

# TRIP Biovigilance

Symposium 2019



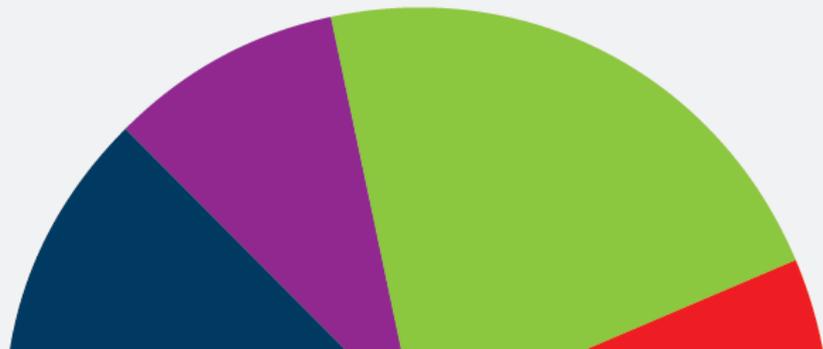
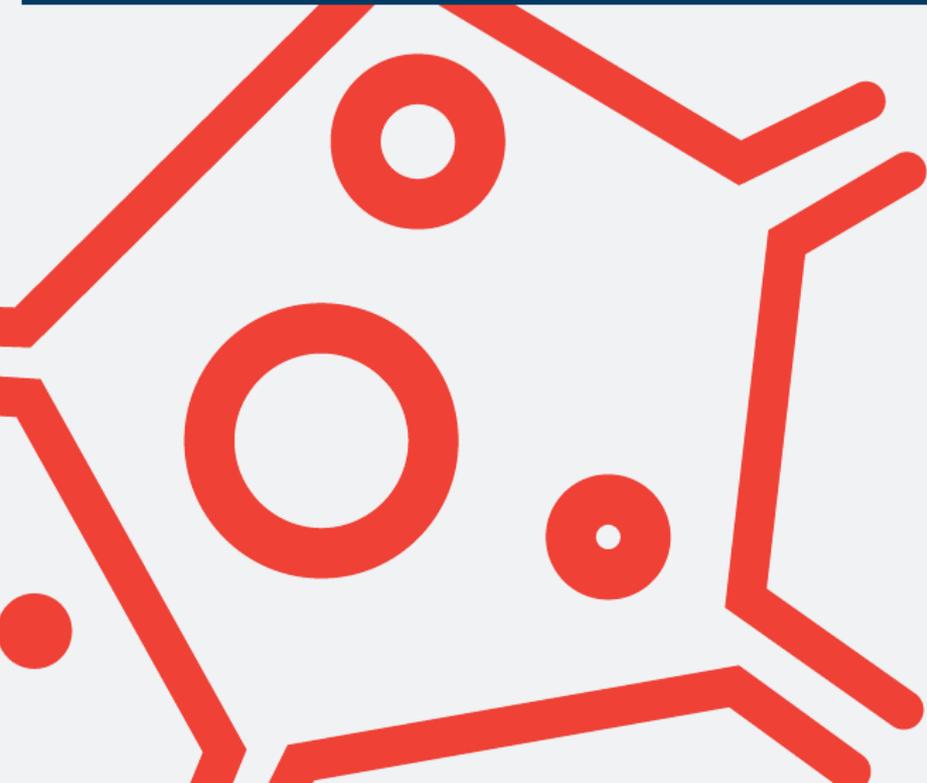
# TRIP

Hemo-en biovigilantie



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

LEIDEN  
THE NETHERLANDS



# **Biovigilance in the Netherlands and the European Union**



**Marjan Happel, TRIP Biovigilance coordinator**



**What is TRIP?**



**EU Competent Authority (CA) survey**



What is TRIP?

