SCOPE Work Package 7
Quality Management Systems

Document and Records Management

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Contents

Acknowledgments

Authors

Zsuzsanna Szabóné Cserjés and Júlia Pallós

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1. Introduction

1.1 Purpose of the document

The purpose of this document is to provide definitions of document, record, document and records management, and to provide some examples in the field of regulatory work of pharmacovigilance according to laws applying in the European Union (EU).

1.2 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
AR	Assessment Report
CAPA	Corrective Action and Preventive Action
EMA	European Medicines Agency
ERMS	Electronic Records Management System
EU	European Union
EC	European Commission
GVP	Guideline on Good Pharmacovigilance Practices
IT	Information Technology
MS	Member State
NCA	National Competent Authority
PV	Pharmacovigilance
RMP	Risk Management Plan
RMS	Records Management System
QC	Quality Control
QM	Quality Manager
QMA	Quality Management Adviser
QMS	Quality Management System
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SOP	Standard Operating Procedure
WHO	World Health Organisation
WP	Work Package

1.3 Background

In the course of the survey for Work Package (WP) 7 Topic 1 – Understanding national quality systems, National Competent Authorities (NCAs) were asked to provide information on the records management and/or Information Technology (IT) systems used to create, store and evaluate pharmacovigilance (PV) data.

As highlighted in the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) survey report for WP7 Topic 1, from the responses of 26 Member States (MSs) given to questions on their document management policy and system including good examples, 30.8% of responding NCAs indicated that they did not have any electronic system in place. Half of the MSs indicated that their Agencies had a common unified document management system for the entire NCA which covered at least partially the handling of PV records. Approximately 27% of NCAs responded that they had stand-alone systems for some PV data, and one MS had a stand-alone system for all records.

On the basis of responses, NCAs are applying a variety of methods to manage incoming and newly generated PV documents. There are quite a few agencies with fully functional electronic document management systems including all PV data. The automated tracking system regarding PV data is uncommon. There are examples that ADR reports are handled in a separate system, or conversely, only Adverse Drug Reaction (ADR) reports are integrated in the common document management system of the Agency. It is also common that document management and tracking are performed on excel spreadsheets, registering incoming and outgoing documents and relevant steps of the procedure. Some NCAs indicated that they used both electronic and paper-based methods for document management, as electronic systems are not able to meet all needs, are incomplete or are under development.

Some discrepancies have been noted in relation to the use of the above concepts among the responding NCAs. Clear definitions with examples might facilitate the understanding and use of these very basic principles of document and records management.

1.4 Context and scope of the toolkit item

The responses to SCOPE WP7 survey regarding document and records management used by NCAs highlighted the need for knowledge of the basic principles, concepts and definitions in this area.

This document is written to give basic concept of document and records management, and to share experience of the NCAs in this field. As there are different document and Records Management Systems (RMSs) in place in the NCAs, there is no unified solution for all NCAs.

This document can be applied to all PV procedures whenever it is necessary to develop, apply or to rebuild the document management system of the PV activities at NCAs either as stand-alone system or integral part of the whole RMS of the NCA.

This tool may also be supporting material in an assessment of the document or record management system in place in a NCA in the field of PV.

2. Document and records management

Document and records management is one of the pillars of a quality management systems (QMS).

Document and records management should not be regarded as an end per se, not just so exists to comply with legal requirements, or fulfilment of claims of relevant guidelines, but it should be seen as in the interests of a NCA, as a NCA with good document and records management can benefit in several ways (e.g. improve agency memory, improve compliance of the agency with legislative requirements, enhance agency reputation). At the same time risks can arise from poor document or records management practice (e.g. it does not meet the requirements for confidentiality; a document or record containing confidential health information gets to an unauthorised person).

2.1 Document and record

The term document encompasses paper, electronic forms and files, emails, faxes, memos, photographs, recording, etc., everything that serves as evidence of proof. The documents of an organisation consist of information or data that can be structured or unstructured and can be accessed by authorised employees. Records are any of those documents that have been made final and are no longer meant to be altered.

