

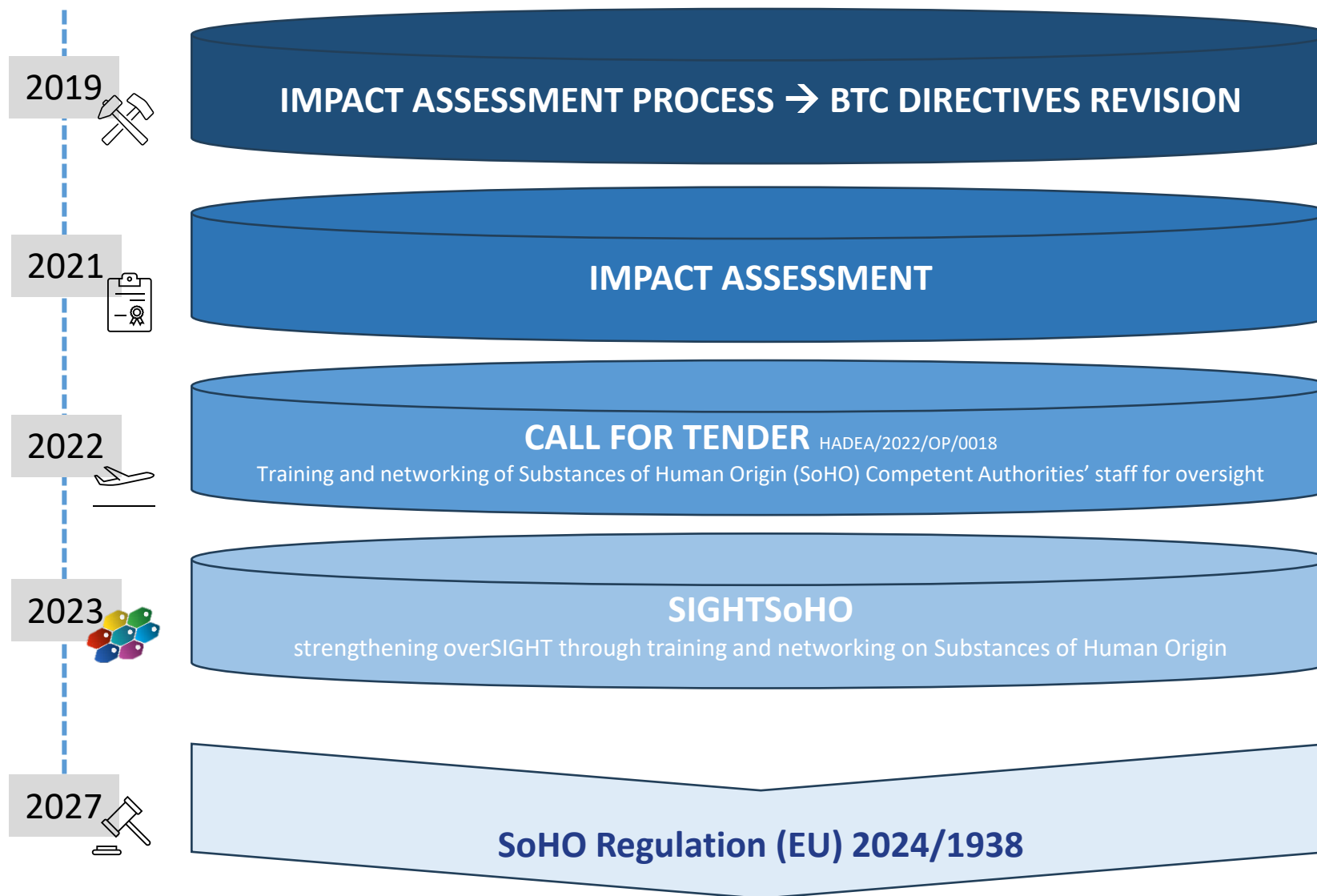
Key EU initiatives: **SIGHTS**oHO

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Rome, April 8th 2025

Tools towards the common approach: Training



2027



SoHO Regulation (EU) 2024/1938

CAs obligations Article 8

- (f) Develop and implement, or provide access to, **training programmes** to ensure that personnel performing SoHO **supervisory activities** receive, for their area of competence, **appropriate training**;
- (g) provide **opportunities** for their personnel **to participate in the Union training**.

