

Workshop 3 - BIOVIGILANCE AND HEMOVIGILANCE

3, 4, 5 July 2024

Tutors and External experts involved:

A. P. Barreiros, R. Barrio, S. Pupella, F. Teskrat, U. La Rocca, J. Kurz, S. Lucas-Samuel (VES - Vigilance Expert Sub-group), A. Navarro and E. Petrisli (Notify experts), DG SANTE

Learning objectives:

- To know the EU common approach on the vigilance management and reporting according to the different SoHO fields and organs;
- To share the EU classification of SARE and to exchange experiences on the follow-up activities;
- To know how to organ vigilance interacts with SoHO vigilance in order to downstream from the recipient to the donation organisation.

Agenda

Day 0. Tuesday 02/07/2024

Time	Session	Title
14:00 - 17:00	Briefing	Briefing session for Facilitators

Day 1. Wednesday 3/07/2024

Time	Session	Title	
8:30 - 9:00		Registration	
9:00 - 9:15		Welcome message	(Training Coordinator - S. Pupella, VES - S. Lucas-Samuel)
9:15 - 9:45		Brief Introduction (overview of related eLearning modules contents outcomes and take-home messages) and Workshop 3 expectations and scope	A.P. Barreiros
9:45 - 11:15	Topic 1	Ongoing EU Legal Provisions towards the new forthcoming Regulation	
9:45 - 10:15		Frontal lecture - (CAs and establishments obligations according to the new regulation)	DG SANTE
10:15 - 10:45		Vigilance experts sub-group: role and tasks also in view of the forthcoming Regulation	S. Lucas-Samuel
10:45 - 11:00		Plenary discussion	
11:00 - 11:15		Coffee break	



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11:15 - 15:15	Topic 2	Biovigilance and interactions between SoHO fields and organs	
11:15 - 11:40	Exercise 1	Brief intro with presentation of the cases study	A. P. Barreiros
11:40 - 13:00		Working groups (3) - 1 Case study on Biovigilance and interactions between SoHO fields and organs (root cause analysis)	A. P. Barreiros, R. Barrio, S. Pupella, U. La Rocca, J. Kurz Observers: S. Lucas-Samuel, A. Navarro and E. Petrisli
13:00 - 14:00		Lunch break	
14:00 - 15:15		Working group rapporteurs presentation, plenary discussion and take-home messages	A. P. Barreiros, J. Kurz
15:15 - 16:45	Topic 3	Organ donor selection and allocation criteria	
15:15 - 15:45		Lecture on process donation and allocation with focus on donor selection criteria and derogations	A. P. Barreiros
15:45 - 16:00		Coffee Break	
16:00- 16:30		Plenary discussion and take-home messages	A.P. Barreiros, S. Lucas-Samuel
16:30 - 16:45		Recap of the day and closing remarks	J. Kurz
19:30		Social dinner at Gusto restaurant Piazza di Sant'Apollinare, 41, 00186 Rome	

Day 2. Thursday 04/07/2024

Time	Session	Title	
8:30 - 9:00		Registration	
9:00 - 12:00	Topic 4	Investigations, evaluation and SAR/E classifications	
9:00 - 9:30		Brief overview of Notify Library tool contents given in the dedicated eLearning module and brief intro to future development	A. Navarro and E. Petrisli
9:30 - 10:00	Exercise 2	Presentation of biovigilance cases study (blood, T&C, MAR, Organs)	A. Navarro and E. Petrisli
10:00 - 11:00		Questions to the audience with discussion	A. P. Barreiros, S. Pupella, R. Barrio, U. La Rocca, J. Kurz



			Observers: S. Lucas-Samuel, A. Navarro and E. Petrisli
11:00 - 11:15		Coffee Break	
11:15 - 16:30	Topic 5	Serious adverse events and reactions reporting	
11:15 - 11:45		Brief Presentation on CA's follow-up actions in response to critical vigilance notifications	S. Lucas-Samuel
11:45 - 12:00		Q&A and plenary discussion	
12:00 - 12:30	Exercise 3	Brief intro and case study presentation on Recall, quarantine, collection of samples for analysis, of products	J. Kurz - F. Teskrat
12:30 - 13:30		Lunch break	
13:00 - 15:00		Working groups (3) - 1 case study	A. P. Barreiros, S. Pupella, R. Barrio, U. La Rocca, J. Kurz Observers: S. Lucas-Samuel, A. Navarro and E. Petrisli
15:00 - 15:15		Coffee break	
15:15 - 16:15		Working group rapporteurs presentation, plenary discussion and take-home messages	J. Kurz
16:15 - 16:30		Recap of the day and closing remarks	J. Kurz

Day 3. Friday 05/07/2024

Time	Session	Title	
08:30 - 09:00		Registration	
09:00 - 10:00		Final Examination	
10:00 - 12:30	Topic 6	Vigilance data reporting, analysis and follow-up actions	
10:00 - 10:30		Lecture on RAB/RATC platforms (The use of the Rapid Alert System in the case of cross-border implications)	S. Lucas-Samuel
10:30 - 10:45	Exercise 4	Brief intro and case study presentation on RATC	F. Teskrat, S. Pupella
10:45 - 10:11		Coffee break	
11:00 - 12:00		Working groups (3) - 1 case study	A. P. Barreiros, S. Pupella, R. Barrio, U. La Rocca, J. Kurz



			Observers: S. Lucas-Samuel, A. Navarro and E. Petrisli
12:00 - 12:45		Working group rapporteurs presentation, plenary discussion and take-home messages	S. Pupella
12:45 - 13:45		Lunch break	
13:45 - 15:00	Topic 7	Biovigilance in the MAR sector	
13:45 - 14:15		Lecture on protection of offspring from medically assisted reproduction and follow-up procedures	R. Barrio, A. Navarro, E. Petrisli
14:15 - 14:45		Q&A and plenary discussion	
14:45 - 15:00		Recap of the day and closing remarks	



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