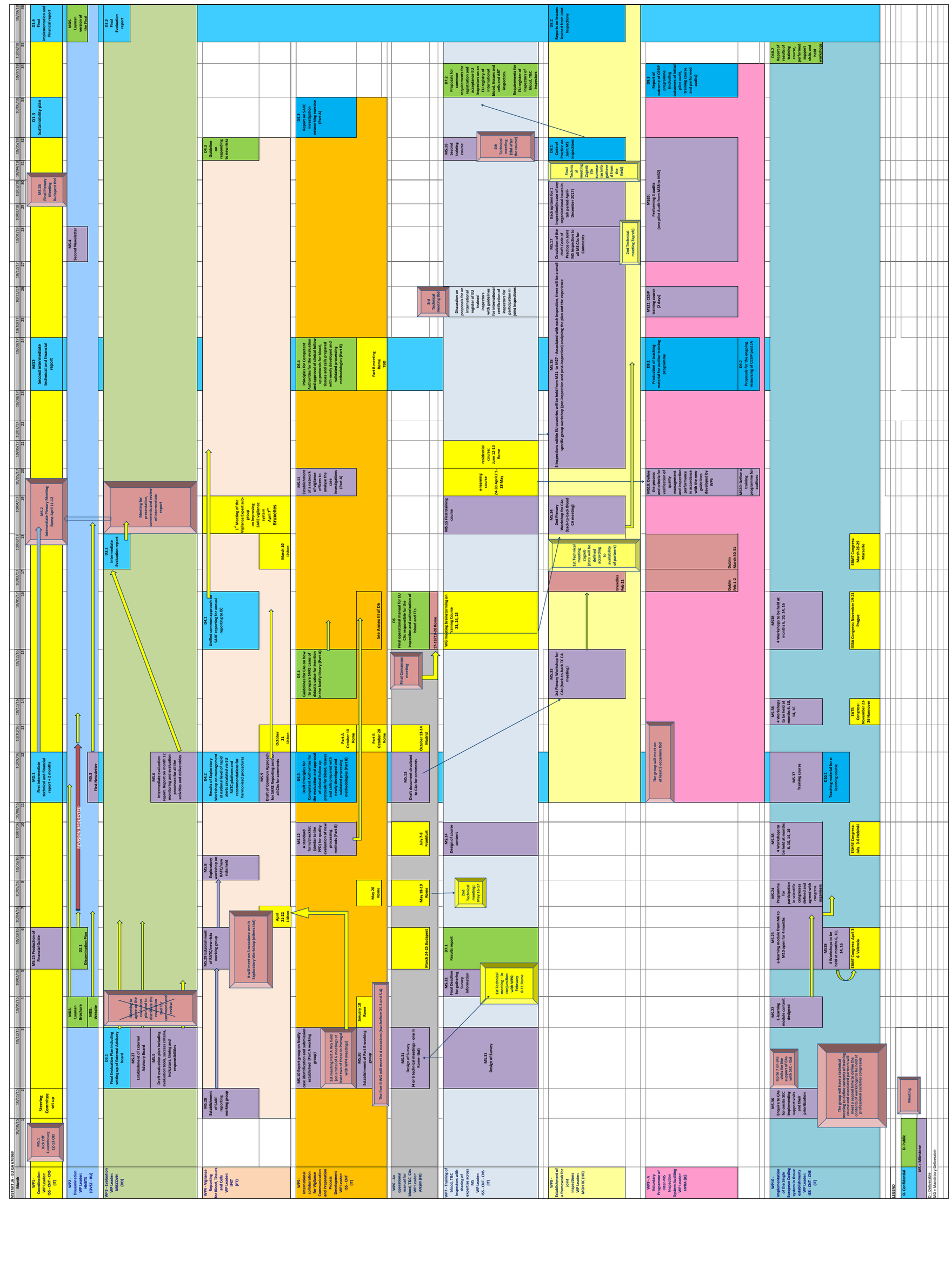
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WP1 - Coordination
WP Leader: ISS - CNT - CNS (IT)
MS:1 Kick Off Luxembourg 13-13 Oct
Steering Committee set up
MS:2 Intermediate Plenary Meeting Rome April 11-12
MS:26 Final Plenary Meeting Budapest tbd
WP2 - Dissemination
WP Leader: NBTC (DYOSC - SAS)
MS:3 Layman Brochure
MS:4 Second Newsletter
MS5: Website
MS6: Layman version of the Final
WP3 - Evaluation
WP Leader: NRSCOVH (RO)
D3.1 Final Evaluation Plan including setting up of External Advisory Board
MS:27 Establishment of External Advisory Board
MS:1 Draft evaluation plan including evaluation tools, success criteria, indicators, timing and responsibilities
Meeting for discussion, comments and review of intermediate report
D3.2 Intermediate Evaluation report
Reporting to teams of the evaluation activities to determine the evaluation plan by external and internal review
D3.3 Final Evaluation report
WP4 - Vigilance Reporting for Blood, Tissues and Cells
WP Leader: IPST (PT)
MS:28 Establishment of SARE reporting working group
1st Meeting of the Vigilance Expert sub-group on improving SARE/SAE reporting system April 7th BRUXELLES
March 10 Lisbon
D4.3 Guideline on reporting to new risks
MS:29 Establishment of RATC/new risks working group
It will meet on 3 occasions: one is Exploratory Workshop (others tbd)
MS:8 Exploratory Workshop on RATC/new risks held
April 21-22 Lisbon
May 20 Rome
WP5 - Enhanced collaboration for Vigilance Competent Authorities and Process Development
WP Leader: ISS - CNT (IT)
MS:10 Expert group on Notify Vigilance Competent Authorities established (Part A working group)
1st meeting Part A WG held (on a total of 6 meetings at least 2 of them physical with WP4 meetings)
MS:30 Establishment of Part B working group