A document is a work in progress and should be managed in a way for authorised users to capture or edit and easily distribute it. **A document is editable** and therefore does not necessarily have to adhere to government or other regulatory standards.

Records are completed documents and they should be managed in a way that is compliant with government and other regulations, such as e.g. agency guidelines or Standard Operating Procedures (SOPs). Because records usually contain highly sensitive information (e.g. a patients' health data) and cannot be recreated or editable, a backup storage system should be in place.

Documents are created by planning what needs to be done and records are created when something is done. Documents can change and records don't (must not) change.

For example: Signed reports or signed contracts are documents and also records. Personal notes or conference brochures are documents, but not records.

In other words **a document may become a record, but not all documents are records. At the same time all records are documents**.

The Business Dictionary defines the term record as follows: "All documented information, regardless of its characteristics, media, physical form, and the manner it is recorded or stored. Records include accounts, agreements, books, drawings, letters, magnetic/optical disks, memos, micrographics, etc. Generally speaking, records function as evidence of activities, whereas documents function as evidence of intentions."

Today a vast majority of documents and records are produced electronically, "born digital" (e.g. emails). Electronic records are those that require electronic devices in order to be created and used.

2.2 Document and records management – records lifecycle

Document management and records management obviously have a common part (as each record is a document) but records management has additional functions.

Document management involves the day-to-day capture, storage, modification and sharing of paper, digital files etc. within an organisation. Document management focuses on:

- Reducing lost and misfiled documents
- Providing faster search and retrieval of documents
- Helping to better organise existing documents
- Improving general work processes and organisational efficiency
- Reducing the amount of physical space used to store documents, such as filing cabinets.

Records management is the practice of maintaining records including the functions of document management described above and **also the following**:

- Identifying what records exist with a records inventory
- Classifying and storing existing records
- Applying required retention periods to stored records
- Identifying the owner of each record (series)
- Managing disposition (disposal of records)
- Developing and administering defined records policy and procedures
- Preserving records throughout their life cycle (e.g. permanent record are accessible and readable for years into the future)

Document and records management differ in three main aspects, in terms of:

- **Goal** (the purpose of each practice)
- **Information** (the content involved in each practice)
- **Methodology (the way each practice is performed)**

2.2.1 Goal

The goal of **document management** is **efficiency**, to handle documents in a way that enables them to be created, shared, organised, stored and retrieved efficiently and effectively (e.g. approving documents faster, automating recurring tasks if it is possible).

The goal of **records management** is **compliance**. A well-oiled RMS helps organisations to avoid penalties when regulators, auditors and other governing bodies come calling (e.g. clearly identify a person, or organisational unit of the organisation responsible for a record or record series).

Document and records management do **share a goal of business continuity**.

2.2.2 Information

The information of **document management** is comprised of **transient content** (e.g. older drafts are discarded, forms pass from submitter to reviewer, invoices are signed and then sent to the next approver, etc.)

The information of **records managemen**t is comprised of **historical content**. (e.g. status of a record is determined by different phases of the records lifecycle as shown below in the figure: create or receive, use and file, transfer and store, dispose, preserve/ archive or destroy).

Records lifecycle

At this point we need to introduce the term **records lifecycle**. This refers to the stages that every record must go through.

