of applicable laws and regulations, notwithstanding the provisions, the Private Business Operators are allowed to retain or prepare electromagnetic records instead of the documents pursuant to the provisions of ordinance of the competent ministry.<br><br>Article 3, Paragraph 1, and Article 4, Paragraph 1 of the Act on Utilization of Telecommunications Technology in Document Preservation, etc. Conducted by Private Business Operators, etc. (Act No. 49, December 1, 2004) |

| Term | Electronic Signature |
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| Alternate Name(s) | eSignature, eSig |
| Definition | Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature. |

| Term | Electronic Signature |
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| **Black's Legal Dictionary** | An electronic symbol, sound, or process that is either attached to or logically associated with a document (such as a contact or other record) and executed or adopted by a person with the intent to sign the document.<br><br>- Types of electronic signatures include a typed name at the end of an e-mail, a digital image of a handwriting signature, and the click of an "I accept" button on an e-commerce site. The term electronic signature does not suggest or require the use of encryption, authentication, or identification measures. A document's integrity (unaltered content), authenticity (sender's identity), and confidentiality (of the signer's identity or document's contents) are not ensured merely because an electronic signature is provided for. |
| **ARMA** | A digital mark, code, or other symbol that identifies an individual and that indicates responsibility for or consent to the content of the material to which it is affixed |
| **North American Legislation** | Electronic signatures that are intended to be the equivalent of handwritten signatures, initials, and other general signings required by predicate rules. Part 11 signatures include electronic signatures that are used, for example, to document the fact that certain events or actions occurred in accordance with the predicate rule (e.g. approved, reviewed, and verified).<br><br>Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. 21 CFR Part 11 - Glossary, section 11.3. |
| **EU/MS Legislation** | • "Electronic Signature means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication"<br><br>• "Advanced Electronic Signature" means an electronic signature which meets the following requirements:<br><br>(a) it is uniquely linked to the signatory;<br><br>(b) it is capable of identifying the signatory;<br><br>(c) it is created using means that the signatory can maintain under his sole control; and<br><br>(d) it is linked to the data to which it relates in such a manner that any subsequent change of the data is detectable".<br><br>Directive 1999/93/EC of the European Parliament and the Council of 13 December 1999 on a Community framework for electronic signatures, Articles 2.1 & 2.2<br><br>• "Certificate means an electronic attestation which links signature-verification data to a person and confirms the identity of that person"<br><br>NOTE: 'signature-verification-data' means data, such as codes or public cryptographic keys, which are used for the purpose of verifying an electronic signature<br><br>Directive 1999/93/EC of the European Parliament and the Council of 13 December 1999 on a Community framework for electronic signatures, Article 2.9<br><br>Also cited in SEC (2009)1643, Implementing Rules for the Decision 2002/47/EC, ECSC, Eurtom on Document Management and Decision 2004/563/EC, Euratom on Electronic and Digitized Documents.<br><br>A signature in digital form (bio-metric or non-biometric) that represents the signatory. This should be equivalent in legal terms to the handwritten signature of the signatory.<br><br>MHRA GXP Data Integrity Guidance and Definitions: Revision 1: March 2018 *page 14* |
| **Harmonized Guidelines** | |

| Term | Electronic Signature |
|---|---|
| Japanese Legislation | Computerised data composed of a series of symbols that are executed, adopted, identified and endorsed by an individual or a corporation. It is placed on an electronic record as a sign which is the equivalent of the handwritten signature or the seal.<br><br>(PFSB Notification No. 0401022 dated April 1, 2005)<br><br>Use of Electronic Records and Electronic Signatures in Submission for<br><br>Approvals, Licenses, etc., of Medicinal and Other Products<br><br>Although the term of "certificate" is not defined under the Japanese legislation, "certificate' is defined in the Legal Terminology Dictionary (9th Edition) as follows:<br><br>A scrap, book, cloth and other materials on which certain thoughts or facts are indicated by characters or other symbols and which could be served as evidence for the indicated contents.<br><br>Although the term of "notarized" is not defined under the Japanese legislation and the Legal Terminology Dictionary (9th Edition), "notarization" is defined in the Legal Terminology Dictionary (9th Edition) as follows:<br><br>"Notarization" means act of a public organ to certify that a certain act is conducted by a due procedure.<br><br>"Electronic Signature" means a measure taken with respect to information that can be recorded in an electromagnetic record (a record that is prepared by an electronic form, a magnetic form or any other form not perceivable by human senses and that is used for information processing by computers), and which falls under both of the following requirements:<br><br>(i) A measure to indicate that such information was created by the person who has taken such measure; and<br><br>(ii) A measure to confirm whether such information has been altered.<br><br>Article 2, Paragraph 1 of Act on Electronic Signature and Certification Business (Act No. 102 of May 31, 2000)<br><br>[SAN comment: This English translation is taken from the Japanese Law Translation made by Ministry of Justice, Japan. http://www.japaneselawtranslation.go.jp/?re=02]<br><br>(Note)<br><br>Any electromagnetic record that is made in order to express information (except for that prepared by a public official in the course of duties) shall be presumed to be established authentically if the Electronic Signature (limited to that which can be performed by the principal through appropriate management of codes and properties necessary to performed this) is performed by the principal with respect to information recorded in such electromagnetic record.<br><br>Article 3 of Act on Electronic Signature and Certification Business (Act No. 102 of May 31, 2000) |

