"Thank You" Letter at Participant Completion of Clinical Study

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 completed participation in a clinical study (but before the results of the study are available, as this could take many months or even years after all participants have completed).
- 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	Dear {Site to fill in Participant's name}: On behalf of {Sponsor Company Name} and {Site Name}, we want to again thank you sincerely for your completed participation in the {study name consistent with informed consent document}.
Purpose of the Study	You were one of approximately {XX} participants in your country and {YY} participants in {XX countries worldwide}. It is only with the help of volunteers like you that we can perform the essential research to

	find a new and effective {treatment, prevention, method, etc.} for {study disease/symptom/etc.}.
Overall Study Status	Once all participants have completed their participation in the clinical study, your study records and test results will be analyzed together with those of all other participants. *Sponsor may choose to provide additional information about approximate time to study completion in terms of ranges, industry averages, etc.:* At the present time, approximately {XX%} of the enrolled participants have completed the study. We anticipate we will have collected all necessary data from participants between {TIME-TIME}.
Why Participation Matters	*Consider using content from the study's informed consent form regarding potential benefits from participation specific to the study/disease, as appropriate:* We realize that participating in this study was time consuming and may have asked a lot of you. We value the time you committed to our research efforts. Your contributions will help others as a result of the medical and scientific knowledge gained from your participation.
Future Access to Information	*If applicable, consider providing participant with option to receive future communications electronically and/or information about the availability, timing, and delivery method of study information after such information has been provided to relevant competent authorities for review. If providing this letter in a paper format, consider providing a point of contact for patients, as typing in a URL may lead to error. Also, consider offering other options for registration if there is a likelihood that the study participants do not have access to the internet and/or have other accessibility problems:* If you wish to receive information about the study in the future, we invite you to register at the following website: {website.com}. Upon registering {a valid email address/mailing address/etc.}, you may receive {updates on study status, notification of study completion, availability of the scientific results of the study, availability of lay summary results, availability of your individual participant data/results}.

	If applicable, and depending upon sponsor's policy with respect to distribution of study results, sponsor may wish to consider providing the following additional information: We expect you will have access to study results via {website.com} in approximately {XX months/years}. *As applicable in the participant's country, providing participant with an option to retrieve a public record of the study might be a good alternative:* If at any time you wish to access a public record of the study, you may locate this information on {clinicaltrials.gov/other registry domain} using the {NCT ID/registry identifier} {XXXX}. *As appropriate, it would help to clarify which of the above information is written for a patient audience, scientific audience, etc. (set expectations).*
Sign Off	Thank you very much again for your participation and for your contribution to medicine and to science! Sincerely, {Name} {Signature} *When assigning a signatory, consider an individual within the site staff with a role that would make the participant feel valued.*

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.