

Guidance for

Date Conventions

Approval Date 15-FEB-2017

This document is freely distributable

Identification

**Authors**

|  |  |  |
| --- | --- | --- |
| **Name** | **Organization** | **Title** |
| Melissa Maberry | PRA Health Sciences | Senior Director, Document Management – TMF Process Owner |

**Contributing Team Members**

|  |  |  |
| --- | --- | --- |
| Name | Organization | Title |
| Kathleen Kirby | Viridian | Consultant |
| Kathie Clark | Wingspan | Vice President, Product Management |
| Sharon Ames | Phlexglobal | Director, Client Solutions |
| Michele Atherton | Purdue | Manager, Records and Systems – Process Management |
| Leah Hiebert | Pharm-Olam International | Senior Manager, Clinical Support |
| Linda McNeil | FHI360 | Associate Director, Science Facilitation |

Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Steering Committee Approval Date** | **Changes** |
| 1.0 | 15-FEB-2017 | N/A |
|  |  |  |

Table of Contents

[1 Overview 4](#_Toc460236483)

[1.1 Purpose 4](#_Toc460236484)

[1.2 Rationale 4](#_Toc460236485)

[1.3 Definitions 4](#_Toc460236486)

[2 Standard Rules 6](#_Toc460236487)

[2.1 Date Format 6](#_Toc460236488)

[2.2 Ambiguous Dates 6](#_Toc460236489)

[2.3 Document Types 7](#_Toc460236490)

[3 Implementation 8](#_Toc460236491)

# Overview

## Purpose

A date convention exists as a way to name or classify a document in an eTMF (e.g. Document Date metadata), reference date for the filing order in a paper TMF or the document date to record in a tracker or database. It is not mandatory but may assist in file reviews and Inspections. Regulators have expressed their desire to order the TMF by document date. This guidance is supplemental to the artifact-level Date Conventions in the TMF Reference Model workbook (column AD).

Included in this guidance are definitions of key terms, recommendations for the date format, standard rules for ease of reference and suggestions for implementation. Note: the scope of this guidance and associated recommendations, does not intend to include dating conventions within document content, address country-specific needs or the potential differences between trial, country and site documents.

The subgroup creating this guidance document operated on the premise of finding the most appropriate date-type per artifact.

## Rationale

This guidance and the associated Date Conventions were developed because:

* There are no industry standard reference dates or date formats
* A ‘meaningful’ date is relevant to the person’s role
* Document dates are often missing, assumed, incomplete, or span across multiple days
* Dates may be dependent on something in another system (i.e. interoperability)

## Definitions

Most date conventions added to the TMF Reference Model workbook are self-explanatory but the following clarification may be helpful for the date types below:

|  |  |
| --- | --- |
| Term | Definition |
| Version Date | Date given to a document by the author, sometimes accompanied by a version number, and intended to establish finalization of a document (i.e. as of this date, document is considered final). Typically, signature dates will be after a given version date. |

|  |  |
| --- | --- |
| Term | Definition |
| Effective Date | Date a document or agreement is ready for use or when a person or organization may begin a specific activity. If no specific Effective Date is provided in the document, this may be implied by the last signature.  |
| Document Date | Document date will be used as the recommended Date Convention and should be the agreed most meaningful date. A date-type of ‘document date’ is only proposed when the artifact content was less predictable and therefore a more specific date type (e.g. signature date) could not be dictated. A Document Date will assist with consistency across organizations.  |

# Standard Rules

## Date Format

When selecting a date format to record in a system or tracker, always ensure the order of the month, date and year are defined and recognized globally. The following two formats meet these recommendations:

1. DD-MMM-YYYY, where the day and year are numeric and the month is alpha
2. YYYY-MM-DD (ISO 8601), where the year, month and day are numeric

Most eTMF products use the ISO date on the backend, but present the DD-MMM-YYYY date in the user interface. Presenting the ISO date in an eTMF does help with documents sorting in a natural order. There are not specific advantages or disadvantages that make one of these formats preferred over the other. The key point is to ensure anyone, despite their location, would recognize the date to be the same and that the organization defines the expected date format for consistency. Do not use date formats such as 06/07/2013; for example, in the United States this would be June 7, 2013, but in Germany this would be July 6, 2013.

Note: if an organization is already using a date format which is not location specific, we do not suggest making a change.

## Ambiguous Dates

|  |  |
| --- | --- |
| Date Issue | Standard Rule |
| No date | 01-Jan-1900 – this has been selected to ensure it cannot be mistaken as a real date. It is only needed where a date in date format is mandated by an eTMF. |
| Month and year only, no day (e.g. May 2016) | 01-MMM-YYYY |
| Day and month only, no year (e.g. May 18) | Try to interpret the year based on context, otherwise use 1900 (e.g. 18-MAY-1900) |
| Year only, no month or day | 01-JAN-YYYY |
| Date Range | Start Date |
| Multiple Signatures | Last Signature Date |

##

## Document Types

|  |  |
| --- | --- |
| Document Type | Standard Rule |
| Functional Plans | Version Date\* (not the template version date) |
| Manuals | Version Date\* |
| Monitoring Visit Documents | Visit Start Date |
| Translated Documents | Date of document being translated |
| Tracking Information | Last Entry Date |
| Filenote | Filenote Date (not signature date) |
| Relevant Communications | Correspondence Date |
| Meeting Material | Meeting Start Date |

*\*If a version date was not given to the document, use the most meaningful document date*

# Implementation

These recommendations are intended to provide a baseline for organizations to implement consistent and effective date formats, standard rules and artifact-level Date Conventions. To achieve consistency, at a minimum, document your organization’s plans for:

* The date format (e.g. DD-MMM-YYYY)
* Standards for ambiguous dates (e.g. missing day)
* Standards for common document types (e.g. functional plans)

If you are considering creating or updating date conventions, please use the recommendations herein as well as the artifact-level date conventions in the TMF Reference Model workbook (column AD). If you choose to make modifications to these recommendations, please keep in mind the following:

* Keep the conventions to a minimum so they are easy to remember
* Ensure standard rules are applied consistently to each artifact
* Select a date convention that can be obtained from the document and would be meaningful to both the author and reviewers. Remember, the person performing TMF quality control or filing may not be an expert on the study activity.
* If signature date is the recommended convention:
	+ It does not imply that a signature is required. For example, the recommended convention for CVs is signature date. If your organization does not require CVs to be signed, then another date convention should be selected.
	+ If you do not sign the artifact, replace the recommendation with another convention
* Filter for common words in artifact names (e.g. approval, license, etc.) to ensure consistency
* Filter your final recommendations across the artifacts to assess outliers
* If your organization is a Contract Research Organization, please refrain from selecting Date Conventions that are specific to *your* document templates and formats
* ‘Expiry date’ was not proposed as a date type in the Conventions as this would never represent the document’s effective or finalization date; but ‘Expiry date’ could be added as an extra piece of metadata if the eTMF system allowed

Lastly, it is rarely value-added to change date conventions on in-progress trials. Therefore, if you intend to update existing conventions, please consider doing so only on a move-forward basis.