Assessors requirements and Joint SoHO preparation Assessments Article 23

Before SoHO preparation assessors take up their duties, SoHO CAs shall provide assessors with:

- **specific induction training** on the procedures to be followed for the assessment of SoHO preparations (4)
- **specialised training** for assessment of processing methods and technologies used for specific types of SoHO preparations (5),
- **continuous training**, as appropriate, throughout the career of the SoHO preparation assessors (5).

SoHO CAs shall Ensure that **SoHO preparation assessors participating in joint SoHO preparation assessments** have completed the **relevant Union training** (5).

Inspectors requirements Article 30

Before inspectors take up their duties, SoHO CAs shall provide inspectors with a **specific induction training** taking into account the relevant best practices documented and published by the SCB (2). The specific induction training shall include at least (3):

- (a) **inspection techniques and procedures to be followed**, including practical exercises;
- (b) **overview of relevant Union and national inspection guidance** (...) and best practices documented and published by the SCB;
- (c) **overview of the authorisation systems in the Member State concerned**;
- (d) **legal framework** applicable to the performance of SoHO supervisory activities;
- (e) overview of the **technical aspects concerning SoHO activities**;
- (f) **SoHO technical guidelines**;
- (g) overview of the **organisation and functioning of national regulatory authorities in the field of SoHO and related fields**;
- (h) overview of the **national healthcare system and SoHO organisational structures** in the Member State concerned.

