

# FRAMEWORK FOR THE DESTRUCTION OF PAPER

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*Created through the DIA Document and Records Management (DRM)  
Special Interest Area Community (SIAC)*

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## Position Statement

The Drug Information Association (DIA) supports the efforts of Special Interest Area Communities (SIAC) 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. Within the SIAC for Document and Records Management, an effort was organized in 2011 and 2012 to develop the critical requirements for a Framework for the Destruction of Paper.

It is the opinion of the professionals within this effort that the reduction of the creation of paper is paramount to the process of better content management. Printing electronic records that then get scanned into a digital format results in process redundancy and inefficient use of resources. When paper is created or collected, this framework recommends the destruction of that paper following a verified conversion of the document into a digital format, conditional on the following:

- 1) A qualified organizational process is in place and monitored 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
- 3) A training plan covering the process flow and applicable SOPs has been created, is available within the organization, and users have successfully completed the training.

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

Creation of this framework was accomplished through the voluntary contributions of the diverse special interest group professionals who provided their expertise and perspective on what is required for paper destruction. Recommendations are derived following extensive discussions and research in 5 focus areas; namely Technology, Quality, Records Management, Regulatory, and Legal. It is the intention of this framework to break through the recurring obstacles that have prevented Industry confidence in this area for well over a decade. The scope of this initial effort is on GCP records created in support of a clinical trial in the International Conference on Harmonization (ICH) regions of North America, Europe, and Japan. The intent of this framework is not to recommend specific organizational decisions on technology tools or internal processes regarding creation of documents.

## Overview

### Framework for the Destruction of Paper (for documents scanned and placed in an ECMS)

The Drug Information Association (DIA), a recognized and highly respected professional association, and their Special Interest Area Community (SIAC) for Document and Records Management (DRM), has supported an initiative to create a framework for the process and parameters concerning the destruction of paper documentation that has been digitized and placed in a validated Electronic Content Management System (ECMS). The focus of this initial effort has been on Good Clinical Practice (GCP) records in the ICH regions of North America, Europe, and Japan. Although perceived to be applicable to other domains of pharmaceutical and device companies and countries and regions of the world, it has not yet been verified to this extent.

Creation of this framework has involved more than 40 professionals (all DIA members) from more than 25 pharmaceutical companies, contract research organizations (CROs), consultancies, and technical vendors. Contributors on this group, through the DIA DRM SIAC, 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 create 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 was drawn to the non-commercial nature of this forum. This group 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. The framework is/will continue to be vetted through many pharmaceutical companies, contract research organizations (CROs), consultancies, 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 the framework is welcomed and encouraged to help it mature and become even more useful.

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, 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. 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. 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, 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

The framework consists of 2 parts: Parameters and Process Diagrams.

### PARAMETERS

With respect to this framework, the working group considered 5 topic areas. The scope of version 1.0 of the framework is limited to assessment in the ICH GCP Guidelines regions of North America, Europe, and Japan. Other regions and countries may be considered in future versions. The framework considered each of the following topics:

- 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, GMP, & GLP standards
- LEGAL: Laws of evidence

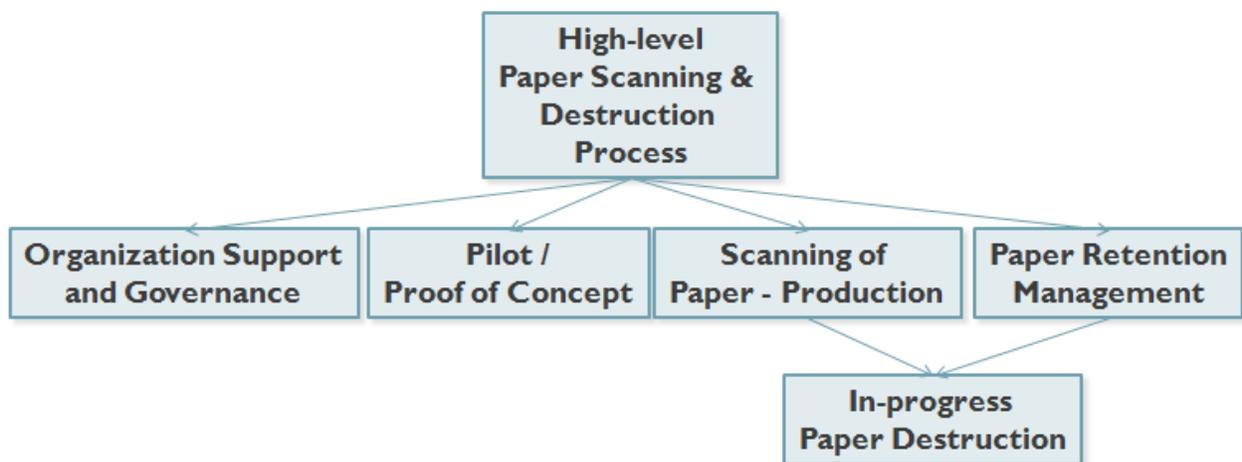
Parameters were created for each topic. Each parameter was created following a thorough assessment of the regulations, laws, guidance, and industry practices currently available. Some other industries that have transitioned to management of electronic content and the elimination of paper have been used as references. Most parameters include: a statement of interpretation of the statement, and a reference or bibliography of the content used to establish the statement (where available), and if applicable, links to specific process step(s). Parameters have not been created for each process step of the process diagrams; however where a parameter is associated with a process step, it is indicated.

## PROCESS DIAGRAMS

The included set of process diagrams is for reference only. They are intended to provide context for the recommendations, and the associated parameters relate to individual process steps. The set of diagrams are hierarchical, following this order:

### Overall Process

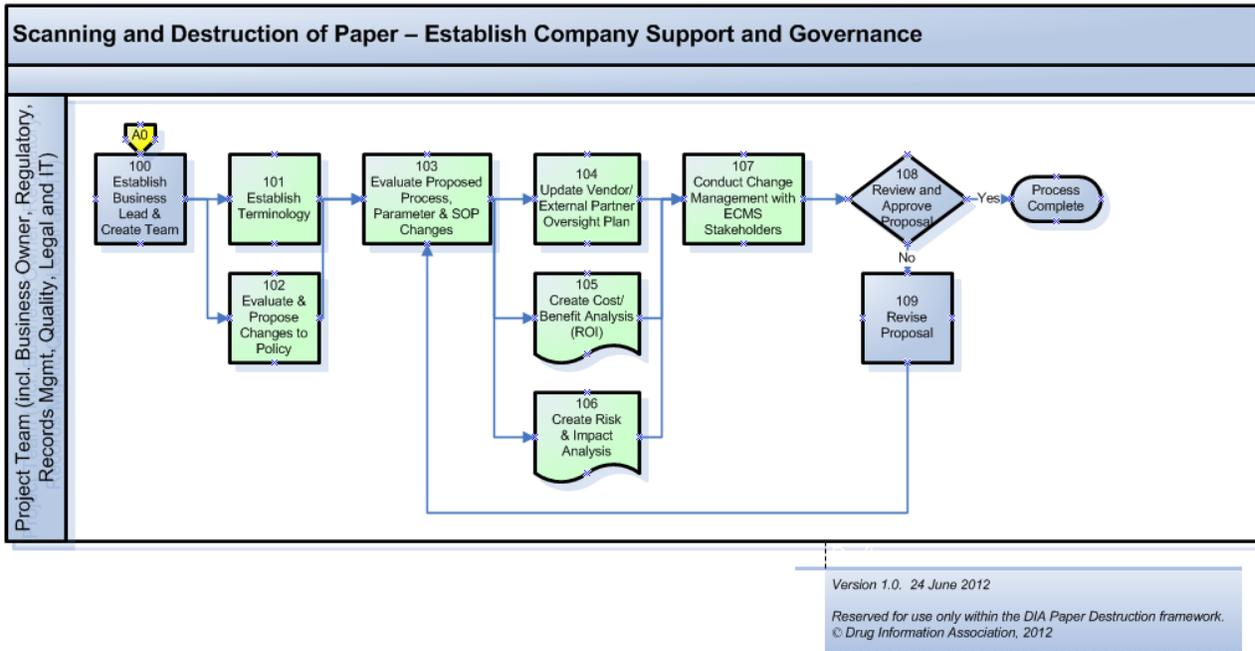
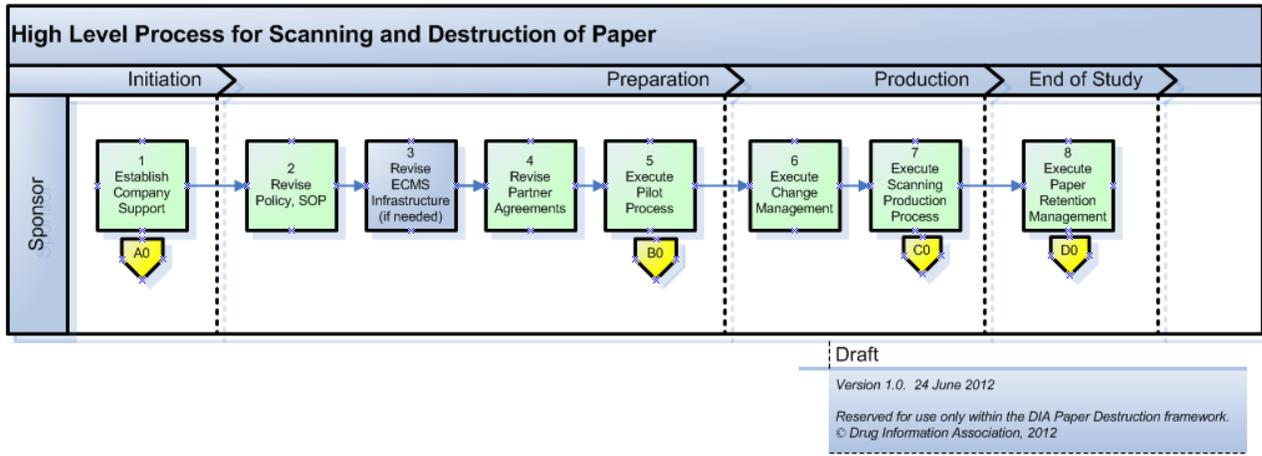
- a. Organization Support and Governance
- b. Pilot / Proof of Concept
- c. Scanning and Destruction of Paper – Scanning Production
- d. Scanning and Destruction of Paper – In-Progress Paper Destruction
- e. Scanning and Destruction of Paper – Paper Retention Management



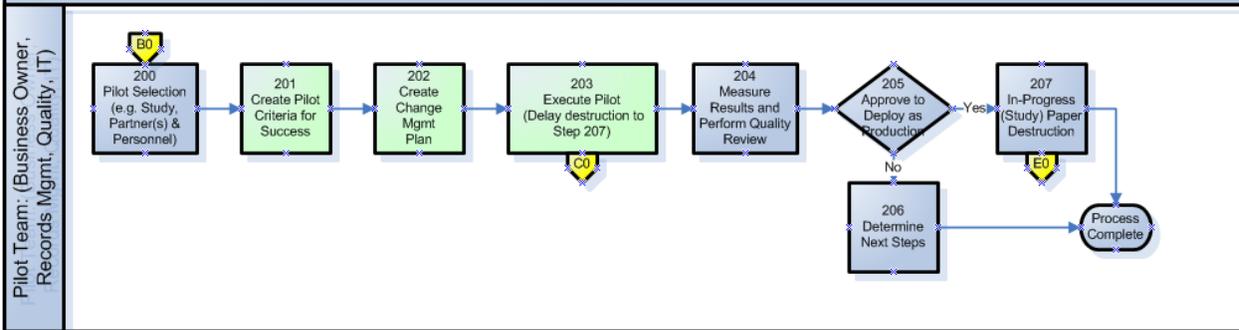
These diagrams are not intended to provide recommendations for all process steps. Several of the steps are color-coded (green) to indicate steps where specific parameters have been created, associated with a process step, in this release of the framework.

