



# ***Roche Group Records Management Directive V2.0***

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## Document Information

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## 1. Purpose

Roche will ensure all records created or received in the course of its business are managed in compliance with any regulatory or other legal obligations to which it is subject. The Directive<sup>1</sup> establishes the corporate wide standards and responsibilities for the creation, management, and final disposal of Roche Records, irrespective of their format. This Directive is designed to ensure that Roche complies with internal Code of Conduct expectations; fulfils external regulatory and legal requirements in regards to retention of business evidence including availability of business relevant information; and has a consistent global approach to Records Management ("RM").

## 2. Scope

This Directive applies to all employees and contractors (collectively for purposes of this Directive "employees") in all Roche legal entities, and global functions and business units. Where third party organizations manage Roche Records, the Roche employee responsible for the relationship with the third party should ensure that Roche Records are treated in a manner consistent with this Directive.

Specific standards will further clarify requirements and responsibilities. If an employee is unsure about the interpretation of this Directive, employees should consult with their Records Management Coordinator or the Corporate Records Management (COREMAP) Team.

## 3. General Requirements

All Roche employees who create, receive, or maintain records of any type are responsible for understanding and complying with this Directive and all other relevant Records Management Procedures. All individual Roche employees are responsible for managing Records within their control from creation or receipt through disposal according to this Directive.

The following general requirements must be complied with:

### 3.1. Ownership

Roche is the exclusive owner of all Records that are created, received, or maintained in the course of business (subject to third party rights). Roche Records do not belong to individual Roche employees.

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<sup>1</sup> The definitions of terms used in this Directive are provided in COREMAP Glossary of Records Management Terms. Terms defined in the Glossary are used with Initial Capitals in the Directive.

All Records and/or Record Collections must have a designated Roche custodian who is knowledgeable about the records and takes responsibility for their management in accordance with this Directive and applicable RM procedures. The custodian is designated the Record Owner within Roche and is initially the Record creator or first Roche recipient. However, over the lifecycle of a Record, the Record Owner may change for business reasons or due to personnel and/or organizational changes. Management is responsible for formally transferring ownership of Records between individuals and/or functions.

### **3.2. Confidentiality and Restricted Access**

Roche employees must maintain the confidentiality of proprietary and sensitive company information in line with Group Directive K 19, as well as personal data requiring privacy protection. Internal access to Records shall be limited to those persons needing access as determined by the business. Some Roche functions, such as Legal, Tax, Audit, and Compliance, may require access to all Records and must follow all applicable local policies and procedures for access approval. To facilitate compliance with applicable regulations, some Roche functions may follow an agreed security classification for specific Official Records.

Third-party access to Roche Records shall be limited to such access as is necessary for the business and should be protected and managed under an appropriate Non-Disclosure Agreement or other contract that describes the obligations of the third-party related to the confidentiality, management, retention, and disposal of Roche Information.

## **4. Types of Records**

### **4.1. Official Records**

Official Records are listed in the Group Records Classification, grouped by record series/retention groups. They belong to Roche and must be accessible independent of the availability of the original creator.

To standardize retention requirements Roche categorizes Official Records into two main groups:

- for business purposes
- for regulatory and long-term preservation purposes (including those having a global impact).

### **4.2. Convenience Records**

Convenience Records should only be kept as long as they are currently in use with a maximum retention period of three years after last modified. All employees have a responsibility to minimize the number of Convenience Records they keep, whether electronically or on paper or another media. In particular, the fewest number of copies of Convenience Records consistent with operational effectiveness should be created and retained. A Convenience Record that is subject to a Legal Hold cannot be destroyed or altered. Roche will usually apply automatic deletion rules on electronic Convenience storage areas upon expiry of the retention period.

### **4.3. Transient Records**

Transient Records are of an ephemeral nature and should be retained for no longer than the periods recommended in the Roche guideline 'Transient Records Retention List'. Roche will usually apply automatic deletion rules on transient storage areas where such records are generated and where it is technically possible to achieve this.

### **4.4. Electronic Mail**

Electronic Mail (E-Mail) should be regularly reviewed and disposed in accordance with the principles within this Directive and in accordance with the Global Roche E-Mail Directive or local policies implementing the Directive, where applicable. The Roche E-Mail system is primarily a system for communication and not document storage. As such, mailboxes are subject to automatic deletion rules. Where Official Records are created or received as E-mails, they should be identified and transferred to an appropriate document repository.