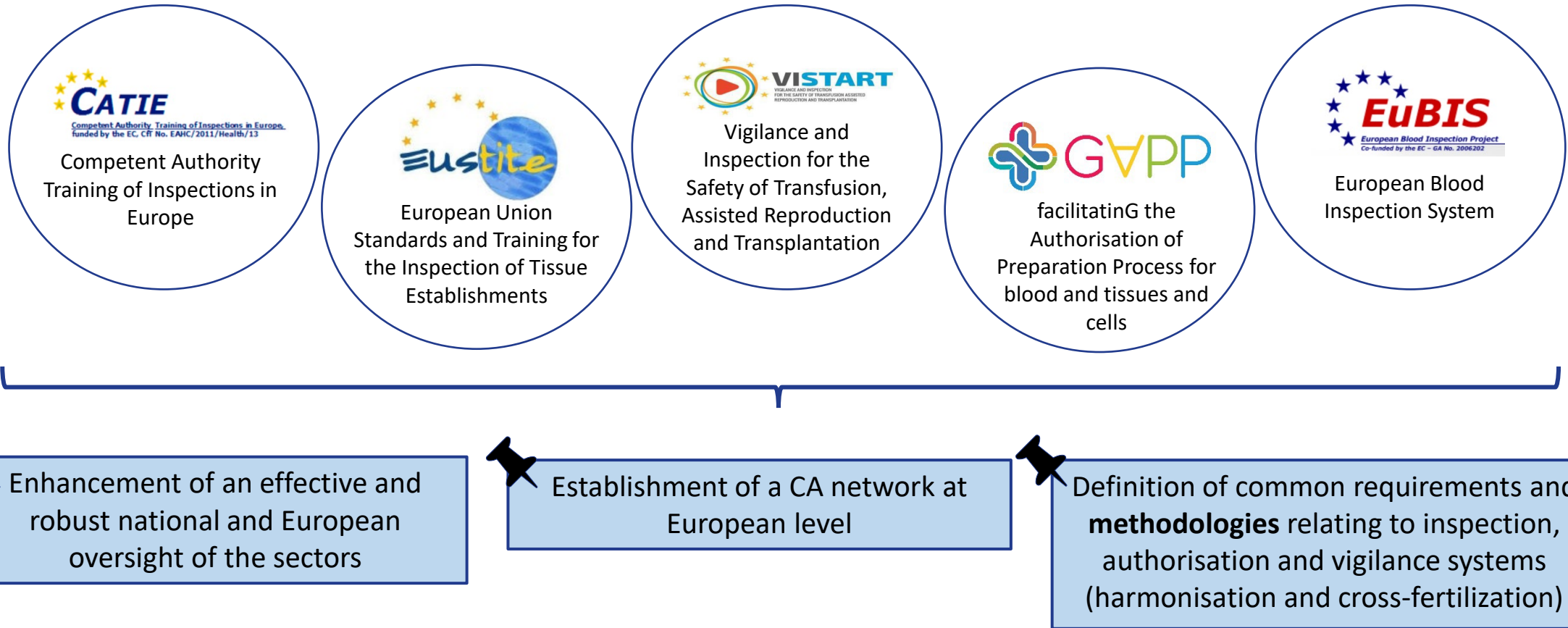
Union Activities CHAPTER X Article 70

1. The Commission shall, in cooperation with SoHO national authorities, organise **Union training on the implementation of this Regulation**.
5. The Commission shall maintain a **list of the SoHO competent authority personnel that have successfully completed the Union training** (...) with a view to facilitating joint activities.

**SoHO oversight system:
the implementation of the new EU regulation with a focus on the obligations for competent authorities**



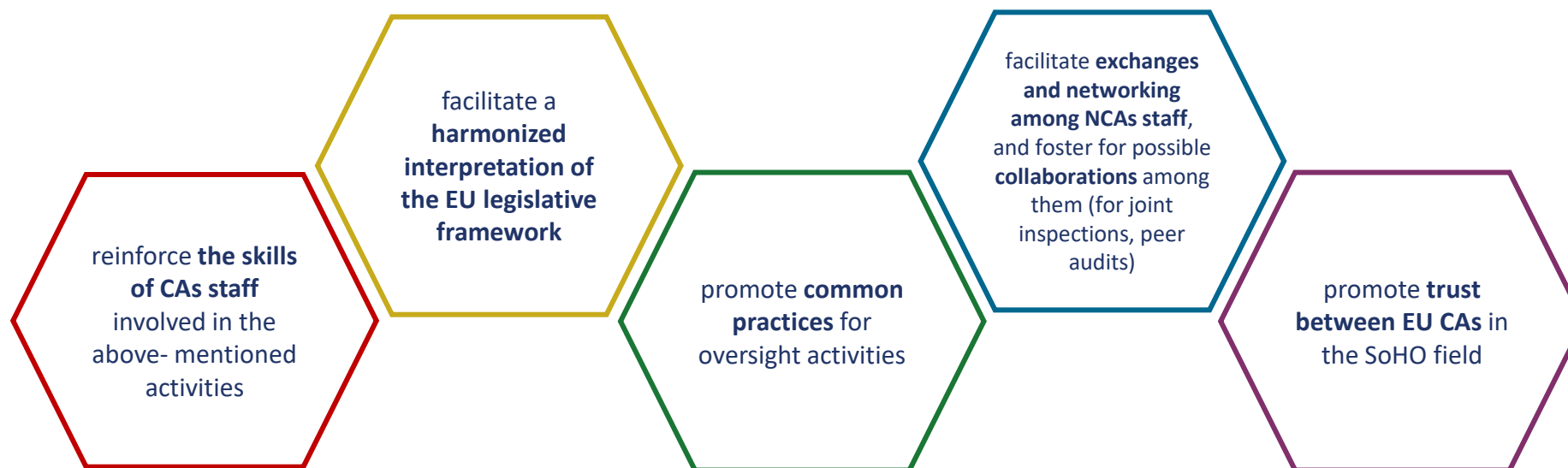
Previous EU Experiences





SIGHTSoHO Objectives



To develop a training programme addressed to Substances of Human Origin (SoHO) national competent authorities' (CAs) staff involved in oversight tasks, particularly inspections, vigilance and BTC preparation processes assessment, aiming to:



2 ROUNDS	First Round	Second Round
 eLearning	27 November 2023 - 01 March 2024	27 January 2025 - 11 April 2025
 Face-to-Face	<ul style="list-style-type: none"> 15-16-17 May 2024: Inspection 5-6-7 June 2024: Preparation Process Authorisation 3-4-5 July 2024: Vigilance 	<ul style="list-style-type: none"> 7-8-9 May 2025: Inspection 11-12-13 June 2025: Vigilance 2-3-4 July 2025: Preparation Process Authorisation



Overall Training Contents

Online weekly modules

1. EU legal provisions;
2. Licensing, Authorisation and Accreditation System (including overview of inspection tools);
3. Quality management system - overview;
4. Quality management system - good practices;
5. Quality risk assessment;
6. BTC preparation processes authorisation;
7. SoHO vigilance and Biovigilance;
8. Serious Adverse Outcomes/Rapid Alerts and Harmonising data collection;
9. Stock and critical supplies; Imports and exports; Single Coding of tissues and cells;
10. Inspection practice, inspection report and post inspection activities;
11. Risk for inspectorate.

