Routemap

# Dissemination of Results


## Trial Close-Out Phase

**The Dissemination of Results station** follows the Clinical Trial Summary Report station and precedes the Archiving station. Dissemination of Results is good practice and is relevant to all trials. This station is part of the 'trial close-out phase' group of stations.

Information about clinical trials is disseminated in the following ways:

- **Trial Registration**: Providing information about planned clinical trials (see Trial Registration station)
- **A Summary of Results:** Providing results for pre-specified primary and secondary end points, details of adverse events and statistical analyses (see Clinical Trial Summary Report station)
- **A Final Study Report**: Providing full details about the trial's methods and results
- **Individual Participant Data**: Sharing with others, de-identified individual-participant data (IPD)

## Reporting to the Research Community

Information concerning publication policy should be included in the protocol and funders will often ensure plans are in place. The ethics application form requires the applicant to confirm how they intend to report and disseminate their results.

The common route to inform the research community of full trial methods and results is through publication in peer-reviewed scientific journals however many publications have documented deficiencies in the reporting of clinical trials. Characteristics of good and poor reporting practices are described below:

## Good Reporting Practice:

- Allows replication (in principle)
- Presented in a way that allows inclusion in future systematic reviews

## Poor Reporting Practice:

- Key information relating to methods and results is missing, incomplete or ambiguous
- Method or findings have been subject to selective reporting
- The interpretation of results is misleading
- There are undeclared changes from the study protocol

CONSORT is an initiative that was developed to improve the reporting of randomised controlled trials, enabling readers to understand a trial's design, conduct, analysis and interpretation and to assess the validity of its results. For non-commercial trials, it is strongly recommended that the CONSORT guidelines are followed when preparing final study reports.

Final reports of studies funded by a number of NIHR programmes will be published as part of the NIHR Journals Library and its guidance for authors must be followed. Authors will be required to report the nature of patient/public involvement in their study and to produce a clear 'plain English' summary within their report so that the findings are widely accessible. The NIHR Journals Library will help disseminate the findings of the research commissioned by these programmes and will provide an important permanent and comprehensive record of the work which has been funded.

## Individual Participant Data

The sharing of the data produced in a clinical trial has the potential to provide benefits to patients and the scientific community. Guidance on the Good Practice Principles for Sharing Individual Participant Data from Publicly Funded Clinical Trials (.PDF), has been produced for publicly funded clinical trials. This guidance summarises the good clinical practice principles to follow when sharing individual

participant data using a controlled access system.

The International Committee of Medical Journal Editors (ICMJE) members simultaneously published an editorial (.PDF) on Sharing Clinical Trials Data that outlines proposed new requirements for authors to comply with mandatory data-sharing practices.

## Information to participants

Informing participants of results acknowledges their contribution, shows respect and sees them not simply as a means to the researchers' ends. It is important to establish whether a participant will want to be actively informed of trial results, or whether they would like the onus to be left with them to obtain the results. Patient and public involvement may help to guide this process. The HRA web pages provide guidance on the communication of research outcomes to participants.

The RECAP project has generated stakeholder informed evidence to provide recommendations on key considerations to support appropriate reporting of clinical trial summaries to participants, as well as recommendations for core content for these summaries.

Any end of study information sheets that have been provided to participants should be submitted alongside the final report to the REC.

It is good practice for investigators to check whether the NHS R&D offices that gave approval require a copy of any publications or reports.

### Further reading:

- Clinical Trial Summary Report station.
- Trial Registration station: Information on trial registration.
- BMJ resources for authors.
- NIHR Journals Library resources for authors.
- Increasing value and reducing waste: addressing inaccessible research by A-W Chan et al.
- AllTrials Campaign - All Trials Registered, All Trials Reported September 2013 (.PDF).