Dissemination strategies and options for plain language summaries

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Harmony and agreement

- EFGCP/EFPIA analysis, approach, and recommendations for dissemination
- Optimal for all participants to receive same information, if they opt to obtain it
  - Regardless of sponsor
  - Regardless of type of trial
  - Regardless of location
- Considerations for complex trials including role of IRB/EC review (and required modifications for document leading to inconsistencies and delays, and burden)
- Roles of other stakeholders including patient organizations
  - Funders: may require return of aggregate result as a condition of funding
  - Challenge of educating over-scheduled healthcare providers, and challenge of lack of coordinated communication path between and among sponsor, investigator, healthcare provider, and participant
- Dissemination pathways are not mutually exclusive (e.g. publicly accessible websites does not foreclose investigator discussions)

Direct and indirect delivery methods

- Direct:
  - Benefits: personalized, opportunity to further explain
  - Challenges: expense (time, effort), site investigator often no longer involved, difficult to obtain assurance that communication has been achieved.
    - If in contract with investigator or site, sponsor cannot close out the study
  - Patient privacy may be compromised by mail
- Indirect:
  - Benefits: cheaper, can provide information regarding site in informed consent and on study
  - If technical solution: option not only for registration but also “push-out” notification system
  - Not all participants have internet access or facility
  - Condordance of information provided as all participants will receive same information, if they opt to obtain it
  - Some studies may be compromised by public dissemination of results
- Non-exclusive choices
- Considerations for complex trials including role of IRB/EC review

Challenges for academia and US

- US – no requirement by regulators or guidance
- Uncompensated activity of overworked investigators
- Few (if any) sites have site-specific websites nor commitment to do sO
- Lack of coordination between and among different stakeholders
- Funding and infrastructure challenges (e.g. Who develops, Where to post?)
- … and all that assumes that the trial completes and results are reported

- Harmonization and cooperation worthwhile

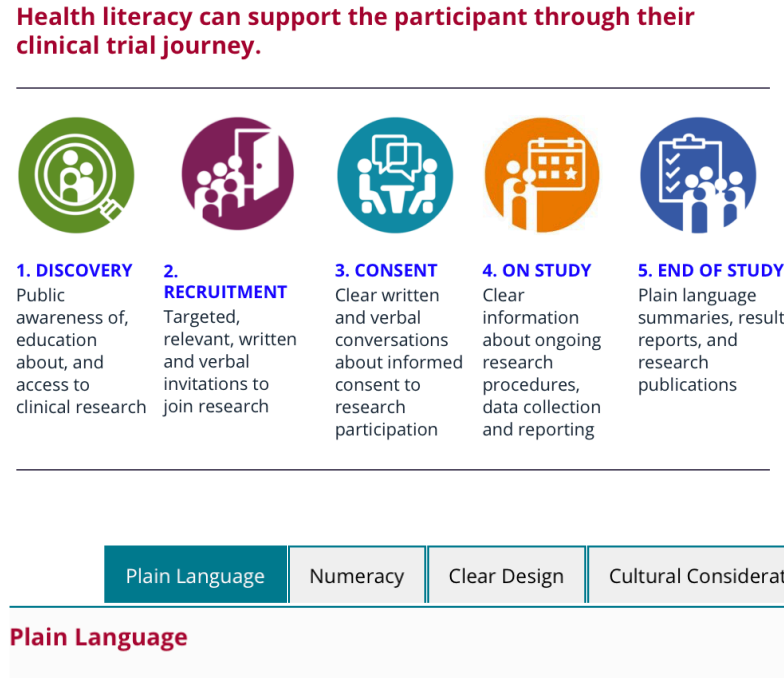
- ClinicalTrials.gov potential opportunity
  - Will not post summary results
  - Current RFI is open

