TRIP: hemovigilance system run by and for professionals

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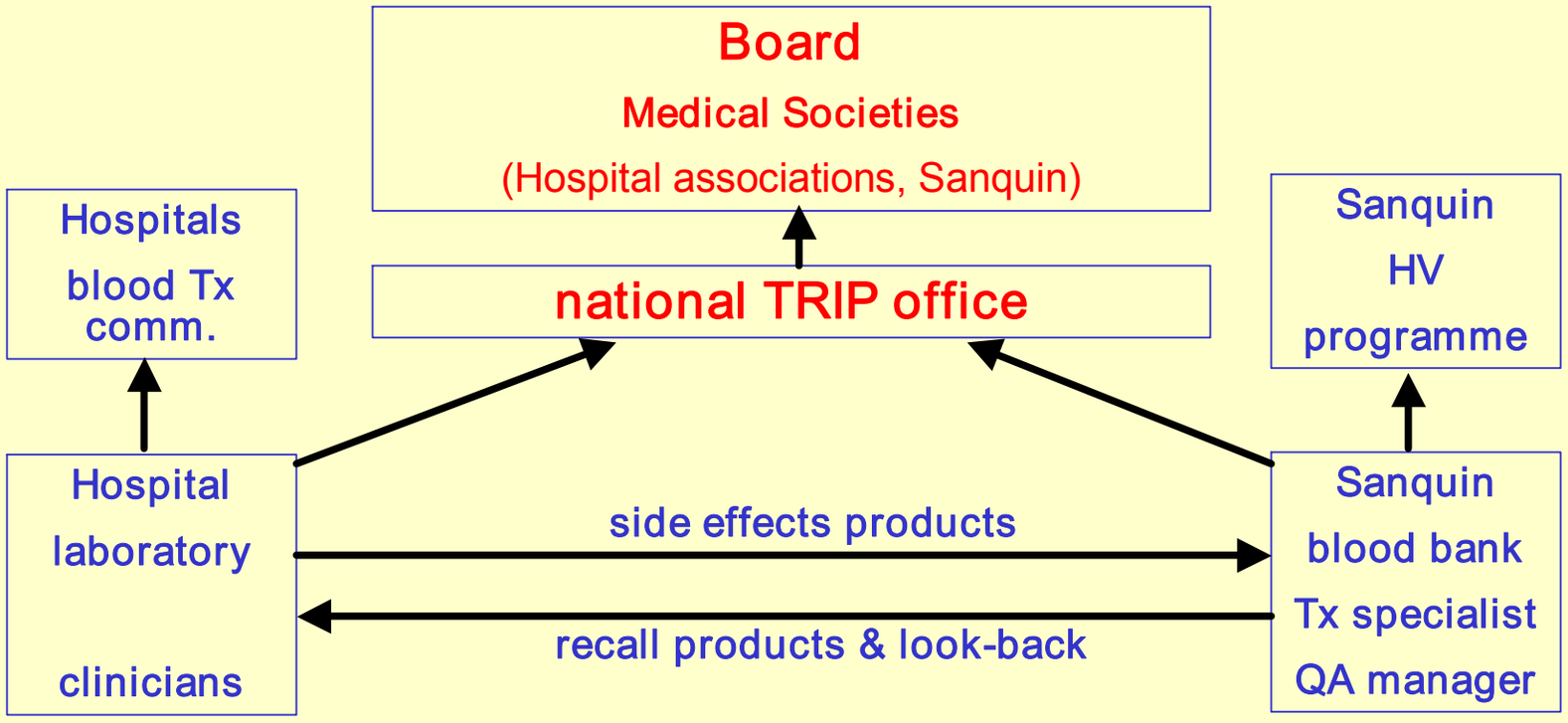
- History
- Dutch blood supply
- ‘Stakeholders’ in hemovigilance, 2007
- Four years of national reporting
- Implementation of EU directive
- Additional factors
  - patient safety movement
  - tissue vigilance
- Impact on transfusion practice

Hemovigilance:
introduction in The Netherlands

- National Blood Transfusion Council
  - "Recommendations" on hemovigilance 1997
- Healthcare Inspectorate
  - 'Sanguis sanus sanat' report 2001
  - Reporting included in hospital performance indicators (2003-6)
- CBO Health Services Quality Organisation Blood Transfusion Consensus guideline 2004

Development of hemovigilance

TRIP foundation created in 2001



TRIP (Transfusion Reactions In Patients)

Hitherto ‘voluntary’ participation,

- regarded as the norm by Inspectorate
- professional standard in consensus guideline

