eTMF and Email

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MHRA "Good Clinical Practice Guide"

Only relevant correspondence that is **necessary for reconstruction of key activities and decisions** (for example, the medical advisor allows a subject to remain in the trial who has taken a banned concomitant medication, or confirmation that the IMP can continue to be used after a temperature excursion), or correspondence that contains other significant information, must be retained.

If some correspondence is not retained (particularly certain emails which may not add any value by being retained, such as email correspondence between investigator site staff and the trial monitor discussing holidays or suitable hotels to stay in near the site), then there should be a **formal process to assist individuals** in the evaluation of whether it contributes to the reconstruction of the trial or not.

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MHRA: eTMF Specific Guidance

- Electronic correspondence may be retained electronically, provided the requirements for eTMF are considered. It is recommended that correspondence is effectively organised; this could be done by segregating correspondence into topic area (for example, protocol development) or into relevant sections (for example, correspondence with the MHRA and REC).
- It is also recommended that correspondence is always filed in chronological order and that duplication of documentation (for example, chain emails) is avoided.
- Electronically attached documents that are not present elsewhere within the TMF must be included where necessary for reconstruction (for example, reports/data reviewed in dose escalation meetings).

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MHRA Blog

Another common area on documentation is correspondence associated with key decision making and trial conduct. We all use email as a key method of communication yet the **correspondence section in the TMF is often very sparse or lacks the relevant emails**. When as an inspector we say that we will raise a deficiency against a problem, it's often the case that a number of emails can be provided to explain the issue but its **unclear why they were not present in the TMF in the first place.**

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European Medicines Agency (EMA)

Relevant correspondence that is **necessary for reconstruction of key trial conduct activities and decisions** or that contains other significant information must be retained… Some CRO organisations for example, rely solely on email correspondence to confirm sponsor approval of processes, documents, and decisions. There is usually extensive important communication (e.g. regarding issues that arise in the trial conduct and how they are dealt with) between sponsors, CROs, investigator sites, ethics committees and competent authorities.

Reflection paper on GCP compliance in relation to trial master files (paper and/or electronic) for management, audit and inspection of clinical trials

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EMA: eTMF Specific Guidance

- Electronic correspondence (emails) may be retained electronically, provided the requirements for eTMF and electronic archiving are considered.
- Emails are recommended to be saved to ensure that the associated metadata is retained, **for example as .pst files** rather than pdf documents or being printed and signed.
- Correspondence (paper and emails) are recommended to be **effectively organized** and **filed in chronological order** in an appropriate section in the file.
- Duplication of any documentation in the TMF is recommended **to be avoided, but this often occurs with email correspondence and with attachments**. Sections including correspondence must be complete…
- During GCP inspections it is often seen that **only copies of letters received** rather than those both sent and received are filed (such as Research Ethics Committee correspondence), such that the TMF only contains half of the audit trail.

