1 Purpose

All Aseptika records, whether analogue or digital, are subject to the retention requirements outlined in this procedure.

This procedure satisfies the requirements stipulated within clauses 4.2.4 Control of documents and 4.2.5 Control of Records of EN ISO 13485:2016+A11:2021 and 7.3.9 Control design and development changes of EN ISO 13485:2016+A11:2021 and 910/2014/EU e-IDAS Regulation on electronic identification and trust services for electronic transactions in the internal market.

This procedure satisfies the requirements stipulated within EU MDR 2017/745, in part, Article 10 General Obligations of a Manufacturer and Annex XIV, Part A on Clinical Evaluation and Post-Market Clinical Follow-up, and finally Annex XV on Clinical Investigations.

Retention of personal data is also covered by the UK GDPR, Data Protection Act 2018 (UK), EU GDPR, Common Lay Duty of Confidentiality (UK only), Human Rights Article & HRA 1998.

2 Scope

Aseptika may store data for longer periods if the personal data is to be processed solely for archiving purposes in the public interest, scientific, historical research purposes, statistical purposes and regulatory support, subject to the implementation of appropriate technical and organisational measures to safeguard the rights and freedoms of the data subject.

3 Policy Guidance

3.1 Preservation of Patient Data

The NHS[x] Records Management Code of Practice 2021, is a guide to the management of health and care records, for consistent and effective records management based on established standards. The Public Records Act 1958 requires organisations to select records for permanent preservation. It is designed to ensure the permanent preservation of a small core (typically 2-5%) of key records, which will:

- Enable the public to understand the working of the organisation and its impact on the population it serves.
- Preserve information and evidence likely to have long-term research or archival value.

The preservation of patient account details (either anonymised or pseudonymised) can be applied to Aseptika user data, particularly 4, 5 and 6 below, when:

1. The Organisation has an unusually long or complete run of records of a given type.
2. The records relate to population or environmental factors peculiar to the locality.
3. The records relate to an event or issue of significance local or national importance.
4. The records relate to the development of new or unusual treatments or approaches to care or the organisation is recognised as a national or international leader in the field of medicine or care concerned.

5. The records throw particular light on the functioning or failure of the organisation or the NHS or social care in general.
6. The records relate to a significant piece of published research.

In addition, the NHS[x] Records Management Code of Practice 2021, outlines the retention period for patient or service user portals or via apps. Information stored in a portal or app, such as the Activ8rlives Clinical Portal and Asthma+me, Active+me REMOTE and Activ8rlives[4] Health+Wellness Apps, should be retained in line with the retention schedules outlined in this Code (e.g. adult health records for 8 years after last seen; children health records up to 25th or 26th birthday; long-term illness or illness that may reoccur 20 years or 10 years after death; research datasets no longer than 20 years but the medical device Regulators require it for the lifetime of the product; subject access requests 3 years; litigation records for 10 years).

Data retention is still considered as data processing and, therefore, Aseptika has to justify the legal basis to process for a purpose and subsequent controls that are put in place, e.g. anonymised or pseudonymised, etc). There are various retention periods for different types of research and the party responsible for this research data.

- Clinical trial: The Sponsor requires the Trial Sites to retain source documentation from the trial (also including service evaluation, usability studies etc.) and it cannot be deleted unless there is instruction from the Sponsor to do so. In this circumstance both the Sponsor and Trial site will be considered as Joint Controllers.
- Trial Master File (TMF): Retention for at least 25/15 years after the Study has been completed.
- Basic research: 10 years after the Study has been completed.
- Longitudinal Studies: Often indefinitely, however, there needs to be justification as to why the data sets are to be preserved indefinitely.
- Research data relating to Studies which directly inform national policymaking should be considered for permanent preservation.

3.2 Archiving of Patient Data

Data archiving is the process of moving data that is no longer actively used to a separate storage device for long-term retention. Archive data consists of older data that remains important to the organisation or must be retained for future reference or regulatory compliance reasons.