The process diagrams are only a suggestion for a high-level comprehensive process. Each organization may decide to follow all process steps, or perhaps limit their effort to several crucial ones. It will be their choice. However, to pursue anything less than a careful, comprehensive, quality driven process could yield results that would not support the destruction of scanned paper.

# Process Diagrams



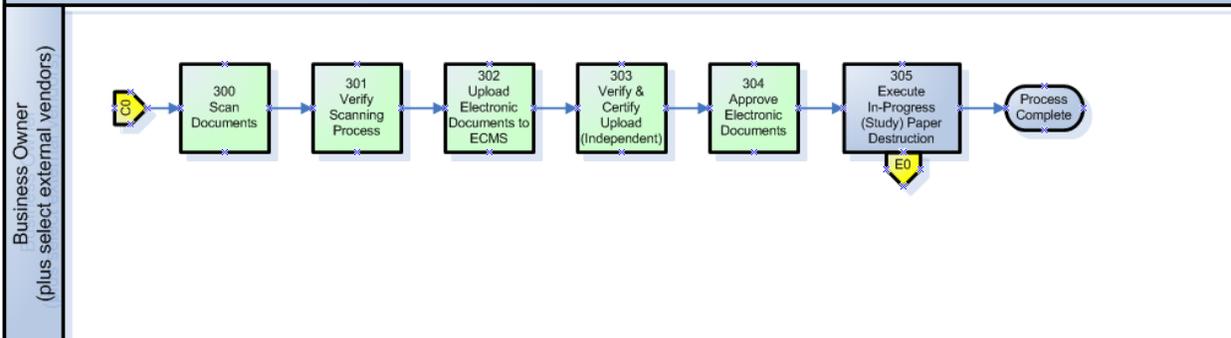
## Scanning and Destruction of Paper – Pilot / Proof of Concept



Version 1.0. 24 June 2012

Reserved for use only within the DIA Paper Destruction framework.  
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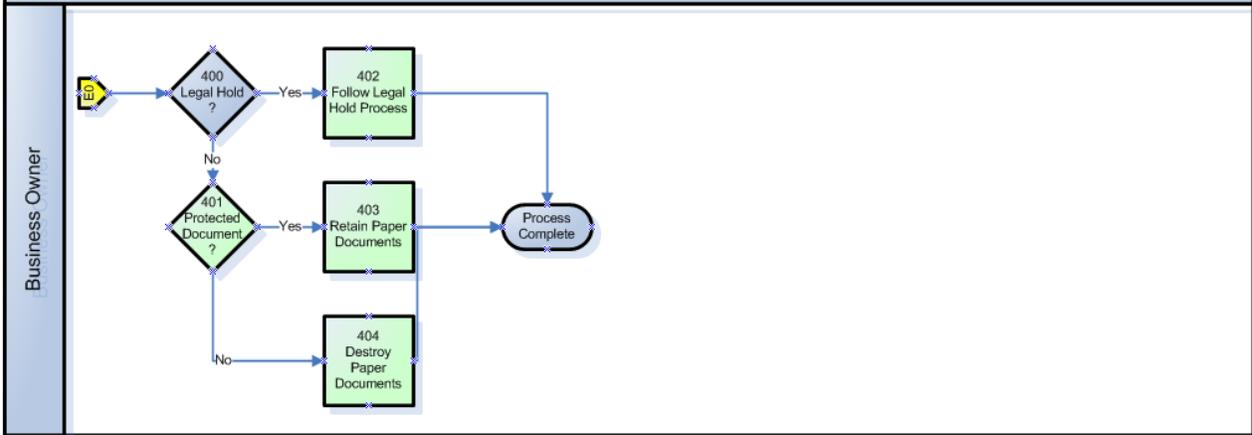
## Scanning and Destruction of Paper – Scanning Production



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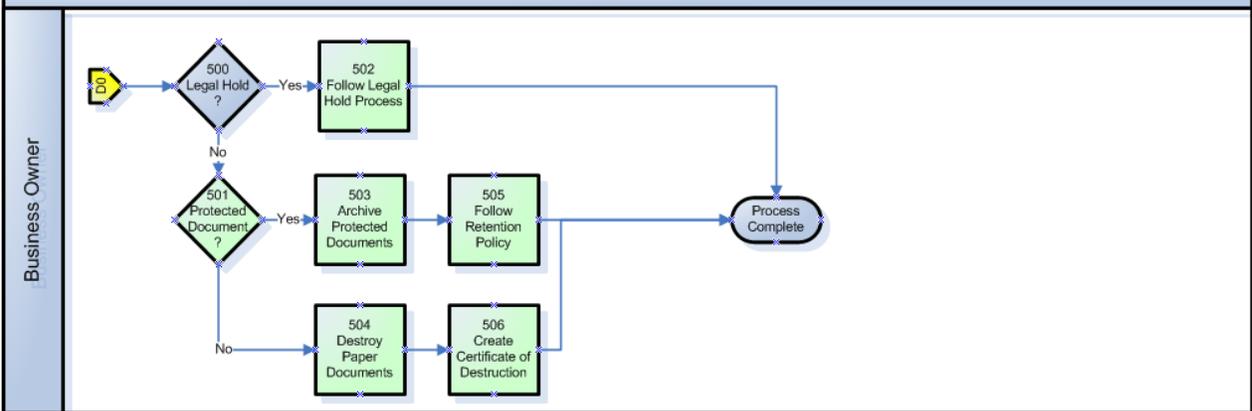
## Scanning and Destruction of Paper – In-Progress Paper Destruction



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## Scanning and Destruction of Paper – Paper Retention Management



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## Technology Parameters

<p>T 1</p>	<p><b>There are minimum requirements for scanner settings to scan and upload documents into an ECMS.</b></p> <p><b>INTERPRETATION</b></p> <ul style="list-style-type: none"> <li>• 300 dots per inch (dpi). This resolution is recommended to ensure that the pages of the document are legible both on the computer screen and when printed and, at the same time, to minimize the file size. “Paper documents containing handwritten notes should be scanned at 300 dpi.”</li> <li>• Simplex or Duplex for documents that have information on back pages</li> <li>• Bi-tonal (Black/White)             <ul style="list-style-type: none"> <li>○ If there are attributes to a paper document that are 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.</li> </ul> </li> <li>• PDF/A</li> </ul> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. United States, Food and Drug Administration. <i>FDA Industry Guidance – Portable Document Format Specifications</i>. 4 Jun. 2008. 17 Sep. 2011. &lt;<a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163565.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163565.pdf</a>&gt;</li> <li>2. United States, Food and Drug Administration. <i>Guidance for Industry - Providing Regulatory Submissions in Electronic Format — General Considerations</i>. Oct. 2003. 17 Sep. 2011. &lt;<a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm124751.pdf">http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm124751.pdf</a>&gt;</li> </ol> <p><b>PROCESS STEPS:</b> 7, 203, 300</p>
<p>T 2</p>	<p><b>Optical Character Recognition (OCR) technology can be utilized for both ease of content identification and increased search ability within ECMS.</b></p> <p><b>INTERPRETATION</b></p> <p>When an organization decides to convert paper documents to an electronic format and destroy the paper after the conversion, the organization should 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. In addition, 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.”</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. United States, Food and Drug Administration. <i>FDA Industry Guidance – Portable Document Format Specifications</i>. 4 Jun. 2008. 17 Sep. 2011. &lt;<a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163565.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163565.pdf</a>&gt;</li> <li>2. United States. Food and Drug Administration. <i>Guidance for Industry. Providing Regulatory Submissions in Electronic or Paper Format to the Office of Food Additive Safety</i>. Mar. 2010. 17 Sep. 2011.</li> </ol>

	<p><a href="http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/RegulatorySubmissions/UCM201599.pdf">http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/RegulatorySubmissions/UCM201599.pdf</a></p> <p><b>PROCESS STEPS:</b> 7, 203, 300</p>
<p><b>T 3</b></p>	<p><b>Change management programs facilitate the successful migration from a paper format to electronic format in ECMS.</b></p> <p><b>INTERPRETATION</b></p> <p>When an organization decides to convert paper content to an electronic format and destroy the paper content, before, during and after the conversion, the organization needs to facilitate the change management and manage the changes appropriately. Part of the change management process could include preparing a value proposition with appropriate communication pieces, establishing change champions and providing proper training to follow the new processes and to use an appropriate scanner and ECMS. Adopting these other related technologies are critical to the success of migrating documents from paper to electronic format.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. Jones, John, Aquirre, DeAnne, and Calderone, Matthew. "Ten principles of Change Management." <u>Strategy + Business</u>. 15 Apr. 2004. 17 Sep. 2011. <a href="http://www.strategy-business.com/article/rr00006?gko=643d0">http://www.strategy-business.com/article/rr00006?gko=643d0</a></li> <li>2. "ADKAR Change Management Model." <u>Change Management Learning Center</u>. 1996-2007. 17 Sep. 2011. <a href="http://www.change-management.com/tutorial-adkar-overview.htm">http://www.change-management.com/tutorial-adkar-overview.htm</a></li> </ol> <p><b>PROCESS STEPS:</b> 6, 106, 107, 202</p>
<p><b>T 4</b></p>	<p><b>There are minimum requirements in electronic document formatting for the purposes of long term retention and future document reproduction capabilities.</b></p> <p><b>INTERPRETATION</b></p> <p>Companies require assurances that images of the paper documents, which have been scanned, and the resulting original paper destroyed, are able to be reproduced years later. On September 28, 2005 the International Standards Organization (ISO) approved a new Standard governing electronic document archiving; PDF/A as the new archiving standard. PDF/A is expected to establish itself as the new electronic archiving standard. PDF is prevalent in public and private sectors worldwide and is already an accepted archiving format in countless markets. The PDF/A Standard will help ensure that users get the guarantee of long-term reproducibility.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. "ISO-19005-1 - Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF 1.4 (PDF/A-1)." 17 Sep. 2011. <a href="http://synthis.amcanet.com/browse/perm/ad63b7e0-82e-d10-048-095e31ec07a721f.pdf">http://synthis.amcanet.com/browse/perm/ad63b7e0-82e-d10-048-095e31ec07a721f.pdf</a></li> <li>2. Reeves, Roger and Bärffuss, Hans. "PDF/A – A New Standard for Long-Term Archiving." <u>PDF Association</u>. 4 Aug. 2011. 17 Sep. 2011. <a href="http://www.pdfa.org/2011/08/pdfa-a-new-standard-for-long-term-archiving/">http://www.pdfa.org/2011/08/pdfa-a-new-standard-for-long-term-archiving/</a></li> </ol> <p><b>PROCESS STEPS:</b> 5, 7, 203, 300, 302, 304</p>