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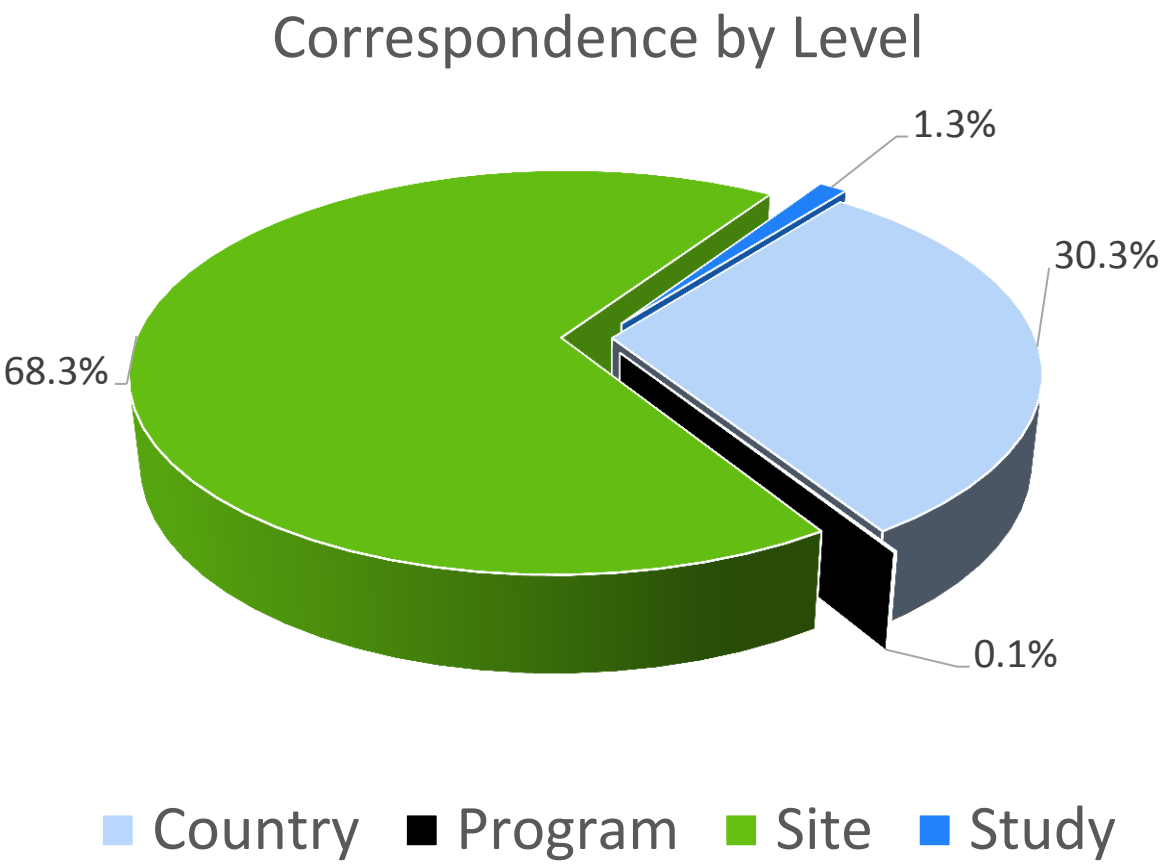
eTMF Case Study 1

Studies
600+

Documents
2.6 M

% Correspondence
29.5 %



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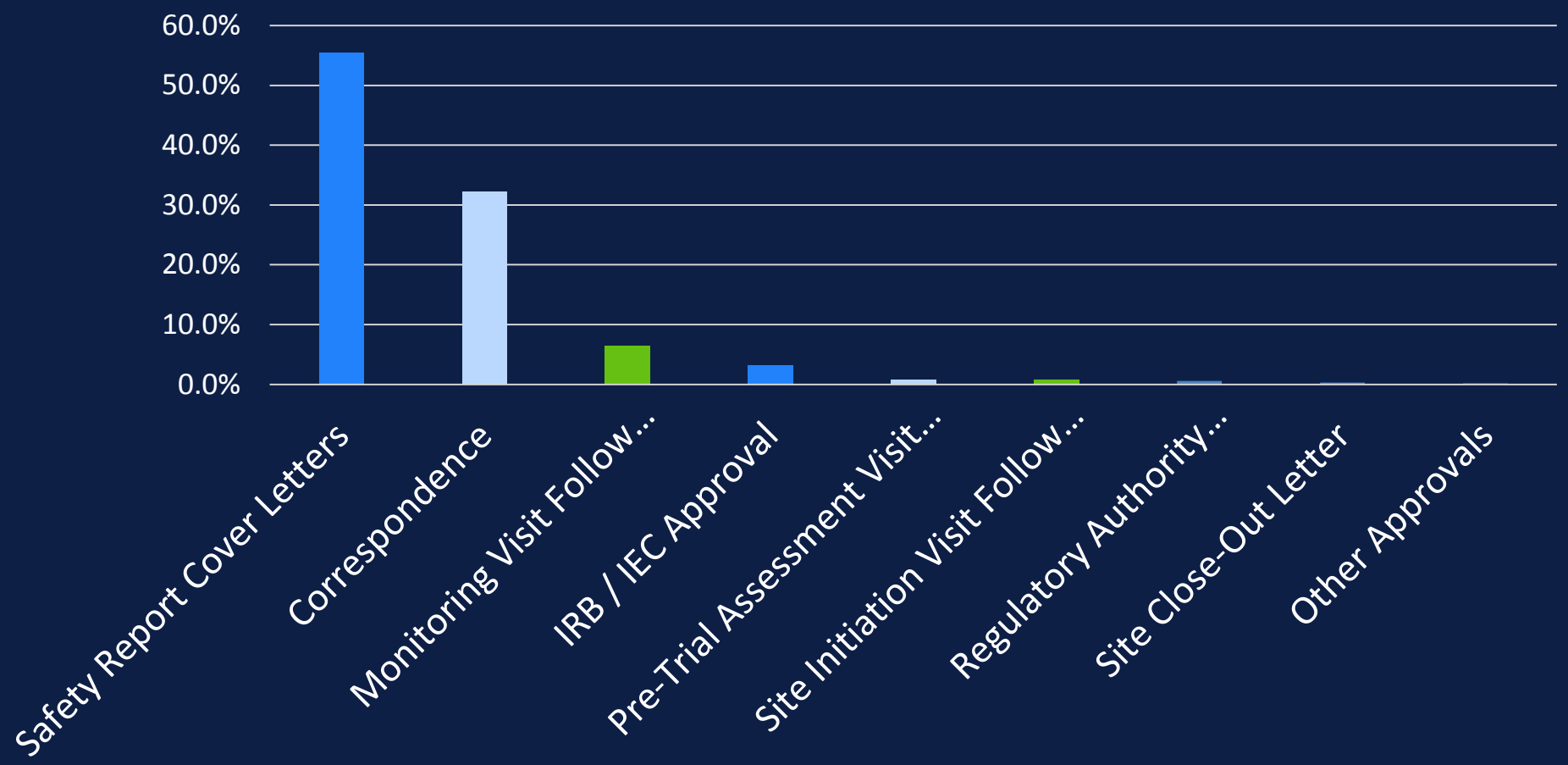
Top 9 Types of Correspondence