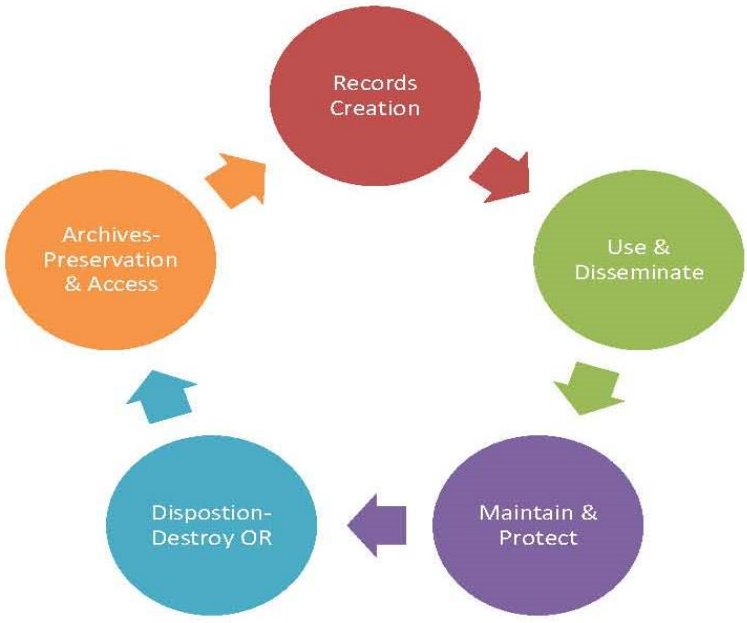

Figure 1. The records lifecycle
(https://slcoarchives.wordpress.com/2012/04/13/managing-records-now-for-the-future/)

When a record is created, it must be filed (in other words registered/entered) according to a well-defined, logical scheme into a managed repository (usually a system of folders with electronic files, which can be used e.g. on the organisation's intranet) where it will be available for authorised users. When the information contained in a record no longer has any immediate value, the record should be removed from active accessibility, archived or destroyed.

The records lifecycle has an **active** and an **inactive** phase, as can be seen in **Figure 2** below. The various drafts, versions and copies of active documents generated in active phase are documents. When they are consolidated into what is only essential for the purpose of compliance (this point is the beginning of the inactive phase), documents become records.

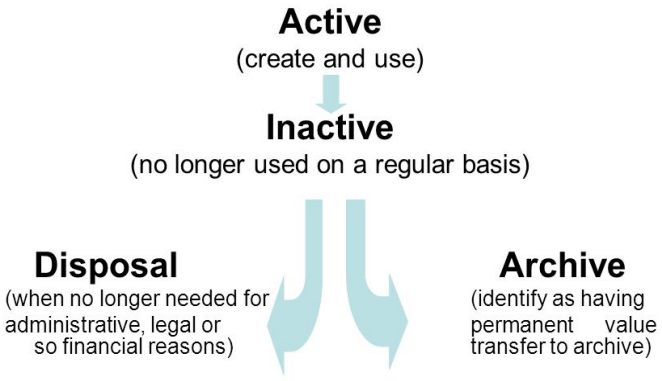

Figure 2. Active and inactive phases of the records lifecycle

When a record is created, some additional descriptive data are generated on the record itself, e.g. type of the record, owner's name of the record. These data are called **metadata**.[1]

2.2.3 Methodology

The methodology of **document management** is **content-driven**. Thus, the document repositories are usually organised with the needs of general users in mind: finding documents by keyword or title, keeping all documents together e.g. by topic, employee or project.

The methodology of **records management** is **context-driven**. Retention schedules are the catalyst for records-related activity, as different types of records must be kept for different lengths of time and under different conditions.

[1] **Metadata** describes other data. The shortest definition for the term is "data about data" (e.g. summary of the contents of a library or archive, like card catalogue, contain metadata).

2.3 Paper based Records Management System (RMS) versus Electronic Records Management System (ERMS)

Organisations may have a well maintained paper records system but this is not necessarily appropriate as a template for managing electronic records. This is because of the volume of electronic records, and variety of file formats, combined with the ease of creation. Electronic records management needs however, to be very carefully considered and structured to ensure that the integrity of the records are not compromised upon capture and remain retrievable for as long as they are required.

Can we achieve record management without Electronic Record Management Systems (ERMSs)? The answer is 'Yes'. At the same time, unlike physical records (e.g. paper records), electronic records cannot be managed without a computer, but can be managed without an ERMS.

An ERMS is a computer program or set of programs used to manage electronic records stored in an associated database. It provides a variety of functions including access controls, auditing and also disposal using a combination of system and user generated metadata. Records management software is a computer program used to track and store records. Records management applications commonly provide specialised security and auditing functionalities.

2.4 Compliance with laws applying to EU

"For performing their PV activities, marketing authorisation holders, NCAs of MSs shall establish and use quality systems that are adequate and effective for this performance." (IR 520/2012, Art 8(1)) [21].