Reporting system

what types, definitions, recommended further investigation

how to report: paper / online

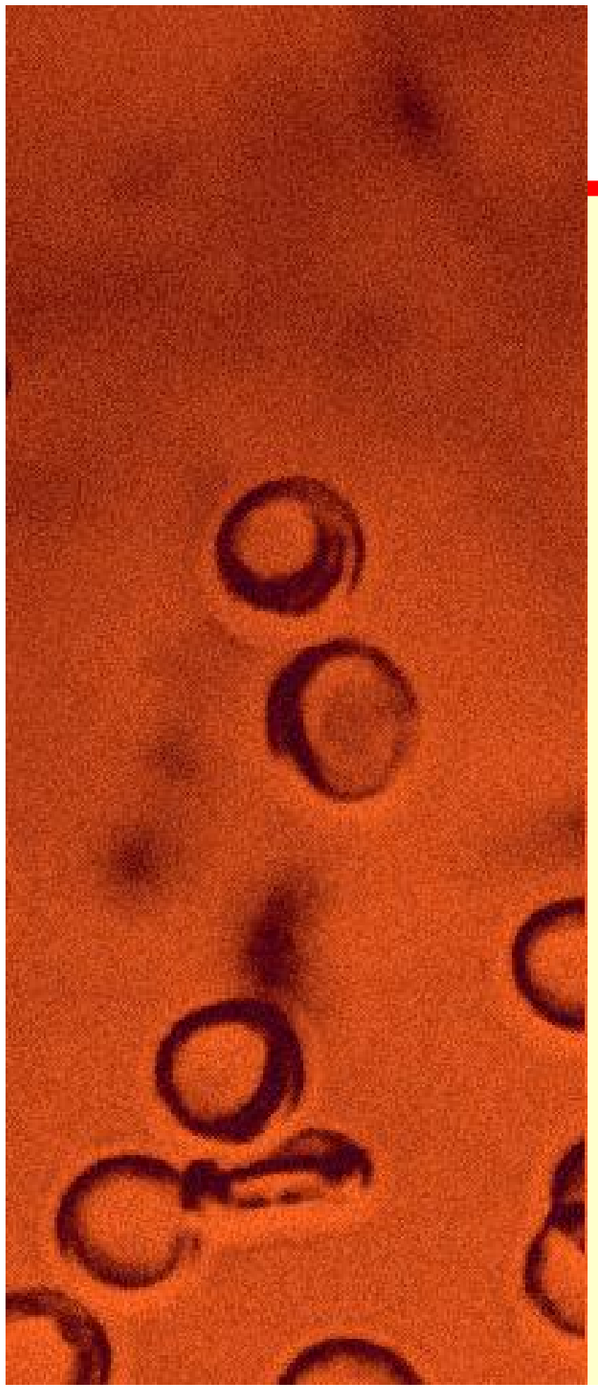
Verification (expert review)

Denominator data, statistical analysis

Publication (transparency)

Blood supply

- 4 regional blood bank divisions
- Self-sufficiency
- 851,270 donations (2006)
  - 578,145 whole blood
  - 272,909 apheresis
  - Doctor on site
- 439,000 voluntary unpaid donors (population 17 million)
- Divisions for Plasma fractionation, Research and Diagnostics



Blood supply:

National organisation (Sanquin)
created by law in 1998

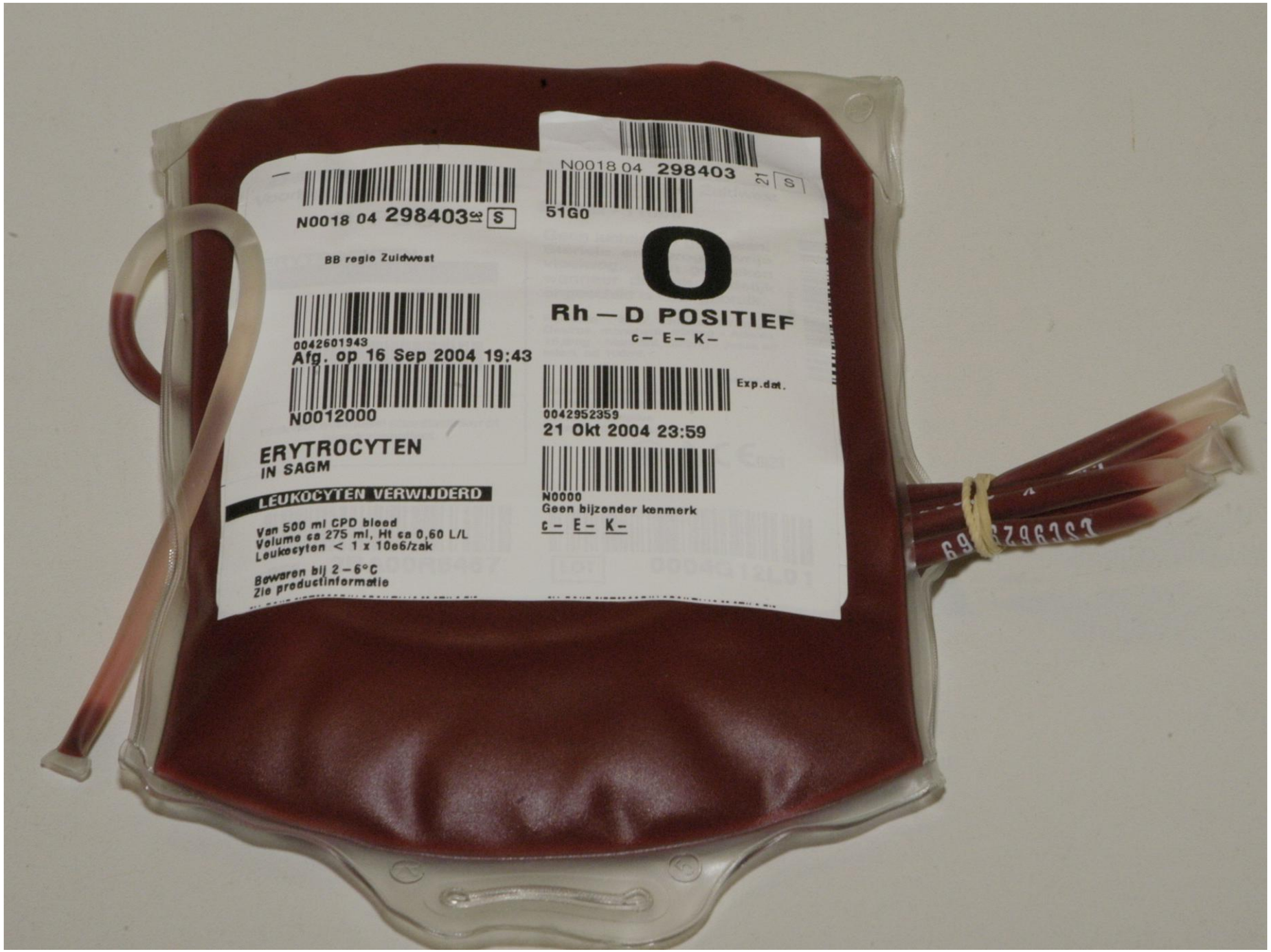
Sanquin Bloedbank

Blood supply (2)

