famhp
federal agency for medicines and health products

# Biovigilance Annual Report 2023

## Key points

Biovigilance is the systematic monitoring (alerting, managing and preventing) of the risk (by serious adverse events and reactions) from the selection of the donor to the follow-up of the recipient in order to put collaboratively in place the necessary public health measures to make the application of different substances of human origin (tissues, cells, MAR) safer and more effective.

This report is a summary of all events and side effects related to the processing and application of human tissues and cells for the reporting period 2023 (January 1, 2023 to June 30, 2024).

The data are reported to the Biovigilance Entity of the FAMHP in 2023 by 45 Belgian tissue establishments and hospitals, of which 26 establishments for reproductive human body material (REPRO) and 19 establishments for non-reproductive human body material (NON REPRO).

## Abbreviations

| | |
|---|---|
| FAMHP | Federal Agency for Medicines and Health Products |
| HSCs | Hematopoietic stem cells |
| ESB | European Sperm Bank |
| HBM | Human Body Material |
| RA | Rapid alert |
| REPRO | From the reproductive system |
| NON REPRO | Not from the reproductive system |
| SAE | Serious adverse event |
| SAR | Serious adverse reaction |
| SAR donor | Serious adverse reaction for donor |
| OHSS | Ovarian hyperstimulation syndrome |

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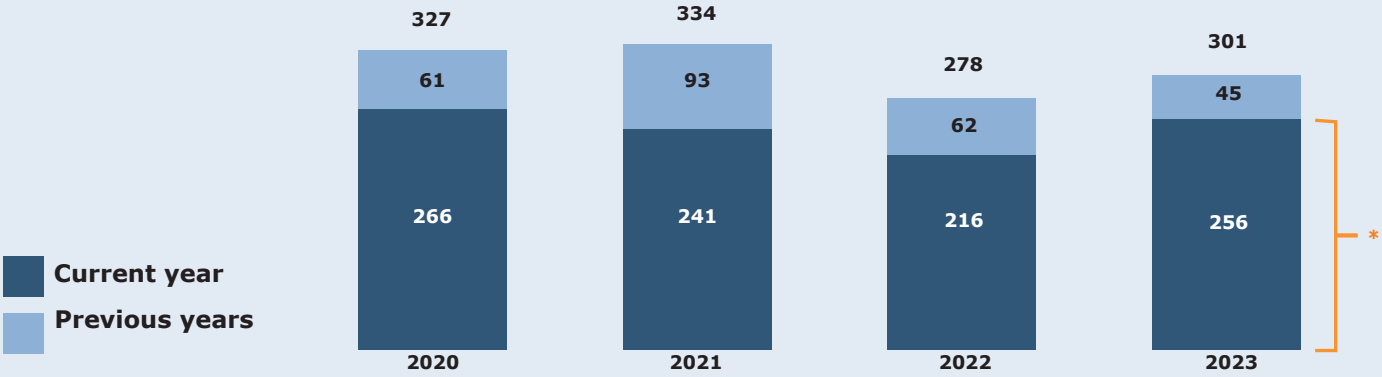
# General information

## Number of notifications




Number of notifications for the last four years including current year and previous years (occurrence from a previous year whose file was closed in the current year) notifications.

* Late notifications (2023 notifications received and closed until June 30, 2024) = 25.
Total for 2023: 256 + 25 = 281.

