

A national biovigilance system: What does 7 years of reporting SAR and SAE on tissues and cells in the Netherlands show?

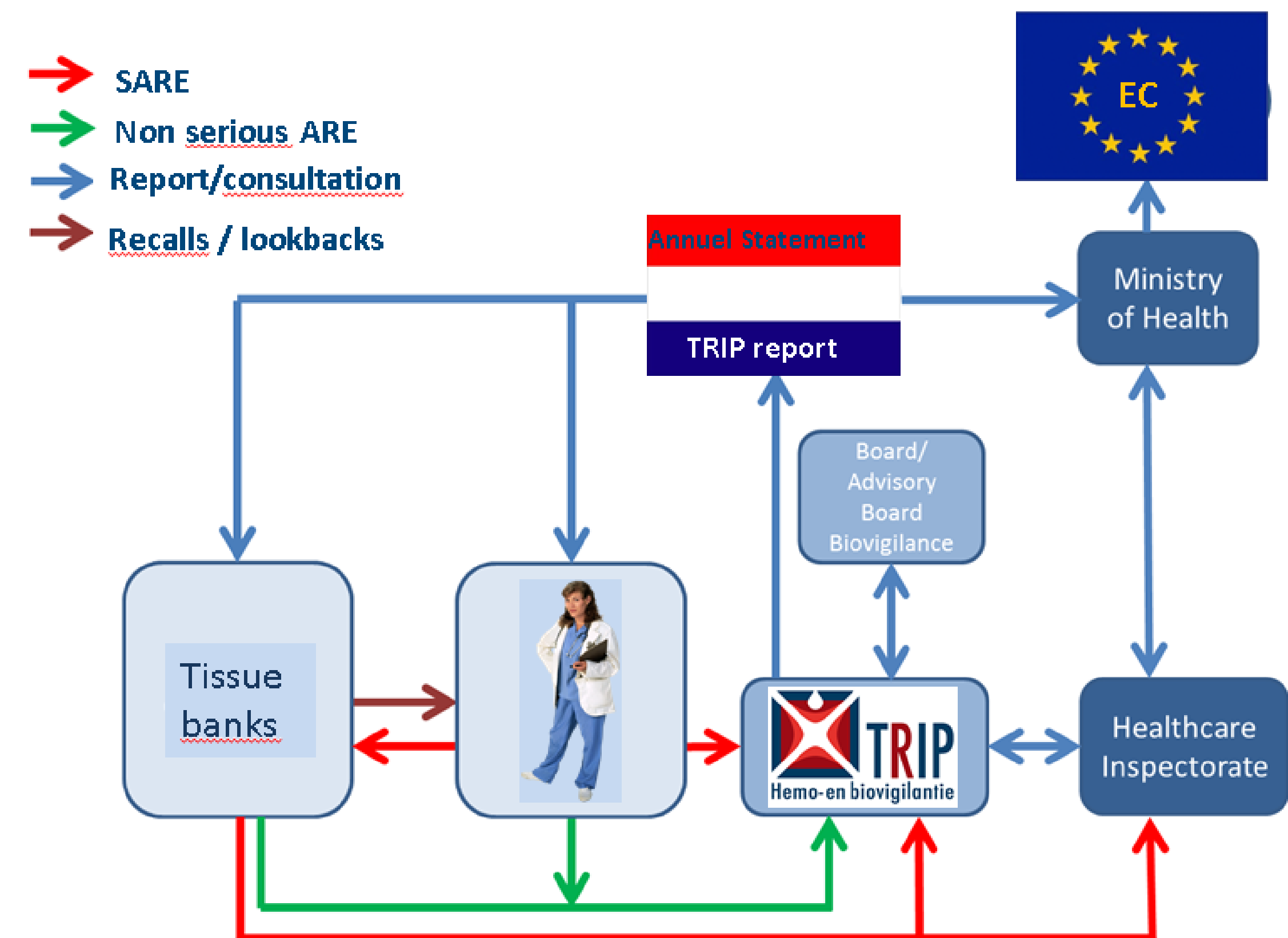


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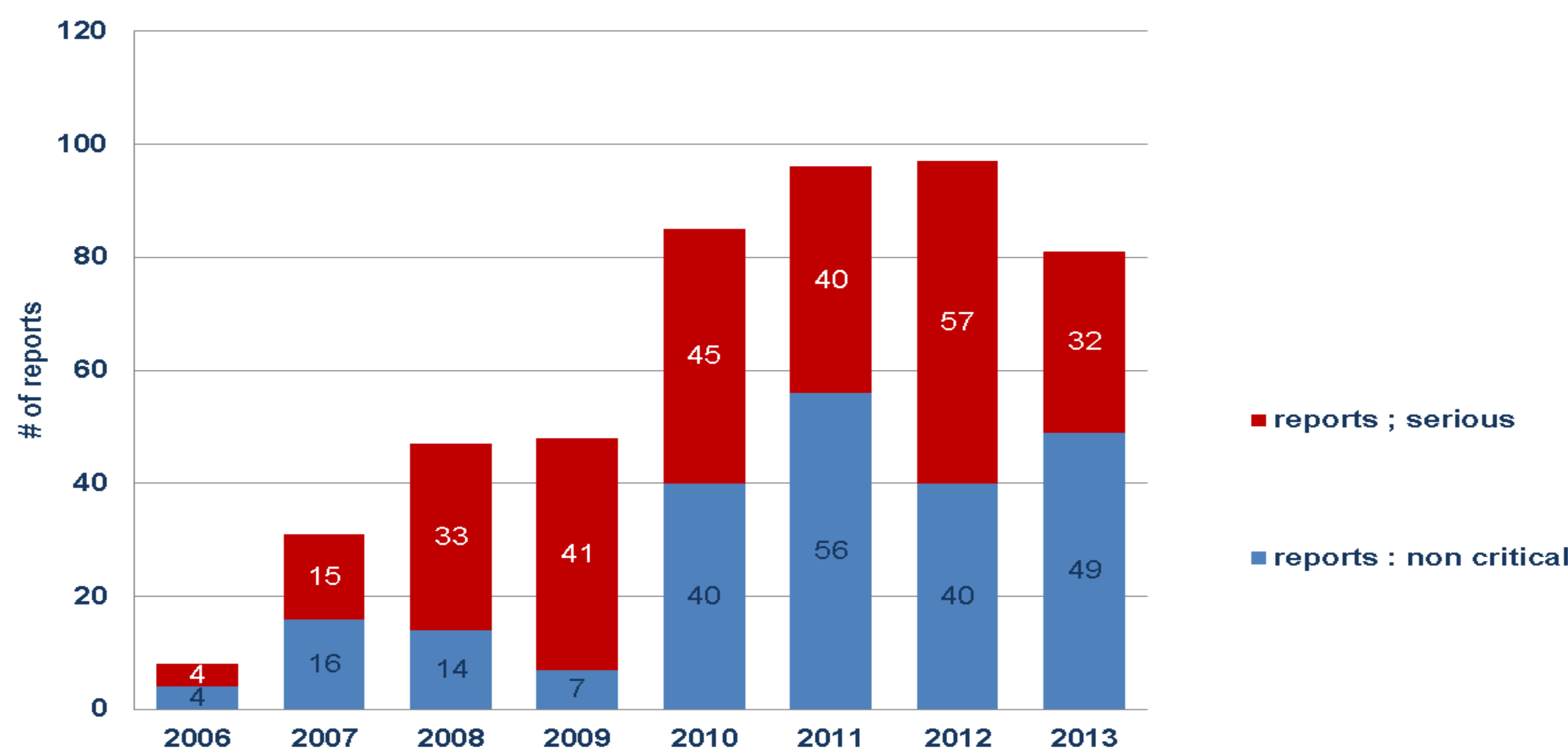
Introduction

- TRIP is a national foundation founded by hospitals and users of blood.
- EU Directive 2004/23: national system for biovigilance is mandatory.
- TRIP collecting hemovigilance data since 2002 in collaboration with network in hospitals and established a similar network of biovigilance offers in all Dutch hospitals.
- Tools: web based reporting system, definitions, close collaboration with the banks, advisory committee with experts.