Archiving must undertake:

- Be archived in a way that ensures that it is readily available and accessible, upon request, to a regulator(s).
- Any transfer of ownership of the content of the research file should be documented. The new owner will assume all the responsibilities to those individuals.
- The Sponsor will appoint individuals within its organisation to be responsible for archives. Access to these archives will be restricted throughout the period of retention.
- The media used to archive the content of the research should be such that the content remains complete and legible throughout the period of retention.
- Any alteration to the content of the research should be traceable.

3.3 Common Law Duty of Confidentiality

Aseptika considers the Common Law Duty of Confidentiality takes over from the UK GDPR or EU GDPR where appropriate, after the death of the person concerned and take into consideration that current care regulations require all records are kept on a service user to be retained for not less than three years from the date of the last entry but there are varying differences, see NHS[x] Records Management Code of Practice, August 2021.

4 Responsibilities

The Managing Director (also SIRO) is accountable for the record retention and disposal arrangements. The Quality Regulatory & IG Director/DPO/Caldicott Guardian is responsible for ensuring that retention and destruction is undertaken in accordance with this procedure and the regulations and Acts listed above.

5 Procedure

1. The required retention periods are recorded in Appendix A and also references in greater detail in the NHS[x] Records Management Code of Practice 2021.
2. The access control policy determines the rights for accessing stored data.
3. Deletion of customer data from electronic data systems will be undertaken in accordance with the schedule and the Quality Regulatory & IG Director is responsible for confirming that the deletion run can take place. The Quality Regulatory & IG Director is responsible for identifying any records (e.g. may be subject to complaint), which must be excluded from the deletion run or as requested by a customer.
4. Electronic data will be logically deleted from the media on which the data is held and this will be subject to electronic shredding or physical destruction.
5. The responsibility for the destruction of paper information via shredding rests with the manager who holds the data.
6. Portable/removable storage media are physically destroyed.

Appendix A Retention Schedule

Record type	Retention period required by law	Organisation retention period	Retention period to start from (creation, submission, payment, etc.)	Retention justification	Record medium	Disposal method
Customer/patient data, including consent information		15 years – indefinitely. Children's records up to 25th or 26th birthday.	After customer/patient ceases to be a customer.	Can be kept indefinitely if this data contains longitudinal data that has or might be used as basis of regulation of medical devices now and in the future. Includes Trial Master File.	Paper & electronic.	Anonymisation & Pseudonymisation of account and keep data, with Key to patient ID kept separately.
Finance data	7 years	7 years	The end of financial year after accounts have been closed.	HMRC requirements.	Electronic.	Logical deletion and/or archiving.
Intellectual Property/patents		Lifetime of Patent or 6 years from end of license or action.	Lifetime of Patent or 6 years from end of license or action.	Freedom to operate infringements and granted patents from Patent Offices around the World.	Paper & electronic	Logical deletion and/or archiving.
Policies/procedures /processes/privacy notices		5 years – archive.	After the policy is superseded.	Requirement to go back to demonstrate policies in place at the time is required, so archiving is the method to use.	Electronic.	Archiving.
Third-party contracts/ agreements		10 years or lifetime of medical device.	Archive after end of contract or 10 years or lifetime of medical device if contract relates to manufacturing under ISO 13485:2016 & MDR 2017/745.	Under ISO 13485:2016 & MDR 2017/745 all records of manufacturing are required for 10 years or lifetime of medical device.	Paper and electronic.	Archive & logical deletion.

