

# Global Issues and Regulatory Aspects in in Eye Banking

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# Topics

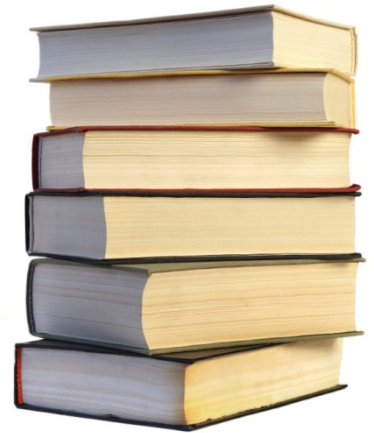


Australia and New  
Zealand Eye Banking



Global Issues

Regulations for  
Biologicals







## *Australia and Europe area comparison*

Australia's area: 7.7 million sq km

Europe's area (shown): 3.5 million sq km

Darwin to Perth 4396 km • Perth to Adelaide 2707 km • Adelaide to Melbourne 726 km  
 Melbourne to Sydney 887 km • Sydney to Brisbane 972 km • Brisbane to Cairns 1748 km







PERTH

ADELAIDE

MELBOURNE

SYDNEY

BRISBANE

AUCKLAND



2011

1288 donors

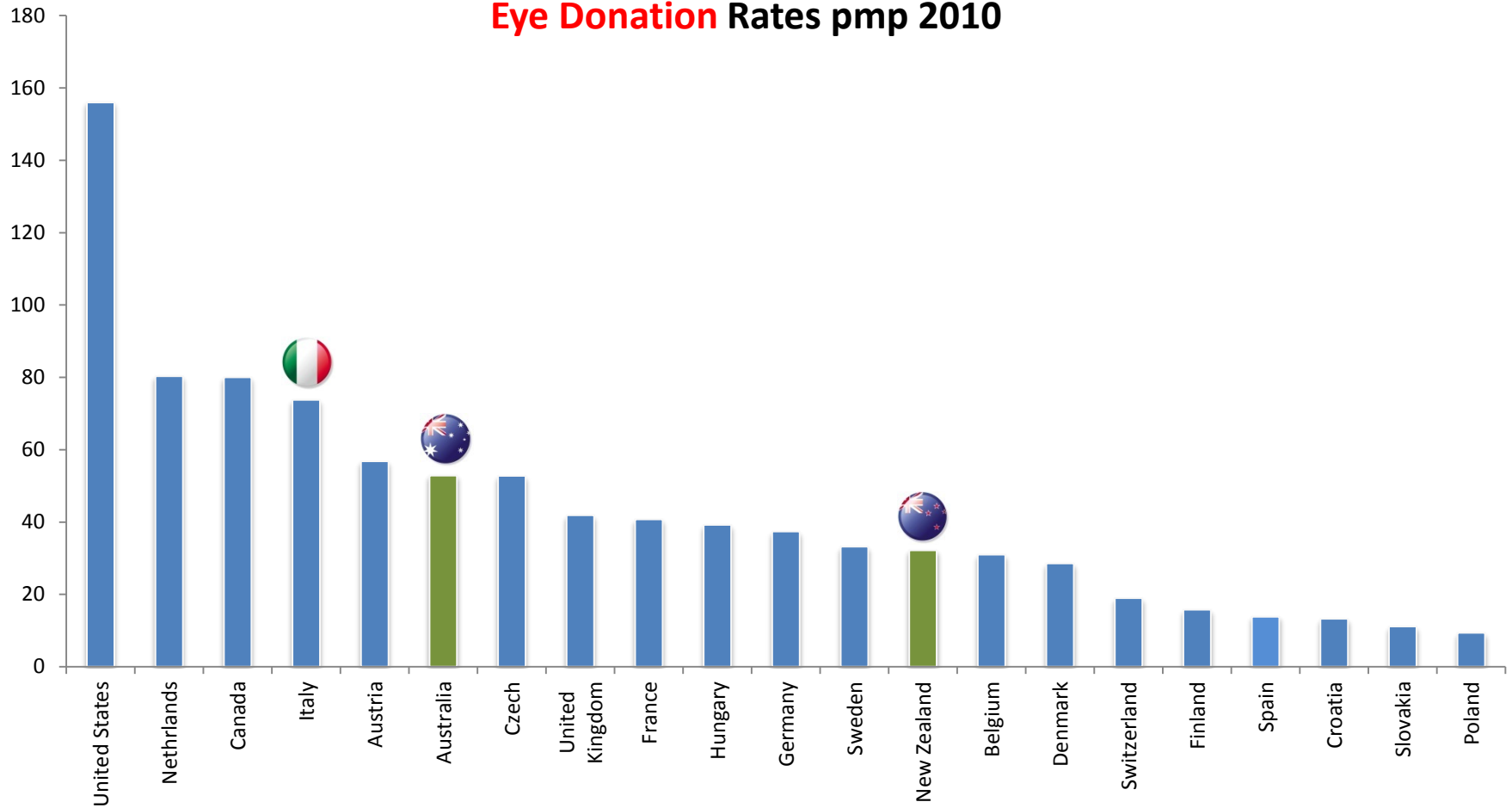
77%

Utility rate

1992 transplants



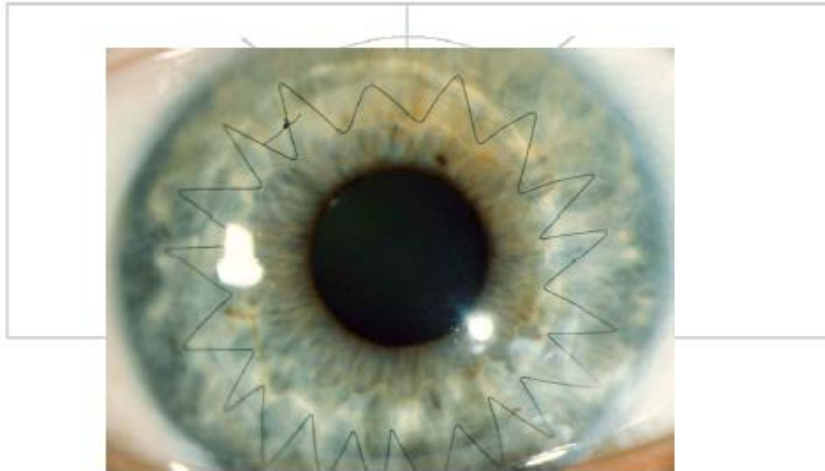
## Eye Donation Rates pmp 2010







## THE AUSTRALIAN CORNEAL GRAFT REGISTRY



### 2012 REPORT

This report was published with assistance from

The Australian Organ and Tissue Donation and Transplantation Authority  
(DonateLife)

23,000 transplants

26 years

Recipient  
Donor  
Eye Bank Practices  
Operative Procedure

Google  
*"Australian Corneal Graft  
Registry"*  
for full 248 page report.