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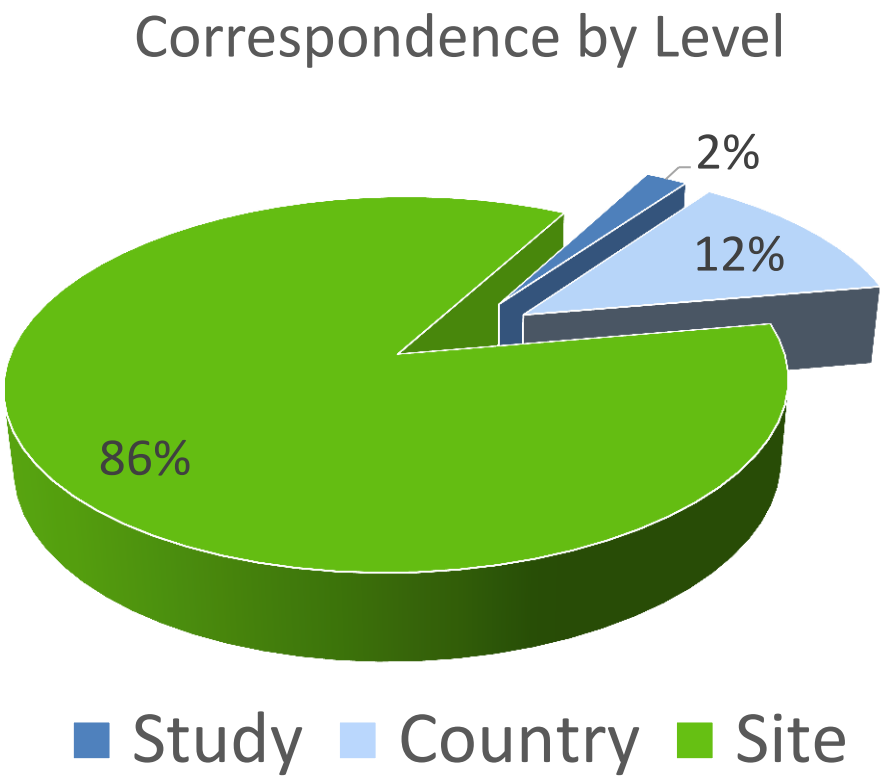
eTMF Case Study 2