## **5. Creation, Management, and Disposal of Roche Records**

### **5.1. Record Creation**

The content, style and distribution of Records must be considered carefully when creating Records as the impact throughout the life of the Record may be wider than originally intended. In particular, Record creators should:

- Decide whether it is necessary to create a Record, and be prepared to manage the Record as a Record Owner.
- Avoid creating content that violates laws, including tax, competition and anti-discrimination laws.
- Avoid misleading and suggestive wording and avoid undue exaggeration or inappropriate characterizations.
- Consider carefully whether the Record requires signature(s), the intent of the signature(s) and whether the signature(s) should be captured using accepted electronic methods.
- Ensure that an appropriate system of version control is used to control Official Records. Such a system should be documented (e.g. in a Policy or Procedure), should clearly differentiate draft Records from final Records and should allow for different versions of the same Record (draft and final) to be distinguished from each other.
- Distribute the Records only as needed, avoiding unnecessary copies and maintaining the confidentiality of sensitive and/or personal information.

## 5.2. Record Storage

Official Records must be stored in a way that ensures the reliability, authenticity, usability, integrity and confidentiality during the entire lifecycle. Consideration should be given to determine if these characteristics can be better preserved if the Record is retained as a physical Record or an electronic Record. Official Records which are no longer needed for operational reasons, but must continue to be retained in accordance with local retention policies, should be transferred to a physical or electronic Archive. Archives for Global Impact Records should be managed by a trained archivist, or contracted to an external archive service provider meeting Roche standards<sup>2</sup>.

Roche employees managing external archives (including electronic archives) should ensure that these facilities comply with relevant standards and procedures for the type of Records stored.

- **Electronic Records and Electronic Record Stores**

Electronic Records must be managed in accordance with the requirements described in the Roche 'Standard for the Management and Retention of Electronic Records'. If Official Records are held in an electronic system, the Record/Data Owner must ensure that the system is suitable, and in particular that the input, access control, backup, metadata, and retrieval and deletion capabilities are suitable. This should be verified with the Solution Owner, if necessary. The Record/Data Owner should carry out regular checks on the integrity and usability of the data.

True and accurate digital image copies of paper Records may be retained in lieu of original wet-ink signed Records and wet-ink signed Records may be disposed where not expressly prohibited by local law (see Position Paper – 'Destruction of Original Paper Records'). In case both co-exist the Record with wet ink information (e.g. signatures or stamps) is considered the Official Record. All other copies should be treated as Convenience Records and should be disposed when no longer operationally needed unless subject to a Legal Hold.

For multiple copies of electronic Records, the Record/Data Owner should decide which is regarded as the Official Record. In the case of digitally signed Records the Official Record is the one carrying Trusted Signature information.

- **Physical Records and Physical Record Stores**

If Official Records are held in a physical storage facility, the Records Management Coordinator and Record Owner must ensure that it is suitable for the type of Record, checking with the archivist and/manager of the storage facility, if necessary. The Record Owner must ensure that access control, metadata, and retrieval and disposal capabilities are suitable. Global Impact Records must be stored in accordance with the requirements described in the Roche 'Standard for the Management and Retention of Physical Records'.

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<sup>2</sup> Standard for the Management and Retention of Physical Records at Roche  
Standard for the Management and Retention of Electronic Records at Roche



### 5.3. Retention Schedules

Official Records shall be retained in accordance with local, national and international recordkeeping laws and regulations, as well as site and global business requirements. Roche maintains a Group Records Classification identifying Official Records retained by the Company. Affiliates shall use the Group Records Classification as a reference for developing binding local Retention Schedules. The local Retention Schedule may be implemented as part of site inventories.

Where records have a potential global impact (designated as Global Impact Records in the Group Records Classification) the minimum retention periods are globally binding. For Records needed to be retained for local business or local legal reasons only (designated as Local Impact Records in the group classification), the minimum retention period is advisory only. The Retention Period defined in local retention schedules must comply with local business, legal and regulatory requirements.