The minimum requirements of these quality systems are set out in the Commission Implementing Regulation (EU) No 520/2012 on the Performance of PV Activities Provided for in Regulation European Commission (EC) No 726/2004 and Directive 2001/83/EC.

Minimum requirements of the quality system include, among others, record management and documentation (IR 520/2012, Art 8(2)).

"All elements, requirements and provisions adopted for the quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality plans, quality manuals and quality records." (IR 520/2012 Art 8(4)). "The national competent authorities and the Agency shall record all PV information and ensure that it is handled and stored so as to allow for accurate reporting, interpretation and verification of that information." "They shall put in place a record management system for all documents used for PV activities that ensures the retrievability of those documents as well as the traceability of the measures taken to investigate safety concerns, of the timelines for those investigations and the decisions on safety concerns, including their date and decision-making process." (IR 520/2012 Art 16(1)).

2.5 Record management and documentation of quality systems according to GVP Module 1

The Guideline on Good Pharmacovigilance Practices (GVP) Module 1 –Pharmacovigilance systems and their quality systems (EMA/541760/2011, I.B.10.) lists the main broad activities which have to be supported by a record management system:

- The management of the quality of PV data, including their completeness, accuracy and integrity
- Timely access to all records
- Effective internal and external communication
- The retention of documents relating to the PV systems and the conduct of PV for individual medicine products, in accordance with the applicable retention periods.

The guidance on quality systems and within the record management of this Module is consistent with the general principles of the ISO 9001:2008 Standards on quality management systems, issued by the International Organisation for Standardisation (ISO). The new version, ISO 9001:2015 also applies to the records lifecycle strategy but the term “record” is replaced by “documented information”.

Quality record

The GVP Module 1 – Pharmacovigilance systems and their quality systems (EMA/541760/2011, I.B.11.) refers to a quality record as “**a document stating results or providing evidence of activities performed**”.

The quality system shall be documented by the following documents:

- Documents on organisational structures and assignments of tasks to personnel
- Training plans and records
- Instructions for the compliance management processes
- Appropriate instructions on the processes to be used in case of urgency including business continuity

Records management policy

The guideline recommends that the documentation of a quality system shall include (among others) the records management policy too. At the same time the guideline does not contain any additional information on what kinds of information the documentation shall contain on this.

2.6 Minimum requirements according to Commission Implementing Regulation

Minimum requirements regarding records management and documentation of PV quality systems (according to Commission Implementing Regulation (EU) No 520/2012 on the Performance of PV Activities Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC) include the use of a suitable RMS which is able to handle all important PV information, according to the lifecycle concept of records management: to create, use, store, archive/destroy records. These activities related with RMSs shall be recorded, that is NCAs have to produce written procedures (such as Standard Operating Procedures (SOPs)) in the form of appropriate rules for all PV processes, and their connections. These written rules have to be in accordance with the PV guideline and Commission Implementing Regulation in force at the time. The RMS implemented by a NCA has to be able to support accurate reporting, interpretation and verification of that information. The implemented RMS has to ensure accessibility, retrievability, and traceability of those safety parameters (saved in PV records) which are necessary for investigation on safety concerns and decision-making processes.

3. Examples

In this section some examples obtained from three NCAs (HR, BG and NL) are presented in order to demonstrate how to:

- Regulate the steps of document management on content quality within the system of a NCA (Example 1, HR)
- Define the main activities on documents in connection to quality management (Example 2, HR)
- Organise and structure the main decision steps/phases of document management in an Agency (Example 3, HR)
- Manage giving a unique code and appropriate level of secrecy to each document (Example 4, HR)
- Distribute documents on quality contents to the right persons inside the Agency (Example 5, HR)
- Store documents on a quality system (Example 6, HR)
- Terminate (destroy) or archive a document (Example 7, HR)
- Keep the register on approved quality documents in electronic form (Example 8, HR)
- Create, store and archive documents and records related to PV and clinical trials according to the relevant SOPs of a NCA (Example 9, BG)
- Handle and share ADR and signal reports using a knowledge management system for signal screening and for tracking signal detection activities (Example 10, NL).

