



Return of Aggregate Results to Participants Principles

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) Return of Results workgroup developed a practical guidance document for all sponsors (e.g., industry, non-profit, government, academic) to address key challenges in returning results and potential solutions. The purpose of creating and disseminating general clinical trial result summaries to participants is to ensure that study participants are informed about the trial results, that they know that their participation is and has been respected and appreciated, and that they understand the value of their contribution to science and public health. The foundation of returning aggregate results to participants has been summarized in 8 principles:

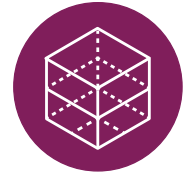
1. **Participants or their designees should be the recipients of plain language summaries.**
2. **Returning results to trial participants respects their volunteerism and their partnership in research; we recommend, therefore, that sponsors offer to provide results to study participants for all clinical studies.**
3. **Sponsors should prepare and disseminate plain language summaries in a manner that is fair, balanced, factual and non-promotional.**
4. **Plain language summaries should be written clearly and concisely, employing a patient-centric approach and incorporating principles of health literacy, cultural literacy and numeracy.**
5. **When offered, participants should be able to choose whether or not to receive plain language summaries.**
6. **Considerations pertaining to the return of aggregate plain language summaries to trial participants should be integrated into the clinical trial and proactively planned.**
7. **Clinical research sites should support and participate in the dissemination of research summaries to all study participants who wish to receive results.**
8. **Return of aggregate results should be planned and executed in compliance with institutional policies and local, regional, and national laws and regulations.**



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Principle 1: Participants or their designees should be the recipients of plain language summaries.

The first level of summary information contains an overview of the study and presents the conclusions of the study in simple language that uses concepts of health literacy. This general results summary is intended for trial participants, but may also be considered as a more public version of the summary, if such uses are desired (e.g., for media, IRBs, study sites, community groups, patient advocacy organizations, future participants). The summary might also be posted on EudraCT, ClinicalTrials.gov (although the website does not currently support this function), or other searchable sites.

Principle 2: Returning results to trial participants respects their volunteerism and their partnership in research; we recommend, therefore, that sponsors offer to provide results to study participants for all clinical studies.

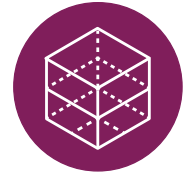
When determining with whom the results should be shared, we recommend that, at a minimum, results should be provided to all participants (or the Legally Authorized Representative, the parent or guardian) who were consented to participate in the study—whether or not the participant was later randomized or completed the clinical trial—and who opted to receive results.

Principle 3: Sponsors should prepare and disseminate plain language summaries in a manner that is fair, balanced, factual and non-promotional.

Communication about research results should (a) be factual, (b) ensure that the summary does not prematurely claim efficacy and/or safety, and (c) not appear to promote an unapproved use of an investigational or approved medicine. The written summary should reflect data and findings neutrally and objectively.

Principle 4: Plain language summaries should be written clearly and concisely, employing a patient-centric approach and incorporating principles of health literacy, cultural literacy and numeracy.

Plain language summaries should be written in plain language and presented in a well-organized format. If medical terms must be used, a simple explanation should be included. In addition, summaries should be translated into languages used by all trial locations, and results should be stated in culturally-appropriate terms. Finally, when sharing numeric data, simple explanations should be used instead of complex fractions, percentages or statistical terms.



Principle 5: When offered, participants should be able to choose whether or not to receive plain language summaries.

Participants should have the opportunity to decide whether or not to receive aggregate results at the end of the study.

Principle 6: Considerations pertaining to the return of aggregate plain language summaries to trial participants should be integrated into the clinical trial and proactively planned.

Creating a results sharing plan in advance of the initiation of a clinical trial can help to ensure that, at the time of consent, participants will be aware of the opportunity to receive results and decide how and to whom these results are communicated.

Principle 7: Clinical research sites should support and participate in the dissemination of research summaries to all study participants who wish to receive results.

Clinical site staff may support communication of plain language summaries by referring participants to appropriate resources or by directly discussing results in plain language. Investigators and study staff should factually and neutrally communicate results in order to ensure that information is presented in a non-promotional manner. When delivering study results, staff may also answer, or provide referrals for, questions raised by participants.

Principle 8: Return of aggregate results should be planned and executed in compliance with institutional policies and local, regional, and national laws and regulations.

Any recommendations for return of aggregate results should comply with institutional policies of the sponsor and investigator and the sovereign laws and regulations of the country in which the participant resides and in which the sponsor, investigator and/or institution operates.



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