<p><b>T 5</b></p>	<p><b>There are core requirements to be followed in addressing the challenges of long term archiving.</b></p> <p><b>INTERPRETATION</b></p> <p>When using a digital environment, steps must be taken 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.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. Lu, Maohua and Chiueh, Tzi-cker. "Challenges of Long-Term Digital Archiving: A Survey" Department of Computer Science, Stony Brook University, Stony Brook, NY-11794. 17 Sep. 2011. <a href="http://www.ecsl.cs.sunysb.edu/tr/rpe19.pdf">http://www.ecsl.cs.sunysb.edu/tr/rpe19.pdf</a></li> </ol> <p><b>PROCESS STEPS:</b> 2, 3, 6, 8, 105</p>
<p><b>T 6</b></p>	<p><b>Documents scanned or uploaded must be secured in a validated ECMS.</b></p> <p><b>INTERPRETATION</b></p> <p>Companies scanning or uploading documents into an EDMS or ECMS must ensure that the system and repository is fully validated in compliance with 21 CFR Part 11 and GAMP5 standards. Refer to Quality Parameters Q1 &amp; Q2 for additional information.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. United States. Food and Drug Administration. <i>Electronic records; electronic signatures – Scope and Application, 21 CFR Part 11</i>. Aug. 2013. 17 Sep. 2011. <a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf">http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf</a></li> <li>2. GAMP5. A Risk-Based Approach to Compliant GxP Computerized Systems. ISPE 2008.</li> </ol> <p><b>PROCESS STEPS:</b> 7, 106, 107, 202</p>

## Quality Parameters

<b>Q 1</b>	<p><b>There should be a controlled, quality driven process for document scanning and uploading into a validated Electronic Content Management System (ECMS).</b></p> <p><b>INTERPRETATION</b></p> <p><b>Steps for consideration:</b></p> <p>A scanner should be selected that can produce scanned images in a way that meets the technology requirements previously identified, including but not limited to scanner settings.</p> <p>The minimum resolution of 300 dpi as identified under the Technology parameters T1 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.</p> <p>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.). After scanning, avoid re-sampling to a lower resolution. A captured image should not be subjected to non-uniform scaling (i.e. sizing).</p> <p>Digitized documents should be PDFs. Refer to Technology parameters for version recommended. No additional software must be needed to read and navigate the PDF files.</p> <p><b>Preparation Steps for Scanning Documents:</b></p> <ul style="list-style-type: none"><li>• Removal of wallets/staples/binding/paperclips</li><li>• A QC check of 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 will have to be manually scanned in simplex setting.</li></ul> <p><b>There Are 2 Scenarios For Consideration Depending On Scanning Process:</b></p> <ul style="list-style-type: none"><li>• Individual document scanning</li><li>• Batch scanning</li></ul> <p>Documents can be batched 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. Metadata for indexing should be considered in the process.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"><li>1. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically." <u>British Standards Institution (BSI)</u>. &lt;<a href="http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030186227">http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030186227</a>&gt;</li><li>2. United States. Food and Drug Administration. <u>Portable Document Specifications</u>. &lt;<a href="http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163179.pdf">http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163179.pdf</a>&gt;</li><li>3. United States. Food and Drug Administration. <u>Guidance for Industry Providing Regulatory Submissions in Electronic Format —General Considerations</u>. <a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm124751.pdf">http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm124751.pdf</a></li><li>4. United States. Food and Drug Administration. <u>Guidance for Industry: Computerized</u></li></ol>
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	<p><u>Systems Used in Clinical Investigations.</u>  <a href="http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf">www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf</a></p> <p>5. Industry opinion and practice though not formally cited in the public domain. Various documents compiled by quality topic team members outlining process and quality control checks, including scanning settings, pdf version required for scanning (PDF/A is an ISO Standard for using PDF format for the long-term archiving of electronic documents), batch scanning, indexing, QC of scanned documents and importing to an ECMS</p> <p><b>PROCESS STEPS:</b> 7, 300, 301</p>
<p><b>Q 2</b></p>	<p><b>The authenticity of scanned images as certified copies must be established.</b></p> <p><b>A QC process should be defined to review the scanned document(s), whether they are bar-coded or routed directly to indexed files.</b></p> <p><b>A quality driven process should be established for image quality, indexing quality, and verification of the certified copy. Completion of manual QC processes must be documented including a signature to attest for accuracy and completeness. If completion of QC steps is being documented electronically, then audit trail and/or electronic signature functionality should be implemented as part of the overall validation of the ECMS. All QC may be done at individual document level or at a batch level, as per organization process.</b></p> <p><b>INTERPRETATION</b></p> <p><b>Criteria For QC: Image Quality (Not In Order of Priority)</b></p> <p>The following are considerations for companies to assess and to best define their own organization-specific requirements for image quality:</p> <ul style="list-style-type: none"> <li>• Are all pages present? Are there any double feeds?</li> <li>• Is everything in paper present in the electronic image (i.e. information such as headers/footers is not cut off? Pages with only header and footer information are not to be considered as blank pages)?</li> <li>• If scanning duplex, does the image contain all of the information?</li> <li>• If scanner settings are duplex, are true blank pages removed?</li> <li>• Is the document the right size and orientation (e.g., US Letter, A4; landscape)? Are all pages rotated the right way?</li> <li>• Is the image too light/too dark?</li> <li>• Are pages skewed?</li> <li>• Any post it notes inadvertently scanned? <ul style="list-style-type: none"> <li>○ Determination if these notes are to be scanned and added to the electronic document as well or replaced onto paper documents that are on Legal Hold is to be determined by the organization.</li> </ul> </li> <li>• Is all content legible?</li> <li>• Are all signatures legible?</li> <li>• Are pages in the correct sequence?</li> <li>• Are there any bent corners blocking document content?</li> <li>• Removal of hole punches on images is not recommended.</li> <li>• Removal of any content from the original document is not permitted (e.g. fax header information).</li> </ul>

- De-speckling capabilities were not used.

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 prior to or after scanning, depending on organization processes, but all attributes should be checked for accuracy before QC process is completed and the images are uploaded into an ECM system.

#### **Considerations for QC To Create A Certified Copy - Process To Be Defined Or Approved**

- QC process to document the chain of custody and process through the life of the original and electronic document.
  - Tracks how the document came in, who scanned documents and reviewed the image; capabilities exist to capture scanning parameters.
  - Tracks quantity in terms of number of pages and image quality.
  - Tracks who has uploaded and approved the document.
- If companies wish to use scanned copies in lieu of the scanned paper and destroy the original paper, the scanned copies must meet the definition of a certified copy. Organization records management policies must be followed.
- Any protected documents not to be destroyed should be defined, listed, and maintained through the life of the trial. (*Refer to Glossary for definition of "protected document"*)
- It is recommended that QC steps are performed by a different person than the person that performed the scanning and indexing.

#### **BIBLIOGRAPHY/REFERENCES**

1. "BS 6498:2002 Guide to preparation of microfilm and other microforms that may be required as evidence" British Standards Institution (BSI)  
<<http://shop.bsigroup.com/en/ProductDetail/?pid=000000000019998064>>United States. Food and Drug Administration.
2. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically." British Standards Institution (BSI).  
<<http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030186227>>
3. Draft Guidance: Electronic Source Documentation in Clinical Investigations. Dec. 2010.  
<<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf>> United States. National Archives and Records Administration (NARA).
4. Technical Guidelines for Digitizing Archival Materials for Electronic Access: Creation of Production Master Files – Raster Images. June. 2004.  
<<http://www.archives.gov/preservation/technical/guidelines.pdf>> Page 43
5. Industry opinion and practice though not formally cited in the public domain

**PROCESS STEPS:** 302, 303, 304

**Q 3**

**There must be a documented quality driven process for destruction of paper documents and maintaining certified copies in an ECMS; in compliance with regulations and legal requirements.**

**INTERPRETATION**

**ECM systems**

If companies wish to retain the electronic copies in an ECMS in lieu 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)<sup>1</sup>. These references include the following additional requirements:

- Computerized system validation
- Maintenance of SOPs for the use of the system
- Maintenance of an audit trail of data changes ensuring that there is no deletion of entered data or scanned documents
- Maintenance of a security system to protect against unauthorized access
- Maintenance of list of the individuals authorized to make data changes
- Maintenance of adequate backup of the data, safeguard the blinding of the trial and archiving of any source data (i.e. hard copy and electronic). Minimum standards for back up should be organization specific.
- Appropriate training records for those involved in the scanning and uploading processes. Documents being easily located and traceable in the system

**BIBLIOGRAPHY/REFERENCES**

1. European Medicines Agency. Q&A: Good Clinical Practice (GCP). Expectations of EU competent authorities on the use of electronic Trial Master Files.  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q\\_and\\_a/q\\_and\\_a\\_detail\\_000016.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800296c5&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000016.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800296c5&jsenabled=true)
2. 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.[www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf](http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf)
3. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically." British Standards Institution (BSI).  
<http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030186227>

**PROCESS STEPS:** 302, 303, 304, 501, 502

**Q 4**

**All training must be completed and documented.**

**INTERPRETATION**

All personnel involved in the scanning, uploading, and QC processes, should have appropriate training to enable that person to perform the assigned functions. All training must be documented, and training records must be maintained. Competency levels checked and assessed at the time of training completion, and personnel certification documentation should be maintained

**BIBLIOGRAPHY/REFERENCES:**

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.

	<p>2. <u>European Commission</u>. Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use Eudralex, Vol 4, Chapter 2 Personnel. <a href="http://ec.europa.eu/health/files/eudralex/vol-4/2011-7_gdpguidline_publicconsultation.pdf">http://ec.europa.eu/health/files/eudralex/vol-4/2011-7_gdpguidline_publicconsultation.pdf</a></p> <p><b>PROCESS STEPS:</b> not applicable</p>
<p><b>Q 5</b></p>	<p><b>Third party requirements must be specified for when activities are transferred to consultants and vendors.</b></p> <p><b>INTERPRETATION</b></p> <p>Any duty or function that is transferred to a third party (e.g., CRO, consultants, 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 in this document are included in vendor contracts, agreements, oversight plans, etc., as appropriate.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. <u>Guideline for Good Clinical Practice E6</u>. ICH Harmonized Tripartite. Section 5.2, Contract Research Organization</li> <li>2. United States. Food and Drug Administration. <u>Code of Federal Regulations, Title 21, Volume 4. Revised as of April 1, 2011. Sec. 211.34</u> Consultants.</li> </ol> <p><b>PROCESS STEPS:</b> 104,107</p>
<p><b>Q 6</b></p>	<p><b>Monitoring of quality must take place.</b></p> <p><b>INTERPRETATION</b></p> <p>It is recommended that continuous review or conduct of routine monitoring and/or audits of systems occur to ensure validation processes and specified requirements are being met and maintained.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. United States. Food and Drug Administration. <u>Code of Federal Regulations, Title 21, Volume 4. Revised as of April 1, 2011. Sec. 21 CFR 820.22</u> Quality Systems.</li> <li>2. <i>United States. Food and Drug Administration. <u>Code of Federal Regulations, Title 21, Volume 4. Revised as of April 1, 2011. Sec. 21 CFR 820.75b</u> Process Validation.</i></li> </ol> <p><b>PROCESS STEP:</b> 106, 108</p>
<p><b>Q 7</b></p>	<p><b>It is critical to perform a risk assessment</b></p> <p><b>INTERPRETATION</b></p> <p>A risk management and mitigation plan should be established in a Paper Destruction pilot process.</p> <ul style="list-style-type: none"> <li>• Milestones and considerations throughout the pilot, as well as at the end of the pilot to determine how to proceed with a paper destruction process are recommended.</li> </ul> <p>This risk management and mitigation plan must align with organization’s risk management policies.</p>