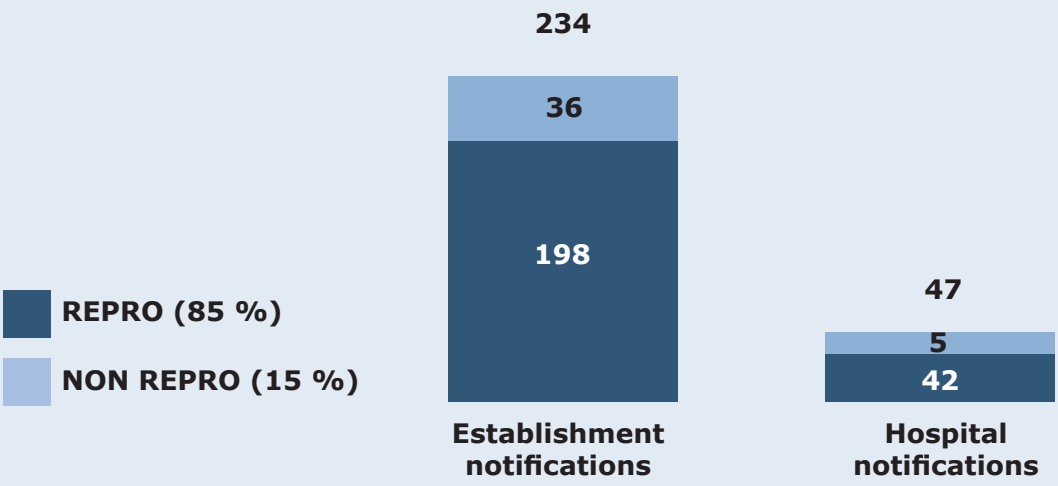
## Number of notifications by type of notifiers

45/107 tissue establishments
234/281 notifications = 83 %

8/103 hospitals
47/281 notifications = 17 %

There are twelve different types of HBM in Belgium. In 2023, notifications mainly concerned the reproductive system, followed by stem cells, the musculoskeletal system and the cardiovascular system.

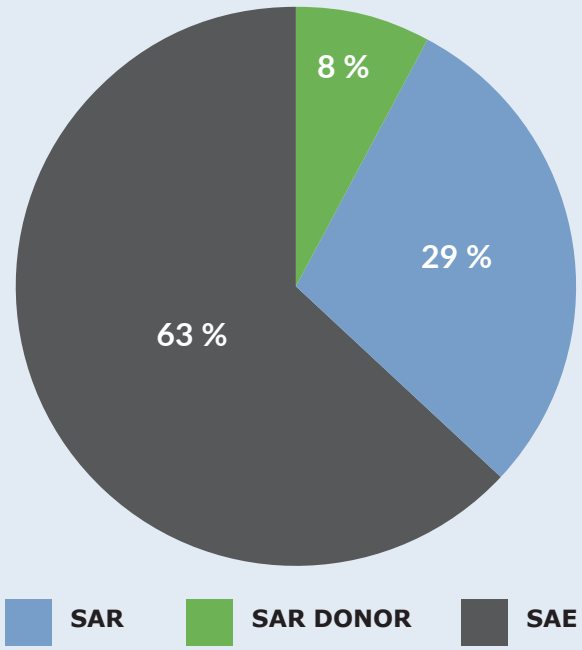
## Type of HBM




Number of notifications by tissue establishments and hospitals and by type of HBM (REPRO, NON REPRO).
In total, there are 85 % of REPRO notifications and 15 % of NON REPRO notifications.

## Classification of notifications received by type of occurrence (n = 281)

| | Received | |
|---|---|---|
| Occurrence | Number | % |
| SAR | 81/281 | 29 % |
| **SAE** | **176/281** | **63 %** |
| SAR DONOR | 24/281 | 8 % |
| **Total** | 281 | 100 % |




## Classification of notifications received by type of HBM (n = 281)

| | Received | |
|---|---|---|
| Occurrence | **REPRO** | NON REPRO |
| SAR | 27,4 % (77/281) | 1,4 % (4/281) |
| **SAE** | **50,2 % (141/281)** | **12,5 % (35/281)** |
| SAR DONOR | 7,8 % (22/281) | 0,7 % (2/281) |
| **Total** | **85,4 %** | 14,6 % |

# Evaluation

Reportable SARE are those "which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells".

Evaluation is performed by evaluators of biovigilance. It consists to analyse all investigation results received in the investigation form and to determine if a link exists between the occurrence and the quality and safety of tissues and cells. If this link exists, the occurrence will be classified into SAE, SAR or SAR donor.