- No whole blood transfused
- RBC with SAG-M
- Platelets
  - pooled BC of 5 donors (in plasma or PAS)
  - one-sixth of total are apheresis platelets
  - Bacteriological screening
  - Shelf life 5 - 7 days (PAS/plasma)
- Fresh frozen plasma from quarantine apheresis plasma
- Little preoperative autologous donation

Blood supply (3)

- Testing for infectious diseases (including minipool NAT for HCV and HIV); malaria test applied for ex-patients
- Universal leukodepletion since autumn 2001 (and exclusion of UK donors)
- Exclusion of transfusion donors since February 2005; male-only plasma for transfusion since 2007
- Two vCJD cases reported to date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Transfusion chain

- Doctors prescribe
- Transfusion by nurses
- Transfusion in hospital, day care, occasionally in residential care or at home

- Hospital blood transfusion committees
- 2004: consensus guideline for Blood transfusion

Hemovigilance staff

Hemovigilance staff (n=104 hospitals)	In post 2004 (TRIP questionnaire)	In post 2007 (Questionnaire by national HV platform, response n=62)
HV officer	42 Clinical chemist 12 Physician 1 Senior biomedical scientist 1 Nursing specialist 27 formally appointed	(No information requested)
HV assistant	25 Biom. scientist 4 nurse 1 anaesth. nurse 1 hygienist 1 nurse and biom scientist 1 quality officer	28 Biom. scientist 7 nurse 1 physician 1donation counsellor 1 anaesth.nurse 1 (role fulfilled by hospital transfusion committee)

Consensus Guideline
(a few highlights)

- Compatible blood not to be issued unless blood group has been determined twice on independent samples (0- use monitored!)
- Type and screen / electronic crossmatch acceptable

Consensus Guideline (2)

"4-5-6 rule"

Transfusion thresholds of

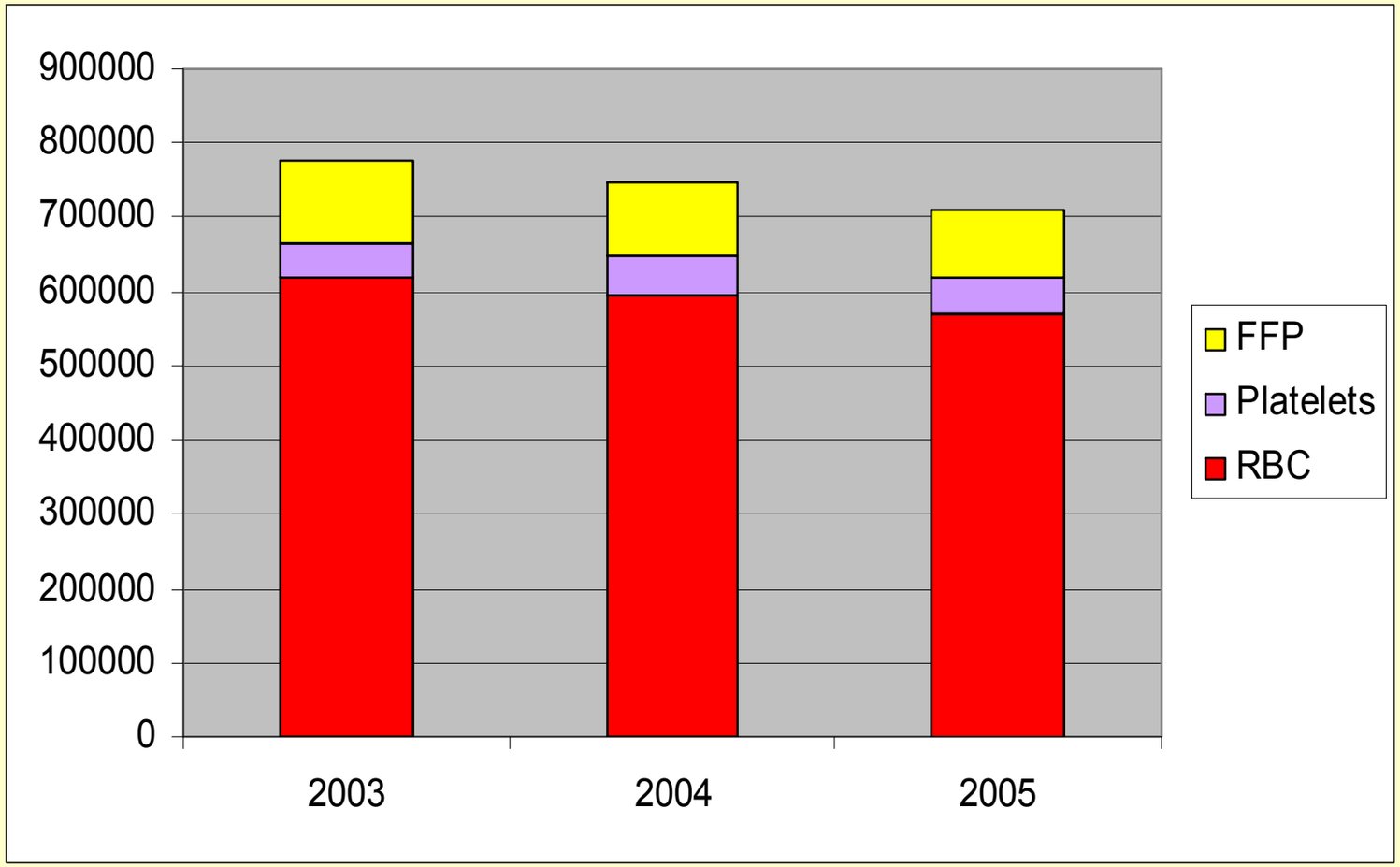
4 mMol/L (6.4 g/dl)