F2F workshops

1. Inspection practice;
2. Biovigilance and Hemovigilance;
3. Preparation Process Authorisation.

F2F main contents

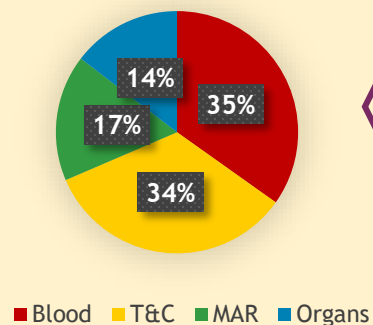
1. EU legal provisions;
2. Preparation Process Authorisation;
3. State-of-the-art of processing, testing laboratories, facilities, storage, transport, transplantation/transfusion;
4. Preparation and performance of inspection;
5. Practical on-site inspection;
6. Assessment of non-compliances and classification of deficiencies;
7. Joint inspections;
8. Vigilance protocols, follow-up, activities and serious adverse reactions and events reporting using common denominators, annual vigilance data analysis.

SIGHTSoHO Round 1 eLearning



78 Participants
coming from **23 EU MSs** plus **one non-EU Country**

SoHO Coverage



Professional activity Coverage

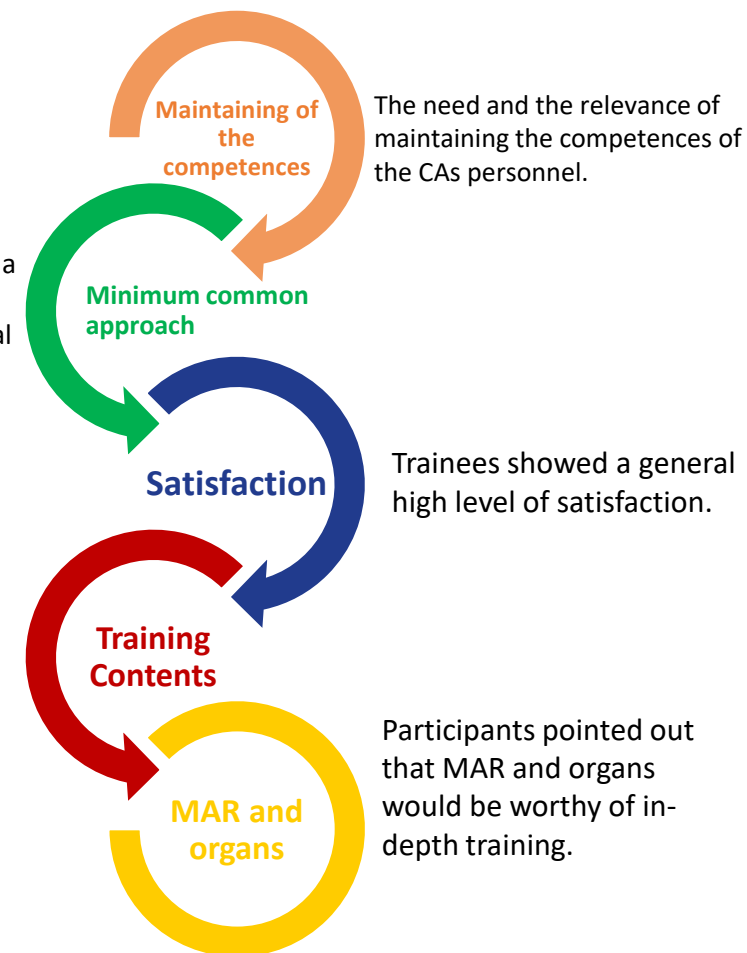


Knowledge improvement
17.5%

The concrete feasibility to provide European training on a minimum common approach referred to SoHO, professional activities and geographical coverage.

Trainees particularly appreciated on SA outcomes/Rapid alerts and harmonising data collection.

