

1st European Training course on Biovigilance for Tissues and Cells

Programme

16 to 23 September 2021

Module 1:

Introduction to general concepts in biovigilance

Pre-recorded lectures:

Introduction to the course.

Mar Lomero

Introduction, history and EU activities related to Biovigilance.

Jacinto Sánchez Ibáñez

Why biovigilance is important.

Sinéad Masterson

EU SARE exercise (Why it exists, importance, dissemination of data).

Jo Wiersum

Other biovigilance systems: organs, blood and devices.

Aurora Navarro

EU Survey about biovigilance systems at European level.

Donna Harkin

The Notify project.

Aurora Navarro

Live session Thursday 23 September 2021 (14-16h)

- Practical workshop.
- Q&A.

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23 to 30 September 2021

Module 2:

Serious Adverse Reactions (SAR)

Pre-recorded lectures:

General session: How to perform the assessment of severity, imputability or causes, probability of recurrence, consequences and impact, and how donor's reactions are assessed.

Ieva Bekere

Assessment of SAR in non-reproductive and SAR in HPC (including donors).

Jacinto Sánchez Ibáñez

Assessment of SAR in reproductive tissue (including donors).

Edith Coonen

Assessment of SAR in reproductive tissue with special emphasis on genetic disease in children conceived with non-partner gametes.

Anne-Cathrine Bollerup

Live session Thursday 30 September 2021 (14-16h)

- Practical workshop.
- How to assess SAR in real life.
- Q&A.

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30 September to 7 October 2021

Module 3:

Serious Adverse Events (SAE)

Pre-recorded lectures:

General session: SAE Assessment.

Ieva Bekere

SAE assessment in non-reproductive and HPC.

Jacinto Sánchez Ibáñez

SAE assessment in reproductive tissue.

Edith Coonen

SAE assessment in reproductive tissue with special emphasis on genetic disease in donors.

Anne-Cathrine Bollerup

Live session Thursday 7 October 2021 (14-16h)

- Practical workshop.
- How to assess SAE in real life.
- Q&A.

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7 to 15 October 2021

Module 4: European Biovigilance Network

Pre-recorded lectures:

Denominators.

Jacinto Sánchez Ibáñez

Rapid alerts (importance and benefits) and communication of risks.

Sinéad Masterson

Rapid alerts of genetic disease in gamete donors and children conceived with donors.

Anne-Cathrine Bollerup

EU Vigilance Expert Subgroup, what is their role?

Donna Harkin

Harmonising activity data collection exercises in the field of tissues and cells in Europe.

Jaime Marco

Benefit of reporting "learning cases" and the importance of getting benefit of sharing knowledge.

Aurora Navarro

Biovigilance in the EU. Current and future perspective.

Deirdre Fehily

Live session Thursday 14 October 2021 (14-16h)

- Analysis of real cases proposed by the participants.
- General discussion: additional questions.
- Concluding remarks and take home messages.