SoHO Coordination Board (SCB)

Recommendations and Guidance document for the Management of SoHO in Hospital Entities

This report was produced under the EU4Health Programme under a service contract (ReaderSHip Project) with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission, reviewed by the Registration WG of the SCB and adopted by the SCB.

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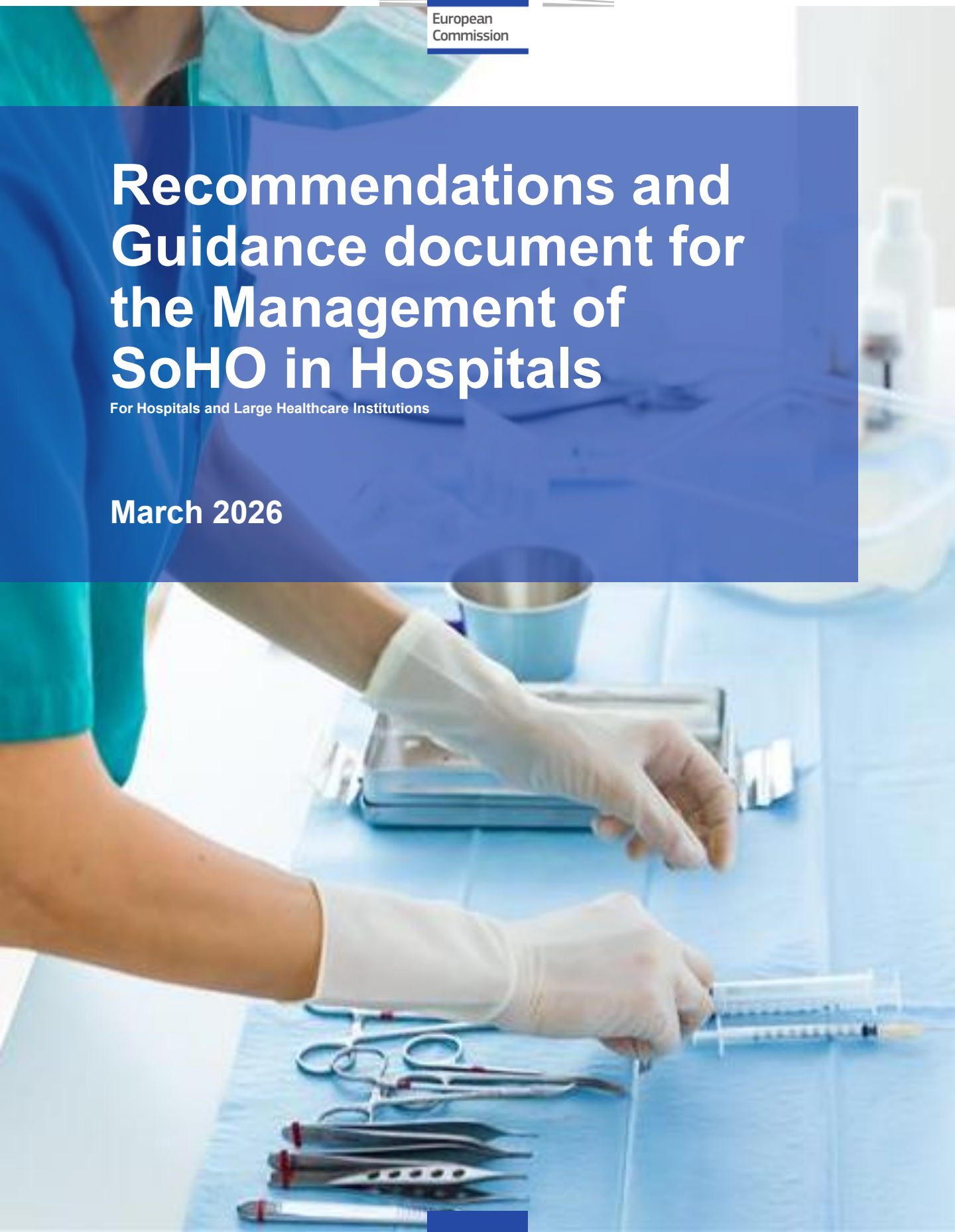
Recommendations and Guidance document for the Management of SoHO in Hospitals

For Hospitals and Large Healthcare Institutions

March 2026



Recommendations and Guidance Document for the Management of Substances of Human Origin in Hospitals (ReaderSHip Project).

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Table of contents

Table of abbreviations

Acronym	Description
ECDC	European Centre for Disease Prevention and Control
EDQM	European Directorate for the Quality of Medicines and HealthCare
EU	European Union
SoHO	Substances of Human Origin
SPA	SoHO Preparation Authorisation
SEC	Single European Code
ICCBBA	International Council for Commonality in Blood Banking Automation

Glossary

Term	Definition
Adverse Event	Any incident or error associated with SoHO activities that can affect the quality or safety of SoHO in such a way that implies a risk of harm to a living SoHO donor, to a SoHO recipient or offspring from medically assisted reproduction *(Article 3 (44) of the SoHO Regulation).*
Adverse Reaction	Any incident which could be reasonably associated with the quality or safety of SoHO, or their collection from a SoHO donor or human application to a SoHO recipient, that caused harm to a living SoHO donor, to a SoHO recipient or offspring from medically assisted reproduction *(Article 3 (43) of the SoHO Regulation)*.
Clinical-outcome Monitoring Plan	A programme for evaluating the safety and effectiveness of a SoHO preparation following human application *(Article 3 (32) of the SoHO Regulation)*.
Collection	A process by which SoHO are obtained from a person, including any preparatory steps, such as hormone treatment, needed to facilitate the process at, or under the supervision of, a SoHO entity *(Article 3 (22) of the SoHO Regulation)*.
Committee	A subgroup or organisation officially designated to perform a specific function, discussing, or making decisions on particular fields within the hospital. In the context of this document, a committee may include board nurses, physicians, designated delegates, and other relevant personnel. Examples of such committees include the Transfusion Committee and the Transplant Committee, amongst others.
Critical SoHO	A SoHO for which an insufficient supply will result in serious harm or risk of serious harm to recipients' health or in a serious interruption in the manufacture of products regulated by other Union legislation, as referred to in Article 2(6) of the SoHO Regulation, where an insufficient supply of such products will result in serious harm or risk of serious harm to human health *(Article 3 (2) of the SoHO Regulation)*.
End-user	An individual who applies the SoHO to a recipient.
Grey Literature	Information produced on all levels of government, academia, business and industry in electronic and print formats not controlled by commercial publishing i.e., where publishing is not the primary activity of the producing body.
Haemovigilance	A set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their followup. Haemovigilance includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, as well as the development and implementation of recommendations to prevent their occurrence or recurrence.
Human Application	Being inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred, inseminated or otherwise added to the human body in order to create a biological interaction with that body *(Article 3 (19) of the SoHO Regulation)*.

Physician	In the scope of this document, a person who performs the tasks defined in Article 50 (2) of the SoHO Regulation in the same Member State, and who meets the following minimum requirements: (a) possession of formal qualification as a physician; and (b) at least two years of practical experience in the relevant field.
Personal Data	Any information relating to an identified or identifiable natural person ('data subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
Pseudonymisation	The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data is not attributed to an identified or identifiable natural person.
Quality Manager	The Quality Manager is the person responsible for managing the quality system. Their duties include, but are not limited to, ensuring the implementation of the following: (a) qualification of personnel, (b) verification or validation of processes, (c) qualification, (d) maintenance, (e) cleaning of premises and equipment (f) disinfection and monitoring of premises and equipment, (g) verification or validation of test methods, (h) qualification of materials, (i) qualification and monitoring of suppliers and contractors, (j) document control, (k) retention of records, (l) compliance of all other personnel with requirements, (m) scheduling and follow-up of audits (internal or external ones), (n) follow-up of non-compliances and corrective measures, (o) implementation of risk mapping as part of the quality management system, (p) notably for critical activities.
Quality Management System	A formalised system that documents the process, procedures, and responsibilities to support achieving defined quality standards in a consistent manner (Article 3 (49) of the SoHO Regulation).
Releasing Officer	The person responsible for the release of SoHO within a SoHO establishment who is in the possession of a diploma, certificate or other evidence of formal qualifications in the field of medical, pharmaceutical or life sciences, awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned, and who has at least two years of experience in the relevant field (Article 49 of the SoHO Regulation).
Responsible Person	An appointed person in a SoHO entity who has the responsibility of ensuring compliance with the SoHO Regulation (Article 3 (36) of the SoHO Regulation).
Serious Adverse Event	Adverse event that poses a risk of any of the following: a) inappropriate SoHO distribution of, b) a defect posing a risk to SoHO recipients or SoHO donors is detected in one SoHO entity that would have implications for other SoHO recipients or SoHO donors because of shared practices, services, supplies or critical equipment; (c) loss of a quantity of SoHO that causes human applications to be postponed or cancelled; (d) loss of highly matched SoHO or SoHO for autologous use; (e) a mix-up of reproductive SoHO in such a way that an oocyte is fertilised with sperm from a person other than the intended person, or reproductive SoHO are applied to a SoHO recipient other than the intended SoHO recipient; (f) loss of the traceability of SoHO (Article 3 (46) of the SoHO Regulation).

Serious Adverse Reaction	Adverse reaction that results in any of the following: (a) death; (b) life-threatening, disabling or incapacitating condition, including transmission of a pathogen or of a toxic substance that might cause such condition; (c) transmission of a genetic disorder that: (i) in the case of medically assisted reproduction with third-party donation, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction; or (ii) in the case of medically assisted reproduction in the context of within-relationship use, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction, due to a pre-implantation genetic test error; (d) hospitalisation or prolongation of hospitalisation; (e) the need for a major clinical intervention to prevent or reduce the effects of any of the results referred to in points (a) to (d); (f) prolonged sub-optimal health of a SoHO donor following single or multiple SoHO donations *(Article 3 (45) of the SoHO Regulation)*.
Single European Code	The unique identifier applied to certain SoHO distributed in the Union *(Article 3 (54) of the SoHO Regulation)*.
SoHO Activity	Those activities that have a direct impact on the quality, safety or effectiveness of SoHO, as follows: (i) SoHO donor registration; (ii) SoHO donor history review and medical examination; (iii) testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship use; (iv) collection; (v) processing; (vi) quality control; (vii) storage; (viii) release; (ix) distribution; (x) import; (xi) export; (xii) human application; (xiii) clinical-outcome registration *(Article 2 of the SoHO Regulation)*.
SoHO Compendium	A list kept up-to-date by the SoHO Coordination Board of decisions, taken at Member State level, and opinions, issued by SoHO Competent Authorities and by the SoHO Coordination Board, on the regulatory status of specific substances, products or activities, and published on the EU SoHO Platform *(Article 3 (41) of the SoHO Regulation)*.
SoHO Competent Authority	An authority designated by the Member State which is conferred with the responsibility for SoHO supervisory activities. The SoHO competent authority or authorities designated shall be independent from any SoHO entity *(Article 5 of the SoHO Regulation)*. SoHO Competent Authorities shall be responsible, within their territory, for SoHO supervisory activities in order to verify the effective compliance by: (a) SoHO entities with the requirements set out in this Regulation; and (b) SoHO preparations with their corresponding authorisation *(Article 8 of the SoHO Regulation)*.
SoHO Coordination Board	A body established to promote coordination between Member States concerning the implementation of the SoHO Regulation (Regulation (EU) 2024/1938) and of the delegated and implementing acts adopted pursuant thereto, and to support them in that coordination, as well as to facilitate cooperation with stakeholders in that regard. It is composed of two permanent members per Member State, nominated based on their role and expertise within their respective SoHO Competent Authorities, along with two alternates. The Board is co-chaired by one representative of the European Commission and one representative of the SoHO national authority of a Member State, elected by and from among its members, with the Commission also providing the secretariat. Observers and experts may be invited to participate in the activities of the SoHO Coordination Board *(Article 68 of the SoHO Regulation)*.

