Quality Control Document:

Guide to Retention Times

# Purpose

This guide has been developed to provide further information on the required retention period for material that needs to be archived as part of a clinical research project. This document can be used in conjunction with the Archiving SOP (UoB-ARC-SOP-001) to establish the required retention period for the project material.

# Related documents

* UoB-ARC-QCD-001 Archiving Plan
* UoB-ARC-QCD-002 Archive Label
* UoB-ARC-SOP-001 Archiving

Access to the full UoB QMS for clinical research is available via the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx).

| Project type | Retention period (minimum) | Reference  |
| --- | --- | --- |
| UoB Policy |
| UoB REC-approved clinical study | 10 years | The [Concordat on Open Research Data (PDF – 180 KB)](https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-ConcordatonOpenResearchData.pdf) and the [UoB Research Data Management Policy](https://intranet.birmingham.ac.uk/as/libraryservices/library/research/rdm/Policies/Research-Data-Management-Policy.aspx) state that primary research data and research evidence should be preserved and accessible for a minimum of 10 years. |
| HRA-approved clinical study |
| Non-CTIMP |
| CTIMPs |
| Any clinical study, non-CTIMP or CTIMP of clinical importance | 20 years | The [UoB Research Data Management Policy](https://intranet.birmingham.ac.uk/as/libraryservices/library/research/rdm/Policies/Research-Data-Management-Policy.aspx) states that research data should normally be preserved and accessible for 10 years, but for projects of clinical or major social, environmental or heritage importance for 20 years or longer. |
| Regulations |
| CTIMPs not used to support marketing authorisation | 5 years(10 years for UoB policy) | The [Medicines for Human Use (Clinical Trials) Regulation 2004 (PDF – 307 KB)](https://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf). Documents would need to be archived for 10 years as per the UoB policy (except where a trial did not open to recruitment). |
| CTIMPs to support marketing authorisation | 15 years | The [European Directive 2003/63/EC (PDF – 366 KB)](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:159:0046:0094:en:PDF) states that where trial results are planned to be used for registration purposes, essential clinical trial documents are required to be archived for at least:* 15 years after the trial’s completion or discontinuation or
* 2 years after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the European Community, or
* 2 years after the formal discontinuation of the clinical development of the investigational product.
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| Paediatric trials | As above | The [Medicines for Human Use (Clinical Trials) Regulation 2004 (PDF – 307 KB)](https://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf).[European Directive 2003/63/EC (PDF – 366 KB)](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:159:0046:0094:en:PDF).Note – data may not be used for a marketing authorisation application when the TMF has only been maintained for 5 years.  |
| CTIMPs run in EU countries | 25 years | The [Clinical Trial Regulation (EU) No536/2014 Article 58 (PDF – 757 KB)](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf) states that the content of the TMF will be archived for at least 25 years after the end of the clinical trial. |
| ATIMP | 30 years | The sponsor of the trial and the investigator/institution where the ATIMP is used must keep their parts of the traceability records (as per [Annex 1 of EudraLex Volume 10, Chapter 5, ‘Detailed guidelines on good clinical practice specific to advanced therapy medicinal products’ (PDF – 406 KB)](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/atmp_guidelines_en.pdf)) for a minimum of 30 years after the expiry date of the product. |