

# Welcome in Leiden







# TRIP Biovigilance

Symposium 2019



# TRIP

Hemo-en biovigilantie



28<sup>TH</sup> CONGRESS  
OF EUROPEAN  
ASSOCIATION  
OF TISSUE AND  
CELL BANKS

LEIDEN  
THE NETHERLANDS





# Biovigilance 2018

96% overall participation by organisations with a role in biovigilance in 2018

100%



105

Tissue establishments

98%



79/81

Hospitals

93%



14/15

Clinics

91%



52/57

Oral implantology practices

## 96 Reports of adverse events and reactions in 2018

Donation complications

4

Adverse reactions

2

Adverse events

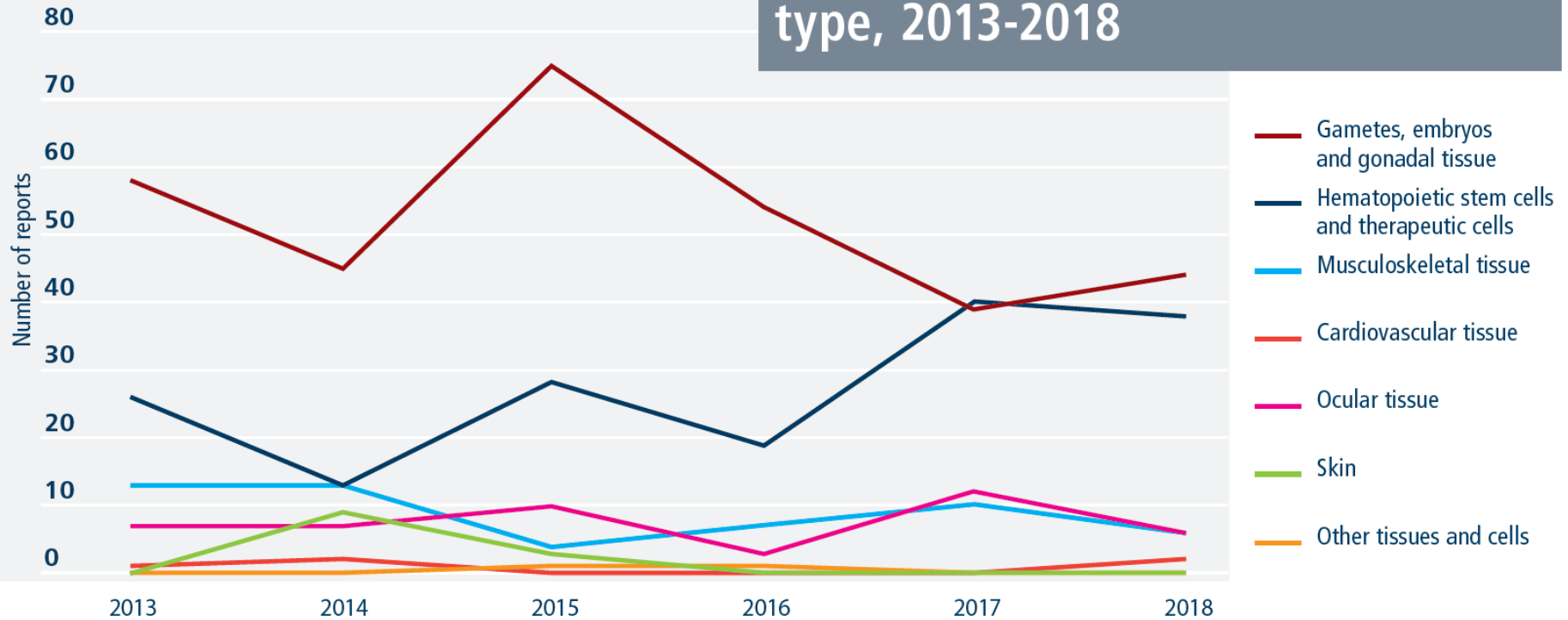
38

■ Non-serious reports  
■ Serious reports

85%  
are  
adverse  
events

0 10 20 30 40 50 60 70 80 90 100

