Conveying Medical Guidance in Clinical Trials – A Survey : Communication Challenges

Authors

Mohamed El Malt, MD, PhD* and Vijayanand Rajendran, MD*
(*) Medical Consultancy division, Europital. www.europital-mc.com
Correspondence: Dr Vijay Rajendran, info@europital-mc.com

Background:

With the incremental demand for proactive safety surveillance throughout the conduct of clinical trials, the role of Medical Management is at the fore in ensuring the safety and wellbeing of the participants. The complex responsibilities of a Medical Monitor (MM) starts from the design and development phase, through to the close out of the study. Understanding the principle behind the protocol and the prospective medical solution the study would deliver forms the bloodline for the MM role. In addition to acting as therapeutic area expert, the Medical Monitor is engaged in conserving clinical equipoise during knotty situations. Often, the MM is the face of contact for both the site personnel and the study team members with regard to medical, safety and scientific issues within the project. Hence medical knowledge, conflict management and decision making skills are quintessential for effectual Medical Management.

When it comes to medical guidance, the communication channel used to deliver solutions contributes to a large extent in effectively managing decisive situations. Our previous study on acquiring medical guidance from an operations team perspective (1) revealed that E-mails were the most used communication method. In our efforts to further strengthen the mode of medical guidance delivery, we designed a survey to study the existing trend and constraints in this communication chain management.

Objectives:

The primary objective of the survey was to study the convenience of utilizing E-mails in managing multiple projects whilst providing medical guidance by the Medical Monitors. The regulatory perspective of e-mail documentation and the inclination of MMs to use alternate communication tool were also explored.

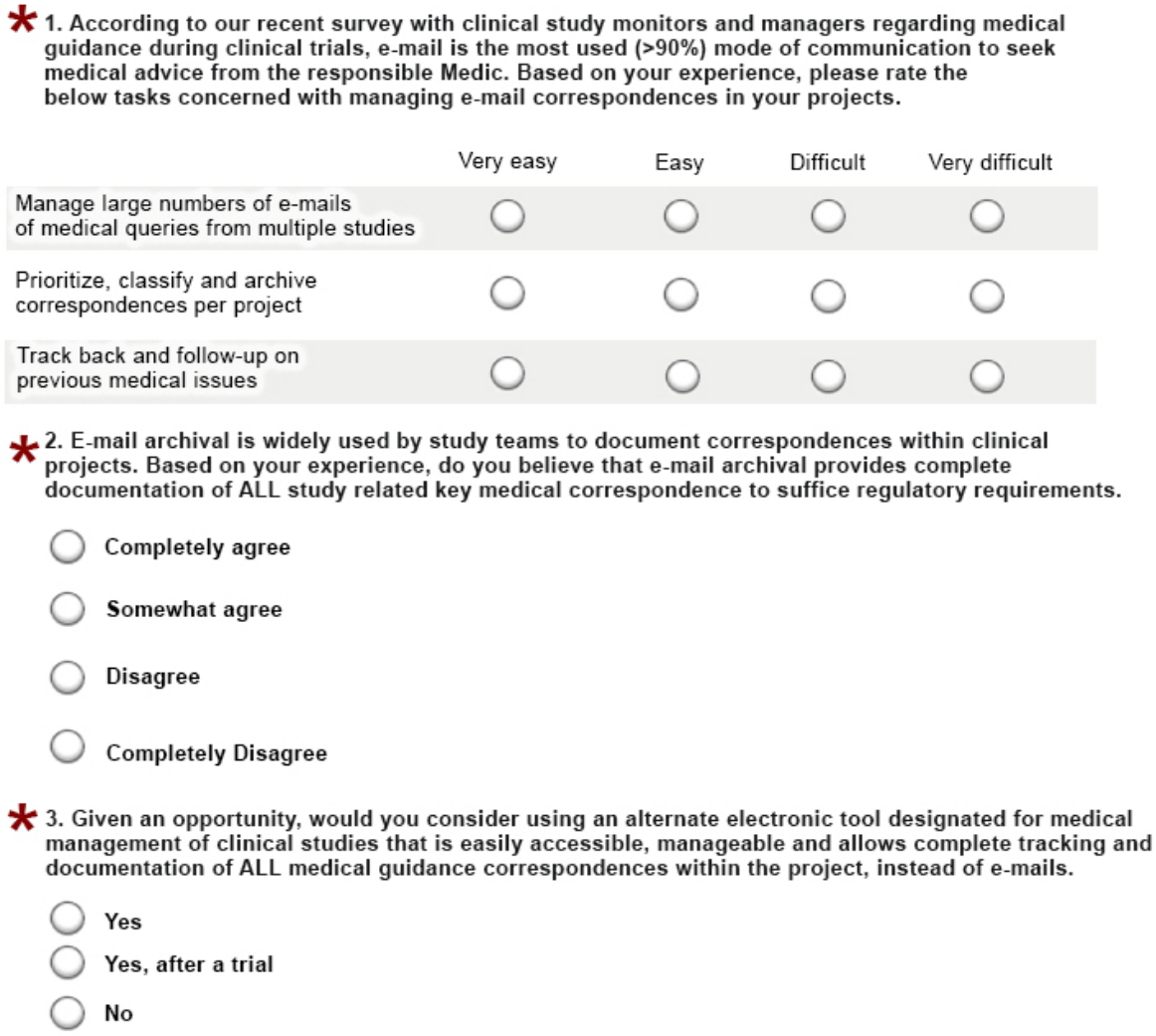
Methodology:

