This table is not an exhaustive list, and other trial records may also be considered essential by the sponsor or the investigator.

C.3.3 For some trial records listed in the Essential Record Table, their presence and nature are dependent on the trial design, trial conduct and risk proportionate management of the trial and may not be produced.

Essential Records Table If these trial records are produced, they are considered essential and should be retained (see sections C3.1 and C3.2). *Note: An asterisk (*) identifies those essential records that should generally be in place prior to the start of the trial (see section C2.5).*
Investigator's Brochure or basic product information brochure (e.g., summary of product characteristics, package leaflet or labelling)*
Signed protocol* and subsequent amendments during the trial
Dated, documented approval/favourable opinion of IRB/IEC of information provided to the IRB/IEC*
IRB/IEC composition*
Regulatory authority(ies) authorisation, approval and/or notification of the protocol* and of subsequent amendments during the trial (where required)
Completed signed and dated informed consent forms
Completed participant identification code list and enrolment log
- Notification by originating investigator to sponsor of serious adverse events (SAEs) and related reports, where required - Notification by sponsor and/or investigator, where required, to regulatory authority(ies) and IRB(s)/IEC(s) of suspected unexpected serious adverse reactions (SUSARs) and of other safety information - Notification by sponsor to investigators of safety information, where required
Interim or annual reports to IRB/IEC and regulatory authority(ies) (where required)
Source records
Data and relevant metadata (including documentation of data corrections) in the data acquisition tools
Final report to IRB/IEC and regulatory authority(ies), where required
Interim (where applicable) and final clinical trial reports
Sample of data acquisition tools (e.g., case report forms (CRFs), diaries, clinical outcome assessments, including patient-reported outcomes) that are provided to the investigator and/or IRB/IEC*
Sample of information given to trial participants* - Informed consent materials (including all applicable translations)

Essential Records Table If these trial records are produced, they are considered essential and should be retained (see sections C3.1 and C3.2). *Note: An asterisk (*) identifies those essential records that should generally be in place prior to the start of the trial (see section C2.5).*
- Any other documented information (e.g., instructions for use of an investigational product or a device) - Advertisement for participant recruitment
Arrangement between parties on the financial aspects of the trial*
Insurance statement*
Signed agreement between involved parties,* for example: • Investigator/institution and sponsor • Investigator/institution and service providers • Sponsor and service providers • Sponsor and IDMC and/or adjudication committee members
Documentation of selection, assessment* and oversight of service providers conducting important trial-related activities
Relevant documents evidencing qualifications of investigator(s) and sub-investigator(s) (e.g., curriculum vitae) involved in conducting the trial*
Trial-specific training records*
Documentation of delegation of trial-related activities by the investigator*
Signature sheet documenting signatures and initials, unless only electronic signatures are used (of investigator and individuals delegated by the investigator)* (can be combined with documentation of delegation above)
Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol*
Certification or accreditation or other documentation including of validation (where required) to confirm the suitability of medical/laboratory/technical procedures/tests used during the trial conduct*
Documentation of collection, processing and shipment of body fluids/tissue samples
Documentation of body fluids/tissue samples storage conditions
Record of retained body fluids/tissue samples at the end of the trial
Sample of label(s) attached to investigational product container(s)
Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or Investigator's Brochure), for example, pharmacy manual*
Shipping records for investigational product(s) and trial-related materials*
Certificate(s) of analysis of investigational product(s) shipped*
Investigational product(s) accountability at investigator site

Essential Records Table If these trial records are produced, they are considered essential and should be retained (see sections C3.1 and C3.2). *Note: An asterisk (*) identifies those essential records that should generally be in place prior to the start of the trial (see section C2.5).*
Documentation of investigational product storage conditions, including during shipment
Records of relabelling of investigational product at the investigator site
Documentation of investigational product destruction or alternative disposition
Emergency decoding procedures for blinded trials*
Master randomisation list*
Instructions for use of important trial-specific systems (e.g., interactive response technologies (IRTs) user manual, electronic CRF (eCRF) manual)*
Records demonstrating fitness for purpose (e.g., maintenance and calibration) for equipment used for important trial activities*
Treatment allocation and decoding documentation
Completed participants screening log
Site monitoring reports (including site selection,* initiation,* routine and close-out)
Centralised monitoring reports
Records and reports of noncompliance including protocol deviations and corrective and preventative actions
Documentation of relevant communications and meetings
Audit certificate
Documentation relating to data finalisation for analysis (e.g., query resolutions, SAE reconciliation, quality control reports, coding completion, output data sets)
Documentation of trial-specific computerised system validation (e.g., specifications, testing, validation report, change control)*
Documentation of the assessment of fitness for purpose for non-trial-specific computerised systems used in the trial (e.g., clinical practice computerised systems)*
Documentation relating to the statistical considerations and analysis (e.g., sample size calculations,* analysis sets decisions, analysis data sets, analysis programs, quality control records and outputs)
Trial-specific plans (e.g., risk management,* monitoring,* safety,* data management,* data validation* and statistical analysis) and procedures
Procedures,* meeting minutes and submissions to the IDMC/adjudication committee(s)