GCP Records Managers Association

GCP - RMA

Relevant Communications Guidance Document

Introduction

1. This document is intended to supplement the ICH Guideline for Good Clinical Practice section 8.3.11 “Relevant Communications Other Than Site Visits”.
2. In particular, to provide guidance on how to decide whether a communication is ‘relevant’ or not.

What is a communication?

1. A communication may comprise a letter, email, telephone contact, fax or meeting minutes.
2. Some forms of ‘communication’ are ICH-GCP documents in their own right, e.g. a letter from a Regulatory agency giving approval is not filed as correspondence but as ‘regulatory approval’.
3. All communications (including emails) should be business-like and not contain personal information. They should be professional, courteous, not chatty, only discuss study matters and one study per piece of correspondence.

What is relevant

1. Communications that document any agreements or significant discussions regarding:
    - trial administration;

- protocol violations;
- trial conduct; and
- adverse event reporting.

2. When deciding whether an email message constitutes a record, the context and not just the content of the email message needs to be considered. The types of e-mail that may need to be included as a record could pertain to:

    - substantial discussions/exchanges;
    - information distributed to groups of people expected to take action or to comply with instructions, or to raise their awareness of a critical situation, etc.; and
    - agreement(s) to proceed.

3. E-mail messages could provide supporting reasons(s) for a particular course of action being followed. This means that it is necessary to capture not only the e-mail related to the final decision but also any discussions that might indicate the reason(s) for the decision having been reached. For example:

    - The decision-making process around whether or not to include a patient into the study, the background discussion of the issues and the manner in which these are addressed might have taken place via e-mail and should therefore be captured and retained safely as part of the record of the decision.
    - Communications that document processes that were followed or decisions that were made where there is no SOP/Policy to support that process or decision, or when the existing SOP/Policy was not followed; and

- Exceptional/study related circumstances that may occur will require retention of related communications. The Study/Project Manager (that is, the person who is responsible for the study) must assess relevance on a case-by-case situation.

4. To ensure legal admissibility, preserve provenance and integrity, and to capture header metadata, e-mail messages should be saved in their native format (e.g. MS Outlook e-mails should be saved as a .msg file). This holds true for both the initial e-mail and for each subsequent receipt and response. The reason is that when using the “Reply” or “Forward” function, header information is embedded into the response as alterable text and may therefore be changed. When converting to other formats e.g. Portable Document Format (pdf) or Extensible Markup Language (xml) ensure, there possible, that the header metadata is retained.

What is not relevant

1. Communications related to a decision captured elsewhere in a formal document held within the TMF need not be kept e.g. attendance at teleconferences, which is captured in meeting minutes.
2. Ephemeral (transient/temporary) communications should not be kept. Ephemeral documents are defined as documents of a trivial nature and therefore not business-critical) or of such short-term value that they do not support or contribute to the decision making process or any outcomes. These records are generally only needed for a few hours or a few days e.g. an email invitation to a meeting. In broad terms, ephemeral documents include:
    - documents of a routine or trivial nature;
    - documents that duplicate (or extract) information already held elsewhere; and
    - documents with little or no value as a record of compliance (or non-compliance) with Good Clinical Practice.

Location of Relevant Communications within the TMF

1. Relevant communications should be filed in the TMF in a way that allows for ease of retrieval. Three approaches are suggested;

    - File all communications in one dedicated “communications” section in the TMF.

    - File communications according to the subject to which they relate eg communications related to drug supplies are filed with other drug supply records (rather than in a separate communications section).

    - Use a hybrid system, filing some communications according to the subject to which they relate (e.g. for those areas considered to be of critical importance such as Regulatory, Ethics etc.) and filing other communications in an “Additional Communications” section.

2. Where using a “communications” section either for all correspondence or according to the hybrid system, we recommend subdividing by ”Internal communications” , “ Third Party Communications” and (if relevant for CROs) “Sponsor Communications”.

3. Subdivisions such as these enhance ease of retrieval when faced with a large number of communications. Whichever option is chosen it should be remembered that regulatory inspectors require trial document to be “readily available, upon request, to the competent authorities”. The filing system should therefore facilitate easy and rapid location of document requested by the competent authorities.