How to guide: Study conclusion (closedown)

This guide outlines general guidance on the process for study conclusion (closedown).

Key information you should be aware of:

- The practice is responsible for the ongoing treatment of its patients, and for ensuring that patients and patient data are treated with due care.
- Sponsors are responsible for the management of a specific study.
- Chief Investigators (CIs) are responsible for the conduct of a specific study within the UK.
- Archiving of study documentation is necessary to enable any subsequent evaluation of study conduct.
- The Clinical Trials Regulations and specifically, Regulation 31A of the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, define the archiving requirements for Clinical Trials of Investigational Medicinal Products (CTIMPs). See the NIHR Toolkit for Archiving: https://www.ct-toolkit.ac.uk/routemap/archiving/

Highlights

- Study conclusion
- Archiving

See also

- Roles and terminology guide
- Data protection guide
- Retention of documents guide

Full guide

Study conclusion

- The protocol or subsequent agreement(s) will determine the date for the conclusion of the study.
- The study team should inform the local Principal Investigator (PI) of the closure of the study.
- Some studies may conclude before the conclusion date or event for a variety of reasons.
- The site (GP practice) should keep a record of study conclusion dates.

Archiving

- Archiving of study documentation is necessary to enable any subsequent evaluation of study conduct.
- The Study protocol should outline the process for archiving study documents including the length of time these need to be kept. If there is any doubt, please contact the study team.
- Archiving should be carried out in line with the study protocol alongside your local policy for archiving and storage.

Glossary of Acronyms and Terms

CI	Chief Investigator
PI	Principal Investigator