Records are classified into Record Series, with each Record Series having an archive trigger event and a Retention Period following the trigger event. To simplify retention and disposition, Record Series are also organized into Retention Groups. However, it is often not practical to manage the retention of Records as individual Record Series and for this reason, Record Series are organized in the group classification into Retention Groups. Where Records are managed in Retention Groups, they are typically migrated in bulk into the designated archive solution and subsequently disposed of in bulk according to the Retention Period that is applicable to the Retention Group, based on either the date of ingestion into the designated archive or the date the group of Records is finalized, whichever trigger can be more consistently applied. It is understood that when Records are managed in Retention Groups, the Retention Period may exceed that of the constituent Record Series.

The group classification will be reviewed every two years by COREMAP. Where these reviews result in a change in Retention Period, the change will be reviewed for inclusion in local retention schedules. Any change of Retention Period will be applied prospectively.

### 5.4. Disposing of Records

Official Records should be disposed of when specified in the applicable Retention Schedule and Convenience Records when no longer required but no later than three years after the last modified date. Some specific Records (e.g. Records showing Personally Identifiable Information (PII)) must be disposed of immediately following its intended purpose or use. Routine disposal must be suspended where there are current relevant Legal Holds and for Records required for the Historical Archive.

With the exception of Global Impact Records, the disposal of Records following expiry of the Retention Period does not generally require specific approval if there is assurance that no Legal Holds are applicable. In the case of electronic Records, deletion may be automated following expiry of the Retention Period and subject to no Legal Holds being applicable. Global Impact Records will require documented approval prior to disposal.

The disposal should be carried out securely, either on a Roche site or externally, in a manner consistent with the confidentiality level of the Record. Evidence of the disposal of Global Impact Records is required, for example completion of a certificate of destruction. Sites/Departments should perform clean-up days at least annually to ensure appropriate time and resources is made available for the disposal of Records.

Official Records with multiple retention periods interfiled, e.g. within database applications may be retained for the longest retention period of the records held within the system if no reasonable process exists to segregate and dispose the records with shorter retention periods or if the application has limited ability to dispose of records. In these instances, disposal of records may occur in regular intervals (e.g. for business purpose records 10 years after declaration), at system decommissioning, or when system updates allow for the efficient and trustworthy disposing of records. Any hardcopy or electronic files stored outside of these systems but supporting these records should still be disposed according to the Retention Schedule.

## **6. Special Control Situations**

### **6.1. Legal Holds**

A Legal Hold (also known as Law/Litigation Hold or Order of Suspension) occurs when it is necessary to stop all disposing of Records related to the subject matter of a current or anticipated litigation, legal dispute, investigation and/or audit. Legal Holds are issued by the Legal Department. All Records, whether Official Records, Convenience Records, Active Records or Inactive Records, whether paper or electronic, falling within the scope of a Legal Hold must be retained, even if, under the applicable Retention Schedule, the Record would or could otherwise be disposed of. The Legal Department will decide when a Legal Hold is required and inform impacted employees. If there is any question whether a Record falls within the scope of a Legal Hold, the employee should immediately contact the Legal Department prior to disposing of any such Record.

Impacted employees must immediately:

- Identify and take steps to safeguard all potentially relevant Records of any type, including Convenience Records and handwritten notes.
- Ensure that relevant Records are not disposed of until the Legal Hold is lifted.

The Legal Department will lift the Legal Hold when no longer needed and will inform relevant employees. Normal retention and disposal should then resume.

### **6.2. Historical Archive**

The Roche Historical Collection and Archive is a collection of objects and Records of historical importance to the Roche Group. Any Records (or other materials) which could be considered of historic value should not be disposed at the end of their retention period, but should instead be provided to the Roche Historical Collection and Archive or local historical collection if applicable for evaluation.

### **6.3. In-licensing, Out-licensing, Divestments and Acquisitions**

Where Records are introduced into Roche from external sources, such as occurs in a product, company or technology acquisition or an in-licensing contract, the Records to be acquired should be evaluated as part of the Due Diligence process. An evaluation and risk assessment of the Records brought into the company should be carried out by the acquiring

team in consultation with COREMAP and a decision made on what should be retained, where and how it should be stored, and how it should be classified.

In the case of a site or department closure, a divestment or an out-licensing contract, the deployment of the Records involved should be reviewed by the responsible business team. Continuous records ownership must be ensured for those Records remaining in the company. The COREMAP Team should be consulted if ownership cannot be established.