Glossary

SoHO Donor	A living or deceased SoHO donor. A living SoHO donor refers to living person who has volunteered to a SoHO entity or has been presented by a person granting consent on their behalf, in accordance with national legislation, with a view to making a donation of SoHO, for the purpose of use in a person other than themselves, and other than in situations of within-relationship use. A deceased SoHO donor refers to a deceased person who has been referred to a SoHO entity with a view to SoHO collection, and from whom consent had been granted in that respect or from whom SoHO collection is permitted, in accordance with national legislation *(Article 3 (6) (7) (8) of the SoHO Regulation)*.
SoHO Entity	An entity legally established in the Union that carries out one or more of the SoHO activities: (i) SoHO donor registration; (ii) SoHO donor history review and medical examination; (iii) testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship use; (iv) collection; (v) processing; (vi) quality control; (vii) storage; (viii) release; (ix) distribution; (x) import; (xi) export; (xii) human application; (xiii) clinical outcome registration *(Article 3 (33) of the SoHO Regulation)*.
SoHO Establishment	A SoHO entity that carries out any of the following SoHO activities: both processing and storage, release, import, export *(Article 3 (35) of the SoHO Regulation)*.
SoHO Management	Refers to the oversight, coordination, and implementation of standards and procedures related to any SoHO activities identified in Article 2 of the SoHO Regulation.
SoHO Management Pillars	In this document, SoHO management pillars refer to the key functional areas that structure the recommendations. These pillars include: SoHO Entity Registration; Activity Data Collection and Reporting; Vigilance and Reporting; SoHO Preparation Authorisation; and Traceability. Throughout the document, references to SoHO Management Pillars will correspond to these defined areas.
SoHO National Authority	An authority designated by the Member State which is conferred with the responsibility for SoHO supervisory activities. While Member States may appoint multiple Competent Authorities, SoHO National Authority serves as the central point of contact, facilitating effective communication and regulatory oversight. In Member States where only one Competent Authority is designated, it is considered the SoHO National Authority by default. The designation of a single SoHO national authority shall not prevent the Member State from assigning certain tasks to other SoHO competent authorities, in particular the management of SoHO rapid alerts *(Article 5 of the SoHO Regulation)*.
SoHO Preparation	A type of SoHO that has been subjected to processing and, where relevant, one or more other SoHO activities referred to in Article 2(1) point (c) of the SoHO Regulation; has a specific clinical indication; and is intended for human application to a SoHO recipient or is intended for distribution *(Article 3 (37) of the SoHO Regulation)*.
SoHO Preparation Authorisation	The formal approval by a SoHO Competent Authority of a SoHO preparation *(Article 3 (38) of the SoHO Regulation)*.
Substance of Human Origin	Any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance *(Article 3 (1) of the SoHO Regulation)*.

Traceability	The ability to locate and identify SoHO from collection to human application, disposal or distribution for the manufacture of products regulated by other Union legislation, as referred to in Article 2(6) of the SoHO Regulation *(Article 3 (53) of the SoHO Regulation)*.
Vigilance	A set of organised surveillance and reporting procedures relating to adverse reactions and adverse events *(Article 3 (42) of the SoHO Regulation)*.

Table of SoHO activities

SoHO activities that have a direct impact on the quality, safety or effectiveness of SoHO
SoHO donor registration
SoHO donor history review and medical examination
Testing of SoHo donors or of persons from whom SoHO are collected for autologous or within-relationship use
Collection
Processing
Quality control
Storage
Release
Distribution
Import
Export
Human application
Clinical-outcome registration

1. Background

Substances of Human Origin (SoHO) play a crucial role in modern medicine, enabling both life-saving and life-enhancing treatments. In the European Union, each year, approximately **25 million units of blood** are transfused to support surgical procedures and trauma care, while around **36,000 stem cell transplants** provide essential therapy for blood cancers. SoHO also facilitates life-creating procedures: an estimated **940,000 cycles of *in vitro* fertilisation** are carried out annually, in addition to life-improving interventions such as **14,500 corneal transplants** restoring vision or **2,000 skin transplants** that aid recovery from burns and severe injuries[1,2,3,4].

During the 1980s and 1990s, Europe experienced major public health crises resulting from the so-called 'tainted blood' scandals, in which thousands of patients were infected with Human Immunodeficiency Virus and hepatitis through contaminated blood and plasma-derived medicinal products. Similar viral transmissions were also identified in tissues and cells. In response to these events, the **Treaty on European Union** (since 1999) empowered the European Union (EU) to establish stringent safety and quality standards for these substances. This led to the adoption of the **Blood Directive (2002/98/EC[5])** and the **Tissues and Cells Directive (2004/23/EC[6])**, which introduced minimum requirements for quality and safety across all stages, from donation to follow-up, to protect patients receiving SoHO-based therapies[4,7].

After two decades, the **legislation on blood and on tissues and cells no longer reflected developments in health systems or wider societal changes**. An evaluation conducted by the European Commission[8] in 2019 confirmed that, while the legislation had contributed to improved safety and quality across the EU, it also exposed shortcomings in keeping pace with scientific and technological advancements, shifting sociodemographic trends, and emerging threats, including communicable diseases. The increasing commercialisation and globalisation of the sector raised additional concerns around ethical sourcing, equitable access, and safety. Furthermore, the **COVID-19 pandemic** highlighted existing weaknesses in **supply sufficiency** and the **prevention of disease transmission** under the current regulatory framework[1,8,10].

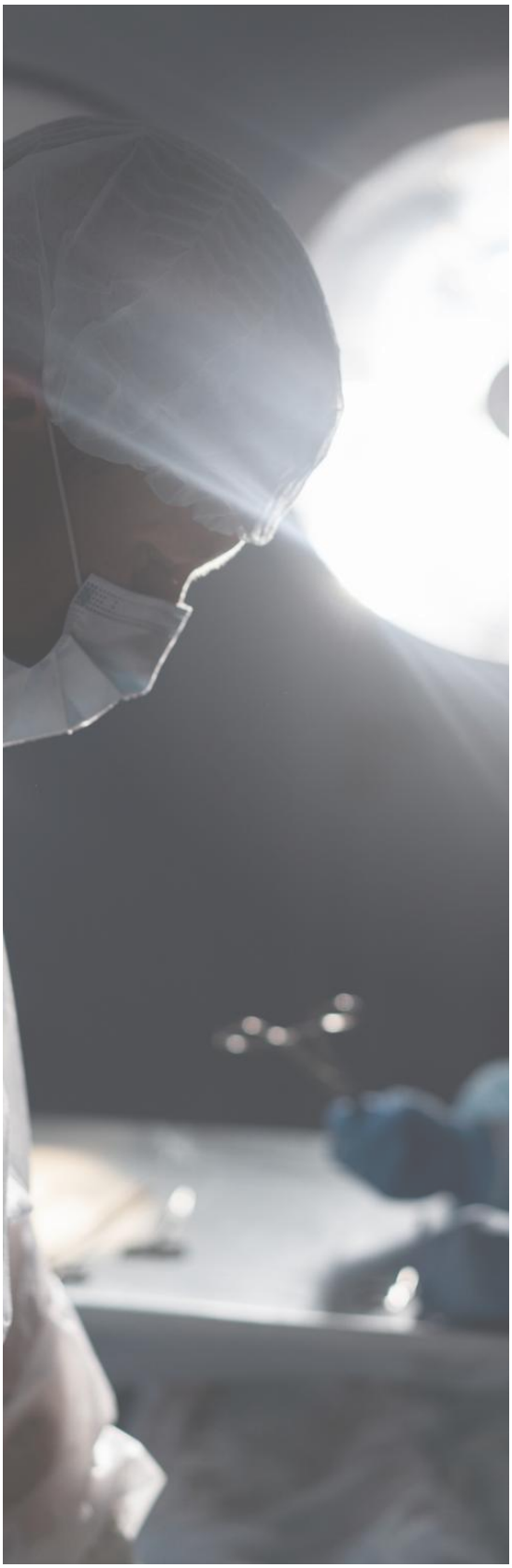
To address these challenges, in July 2022 the European Commission put forward a proposal[9] to strengthen the safety and quality framework for SoHO. The proposal extended regulatory oversight to include human breast milk, intestinal microbiota, and any other SoHO intended for therapeutic use in the future, which had previously not been regulated at EU level[1]. Its aim was to enhance **harmonisation across Member States**, ensuring a uniform level of protection throughout the Union while facilitating **cross-border exchange** and access to **SoHO-based therapies[10].**

In July 2024, the new **Regulation on Quality and Safety for SoHO Intended for Human Application** (hereinafter referred to as SoHO Regulation) was adopted by the Council of the European Union and approved by the ▶

European Parliament, replacing the Blood Directive (2002/98/EC[5]) and the Tissues and Cells Directive (2004/23/EC[6]). The SoHO Regulation will enter into force in 2027, three years after its publication. It establishes high standards of safety and quality, while granting Member States the flexibility to adopt stricter measures to align with their national healthcare systems. The updated EU rules aim to[12]:

- Support the **continued provision of SoHO therapies**, now and in the future, based on **high safety and quality standards** and up-to-date technical rules;
- **Extend protective measures** to new groups of patients, to donors and to offspring born from medically assisted reproduction;
- Improve **harmonisation** across Member States, facilitating **cross-border exchange** of SoHO and **enhancing patient access** to necessary therapies;
- Create conditions for **safe, effective and accessible innovation** in a unique sector driven by public health services and voluntary and unpaid donations;
- Strengthen **crisis preparedness and resilience** to safeguard access to therapies;
- Implement **digital-ready policies**;
- Contribute to the **European Health Union** by pooling of technical expertise and achieving economies of scale.

