

## Results Letter at 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 the full clinical study is completed and results of the study are known.
- The communication could 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 participation in the {study name} and for your role in the advancement of {field of study}.
Participant Commitment Impact	Your commitment and the commitment of all other participants allowed {us to meet our study objectives / contribute to medical science / benefits to future patients etc.}. Together, {number of participants} participants collectively completed {XX} visits to {XX} sites across {XX countries}.

	<p><i>Consider adding a statement describing the individual participant's commitment:</i></p> <ul style="list-style-type: none"> <li>• <i>Examples:</i> <ul style="list-style-type: none"> <li>○ <i>Participation duration – e.g., Number of months involved</i></li> <li>○ <i>Total # of site visits</i></li> <li>○ <i>Procedures/activities conducted throughout the study</i></li> <li>○ <i>Additional personalized anecdotes (e.g. feedback person provided that was useful to the design/conduct of trial)</i></li> </ul> </li> </ul> <p><i>Consider adding a statement describing the overall commitment of all participants:</i></p> <ul style="list-style-type: none"> <li>• <i>Examples:</i> <ul style="list-style-type: none"> <li>○ <i>Total # of site visits made</i></li> <li>○ <i>Describe overall or summary statistics in a creative way</i></li> </ul> </li> </ul>
<p>Study Results</p>	<p><i>Indicate where complete and/or summarized results of the study may be accessed; at the very least, sponsors should consider making available information on where to find general summary results in the public domain (such as through a government registry):</i></p> <p>The {complete/summarized} results of this clinical study may be found at: {companyname.com; clinicaltrial.gov; or 'other'}.</p> <p><i>If applicable, additionally the sponsors can indicate the location where a lay summary may be found (for studies conducted in the EU – refer to designated EU platform).</i></p> <p><i>As appropriate, it would help to clarify which of the above information is written for a patient audience, scientific audience, etc. (set expectations).</i></p>
<p>Non-Proprietary Intervention Information</p>	<p><i>Providing participants with the international nonproprietary name of the intervention used during the study would enable patients to retain this information, along with this letter, for future reference and during future discussions with their health care professionals.</i></p> <p>The name of the {intervention type} studied during your participation in the clinical study is {international nonproprietary name}.</p> <p>You may choose to reference this information, and the contents of this letter, during future discussions with your health care team.</p> <p><i>If the drug has or will be approved for use, consider providing commentary regarding how the drug may be marketed under various names in</i></p>

	<i>different countries, but if this happens the nonproprietary name would remain consistent and may still be associated with the marketed name.</i>
Participant's Intervention Type	<p><i>While staying consistent with the language used in the informed consent form given to the participant and adhering to applicable laws/regulations/guidance, the sponsor may wish to share whether the participant received the investigational product, placebo, comparator, etc. (as applicable to your study).</i></p> <p>While participating in the study, you received {XYZ}. This means that {description}.</p>
Sign Off	<p>We encourage you to speak with your {site staff contact / primary care physician / healthcare provider} regarding your individual participation in this trial or for more information about clinical trials.</p> <p>Thank you very much again for your participation and for your contribution to medicine, to science and to potential benefits for future patients.</p> <p>Sincerely,</p> <p>{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.