	<p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. "ISO 31000:2009. Risk Management- Principles and Guidelines." <u>International Organisation for Standardization</u> <a href="http://www.iso.org/iso/catalogue_detail?csnumber=43170">http://www.iso.org/iso/catalogue_detail?csnumber=43170</a></li> <li>2. Industry opinion and practice though not formally cited in the public domain</li> </ol> <p><b>PROCESS STEPS:</b> 106, 201</p>
<p><b>Q 8</b></p>	<p><b>The paper destruction process and certification of destruction requirements need to be defined by the organization.</b></p> <p><b>INTERPRETATION</b></p> <p>Companies must develop a destruction policy.</p> <ul style="list-style-type: none"> <li>• The destruction process should be defined by the organization. (For example, when a certificate of destruction should be created and if created, be maintained and at what level: batch level or individual document level, etc.)</li> <li>• Certificates of destruction demonstrate that destruction was conducted per process and regulations. Note that local regulation and statutory requirements are to be also considered.</li> <li>• The timing of paper destruction needs to be considered in line with country specific regulations and organization retention policies.</li> </ul> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. "BS EN15713:2009. Secure Destruction of Confidential Material; Code of Practice." <u>British Standards Institution (BSI)</u>.</li> </ol> <p><b>PROCESS STEP:</b> 1, 8, 111, 102, 106, 107, 504, 506</p>

## Records Management Parameters

RM 1	<p><b>Certain characteristics are required for the archiving, retrieval, and retention processes involving electronic records. These are necessary to ensure authenticity, reliability, integrity, and usability of the electronic records over the long-term.</b></p> <p><b>INTERPRETATION</b></p> <p>Characteristics of paper and electronic archiving are not that different; the same overall steps need to be followed. However, there must be an understanding of what it takes to safeguard an eRecord versus other media/paper throughout the retention time. This will be part of a cost/ benefit assessment companies have to do to ensure appropriate and comprehensive archiving of the electronic record after it has been scanned into an ECMS. Some high level requirements are listed below, however full requirements may be found in the referenced material.</p> <p><b>Functional Business Requirements Include:</b></p> <p><b>Appraisal</b> – Assess which records are required to be retained and how long they should be kept.</p> <p><b>Transformation</b> – Where required, transformation is the process of preparing records for the eArchive system by converting records from their native form to preferred preservation formats. This process includes providing mechanisms to ensure the content, structure and authenticity of records is maintained during transformation. Preservation ready formats include DOCX, XLSX, PPTX, PDF, PDFa, XML, HTML, PNG, JP2000 and TIFF.</p> <p><b>Transfer</b> – This is the process of moving the records from an operational system to the eArchive. Transmittal records should be created to verify successful transfer of records for audit trail/chain of custody requirements.</p> <p><b>Migration</b> – This is the process of receiving records, applying metadata and assigning classification for storage within the eArchive. After migration, records should be qualified to ensure they are in a preservation format and include the required metadata. There should be sufficient checks to identify files that have failed or have been rejected during the migration process, or are duplicates</p> <p><b>Storage</b> – Unique identifiers should be assigned to records. The eArchive should prohibit any changes to the material content of records stored in the eArchive.</p> <p><b>Retention</b> – Authorized users should be enabled to assign retention rules to records</p> <p><b>Legal Hold</b> – The eArchive should enable authorized users to apply and remove holds on records.</p> <p><b>Search and Retrieval</b> – The eArchive should allow authorized users to browse or search using a variety of values. Search results and viewing rights should be limited according to privileges assigned to the authorized user.</p> <p><b>Monitoring and Reporting</b> – 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.</p> <p><b>Preservation and Maintenance</b> – The eArchive should be able to maintain the authenticity of an electronic record during access and maintenance. An audit trail should be maintained of all archived record preservation processing and any resulting changes or updates. There should be sufficient safeguards to protect against archive</p>
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media degradation or technology obsolescence. The eArchive should maintain the authenticity of corresponding electronic signatures associated with the record during ingest and throughout the lifespan of the record.

**Disposition and Destruction** – Authorized users should be able to generate a destruction report to list records eligible for destruction. There must be a mechanism to ensure electronic records selected for destruction are not recoverable.

**Non-Functional Business Requirements Include:**

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

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

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

**Infrastructure and Technical** – Technical and infrastructure requirements of the eArchive 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. 16 Sep. 2011
3. Food and Drug Administration. Electronic records; electronic signatures, 21 CFR, pt. 11. 2003. Web. 16 Sep. 2011

**PROCESS STEPS:** 107, 103, 105, 106, 502, 505, 503

**RM 2****There are specific requirements for retaining both wet ink and electronic signatures.****INTERPRETATION**

This interpretation provides an evaluation of which signatures are required by regulations and when procedures may suffice.

Signatures are generally used for three purposes:

1. to document agreement or contract between parties (e.g. contract)
2. to confirm correctness of statements made or data entered
3. to verify procedural requirements (e.g. confirmation of steps in workflows, e.g. signatures on shipment records or dispensing logs)

The cited regulations do not specify the required format (wet ink or electronic)

For the electronic process, it is not appropriate to re-issue previous wet ink signatures as electronic signatures after scanning/conversion of the paper record occurs (e.g. asking a signatory for an additional electronic signature to the contract). Therefore the baseline shall be that signatures on electronic generated and maintained documents in validated electronic environments should be issued as e-signatures.

Signatures on paper documents should be issued as wet-ink signatures. In case a document is presented in electronic format via a non-qualified route (e.g. a document is sent as PDF), the signature should be delivered either on a printed copy or on a signature sheet that identifies exactly the version and date of the signed document. The former expectation that wet ink signature should preferably be issued in non-black ink to differentiate from copies is no longer a requirement in this time of color copiers/printers/scanners.

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.

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.

**BIBLIOGRAPHY/REFERENCES**

1. International Conference on Harmonization: Guideline on Good Clinical Practice E6 (R1): Note for Guidance on Good Clinical Practice CPMP/ICH/135/95. 1997. Web. 16 Sep. 2011
2. Food and Drug Administration. Electronic records; electronic signatures, 21 CFR, pt. 11. 2003. Web. 16 Sep. 2011

**PROCESS STEP:** 103, 403, 503

<p><b>RM 3</b></p>	<p><b>A timeline for the discarding of the paper originals is dependent on following the appropriate procedures.</b></p> <p><b>INTERPRETATION:</b></p> <p>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.</p> <p>Any documents that are categorized as "Protected" must not be destroyed (see also RM9).</p> <p>The paper 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 as noted in RM1, taking into account confidentiality levels and issuing of certificates of destruction where required.</p> <p><b>BIBLIOGRAPHY/REFERENCES:</b></p> <p>1. Industry opinion and practice though not formally cited in the public domain</p> <p><b>PROCESS STEPS:</b> 401, 404, 501, 504</p>														
<p><b>RM 4</b></p>	<p><b>Take risk parameters into account before deciding on a procedure to destroy paper (also, see RM5, RM7).</b></p> <p><b>INTERPRETATION</b></p> <p>Analyze the risks and follow appropriate procedures to mitigate those risks.</p> <table border="1" data-bbox="313 1184 1430 1696"> <thead> <tr> <th>Risks</th> <th>Possible Mitigation(s)</th> </tr> </thead> <tbody> <tr> <td>Authenticity of the electronic record</td> <td>Demonstrate quality and accuracy of the scan and file process as a normal course of business.</td> </tr> <tr> <td>Demonstrate reliability of duplication</td> <td>Establish a quality control process/system that is consistently implemented and periodically checked.</td> </tr> <tr> <td>Demonstrate record as trustworthy</td> <td>Establish proper controls over the management of electronic records.</td> </tr> <tr> <td>Records held in the system can only be changed in an authorized manner</td> <td>Ensuring through adequate safeguards that there are no duplicates of the record. This requires having clear policies, procedures and the ability to demonstrate they are enforced.</td> </tr> <tr> <td>Retention of Audit Logs</td> <td>Audit trails must be automatically created and retained by the system for an agreed period of time.</td> </tr> <tr> <td>Technology</td> <td>Evaluate longevity of technology solutions and migration plans for the times when technology must be changed.</td> </tr> </tbody> </table> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <p>1. <u>The Uniform Rules of Evidence</u> (US 128-0060-00 to 0170-00) , has been adopted by the United States federal courts and 34 states</p> <p><b>PROCESS STEPS:</b> 103, 106</p>	Risks	Possible Mitigation(s)	Authenticity of the electronic record	Demonstrate quality and accuracy of the scan and file process as a normal course of business.	Demonstrate reliability of duplication	Establish a quality control process/system that is consistently implemented and periodically checked.	Demonstrate record as trustworthy	Establish proper controls over the management of electronic records.	Records held in the system can only be changed in an authorized manner	Ensuring through adequate safeguards that there are no duplicates of the record. This requires having clear policies, procedures and the ability to demonstrate they are enforced.	Retention of Audit Logs	Audit trails must be automatically created and retained by the system for an agreed period of time.	Technology	Evaluate longevity of technology solutions and migration plans for the times when technology must be changed.
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**RM 5**

**Access to electronic records must be facilitated continuously across time (also see RM1, RM4, RM7).**

**INTERPRETATION**

The minimum required document retention times are considerable and may exceed 25 years. Even considering only the duration of media, migration may be the only way to protect the electronic assets. Major systems typically require significant upgrades or replacement every 3 to 5 years. Therefore, there is a high probability that more than one migration will be needed over the lifetime of a document.

However, there are other reasons beyond life of media and potential system upgrades that can require further migrations. These could potentially impact ownership, meta-data and content:

- Appropriate organizational commitment and control is the strongest driver for long-term access and retrieval
- Strategies for the migration of data should be part of the system planning and fit for purpose. A system can be seen as 'temporary shelter' for the data.
- Metadata and indexing practices may need to be revised over time
- The variety of content structures and formats need controls. They should follow widely applied industry practice and standards, as much as possible

The following requirements will provide the foundation for long-term continuous access and should be addressed in the very beginning:

**1. Setting Up A New System:**

- The data of today which is created in the system will be the legacy data of the future. Therefore, the long-term retention of data should be explicitly stated as a guiding principle, meaning that there will be a clear intention to migrate all data without losing critical information for retrieval and access.
- Necessary migration functionality should be stated as user requirements to support future migration.
- System design should be appropriate, e.g. readiness for batch export/transfer of metadata and content into transparent external format in decent time (when dealing with millions of records performance could be an issue).
- The concept for migrating electronically signed documents should be clarified. Particularly as a technical alteration of the files could be required in the course of future long-term migrations.

**2. Operating The New System:**

- The number of different content structures and formats (and their related versions) should be limited as much as possible. The more types of formats you have, the greater the risk in migration and validation processes.
- Widely applied standard formats should be used wherever possible during use of the system (office formats to PDF/A; scanning to PDF/A).
- Consistency and quality of metadata should be checked continuously.
- The data model should be adjusted on an ongoing basis to keep all documents up-to-date with regular system usage.