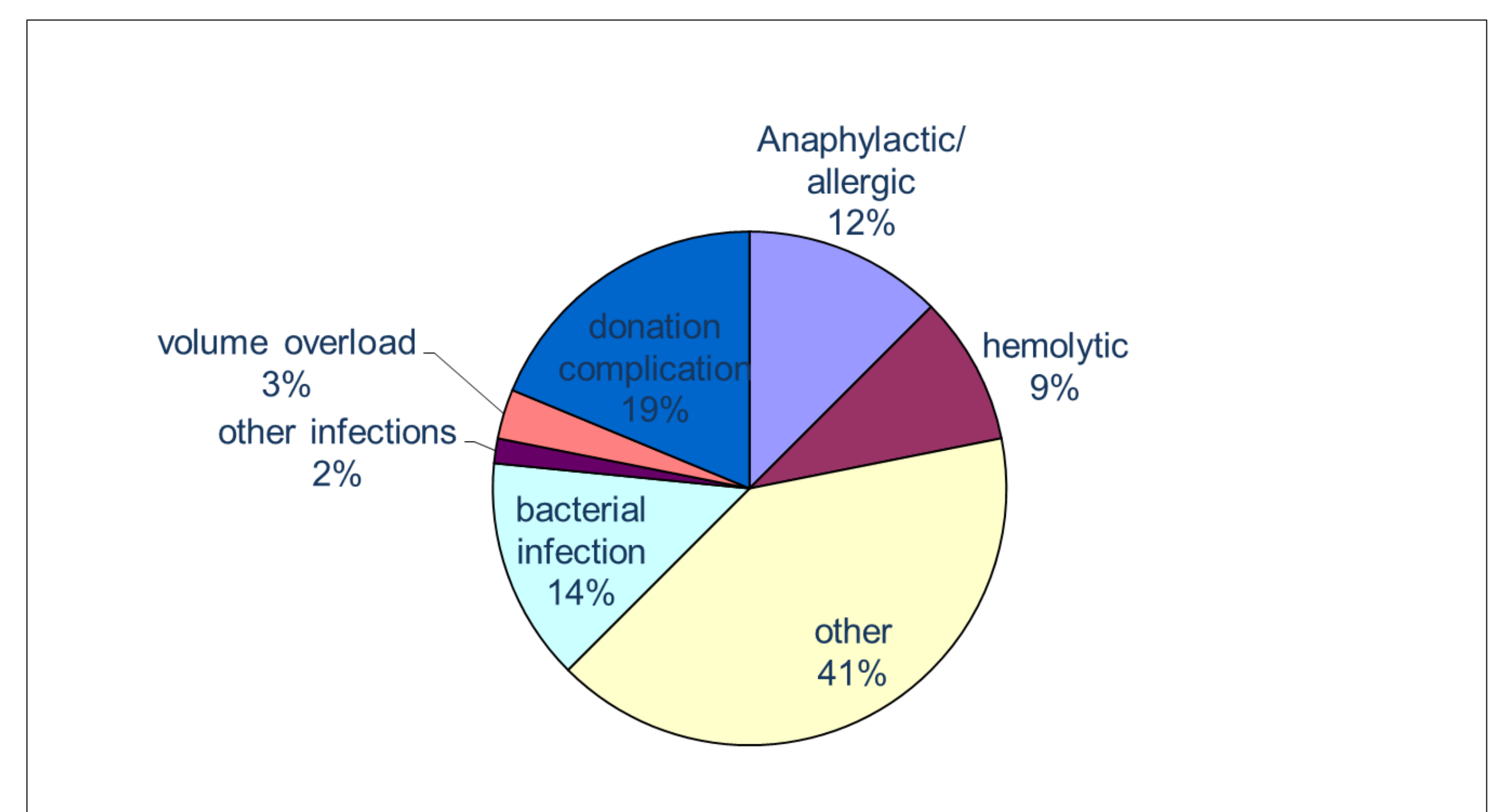
Reporting system



Biovigilance reports 2006-2013



Type of reported adverse reactions



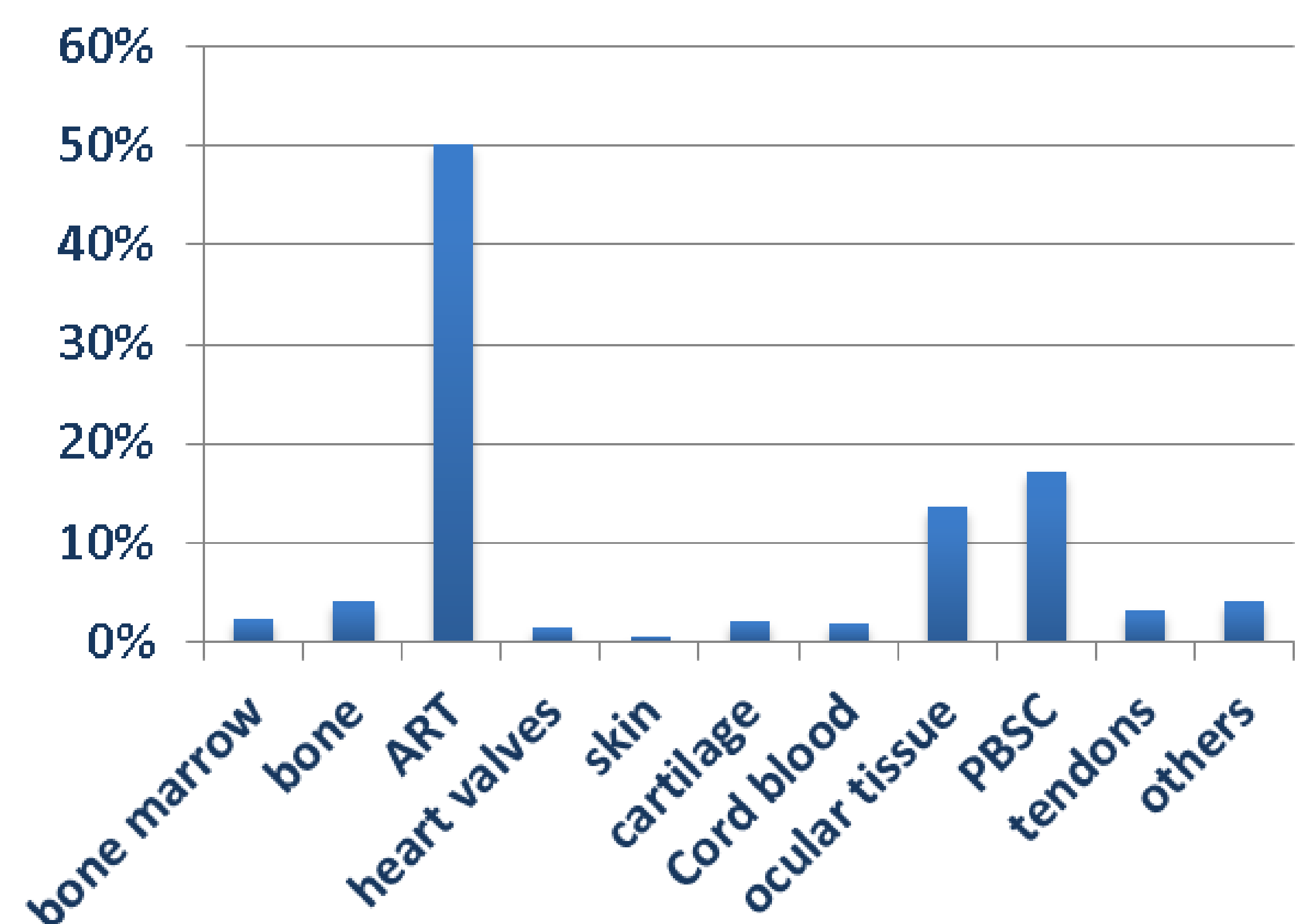
Type of reported adverse events

- Substantial loss of cells/tissue and other incident.
- 46% of report of loss of tissue is ART related.
- Category other: technical failures, processing issues, product deficiencies, communication and storage conditions.

Trends

- Leakage PBSC storage bags: increasing reports of leaks and tears in the storage bags for PBSC.
- Identification errors in relation to control method.

Type of report/tissue



Lessons learned sofar..

- To create a biovigilance system cooperation of hospitals is essential.
- Awareness among clinicians to recognize and report SAR/SAE of tissue and cells is low and need continuous education.
- A central system helps to recognize trends that can't be identified in a single institute.
- Biovigilance doesn't only concerns patients, if also monitors the (living) donor.
- Majority of reports are adverse events. They often caused negative effects for patients although transplantation didn't take place.
- Analysis of biovigilance data contributes to better information for donor and recipient on the risk involved with tissue and cells.