January 18 Rome
The Part B WG will meet in 4 occasions (two before D5.3 and 5.4)
D5.2 Report on EU-Joint investigation networking exercise (Part A)
D5.4 Principles for competent Authorities for the evaluation and approval of clinical follow-up and analytical studies on tissues and cells proposed with newly developed and validated processing methodologies (Part B)
Part B meeting Rome TBD
MS:11 Establishment of a network of vigilance officers to analyse the case investigations (Part A)
D5 Guidelines for the evaluation and approval of clinical follow-up and analytical studies on tissues and cells proposed with newly developed and validated processing methodologies (Part B)
WP6 - An operational manual for blood, T&C inspections
WP Leader: ANSM (FR)
MS:31 Design of Survey (4 or 6 technical meetings - one in Rome- tbd)
MS:31 Design of Survey
MS:32 Final Deadline for gathering Survey information
1st Technical meeting Rome (date will be defined according to availability of partners)
D7.1 Results report
Haren 24-25 Budapest
May 18-19 Rome
2nd Technical meeting: May 16-17
July 7-8 Frankfurt
MS:14 Design of course content
WP7 - Training of blood, T&C inspectors with a view of expertise across MS
WP Leader: ISS - CNT - CNS (IT)
MS:15 First training course
e-learning course 24-30 April / 1-26 May
residential courses: June 2-13 Rome
3rd Technical meeting (tbd)
Discussion on proposals for an international register of EU accredited inspectors with guidelines for assessment and certification of inspectors for participation in joint inspections
MS:16 Second training course
4th Technical meeting (tbd after this course)
D7.2 Proposals for common requirements for registration and acceptance EU inspectors and an EU registry of international blood establishment and cells and ABT inspectors.