Record type	Retention period required by law	Organisation retention period	Retention period to start from? (at creation, submission, payment, etc.)	Retention justification	Record medium	Disposal method
Research records & data sets (not basic research)		In accordance with research protocol, lifetime of medical device & indefinitely for longitudinal data.	In accordance with research protocol and ISO 13485:2016 and MDR 2017/745.	Under ISO 13485:2016 & MDR 2017/745 all records of manufacturing and clinical research are required for 10 years or lifetime of medical device, for ongoing longitudinal studies & support of regulation of medical devices.	Paper and electronic.	Anonymisation, Pseudonymisation, with Key to patient ID kept separately.
Personnel records, including employee contracts, occupational health & training records.		5 -10 years or lifetime of medical device.	After termination of employment up to 5 years but training records for lifetime of medical device.	Training records that relate to medical devices needs to be retained for 10 years or lifetime of medical device.	Paper and electronic.	Logical deletion, shredding & Archive for training records.
Reports of accountants.		7 years		HMRC requirements.	Paper and electronic.	Logical deletion and shredding.
Employee payroll records.		7 years		HMRC Requirements.	Paper and electronic.	Logical deletion and shredding.
Employment applications.		6 months	After the application has closed.		Paper and electronic.	Logical deletion and shredding.
Subject access requests & FOI.		5 years	After the subject access or FIO request has been completed.	ICO requirements.	Paper and electronic.	Logical deletion.
Software licenses.		10 years or lifetime of medical device.	10 years or lifetime of medical device where the software and/or product where they are incorporated.	Where feasible to back date software, retain for 10 years or lifetime of medical device where the software and/or product where they are incorporated.	Electronic.	Logical deletion.

Record type	Retention period required by law	Organisation retention period	Retention period to start from? (at creation, submission, payment, etc.)	Retention justification	Record medium	Disposal method
System audit trails.		2 years		Who has had access to data, in particular patient data.	Electronic	Logs automatically overwrite 2ys.
Incident, both relating to medical device and IG records.	10 years or lifetime of medical device.	Minimum 10 years or lifetime of medical device.	After incident is closed. Incidents potentially subject to legal action (e.g. customer safety issues) retained for 10 years or lifetime of MD.	Under ISO 13485:2016 & MDR 2017/745 all records of manufacturing are required for at 10 years or lifetime of MD.	Paper and electronic.	Archive & logical deletion.
Software design, development and testing documents.	10 years	Minimum 10 years or lifetime of medical device.	A minimum of 10 years or lifetime medical device under ISO 13485:2016 & MDR 2017/745.	Under ISO 13485:2016 & MDR 2017/745 all records of manufacturing are required for at 10 years or lifetime of MD.	Paper and electronic.	Archive & logical deletion.
Long-term illness or illness that may reoccur – patient records.	10-20 years	20 years or 10 years after death.	20 years or 10 years after death.	Necessary for continuation of clinical care, where a long-term illness or illness that may reoccur – patient records, for ongoing longitudinal studies & regulatory support of MD.	Paper and electronic.	Anonymisation & Pseudonymisation of account, keep data, Key to patient ID kept separate.
DPIA and PIAs.	6 years after the activity ends.	10 years or lifetime of the medical device.	10 years or lifetime of the medical device.	Under ISO 13485:2016 & MDR 2017/745 all records of manufacturing are required for at 10 years or lifetime of MD.		Archive & logical deletion.

6 Document History

Version	Date	Authors Initials	Reviewers Initials	Changes from Previous Version	Authorised by & date
1.0	12.02.2018	GL		First Draft	
1.1	14.02.2018	KAA		Formatting	
1.3	15.02.2018	KAA		Policy Number added	
1.4	15.02.2018	JMA		Updated	
1.5	28.2.2018	KAA		Updated to make Public	
1.6	02.05.2018	ETRA		Update to a new template and change the policy number	
2.0	11/12/2018	ETRA	KAA, JAA, CB	Annual review and part of CC2018-0187	
3.0	02.12.2019	JA	MP	MDR Transition update, part of CC2019-057	KAA
4.0	22.11.2021	JA	GE	Annual review, CC2021-075	Kevin A Auton 23.12.2021
5.0	07.03.2022	JA	GE	Update language CC2022-018	Kevin Auton 18.03.2022
6.0	24.06.2022	JA	GE	Update policies CC2022-041	KAA 04.07.2022
7.0	27.10.2022	JA	GE	Migrate to AWS CC2022-063	KAA authorise JA 02.11.2022