Studies
95

Documents
727 000

% Correspondence
14.7 %



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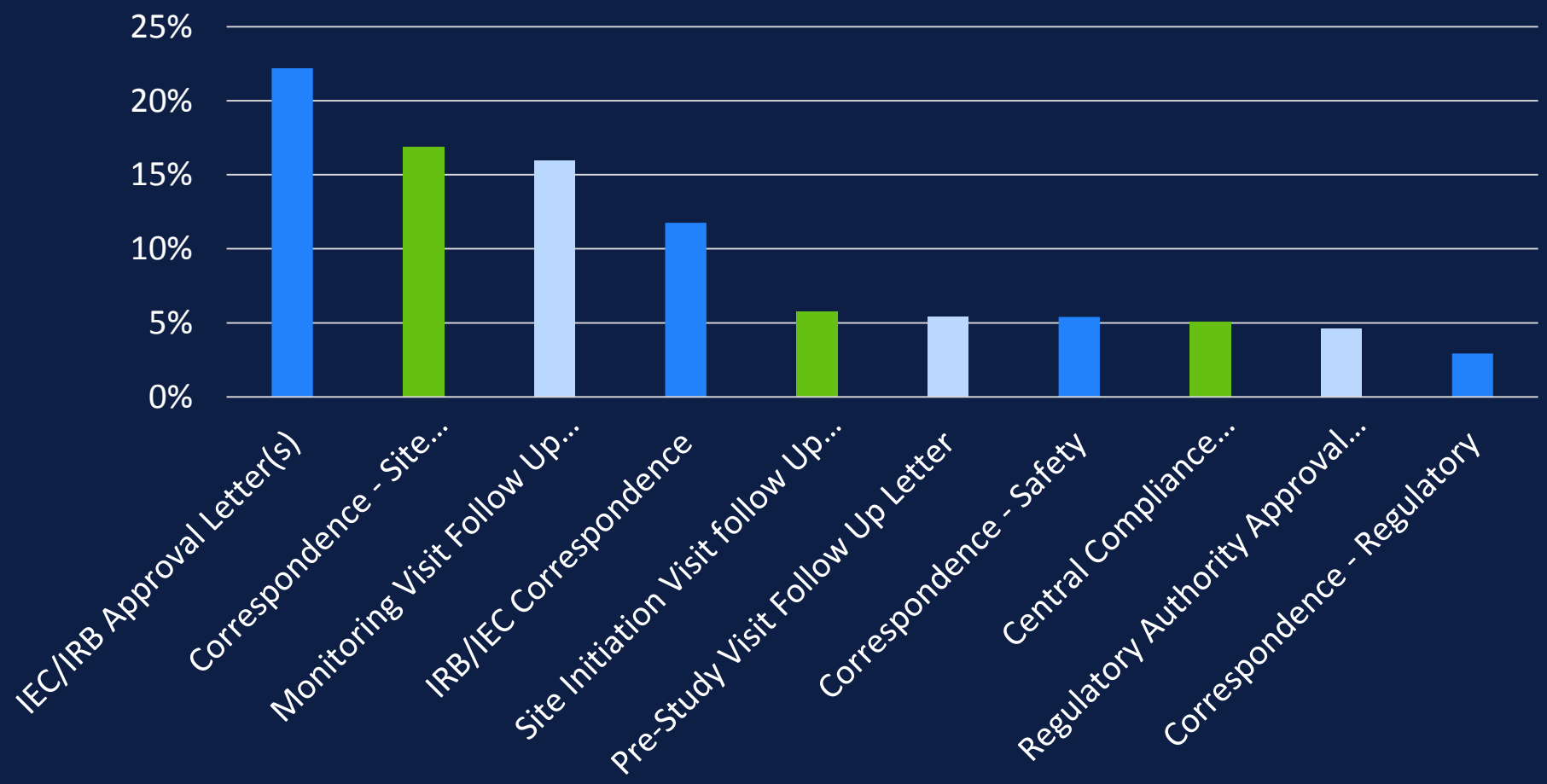
Top 10 Types of Correspondence



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Technical Considerations

- Automated processes for ingestion
- Processing of envelope information
- Handling of threads
- Handling of attachments
- Formats and ability to archive

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