5 mMol/L (8.0 g/dl)

6 mMol/L (9.6 g/dl)

According to age, cardiac status, rate of blood loss and symptoms

Dutch blood use



The stakeholders

Ministry / Healthcare Inspectorate

EU: blood component safety

TRIP: safety in the whole transfusion chain (working through professionals)

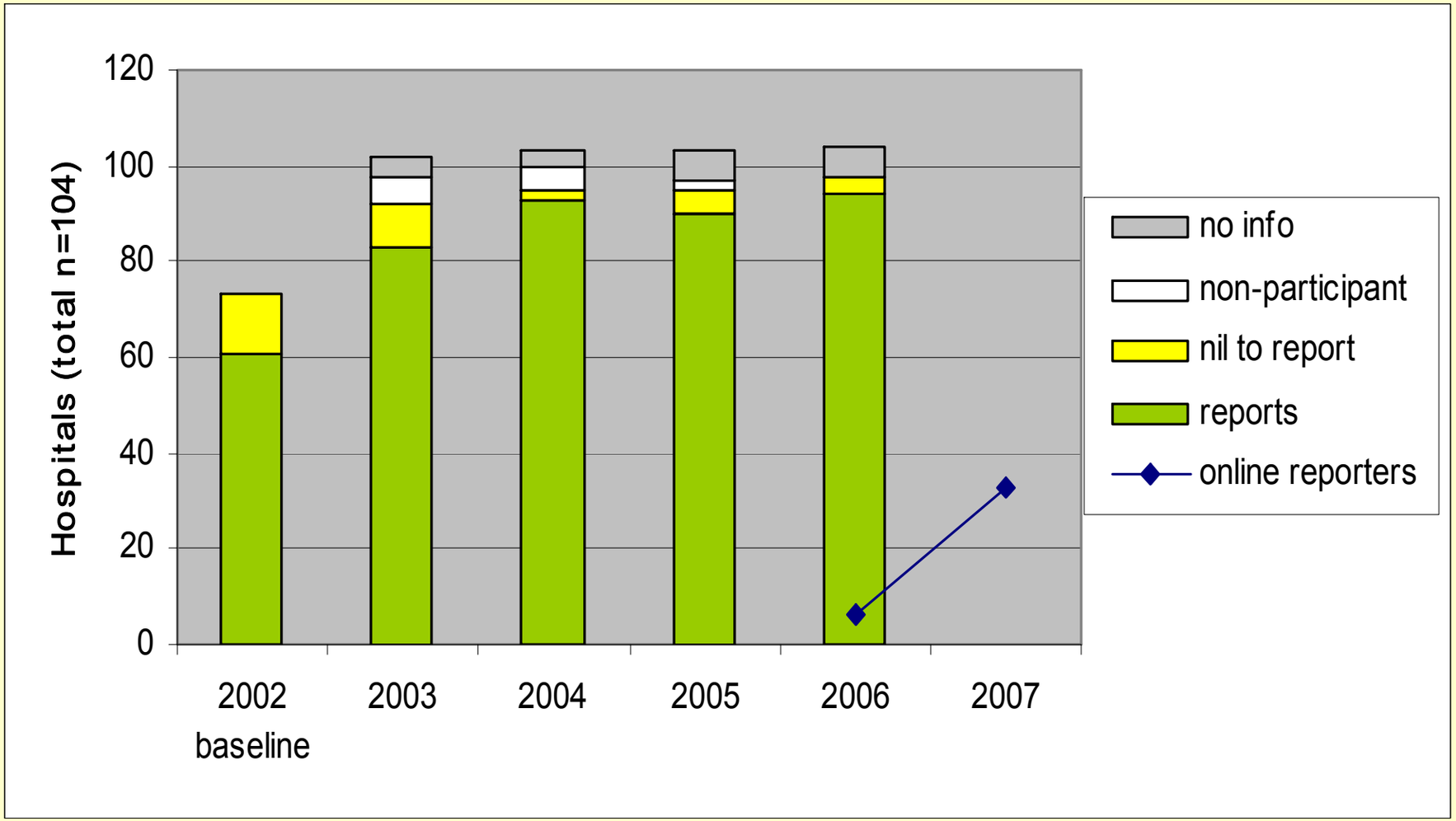
Sanquin blood supply foundation

Hospitals

Four years of national reporting

- Participation
- Reports
- International comparison