| Term | Digital Archive |
|---|---|
| Alternate Name(s) | Electronic archive |
| Definition | A digital archive is a repository that stores one or more collections of digital information objects with the intention of providing long-term access to the information. The archive repository should be designed to preserve the content, prevent or track alterations and control access to electronic records it contains |
| NPS | Refers to the long-term preservation and research accessibility of digital data in an institutional setting. Digital archiving is achieved by following selection criteria for what will be archived, managing intellectual property rights, following open system standards, migrating and refreshing data regularly, maintaining sufficient software and hardware, and developing target scanning resolutions for different materials. |
| ARMA | |

| Term | Digital Archive |
|---|---|
| North American Legislation | |
| EU/MS Legislation | |
| Harmonized Guidelines | |
| Japanese Legislation | |

| Term | Handwritten Signature |
|---|---|
| Alternate Name(s) | Wet-ink Signature |
| Definition | Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate content in a permanent form. |
| Black's Legal Dictionary | 1. A person's name or mark written by that person or at the person's direction.<br>2. (Commercial law) Any name, mark, or writing used with the intention of authenticating a document. UCC 1-201(b) (37), 3-401(b). |
| ARMA | |
| North American Legislation | Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate writing in a permanent form. The acts of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.<br><br>21 CFR 11 |
| EU/MS Legislation | |
| Harmonized Guidelines | |
| Japanese Legislation | |

| Term | Official or Authoritative Source Document |
|---|---|
| Alternate Name(s) | Source data, Source document, Official record |
| Definition | The Official Record is the instantiation that is declared to be Official through written policies and procedures of the organization. It may be the Original or may be a Verified Copy. |
| Black's Legal Dictionary | A document that shows evidence of a transaction or business deal such as an invoice, receipt, cash slip, deposit slip. |
| ARMA | 1. Reprographics · The original from which a copy is made.<br>2. Computing · A document containing information entered into a computer during data entry; an input record. |
| North American Legislation | • "Authoritative Source: A source of data or information that is recognized by members of a Community of Interest (COI) to be valid or trusted because it is considered to be highly reliable or accurate or is from an official publication or reference (e.g., the United States (U.S.) Postal Service is the official source of U.S. mailing ZIP codes)".<br><br>Department of Defense (DoD) Directive 8320.2, "Data Sharing in a Net-Centric Department of Defense," December 2, 2004 |
| EU/MS Legislation | |
| Harmonized Guidelines | |

| Term | Official or Authoritative Source Document |
|---|---|
| Japanese Legislation | We could not find the definition of the term “official” neither in the Japanese legislation nor the Legal Terminology Dictionary (9th edition).<br><br>“Source documents” mean the data and other records obtained from administration to or treatment of the subject with the trial product or post-marketing trial product.<br><br>Article 2, Paragraph 10 of Standards for the Implementation of Clinical Trials on Pharmaceutical Products (MHW Ordinance No. 28, March 27, 1997)<br><br>(Note)<br><br>Under the Japanese legislation, the term of “Source Documents” are used in the context of clinical trials.<br><br>We could not find the definition of the term “authoritative source” neither in the Japanese legislation nor the Legal Terminology Dictionary (9th edition). |