**Hemovigilance**



**Biovigilance**





# 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

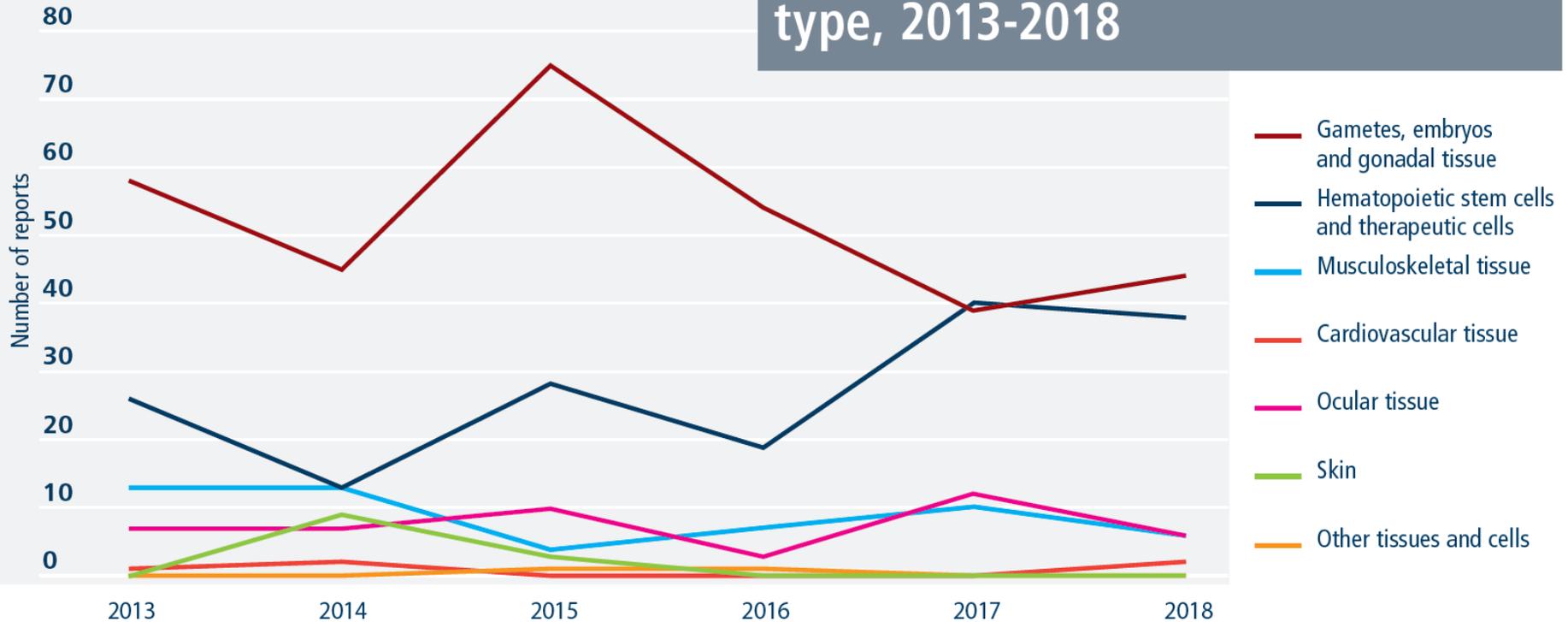
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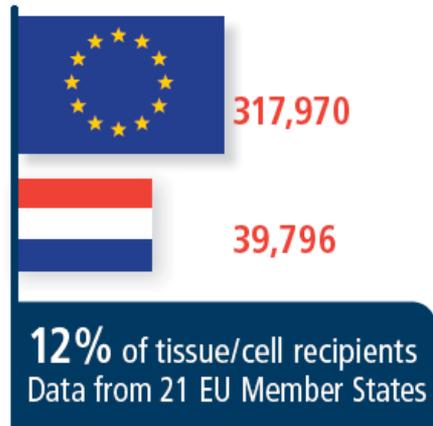
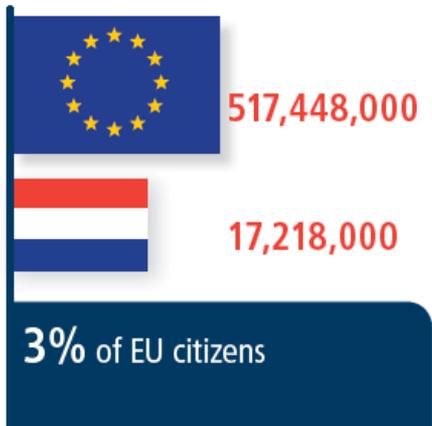
Non-serious reports  
Serious reports

85%  
are  
adverse  
events

0 10 20 30 40 50 60 70 80 90 100

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





## High standard of biovigilance data in The Netherlands

3% of EU reported serious adverse reactions came from NL

4% of EU reported serious adverse events came from NL

## Single European Code

### RECOMMENDATION 1

The validation of the Single European Code generation by a tissue establishment should be based on verification of both the eye-readable code and the bar or QR code.