Importantly, the SoHO Regulation introduces **new requirements for SoHO management in SoHO entities and SoHO Competent Authorities** which will **affect the daily activities of actors involved in SoHO management**, including hospitals, among others. As a result, these actors will need to adapt their current coordination models for administrative and legal support, as well as revise their internal processes to ensure the efficient supply and use of SoHO within hospital settings. In recognition of the significance of the SoHO Regulation within the evolving SoHO landscape, the European Commission has already implemented, and will continue to propose, a range of measures to support stakeholders across Member States in the coming years, in accordance with Chapter X (Articles 70-72) of the SoHO Regulation[11].■



2. Purpose of the document

The "Recommendations and Guidance Document for the Management of SoHO in Hospitals" is a practical tool **designed** to **support hospital managers and professionals involved in the use of SoHO in their daily activities**. It provides legal and administrative guidance to enhance quality and safety in SoHO management and to ensure compliance with the SoHO Regulation (Regulation (EU) 2024/1938). SoHO management refers to the oversight, coordination, and implementation of standards and procedures related to any SoHO activities that impact the safety and quality of SoHO, as identified in Article 2 of the SoHO Regulation.

This document is specifically intended for **any SoHO activities on blood, tissues, or cells – from donation over processing and storage to human application – that are managed by SoHO entities** (as defined in Article 3 of the SoHO Regulation) **in hospitals.** The recommendations contained herein do **not apply to SoHO activities performed by authorized SoHO establishments** (as defined in Article 3 of the SoHO Regulation).

SoHO entities managing other SoHO types may also find this document useful, while they are encouraged to consult additional technical guidelines issued by the Commission. These other SoHO types that are becoming increasingly common include human breast milk, intestinal microbiota, blood preparations that are not used for transfusion, and any other SoHO that might be applied to humans in the future.

This document is structured into several sections. The **Background** provides an overview of the SoHO landscape, its regulatory evolution, and the rationale for updated EU legislation. The **Roadmap for SoHO Entities** sets out the steps to be followed for proper SoHO entity registration, which constitutes the first step towards implementing the recommendations in practice. Next, the **Recommendations** are presented, structured into **general recommendations**, applicable across all SoHO activities, and **specific recommendations** that address concrete aspects of SoHO Entity Registration, SoHO Preparation Authorisation (SPA), Activity Data Collection and Reporting, Traceability, and Vigilance and Reporting. The specific recommendations are supplemented by a **SoHO Activity Checklist**, which outlines key regulatory considerations to support contextualisation. Lastly, the **Methodological Approach** outlines the phases and key activities undertaken in the development of these recommendations.

Finally, the implementation of the recommendations calls for **enhanced coordination** between **SoHO entities, SoHO establishments**, and other relevant stakeholders, to ensure that the entire SoHO management value chain meets the highest standards of quality and safety.

The present Recommendations and Guidance Document aims to **simplify processes and reduce the administrative burden** for SoHO entities and professionals, without requiring the creation of new structures or roles. Throughout this document, the term **"Responsible Person"** refers to the individual designated in accordance with **Article 36 of the SoHO Regulation**.■

3. Roadmap for SoHO entities

Under the SoHO Regulation (see Article 35), all SoHO entities are required to register using the EU SoHO Platform or a national register (see Article 16). To support an effective registration process, a structured set of steps is proposed for entities to follow.

Following a thorough review of the SoHO Regulation and the present document, an entity should undertake several key steps. These include identifying all SoHO-related activities conducted within the hospital; engaging the professionals involved in SoHO practices and designating a potential Responsible Person; identifying or establishing an appropriate Quality Management System; evaluating the applicable registration mechanisms for the hospital or entity; and compiling all necessary information to ensure accurate and complete registration. Figure 2 presents a roadmap outlining the registration process for SoHO entities:

- **Review** the SoHO Regulation and key guidance documents relevant to your activities.
- **Identify the SoHO activities carried out** within the hospital (e.g., collection, processing, human application, etc.)
  See Article 2 of the SoHO Regulation for further detail.
- **Identify professionals** working with SoHO in the hospital to provide information on the activities performed.
- **Identify professionals eligible** (according to the SoHO Regulation criteria) **to be appointed as the Responsible Person** of the SoHO entity.
  See Article 36 of the SoHO Regulation for further detail.
- **Appoint a Responsible Person for the SoHO entity**. Each SoHO entity must have a Responsible Person. The SoHO Competent Authority must be informed of the name and contact details of the Responsible Person. In the event of a replacement, the updated information must also be promptly communicated.
  See Article 36 of the SoHO Regulation for further detail.
- **Examine whether the SoHO entity has an existing Quality Management System**.
- **Assess whether the identified Quality Management System can be adapted** to the needs of the SoHO entity.
  See Article 37 of the SoHO Regulation for further detail.
- **Establish, maintain and update a Quality Management System** for the SoHO entity. Each SoHO entity must have its Quality Management System (new or existing).
  See Article 37 of the SoHO Regulation for further detail.
- **Discuss whether the hospital will be registered as a single SoHO entity or as several separate** SoHO entities.
  See Article 35 of the SoHO Regulation for further detail.
- **Gather all information needed for the registration** of the SoHO entity.
  See Article 35 of the SoHO Regulation for further detail.
- **Register the SoHO entity** via the EU SoHO Platform or a national registry. To register, the requested information shall be provided to the Competent Authority. Any changes to the registered information must be promptly communicated.
  See Articles 16 and 35 of the SoHO Regulation for further detail.
- **The SoHO entity is now registered and can carry out the activities for which it has been verified under the new SoHO Regulation.**

Figure 1. Roadmap for the registration of a SoHO entity

4. Recommendations

The preceding Roadmap for SoHO entities outlines the main steps that an entity may undertake to achieve proper registration as a SoHO entity.

Following registration, the SoHO entity may commence or continue carrying out the activities for which it has been registered. To conduct these SoHO activities, a set of recommendations has been proposed to facilitate compliance with the new SoHO Regulation, while simplifying processes and reducing administrative burden for SoHO entities and professionals.

An overview of these recommendations is presented below (Figure 2).■

Recommendations applicable to all SoHO management activities

- **R1** Leverage existing roles for the designation of the Responsible Person
- **R2** Designate one or more professionals to support the Responsible Person in overseeing SoHO management
- **R3** Implement standardised processes for SoHO management oversight
- **R4** Gather and use supporting documents to integrate best practices for SoHO management
- **R5** Involve committees, where feasible and advisable, in overseeing SoHO management
- **R6** Communicate with SoHO Competent Authorities or delegated bodies to ensure alignment with the SoHO Regulation and guarantee effective SoHO management

Recommendations applicable to specific SoHO management activities

Registration

- **R7** Implement standardised processes for the collection of administrative information for SoHO entity registration
- **R8** Involve one or more professionals in the oversight of the SoHO entity registration process

Vigilance and reporting

- **R9** Implement a standardised process for Vigilance and Reporting
- **R10** Ensure end-users are involved in the monitoring and reporting of Adverse Reactions and Adverse Events
- **R11** Ensure pseudonymisation when sharing data
- **R12** Involve one or more professionals in the oversight of vigilance and reporting
- **R13** Gather and use supporting documents to integrate best practices and ensure team's capacities for vigilance and reporting protocols

Activity data collection and reporting

- **R14** Implement a standardised process for SoHO activity data collection and reporting
- **R15** Involve one or more professionals in the oversight of SoHO activity data collection and reporting
- **R16** Gather and use supporting documents to integrate best practices and ensure team's capacities for internal SoHO activity data collection and reporting protocols

Traceability

- **R17** Implement standardised processes to ensure traceability
- **R18** Involve one or more professionals in the oversight of traceability
- **R19** Gather and use supporting documents to integrate best practices and ensure team's capacities for traceability protocols

SoHO Preparation Authorisation

- **R20** Establish effective collaboration with SoHO establishments
- **R21** Engage professionals to gather all relevant information related to the authorisation procedures of novel SoHO preparations

Figure 2 Overview of the Recommendations

4.1 General recommendations for implementing the SoHO Regulation

SoHO entities shall establish and maintain an appropriate oversight framework to ensure effective management of SoHO in compliance with the SoHO Regulation, including clear allocation of responsibilities, adequate support structures, and effective coordination with the SoHO Competent Authorities or delegated bodies.

Recommendation 1. Leverage existing roles for the designation of the Responsible Person.

Recommendation 2. Designate one or more professionals to support the Responsible Person in overseeing SoHO management.

Recommendation 3. Implement standardised processes for SoHO management oversight.

Recommendation 4. Gather and use supporting documents to integrate best practices for SoHO management.

Recommendation 5. Involve committees, where feasible and advisable, in overseeing SoHO management.

Recommendation 6. Communicate with SoHO Competent Authorities or delegated bodies to ensure alignment with the SoHO Regulation and guarantee effective SoHO management.

Recommendation 1

Leverage existing roles for the designation of the Responsible Person

In accordance with **Article 36** of the **SoHO Regulation, SoHO entities must designate a Responsible Person to ensure that all SoHO activities carried out within the entity comply with the requirements of the SoHO Regulation.** While the Responsible Person must be actively engaged in and aware of all ongoing SoHO activities, they are not necessarily required to perform these activities personally (see Recommendation 2 for further details).

The designated Responsible Person must **meet the following criteria**, as stipulated in **Article 36**:

- Be in possession of a diploma, certificate, or other formal qualification in medical, pharmaceutical, or life sciences, awarded upon completion of a university course or recognised as equivalent by the Member State.
- Shall have at least two years of professional experience in the relevant field.

When designating the Responsible Person, SoHO entities are encouraged to **leverage existing roles**, such as haemovigilance or biovigilance officers, laboratory directors, or medical directors, where appropriate. To properly identify existing roles, an organisational chart can be drafted which shows the deployment of SoHO activities and all the units and professionals involved.

To ensure continuity, alternate professionals capable of assuming the responsibilities of the Responsible Person during absences (e.g. annual leave, sick leave) should be identified. These professionals should align with those designated in the Quality Management System in place. Any alternate professional which may replace the Responsible Person permanently or temporarily must also meet the qualification criteria set out above at the time taking over the responsibility of the previous Responsible Person. In the event of a replacement, the SoHO entity must inform their SoHO Competent Authority without undue delay of the name and contact details of the new Responsible Person and the date on which the responsibility of that person is assumed.■

Recommendation 2

Designate one or more professionals to support the Responsible Person in overseeing SoHO management

The activities encompassed within the SoHO management oversight, as carried out by the Responsible Person, **may be supported by other professionals** to streamline processes and ensure alignment with the SoHO Regulation. It is important to note that, although tasks can be delegated, legal responsibility for ensuring that SoHO activities comply with the requirements of the SoHO Regulation remains solely with the Responsible Person.

When identifying these professionals, **the size of the SoHO entity and the nature and scope of its SoHO activities** should be considered. For example:

- **Large SoHO entities** - i.e., those performing more than two SoHO activities or handling an activity volume of over 1,501 processes per year **– and medium-sized SoHO entities** - i.e., those performing two SoHO activities or handling between 101 and 1,500 processes per year - may require the involvement of several professionals, including individuals with specific roles within the Quality Management System, who report to the Responsible Person.
- **Small SoHO entities** - i.e., those performing a single SoHO activity with an annual volume of fewer than 100 processes - may find that one supporting professional is sufficient.

In addition, the following actions should be considered:

1. Define the key responsibilities of the professionals supporting the Responsible Person in SoHO management oversight.
2. Designate alternates to cover for support professionals during absences.
3. Ensure that professionals have access to the necessary tools.
4. Ensure that professionals receive appropriate training and possess the required knowledge, skills, and competencies to support the Responsible Person effectively.