	<p><b>3. Migrating Documents (When Implementing A Successor System):</b></p> <ul style="list-style-type: none"> <li>• Each migration offers the opportunity to evaluate the possible harmonization of file formats, reducing the variety of formats used.</li> <li>• Data model requirements for the new system should consider the legacy documents right from the beginning and not after the new business needs have been implemented. This includes corresponding retrieval functions and usability not available with the successor system.</li> <li>• Holding legacy documents into special areas outside the regular system usage and knowledge will create silos of neglect and pose a risk for retrieval and access.</li> </ul> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. ISO 15489-1:2001: <u>Information and documentation -- Records management – Part 1: General</u>. 2001. Print</li> <li>2. ISO 15489-2:2001: <u>Information and documentation -- Records management – Part 2: Guidelines</u>. 2001. Print</li> </ol> <p><b>PROCESS STEPS:</b> 103, 106, 505</p>
<p><b>RM 6</b></p>	<p><b>There are essential business requirements that must be considered in creating a viable electronic archiving program.</b></p> <p><b>INTERPRETATION</b></p> <p>When deciding about paper versus electronic archiving it is recommended to first perform a risk evaluation in addition to a cost/benefit assessment. The characteristics may favor the electronic archives process with characteristics such as:</p> <ul style="list-style-type: none"> <li>• immediate accessibility across geographies</li> <li>• availability in inspections</li> <li>• reusability by downstream processes and data mining</li> </ul> <p>The trustworthiness of the retained records – accuracy, security, reliability, integrity, and usability (see also RM1, RM7) must be ensured throughout the required retention time. Procedures detailing how this will be achieved, including roles and responsibilities in the process, and applicable controls need to be in place.</p> <p>Archiving records electronically may be the preferred solution when:</p> <ul style="list-style-type: none"> <li>• Records are generated and delivered to the ECMS in electronic format</li> <li>• 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 the access rate.</li> <li>• Accessibility across geographies is required.</li> </ul> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. Industry opinion and practice though not formally cited in the public domain</li> </ol> <p><b>PROCESS STEPS:</b> 103, 106, 503</p>

**RM 7**

**The risks associated with the reliability of electronically converted and stored documents must be assessed (as compared to paper) (also see RM1, RM4 and RM5).**

**INTERPRETATION**

As shown in RM1 and RM4, the underlying records management principles are largely identical for paper and electronic. Situations where a hybrid approach (both paper and electronic) is utilized, then one of the two must be designated as the official or authoritative source.

In most aspects, electronically handled documents can be considered to be more reliable because:

- Alteration/deletion is prevented or controlled by system controls
- Access is independent from physical location
- Indexing and filing can be multi-dimensional
- Transfer, quality assurance (QA) and retention are independent of media

In addition, reliability could potentially be harmed by human error, environmental conditions, poorly set up processes and systems or fraud.

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 afterwards, by individuals who have direct knowledge of the facts or by instruments routinely used within the business to conduct the transaction

In detail, issues could arise if documents are:

- Not captured (RM)
- Not complete (QA)
- Not representing all relevant information (QA)
- Illegible (QA)
- Incorrect; not what they should be (QA)
- Without context (RM)
- Altered/manipulated (QA, Technical)
- Deleted (Technical)
- Vanished (RM, Technical)
- Insufficiently or inconsistently indexed (RM, QA)
- Not retrievable (RM, QA, Technical)
- Not accessible (RM, Technical)
- Hidden for relevant usage (RM, QA, Technical)
- "Forgotten", knowledge for retrieval not available (RM)

**BIBLIOGRAPHY/REFERENCES**

1. ISO-15489 standard set of definitions
2. Industry opinion and practice though not formally cited in the public domain

**PROCESS STEP: 106**

<p><b>RM 8</b></p>	<p><b>There are numerous stakeholders surrounding the management of content. A plan to anticipate and remediate the concerns of the stakeholders through communications and education should be prepared as part of a project.</b></p> <p><b>INTERPRETATION</b></p> <p>Managing expectations within the stakeholders involved in creation, management, use, and archival of content is essential. Stakeholders would include representatives from (but not limited to) Clinical Operations, Pharmacovigilance, Regulatory, Clinical Supplies, Medical Writing, Legal and Patents, Biostatistics, Data Management and Quality. The intent of these activities would be to involve each of the process streams engaged in the conduct of the trial so that concerns can be voiced and resolved.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <p>1. Industry opinion and practice though not formally cited in the public domain</p> <p><b>PROCESS STEP:</b> 107</p>
<p><b>RM 9</b></p>	<p><b>Some document types must be identified as “Protected” in order to prevent the destruction of those paper documents.</b></p> <p><b>INTERPRETATION</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>• <b>Protected</b> - The paper document must be retained for reference according to an effective document retention policy.</li> <li>• <b>Retain Until Established Period in Time</b> - 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).</li> <li>• <b>Non-Protected</b> - Able to destroy the paper document while the trial is in-progress.</li> </ul> <p>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). A legal analysis will likely be required within an organization to understand the extent of these exceptions.</p> <p>A method should be devised to track changes to this Protected Document Types map so that investigations 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.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <p>1. Industry opinion and practice though not formally cited in the public domain</p> <p><b>PROCESS STEPS:</b> 401, 501, 503</p>

## Regulatory Parameters

<p>R 1</p>	<p><b>For each record required to be maintained under predicate rules, it must be determined in advance whether there is a plan to rely on the electronic record or paper record to perform regulated activities, and that decision documented (e.g., in a Standard Operating Procedure (SOP), or specification document). This requirement includes establishing a business continuity plan to address the event of a disaster or disruption of technology services.</b></p> <p><b>INTERPRETATION</b></p> <p>“In some cases, actual business practices may dictate whether you are using electronic records instead of paper records under § 11.2(a). For example, if a record is required to be maintained under a predicate rule and you use a computer to generate a paper printout of the electronic records, but you nonetheless rely on the electronic record to perform regulated activities, the Agency may consider you to be using the electronic record instead of the paper record. That is, the Agency may take your business practices into account in determining whether part 11 applies.”</p> <p>There must be consistency in the use of electronic records versus paper records.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. United States. Food and Drug Administration. <i>Electronic records; electronic signatures – Scope and Application, 21 CFR Part 11</i>. Aug. 2013. 17 Sep. 2011. <a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf">http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf</a></li> <li>2. Food and Drug Administration. <u>Electronic records; electronic signatures, 21 CFR, pt. 11</u>. 2003. Web. 16 Sep. 2011.</li> </ol> <p><b>PROCESS STEPS:</b> 103, 303, 304</p>
<p>R 2</p>	<p><b>Create an organization-wide inventory of your tools and assess whether they perform quality or business critical functions (e.g., publishing systems, ECMS, Adobe Acrobat, Public Key Infrastructure, etc.), and determine if validation is necessary. If an ECMS is to hold the digitized copy of a paper document and that paper document is then destroyed, the ECMS needs to be validated.</b></p> <p><b>INTERPRETATION</b></p> <p>The FDA recommends utilizing a risk-based assessment process to determine whether validation is necessary. You should consider a system’s impact to product quality, safety, and records integrity.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. Food and Drug Administration. <u>Quality System Regulations, 21 CFR, pt. 820.70</u> Revised as of April 1, 2011. Web. 17 Sep. 2011.</li> <li>2. Almeida, Carlos “Computer System Validation: A Closer Look at 21 C.F.R. §820.70(i) and FDA Warning Letters”. <u>SPK and Associates</u>. 16 Mar. 2011. 17. Sep.2011. <a href="http://www.spkaa.com/computer-system-validation-a-closer-look-at-21-c-f-r-%c2%a7820-70i-and-fda-warning-letters">http://www.spkaa.com/computer-system-validation-a-closer-look-at-21-c-f-r-%c2%a7820-70i-and-fda-warning-letters</a>.</li> </ol> <p><b>PROCESS STEPS:</b> 103, 303, 304</p>

R 3

Ensure that computerized technologies meet, at minimum, applicable current requirements which may include any or all of the following:

- **FDA Guidance for Industry and FDA Staff: General Principles of Software Validation**
- **Industry guidance such as the GAMP 4 Good Practice Guide (Good Automated Manufacturing Practice)**
- **Personal Information Protection and Electronic Documents Act (PIPEDA)**
- **Uniform Electronic Transactions Act (UETA)**
- **EU Directive on Electronic Signatures (EU Electronic Signatures Directive)**
- **German Digital Signature Act**
- **United Nations Commission on International Trade Law (UNCITRAL)**
- **Electronic Signatures in Global and National Commerce Act (ESIGN)**
- **Japanese ERES Guideline (Electromagnetic Records and Electronic Signatures)**

#### **BIBLIOGRAPHY/REFERENCES**

1. United States. Food and Drug Administration. FDA Guidance for Industry and FDA Staff: General Principals of Software Validation. Issued Jan.2002. <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126954.htm>. Sep.2011.
2. International Society for Pharmaceutical Engineering (ISPE). GAMP4: Good Practice Guides. [http://www.ispe.org/cs/gamp\\_publications\\_section/gamp\\_publications\\_overview](http://www.ispe.org/cs/gamp_publications_section/gamp_publications_overview). Sep.2011.
3. Department of Justice Canada. Personal Information Protection and Electronic Documents Act (PIPEDA). Amended Apr.2011. <http://laws-lois.justice.gc.ca/eng/acts/P-8.6/>. Sep.2011.
4. National Conference of Commissioners on Uniform State Laws (NCCUSL).Uniform Electronic Transactions Act (UETA). Issued 1999. <http://www.law.upenn.edu/bll/archives/ulc/fnact99/1990s/ueta99.htm>. Sep.2011.
5. Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures (EU Directive on Electronic Signatures). Issued Jan.2000. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0093:en:HTML>. Sep.2011.
6. German Signature Law of 2011. Revised 2001. [http://www.gesetze-im-internet.de/sigg\\_2001/index.html](http://www.gesetze-im-internet.de/sigg_2001/index.html). Sep.2011
7. United Nations Commission on International Trade Law (UNCITRAL). <http://www.uncitral.org/uncitral/en/index.html>. Sep.2011.
8. United States Congress. Electronic Signatures in Global and National Commerce Act (ESIGN). Enacted Jun.2000. [http://www.law.cornell.edu/uscode/15/usc\\_sup\\_01\\_15\\_10\\_96.html](http://www.law.cornell.edu/uscode/15/usc_sup_01_15_10_96.html). Sep.2011.
9. Japanese ERES Guideline. Using electromagnetic records and electronic signatures for application for approval or licensing of drug. Apr.2005. <http://ecompliance.co.jp/english/Japanese%20ERES%20Guideline.html>. Sep.2011.

**PROCESS STEPS:** 103, 303, 304

R 4

Ensure selected technology provides an audit trail for signatures that captures date, time, or the sequence of events in a particular instance. Ensure appropriate use of electronic vs. digital signatures.