01397-12/12D

SEC: XX000048000000S101397 E000002100120140802

**3**  
reports of incorrect  
Single European Code



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

**DG SANTE**

**VIGILANCE EXPERT SUB-GROUP for BLOOD, TISSUES AND CELLS**

**VES-BTC**





What is TRIP?



**EU Competent Authority (CA) survey**

# EU CA survey



**31 countries approached**  
(28 EU Member States and 3 EEA countries)

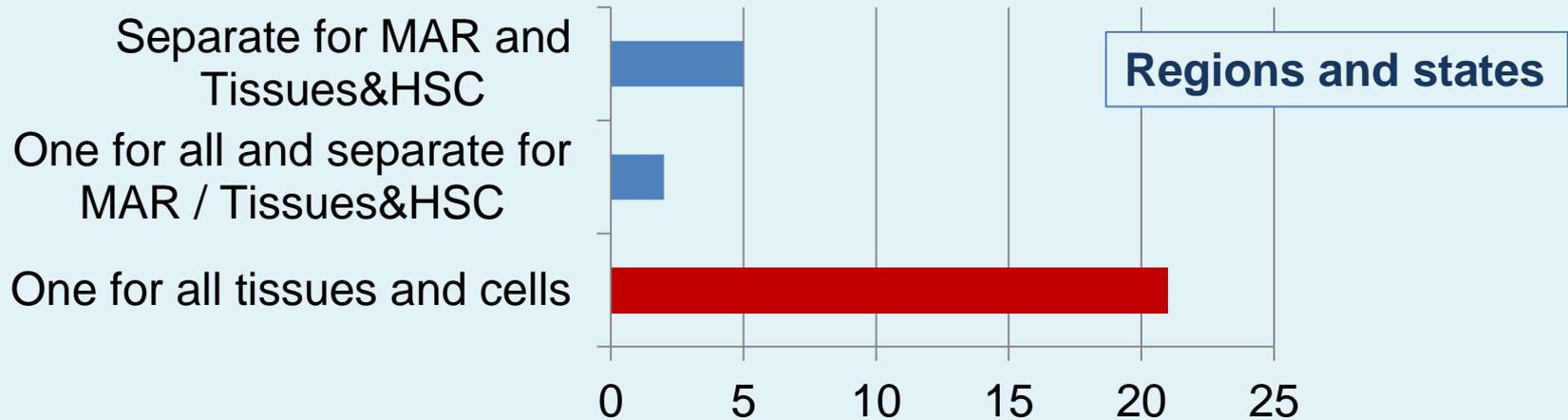
**28 countries replied**  
(32 Competent Authorities)

**90% participation !**

# EU CA survey



**Are there separate CAs for Tissues, Medically Assisted Reproduction (MAR) and Hematopoietic Stem Cells (HSC) in your country?**