Requirements for EU register of inspectors of blood, T&C inspectors
WP8 - Establishment of a framework for joint inspections
WP Leader: MoH - AC (HR)
MS:18 5 inspections within EU countries will be held from M21 to M27.- Associated with each inspection, there will be a small specific group workshop (pre-inspection and post-inspection) analysing the pain and the experience
1st Technical meeting Zagreb (date will be defined according to availability of partners)
2nd Technical meeting Zagreb)
MS:17 Circulation of the draft Code of Practice on Joint MS Inspection to all MS CAs for Comments
Back up time for 1 inspection(in case of any unavailability due to an ish period April-December 2017)
Final Technical + 1 meeting Zagreb (by a summarize info collected from the visits)
D8.1 Code of Practice on Joint MS inspections
D9.2 Proposals for the ongoing resourcing of CESP post JA
WP9 - A Voluntary Programme of Inter-MS Inspection Sharing
WP Leader: HPRA (IE)
MS35: Define the process and criteria for verification of quality management and inspection performance for CESP trainees with the new guidelines developed by WP6
MS36: Define a training programme for auditors
D9.1 Production of teaching material for CESP training programme
MS321 CESP training course (1-6 July)
Performing 3 audits (one pilot-Audit from M23 to M32)
D9.3 Report of outcomes of CESP programme (including recommendations of pilot audit, training course and joint mutual audits)
Dublin Feb 1-2
Dublin March 30-31
Brussels Feb 21
WP10 - Implementation of the Single Electronic Data system in tissue establishments
WP Leader: ISS - CNT - CNS (IT)
MS:35 Enquire to CAs for onsite SSC Reference visits support visits and their prioritization
Up to 7 on site Reference visits in support of CAs with SSC - tbd
The group will have a technical meeting to define contents of training programme and then it will meet 4 second time to define the programme of workshops at professional societies congresses
MS:22 E-learning module content designed
MS:23 e-learning module from M6 to M19 open for 4 months
MS38 4 Workshops to be held at months 6, 10, 14, 16
EBMT Congress: April 3 6 Valencia
MS:24 Programme for participation in scientific congresses of activities defined with congress organisers
ESHRE Congress: July 5-8 Helsinki
MS:38 4 Workshops to be held at months 6, 10, 14, 16
MS:37 Training course
D10.1 Teaching material for e-learning course
MS:39 4 Workshops to be held at months 6, 10, 14, 16
EATIS Congress: November 22-26 Hannover
MS38 4 Workshops to be held at months 6, 10, 14, 16
EBBA Congress: November 19-21 Prague
EBMT Congress: March 26-29 Marseille
The group will meet on at least 5 occasions tbd
WG meeting brainstorming on Training Course 23, 24, 25
MS:33 1st Plenary Workshop for CAs (in July's TCCA meeting)
D6 Final operational manual for EU CAs responsible for the inspection/evaluation of blood and TEs
Final Consensus meeting
13?-15?/19-20 Rome
October 13-14 Madrid
D5.1 Guidelines for EU CAs on how to prepare SARE cases of didactic value for insertion in the Notify library (Part A)
Part A October 10 Rome
Part B October 28 Rome
October 21 Lisbon
D4.1 Unified common approach for SARE reporting to EC
D5.3 Draft Principles for Competent Authorities for the evaluation and approval of clinical follow-up and analytical protocols for blood, tissues and cells prepared with newly developed and validated processing methodologies (Part B)
MS:12 A standard form/checklist (similar to the one used in the evaluation of new processing methods (Part B)
MS:13 Draft document circulated to CAs for comments
D4.2 Results of Exploratory Workshop on management of RATC/new risks and alerts circulated via EU RATC platform and recommendations for harmonised provisions
MS:9 Draft of Common Approach for SARE Reporting sent to all CAs for comments
MS:4 Intermediate evaluation report. Report on month 12 monitoring and evaluation activities and deliverables
MS:25 Production of Financial Docket
D2.1 Dissemination Plan
MS:1 First Consolidate technical and financial report + 2 months
D1.3 Sustainability plan
D1.4 Implementation and Financial report
M12 - Evaluation
M24 - Evaluation
M36 - Evaluation
LEGEND
D: Confidential
D: Public
MS = Milestone
D = Deliverable
M3 = Mandatory Deliverable
Meeting