

SIGHTSoHO

strengthening overSIGHT through training and networking on
Substances of Human Origin

Joint Meeting of the Competent Authorities on: Blood and Blood Components Tissues and Cells Organs

May 24, 2023

Livia Cannata, Paola Di Ciaccio (ISS-CNS/CNT)

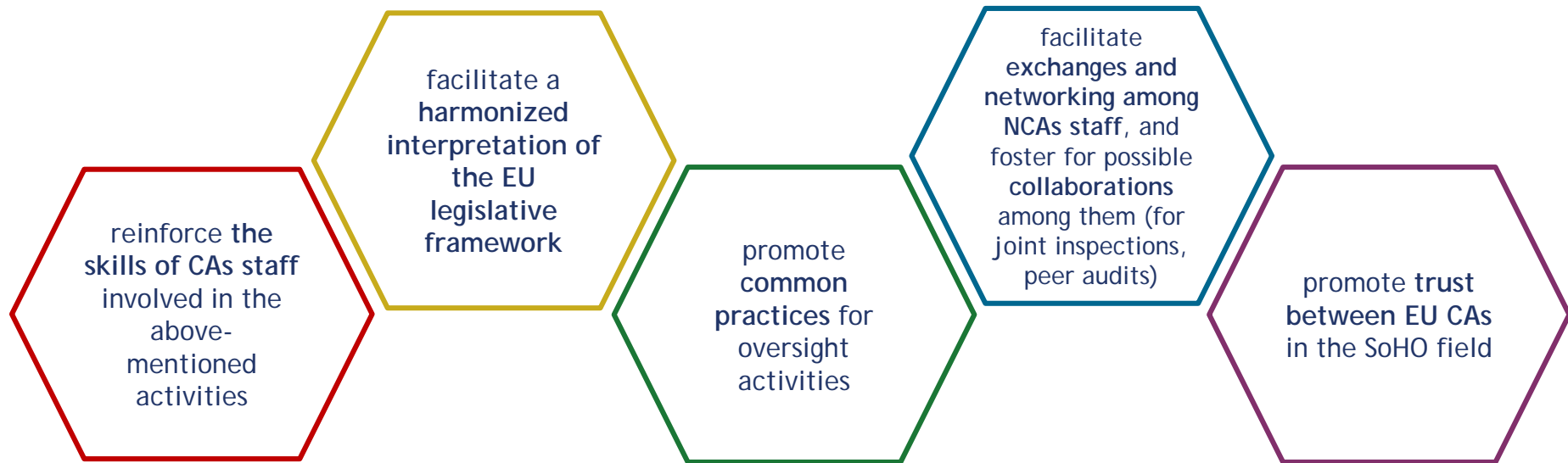
On behalf of the SIGHTSoHO Team



Tender 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:





Launch of the tender

August 4th, 2022



We have been
selected

December 14th, 2022



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**



ISS/CNS-CNT Team:

S. Pupella, L. Cannata, A. Palmieri, U. La Rocca, M. Gentile, P. Di Ciaccio, C. Carella, M. Mareri, F. Bariani, A. Vassanelli

ISS Training Office

ISS Data Protection Office

Zadig Team:

P. Dri, M.R. Valetto, R. Daghini, S. Emendi

External Tutors:

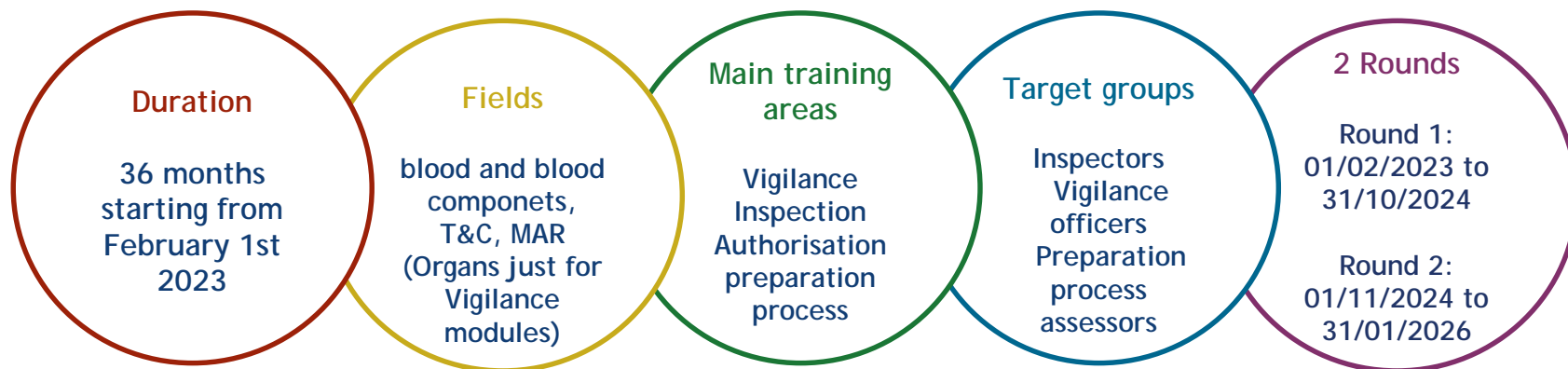
S. Masterson, H. Kurz, A. P. Barreiros, R. Barrio, A. Kurzreiter, F. Teskrat



Scope of the Service



Strengthening the implementation of oversight in the field of SoHO in the EU Member States (MS), and also EFTA associated countries, through training and networking of SoHo competent authorities for oversight.



Forthcoming appointments for CAs (1/2)

Within end of June / early July 2023 → Announcement to CAs, including



Application form



and



Launch of the Platform



In the Application Form participants will be requested to specify:

- field of competence,
- years of experience in the field,
- professional activity,
- previous participation in other European courses.

Public area of the platform will be accessible with the overall training Programmes (eLearning and F2F)

Participants will be invited to indicate the weekly training modules they would like to attend.



! Please, take into consideration that some weekly training modules will be considered as preparatory to access the F2F workshops. Further information will follow in due course.

Forthcoming appointments for CAs (2/2)



Within the end of Sept. 2023:



List from CAs and application forms filled in by participants.



Within Oct. 2023:

Participants Registration to the platform



Weekly online trainings will start in **December 2023** and end in early **March 2024**

30 to 60 participants for each weekly training module



3 workshops of 3 days in Rome:

- Preparation Process Authorisation - **May 2024**
- Inspection - **June 2024**
- Vigilance - **July 2024**

30 to 50 participants for each workshop

Overall Training Contents

Online

1. EU legal provisions;
2. Certification/authorisation system;
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

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.

Thank you!

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