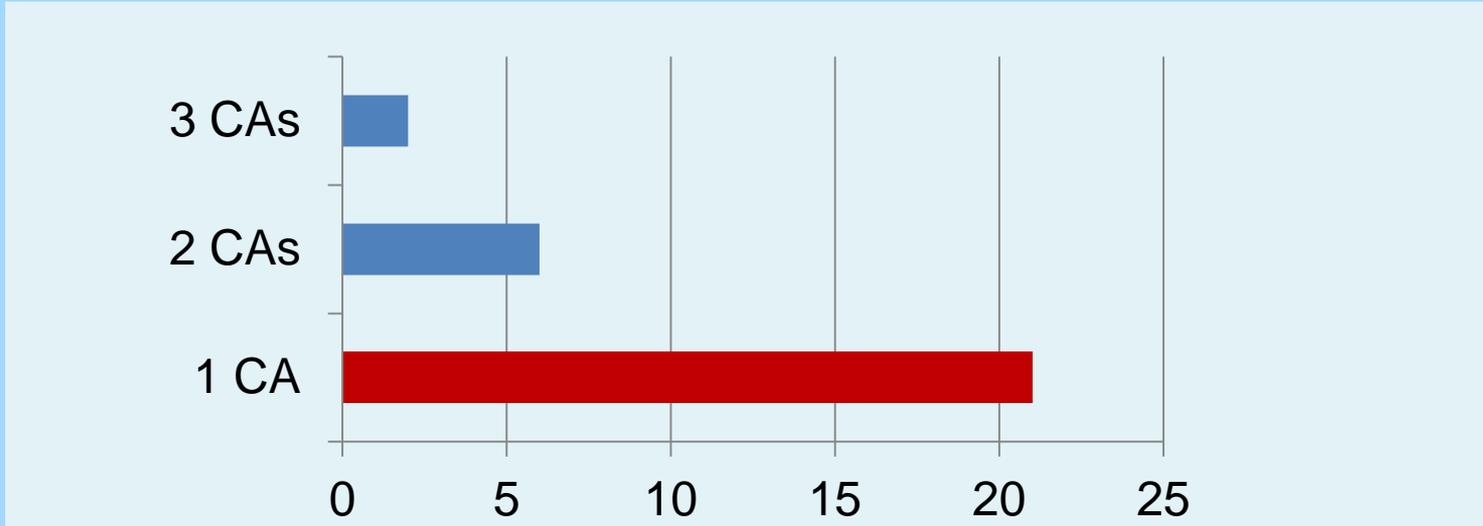


28 countries

# EU CA survey



**How many CAs in your country are involved in the SARE reporting for T&C?**

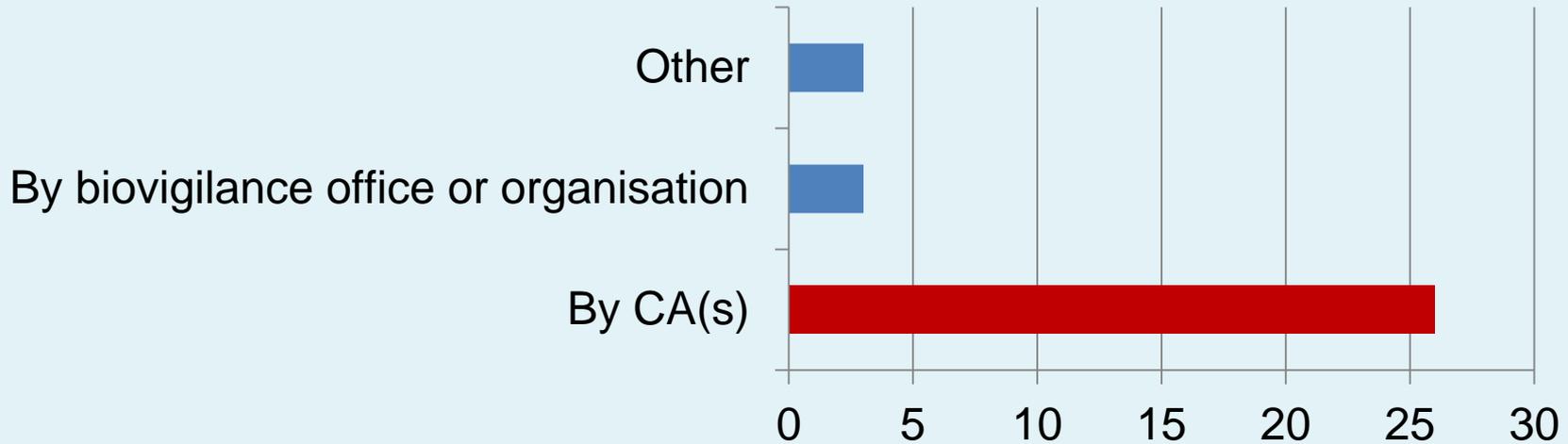


28 countries

# EU CA survey



**By who(m) is the data collected for SARE reporting?  
(multiple answers possible)**