## Reports received per tissue or cell type, 2013-2018





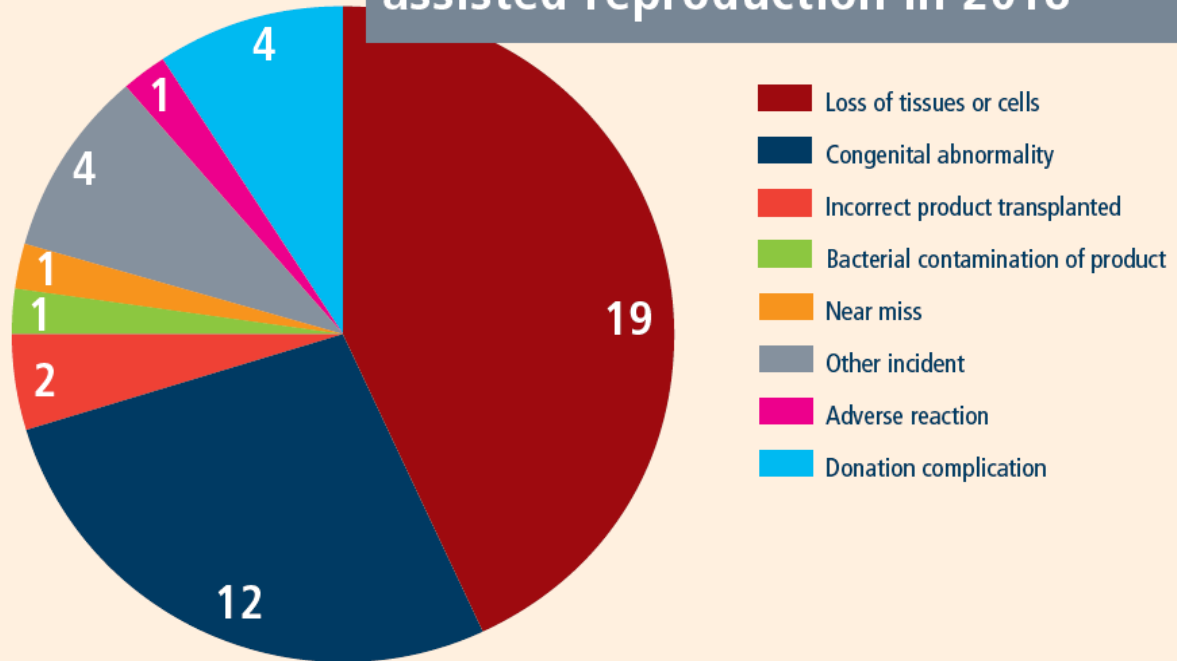
## RECOMMENDATION 2

The reports of congenital abnormalities associated with medically assisted reproduction using donor gametes should be considered over a period of several years. A distinction should be drawn between genetic and non-genetic abnormalities.

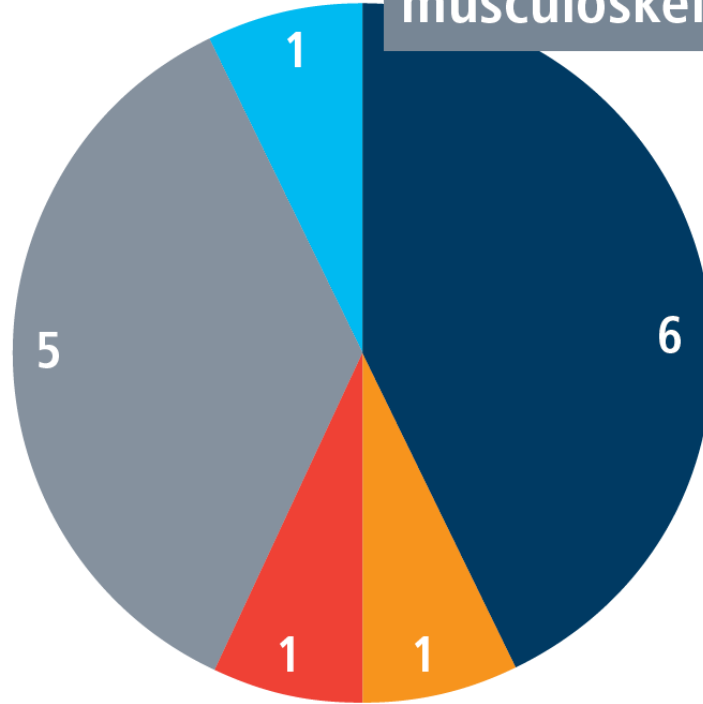
## RECOMMENDATION 3

Identification errors associated with the application of gametes or embryos can potentially be further reduced by electronic verification of the correspondence between product and recipient or by an independent second check performed by a person not involved in the recipient's treatment.