Participation by hospitals



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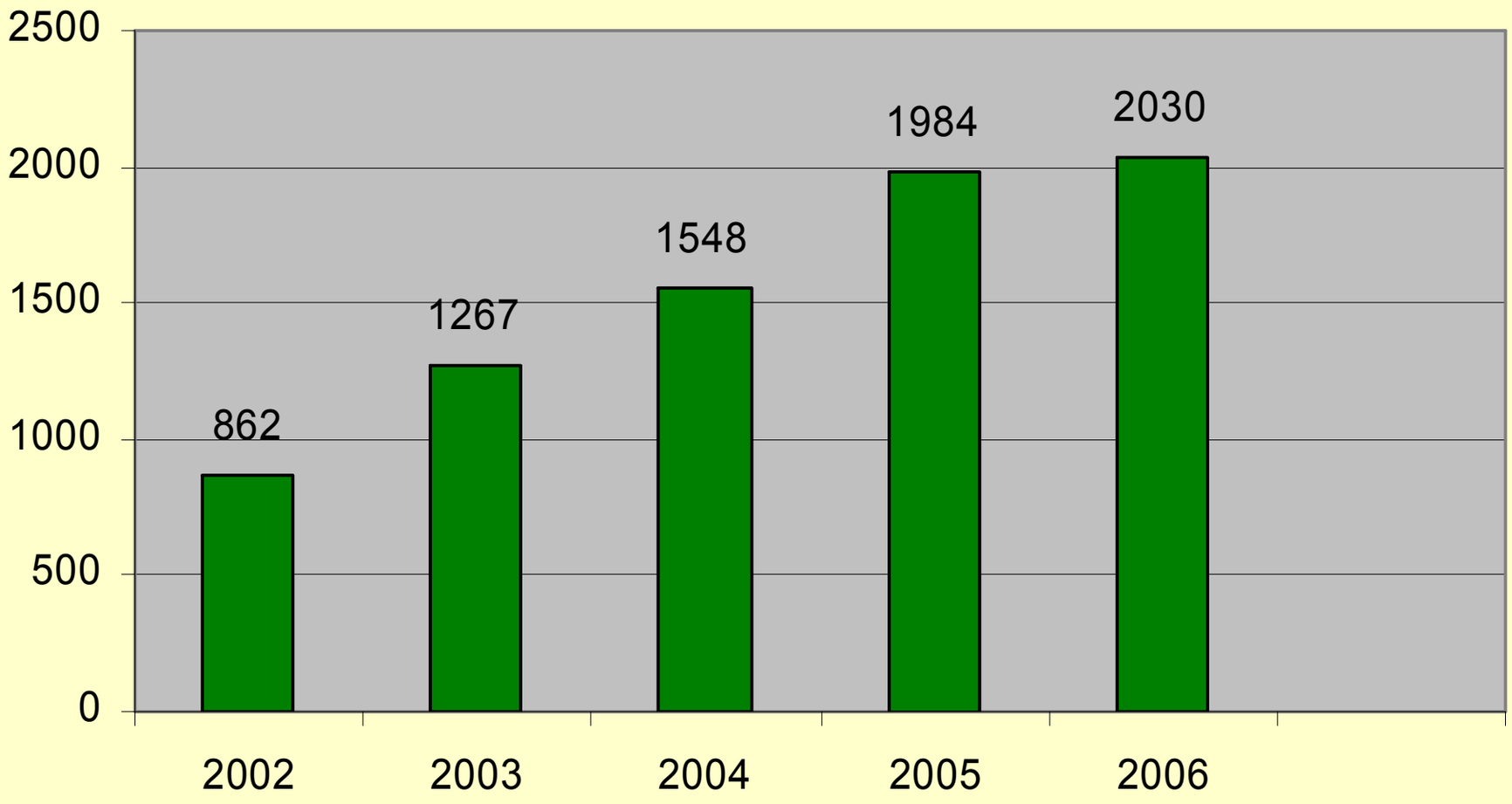
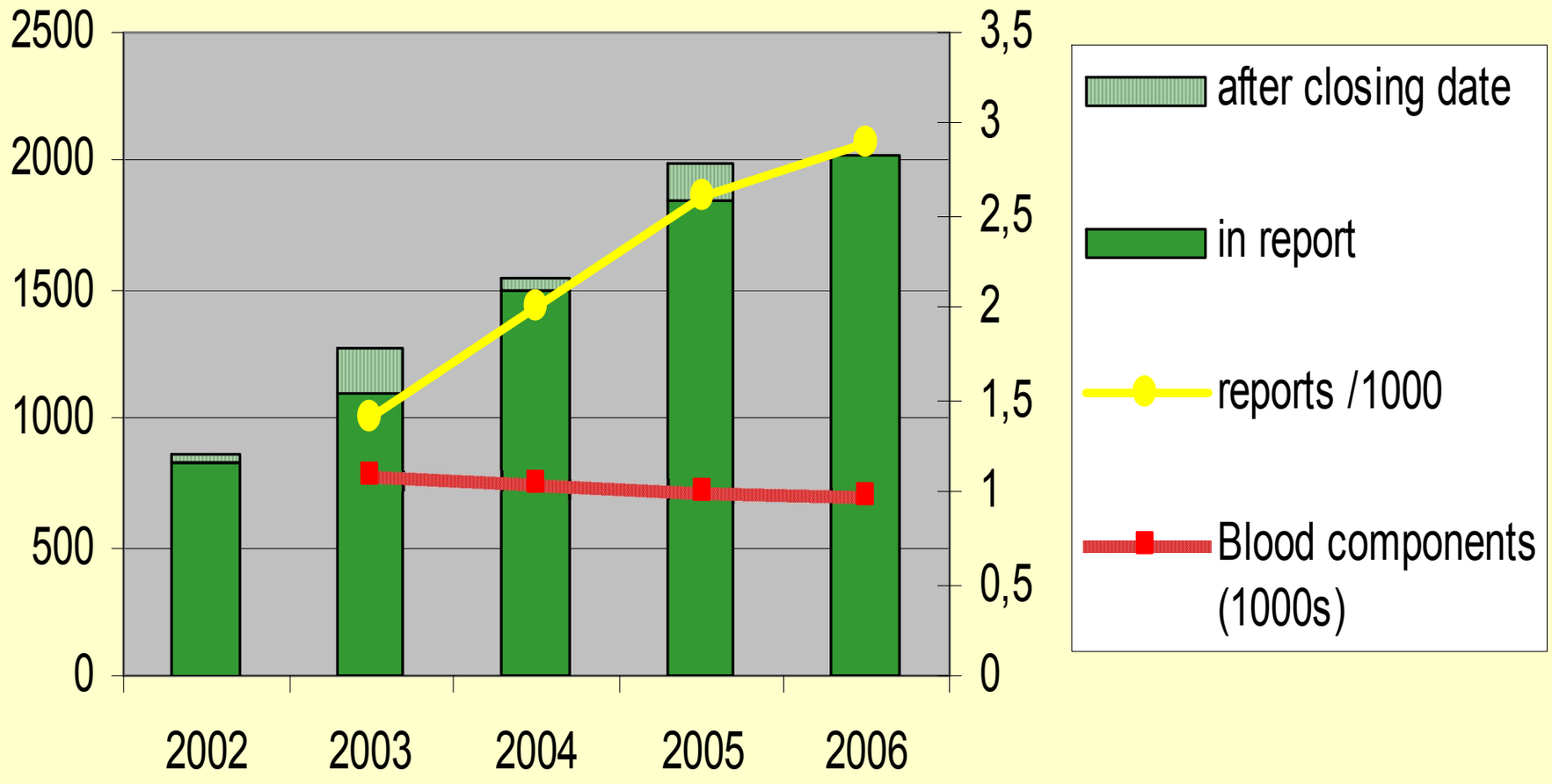
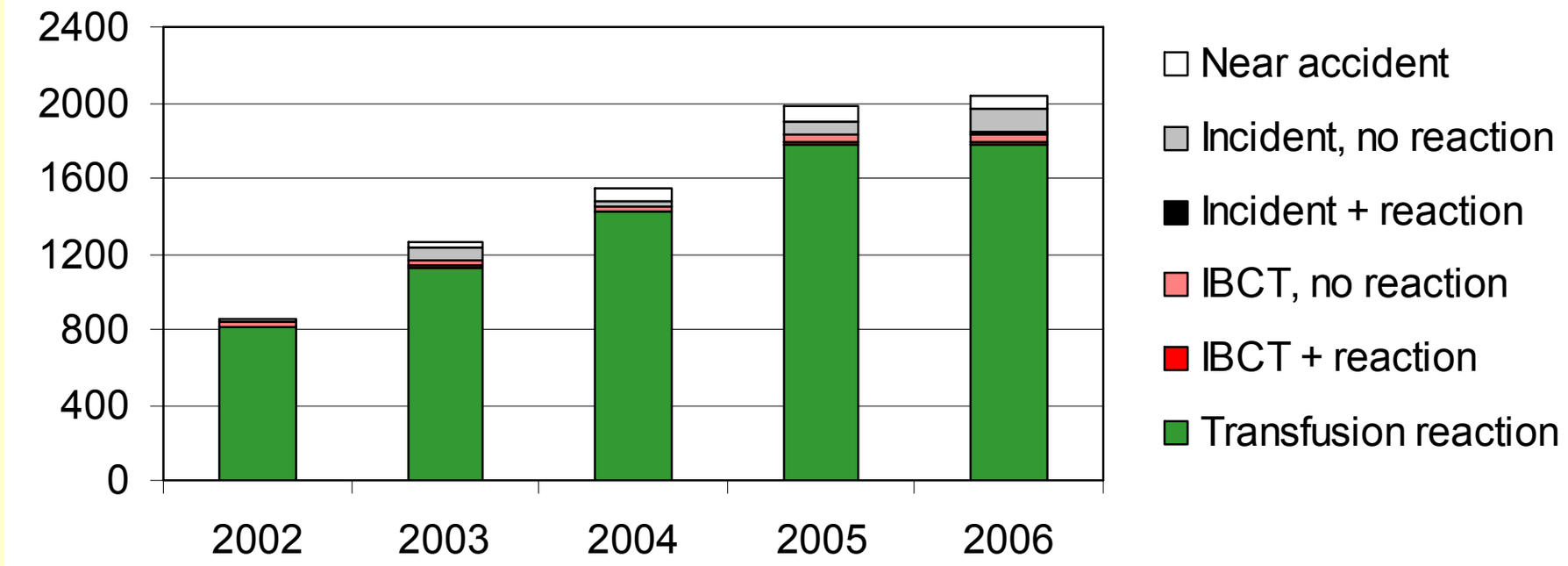
Reports per year