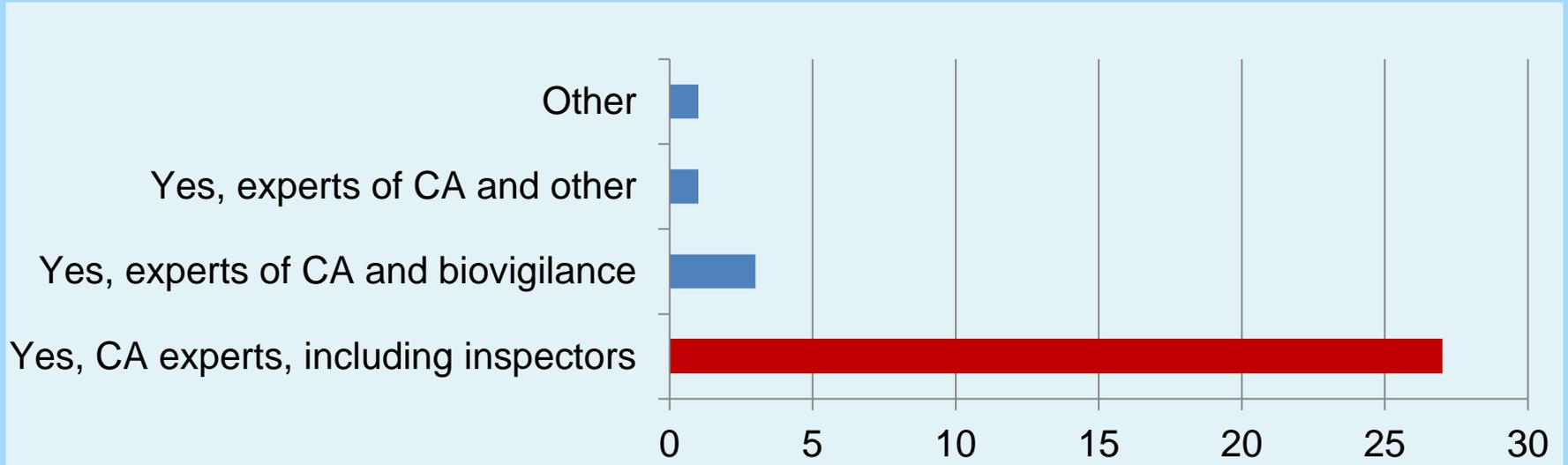


32 CAs

# EU CA survey



**Is the content of the SARE reports assessed by the CA(s)?  
(multiple answers possible)**



32 CAs

# EU CA survey



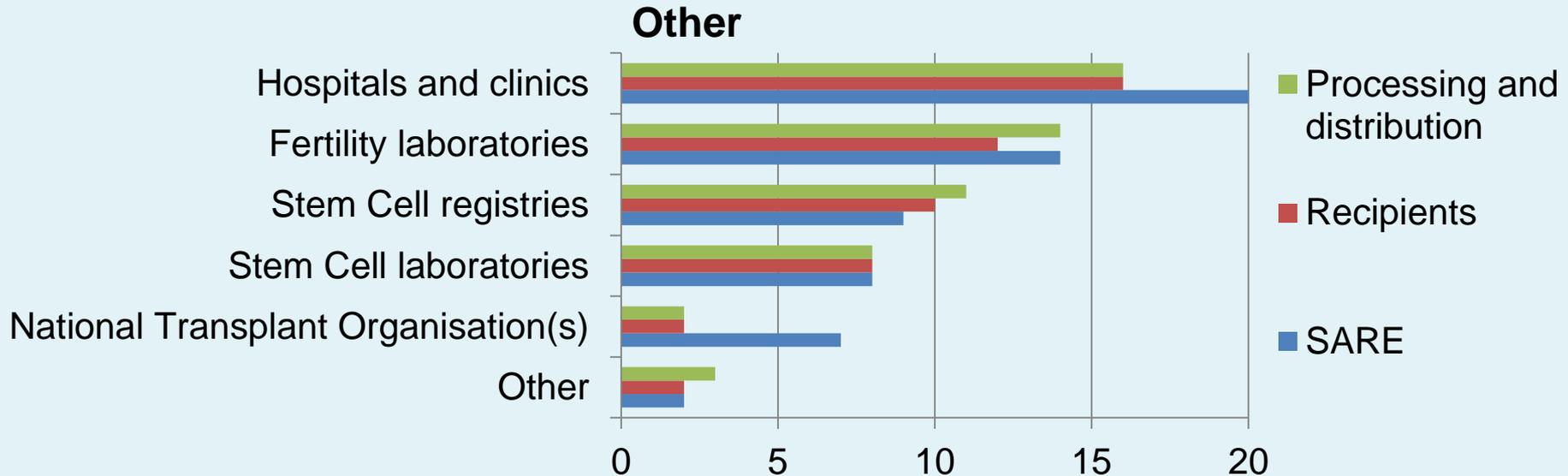
**Which organisations provide the data of processing and distribution, recipients and SARE?  
(multiple answers possible)**