Definitions: Electronic vs. Digital Signatures

**Electronic Signatures (from CFR Part 11):**

- 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

**Digital Signatures (from CFR Part 11)**

- An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified

When to Use: Electronic vs. Digital Signatures

**Electronic Signatures:**

- Documents for which you only need to demonstrate the identity of the individual performing a function e.g. document review, document approval, document understood

**Digital Signatures:**

- Documents that are mandated to be signed by regulation or legislation
- Document marked as bearing a valid signature
- Change to document invalidates signature

**INTERPRETATION**

Ensure appropriate use of electronic vs. digital signatures. If implementing digital signatures, ensure they are based on a qualified certificate and that are created by a secure-signature-creation device, a) satisfy the legal requirements of a signature in relation to data in electronic form in the same manner as a handwritten signature satisfies those requirements in relation to paper-based data, and b) are admissible as evidence in legal proceedings.

Having audit trails or other physical, logical, or procedural security measures in place helps ensure the trustworthiness and reliability of the records.

**BIBLIOGRAPHY/REFERENCES**

1. United States. Food and Drug Administration. *Electronic records; electronic signatures – Scope and Application, 21 CFR Part 11*. Aug. 2013. 17 Sep. 2011. <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf>.
2. Food and Drug Administration. Electronic records; electronic signatures, 21 CFR, pt. 11. 2003. Web. 16 Sep. 2011.

**PROCESS STEPS:** 103, 303, 304

<p><b>R 5</b></p>	<p><b>When used, time stamps must be implemented with a clear understanding of the time zone applied.</b></p> <p><b>INTERPRETATION</b></p> <p>When using time stamps, they 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 zone acronyms or other naming conventions.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. United States. Food and Drug Administration. <i>Electronic records; electronic signatures – Scope and Application, 21 CFR Part 11</i>. Aug. 2013. 17 Sep. 2011. <a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf">http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf</a></li> <li>2. Food and Drug Administration. <u>Electronic records; electronic signatures, 21 CFR, pt. 11</u>. 2003. Web. 16 Sep. 2011.</li> </ol> <p><b>PROCESS STEPS:</b> 103, 303, 304</p>
<p><b>R 6</b></p>	<p><b>Electronic Signatures must demonstrate or include the following components:</b></p> <ul style="list-style-type: none"> <li>• <b>A method to identify the signer, including name, and be unique to the person using it;</b></li> <li>• <b>Date and time of the signature</b></li> <li>• <b>Capable of verification;</b></li> <li>• <b>Under the sole control of the person using it;</b></li> <li>• <b>Linked to the data in such a manner that if the data is changed, the signature is invalidated;</b> <ul style="list-style-type: none"> <li>○ <b>changing data in an electronically signed document results in the creation of a new version (or new document, if versioning is not supported) that requires new signatures for approval</b></li> </ul> </li> <li>• <b>A method to indicate the signer's approval with the meaning associated in the message (i.e. reason for signature); and</b></li> <li>• <b>A method used must be as reliable as was appropriate for the purpose for which the message was generated or communicated.</b></li> </ul> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. United States. Food and Drug Administration. <i>Electronic records; electronic signatures – Scope and Application, 21 CFR Part 11</i>. Aug. 2013. 17 Sep. 2011. <a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf">http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf</a></li> <li>2. Food and Drug Administration. <u>Electronic records; electronic signatures, 21 CFR, pt. 11</u>. 2003. Web. 16 Sep. 2011.</li> <li>3. United States Congress. <u>Electronic Signatures in Global and National Commerce Act (ESIGN)</u>. Enacted Jun.2000. <a href="http://www.law.cornell.edu/uscode/15/usc_sup_01_15_10_96.html">http://www.law.cornell.edu/uscode/15/usc_sup_01_15_10_96.html</a>. Sep.2011.</li> <li>4. <u>Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures (EU Directive on Electronic Signatures)</u>. Issued Jan.2000. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0093:en:HTML">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0093:en:HTML</a>. Sep.2011.</li> <li>5. Department of Justice Canada. <u>Personal Information Protection and Electronic Documents Act (PIPEDA)</u>. Amended Apr.2011. <a href="http://laws-lois.justice.gc.ca/eng/acts/P-8.6/">http://laws-lois.justice.gc.ca/eng/acts/P-8.6/</a>. Sep.2011.</li> </ol>

	<p>6. United Nations Commission on International Trade Law (UNCITRAL).  <a href="http://www.uncitral.org/uncitral/en/index.html">http://www.uncitral.org/uncitral/en/index.html</a>. Sep.2011</p> <p><b>PROCESS STEPS:</b> 103, 303, 304</p>
<p><b>R 7</b></p>	<p><b>An electronic certificate of authority signed by a credible and verifiable notary representative is required for each notarized electronic document.</b></p> <p><b>INTERPRETATION</b></p> <p>On a notarized electronic document transmitted to another state or country, electronic evidence of the authenticity of the official signature and seal of an electronic notary, shall be attached to or logically associated with the document and shall be in the form of an electronic certificate of authority signed by a credible representative that is independently verifiable and will be invalidated if the underlying document is modified.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. Title 29. State Government. State Agencies and Offices Not Created by Constitution. Chapter 43. Notaries Public. Subchapter II. Notarial Acts.  <a href="http://delcode.delaware.gov/title29/c043/sc02/index.shtml">http://delcode.delaware.gov/title29/c043/sc02/index.shtml</a>. Sep.2011.</li> <li>2. <u>Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures (EU Directive on Electronic Signatures)</u>. Issued Jan.2000. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0093:en:HTML">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0093:en:HTML</a>. Sep.2011.</li> </ol> <p><b>PROCESS STEPS:</b> 103, 303, 304</p>
<p><b>R 8</b></p>	<p><b>Documented rules governing the conduct of parties using electronic signatures must be available.</b></p> <p><b>INTERPRETATION</b></p> <p><b>Ensure That At A Minimum The Responsibility Of The Person Obtaining A Digital Certificate Is To:</b></p> <ul style="list-style-type: none"> <li>• Make truthful representations in applying for a certificate;</li> <li>• Review and accept a certificate before using it;</li> <li>• Make certain representations upon acceptance of the certificate;</li> <li>• Control and keep confidential the person's private key; and</li> <li>• Promptly terminate/revoke the certificate upon compromise of the underlying private key <ul style="list-style-type: none"> <li>○ Notify certification authority of compromise, where applicable</li> </ul> </li> </ul> <p><b>Ensure That At A Minimum The Responsibility Of The Party Issuing A Digital Certificate:</b></p> <ul style="list-style-type: none"> <li>• Use a trustworthy system;</li> <li>• Disclose its practices and procedures;</li> <li>• Properly identify a prospective applicant for a certificate;</li> <li>• Publish issued certificates in a repository;</li> <li>• Promptly suspend and/or revoke certificates upon compromise of the underlying private key;</li> <li>• Make warranties to the certificate applicant upon issuance of the certificate; and</li> <li>• Make warranties to persons using the certificate to verify digitally signed messages.</li> </ul>

	<p><b>Ensure You Have Addressed The Following Issues Related To The General Use Of Electronic Signatures, Including Rules Regarding:</b></p> <ul style="list-style-type: none"> <li>• The creation and control of signature devices used by the signers of electronic messages to produce a unique electronic signature</li> <li>• Instances in which signatures would be attributed to the named signer;</li> <li>• The unauthorized use of signature devices;</li> <li>• Whether a party is obligated to accept an electronic signature; and</li> <li>• The circumstances under which the parties to a transaction may vary the provisions of the statute (i.e., party autonomy).</li> </ul> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. Smedinghoff, Thomas J and Bro, Ruth Hill. Baker &amp; McKenzie LLP. 1999. <u>Electronic Signature Legislation</u>. <a href="http://library.findlaw.com/1999/Jan/1/241481.html">http://library.findlaw.com/1999/Jan/1/241481.html</a>. Sep.2011.</li> <li>2. National Conference of Commissioners on Uniform State Laws (NCCUSL). <u>Uniform Electronic Transactions Act (UETA)</u>. Issued 1999. <a href="http://www.law.upenn.edu/bll/archives/ulc/fnact99/1990s/ueta99.htm">http://www.law.upenn.edu/bll/archives/ulc/fnact99/1990s/ueta99.htm</a>. Sep.2011.</li> </ol> <p><b>PROCESS STEPS:</b> 103, 303, 304</p>
<p><b>R 9</b></p>	<p><b>Adopt/create and train all employees on a corporate level policy detailing the use of electronic signatures.</b></p> <p><b>INTERPRETATION</b></p> <p>A signature, whether electronic or on paper, is first and foremost a symbol that signifies intent. Thus, a policy detailing the use of electronic signatures in the Uniform Commercial Code includes "any symbol" so long as it is "executed or adopted by a party with present intention to authenticate a writing". While handwritten signatures in most cases serve merely to indicate the signer's intent, signatures in an electronic environment typically serve three critical purposes for the parties engaged in an e-commerce transaction - i.e., to identify the sender, to indicate the sender's intent (e.g., to be bound by the terms of a contract), and to ensure the integrity of the document signed.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. United States. Food and Drug Administration. <i>Electronic records; electronic signatures – Scope and Application, 21 CFR Part 11</i>. Aug. 2013. 17 Sep. 2011. <a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf">http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf</a></li> <li>2. Food and Drug Administration. <u>Electronic records; electronic signatures, 21 CFR, pt. 11</u>. 2003. Web. 16 Sep. 2011.</li> <li>3. Smedinghoff, Thomas J and Bro, Ruth Hill. Baker &amp; McKenzie LLP. 1999. <u>Electronic Signature Legislation</u>. <a href="http://library.findlaw.com/1999/Jan/1/241481.html">http://library.findlaw.com/1999/Jan/1/241481.html</a>. Sep.2011.</li> </ol> <p><b>PROCESS STEPS:</b> 103, 303, 304</p>
<p><b>R 10</b></p>	<p><b>Address the concern for Japanese raised seals.</b></p> <p><b>INTERPRETATION</b></p> <p>It is recommended that this document type is considered a "Protected Document" and maintained in its original form until technology solutions and guidance for authentic preservation is more feasible. In Japan, Hanko (or called Inkan) or a Japanese seal,</p>

is often required as proof of verification of a transaction or as an official acknowledgement of a situation or event, instead of using a hand-written signature. Based on the following – the Jitsu-In stamp is legally binding. Unknown how to determine the type of stamp; however, corporate use of Inkan is always legally binding and should be synonymous to wet-signatures. The Japanese are moving towards electronic signatures. As a result, both the Jitsu-In (corporate signature) and electronic signatures are used during official activities.

**BIBLIOGRAPHY/REFERENCES**

1. Japan. Law Concerning Electronic Signatures and Certification Services. May.2000. <http://www.meti.go.jp/english/report/data/gesignconte.html>. Sep.2011.