Target Participants: As the survey was meant to obtain the medical team perspective on tools employed for delivering medical guidance in clinical trials, the target participants were Medical professionals currently functional as Clinical Research Physicians (CRP), Medical Managers, Medical Directors and Chief Medical Officers.

Survey Questions: To ensure the simplicity and punctuality of the survey, it was designed to include only 3 straightforward questions that capture the most relevant information concerning the usage of E-mails

in answering medical questions for multiple studies. Figure 1 shows the 3 questions posed to the participants in this survey.

Figure 1: Survey Questionnaire



* **1. According to our recent survey with clinical study monitors and managers regarding medical guidance during clinical trials, e-mail is the most used (>90%) mode of communication to seek medical advice from the responsible Medic. Based on your experience, please rate the below tasks concerned with managing e-mail correspondences in your projects.**

	Very easy	Easy	Difficult	Very difficult
Manage large numbers of e-mails of medical queries from multiple studies	○	○	○	○
Prioritize, classify and archive correspondences per project	○	○	○	○
Track back and follow-up on previous medical issues	○	○	○	○

* **2. E-mail archival is widely used by study teams to document correspondences within clinical projects. Based on your experience, do you believe that e-mail archival provides complete documentation of ALL study related key medical correspondence to suffice regulatory requirements.**

- ○ **Completely agree**
- ○ **Somewhat agree**
- ○ **Disagree**
- ○ **Completely Disagree**

* **3. Given an opportunity, would you consider using an alternate electronic tool designated for medical management of clinical studies that is easily accessible, manageable and allows complete tracking and documentation of ALL medical guidance correspondences within the project, instead of e-mails.**

- ○ **Yes**
- ○ **Yes, after a trial**
- ○ **No**

Communication: To ensure the ease and protected access to the survey by the participants, it was posted online on a designated/protected page of our organization server. A link to the survey page was provided to the targeted participants both via email and social media portals (LinkedIn, Twitter).