# EU CA survey



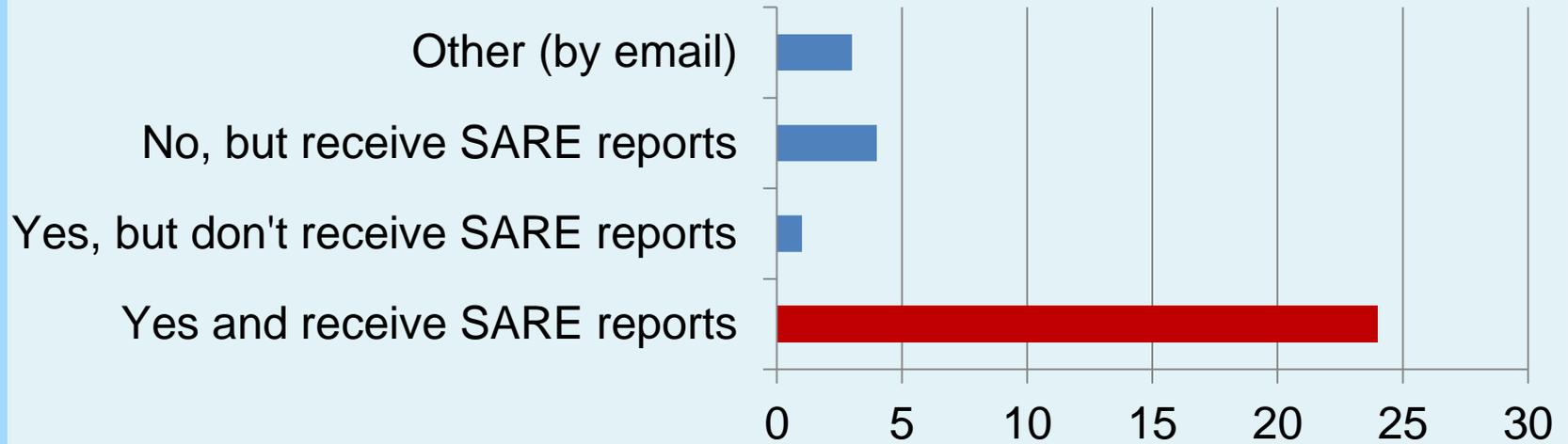
**Which organisations provide the data of processing and distribution, recipients and SARE?  
(multiple answers possible)**



# EU CA survey



Do you have a reporting system for SARE in place?