Cooperative development of resources and best practices

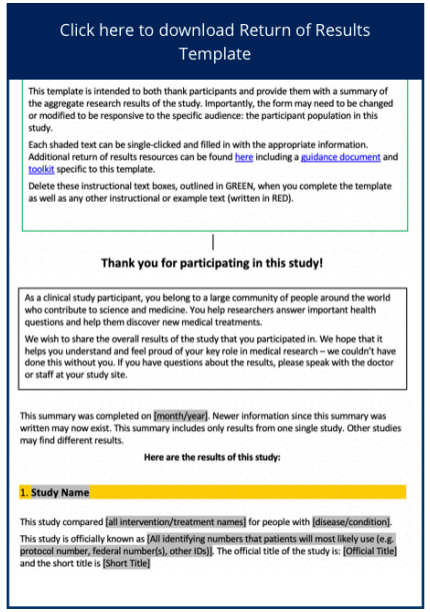
- Harmonized international guidelines and/or regulations
- Return of aggregate results is independent of sponsor, whether industry or academic, private or public
- Common expectations across the globe
  - Available information for participants (and the public) equivalent in Brussels ~ Boston ~ Botswana ~ Beijing ~ Bahrain
- Access to information for participants and the public is democratized
- Funding for return of aggregate results is an anticipated cost of human participant research
- Resources shared to minimize burden

Cooperative development of resources and best practices

https://mrctcenter.org/health-literacy/



Cooperative development of resources and best practices



https://mrctcenter.org/health-literacy/tools/overview/return-of-results/

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MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOURCES BY ROLE

Return of Results

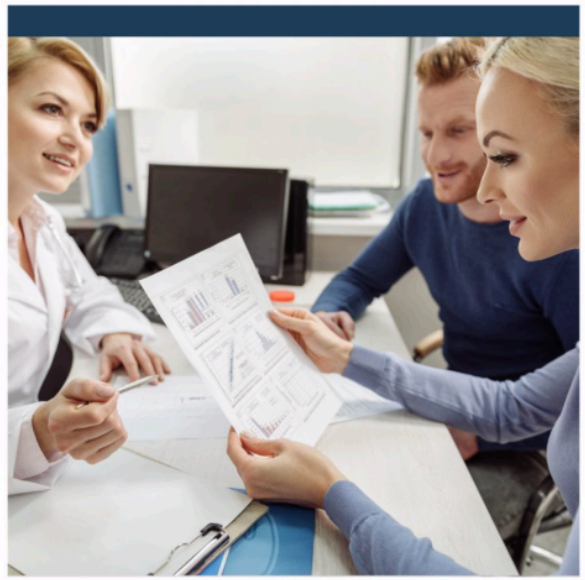
Home > Best Practices > Overview > Return of Results

Create and disseminate general clinical trial result summaries

(also known as Lay Summaries or Plain Language Summaries) so clinical trial participants:

- are informed about the trial results,
- know their participation is respected and appreciated
- understand the value of their contribution to science and public health.

More information about previous MRCT Center work on Return of Results can be found here.



Download this fillable Return of Results template and adapt it to your study situation.

Cooperative development of resources and best practices

- Development of a **common plain language glossary for clinical research**

To present definitions, context, and usage of terms, and images or icons (as applicable) in an intuitive and user-friendly way

- Accurate
- Efficient
- Consistent
- Transparent
- Trustworthy

Glossary

This glossary is a work in progress, please check back for updates.

TERM	DEFINITION	ALSO KNOWN AS:
Blinding	A way to keep participants and researchers from knowing who is getting the treatment or test being studied.	masking
Clinical Trial	A research study to determine whether an intervention is safe and effective	clinical research study, international study

https://mrctcenter.org/health-literacy/

Examples of research terms, definitions, usage and possible icons (all draft and not approved)

Research Term	Definition	Example of use	Sample Icon/Image(s)
Clinical Trial	A research study to find out if an intervention is safe and works as intended	This **clinical trial** is studying whether a new drug for asthma works, when compared to the usual standard of care	
Research Participant	A person who joins a research study	The study includes **research participants** who will help test whether meditation decreases hot flashes in women with breast cancer.	

A global cooperative effort

- Ongoing research to understand:
  - Participant and public expectations, understanding, and utility of information
  - Potential benefits and potential risks of sharing aggregate results
  - Best practices for dissemination particularly given variety of studies
    - From ultra-rare diseases to common conditions with thousands of participants
    - Of RCTs to PCTs to adaptive trials to observational and real-world trials
    - From neonates to the elderly
- Return of aggregate study results evolves from a requirement to an expectation
- Respect for persons demands nothing less

Thank you

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