



Harmonize



Biovigilance

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Aim of biovigilance

Identify, document and report SARE

- Serious adverse events (**SAE**) – related to the SoHO
- Serious adverse reactions (**SAR**) – related to the recipient

Identify patterns of adverse reactions over time

Case-by-case evaluation of high-risk scenarios

- Risk assessment and action to reduce future risk
- Expanded access



Definitions

Vigilance = a set of organised surveillance and reporting procedures relating to adverse reactions and adverse events

SoHO Regulation, 542

Adverse reaction (AE): any incident which could be reasonably associated with the quality or safety of SoHO, or their collection from a SoHO donor or human application to a SoHO recipient, that caused harm to a living SoHO donor, to a SoHO recipient or to offspring from medically assisted reproduction.

SoHO Regulation, 543

Serious adverse reaction (SAR): adverse reaction that results in death, life-threatening, disabling or incapacitating condition, including transmission of a pathogen or of a toxic substance that might cause such condition, transmission of a genetic disorder, hospitalisation or prolongation of hospitalisation, need for a major clinical intervention to prevent or reduce the effects of any of the results referred to in points (a) to (d), prolonged sub-optimal health of a SoHO donor following single or multiple SoHO donations.

SoHO Regulation, 543

Serious adverse event (SAE): adverse event that poses a risk of inappropriate SoHO distribution, a defect posing a risk to SoHO recipients or SoHO donors is detected in one SoHO entity that would have implications for other SoHO recipients or SoHO donors because of shared practices, services, supplies or critical equipment, loss of a quantity of SoHO that causes human applications to be postponed or cancelled, loss of highly matched SoHO or SoHO for autologous use, a mix-up of reproductive SoHO in such a way that an oocyte is fertilised with sperm from a person other than the intended person, or reproductive SoHO are applied to a SoHO recipient other than the intended SoHO recipient, loss of the traceability of SoHO.

SoHO Regulation, 543



Activity documentation (per year)

SoHO donor registration

Collection

Distribution

Import or export

Human application

Occurrence of SAE or SAR (SARE)



SARE analysis

Step 1: Assessment of the likelihood of occurrence/recurrence of the SARE

Step 2: Assessment of the impact/consequences of the SARE should it recur

Step 3: Application of the impact matrix.

Consider reporting (suggested cut-off score 8)

Consider preventive and corrective measures



SARE analysis

Likelihood of recurrence →	1 Rare	2 Unlikely	3 Possible	4 Likely	5 Certain/almost certain
Impact of recurrence ↓					
0 Insignificant	0	0	0	0	0
1 Minor	1	2	3	4	5
2 Moderate	2	4	6	8	10
3 Major	3	6	9	12	15
4 Catastrophic/extreme	4	8	12	16	20



Boards and conferences in CEFTA



ChatGPT 08AUG2025

Clinical safety board

Annual meeting: Review the past year's events

Ad hoc meeting: Case-by-case discussion

Expanded access (compassionate use)

Expanded access: protocol for evaluation and use

Clinical specialists (IBD conference)

Clinical conference

National video conference every other month

Discussion of difficult *C. difficile* cases

Gastroenterology, infectious diseases, microbiology, immunology



Vigilance in an FMT centre

Maintain vigilance system

- Activity documentation (Article 41)
- Traceability (Article 42)
- Reporting (Article 44)

Procedure for SoHO withdrawal

Procedure for SARE identification and analysis

Who identifies, reports, analyses ...



Case 1: *E. coli* sepsis after FMT

A 71-years old woman receives FMT for *C. difficile*.
The day after FMT, she is admitted with clinical sepsis.
Blood cultures are positive for *E. coli*.
After four days treatment: abscess in her psoas muscle.

What to do, in terms of vigilance?
Who does what?



Case 2: Encephalopathy after FMT

A 52-years old man with established liver cirrhosis and portal vein thrombosis receives FMT for recurrent *C. difficile*.

The morning after FMT, the home care nurse finds him unconcious, and he is admitted to hospital. Clinical diagnosis: Grade 4 HE.

What to do?



Summary

Biovigilance is an integral part of an FMT system

- Describe documentation practices
- Clinical safety board

Describe local and National reporting systems



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