Reports per year



Types of event



International comparison

Country	captures	reports/ 1000 units (IBCT/1000)	Status
France (2005)	all	2.8 (0,08)	Mandatory
UK (2005)	serious	0,20 (0,16)	Voluntary
Ireland (2005)	serious	1,22 (0,72)	Voluntary
TRIP 2006	all	2,9 (0,09)	voluntary

Implementation of the EU directive

- Near-optimal blood supply
- TRIP widely accepted, will continue to provide scientific analysis and comment
- Inspectorate will focus on regulatory aspects

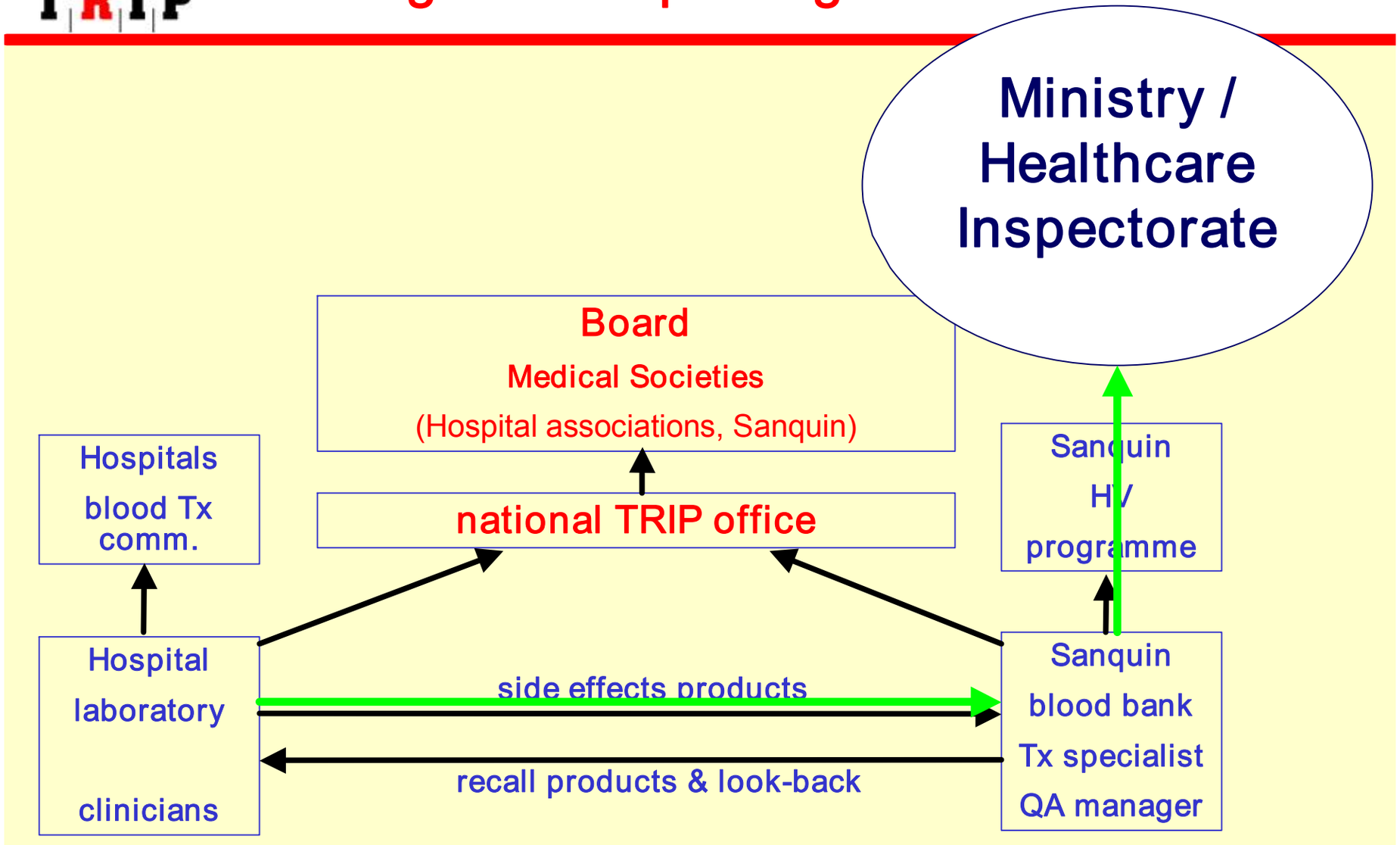
TRIP's position

- Impartial (independent from blood supplier and hospitals)
- Experience and expertise
- Over 90% voluntary participation by hospitals: our interest is to continue to receive all reports!
- Public reporting of anonymous information
- Ongoing funding committed (since 2006)

Electronic solution

- Electronic report to Inspectorate generated (reporter indicates ‘serious adverse reaction or serious adverse event’ or ‘calamity’ *=very serious safety incident*)
- Inspectorate takes action as appropriate
- Cross-referencing between systems to remove double reports

Hemovigilance reporting under the Directive



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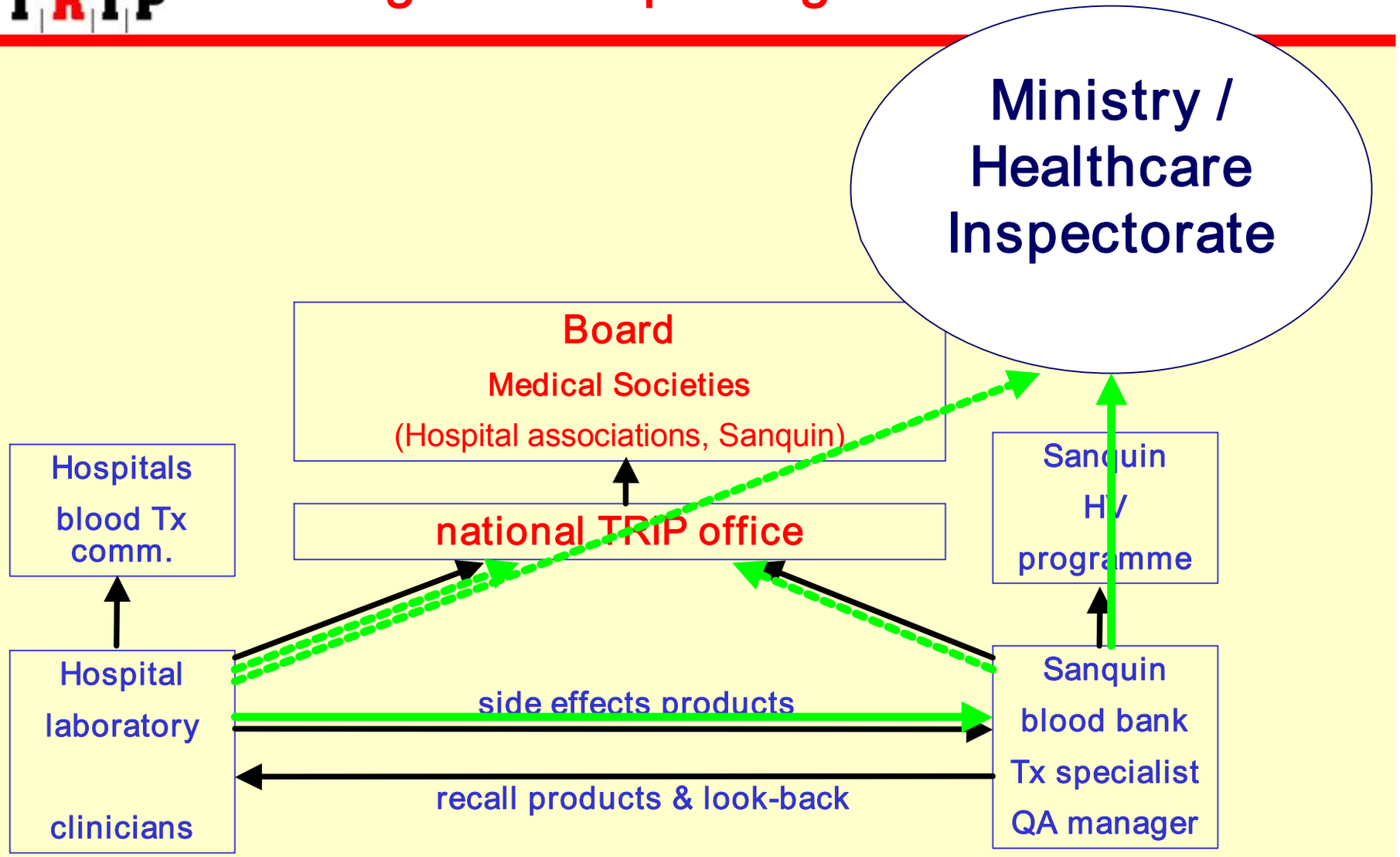