SoHO management oversight is required through the end-to-end activities performed by the SoHO entity. The following areas, in particular, may benefit from targeted supervision:

- SoHO Entity Registration
- SoHO Preparation Authorisation
- Activity Data Collection and Reporting
- Traceability
- Vigilance and Reporting

Further details on the roles and responsibilities of the Responsible Person and supporting professionals are provided in the following recommendations: Recommendation 1, Recommendation 8, Recommendation 21, Recommendation 15, Recommendation 18, and Recommendation 12.■

Recommendation 3

Implement standardised processes for SoHO management oversight

Implementing standardised processes can facilitate the effective implementation of the SoHO Regulation across the various SoHO management pillars, namely:

- SoHO Entity Registration,
- SoHO Preparation Authorisation,
- Activity Data Collection and Reporting,
- Traceability,
- Vigilance and Reporting.

Standardised processes support the identification of the information, data, and actions required for **effective oversight**, while also providing **clear guidance** to ensure compliance with the SoHO Regulation.

The **definition and implementation of these standardised processes** should be proportionate to the size of the SoHO entity and scope and complexity of the SoHO activities performed. Aligning processes with the specific operational needs of the entity will facilitate oversight and enhance implementation feasibility.

To begin developing these processes, SoHO entities should **consider the following criteria**:

- **All SoHO activities listed in Article 2 of the SoHO Regulation conducted within the SoHO entity** should be taken into account.
- **Information contained in the Quality Management System** may be consulted and used to inform the process design.
- All processes should be **aligned with the Quality Management System** of the SoHO entity;
- The processes should encompass, at least, the following SoHO management pillars:
  - SoHO Entity Registration
  - SoHO Preparation Authorisation
  - Activity Data Collection and Reporting
  - Traceability
  - Vigilance and Reporting

To support the **development and implementation of these processes**, SoHO entities may consider the following actions:

1. **Engage relevant stakeholders within the SoHO entity or hospital** to coordinate, ▶

develop, and disseminate standardised processes. These may include:

- The Responsible Person
- Professionals supporting the Responsible Person
- Other personnel involved in or working with the Quality Management System (e.g., Quality Managers)
- Existing committees, where appropriate (see Recommendation 5).

2. **Use existing information and documentation** related to SoHO activities, SoHO personnel and available guidelines to:
    1. **Identify** which activities within the SoHO entity or hospital require formalised processes.
    2. **Gather documents, guidelines, or data** useful for defining standardised processes. Examples of sources from which guidelines could be obtained are:
        - SoHO Competent Authorities
        - European Centre for Disease Prevention and Control (ECDC)
        - European Directorate for the Quality of Medicines and HealthCare (EDQM)
        - World Health Organisation (WHO)
    3. **Define and document the processes to be implemented.**
    4. **Identify existing tools, systems, or databases within the entity or hospital** that could be used to implement and monitor the defined processes. If suitable tools are available, they should be reused where appropriate.
3. **Define key performance indicators** to the effectiveness of the implemented processes which facilitates self-assessment.

Additional specific actions for each SoHO management pillars are detailed in the corresponding recommendations: Recommendation 7, Recommendation 14, Recommendation 17, and Recommendation 9.■

Recommendation 4

Gather and use supporting documents to integrate best practices for SoHO management

Collecting and using relevant **supporting documents, and integrating best practices**, will help ensure that all professionals involved in SoHO management are adequately trained and able to carry out their responsibilities effectively.

Supporting documentation may include existing materials and guidelines issued by organisations that promote quality, safety, and efficiency in the field. Examples include:

- **Technical guidelines** published by the **ECDC and the EDQM**, which will be made available via the EU SoHO Platform
- **Best practices** developed by the **SoHO Coordination Board** and available via the EU SoHO Platform.
- Guidelines and recommendations from professional societies.

Other non-exhaustive examples of standards from scientific and professional societies that may be relevant include:

- National guidelines and best practices provided by the Competent Authorities
- FACT-JACIE Standards developed by the European Society for Blood and Marrow Transplantation
- Guidelines developed by the European Association of Tissue and Cell Banks
- Guidelines published by the European Society of Human Reproduction and Embryology
- Documents provided by the European Blood Alliance

The Responsible Person must ensure that all professionals involved in SoHO management receive adequate training to carry out SoHO activities, in accordance with regulatory requirements, ensuring the highest standards of quality and safety.

To support this objective, SoHO entities may **designate professionals to assist the Responsible Person** with the implementation of this recommendation. The following actions are suggested:

1. **Identify the professionals** who require training.
2. **Ensure that the most recent guidelines, templates, and best practices** from external sources (e.g., the EU SoHO platform, SoHO Competent Authorities, expert group(s), and relevant European Commission institutions) **are incorporated** into the SoHO entity's training materials and in the Quality Management System.
    - For small SoHO entities, staying up to date with the latest guidelines may present challenges. To address this, they may consider subscribing to regular communications from the ECDC, the EDQM, and other relevant European Commission institutions. Asking for support from Competent Authorities or larger neighbouring SoHO entities could also be considered.
3. **Ensure that all available resources are easily accessible** to the identified staff.
4. **Communicate and coordinate with the Releasing** Officer (as in **Article 49**) **and/or the Physician** (as defined in **Article 50**) **of the collaborating SoHO establishment** that receives the collected SoHO or provides the applied SoHO preparations to exchange relevant information and supporting documents.
5. **Use internal communication channels such as emails, newsletters, or Bulletin systems** to share updates and encourage staff to review new or revised documents.
6. **Define metrics to assess the effectiveness of document integration and training efforts,** in alignment with the Quality Management System in place, such as: ▶

- Percentage of staff trained on SoHO guidelines
- Number of updated documents incorporated into the SoHO entity's Quality Management System
- Frequency of internal compliance audits related to SoHO management

7. **Explore and integrate additional training opportunities** offered by European scientific societies and associations. Examples of such organisations include the European Blood Alliance, the European Association of Tissue and Cell Banks, the European Society of Human Reproduction and Embryology, the European Society for Blood and Marrow Transplantation, and the European Eye Bank Association, among others.

The use of supporting documentation and the integration of best practices is recommended throughout the entire end-to-end SoHO management process. Further details on training-related considerations for each SoHO management pillar can be found in the corresponding recommendations: Recommendation 16, Recommendation 3, and Recommendation 13.■

Recommendation 5

Involve committees, where feasible and advisable, in overseeing SoHO management

Committees represent a group of professionals with relevant expertise in the field of SoHO who meet regularly to discuss procedural, quality and operational aspects of SoHO activities (see Glossary). Involving such **committees** (e.g. hospital transfusion committees, haemovigilance committees, amongst others), where feasible and advisable, depending on the size of the SoHO entity and the scope of activities performed, **can support effective SoHO management and facilitate alignment with the SoHO Regulation**. By engaging professionals involved in SoHO activities, these committees can also promote the exchange of information related to SoHO and its management.

To involve **existing hospital committees**, SoHO entities should:

1. **Identify existing committee(s) within the hospital** that could contribute to the oversight of SoHO management.
2. **Evaluate the responsibilities of the identified committee(s)** to determine their relevance to SoHO oversight.
3. **Define** a **map outlining the interrelationships among intra-hospital committees,** detailing their scope, objectives, members, meeting frequency, and interdependencies. In cases where the hospital is part of a larger structure or take part in a hospital network, **inter-hospital committee mapping** is also recommended.
4. **Engage these committee(s) in the oversight** of SoHO activities.
5. **Promote collaboration between relevant committee(s),** for example, haemovigilance and biovigilance committees in relation to vigilance and reporting.

In case of **medium and small-sized SoHO entities, establishing or engaging with internal committees may present operational challenges**. These SoHO entities could consider the following alternatives:

1. **Seek support from regional committees or larger hospitals.**
2. **Use existing Quality Management committees** to support SoHO activities.

To facilitate committee engagement in SoHO management, SoHO entities may also consider the following actions:

1. **Clearly define the roles** and responsibilities of each committee in relation to SoHO management.
2. **Ensure that committees collaborate with the Responsible Person** in coordinating and supervising SoHO activities, thereby supporting compliance with the SoHO Regulation.
3. **Schedule meetings at an appropriate frequency** (e.g. annually, biannually, quarterly, or monthly) to address specific aspects of SoHO management oversight and establish expectations for the frequency of these tasks.■

Recommendation 6

Communicate with SoHO Competent Authorities or delegated bodies to ensure alignment with the SoHO Regulation and guarantee effective SoHO management

Effective **communication between SoHO entities and SoHO Competent Authorities or delegated bodies** pursuant to Article 9 of the SoHO Regulation is essential to ensure alignment with the SoHO Regulation and to facilitate proper oversight of SoHO management. Communication may be initiated by the SoHO Competent Authority or the delegated body; however, SoHO entities should adopt a proactive approach in fostering and maintaining a two-way dialogue.

The following scenarios particularly warrant bidirectional communication:

- Implementation of changes to registered activities that may require prior authorisation.
- Planned modifications to quality systems that could impact traceability; safety, or efficacy of SoHO.
- Clarification of regulatory grey areas or queries arising from cross-border collaboration projects involving SoHO.
- Addressing safety concerns.
- Seeking guidance on regulatory requirements for new products.
- Resolving issues related to registration, biovigilance, or clinical-research questions, among others.

The **Responsible Person** should act as the **designated liaison for communication with the SoHO Competent Authority or the delegated bodies**, facilitating clarity, consistency and accountability.

To strengthen communication, the following actions are recommended:

1. **Establish and maintain communication channels** (e.g., email correspondence, formal meetings, or other communication tools), as agreed with or provided by the SoHO Competent Authority or the delegated body. These channels should be used to raise questions, seek clarifications, and remain informed about regulatory updates and expectations, among others.
2. **Attend to the workshops or training sessions if organised by SoHO Competent Authorities** to remain up to date with evolving regulatory requirements, technical standards, and best practices.■

4.2 SoHO entity registration

According to the SoHO Regulation, any entity intending to carry out SoHO activities must be registered as a SoHO entity via the EU SoHO Platform or through tool indicated by the SoHO Competent Authority. The objective of this registration is to ensure that all SoHO activities undertaken in SoHO entities are known to the national or local authorities. Furthermore, SoHO entities are required to promptly report any significant updates regarding their activities, processes, and status (e.g., changes or cessation of activities) via the EU SoHO Platform or the tool designated by the SoHO Competent Authority.

Recommendation 7. Implement a standardised process for the collection of administrative information for SoHO entity registration.

Recommendation 8. Involve one or more professionals in the oversight of the SoHO entity registration process.

Recommendation 7

Implement a standardised process for the collection of administrative information for SoHO entity registration

Following a **standardised process** can support compliance with the SoHO Regulation in relation to Registration, by helping to **identify the information, data, and activities** required to meet the requirements set out in **Article 35.**

To properly go through the registration process, SoHO entities may consider the following actions (if provided by the SoHO Competent Authorities):

1. **Decide on the appropriate registration model**. SoHO entities may choose between:
   - **Centralising the registration of multiple SoHO entities under one SoHO entity** is only possible if all of them are part of the same legal entity. In such cases, a single Quality Management System (article 37) must be implemented, and one single Responsible Person must be designated (article 36).
   - **Registering multiple, separate SoHO entities,** each of which must have its own Quality Management System (**Article 37**) and Responsible Person (**Article 36**).

