

## “Thank You” Letter at Start of Clinical Study Enrollment

### Template Purpose & Context:

- This document was created to identify key pieces of information that sponsors may wish to consider including in a communication to a clinical study participant after he/she has enrolled in a clinical study (after the informed consent process and after the screening process has determined he/she is eligible to participate and move forward).
- 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.
- This document is a template only and proposes sample language only. It is not intended to specify exact language or formatting for a study participant communication. It is expected that the sponsor or site staff would customize the communication based on the unique needs of the study and/or preferences of the patient population involved in the study. This particular template was written with a “letter” format in mind.
- This is one of three documents/templates developed by the TransCelerate Information Exchange sub-team. 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, and (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.
- When reading the template below, keep in mind that 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.

Section	Sample Text/Considerations
Introduction	<p>Dear {Site to fill in Participant’s name; may require adjustment depending upon local culture to include salutation of ‘Mr.’ or ‘Mrs.’}:</p> <p>On behalf of {Sponsor Company Name} and {Site Name}, we want to thank you sincerely for your participation in the {study name consistent with informed consent document}.</p>
Enrollment Status	<p>The enrollment phase of this study {was recently completed/is currently ongoing}. This study {is/was} planned to enroll {XX} participants across approximately {XX} countries.</p>

Next Steps	<p>Enrolled patients will begin participating in the {study intervention} as described during the Informed Consent process. After all participants have finished their participation and the study data have been collected, the data will be analyzed to evaluate both the safety and the efficacy of {study intervention} in individuals {with study disease}.</p> <p>Many clinical studies involve a lengthy process. On average, studies at the same stage of development as this one (Phase {XX}) take between {XX-XX} {months/years} from start to finish.</p>
Why Participation Matters	<p>Before any new {medication/vaccine/etc.} can be approved for use by patients, it must undergo clinical studies to see if its benefits outweigh its risks in one or more conditions of use. No new or improved treatments for {study condition} will ever be found without volunteers like you.</p> <p>We want to thank you and tell you how much your participation is appreciated. You are a part of advancing medical science!</p>
Comforting Message to Participant	<p>Lastly, we realize that participating in this study may be time consuming and may ask a lot of you. We also realize that your circumstances may change over time. If you have any concerns or questions, please raise these with {study staff at site as specified in the informed consent form/document}. Our job is to ensure you receive excellent care.</p> <p><i>Ensure process for raising concerns is consistent with the informed consent form.</i></p>
Sign Off	<p>Thank you very much again for your participation and for your contribution to medicine and to science.</p> <p>Sincerely,  {Name}  {Signature}</p> <p><i>When assigning a signatory, consider an individual within the site staff with a role that would make the participant feel valued.</i></p>

**Note:** Nothing in this template should be construed as legal advice, nor does anything in this template imply or warrant that use of this approach complies with applicable laws or regulations. Users implement the approach outlined in this template at their own risk and bear the sole responsibility for ensuring their compliance with applicable laws and regulations in their respective jurisdictions.