The above examples cannot be considered as the best practices in the EU, but only as examples which are put in place in one of the NCAs of the EU, and which work with satisfactory results in complying with the relevant European and national laws. The majority of examples relate to document management (Example 1 – 8). In the last but one example (Example 9) the main steps and related to practical definitions of a document and RMS put in place is shown. In the last example (Example 10) the usage of an E2B compatible tracking system and database in the field of PV is described.

Example 1 (HR)

How to regulate the steps of document management on content quality within the system of a NCA?

Generally:

To regulate the steps of document management on content quality within the system of the Agency in order to ensure the application of relevant steps only, along with task specifications which are already approved and confirmed, coded and accessible to employees who should apply them. At the same time the old versions of the documents are removed.

Note: This example gives a high level description of document management at the Agency, which gives very important, but only general intentions.

Example 2 (HR)

How to define the main activities on documents in connection to quality management?

Documents on quality contents, which are to be applied when managing documents, are documents which can be found in range of quality defining the outlooks and contents (regulations of quality, standard operative steps general steps, task directions, analytical steps, validation steps, controllers, books on equipment and supply, forms, reports) and certain external documents which are stored in the Agency.

Overview of documents on quality means reviewing the adequacy of documents as to whether they answer the requirements of the quality criteria (technical and professional).

Approval of the documents on contents is a procedure of approving and accepting the same.

Revision means regular, fore-planned procedure of correction, improvement or adjustment of documents on quality contents.

Withdrawal of documents means entire seizure of documents on contents quality from practice after it has been stated that it is no longer necessary.

Note: In this example the term “certain external documents” should be specified.

Example 3 (HR)

How to organise and structure the main decision steps/phases of document management in an Agency?