### 6.4. Audit

Departments or Sites may be monitored and audited for their compliance with this Directive by the COREMAP Team. Standard checks for RM compliance will also be part of regular audits conducted by the Group Audit and Risk Advisory Team.

## 7. Roles / Responsibilities

### 7.1. Corporate Records Management (COREMAP) Team

The COREMAP Team will maintain the Corporate Records Management Program consistent with this Directive. The Records Management Program will include, but not be limited to:

- Development and maintenance of a governance framework consisting of the following elements:
  - Policy guidelines in the form of a Records Management Directive;
  - Group Records Classification organised on a function and activity basis, consistent with the principles of ISO-15489-1<sup>3</sup>;
  - Standards applicable to physical and electronic records;
  - Any other required position papers, instructions, and clarifications in the area of records management and information governance
- Dissemination throughout Roche of the governance framework elements;
- Coordination and training of Records Management Coordinators with governance and operational responsibilities in their respective entities;
- Awareness of all employees about record management and information governance related requirements and obligations;
- High-level oversight on where important assets are stored including oversight of companywide systems dedicated to the management of records long-term;
- Monitoring of compliance with records management requirements, reviewing and revising policies, guidelines and training in the light of monitoring outcomes.

The COREMAP team also:

- Reviews and approves exceptions to Records retention and disposal procedures;
- Provides RM consultation to IT responsible and Solution Owners in the identification and management of IT systems and tools for Records Management and archiving;
- Selects external archive and information governance service providers;
- Approves records ingest into global electronic retention systems/electronic archives;

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<sup>3</sup> ISO-15489-1: Information and Documentation – Records Management

- Takes on ownership for Official Records requiring further retention where no owner can be established.

### **7.2. Function/Site Heads**

Function/Site Heads are accountable for the protection and availability of the Vital Records in their respective areas and for compliance with this Directive. To achieve this, they must implement local RM procedures consistent with this Directive and appoint Function/Site Records Management Coordinators (RMCs). The Function/Site Head is responsible for ensuring that RMCs receive necessary training and are assessed in their role.

Together with Departmental/Site RMCs, Departmental/Site Heads must ensure that staff is aware of, trained in and follow global and local RM procedures, including Legal Holds. They should promote good RM practice and ensure that time is scheduled for regular disposal of Records that are not required on at least an annual basis.

### **7.3. Records Management Coordinators**

Records Management Coordinators (RMCs) have governance or operational responsibilities in order to ensure alignment with this global Directive. RMCs are the link between local and functional units and the COREMAP Team. They also function as a source of local education and training and give advice locally on best practice. They establish controls to identify, locate and manage Official Records and ensure local inventories and local Retention Schedules are in place. Their specific responsibilities include:

- Set-up and maintenance of local/function RM policies and procedures
- Set-up and maintenance of local inventories and associated retention times
- Monitor records management and ensure compliance with applicable laws and regulations for the function/sitePerform RM awareness activities and clean-up events

### **7.4. Line Managers**

It is the responsibility of the Line Managers to ensure that employees are following all applicable records management procedures. It is the role of the Line Manager to ensure that Official Records under the ownership of employees are transferred and secured in case of role changes or departure from the Company.

### **7.5. Record Owners**

Official Records must have a person responsible for them, known as the Record Owner.

The Record Owner must:

- Ensure Official Records are maintained and correctly stored with appropriate metadata (in a specified location while the Record is active, and once the Record is inactive, in a compliant storage facility, e.g. archive), to protect the reliability, authenticity, usability, integrity and confidentiality of the Record;

- Ensure controls to identify, locate and manage their Records, including the application of agreed version control procedures for Official Records;
- Ensure Official Records are correctly disposed of at the end of their retention period;
- Ensure Convenience Records are disposed of when they are no longer needed;
- Authorize access to the Records as appropriate; and
- Transfer ownership as appropriate.

In addition, Records Owners of Electronic Records must

- Ensure that the IT system or facility in which their Records are stored is appropriate for their Records in terms of security, record integrity and backup;
- Ensure that the Records are stored in appropriate formats allowing for long-term usability; and
- Ensure periodical checks of the usability of their Records and planning for migration as necessary.