## Classification of notifications after evaluation: REPRO (n = 240) and NON REPRO (n = 41)

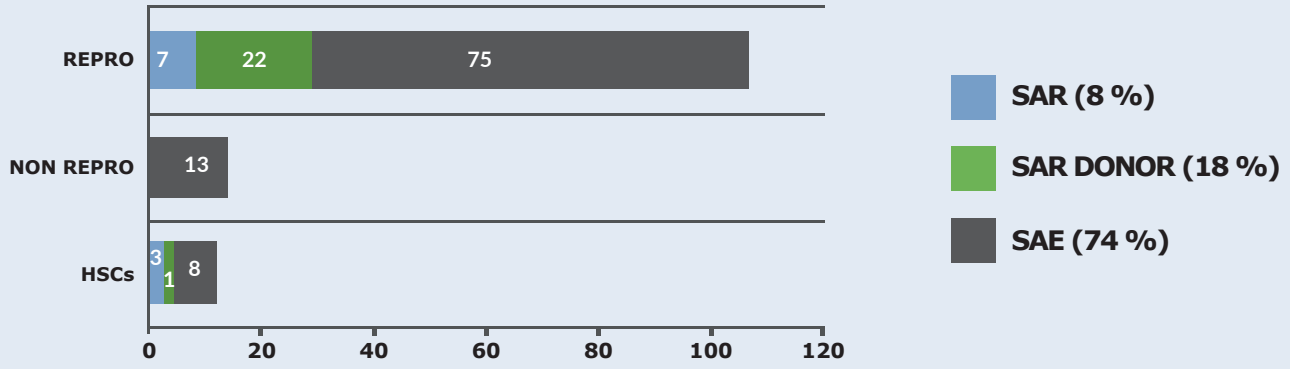
| | Evaluated | | | |
|---|---|---|---|---|
| | REPRO | | NON REPRO | |
| SAR | 7/240 | 2,9 % | 3/41 | 7,3 % |
| **SAE** | **75[1]/240** | **31,2 %** | **21/41** | **51,2 %** |
| SAR donor | 22/240 | 9,2 % | 1/41 | 2,45 % |
| No SAR | 40/240 | 16,7 % | 1/41 | 2,45 % |
| No SAE | 49/240 | 20,4 % | 13/41 | 31,7 % |
| No SAR donor | 0/240 | 0 % | 1/41 | 2,45 % |
| Open files | 47/240 | 19,6% | 1/41 | 2,45 % |
| **Total** | 240 | 100 % | 41 | 100 % |

**n = 129**

| Occurence | HBM type | Number | % |
|---|---|---|---|
| SAR | REPRO | 7 | 5,5% |
| | NON REPRO | 0 | 0 % |
| | HSCs | 3 | 2,5 % |
| **SAE** | **REPRO** | **75[1]** | **58 %** |
| | NON REPRO | 13 | 10 % |
| | HSCs | 8 | 6 % |
| SAR donor | REPRO | 22 | 17 % |
| | NON REPRO | 0 | 0 % |
| | HSCs | 1 | 1 % |
| **Total** | | 129 | 100 % |

Classification of notifications after evaluation: REPRO (n = 240) and NON REPRO (n = 41). SAE/SAR/SAR donor: when the investigation proves that it was a SAE/SAR/SAR donor. No SAE/no SAR/no SAR donor: when the investigation did not confirm the SAE/SAR/SAR donor. Open files: when the investigation form has not been received.

## Classification by type of occurrence and type of HBM (n = 129)




[1] With 31 SAEs due to Rapid Alert notifications + 21 SAEs due to Belgian SAR (not notified to EU).

# Serious adverse reactions (SAR) and serious adverse reactions for donor (SAR donor)

**Unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of human body material that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.**