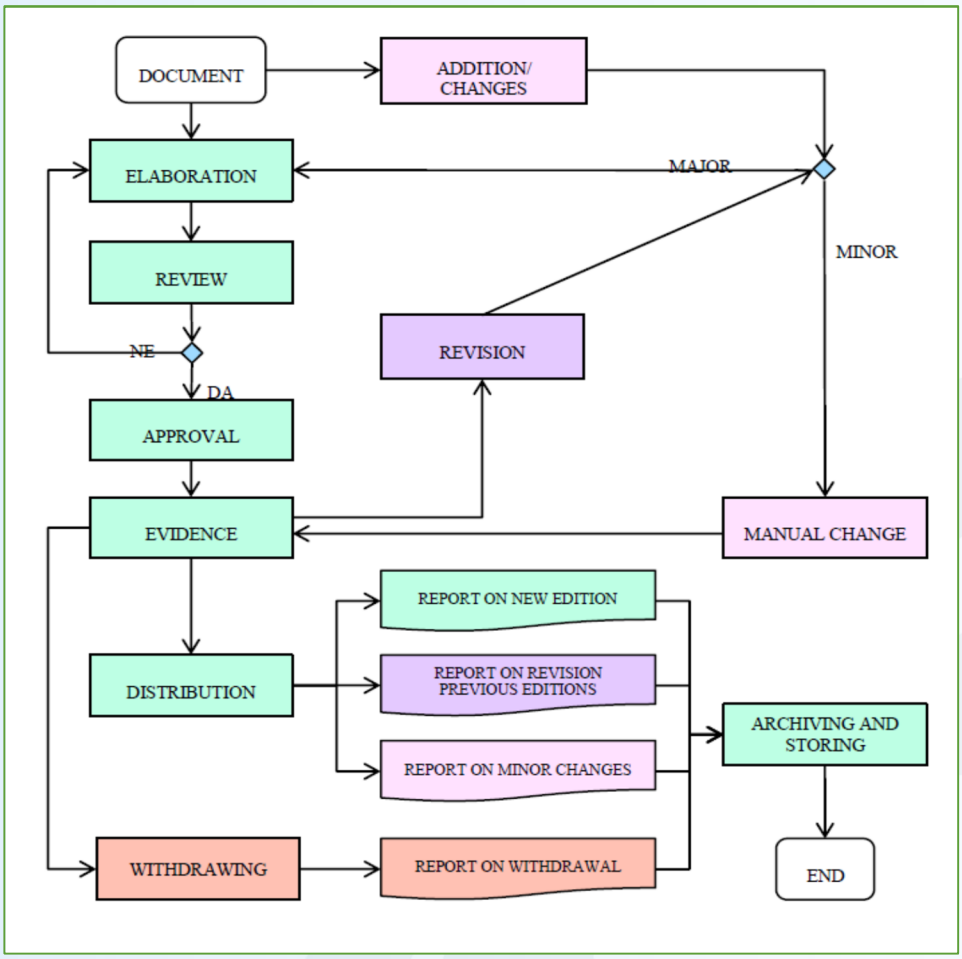

Figure 3. Diagram of procedure flow of managing documents on quality at an NCA (HR)
Note: Notations in the flowchart: DA – Yes, NE: No.

This example shows the main steps of document management at the NCA.

Meaning the terms of document, overview, approval, revision and withdrawal see the previous example (Example 2).

Two checking points are involved in the process: The first one is performed after review of the document (if the content or quality of the document is not satisfactory, the elaboration and review steps are repeated until the document can be approved. The second checkpoint is performed after the steps of 'approval' and 'evidence'. In this step the document may become evidence (and thus a record), if a major issue does not occur in connection with the document (see 'revision', 'major and 'minor signs in the figure). In case of a major issue(s) the document is sent back to the 'elaboration' phase.

Example 4 (HR)

How to manage giving a unique code and appropriate level of secrecy for each document?

Coding: The Quality Management Adviser (QMA) gives a code to each document on quality contents in accordance with the procedure steps specified in the Agency's' SOP titled "Coding documents on quality contents".

Codes for Business Secret documents: QMA completes coding documents with signs "Business Secret", in accordance with the regulated procedure specified in the Agency's' "Business Secret" SOP, by the Agency's Statutory for medicines and medical products, as well as by the regulations on data protection and business secrets. The sign should be obvious on each page of the document (in both paper and electronic form). For instance, the standard operative steps related to analytical procedures or producer are classified as business secrets.

Note: This and the next 4 examples below, show that the agency has a QMA. This is not obviously the case for each NCAs.

Example 5 (HR)

How to distribute documents on quality contents to the right persons inside the Agency?

Distribution of documents on quality contents is provided **by electronic mail** and there is one member of the Quality Management Office who sends the report to the other members whose names are included in a specific list of the Agency. The form of text is specified in a document which has to be sent by email.

The text of the message which is sent, as well as the list of addresses to which the message has been forwarded, are to be signed by the QMA, and after that he/she arranges archiving and storage of the same within the register of "Originals of quality contents documents". The list of email addresses is used as proof of sending and of distributing the information. It is allowed that a sent message is deleted in pdf format together with its electronic signature, and that the storage of documents in the file are to be stored under a special domain and following that, a link should be put alongside the document on the list of valid SOPs.

Example 6 (HR)

How to store documents on the quality system?

Storage period: The documents on quality systems must be kept for a while even after their termination (expiration) or change into new ones, in accordance with the following:

- Documents in paper forms:
  - Quality regulations: for 5 years
  - Standard operative steps/work processes: for 5 years
- Documents stored on electronic media:
  - Quality regulations: permanently
  - Standard operative steps/work processes: permanently

After the storage period expires, the documents should be eradicated by paper exterminator or other appropriate ways. The extermination of documents on quality is arranged by the responsible QMA in cooperation with the Manager of Department of Archives and Project Developments.

Storing safety: The originals of the documents on quality are placed in the registers in temporary storage of the Quality Management Department. Access to the original documents on quality contents is allowed only to the members of the Quality Management Branch.

The Manager of Department of Information is obliged to secure a special kind of program support for storage of these types of documents so that they are always and permanently accessible and stored on that electronic media.

The Manager of Information Branch arranges the elaboration and maintenance of security contents for documents on quality in electronic form.

Example 7 (HR)

How to terminate a document?