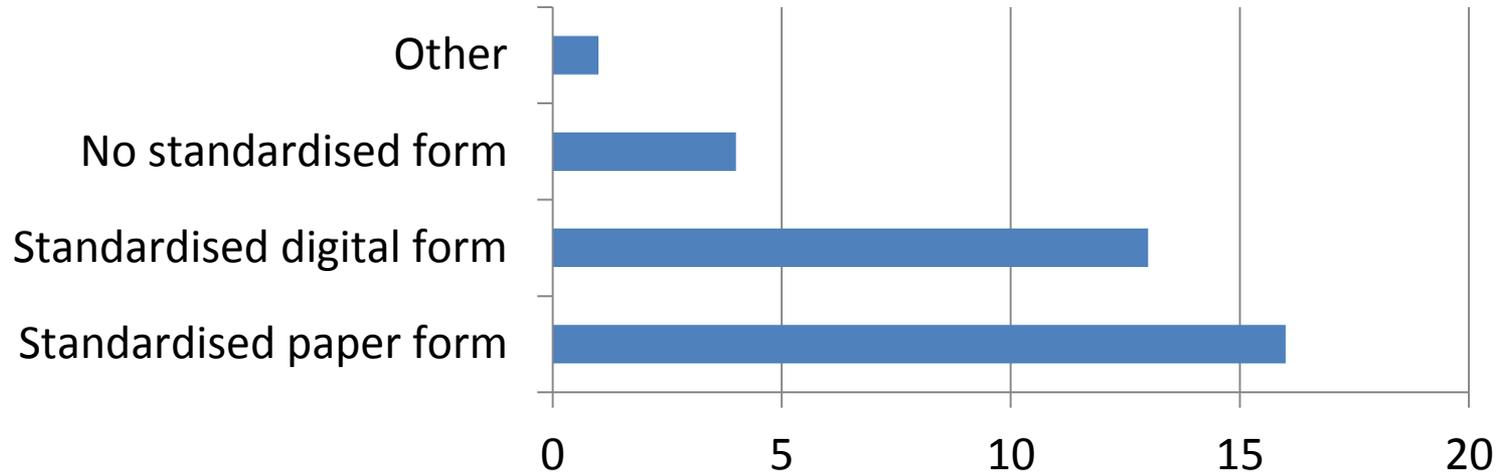


32 CAs

# EU CA survey



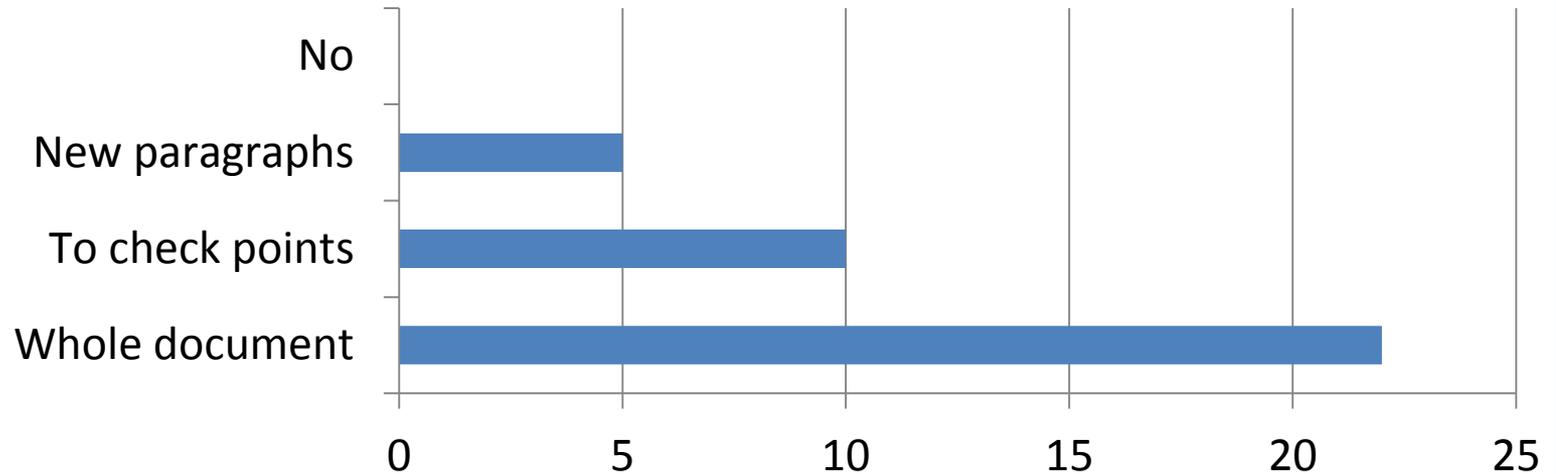
If you have a reporting system in place, is this digital or on paper? (multiple answers possible)