     This decision should reflect the specific SoHO activities carried out within the hospital setting and be aligned with the strategic guidance of the SoHO Competent Authority. SoHO entities may request an opinion from a SoHO competent authority or delegated body in their territory as to whether the activities they carry out are subject to the registration requirements of the SoHO Regulation. Best practices developed by the SoHO Coordination Board may also support SoHO entities in the registration process.
2. **Involve one or more professionals,** either the designated Responsible Person or supporting professionals (see Recommendation 8), **in overseeing the SoHO entity registration process.**
3. **Identify all administrative information required for SoHO entity registration,** as outlined in **Article 35** of the SoHO Regulation. This includes all necessary data to ensure regulatory compliance and proper registration of the SoHO entity.
   - SoHO entities shall carry out a self-assessment to determine whether they qualify as a critical SoHO entity. In conducting this assessment:
     - The SoHO entity should follow a common method to review the criteria for critical SoHO and critical SoHO entities developed by the SoHO Coordination Board.
     - If the self-assessment indicates that the SoHO entity may meet the criteria, this information should be reported to the SoHO Competent Authority, which will then assess and confirm its critical status.
     - If the entity is defined as a **critical SoHO entity,** all additional information required for registration must also be collected and submitted.
4. **Identify existing tools, systems, or databases within the SoHO entity or hospital** that could support the collection and centralisation of registration data. Where appropriate, existing tools may be reused for this purpose.
5. **Register the SoHO entity** using the system designated by the SoHO National Authority. This may include the EU SoHO Platform, or national registries, as defined in **Article 16** of the SoHO Regulation.■

Recommendation 8

Involve one or more professionals in the oversight of the SoHO entity registration process

The Responsible Person must be informed of and engaged in the SoHO entity registration process. Oversight of this process is essential, and may be carried out either by the Responsible Person or by specifically designated professionals, depending on the size of the SoHO entity and the range of activities performed.

Specifically, the Responsible Person must undertake the following activities to strengthen registration oversight:

1. **Verify that all submitted information complies with regulatory standards** and accurately reflects the SoHO entity's activities.
2. **Notify the SoHO Competent Authorities** and submit updates via the EU SoHO Platform or the tool indicated by the SoHO Competent Authority, **in the event of changes** (e.g., modifications to processes, cessation of activities, or organisational restructuring) to the information registered. Information and guidance on how to make a change to the SoHO entity registration can be found on the National SoHO Competent Authority's website and the SoHO Platform.

In addition to the responsibilities of the Responsible Person, the Quality Manager may also contribute to SoHO entity registration oversight by:

1. **Ensuring that all required information** (as specified in **Article 35**) **is available** to meet the registration requirements of the SoHO Regulation.
2. **Tracking updates to SoHO activities, processes, or organisational changes** that must be reported to the Competent Authorities.■

4.3 Vigilance and Reporting

*SoHO entities shall ensure that any suspected serious adverse event or reaction (**Article 3.45 and 3.46 SoHO Regulation**) are reported without delay to the Competent Authority. They must investigate such events or reactions, take corrective and preventive actions, and document the outcomes to prevent recurrence. In this process, SoHO entities shall cooperate with other involved entities and authorities to trace and manage risks related to SoHO safety and quality. According to the SoHO Regulation, SoHO entities must establish a system for detecting, investigating, and recording information related to adverse reactions and adverse events. They are also required to promptly notify their Competent Authorities of any suspected Serious Adverse Reactions or Events (SAR or SAE), submitting detailed information and subsequent assessments through follow-up reports as necessary.*

Recommendation 9. Implement a standardised process for Vigilance and Reporting.

Recommendation 10. Ensure end-users are involved in the monitoring and reporting of Adverse Reactions and Adverse Events.

Recommendation 11. Ensure pseudonymisation when sharing data.

Recommendation 12. Involve one or more professionals in the oversight of vigilance and reporting.

Recommendation 13. Gather and use supporting documents to integrate best practices and ensure team's capacities for vigilance and reporting protocols.

Checklist for Vigilance and Reporting

The recommendations for vigilance and reporting are intended to support compliance with the accompanying checklist and, by extension, with the SoHO Regulation.

- ❑ **Maintain a system** for detecting, investigating and recording information concerning Adverse Reactions and Adverse Events, including those detected during clinical-outcome monitoring as part of a SoHO Preparation Authorisation application, as per **Article 44(1)**.
- ❑ In case of **emergence of concerning serious genetic conditions** in children born from third-party donation (**Article 44(2)**):
  - ❑ **Encourage prospective parents** to promptly inform the SoHO entity where they were treated, in alignment with applicable national legislation;
  - ❑ **Inform the SoHO establishment without undue delay** that released the reproductive SoHO for human application, so that the SoHO establishment can investigate **the suspected Serious Adverse Reaction and Event** and prevent further distribution of SoHO from the implicated SoHO donor.

Notification responsibilities vary depending on the type of SoHO entity and its relationship with a SoHO establishment:

SoHO entities operating under an agreement with a SoHO establishment or receiving SoHO from such establishments shall:

- ❑ Communicate without undue delay any Adverse Reactions or Events to the SoHO establishment for which they perform SoHO activities or to the SoHO establishment that distributed the SoHO to them. In these cases, the SoHO establishment is responsible for investigating and reporting to the SoHO Competent Authority (**Article 44(4)**).

SoHO entities not operating under an agreement with a SoHO establishment or receiving SoHO from one shall:

- ❑ Submit a notification to the SoHO Competent Authority without undue delay in case they detect or suspect that an Adverse Reaction or Event falls within the definition of a Serious Adverse Reaction or Serious Adverse Event as defined in the SoHO Regulation. The required content for the notification is detailed in **Article 44(3)**.
- ❑ Investigate and report Serious Adverse Reactions or Events directly to the SoHO Competent Authority (as per **Article 44(4)**).

- ❑ If the SoHO entity receives information regarding a serious incident and associated safety corrective actions related to a medical device or in vitro diagnostic medical device used by a SoHO entity, this information must be **communicated to the SoHO Competent Authority,** as per **Article 44(5)**).
- ❑ **Establish a procedure** to withdraw from distribution or use any SoHO affected (or suspected to be affected) by Serious Adverse Reactions and/or Events. Procedures involving reproductive SoHO must align with national legislation (**Article 44(6)**).
- ❑ Conduct an **investigation** of each Serious Adverse Reaction and/or Event detected by or communicated to the SoHO entity.
  - ❑ **Provide an investigation report** of the Serious Adverse Reaction and/or Event to the SoHO Competent Authorities with the information indicated in **Article 44(7)**.
- ❑ **Communicate** the necessary information to facilitate traceability and ensure quality and safety concerning a Serious Adverse Reaction or Event to (**Article 44(8)**):
  - ❑ Other SoHO entities engaged in the collection, processing, testing, storage and ▶

distribution of SoHO collected from the same SoHO donor, or otherwise possibly affected.

- **The organ procurement organisation,** in cases where the implicated SoHO donor has also donated organs;
- **Manufacturers,** in cases where SoHO collected from that SoHO donor have been distributed for the manufacture of products regulated by other Union legislation.■

Recommendation 9

Implement a standardised process for Vigilance and Reporting

SoHO entities could adopt standardised processes for a prompt reporting, investigation, and mitigation of serious adverse events and reactions. These processes should facilitate timely detection, consistent documentation, and effective communication with competent authorities and other actors involved.

To define and implement such processes, SoHO entities may consider the following actions:

1. **Enhance end-user engagement** in Vigilance and Reporting (see the definition of *end-user* in the Glossary of this document and see Recommendation 10 for further detail*).*
2. **Involve one or more professionals,** either the designated Responsible Person or supporting professionals (e.g., biovigilance employees) in **overseeing the vigilance and reporting activities** and ensuring compliance with the SoHO Regulation. The professional/s involved could also serve as the central point of contact for vigilance and reporting activities within the SoHO entity (see Recommendation 12).
3. **Identify existing tools, systems, or databases** within the SoHO entity or hospital that may facilitate the collection of vigilance data to be reported (see **Article 44(3)**). Where available, these tools may be reused for this purpose.
4. **Use standardised forms or templates** provided by the SoHO Competent Authorities or the SoHO Coordination Board to report and document incidents.
5. **Regularly review and update the process for detecting, investigating, recording, and communicating** information concerning adverse reactions and adverse events, considering:
   - National and international guidelines (e.g., EDQM) and best practices for monitoring and reporting Adverse Reactions and Events.
   - Best practices issued by the SoHO Coordination Board expert group(s), which guide the reporting of Serious Adverse Reactions and Events related to SoHO.
   - Other EU Regulations relevant to the SoHO activities performed by the SoHO entity, such as the Medical Devices Regulation (EU) 2017/745 or the *In vitro* Medical Devices Regulation (EU) 2017/746.

In case **of Serious Adverse Reactions and Serious Adverse Events**, SoHO entities must ensure safety and quality through efficient response and full compliance with **Article 44** of the SoHO Regulation.

Depending on the relationship with a SoHO establishment, two scenarios may apply:

- SoHO entities **operating under an agreement with a SoHO establishment** or receiving SoHO from such establishments:
  1. **Define** a **communication protocol and establish communication channels** with professionals involved in vigilance and reporting activities within the SoHO entity, and with SoHO establishments and other SoHO entities involved in the collection, processing, testing, storage, or distribution of SoHO from the same donor or otherwise potentially affected. The communication protocol should define the roles and responsibilities, channels, frequency and timing of the communications, escalation procedures, document management, among others.
  2. **Establish protocols for communication with external organisations** (e.g., organ procurement organisations) to notify them or to be notified in the event of a Serious Adverse Reaction or Serious Adverse Event involving a donor who has also donated organs. ▶

3. **Notify the SoHO establishment** event of detected Adverse Reactions or Events. The SoHO establishment will investigate the incident and report it to the SoHO Competent Authorities when the Adverse Reaction or Event is deemed to be a Serious Adverse Reaction or Event (**Article 44(4)**). The SoHO Competent Authority will verify the information, inform the SoHO entity, and initiate a SoHO rapid alert if necessary.
4. Collaborate with the SoHO establishment to **define a process for the removal of any SoHO from distribution or use** if it is affected, or suspected to be affected, by Serious Adverse Reactions or Events.