If the quality document has expired (e.g. the equipment is culled, and the SOPs related to that equipment are not applicable any longer, or if the work process is abandoned), the branch manager who is responsible for the revision of that certain document should suggest that the branch manager terminates it. After this, the branch manager sends a suggestion on termination of SOP to the QMA via email in which he/she reports the name and the code of the SOP which is to be terminated, as well as the reason for it. Following the decision on document termination the QMA proceeds with the steps specified and sends a report on termination of the SOP via email to the members whose area of activities are related to that SOP and arranges steps for storing the confirmation letter on sending the report.

Example 8 (HR)

How to keep the register on approved quality documents in electronic form?

The QMA is responsible for keeping the register on approved quality documents in electronic form on the internet (network) of the Agency on a special domain, which is continually accessible to the members of the Agency.

The following parameters have to be entered (see the table below):

- Code
- Name of the document
- Date of issue
- Date of coming into force
- Date of planned revision
- Links for.pdf and word versions of the document/s
- Links for signed information material on the issue
- Links for supporting forms

Code	Name of document	Issue	Valid from	Revision	PDF-SOP	Word version of last edition	Informing date	Form

Example 9 (BG):

How is the records management performed at a NCA (how the term document is defined in the practice of the NCA and how records are created, used and archived according to the relevant SOPs, how long are retention periods of different types of deeds)?

Document: that contains results for activity or represents an evidence of performed activities.

Deed is defined as a set of linked documents associated by content, type, author, place and history. One deed consists only from documents of the same retention period of up to 250 sheets in each folder. One deed can contain only one document also.

SOP of records management connected with quality system: determines the scope, sequence, responsibilities and actions undertaken to create, identify, archive and destroy records

Creation of records: The records are developed in implemented forms to the corresponding SOPs. Records can also be prepared in free form.

The records are created according to inner rules for mandatory requisites:

- Upper header: logo of the NCA
- Footer: document identification, contact information, checkboxes to point to the category of the document (confidential, internal restricted use, internal common use and accessible to all).

Records are created on hard or electronic carriers.

Record management documents at the NCA are the following:

- Plans and audit reports
- Reports of non-conformities
- Inspections reports
- Assessments of documents
- Protocols from management reviews
- CAPA records
- Registries and lists created according to the quality manual, procedures
- Calibration certificates
- Documents for training of the personnel and training plans
- Survey cards and complaints
- Analytical protocols
- Records from assessment of the suppliers

Requirements for paper hardcopy records:

- Available name, date and signature of the creator of the record
- Pointed category of the document
- Records must be readable, clear, easy to identify, renewable, achieved so that records are secured from damage and loss
- Records can be created both in the national language and English
- Corrections are done in a way that the previous data in the record should be visible
- Records are identified by:
  - Name of the NCA
  - Serial number from the front office
  - Type and name of the document
  - Names and signatures of the officials that created or approved the document

Retention period, archiving: Documents created by the activities of the NCA have important historical, practical and referential importance that need to be classified into archival deeds.

The nomenclature represents a systematic list of NCA documents with certain retention periods arranged in sections according to the classification scheme based on structural and functional principle. Sections of the classification scheme are consistent with the structural parts of the NCA and the activities carried out by them.

The nomenclature is made in accordance with Article 43 of the Law on National Archive Fund (SG No. 101/2010) and Art. 40 of the Regulation for organising, processing, examination, storage and use of documents in the institutional archives of the state and municipal institutions.

Retention periods of deeds in the nomenclature are determined by the value of individual documents contained in them.

Types of deadlines are the following:

- **Permanent archive**: Documents with status "P" are of important scientific and historical reference value. These deeds, after expiry of the 20 year shelf life, according to Article 46 of the Law on National Archive Fund, are transferred for permanent archive in the Central State Archive.
- **Temporary retention**: The works that have only temporary operational and/or referential importance are determined with retention period of 1, 3, 5, 10 and 15 years. These cases are destroyed after their retention time according the rules of the Law on National Archive Fund.
- **Long-term retention**: Deeds with longer practical-referential significance are determined with a retention period of 20 or 50 years. They remain deposited in the archives of the office until the expiry of their terms and then are destroyed under the Law on National Archive Fund.
- **Prolongation of retention period by Expert Committee (EC)**: Deeds marked for Expert Committee after the expiry of the determined time in nomenclature are reviewed by an Expert Committee at the NCA, which assessed the documents with important scientific and historical and practical significance. The documents that are designated as valuable are removed from the cases and are in new deeds for permanent preservation. The other documents are destroyed.