## SAR REPRO

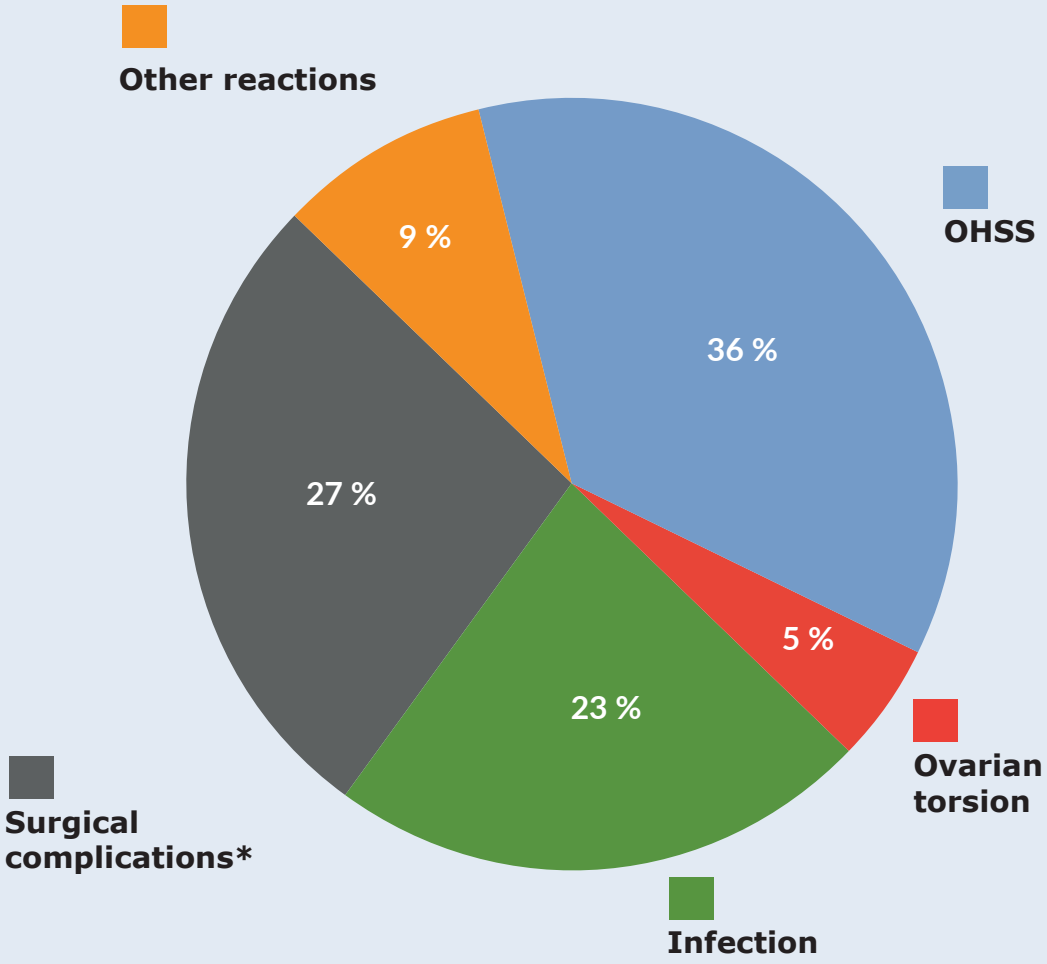
## Classification of SAR REPRO by HBM category and reaction type (n = 7)

| HBM category | Reaction type | Donor origin | RA | Number | % |
|---|---|---|---|---|---|
| Embryo (sperm donor + partner oocyte) | Transmitted genetic conditions | ESB | Yes | 1 | 29 % |
| | | | No | 1 | |
| Embryo (oocyte donor + sperm partner) | Transmitted genetic conditions | Belgian banks | No | 1 | 14 % |
| Sperm (donor) | Transmitted genetic conditions | Cryos | Yes | 1 | 43 % |
| | | ESB | Yes | 2 | |
| Other SAR | Embryo: ectopic pregnancy (requiring surgical intervention or hospitalization) | NA | NA | 1 | 14 % |
| **Total** | | | | 7 | 100 % |

# SAR donor

## Classification of SAR donor by HBM category and reaction type (n = 22)

| HBM category | Reaction type | Number | % |
|---|---|---|---|
| Oocyte general (1) + Oocyte partner (20) | OHSS | 8 | 36 % |
| | Ovarian torsion | 1 | 5 % |
| | Infection | 4 | 18 % |
| | Surgical complications* | 6 | 27 % |
| | Other reactions | 2 | 9 % |
| Testicular tissue | Infection | 1 | 5 % |
| **Total** | | 22 | 100 % |




* Discomfort, bleeding, haematomas and bladder puncture.

