Expectations of ‘Good Lay Summary Practices’

Barbara E. Bierer, MD

Professor of Medicine, Harvard Medical School

Faculty Co-Director, the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital

Harvard Program Director of the Regulatory Foundations, Law and Ethics Program

Harvard Catalyst | the Harvard Clinical and Translational Science Center

bbierer@bwh.harvard.edu
MRCT Center Mission

Engaging diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

- Return of aggregate results termed
- Plain Language Summaries (PLS)
Content of the Good Summary Practices Guidance document

- Whether, what, when, how and to whom to return results
  - **Whether:**
    - Default is to return; rebuttable presumption permitted (e.g. data integrity, potential harm [privacy, physical safety, security] to participants, longitudinal studies, etc.)
  - **What:**
    - Unbiased, balanced, non-promotional, accurate, and understandable summary
    - Essential: goal of the study, study design, conduct, primary outcomes, safety events if influences understanding of primary outcomes, further information
    - Optional: secondary endpoints, if not selective (e.g. only positive secondaries)
  - **When:**
    - After results analyzed, no later than one minute prior to public release or ~1 year
  - **How:**
    - Website, letter, personal communications
    - Balancing personal interactions and understanding with consistency of information exchange
  - **To whom:**
    - All enrolled…and the public (while protecting anonymity of all participants)
Content of the Good Summary Practices Guidance document

- Whether, what, when, how and to whom to return results
- Practical tools and resources
  - Templates, checklists, case examples
  - Tools for observational trials, complex study designs
- Guidance on clear communications (e.g. a ‘how to’ for plain language, numeracy, etc.)
- Stakeholder (e.g. investigator, provider, participant) engagement, from planning to execution
- Special situations (e.g. pediatrics, death, cultural considerations)
- Process for return
- Dissemination
- Commitment to required resources for successful execution
Participant Clinical Trial Results Summaries - Process

- Write in unbiased and non-promotional language
- Use plain language understandable to the audience
- Apply health and numeracy principles, appropriate imagery and visualization
- Obtain review by independent, objective editor(s) and patient representative(s)
- Incorporate the patient’s voice into the summary
- Translate into languages consistent with translations of informed consent
- Make someone from study site or neutral 3rd party available for questions
- Make provisions for vulnerable populations, children, the elderly, others
- Consider as to whether to inform, and whom to inform, in the event of a participant’s death
Planning for and phasing of return of results

**Pre-Study preparation**
- Protocol Development

**During study conduct**
- Identify and Recruit
- Collect Data
- Last Patient Last Visit
- Close-out

**When study ends**
- Communicate Results
- Analyze Data
- Interpret Results

- Organizational Preparation
- Level, timing, methodologies

- Address whether, what, when and how to return results
- IRB/EC review and approval

- Introduce PLS
- Manage expectations
- Engage and communicate

- Prepare summary, aligned with IC, CSR, Manuscript
- Web site or individual outreach through PIs/sites
- Follow up

© MRCT Center
Return of Results Guidance Document


Process flow
Methods
Content of results summaries
Health and numerical literacy

Return of Results Toolkit


Templates for communicating study results
Neutral language guidance
Endpoint table
Useful checklists

Content of the Good Summary Practices Guidance document

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 in detail key challenges in returning results and potential solutions. The purpose of creating and disseminating general clinical trial result summaries to clinical trial 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 6 principles:

1. Participants or their designees should be the recipients of research results 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.

http://mrctcenter.org/projects/return-of-results-to-participants/
Thank you

Barbara E. Bierer, MD
bbierer@bwh.harvard.edu
+1 (617) 827-7413