Funded by the European Union

SIGHTSoHO

strengthening overSIGHT through training and networking on Substances of Human Origin (SoHO)

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Introduction

Background

European Impact assessment

Purpose: to provide a comprehensive evaluation of the EU legislation on BTC and implementing tools

Among others, the need for training programmes was raised in the Consultation

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 srl**

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Tender Objectives

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

- reinforce **the skills of NCAs staff** involved in the above mentioned activities
- facilitate a **harmonized interpretation of the EU legislative framework**
- promote **common practices** for oversight activities
- facilitate **exchanges and networking among NCAs staff**, and foster for possible **collaborations** among them (for joint inspections, peer audits),
- promote **trust between EU NCAs** in the SoHO field

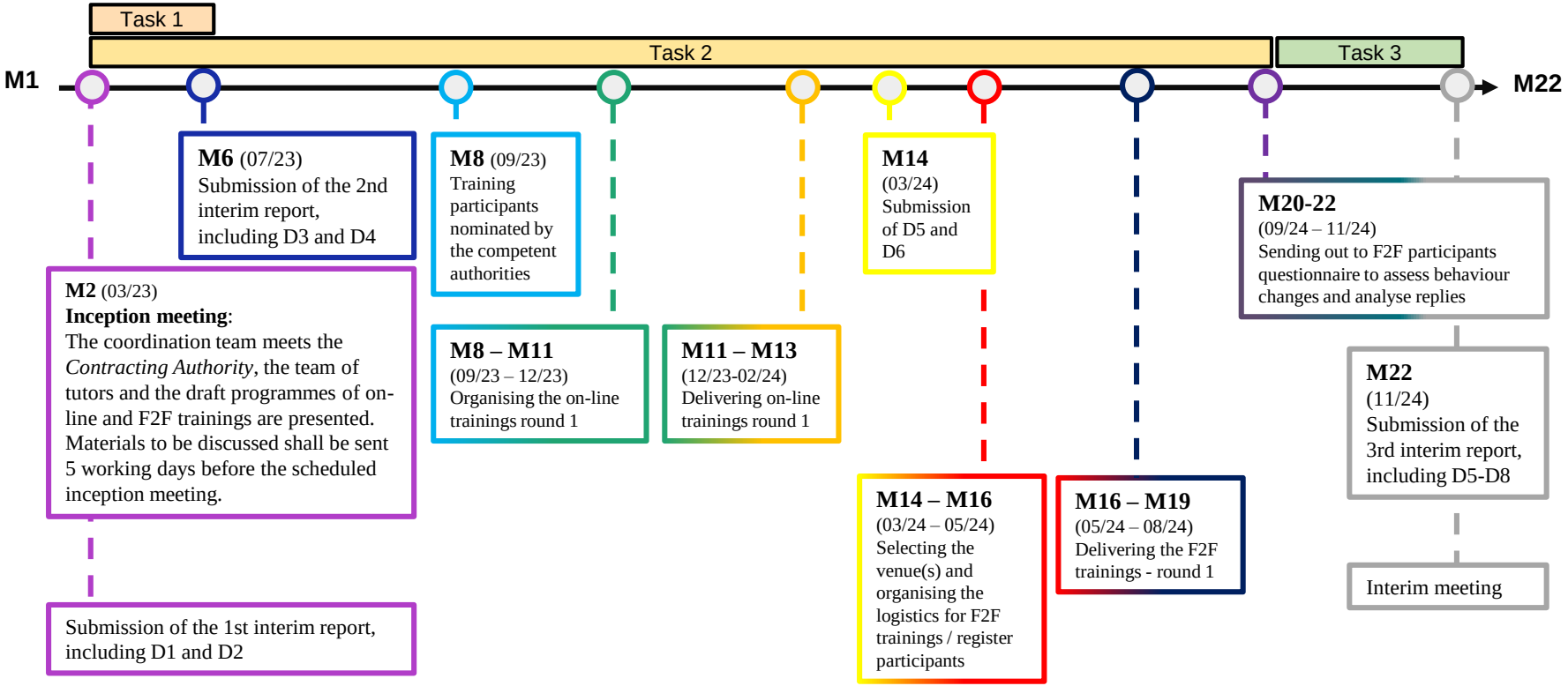
SIGHTSoHO

Scope:
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.