- SoHO entities **not operating under an agreement with a SoHO establishment and not receiving distributed SoHO from one**:
  1. **Define a protocol for reporting** the detected Serious Adverse Reactions and/or Events to SoHO Competent Authorities, in alignment with the requirements set out in **Article 44**.
  2. **Define a protocol for investigating** the detected Serious Adverse Reactions and/or Events.
  3. **Define communication protocols and establish communication channels** to coordinate with professionals involved in vigilance and reporting activities within the SoHO entity, as well as with the SoHO Competent Authorities.
  4. **Use and follow the templates and guidelines** provided by the SoHO Competent Authorities for investigating and reporting Serious Adverse Reactions and Events. Ensure these are aligned with the best practices recommended by the SoHO Coordination Board expert group(s).
  5. **Submit the investigation report to the SoHO Competent Authorities** without delay **following the emergency communication channels** previously agreed upon and **the defined protocol.** The communication should include the information stated in **Article 44**. The SoHO Competent Authority will verify the information, inform the SoHO entity, and initiate a SoHO rapid alert if necessary.
  6. **Define a process to remove any SoHO from distribution or use** if they are affected, or suspected to be affected, by Serious Adverse Reactions or Events.■

Recommendation 10

Ensure end-users are involved in the monitoring and reporting of Adverse Reactions and Adverse Events

The **end-user** is defined as the individual that applies the SoHO to a recipient. **Ensuring end-users are actively involved in the monitoring and reporting of Adverse Reactions and Adverse Events will improve the effectiveness of the vigilance system and enhance patient safety.**

To promote the involvement of end-users, the following actions may be considered:

1. **Define end-user awareness protocols** aligned with best practices from the SoHO Coordination Board expert group(s). These should outline end-user responsibilities across three key phases:
   - **Initial reporting**: end-users should promptly report any suspected adverse reactions in the recipient or adverse events to the appropriate SoHO entity.
   - **Collaborative investigation**: end-users should actively contribute to the investigation process by providing clinical insights and relevant medical history to support evaluation.
   - **Final review:** end-users should assist in the final case closure process to ensure that all necessary follow-up actions are completed, including the implementation of any corrective and preventative measures identified during the investigation of Serious Adverse Reactions and Events.
2. **Implement reporting channels** that facilitate submission and tracking of Adverse Reactions and Events by end-users. These channels should connect with the professionals overseeing vigilance and reporting, who serve as the central point of contact within the SoHO entity.
3. **Inform the end-user of their obligation to report Adverse Reactions and Events and raise awareness of the importance of their responsibility in reporting** Adverse Reactions and Events, and their role in each of the three above-mentioned phases.

Training in vigilance and reporting of Adverse Reactions and Events is also important for end-users (see Recommendation 13).■

Recommendation 11

Ensure pseudonymisation when sharing data

Protecting personal information while maintaining the required level of traceability is of utmost importance across all stages of SoHO management, particularly when sharing data related to Adverse Reactions and Adverse Events.

Pseudonymisation *(see the definition in the Glossary of this document)* can be ensured by implementing the following actions:

1. **Replace personal data with pseudonymised codes** in all Adverse Reaction and Adverse Event reports.
2. **Establish a secure system** to link pseudonymised data to original records.
3. **Use existing systems to collect and report pseudonymised data** on adverse reactions and adverse events.
4. **Involve professionals responsible for data protection and GDPR compliance** within the SoHO entity or the hospital (e.g., the controller, processor and Data Protection Officer) to verify the level of pseudonymisation required for each SoHO activity. The Responsible Person should oversee this verification process.
5. **Where feasible and advisable**, **involve a committee** to regularly review pseudonymisation practices.■

Recommendation 12

Involve one or more professionals in the oversight of vigilance and reporting

To ensure compliance with the SoHO Regulation and enhance the effectiveness of vigilance and reporting systems within SoHO entities, it is recommended that one or more qualified professionals be designated to oversee these activities. The oversight of this process can be performed either by the **Responsible Person**, who must be informed of all the process, or by specifically designated professionals, depending on the size of the SoHO entity and the scope of activities performed.

The Responsible Person or the designated professionals involved may undertake the following actions to ensure effective vigilance and reporting oversight:

1. **Serve as the central point of contact** for vigilance and reporting activities within the SoHO entity.
2. **Coordinate with the Releasing Officer** (as per **Article 49**) or the **Physician** (as per **Article 50**) **of the SoHO establishment**(s) involved in the event of an adverse reaction or event.
3. **Manage reporting processes** with SoHO establishments and Competent Authorities, facilitating communication between clinical teams, SoHO entities, and regulatory bodies to ensure timely and accurate reporting.
4. **Ensure that all staff involved in SoHO activities understand their roles and responsibilities** regarding vigilance and reporting.
5. **Monitor the reporting of Serious Adverse Reactions and Events**, ensuring that thorough investigations are conducted. Where corrective and preventive actions are required, ensure these are properly implemented and followed up.

Training in vigilance and reporting of Adverse Reactions and Events is also important for the professionals involved in this process (see Recommendation 13).■

Recommendation 13

Gather and use supporting documents to integrate best practices and ensure team's capacities for vigilance and reporting protocols

SoHO entities should ensure that professionals involved in vigilance and reporting possess the **required skills and are competent** to carry out their responsibilities. To achieve this, it is essential to **provide supporting documents** (which may be facilitated by the Competent Authority), **integrate best practices and offer appropriate training.**

Examples of areas in which it would be relevant to strengthen the team's capabilities through the use of supporting documentation or training include:

1. **Specific data requirements** for reporting adverse reactions and adverse events, including format, timelines, and submission processes.
2. **The roles and responsibilities of stakeholders** in ensuring prompt notification, investigation, and implementation of corrective and preventive actions.
3. **Raising awareness of the importance of timely and accurate reporting** of adverse reactions and adverse events.■

4.4 Activity data collection and reporting

Under the SoHO Regulation, SoHO entities are responsible for gathering and documenting SoHO activity data related to the volume of SoHO activities carried out, covering the entire process from SoHO donor registration to human application. SoHO entities are required to submit this activity data in the form of annual reports, following a uniform dataset as specified. The recommendations for Activity data collection and reporting are intended to facilitate compliance with the corresponding checklist and, consequently, with the requirements of the SoHO Regulation.

Recommendation 14. Implement a standardised process for SoHO activity data collection and reporting.

Recommendation 15. Involve one or more professionals in the oversight of SoHO activity data collection and reporting.

Recommendation 16. Gather and use supporting documents to integrate best practices and ensure team's capacities for internal SoHO activity data collection and reporting protocols.

Checklist for Activity data collection and reporting 

The recommendations for Activity data collection and reporting are intended to facilitate compliance with the corresponding checklist and, consequently, with the requirements of the SoHO Regulation. The checklist outlines the key steps necessary to collect and report data from the various SoHO activities performed within the SoHO entity, in accordance with the SoHO Regulation.

- ❑ **Identify the SoHO activities conducted** within the SoHO entity from which data must be collected and reported (see **Article 41(1)** of the SoHO Regulation).
- ❑ **Review the most up-to-date list of required datasets**, which are published by the European Commission and available in the EU SoHO Platform.
- ❑ **Collect the required dataset** for each of the SoHO activities identified.
- ❑ **Submit an annual report** of the data collected by a deadline indicated by your Competent Authority of the subsequent year via the tool indicated by the Member State, which may be the **EU SoHO Platform** (see **Article 41(4)**) or a **designated national or international registry** (see **Articles 41(5) and 31(2)**).■

Recommendation 14

Implement a standardised process for SoHO activity data collection and reporting

To ensure **consistency, transparency, and regulatory compliance** across all SoHO entities, it is essential to implement a standardised process for the collection and reporting of SoHO activity data. A harmonised process not only facilitates accurate monitoring and oversight but supports data-driven decision-making and enhances the safety and quality of SoHO-related activities.

To implement the standardised process, SoHO entities may consider the following actions:

1. **Identify the internal sources within the SoHO entity from which SoHO activity data must be collected and reported**, ensuring alignment with the minimum harmonised dataset (defined by the EDQM and the European Commission, endorsed by the SoHO Coordination Board, and included in the EU SoHO Platform).
   - According to **Article 41(1)** of the SoHO Regulation, activity data to be collected and reported includes information on the following SoHO activities:
     - SoHO donor registration;
     - Collection;
     - Distribution;
     - Import;
     - Export;
     - Human application.
   - The Responsible Person, as per **Article 36**, is responsible for ensuring the collection of SoHO activity data, maintaining data integrity and consistently meeting the requirements of the minimum harmonised dataset. This task may be carried out by the Responsible Person or delegated to appropriately trained supporting professionals.
2. **Involve one or more professionals,** including the Responsible Person or supporting staff (e.g., biovigilance employees), to **oversee the SoHO activity data collection and reporting process** (see Recommendation 15).
3. **Identify existing tools, systems, or databases within the SoHO entity or hospital** that can be used to gather all SoHO activity data. Where appropriate, existing tools may be reused for this purpose.
4. **Use the identified tools or systems** (if available) to prepare the annual report based on the collected data.
5. **Submit the annual report by the deadline indicated by your Competent Authority of the following year to the SoHO Competent Authorities** via the tool indicated by the Member State which may be:
   - The EU SoHO Platform (**Article 41(4)**), or;
   - A national or international registry, provided that it collects activity data matching the dataset requirements outlined in the EU SoHO platform (**Article 31(2) and 41(5)**).■

Recommendation 15

Involve one or more professionals in the oversight of SoHO activity data collection and reporting

To ensure data integrity, accuracy, and compliance within the SoHO entity, professionals should oversee activity data collection and reporting. Oversight of this process is essential and may be carried out either by the **Responsible Person**, who must be aware of it, **or by designated professionals**, depending on the size of the SoHO entity and the nature of the activities performed.

The Responsible Person or designated professionals involved in this process could consider the following actions:

1. **Collaborate with relevant departments** to collect SoHO activity data.
2. **Ensure all processes align with regulatory requirements and best practices for SoHO activity data collection and reporting**, as available on the EU SoHO Platform.
3. **Oversee the timely and accurate submission of data and data updates** to the SoHO Competent Authorities.

Training in SoHO activity data collection and reporting is also important for the professionals involved in this process (see Recommendation 16).■

Recommendation 16

Gather and use supporting documents to integrate best practices and ensure team's capacities for internal SoHO activity data collection and reporting protocols

The use of **supporting documents and integration of best practices**, together with ensuring that **staff are adequately trained**, are essential to ensure those involved in SoHO activity data collection and reporting carry out their tasks effectively. Areas in which it would be relevant to strengthen the team's capabilities through the use of supporting documentation or training include:

- **The data to be collected**, including the minimum harmonised dataset required.
- **How and when the data should be reported,** in line with regulatory timelines.
- **Roles and responsibilities**, with clear specifications on who is responsible for reporting the data (e.g., the Responsible Person) and to whom it must be submitted.
- **The correct use of the digital tool**, whether the EU SoHO platform or relevant national or international registries.■

4.5 Traceability

According to the SoHO Regulation, SoHO entities must implement a traceability system that covers the entire process from donor to recipient. This system must enable the identification and linkage of all relevant data concerning each SoHO donor or the person from whom SoHO are collected for autologous or within-relationship use, to their SoHO and to all the documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO at any point.

SoHO entities distributing SoHO outside of their organisation should implement a unique, machine-readable code, unless their size or storage conditions prevent its application, which does not reveal the identity of the SoHO donor and complies with the technical rules of the Single European Code. SoHO entities must also maintain the minimum required set of traceability data for a period of 30 years.