## Serious adverse events (SAE)

Any untoward occurrence associated :

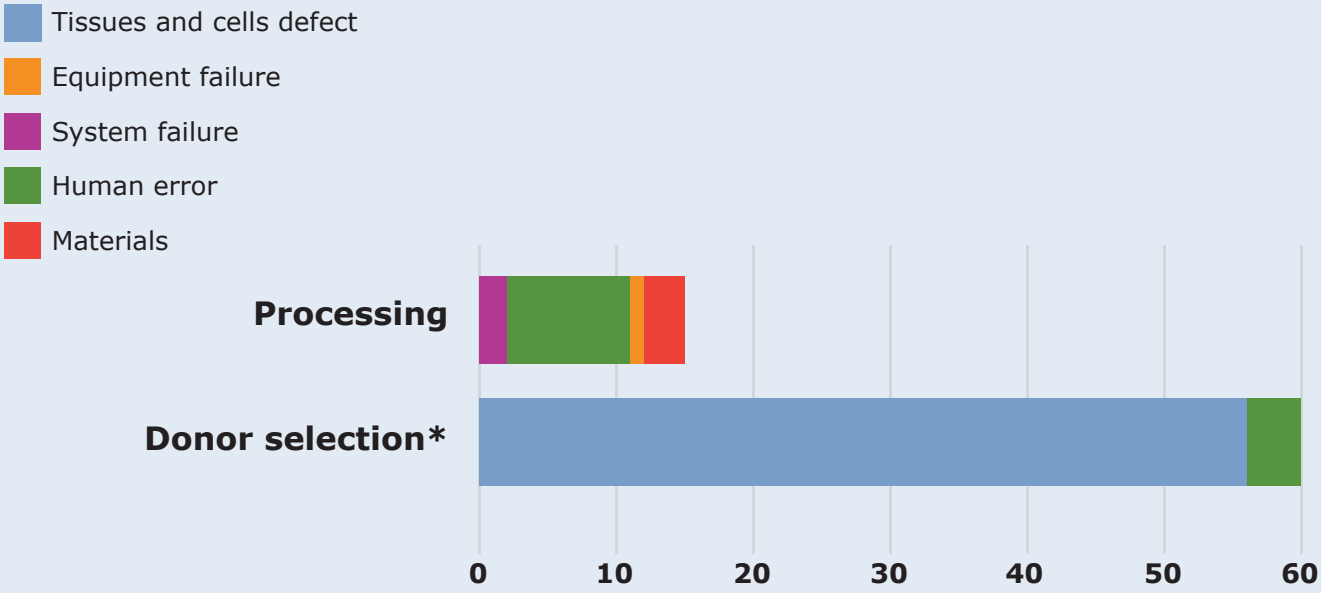
- either with the procurement, that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for the donor or which might result in, or prolong, hospitalisation or morbidity;
- or with the procurement, testing, processing, storage or distribution of human body material, that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for the patient or which might result in, or prolong, hospitalisation or morbidity.

## REPRO

### Classification of SAE REPRO by HBM category and subcategory (n = 75)

| HBM category | HBM subcategory | Number | % |
|---|---|---|---|
| Sperm | Donor | 54 | 79 % |
| | Partner | 5 | |
| Oocyte | Donor | 2 | 5 % |
| | Partner | 2 | |
| Embryo | General | 9 | 16 % |
| | Partner gametes | 2 | |
| | Oocyte donor + sperm partner | 1 | |
| **Total** | | 75 | 100 % |