| Term | Original Record or Document |
|---|---|
| Alternate Name(s) | |
| Definition | The Original Record is the first recording of the data or information, regardless of the medium (e.g., paper, electronic). |
| Black’s Legal Dictionary | The original document that is legally recognized and thus ensuring the quality of a fact when it is established. Official records are documented and kept for the entire duration of their retention. |
| ARMA | |
| North American Legislation | • “An original of a writing or recording is the writing or recording itself or any counterpart intended to have the same effect by a person executing or issuing it. An original of a photograph includes the negative or any print therefrom. If data are stored in a computer or similar device, any printout or other output readable by sight, shown to reflect the data accurately”.<br><br>Fed. R. Evid. 1001(3)<br><br>• “Original data: For the purpose of this guidance, original data are those values that represent the first recording of study data.”<br><br>FDA's Guidance for Industry Computerized Systems Used in Clinical Investigations (May 2007)<br><br>• NOTE: FDA is allowing original documents and the original data recorded on those documents to be replaced by copies provided the copies are identical and have been verified as such (see FDA Compliance Policy Guide # 7150.13)<br><br>• “Source documents: Original documents and records including, but not limited to, hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in a clinical trial”.<br><br>FDA's Guidance for Industry Computerized Systems Used in Clinical Investigations (May 2007)<br><br>For the purpose of this guidance, original data are those values that represent the first recording of study data. FDA is allowing original documents and the original data recorded on those documents to be replaced by copies provided the copies are identical and have been verified as such (see FDA Compliance Policy Guide # 7150.13). |

| Term | Original Record or Document |
|---|---|
| EU/MS Legislation | • “Native Electronic Document or Native Format means an electronic document stored in the original form in which it was created by a computer software program”.<br><br>England Civil procedure Rules Practice Direction Part 31 B, para. 5(8)<br><br>• “Original is a signed or authenticated document containing all the information as transmitted by the sender to the addressee, whether the latter is an individual, an organizational entity or an information system, in so far as the parties involved confer on the document concerned the status of original by mutual consent, by tacit agreement or under a well-established procedure.<br><br>SEC (2009)1643, Implementing Rules for the Decision 2002/47/EC, ECSC, Eurtom on Document Management and Decision 2004/563/EC, Euratom on Electronic and Digitized Documents.<br><br>EMA/INS/GCP/454280/2010<br><br>GCP Inspectors Working Group (GCP IWG)<br><br>Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials:<br><br>Original: This must be the first record made by the appropriate person e.g. ePRO record produced by the subject and not the investigator or the first acceptable result generated in an environment where analysis, tests, scans, imaging, evaluations, etc. are performed in support of clinical trials. |
| Harmonized Guidelines | Original Medical record: See Source Document |
| Japanese Legislation | “Document” means a document, a transcript, extract, authenticated copy, or duplicate of a document or duplicate of a bill or note, or another paper or other tangible objects on which information recognizable to human perception such as characters and shapes is stated.<br><br>Article 2, Paragraph 3 of the Act on Utilization of Telecommunications Technology in Document Preservation, etc. Conducted by Private Business Operators, etc. (Act No. 49, December 1, 2004)<br><br>[SAN comment: This English translation is taken from the Japanese Law Translation website operated by Ministry of Justice, Japan. http://www.japaneselawtranslation.go.jp/?re=02]<br><br>Although the term of “original” is not defined under the Japanese legislation, “original’ is defined in the Legal Terminology Dictionary (9th Edition) as follows:<br><br>Original – A document which is prepared as a final and conclusive version by the preparer in order to indicate certain matters. |

| Term | (Legally) Protected Document |
|---|---|
| Alternate Name(s) | |
| Definition | Some regional and/or country requirements exist where specific paper documents must be retained for the full life cycle according to Retention Schedules. For the purposes of this framework for the destruction of paper, these unique cases are termed legally "protected". A schedule must be maintained of these protected documents, related to market, to be used in determining the disposition of paper. |
| Black’s Legal Dictionary | |
| ARMA | |
| North American Legislation | |
| EU/MS Legislation | |
| Harmonized Guidelines | |
| Japanese Legislation | |

