Notifications and Reminders

Introduction

A component of many DCTs is the ability of the participant and study team to communicate with one another in real-time. In these trials, the site investigator or study team can create and send both automatic and on-demand notifications and reminders to the participant to help increase the completion of study procedures in a timely fashion. Participants themselves may appreciate the receipt of electronic notifications and reminders because they decrease the burden of "having to remember" their responsibilities, among other benefits. Digital engagement platforms typically include systems for sending notifications and reminders. Even in the absence of specific DCT platforms, SMS texts can be sent to the participant's mobile phone, although the financial cost to the participant should be recognized and compensated. How these notifications and reminders are delivered—the frequency, tone, method, etc.—should be optimized to improve the participant's clinical trial experience as well as trial outcomes. Often, the participant can choose how and when to receive the communication (see below), thus increasing engagement and satisfaction, although whether participant will be allowed choice may depend upon the study itself. There are also concerns to address, including those relating to participant confidentiality. Finally, the IRB/EC should consider whether the device is provided by the participant, investigator, or sponsor.

Participant Preferences

As much as possible, digital engagement platforms should be implemented and/or communications (e.g., through a personal mobile phone) should be configured to facilitate participant choice. For example, participants should be allowed to choose:

- Whether to receive the communication as a text, email, or phone call
- When to receive the communication, including frequency, timing, and, if applicable, triggers (e.g., notification if continuous glucose monitoring indicates an action is needed)
- Language preference for communication
    - For example, in the case of a reminder to take a study medication, having chosen to receive this reminder as a text message, the participant could determine:
        - Preference for English or another language
        - Timing of notification, whether 15 minutes before, 5 minutes before, and/or at time study medication is due
        - One, two, or more notifications for the same event
        - Whether a participant action (e.g., acknowledgment via a "like") is required to turn off reminder:

Note: whether, when, and how communications are received and responded to, and whether the communications are required, optional or flexible will often depend upon whether they are an integral part of the research protocol or of safety monitoring.

Risk Mitigation

There are confidentiality concerns with notifications and reminders. The smartphone or other electronic device on which notifications are displayed may not be private and may be shared with others. Even if the device is private, it may be lent to or held by another person, or a third parties may view information on the screen, either intentionally or unintentionally. The information contained within the communication may reveal or imply some private information Of course, the device may be 'hacked' maliciously or stolen. There may be data security concerns with the data platform itself. Mitigation strategies include:

- [ ] Minimize information in notifications, with specific attention to sensitive or potentially sensitive information. While apps can generally be designed so the text of a notification is only shown when the smartphone is unlocked, this protection is more difficult with SMS because the settings are controlled by the smartphone user.
- [ ] Provide information through an app that requires personal log-in information to access (note: this approach may reduce the likelihood that participants will see the notification or reminder, e.g., if they fail to log in regularly)
- [ ] Establish an understanding with the participant about intended uses and potential risks of the device, its ownership, and access in advance
- [ ] Provide a dedicated device, if necessary
- [ ] Require two-factor authentication, when necessary
- [ ] Limit direct messaging to non-sensitive information, when possible
- [ ] Provide for a remote wipe of the device in cases of stolen or potentially hacked devices
- [ ] Assess platform data security measures for compliance with institutional and internal policies and requirements.

There is also the possibility that participants will stop paying attention to, or ignore, the communication. The participant may be annoyed by the disturbance of constant reminders and notifications and may even "turn off" or disable the communication. The communication may be blocked or otherwise not delivered unbeknownst to the participant and/or study team While these are not specific to DCTs, there are somewhat different and heightened concerns in DCTs. Mitigation strategies include:

- [ ] Solicit periodic feedback from the participant regarding experience
- [ ] Intermittent remote monitoring (e.g., determine if notifications are received and/or read)
- [ ] Create a feedback path such that the participant must respond to communication and any failure to respond will alert the study team
- [ ] Modify the content or form of the communication periodically
- [ ] Use an incentive reward system if necessary (see Rewards document)

Questions for IRB/ECs to Consider

- [ ] Is the implementation of notifications or reminders likely to create an undue burden or introduce risks to privacy or confidentiality?
- [ ] Does the communication contain potentially sensitive or identifiable information? Can the inclusion of that information be further minimized?
- [ ] Are there data security concerns introduced by these communications and, if so, can they be eliminated?
- [ ] What control does the participant have over the form, frequency, and content of the communication (e.g., can the participant turn off reminders that are critical for safety?)
- [ ] What is the plan if the participant fails to respond to a safety-related notification?
- [ ] What are the consequences, risks, and potential harms:
  - [ ] If the communication fails?
  - [ ] If the communication is received by a third party?
- [ ] Is there a monitoring plan for the system of notifications and reminders? A monitoring plan is necessary if there are meaningful consequences to the failure of notifications. Note, however, that in a particular trial, smartphone medication reminders might be just a convenience or redundant with other reminders that are in place. If the study team determines that missing an occasional dose is unlikely to cause harm to participants or create a data quality issue, a monitoring plan may not be necessary.
- [ ] Does the study include participant feedback, and is it elective?