### Classification of SAE REPRO by activity and category (n = 75)*

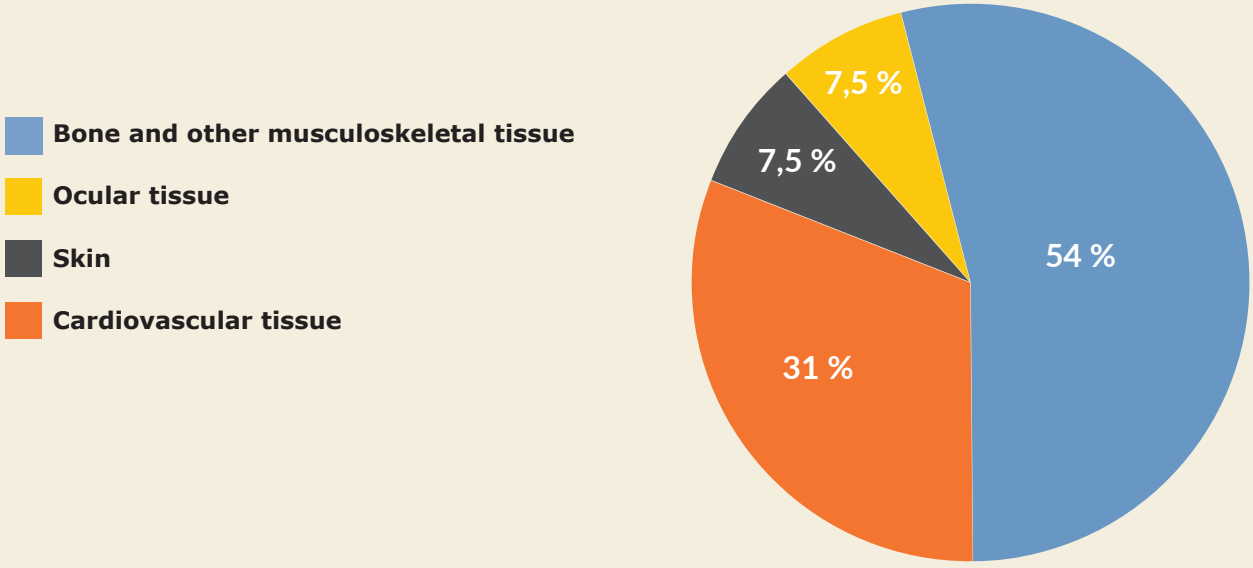



* With 31 SAEs due to Rapid Alert notifications + 21 SAEs due to Belgian SAR (not notified to EU).

# NON REPRO

## Classification of SAE NON REPRO by HBM category and subcategory (n = 13)

| HBM category | HBM subcategory | Number | % |
|---|---|---|---|
| Bone and other musculoskeletal tissue | Bones, tendons, ligaments | 7 | 54 % |
| Cardiovascular tissue | Heart valve, blood vessel | 4 | 31 % |
| Skin | | 1 | 7,5 % |
| Ocular tissue | Cornea | 1 | 7,5 % |
| **Total** | | 13 | 100 % |

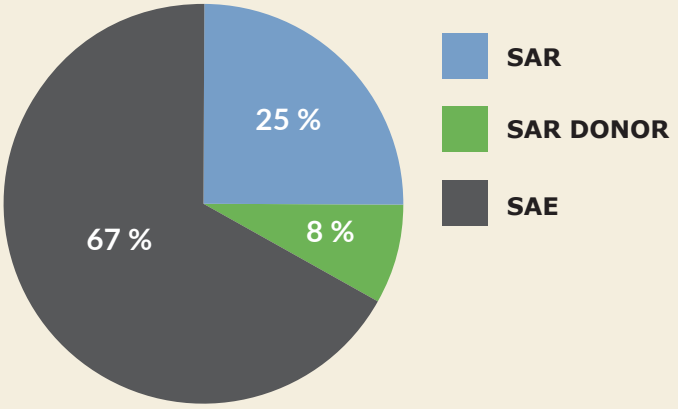



## Classification of SAE NON REPRO by activity and category (n = 13)

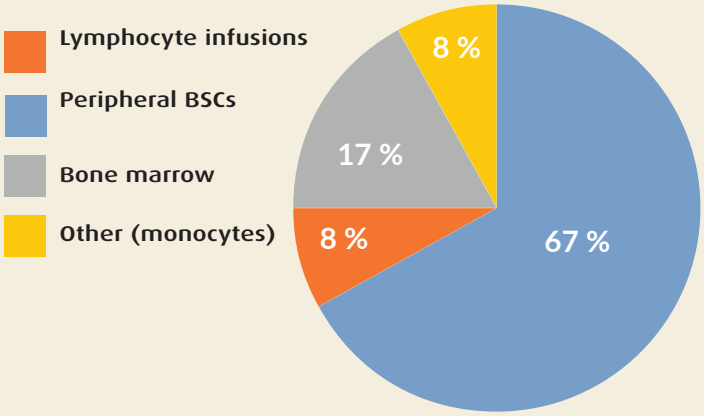
# Hematopoietic stem cells (HSCs) and cells for therapeutic purposes

Hematopoietic stem cells (HSCs) are multipotent primitive cells that can develop into all types of blood cells, including myeloid-lineage and lymphoid-lineage cells. HSCs can be found in several organs, such as peripheral blood, bone marrow, and umbilical cord blood.