| Term | Record |
|---|---|
| Alternate Name(s) | |
| **Definition** | A record is data or information or document created, received, processed and maintained as evidence and information assets by an organization or person, in pursuance of legal obligations or in the transaction of business. |
| **Black's Legal Dictionary** | A written account of some act, transaction, or instrument, drawn up, under authority of law, by a proper officer, and designed to remain as a memorial or permanent evidence of the matters to which It relates. There are three kinds of records, viz.: (1) judicial, as an attainder; (2) ministerial, on oath, being an office or inquisition found; (3) by way of conveyance, as a deed enrolled. Wharton. In practice. A written memorial of all the acts and proceedings in an action or suit in a court of record. The record is the official and authentic history of the cause, consisting in entries of each successive step in the proceedings, chronicling the various acts of the parties and of the court, couched in the formal language established by usage, terminating with the judgment rendered in the cause, and intended to remain as a perpetual and unimpeachable memorial of the proceedings and judgment. At common law, "record" signifies a roll of parchment upon which the proceedings and transactions of a court are entered or drawn up by its officers, and which is then deposited in its treasury in perpetuam rei memoriam. 3 Steph. Comm. 583 ; 3 Bl. Comm. 24. A court of record is that where the acts and judicial proceedings are enrolled in parchment for a perpetual memorial and testimony, which rolls are called the "records of the court," and are of such high and supereminent authority that their truth is not to be called in question. Hahn v. Kelly, .34 Cal. 422, 94 Am. Dec. 742. And see O'Connell v. Hotchkiss, 44 Conn. 53; Murrah v. State, 51 Miss. 656; Bellas v. Mc- Carty, 10 Watts (Pa.) 24; U. S. v. Taylor, 147 U. S. 695, 13 Sup. Ct. 479, 37 L Ed. 335; State v. Godwin, 27 N. C. 403, 44 Am. Dec. 42; Vail v. Iglehart. 69 111. 334; State v. Anders, 64 Kan. 742. 68 Pac. 668: Wilkinson v. Railway Co. (C. C.) 23 Fed. 502; In re Chris- tern, 43 N. Y. Super. Ct. 531. In the practice of appellate tribunals, the word "record" is generally understood to mean the history of the proceedings on the trial of the action below, (with the pleadings, offers, objections to evidence, rulings of the court, exceptions, charge, etc.,) in so far as the same appears in the record furnished to the appellate court in the paper-books or other transcripts. Hence, derivatively, it means the aggregate of the various judicial steps taken on the trial below, in so far as they were taken, presented, or allowed in the formal and proper manner necessary to put them upon the record of the court This is the meaning in such phrases as "no error in the record," "contents of the record," "outside the record," etc. |
| **ARMA** | 1. A written or printed work of a legal or official nature that may be used as evidence or proof; a document. – 2. Data or information that has been fixed on some medium; that has content, context, and structure; and that is used as an extension of human memory or to demonstrate accountability. – 3. Data or information in a fixed form that is created or received in the course of individual or institutional activity and set aside (preserved) as evidence of that activity for BT: Broader Term • NT: Narrower Term • RT: Related Term • DF: Distinguish From AFS_Gloss_02_001-414 reference. – 4. An instrument filed for public notice (constructive notice); see recordation. – 5. Audio · A phonograph record. – 6. Computing · A collection of related data elements treated as a unit, such as the fields in a row in a database table. – 7. Description · An entry describing a work in a catalog; a catalog record |
| **North American Legislation** | |
| **EU/MS Legislation** | Properties of Records according to EMA/INS/GCP/454280/2010<br>GCP Inspectors Working Group (GCP IWG)<br>Guidance on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials:<br>Accurate, Legible, Contemporaneous, Original, Attributable, Complete,<br>Consistent, Enduring, Available when needed |
| **Harmonized Guidelines** | |
| **Japanese Legislation** | |

| Term | Source Data |
|---|---|
| Alternate Name(s) | Raw Data |
| **Definition** | All information in original records and certified copied of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (originals or certified copies). |
| **Black's Legal Dictionary** | |
| **ARMA** | |
| **North American Legislation** | |
| **EU/MS Legislation** | All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). |
| **Harmonized Guidelines** | All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). |
| **Japanese Legislation** | |

| Term | Source Document |
|---|---|
| Alternate Name(s) | |
| **Definition** | Original documents, data, and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies of transcriptions certified after verification as being accurate copies, microfiches, photographs, negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratory, and at medico-technical departments involved in a clinical trial) |
| **Black's Legal Dictionary** | A document that shows evidence of a transaction or business deal such as an invoice, receipt, cash slip, deposit slip. |
| **ARMA** | 1. Reprographics · The original from which a copy is made. – 2. Computing · A document containing information entered into a computer during data entry; an input record. |
| **North American Legislation** | Original documents and records including, but not limited to, hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in a clinical trial. |
| **EU/MS Legislation** | Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).<br><br>CHMP/ICH Guideline: Good Clinical Practice CPMP/ICH/135/95, Topic E6 (R1), Step 5, Jul-2002 |
| **Harmonized Guidelines** | Original documents, data, and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). |

| Term | Source Document |
| --- | --- |
| Japanese Legislation | The term "source documents" as used in this Ministerial Ordinance means data and other records obtained by the administration of investigational products or post-marketing clinical study drug to subjects and the medical treatment of the subjects in the clinical trial<br><br>Ordinance of the Ministry of Health and Welfare No. 161 of December 28, 2012) Ministerial Ordinance on Good Clinical Practices for Drugs |