Recommendation 17. Implement standardised processes to ensure traceability.

Recommendation 18. Involve one or more professionals in the oversight of traceability.

Recommendation 19. Gather and use supporting documents to integrate best practices and ensure team's capacities for traceability protocols.

Checklist for Traceability

The recommendations for Traceability are designed to support compliance with the accompanying checklist and, by extension, with the SoHO Regulation. The checklist sets out the key steps that a SoHO entity should consider when implementing a traceability system in accordance with the SoHO Regulation.

- ❑ Implement a **traceability system** that enables the linkage between the SoHO donor (or the person from whom SoHO are collected for autologus or within realtionship use) and their corresponding SoHO, documents, samples, equipments and disposables used, SoHO preparations, and associated SoHO entities (as per **Article 42(1)** of the SoHO Regulation).
- ❑ **Identify the functional capacities** that the traceability system must support, as outlined in **Article 42(2)**.
- ❑ **Apply a code,** to distributed SoHO that contains the information required by the traceability system, in accordance with **Article 42(3)**.
  - ❑ Ensure that the applied codes are included using one of the following methods, as specified in **Article 42(4)**:
    - ❑ On the labels affixed to the SoHO (prior to its distribution); or
    - ❑ On **accompanying documents**, provided that:
      - ❑ The documents are not separated from the SoHO; or
      - ❑ The documents remain digitally linked to the specific SoHO.
- ❑ **Use a labelling system** that complies with the requirements outlined in the relevant technical guidelines, as referred to in **Article 56(4)** and **Article 59(4)**.
- ❑ **Ensure that each SoHO distributed outside the SoHO entity for human application** carries a Single European Code, in line with the requirements of **Article 43**.
- ❑ **Collect and store all necessary traceability data,** which may be held in electronic format.
- ❑ **Safeguard the data appropriately** and ensure it remains accessible to the SoHO Competent Authority for a minimum of 30 years from the date of SoHO distribution, or from the date of disposal or export, as applicable (**Article 42(6)**).
- ❑ **In case of a SoHO entity <u>ceases</u> its activity** (**Article 42(6)**):
  - ❑ **Notify the SoHO Competent Authority** of the cessation and identify the SoHO entity contracted to maintain traceability.
  - ❑ **Transfer all traceability data** to the designated SoHO entity for the remainder of the required traceability period.■

Recommendation 17

Implement standardised processes to ensure traceability

To ensure full compliance with the traceability and coding requirements outlined in **Article 42** and **Article 43** of the SoHO Regulation, and to promote harmonised, efficient, and secure practices across all relevant settings, SoHO entities should implement standardised processes for traceability. These processes should be designed to support the accurate identification, documentation, and long-term storage of SoHO-related data.

The following actions may be considered when implementing standardised processes for traceability:

1. **Identify existing tools, systems, or databases within the SoHO entity or hospital** that could be used to collect traceability data and information related to SoHO. This identification may also support the development and establishment of the SoHO entity's own traceability system (as referred to in **Article 42(1)**).
2. **Involve one or more professionals**, either the designated Responsible Person or supporting professionals, in **supervising the traceability system** (see Recommendation 18).
3. **Apply unique, machine-readable codes** that contain the information required by the traceability system and meet the criteria established by the SoHO Regulation (as per **Article 42(3)**). The elements of the Single European Code (SEC) shall be applied in cases where SOHO are distributed for human application, SoHO are transferred for further processing in another SoHO entity, released for manufacture of products regulated by other Union legislation, or exported to third countries (as per **Article 43.1**). Other examples (compatible with the SEC) include the ISBT128 system (from ICCBBA) or Eurocode.
4. **No application of SEC is needed for** reproductive SoHO for within-relationship use, blood or blood components for transfusion or for the manufacture of medicinal products, SoHO applied to a SoHO recipient without being stored, SoHO imported into the Union by way of derogation and authorised directly by SoHO competent authorities pursuant to **Article 26(6),** SoHO that are imported to or collected in the same SoHO entity where they are applied.
5. **Use a labelling system** that complies with the requirements set out in the technical guidelines published by ECDC and EDQM, or other guidelines referred to in **Article 56(4)** and **Article 59(4)**.
6. **Enable electronic reading of SoHO traceability codes** via the SoHO entity's patient databases and/or administrative systems, and ensure this information is linked to patient data.
7. **Establish a secure system for storing traceability data,** ensuring that it is accessible to authorised personnel and to the SoHO Competent Authority when required.
8. **Ensure retention of traceability data** for a minimum of 30 years, mandated by **Article 42(6)** of the SoHO Regulation.
9. **Develop a contingency plan for the transfer of traceability data** to another contracted SoHO entity, in the event of the original entity ceasing operations. This ensures continued storage, monitoring, and compliance with the SoHO Regulation (**Article 42(6)**).■

Recommendation 18

Involve one or more professionals in the oversight of traceability

The **Responsible Person** must be aware of the traceability and coding activities implemented within the SoHO entity. To maintain oversight, **the Responsible Person should either directly supervise the traceability system** or delegate this responsibility to designated supporting professionals, who must ensure that **any updates or changes are promptly communicated to the Responsible Person.**

The following activities may be undertaken by the Responsible Person or designated professionals to support effective oversight:

1. **Ensure that traceability processes and systems are correctly implemented**, including the unique identification of all SoHO and the protection of associated data.
2. **Oversee the maintenance and integrity of traceability records** ensuring data is properly safeguarded and accessible to the Competent Authority for a minimum of 30 years, as required by the SoHO Regulation (**Article 42(6)**).

Training in traceability is also important for the professionals involved in this process (see Recommendation 19).■

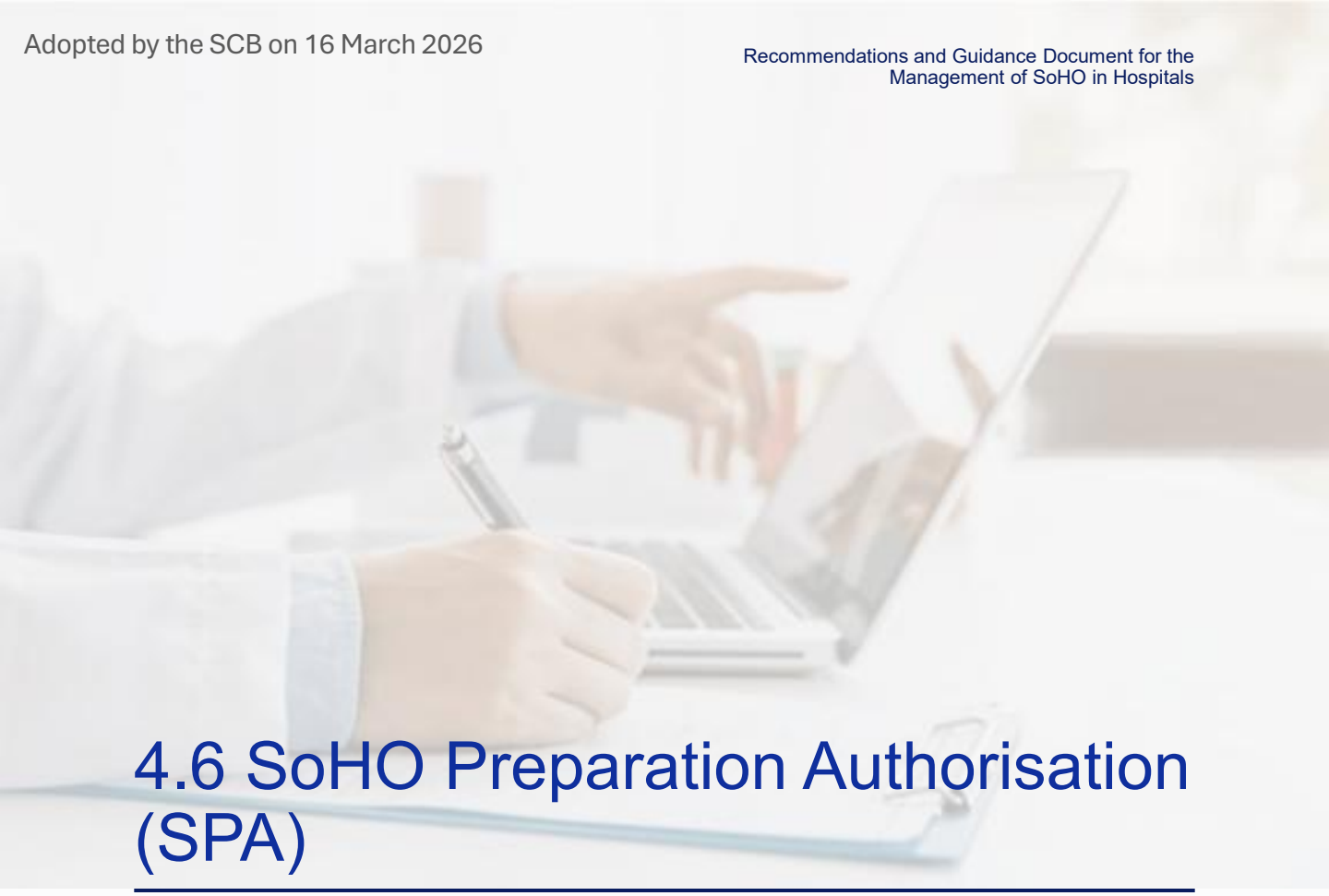
Recommendation 19

Gather and use supporting documents to integrate best practices and ensure team's capacities for traceability protocols

SoHO entities should ensure that professionals involved in traceability activities possess the required skills to perform related tasks effectively. To this end, **relevant supporting documents** should be made available, **best practices** should be integrated, and staff should receive **appropriate training** to have all the competencies required.

Areas in which it would be relevant to strengthen the team's capabilities through the use of supporting documentation or training include:

1. **The application of coding systems** to accurately manage SoHO throughout all stages of the process.
2. **The operation of traceability systems** within the specific context of the SoHO entity.
3. **Privacy and data protection compliance**, with a focus on the secure handling of sensitive donor and recipient information and information of offspring resulting from medically assisted reproduction in accordance with the General Data Protection Regulation (GDPR).■



4.6 SoHO Preparation Authorisation (SPA)

Under the SoHO Regulation, SoHO entities and SoHO establishments shall not release or, in the context of autologous or within-relationship use, shall not prepare and immediately apply to a SoHO recipient, SoHO preparations without prior SoHO preparation authorisation, other than in the context of the implementation of an approved clinical-outcome monitoring plan as part of a SoHO preparation authorisation. SoHO entities responsible for the clinical use of new SoHO preparations must collaborate with SoHO establishments to ensure full compliance with the SoHO Preparation Authorisation requirements set out in Articles 38 and 39 of the SoHO Regulation, in particular when it concerns the authorisation of new SoHO preparations.

Recommendation 20. Establish effective collaboration with SoHO establishments.

Recommendation 21. Engage professionals to gather all relevant information related to the authorisation procedures of novel SoHO preparations.

Checklist for SoHO Preparation Authorisation

The recommendations on SoHO Preparation Authorisation aim to support compliance with the associated checklist and, by extension, with the SoHO Regulation.