Outcomes

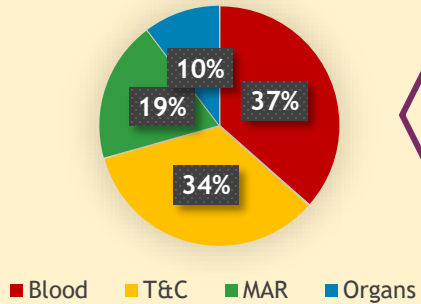


SIGHTSoHO Round 1 Face-to-Face



57 Participants
coming from 18 EU MSs plus one non-EU Country

SoHO Coverage



Professional activity Coverage



Knowledge
improvement
13.47%

The organisation of the **mock inspection** was highly appreciated since it gave the chance to **experience a joint inspection with heterogeneous team**.

Live interaction provided participants and tutors with more room to deeply discuss the applicability of a common approach.

Outcomes

Utility and
relevance

Inspection Practice the most attended workshops and appreciated in terms of:

- **Training programme** utility, interaction and engagement;
- **Relevance to trainees** current/future job

Practical

The topic ended to be the **hardest to follow** since the contents of the materials, being very technical, were a bit more complicated than the others.

PPA

Live
interaction



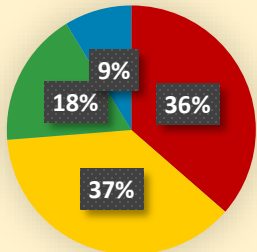
SIGHTSoHO Round 2

eLearning



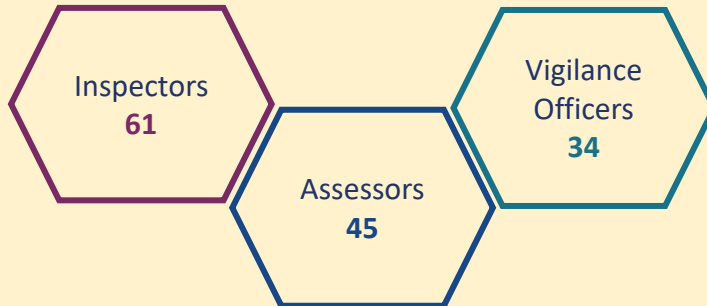
102 Participants coming from 20 EU MSs

SoHO Coverage



■ Blood and blood components
■ Tissues and cells
■ MAR
■ Organs

Professional activity Coverage



Overall **training material** is the **same** as the one used during **Round 1**.



Minor amendments in the **weekly synchronous live sessions** (Wednesdays and Fridays) and in the **Workshops** in which **insights** of the **New Regulation** have been and will be provided.



New methodologies adopted for the Live Interactive Moments: **gaming experiences** (e.g., Who wants to be a millionaire, Hangman, Hidden Picture...).

Preliminary considerations

- ✓ Workshop 2 on Preparation Process Authorisation:
Higher interest in participating than in Round 1
- ✓ Approaching the SoHO regulation full implementation,
A more interest in thematics that in Round 1 were not considered as urgent as now.



SIGHTSoHO preliminary results

In conclusion, **SIGHTSoHO** contributed to

Encourage a **European cross-fertilisation of SoHO fields and professional activities** stimulating the establishment/strengthen of an EU network intended to provide support to CAs and EU MSs.

Provide preliminary **constructive tools to achieve harmonisation**, to support MSs in particular their inspection/authorisation and vigilance systems, which face minor or major difficulties in complying with the requirements set by current and future European legislation.

Increase the level of **confidence** between the inspection, evaluation, authorisation and vigilance systems of the MSs.

It is clear that **additional EU training** addressed to oversight personnel of MSs is **significantly needed and desired**.



Why is additional EU training needed to fill in gaps?

Some examples:

Concern was raised by SIGHTSoHO participants regarding the introduction of the **role of assessor in the new regulation** and the impact that this would have on their CA in terms of resources and training/knowledge etc. This was particularly pertinent for representatives from smaller MS. There is perhaps a lack of understanding/ knowledge regarding how tasks (which may previously be done by inspectors) will/should be divided in the future.

For the assessment of some **Preparation Process Authorisation dossier**, the **Competent Authorities** need to be **supported** by **experts** or advisory committees;

The **composition of the team should be up to the EC** on the basis of a list of auditors including representatives of all MS;

The importance of making the CA providing a **rationale** to the **BE/TE** for the **classification of non-compliance** was also acknowledged as vital.