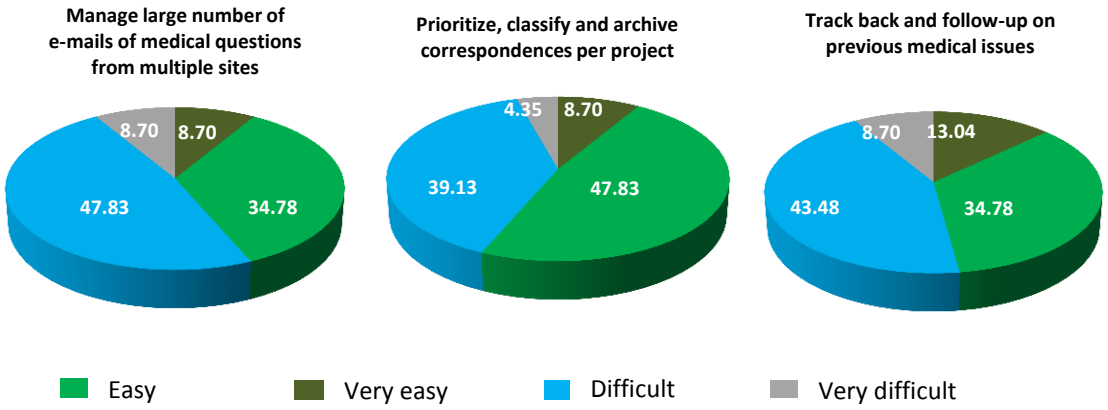
Results

The survey was conducted over a period of one month during which twenty three (23) Medical Professionals, who are contributing to medical management and monitoring of clinical studies, have responded and provided their inputs. 55% of the participating Medics were from Medium-size and Major

Pharmaceutical companies, while 45% were from Global Contract Research Organizations. Identity ofthe participants was kept confidential and any identifying information of the participants was blinded. Additionally, results of the survey were analysed in aggregates.

1. Management of medical questions via email system:

Figure 2: Utility of email in managing medical questions

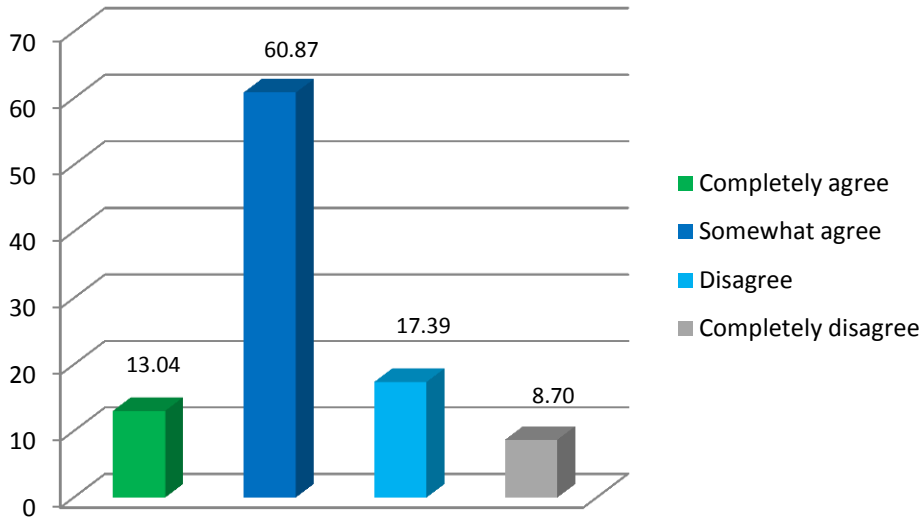


As shown in Figure 2, more than half of the participants (56.5%) considered managing of large number of medical questions from multiple sites by e-mails as difficult or very difficult, while the remaining 43.5% considered this task as easy or very easy. Additionally, tracking back and follow-up of questions received by e-mails was considered difficult or very difficult by 52.2%, while 47.8% considered it easy or very easy. On the other hand, 43.5% of the participants considered prioritizing, classifying and archival of e-mails as difficult or very difficult while 56.5% considered that as easy or very easy.

2. Documentation by E-mail archival :

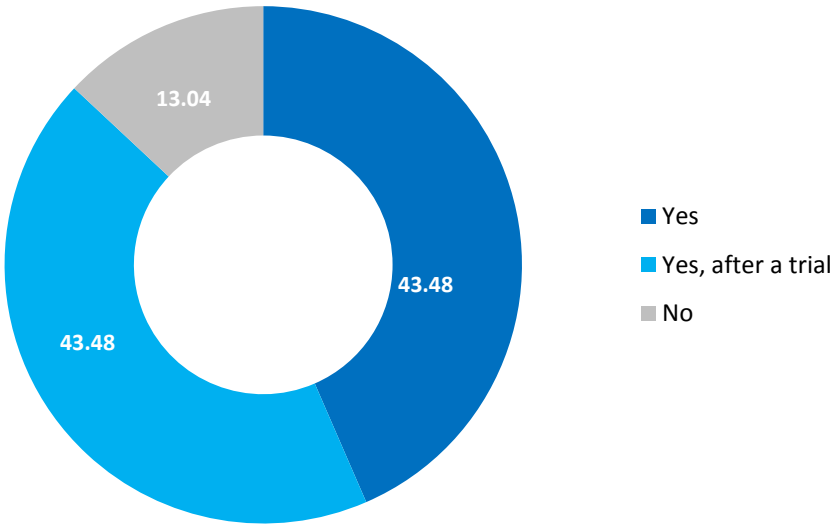
Figure 3 shows the respondents' opinion regarding the use of email archival as documentation tool. Approximately 74% of the respondents considered that documentation by archival of email messages would suffice any regulatory requirements or future audits.