The documents in the scope of the National Archive Fund can be transferred from electronic to hard copy carrier and stored on paper with relevant authentication.

In the nomenclature of the deeds and retention periods the following cases are included regarding the PV and clinical trials department of the NCA:

Index	Name of the case	Retention period (year)
D-01	Clinical trial dossier (application, correspondence, reports, notification, permission or refusal significant change closure declaration)	15*
D-02	Investigator's Brochure	15
D-03	Correspondence in the scope of received suspected unexpected serious adverse reactions in clinical trials, information on ADRs, statements, records, attendance sheets from committee when combined signals quality problem/ADRs are reviewed correspondence with the Ministry of Health and Regional health inspectorates.	P
D-04	Periodic safety update reports (post-marketing), responds to inquiries made by the MAH results from the procedure of PSUR assessment	5
D-05	Materials from the training	3
D-06	Reports from signal detection opinions regarding causal relationship of the ADR/INN, data monitoring (literature, world databases) etc.	P
D-07	Notifications of European and local qualified persons pharmacovigilance	5
D-08	Documents for creating, changing the composition and functioning of the local PRAC	P
D-09	Legal documents, correspondence, reports of money spent and funds for the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) project	10**
D-10	Approved texts, safety manuals, instructions, information on administrative services provided by PhV department to the public	5
D-11	Rapid alert and Non Urgent information	5
D-12	RMP updates	5
D-13	Materials received from MAH with demands for approval of information related to the safety of a medicinal product (DHPC, OM)	15
D-14	Correspondence in the scope of received inquiries from patients, consumers, health professionals, regional health inspectorates, other agencies and institutions	5

*P: permanent, *: at NCA or remote archive site, **: after official end of the project*

Note: Each NCA has to fulfil not only the European but also the requirements of national legislation regarding the document and records management in the field of PV activities.

Example 10 (NL)

How to use and maintain an E2B compatible tracking system and database in the field of PV?

The foundation (which collects and analyses reports of adverse reactions of medicines and vaccine, works independently and transfers ADR and signal reports to the Medicines Evaluation Board of the Ministry of Health, sends anonymous copies of the reports to the European Medicines Agency and the World Health Organisation (WHO), uses a custom developed, E2B compatible tracking system and database. An external IT company is responsible for maintaining and developing the database of the Agency (outsourced – service level agreement). The co-workers are satisfied with their IT system, there is a wish list for the continuous development of the system.

Another application (knowledge management system) is used for signal screening and tracking signal detection activities. IT systems allow for some indicators to be checked regularly, e.g. 15-day reporting timeline for serious cases, 3-week processing timeline for non-serious cases (internal deadline).

The tracking system also includes an automatic duplicate checking algorithm based on sex, age, birthdate, drugs. Potential duplicate hits need manual confirmation later on.

The tracking system checks the status of the report. When it is set to stable the report is sent automatically to EMA/WHO (continuous screening of record status). Compliance with EV business rules is automatically checked. Time log: recording what is sent to whom and when. The IT systems are continuously improved within responsible working groups (topics e.g. causality, follow-up, etc.)

4. Summary and conclusions

This toolkit item intended to give basic definitions regarding document management and record management generally (first 2 sections of this document) and in connection with PV activities too (third section of this document). The NCAs shall put in place a record management system, which should handle all documents used during PV activities according to the EU legal requirements in force. As there is no unique solution on how to put in place a suitable RMS which takes into consideration specific conditions (mainly human and financial) of each NCA, minimum requirements regarding document management and record management were given based on claims of the PV guideline in force.

Examples were presented in order to share experience of the NCAs in the field of RM. This tool may be supporting material in assessments of the document and record management system in place in a NCA in the field of PV.

This document can be applied to all PV procedures whenever it is necessary to develop, apply, expand, or rebuild the RMS of PV activities at NCAs.

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