Information Exchange: Communication Templates

Background, Methodology, and Feedback

Nothing in this deck should be construed as legal advice, nor does anything in this template imply or warrant that use of the proposed approaches described herein comply with applicable laws or regulations. Users implement these approaches at their own risk and bear the sole responsibility for ensuring their compliance with applicable laws and regulations in their respective jurisdictions.
Purpose of this Deck

This deck is intended to summarize the objective, methodology, and considerations for communication templates that sponsors may use, at their discretion, in order to facilitate exchanging information with clinical trial participants. Additionally, this deck provides feedback received and incorporated into the templates from patients, sites, and IRBs. The proposed considerations and templates described in this deck reflect those things that TransCelerate believes and that patients, sites, sponsors, and others have indicated would help improve information exchange. Sponsors may wish to consider undertaking additional steps to improve information exchange with patients. The proposals described herein are not meant to limit in any way any sponsor’s efforts to improve patients’ experiences in clinical trials, but to facilitate those efforts.

Templates described include:

➢ Thank You for Joining Letter – Example Template
➢ Thank You for Participating Letter – Example Template
➢ Post-Trial Completion Letter – Example Template
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About TransCelerate

TransCelerate BioPharma Inc. was launched in 2012 as a non-profit organization with a mission to collaborate across the biopharmaceutical research and development community to identify, design and facilitate the implementation of solutions to drive efficient, effective and high-quality delivery of new medicines, improving the health of people around the world.

Clinical Research Awareness, Access & Information Exchange

The Clinical Research Awareness, Access, and Information Exchange workstreams aim to help patients discover clinical trials and get the most from their experience.

- **Awareness**: Encourage conversations about clinical trials between patients and their HCPs
- **Access**: Facilitate improved clinical trial search and evaluation of enrollment options
- **Information Exchange**: Contribute to a more transparent, informative, and rewarding clinical trial experience
Information Exchange Purpose

Information Exchange is…

Bi-directional sharing of information, data, feedback, etc. between researchers and trial participants

Why Information Exchange, why now?

Current Situation: Patients often lack practical information about a clinical trial before, during, and after their participation; meanwhile, costly and slow recruitment coupled with sub-optimal retention is delaying the delivery of new treatments

Information Exchange Vision

Patients and their HCPs receive clear, useful & timely information regarding clinical trials and trial participation, contributing to a more satisfying clinical trial experience
Communication Templates Purpose

The goal of developing these documents/templates is to close the gap for providing pieces of information that patients have indicated they would like to have:

1. After enrolling in a study
2. After completing a study
3. After their study has been fully completed and results of the study are available

Some study sponsors and sites already communicate this information, however it is done in a variety of methods and at various points in time throughout the trial. Our mission is to make it easier and more efficient for sponsors to provide the information that patients feel they need to remain informed and valued at each stage of their participation.

This is a step towards increasing communication throughout and after the patient’s participation to improve their clinical trial experience.
Considerations for Templates
Considerations for Use of Templates

The templates should not be considered the only communications / status updates to be sent during a clinical study. Particularly for longer studies, regular periodic updates (e.g., twice per year) would be beneficial to participants; dependent upon complexity of trial and patient population.

The communication templates are not intended to specify exact language or formatting for a study participant communication. It is expected that the sponsor would customize the communication based on the unique needs of the study and/or preferences of the patient population involved in the study. These particular templates were written with a “letter” format in mind. Site staff should be involved to personalize the letter for each patient, such as adding the patient’s name.
Considerations for Use of Templates (continued…)

The communication would be delivered to the study participant by a professional at the site/location where the study is conducted, on behalf of the entire site staff as well as the sponsor of the study (e.g., pharmaceutical company).

The communication could take the form of a letter or card that is hand-delivered, sent by postal mail, electronic mail, notification within a mobile application for the study, etc. Before the study begins, the particular patient community involved could be consulted anonymously for their preferences by site staff. The method of communication should respect the patient’s privacy.

If the site contact information differs from signatory, consider additionally listing the site contact information in the letter so that it is readily available to the participant.
Template Tips

When reading the templates, keep in mind…

➢ Text {in brackets with gray highlight} is information that the site or sponsor would fill in and is unique to each study or study participant

➢ Text in italic is meant to help the site or sponsor customize their own communication

➢ The Communication Templates are only templates and provide sample language only
Feedback Groups
Development & Feedback Received

The templates were created with input from TJ Sharpe (patient advocate), member companies’ representatives, and the following groups:

**Patient Advisory Board**
- Virtual meeting held October 30, 2017
- 7 Patient Advisors

**Site Advocacy Group**
- Virtual meeting held October 20, 2017
- 8 Site Representatives

**Institutional Review Boards**
- Central IRBs in Brazil and the United States
- Local IRB in United Kingdom
Patient Advisory Board (PAB) Feedback

Overall:

- A PAB member felt that the communication templates would help to keep the patient engaged and would help set expectations.
- The letters are a good way to have a proper start and finish to their participation.
- Using the same style throughout was thought to be beneficial, and that having a tangible letter would be helpful to refer back to for information. However, some noted that if the study was particularly long, they would want more frequent communications and updates on the study status.
- PAB members noted that depending on the kind of information included in the communication, they might want it in paper form or electronic. Those who were more elderly seemed to prefer paper so they could highlight things, while younger participants wanted something electronic or emailed.
- Making the communication from a person in a senior/executive position at a pharma company was thought to make the letter seem more legitimate, or would make the patient feel more valued and appreciated.
- Inclusion of contact information was much appreciated.
- Liked that the templates are brief, the clear “sections” (orients reader, calls attention to key points) and that they feel personal but also that it makes the person feel part of a group.
Site Advocacy Group Feedback

Overall:

- Ethics approval in advance would help sites
- 2 representatives mentioned that their patients appreciate communications.
- US patients may appreciate a certificate of completion/milestone. EU sites did not think EU patients would like this.
- Patients being called a “Medical Hero” will resonate and be greatly appreciated by US patients. This terminology will not resonate with EU or South American patients. Overall, the sites thought the language was US-centric.
- Sites believed the letter would be more impactful if mailed to their homes.
- Need to recognize site burden and consider this when exploring implementation
IRB feedback

Overall:

• Actual letter, not just template, would need to be IRB approved, assuming study is still open.

• Could be approved without statistics/dates being filled in as long as it is clear what will be in that placeholder
  
  o Be as specific as possible with the intention of how placeholders will be filled in
  
  o To help the IRB understand purpose and facilitate review, suggestion to add comments to templates with detailed description of placeholder purpose and explanation that accurate details will be filled in at time of sending to participant
  
  o Placeholder example: %s regarding overall study status – but sponsor should add language such as “% at time letter is sent will be filled in” or “date range at time letter is sent will be filled in”
  
  o Placeholders for other items that can only be realistically updated at time of sending are reasonable (e.g., patient’s name, site contact information)
Thank You for Joining – Template Letter

Purpose of Template:
Communication to a clinical study participant after he/she has enrolled in a clinical study

Template Specific Feedback:

➢ Patient Advisory Board
  • Enrollment Information Section:
    o Useful; would like to see the number of participants that were enrolled to date
  • Next Steps Section:
    o Deemed critical because it set expectations; did not feel like there were any unknowns
    o Felt very personable, direct, and encouraging
  • Why Participation Matters Section:
    o Very well-received
  • Comforting Message Section:
    • The phrase “receive excellent care” was thought to be very reassuring
    • The language regarding the site’s understanding that circumstances “change over time” implied that the site was listening, caring, and would “have their back”
    • A personal site staff contact name and contact information was preferred

➢ Site Advocacy Group
  • Be clear that participation is valued – do not focus on the negatives lifestyle impacts that study may cause
  • Focus on the excellent care they will receive throughout the study

Template PDF Link:
bit.ly/2q56YYf
Thank You for Participating – Template Letter

Purpose of Template:
Communication to a clinical study participant after he/she has completed participation in a clinical study

Template Specific Feedback:
➢ Patient Advisory Board
  • Important to recap what may have been said before, but certainly rephrase in order to make the communication more unique and professional
  • Wanted to see new information about the study in this letter
  • Use of the word “data” was thought to be too technical
  • Where possible, try to make language more personalized to study/disease
  • Where there is information about where the patient can register for more information, patients felt this might be easier in an email format, in order to avoid copying and typing in a URL
  • If it were going to be a paper format, the patients felt a point of contact to reach out to could be helpful
➢ Site Advocacy Group
  • Patients would be interested in know where can go for more info
  • Patients like to have a link to study results
  • Helps answer questions patients often have for us that we aren’t prepared to answer

Template PDF Link:
bit.ly/2EhJTG5
Post-Trial Completion Summary – Template Letter

Purpose of Template:
Communication to a clinical study participant after the full clinical study is completed and results of the study are available.

Template Specific Feedback:

➢ Patient Advisory Board
  • Very well-received as a way to sum up their clinical trial experience and gave a clear picture of what the patient’s participation meant to the trial
  • Gave confidence that the site had been keeping track of personal data
  • Suggestions: Where possible, include how patients’ comments and feedback were incorporated into their trial or future trials as this would additionally acknowledge their contribution
  • Highlighted the importance of avoiding technical terms
  • Explanation of what it meant to be in each arm of the study was considered helpful
  • Opportunity to follow up with a study staff member would be appreciated to address further patient questions

➢ Site Advocacy Group
  • Suggestion: Split this into 2 communications (1) after data lock (when statistics can be compiled), and (2) after results are available. Don’t delay information until overall results are published
  • Suggestion: run statistics after data lock and get creative with the presentation of results
  • Registration status should be provided to site to communicate when drug is approved
  • Knowing what a patient received is also important because we need to know if they are eligible for another trial in the future

Template PDF Link:
bit.ly/2q6ZiE3