Figure 3: Documentation for regulatory requirements by email archival



3. Alternate tool designated for medical management of clinical studies:
   As shown in Figure 4, the vast majority of the respondents (87%) were willing to use an alternate tool, other than email system, designated for medical management of clinical studies that could be easily accessible, manageable and allows complete tracking and documentation of all medical guidance correspondences within the project.

   Figure 4: Willingness to use an alternate system designated for Medical Management



Discussion

The choice of the participants with respect to the described three components of e-mail management were quite comparable. The overall survey results indicated that half of the Medical professional

respondents expressed difficulties with the use of e-mails systems in medical management during clinical trials, which highlights a significant room for improvement and the need for advancement in streamlining the existing communication paradigm with an innovative approach to tackle the existing challenges and realize efficiencies in management of medical issues within clinical trials context. It is understandable that the user friendliness of the email system would be inversely related to the size and complexity of the study that would significantly impact the number and complexity of issues handled by the responsible Medic in each individual study. Although the options to mark, follow-up, categorize and attach a reminder are embedded in the majority of mail systems, managing large number of medical issues via email could be quite cumbersome, as any action taken on an email is usually done manually with the associated waste of time and risk of human error.

While the majority of respondents (74%) indicated that documentation via archival of email messages would meet regulatory requirements, a question mark would arise regarding the completeness and relevancy of the archived information that will depend, to a great extent, on the applicable archival procedures and methods. The compliance of various team members and their experience will be also another defining factor for the completeness of the required documentation. As the extent of regulatory requirements is not well described with regard to documentation of provided medical guidance within a clinical project, the responsible project team should define in advance, critical and important issues that should be diligently documented.

Over the past few years, email has become an integral part of the business workflow in most organizations worldwide. The rapidity of communication, minimum cost and reachability are the primary business advantages of e-mail communication. For study related medical information exchange, as assessed by our previous survey, about 78% of the clinical monitor use e-mails to communicate with the Medical Monitor. However, as medical guidance correspondences usually include team discussions and involvement of multiple participants with various messages and long chain of emails, archival of email correspondences might consume significant amount of time, especially if selection of the relevant messages is done manually to ensure the complete documentation of correspondences related to the pre-defined critical and important issues. Additionally, it is not uncommon that the task of manual archival of email correspondences is done by a non-medically qualified personnel, where the risk of missing critical medical information would be higher.

It should also be noted that, during a communication chain e-mails can inadvertently be forwarded or sent to unauthorized parties, an important stake holder could be missed in the communication loop, or critical messages can get caught in spam filters or be accidentally deleted. The lack of an audit trail report when using email to communicate is another significant disadvantage.

Recognizing the various difficulties associated with using email systems in medical management of clinical trials by the participants in this survey led to the readiness of 87% of the respondents to use an alternate tool which highlights the existing degree of dis-satisfaction of the stake holders with respect to handling of medical queries by e-mail system.

Conclusion

Currently, e-mail remains the standard practice for medical communications within clinical trials, but the system still lacks the intricacies to set a benchmark for Medical Monitoring correspondences. With the recent transition in industry trend from passive to active safety surveillance methods, innovative approach is needed to design a communication strategy for delivering medical guidance during clinical trials conduct, in a way that facilitates management of specialized, more targeted, and critical medical guidance communications in the context of clinical research projects.

Reference:

1. http://europital-mc.com/medical-guidance-clinical-trials-operations-team-perspective-survey/