## Classification by type of occurrence (n = 12)



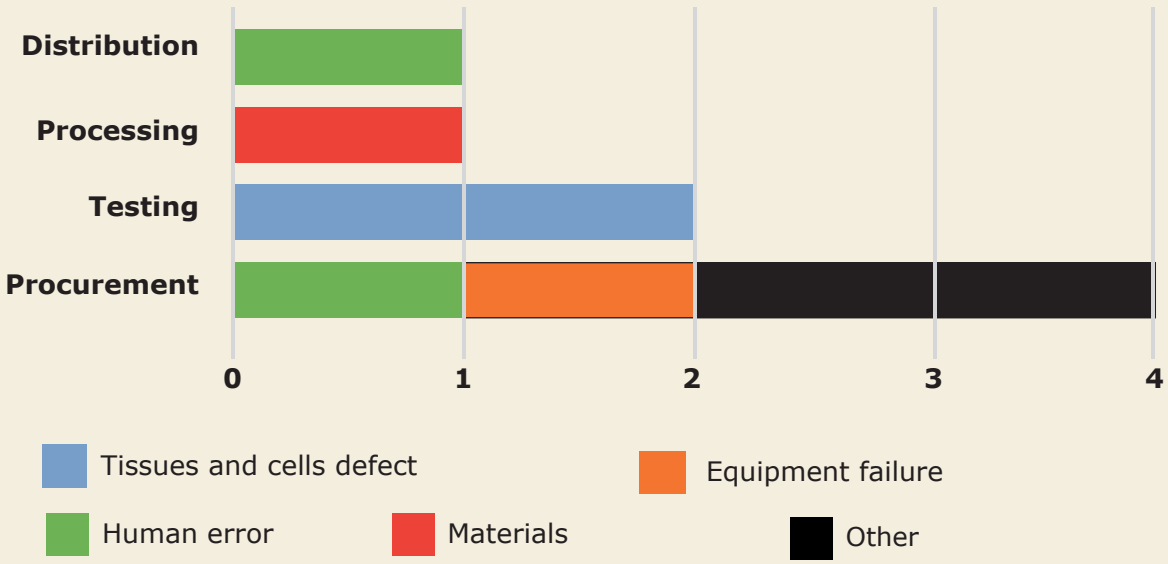

## Classification by cellular origin (n = 12)




## Classification of SAR and SAR donor by reaction type and cellular origin (n = 4)

| Occurrence | Reaction type | Cellular origin | Number | % |
|---|---|---|---|---|
| SAR | Immunological reactions | Peripheral BSCs | 2 | 50 % |
| | Transmissible malignant diseases | Peripheral BSCs | 1 | 25 % |
| SAR donor | Mechanical damage - due to apheresis or bone marrow harvesting | Monocytes | 1 | 25 % |
| **Total** | | | 4 | 100 % |

## Classification of SAE by activity and category (n=8)



# Conclusion

The FAMHP Biovigilance Entity works to raise awareness among all stakeholders about biovigilance with the purpose to improve the quality of reporting of events and serious adverse reactions. The aim is to make the use of various substances of human origin safer and more effective.

It is important for all the persons involved in an efficient biovigilance network to report incidents and serious adverse reactions as quickly as possible, providing a full and adequate analysis of the cause and circumstances.

Events and reactions are reported by healthcare professionals in two successive stages:

1. reporting with a dedicated notification form containing as much relevant information as possible, and information on the actions taken directly;
2. confirmation with a dedicated investigation form, including the results of a thorough investigation that confirms or excludes the link between the event/reaction and any quality or safety deficiencies which may impact on patients' quality of life. It also includes the corrective and preventive actions taken to minimise the probability of recurrence of serious situations that have already occurred.

Thanks to the relevance and quality of the information provided, the employees of the FAMHP Biovigilance Entity will be able to conduct a robust scientific assessment and ensure the most appropriate communication with regard to the situations notified/reported.

The reporting of events and serious adverse reactions to FAMHP benefits all: patients, professionals, tissue establishments and the health system.

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