Timeline for the overall training service

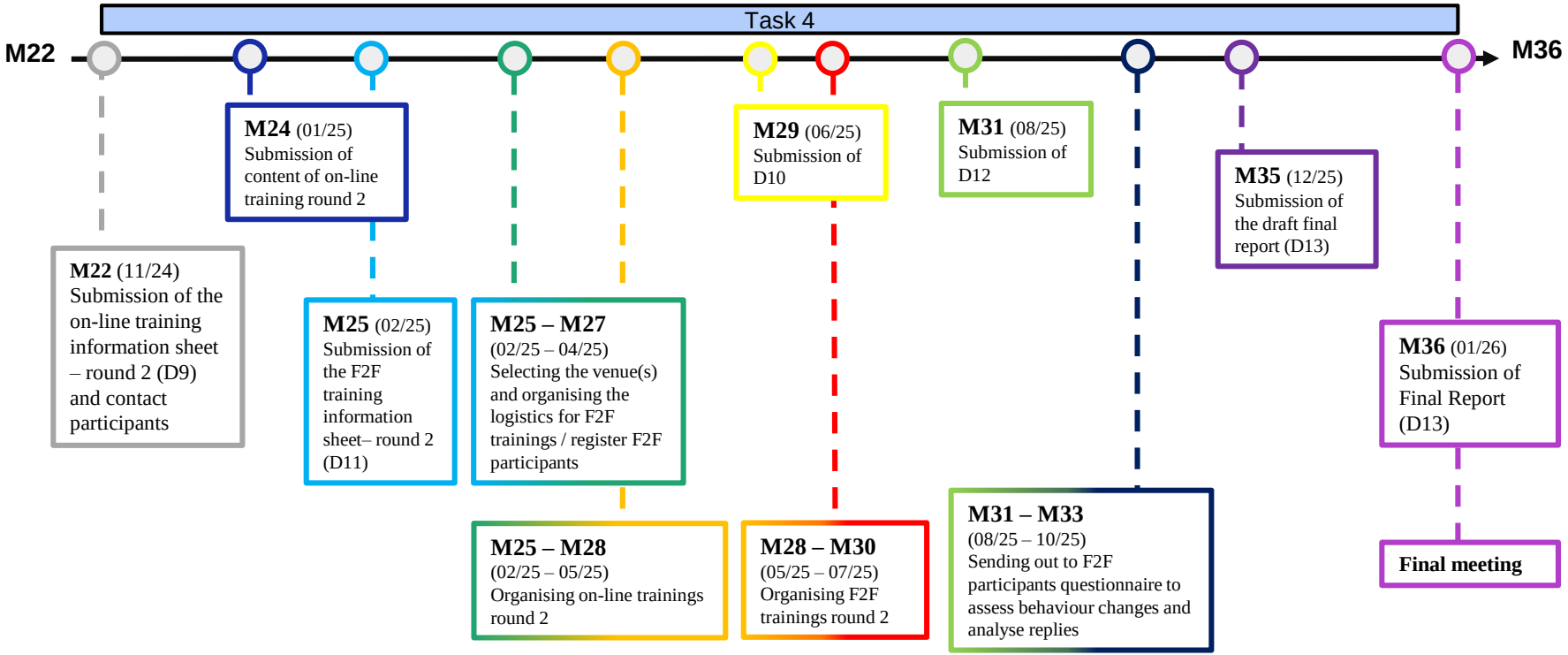
Round 1

M1-M22: 01/02/2023 to 30/11/2024



Round 2

M22-M36: 01/11/2024 to 31/01/2026



Round 1 training course information

Online training

Online

1. EU legal provisions;
2. Quality management systems;
3. Quality risk assessment;
4. Certification/authorisation system;
5. Single Coding of tissues and cells;
6. SoHO vigilance;
7. Imports and exports;
8. Stock and critical supplies;
9. Inspection report as well as post-inspection activities;
10. Risk for inspectorates;
11. Biovigilance;
12. Serious Adverse Outcomes/Rapid Alerts;
13. Harmonising data collection;
14. BTC preparation processes authorisation.

Within July 2023: Announcement sent to CAs, including application form and launch of the platform

30 to 60 participants for each module

Within Sept. 2023:
List from CAs and application forms filled in by participants

Within Oct. 2023:
Participants Registration to the platform

Online training courses will start in December 2023 and end in early March 2024

Use se of blended learning methods with synchronous and asynchronous activities

F2F training

F2F

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

30 to 50 participants for each workshop

3 workshops of 3 days in Rome:

1 Preparation Process Authorisation (May 2024)

1 Inspection (June 2024)

1 Vigilance (July 2024)

Many thanks for your kind attention!