SoHO entities that **perform bedside preparations** may go through the **full SoHO Preparation Authorisation** process.

SoHO entities that apply SoHO Preparations prepared and distributed by SoHO establishments could also be required to **collaborate with SoHO establishments** to:

- ❑ Gather all information necessary to conduct **accurate risk-assessments** for new SoHO preparations**,** including the assessment and estimation of patient risk, and, where applicable, the provision of **scientific evidence to support the risk-benefit evaluation** for patients.

- ❑ **Collect clinical data** within the framework of clinical evaluation protocols and provide it to the SoHO establishment, in order to generate evidence for assessing the safety and efficacy of the (novel) SoHO Preparation, where applicable.■

Recommendation 20

Establish effective collaboration with SoHO establishments

SoHO entities that apply SoHO preparations prepared and distributed by SoHO establishments should collaborate with them to properly assess the risks associated with the clinical use of the SoHO preparation and to facilitate the exchange of information and clinical data.

To ensure effective collaboration between professionals at the SoHO entity and the SoHO establishment, the following coordinated actions may be considered:

1. **Identify the key professionals within the SoHO establishment** involved in the preparation and authorisation procedures of new SoHO preparations.
2. **Establish direct and structured communication channels** between the identified professionals at the SoHO establishment and those at the SoHO entity.
3. **Hold meetings periodically** to exchange information, establish procedures, and address any issues that may arise.
4. **Document and follow-up on all interactions and agreements** with the SoHO establishment to support sustained and effective collaboration.■

Recommendation 21

Engage professionals to gather all relevant information related to the authorisation procedures of novel SoHO preparations

SoHO entities may engage professionals to support risk assessment exercises as an initial step in the authorisation procedures of novel SoHO preparations, and to ensure the collection of clinical data within the framework of clinical-outcome monitoring plans.

To this end, SoHO entities may consider the following actions:

1. **Identify a professional who may be eligible to coordinate with the SoHO establishment.** The appointed individual, who might be the Responsible Person, may act as the primary point of contact between the SoHO entity and the SoHO establishment, facilitating the exchange of information relevant to the SoHO Preparation Authorisation.
2. **Ensure that professionals involved** in the clinical use of novel SoHO preparations are familiar with **the SoHO Preparation Authorisation requirements and definitions**, including the **procedural steps required for submitting an authorisation application.**
3. **Facilitate access to supporting documentation and best practices** for the clinical use of novel SoHO preparations.
4. **Define standardised processes to gather all relevant information** for the preparation and authorisation of novel SoHO preparations and to streamline coordination with the SoHO establishment. When defining these processes, the following considerations may apply:
   - **Utilise tools**, such as the EuroGTP II and the GAPP Joint Action to assess and manage risks associated with novel SoHO Preparations. This tool evaluates potential risks of innovative developments, helps define whether an application for an authorisation of a SoHO preparation is needed, and ensures appropriate safety measures are in place.
   - **Design of clinical outcome monitoring plans** and collect appropriate clinical outcome data, where applicable.■

5. Methodological approach

This report was produced under the EU4Health Programme, within the framework of a service contract with the European Health and Digital Executive Agency (HaDEA) and the Directorate-General for Health and Food Safety (DG SANTE). It is the result of a series of activities undertaken over the course of a 24-month project, carried out by a consulting team and a pool of experts specialised in the field of SoHO, with the support of more than 30 European SoHO organisations. Figure 1 presents the main phases and key interactions implemented during the project.

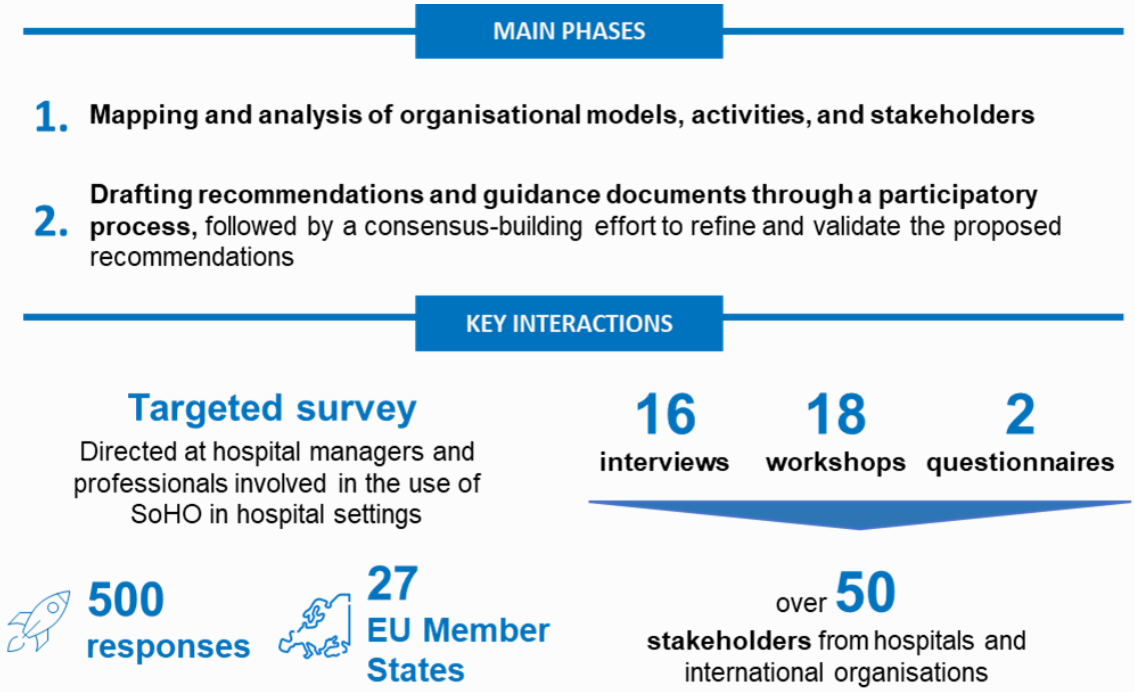


Figure 3. Main phases and key interactions implemented during the project.

As part of the mapping process, a **comprehensive review of over 100 documents** was conducted, including grey literature and academic studies. The review analysed SoHO management practices across EU Member States, with a focus on relevant regulatory developments and state-of-the-art assessments of the end-to-end SoHO management process. EU guidelines, projects, and initiatives relevant to SoHO management were also examined, contributing to the identification of European frameworks addressing key aspects of SoHO management, particularly quality and safety throughout the end-to-end process.

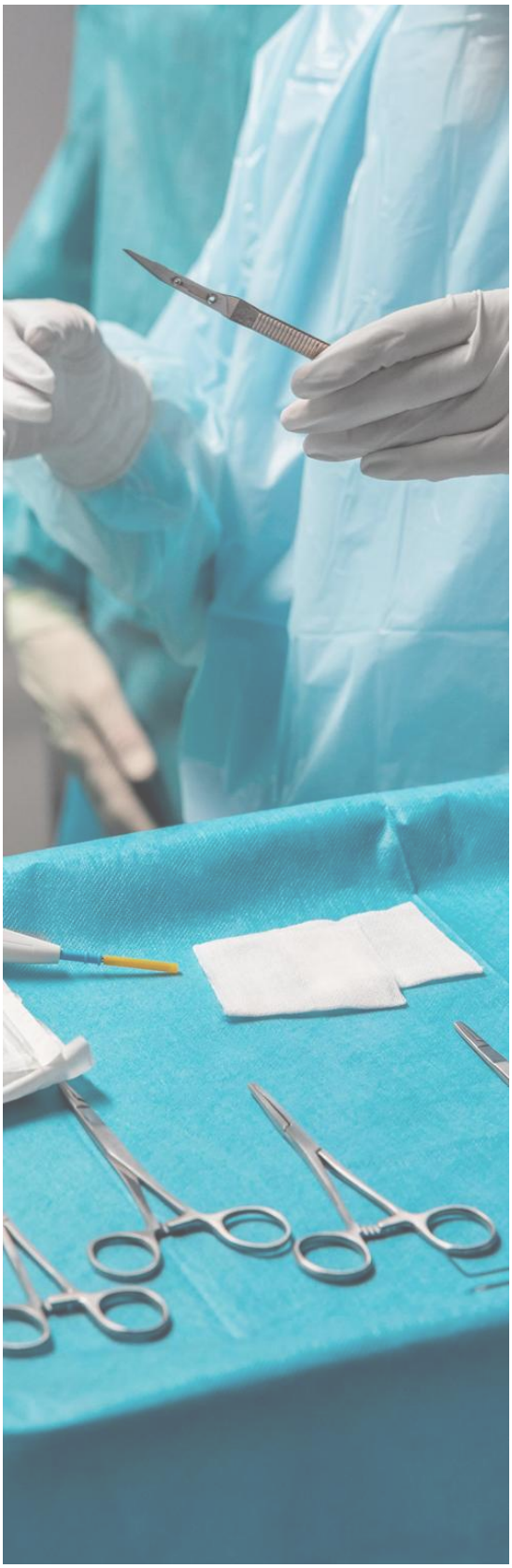
Interviews with hospital representatives across five geographical clusters (i.e., Northern Europe, the Baltics, Southern Europe, Eastern Europe, and Western Europe) enabled the ▶

identification of good practices in **SoHO management**, including organisation and governance, bedside and in-surgery SoHO processing, traceability, the detection and reporting of adverse reactions and adverse events, and activity data collection, among others.

Building on those findings as a baseline, a **participatory process** was initiated involving stakeholders from various EU organisations and associations specialising in different types of SoHO (i.e., blood, tissues, and cells), with the aim of further understanding common practices and identifying potential areas for improvement. As a first step, a survey was conducted receiving nearly 500 responses from hospital managers and healthcare professionals. The survey comprehensive overview of the current state of play across all 27 EU Member States, highlighting substantial differences across different hospital settings and SoHO types.

The survey results were further enriched through 18 working sessions and 16 expert interviews, which aimed to identify key areas for the development of targeted recommendations and guidance. These sessions also enabled iterative refinement of the recommendations, incorporating input from over 55 experts.

Finally, recommendations underwent a **consensus-building process** consisting of two online questionnaires and four additional working sessions, allowing experts to further validate and refine the recommendations and guidance. The recommendations were then **tested in real EU hospital settings across the EU.** The pilot involved two hospitals, one from Germany and another one from Spain, which managed different SoHO types (i.e., blood, tissues, and cells). The pilot aimed to assess the clarity and feasibility of the proposed recommendations, ensuring their practicality and adaptability to real-world hospital environments.■



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European Alliance for Vision Research and Ophthalmology
European Blood Alliance (EBA)
European Centre for Disease Prevention and Control (ECDC)
European Eye Bank Association (EEBA)
European Directorate for the Quality of Medicines & HealthCare (EDQM)
European Hospital and Healthcare Federation (HOPE)
Établissement Français du Sang (EFS)
European Society for Organ Transplants (ESOT)
European Society for Blood and Marrow Transplantation (EBMT)
Hospital Clínic de Barcelona
Hospital Universitari de Bellvitge (HUB)
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World Marrow Donor Association (WMDA)

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