**PROCESS STEPS:** 103, 303, 304, 501, 505, 503

## Legal Parameters

<b>L 1</b>	<p><b>Once records exist, they may be sought as evidence in government inquiries, civil litigation, or criminal prosecution.</b></p> <p><b>INTERPRETATION</b></p> <p>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.</p> <p>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.</p> <p>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. Normal course of business is generally business process driven and therefore it is interpreted and recommended that an organization's business practice for managing records should include written procedures for 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.</p> <p>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, e.g. normal course of business, would not keep interim paper formats once scanned, a 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.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"><li>1. Federal Rule of Civil Procedure 34, "a party must produce documents as they are kept in the usual course of business".</li></ol> <p><b>PROCESS STEPS:</b> 2, 101, 103, 102, 402, 502</p>
<b>L 2</b>	<p><b>If an organization maintains ECMS and scans documents and certifies them as the authoritative source, discovery of these documents "stand on equal footing with discovery of paper documents."</b></p> <p><b>INTERPRETATION</b></p> <p>Building on the first parameter, there is precedent for the use of and reliance on scanned documents for legal discovery and proceedings and thus for establishing written organization procedures for declaring the scanned record 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."</p>

	<p>Also, in two litigated cases, the electronic copy of a record was considered the "same as" the hardcopy and the authoritative source can certainly be the electronic one.</p> <p>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.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. FED. R. CIV. P. 34(a)(1)(A)-(B) and accompanying advisory committee's note.</li> <li>2. 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."</li> <li>3. Anti-Monopoly, Inc. v. Hasbro, Inc., 1995 WL 649934 (S.D.N.Y. Nov. 3, 1995).</li> <li>4. World IP Contacts Handbook 14th edition</li> </ol> <p><b>PROCESS STEPS:</b> 2, 101, 402, 502</p>
<p><b>L 3</b></p>	<p><b>The duty to preserve evidence in support of litigation holds extends to data compilations, computerized data, and other electronically recorded information.</b></p> <p><b>INTERPRETATION</b></p> <p>Federal Rule of Civil Procedure 26 specifically included "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.</p> <p>Ensure the corporate glossary includes the terms "electronically recorded information" and "computerized data".</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. Federal Rule of Civil Procedure 26. Duty to Disclose; General Provisions Governing Discovery Rule 26(a)(1)(A)(ii)</li> </ol> <p><b>PROCESS STEPS:</b> 2, 101, 402, 502</p>
<p><b>L 4</b></p>	<p><b>Electronic signatures and records are equivalent to paper signatures and records, and therefore are subject to the same legal scrutiny to determine authenticity.</b></p> <p><b>INTERPRETATION</b></p> <p>Signatures are not solely determinative in the courts' appreciation of whether paper or electronic is defined as the original so long as the record is authenticated. 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.</p> <p>Ensure the corporate glossary includes the terms "digital signatures", "electronic</p>

	<p>records", "electronic signatures" and "authenticity" and that process elements are captured to ensure a record's signature remains authentic and verified as appropriate.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <p>1. Electronic Signatures in Global and National Commerce Act ("ESIGN")</p> <p><b>PROCESS STEPS:</b> 2, 101, 103</p>
<p><b>L 5</b></p>	<p><b>A process that accurately reproduces or forms a durable medium for reproducing the original [paper], enables destruction of the original [paper] so long as the process is used in the regular course of business [Business As Usual].</b></p> <p><b>INTERPRETATION</b></p> <p>Reliable reproductions, e.g. 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. (See also RM7.)</p> <p>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 conversion process and its conditions. An official at the Japanese competent authorities notably recommended that original paper documents be scanned rather than retyped.</p> <p>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.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. Uniform Photographic Copies of Business and Public Records as Evidence Act (UPA)</li> <li>2. Civil Evidence Act 1995 CHAPTER 38</li> <li>3. Industry opinion and practice though not formally cited in the public domain</li> <li>4. World IP Contacts Handbook 14th edition</li> <li>5. The Japanese Ordinance regarding Standards for the Clinical Trial of Drugs (MH Ordinance No. 72 of 1997, as amended) (the “Ordinance”) <ul style="list-style-type: none"> <li>• Article 26</li> <li>• Article 41</li> </ul> </li> <li>6. Japanese PFAD Circulars No. 1001001 (Oct. 1, 2008)</li> <li>7. Japanese PFAD Circulars No. 0401022 (Apr. 1, 2005)</li> </ol> <p><b>PROCESS STEPS:</b> 2, 101, 102, 103</p>
<p><b>L 6</b></p>	<p><b>Destruction of original paper records should not be prohibited once a complete and accurate electronic rendition is made unless required by a predicate rule or other applicable legal requirement.</b></p> <p><b>INTERPRETATION</b></p>

	<p>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.</p> <p>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.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. The Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 as amended ("the Clinical Trials Regulations") Regulation 31A(7)</li> </ol> <p><b>PROCESS STEPS:</b> 2, 101, 102, 103</p>
<p><b>L 7</b></p>	<p><b>Sponsors of a clinical trial must keep records of the essential documents of this 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 and reliable, and the individuals responsible for the production, amendment and deletion of those records must be clearly identified.</b></p> <p><b>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.</b></p> <p><b>INTERPRETATION</b></p> <p>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.</p> <p>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, e.g. destruction, certification of the electronic original. Changes to corporate records management policies may be required to state requirements and conditions of the conversion and verification process.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <ol style="list-style-type: none"> <li>1. The Japanese Ordinance regarding Standards for the Clinical Trial of Drugs (MH Ordinance No. 72 of 1997, as amended) (the "Ordinance") <ul style="list-style-type: none"> <li>• Article 26</li> <li>• Article 41</li> </ul> </li> <li>2. Japanese PFAD Circulars No. 1001001 (Oct. 1, 2008)</li> <li>3. Japanese PFAD Circulars No. 0401022 (Apr. 1, 2005)</li> </ol>

	<p>4. Industry opinion and practice though not formally cited in the public domain</p> <p><b>PROCESS STEPS:</b> 2, 101, 102, 103</p>
<p><b>L 8</b></p>	<p><b>Policies, procedures, and other quality and compliance documentation, including partner agreements, developed or modified to support the paper destruction process should 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).</b></p> <p><b>INTERPRETATION</b></p> <p>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 third party 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 enterprise to ensure the same quality is applied throughout the process regardless of which group is responsible for a particular activity in the paper destruction process.</p> <p><b>BIBLIOGRAPHY/REFERENCES</b></p> <p>1. Industry opinion and practice though not formally cited in the public domain</p> <p><b>PROCESS STEPS:</b> 1, 2, 4, 101, 102, 103, 106</p>

## **Last Words: Glossary, Feedback, Next Steps, Acknowledgements**

The Framework for the Destruction of Paper is free and available through the following link: <http://www.diahome.org/en/News-and-Publications/Publications-and-Research/EDM-Corner.aspx>.

### **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 and Future Renditions**

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 path for this framework has not ended, but just begun. Evolution of the framework will continue as the work group accepts and evaluates feedback following the formal release of this framework, version 1.0 on 24 June 2012. This mechanism for feedback is described on the last page of this document.

Besides evaluation of all feedback that is received in the manner requested, this work group may also begin focusing on verification of this framework to other domains of the biopharmaceutical and medical device research & development industry as well as country and regional variations beyond the ICH regions.

### **Team Membership**

This team welcomes new members, in whatever capacity they can contribute. To become involved with the continued finalization, enhancement, and maintenance of this framework, contact the DIA DRM SIAC chairman or DIA 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.

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### **Acknowledgements**

Finally, it would be a very significant misstep if the amount of time and professional expertise that was contributed selflessly to the development of this framework were not acknowledged. This framework is the product of thousands of hours of volunteers individually given in addition to the companies, large and small, who supported the effort.

## Glossary

Term	Archive
Alternate Name(s)	
Definition	To deposit a record into a storage medium and location which will enable long-term preservation, minimize deterioration, and ensure long-term viability for the entire retention period.
Black's Legal Dictionary	
ARMA	
North American Legislation	
EU/MS Legislation	
Harmonized Guidelines	
Japanese Legislation	

Term	Authentication
Alternate Name(s)	
Definition	Authentication is verification of the genuineness of a document or signature, to make it effective or valid.
Black's Legal Dictionary	
ARMA	Process of verifying that a record is what it purports to be.
North American Legislation	
EU/MS Legislation	
Harmonized Guidelines	
Japanese Legislation	

<b>Term</b>	<b>Certified Copy</b>
<b>Alternate Name(s)</b>	Attested copy, Exemplified copy, Verified copy
<b>Definition</b>	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.
<b>Black's Legal Dictionary</b>	A duplicate of an original (usually official) document, certified as an exact reproduction usually by the officer responsible for issuing or keeping the original.
<b>ARMA</b>	
<b>North American Legislation</b>	<ul style="list-style-type: none"> <li>• "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".</li> </ul> <p>FDA's Guidance for Industry Computerized Systems Used in Clinical Investigations (May 2007)</p> <ul style="list-style-type: none"> <li>• "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".</li> </ul> <p>Fed. R. Evid. 1001(4)</p>
<b>EU/MS Legislation</b>	<p>"Originals or copies certified after verification as being accurate copies"</p> <ul style="list-style-type: none"> <li>• EMA, ICH Topic E6 (R1) - Guideline for Good Clinical Practice, CPMP/ICH/135/95</li> </ul>
<b>Harmonized Guidelines</b>	<ul style="list-style-type: none"> <li>• "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"</li> <li>• "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".</li> </ul> <p>CDISC Clinical Research Glossary Version 8.0, (Dec. 2009)</p>
<b>Japanese Legislation</b>	<p>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":</p> <p>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."</p> <p>We could not find the definition of the term "certified copy" neither in the Japanese legislation nor the Legal Terminology Dictionary (9th edition).</p> <p>We could not find the definition of the term "record copy" neither in the Japanese legislation nor the Legal Terminology Dictionary (9th edition).</p> <p>"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.</p>

<b>Term</b>	<b>Electronic Record</b>
<b>Alternate Name(s)</b>	eRecord, Electronic Document
<b>Definition</b>	<p>An electronic record is the combination of an electronic document plus additional metadata that defines the context and history of that content.</p> <p>An electronic document may be one or more document objects that as a collection represent the whole content and presentation of the document. Several examples of electronic documents that contain multiple objects are 1) SGML content and format files, or 2) compound documents that comprise many individual elements included in a structure.</p> <p>An electronic document may be a copy of a paper document that is an accurate representation or image of what content was contained on that original document.</p>
<b>Black's Legal Dictionary</b>	
<b>ARMA</b>	
<b>North American Legislation</b>	<ul style="list-style-type: none"> <li>• “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”.</li> </ul> <p>FDA's Guidance for Industry Computerized Systems Used in Clinical Investigations (May 2007)</p> <ul style="list-style-type: none"> <li>• “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.</li> </ul> <p>“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”</p> <p>Uniform Commercial Code para. 5-102 (6) and (14)</p>
<b>EU/MS Legislation</b>	<ul style="list-style-type: none"> <li>• “Document means anything in which information of any description is recorded”.</li> </ul> <p>England Civil procedure Rules, Part 31, Rule 31.4</p> <ul style="list-style-type: none"> <li>• “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”.</li> </ul> <p>England Civil procedure Rules Practice Direction Part 31 B, para. 5(3)</p> <ul style="list-style-type: none"> <li>• “Electronic Image means an electronic representation of a paper document”.</li> </ul> <p>England Civil procedure Rules Practice Direction Part 31 B, para. 5(4)</p> <ul style="list-style-type: none"> <li>• “ 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”</li> </ul> <p>Rules Governing Medicinal Products in the EU, Vol. 4, Good Manufacturing Practice, Chap. 4 Documentation.</p>