## Reports associated with medically assisted reproduction in 2018



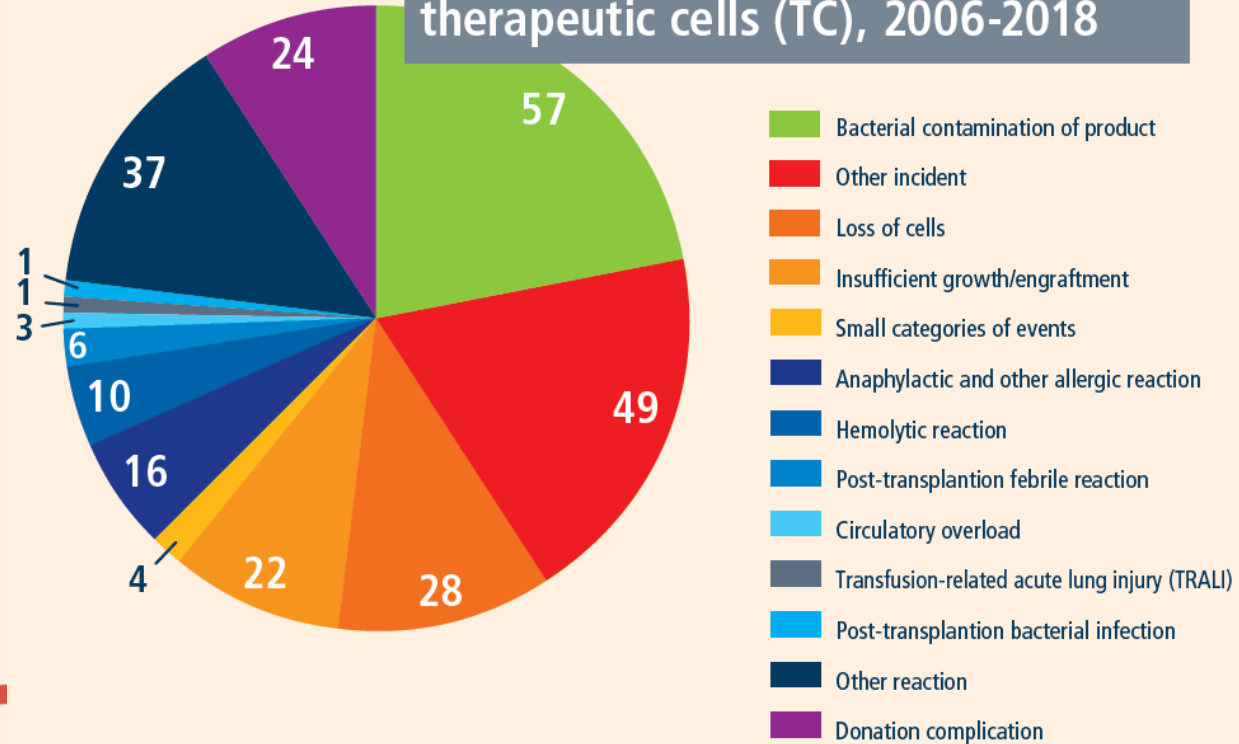
## Reports associated with ocular, cardiovascular and musculoskeletal tissue in 2018



- Ocular, serious
- Cardiovascular, non-serious
- Cardiovascular, serious
- Musculoskeletal, non-serious
- Musculoskeletal, serious



## Reports associated with hematopoietic stem cells (HSC) and therapeutic cells (TC), 2006-2018



TRIP HIGHLIGHTS 2018

# Biovigilance



The full TRIP report  
biovigilance 2018, extended  
version, will be published  
online as soon as possible.