# EU CA survey



**Do you read the Common Approach before entering data in the reporting template? (multiple answers possible)**



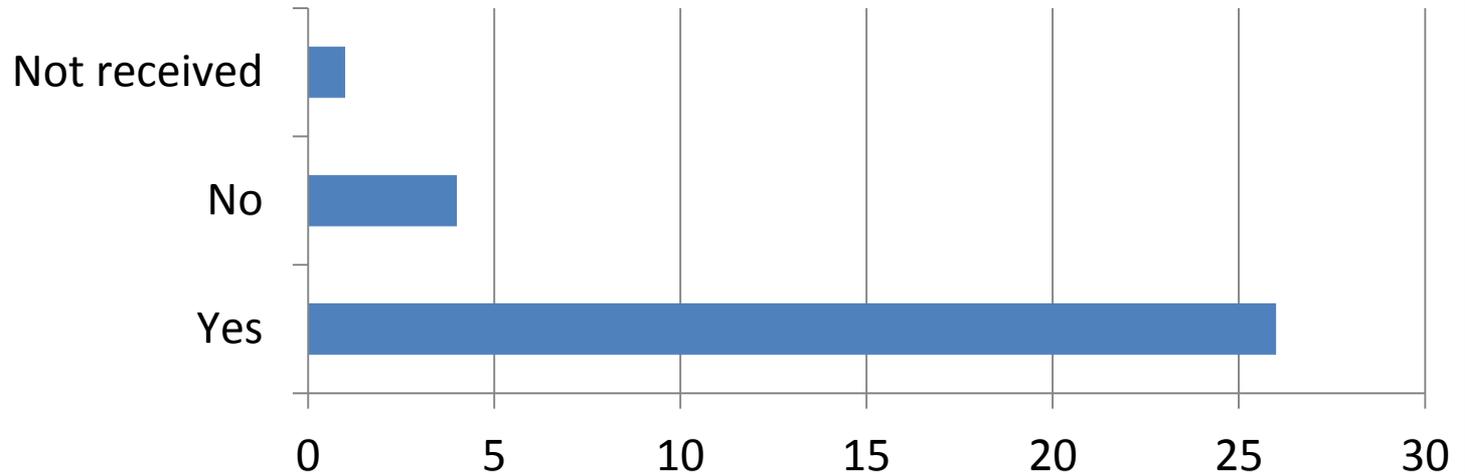
32 CAs

# EU CA survey



Do you collect Serious Adverse Reactions in Donors (SARD)?

*Voluntary*



32 CAs

# EU CA survey



## Open Question:

What problems do you experience with the collection of numbers of processed and distributed T&C and recipients?

Late provision of data

Incorrect or incomplete

Especially data of recipients

Some data not available

Unsuitable definitions  
(MAR, SC) operators

Definition of Distribution unclear

# EU CA survey



## Open Question:

What problems do you experience with the collection of SARE?

Unclear SARE definitions

Underreporting

Late reporting by TEs

No SAR reporting by TEs

Multiple CAs delay EU reporting

Insufficient detection or interpretation of SARE

# EU CA survey



## Open Question:

What problems do you experience with the collection of SARD?

Differences between national and EU legislation

Underreporting (voluntary)

Late reporting

Low awareness of clinicians

Not enough space on form

Lack of reporting criteria

# EU CA survey



## Open Question:

What problems do you experience with the completing the reporting template?

Differences in interpretation of definitions

Incomplete or incorrect

None

Yearly changes

Multiple CAs in 1 form

Denominators MAR and HSC

Free text in SAE

Errors in reporting template

# EU CA survey



## Open Question:

Do you have any suggestions for easier data collection and improving the SARE reporting template?

Extra specification for SAE:  
System failure

Standard forms for all countries

Online application

Breakdown of 'Other' categories

Clear and binding definitions

New denominators MAR and HSC

Individual reporting

Training course for CAs

Dropdown menu with SAE categories

**Slides will be available at**  
**[www.tripnet.nl](http://www.tripnet.nl)**



# **Thanks to:**

**DG SANTE: SoHO team**  
**Members of the VES-BTC**  
**CAs of EU MS and EEA**  
**TRIP colleagues**

**And all of you!!**