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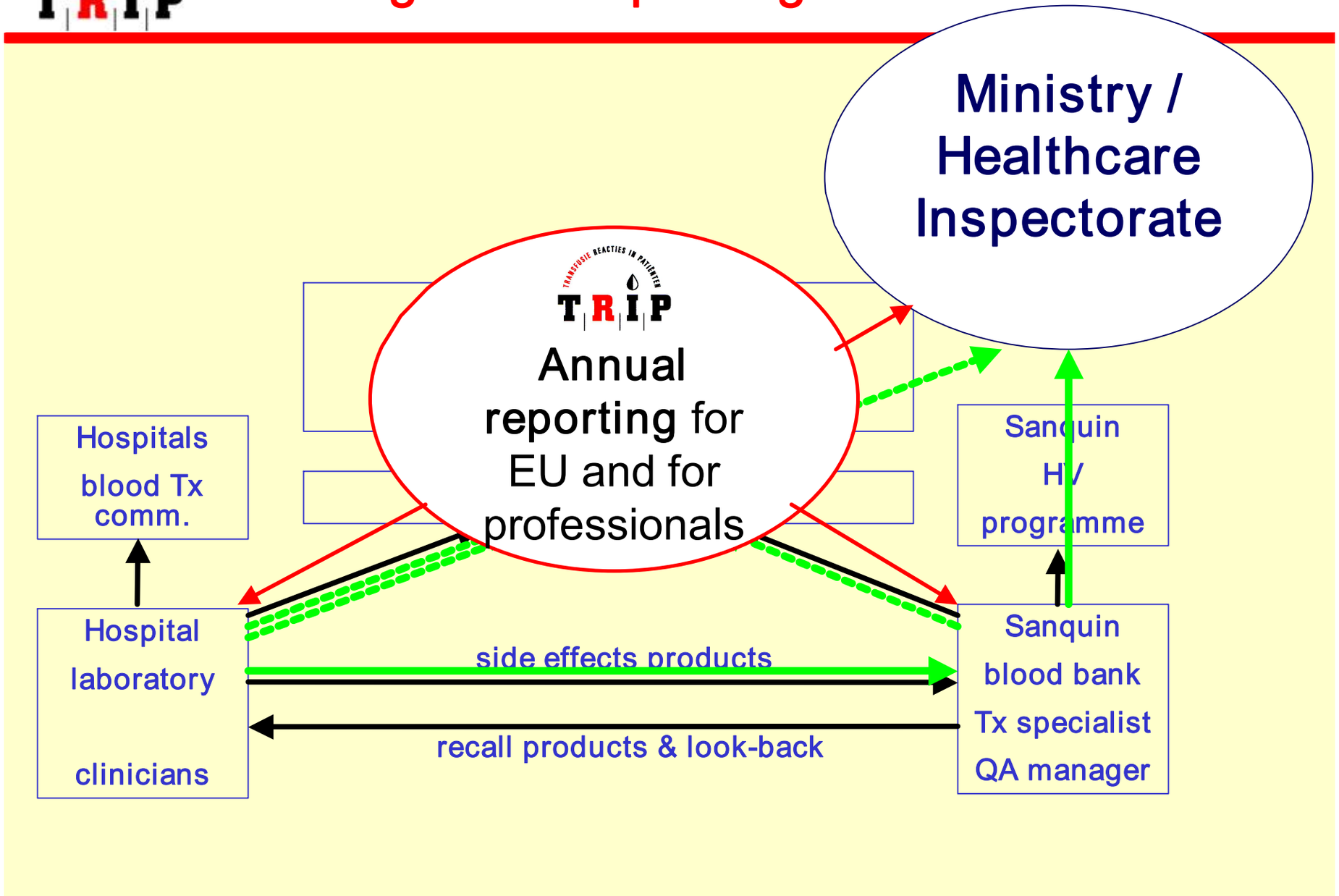

Additional factors

1. Patient safety movement

2. Tissue vigilance

Patient safety movement

All hospitals must implement a risk management system by 1st January 2008

Patient safety movement (2)

- Commercial activity
- One department of a hospital doesn't know what another is already doing
- Challenge to TRIP to ride this wave and turn it to the advantage of hemovigilance

Tissue vigilance

- Directive 2004/23/EC
- TRIP asked to set up compliant tissue vigilance system
  – read more about this on our poster
- Links between hemovigilance and tissue vigilance activity will lead to mutual benefit.

Advantages of the TRIP system

- scientifically validated data using agreed definitions
- more complete, speedier information (electronic reporting)
- user-friendly system (no need for paper reports)
- stimulus for research
- relatively cheap (€ 360,000 p.a.)

Advantages of the TRIP system 2

- strengthening of (international) scientific ties, learning from each other
- not just product focus, but chain-wide approach
- findings available to professionals in the transfusion and transplantation chains
- development of professional standards

Weaknesses of TRIP system

- Dependent on willingness of professionals to report
- Late reporting (cold hemovigilance)
- Difficult to fund staff in the hospitals
- Simultaneous initiatives on the same subject possible (no official central steering)
- “Polder model”: many people decide. Democratic, effective but slow !