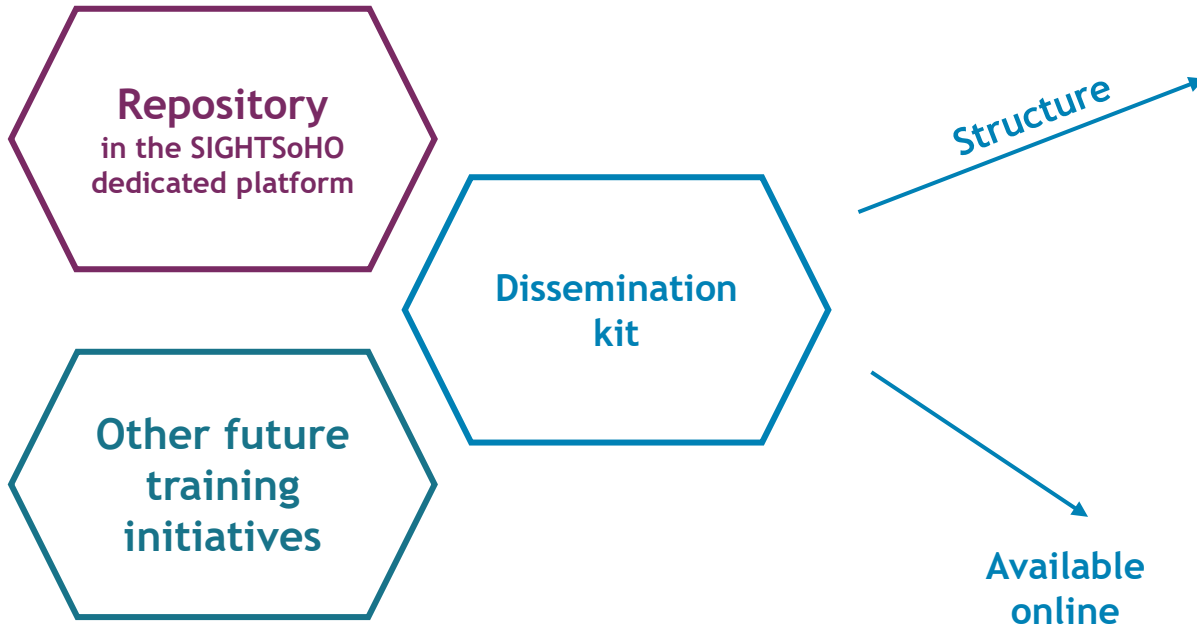
The **risk assessment methodologies** are **useful** not only for inspectors, but also for professionals that work on PPA and for vigilance officers, as well **for any CA staff dealing with PPA**;

Prompt communication and notification must be ensured in **vigilance procedures** (interaction among inspectorates mostly exists but without systematic procedures in place in many cases); **Communication between different involved institutions** (CA, BTC etc.) is crucial and has to be encouraged;

Recommendations and guidelines on how to **assess the compliance of BTE with the vigilance requirements** would be helpful in terms of harmonization.



Sustainability



It includes all the necessary **tools** and **resources** intended for the design and delivery of any training initiative using the SIGHTSoHO approach and contents.



Tool 1 - Training information sheets: detailed outlines of eLearning modules



Tool 2 - Educational material: presentations, case studies, assignments



Tool 3 - Syllabus: compendium of the glossary used during the training organised per thematic area.



Tool 4 - Current legislation: European legislation, guidelines and European projects outputs/deliverables organised per thematic area.



Tool 5 - Train the Trainers (T4T) Guide: brief methodological guide, including suggestions and tips, addressed to SIGHTSoHO participants who wish to share the knowledge and skills acquired within the SIGHTSoHO training course with their colleagues.



Tool 6 - Podcast: Questions&Answers organised per thematic area.



Tool 7 - Videoclip: Video animations that summarise the Take-home messages produced at the end of each training session.



Team composition



Istituto Superiore di Sanità (ISS) is the **Contractor** through the **Italian National Blood Centre (CNS)** and the **Italian National Transplant Centre (CNT)**
In collaboration with the **Joint Tenderer Zadig ltd**



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Thank you!



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more info on
SIGHTSoHO