Term	Electronic Record
<p><b>Harmonized Guidelines</b></p>	<ul style="list-style-type: none"> <li>• “ 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.</li> </ul> <p>CDISC Clinical Research Glossary Version 8.0, (Dec. 2009)</p> <ul style="list-style-type: none"> <li>• “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”.</li> </ul> <p>ICH Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance</p>
<p><b>Japanese Legislation</b></p>	<p>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.</p> <p>In order to secure trueness, the following requirements must be met:</p> <p>(1) Rules and procedures for maintaining security of the system are documented and performed appropriately.</p> <p>(2) The creator of stored information is clearly identifiable. When modifying 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.</p> <p>(3) A procedure for making a back-up of electronic records is documented and performed appropriately.</p> <p>3.1.2. Readability of an electronic record</p> <p>“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.)</p> <p>3.1.3. Keepability of an electronic record</p> <p>“Keepability” means an electronic record can be retained for a period while reserving its trueness and readability.</p> <p>In order to secure keepability, the following requirements need to be met:</p> <p>(1) Procedures for securing keepability, for example management of electronic recording media, are documented and performed appropriately.</p> <p>(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.</p> <p>“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.</p> <p>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)</p> <p>[SAN comment: This English translation is taken from the Japanese Law Translation website operated by Ministry of Justice, Japan. <a href="http://www.japaneselawtranslation.go.jp/?re=02">http://www.japaneselawtranslation.go.jp/?re=02</a>]</p> <p>(Note)</p> <p>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.</p> <p>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)</p>

<b>Term</b>	<b>Electronic Signature</b>
<b>Alternate Name(s)</b>	eSig
<b>Definition</b>	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.
<b>Black's Legal Dictionary</b>	<p>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.</p> <p>- 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.</p>
<b>ARMA</b>	
<b>North American Legislation</b>	<p>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).</p> <p>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.</p>
<b>EU/MS Legislation</b>	<ul style="list-style-type: none"> <li>• "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"</li> <li>• "Advanced Electronic Signature" means an electronic signature which meets the following requirements: <ul style="list-style-type: none"> <li>(a) it is uniquely linked to the signatory;</li> <li>(b) it is capable of identifying the signatory;</li> <li>(c) it is created using means that the signatory can maintain under his sole control; and</li> <li>(d) it is linked to the data to which it relates in such a manner that any subsequent change of the data is detectable".</li> </ul> </li> </ul> <p>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 &amp; 2.2</p> <ul style="list-style-type: none"> <li>• "Certificate means an electronic attestation which links signature-verification data to a person and confirms the identity of that person"</li> </ul> <p>NOTE: 'signature-verification-data' means data, such as codes or public cryptographic keys, which are used for the purpose of verifying an electronic signature</p> <p>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</p> <p>Also cited in SEC(2009)1643, Implementing Rules for the Decision 2002/47/EC, ECSC, Euratom on Document Management and Decision 2004/563/EC, Euratom on Electronic and Digitized Documents.</p>
<b>Harmonized Guidelines</b>	

Term	Electronic Signature
Japanese Legislation	<p>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.</p> <p>(PFSB Notification No. 0401022 dated April 1, 2005)</p> <p>Use of Electronic Records and Electronic Signatures in Submission for Approvals, Licences, etc., of Medicinal and Other Products</p> <p>Although the term of "certificate" is not defined under the Japanese legislation, "certificate" is defined in the Legal Terminology Dictionary (9th Edition) as follows:</p> <p>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.</p> <p>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:</p> <p>"Notarization" means act of a public organ to certify that a certain act is conducted by a due procedure.</p> <p>"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:</p> <ul style="list-style-type: none"> <li>(i) A measure to indicate that such information was created by the person who has taken such measure; and</li> <li>(ii) A measure to confirm whether such information has been altered.</li> </ul> <p>Article 2, Paragraph 1 of Act on Electronic Signature and Certification Business (Act No. 102 of May 31, 2000)</p> <p>[SAN comment: This English translation is taken from the Japanese Law Translation made by Ministry of Justice, Japan. <a href="http://www.japaneselawtranslation.go.jp/?re=02">http://www.japaneselawtranslation.go.jp/?re=02</a>]</p> <p>(Note)</p> <p>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.</p> <p>Article 3 of Act on Electronic Signature and Certification Business (Act No. 102 of May 31, 2000)</p>

<b>Term</b>	<b>Digital Archive</b>
<b>Alternate Name(s)</b>	Electronic archive
<b>Definition</b>	Electronic archival with long term repositories for the storage of electronic records that preserve the content, prevent or track alterations and control access to electronic records.
<b>NPS</b>	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.
<b>ARMA</b>	
<b>North American Legislation</b>	
<b>EU/MS Legislation</b>	
<b>Harmonized Guidelines</b>	
<b>Japanese Legislation</b>	

<b>Term</b>	<b>Handwritten Signature</b>
<b>Alternate Name(s)</b>	Wet-ink Signature
<b>Definition</b>	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.
<b>Black's Legal Dictionary</b>	1. A person's name or mark written by that person or at the person's direction. 2. (Commercial law) Any name, mark, or writing used with the intention of authenticating a document. UCC 1-201(b) (37), 3-401(b).
<b>ARMA</b>	
<b>North American Legislation</b>	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.  21 CFR 11
<b>EU/MS Legislation</b>	
<b>Harmonized Guidelines</b>	
<b>Japanese Legislation</b>	

Term	Official or Authoritative Source Document
Alternate Name(s)	
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	Authorized or approved by a proper authority.
ARMA	
North American Legislation	<ul style="list-style-type: none"> <li>• "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)".</li> </ul> <p>Department of Defense (DoD) Directive 8320.2, "Data Sharing in a Net-Centric Department of Defense," December 2, 2004</p>
EU/MS Legislation	
Harmonized Guidelines	
Japanese Legislation	<p>We could not find the definition of the term "official" neither in the Japanese legislation nor the Legal Terminology Dictionary (9th edition).</p> <p>"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.</p> <p>Article 2, Paragraph 10 of Standards for the Implementation of Clinical Trials on Pharmaceutical Products (MHW Ordinance No. 28, March 27, 1997)</p> <p>(Note)</p> <p>Under the Japanese legislation, the term of "Source Documents" are used in the context of clinical trials.</p> <p>We could not find the definition of the term "authoritative source" neither in the Japanese legislation nor the Legal Terminology Dictionary (9th edition).</p>

Term	Original Record or Document
Alternate Name(s)	
Definition	<p>The Original Record is the first recording of the data or information, regardless of the medium.</p> <p>Original document rule/ Best evidence rule: The evidentiary rule providing that, to prove the contents of a writing (or a recording or photograph), a party must produce the original writing (or a mechanical, electronic, or other familiar duplicate, such as photocopy) unless it is unavailable, in which case secondary evidence – the testimony of the drafter or a person who read the document – may be admitted (see Fed. R. Evid. 1001-1004).</p>
Black's Legal Dictionary	<p>"Original evidence" refers to "evidence". Evidence – 1. Something (including testimony, documents, and tangible objects) that tends to prove or disprove the existence of an alleged fact. 2. See fact in evidence under fact. 3. The collective mass of things, esp. testimony and exhibits, presented before a tribunal in a given dispute. 4. The body of law regulating the admissibility of what is offered as proof into the record of a legal proceeding. Documentary evidence – Evidence supplied by a writing or other document, which must be authenticated before the evidence is admissible.</p>
ARMA	
North American Legislation	<ul style="list-style-type: none"> <li>• "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".</li> </ul> <p>Fed. R. Evid. 1001(3)</p> <ul style="list-style-type: none"> <li>• "Original data: For the purpose of this guidance, original data are those values that represent the first recording of study data."</li> </ul> <p>FDA's Guidance for Industry Computerized Systems Used in Clinical Investigations (May 2007)</p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• "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".</li> </ul> <p>FDA's Guidance for Industry Computerized Systems Used in Clinical Investigations (May 2007)</p>
EU/MS Legislation	<ul style="list-style-type: none"> <li>• "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".</li> </ul> <p>England Civil procedure Rules Practice Direction Part 31 B, para. 5(8)</p> <ul style="list-style-type: none"> <li>• "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.</li> </ul> <p>SEC(2009)1643, Implementing Rules for the Decision 2002/47/EC, ECSC, Euratom on Document Management and Decision 2004/563/EC, Euratom on Electronic and Digitized Documents.</p> <p>EMA/INS/GCP/454280/2010</p> <p>GCP Inspectors Working Group (GCP IWG)</p> <p>Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials:</p> <p>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.</p>

Term	Original Record or Document
Harmonized Guidelines	
Japanese Legislation	<p>“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.</p> <p>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)</p> <p>[SAN comment: This English translation is taken from the Japanese Law Translation website operated by Ministry of Justice, Japan. <a href="http://www.japaneselawtranslation.go.jp/?re=02">http://www.japaneselawtranslation.go.jp/?re=02</a>]</p> <p>Although the term of “original” is not defined under the Japanese legislation, “original” is defined in the Legal Terminology Dictionary (9th Edition) as follows:</p> <p>Original – A document which is prepared as a final and conclusive version by the preparer in order to indicate certain matters.</p>

Term	Partner Relationship Model
Alternate Name(s)	
Definition	<p>External business partners are often engaged to provide services to a sponsor, with the intent to aid and assist in the conducting of a clinical trial. Each of these partners offer slightly different services and the sponsor’s relationship to that partner takes on different responsibilities, privileges and constraints. It is proposed that each partner not be completely unique, but rather that the sponsor sets up tiers of relationship and slots different partners into behaving in similar manners to others in the same tier.</p>
Black’s Legal Dictionary	
ARMA	
North American Legislation	
EU/MS Legislation	
Harmonized Guidelines	
Japanese Legislation	

Term	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 our guidelines for Paper Destruction, these unique cases are termed "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	Records are documents [or more generally, information] 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 documentary account of past events, usu. Designed to memorialize those events. 2. Information that is inscribed on a tangible medium or that, having been stored in an electronic or other medium, is retrievable in perceivable form. UCCD 5-102(a)(14). 3. The official report of the proceedings in a case, including the filed papers, a verbatim transcript of the trial or hearing (if any), and tangible exhibits.
ARMA	Recorded information, regardless of medium or characteristics, made or received by an organization in pursuance of legal obligations or in the transaction of business
North American Legislation	
EU/MS Legislation	Properties of Records according to EMA/INS/GCP/454280/2010 GCP Inspectors Working Group (GCP IWG) Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials: Accurate, Legible, Contemporaneous, Original, Attributable, Complete, 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	
ARMA	
North American Legislation	
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).  CHMP/ICH Guideline: Good Clinical Practice CPMP/ICH/135/95, Topic E6 (R1), Step 5, Jul-2002

Term	Source Document
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).
Japanese Legislation	

Term	Vital Record
Alternate Name(s)	
Definition	Records containing information required to re-establish or continue an organization in the event of a disaster; records containing unique and irreplaceable information necessary to recreate an organization's legal and financial position and preserve the rights of the organization and its employees, customers, shareholders and other constituent groups. Vital records include records whose informational value to the organization is so great, and the consequences of loss are so severe, that special protection is justified in order to reduce the risk of loss.
Black's Legal Dictionary	
ARMA	Records that are fundamental to the functioning of an organization and necessary to continue operations without delay under abnormal conditions  Source: Vital Records: Identifying, Managing, and Recovering Business-Critical Records (ANSI/ARMA 5-2003) [6].
North American Legislation	
EU/MS Legislation	
Harmonized Guidelines	
Japanese Legislation	



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