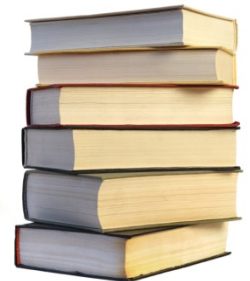
# Regulatory Aspects



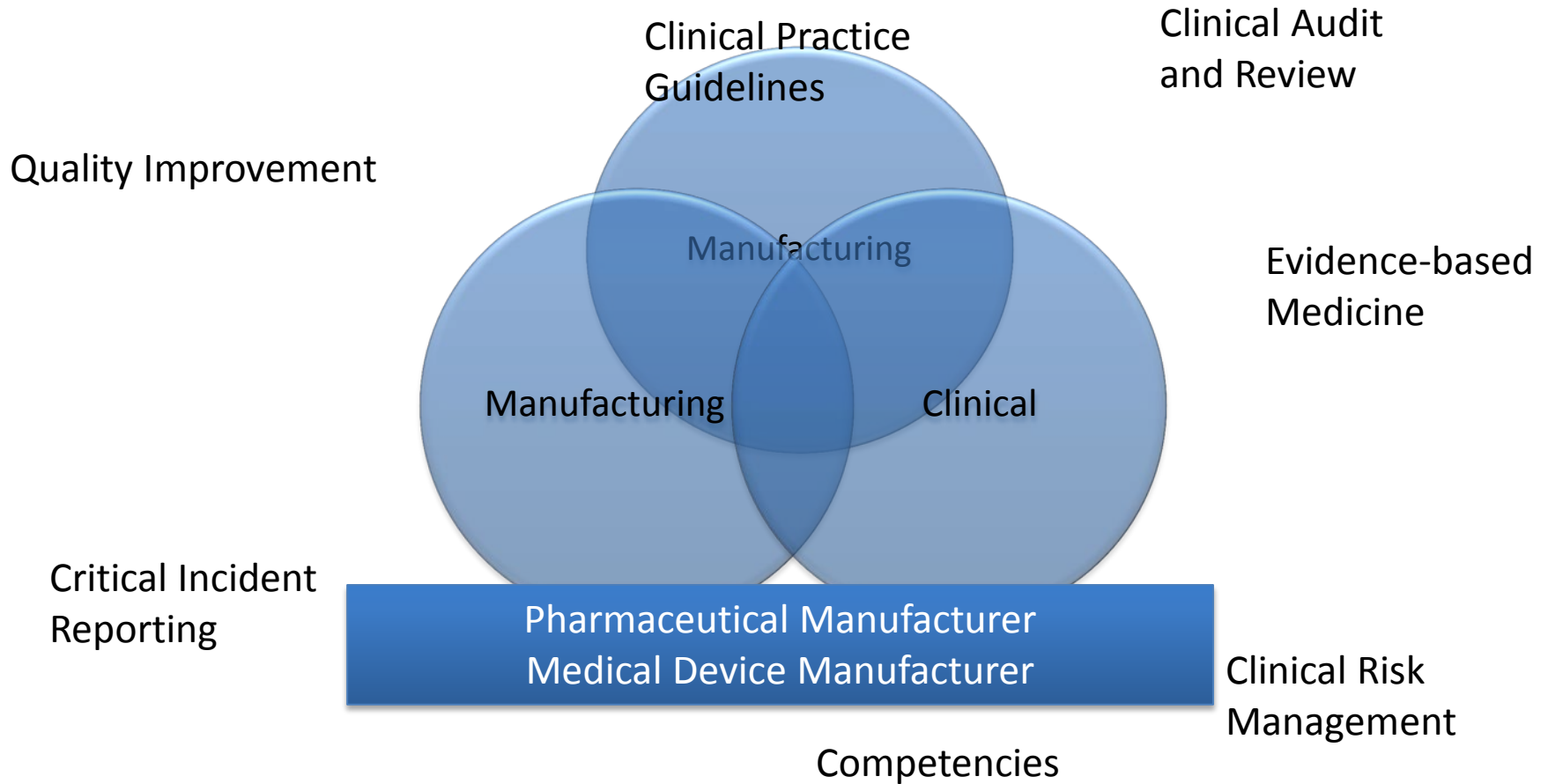


# Therapeutic Goods Administration (TGA)

- Competent Authority
  - Pharmaceuticals and Medical Devices
- Regulated, Audited and Licensed Eye Banks since 1995
- Used ISO approach of Good Manufacturing Practice



# Approaches to Quality



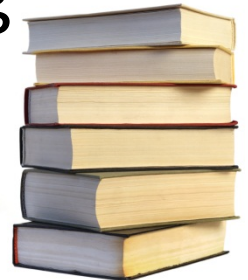


# Therapeutic Goods Administration (TGA)

- Revised approach in 2010
  - Biologicals Framework
  - Standards based on Eye Bank Association of Australia and New Zealand Medical Standards
  - Risk management approach to regulation

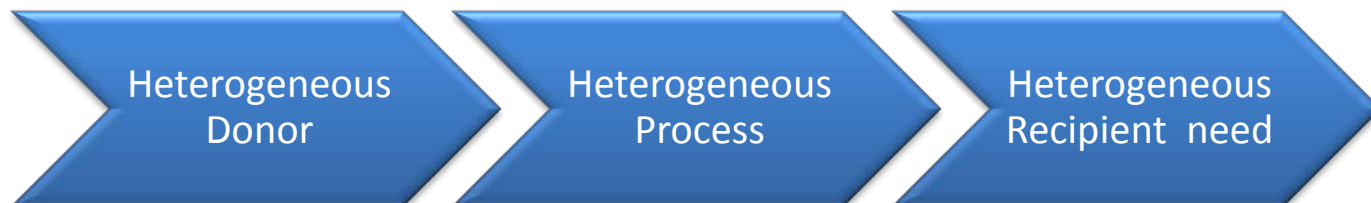
*but*

- Implementation still uses manufacturing approach



# How well does the Manufacturing Approach to Quality Fit with Eye Banking?

Principles	Eyes
Standard starting materials (specifications)	
Processing (=manipulation & change)	 
Batch test	
Meet final specifications	 
Sterile	





# Disagreement

## Microbiology

- Sterility
- Bioburden Testing

## Degree of Risk

## Validation

- Testing for Infectious Disease
- Processes
- Microbiology



# Residual Risk

## Serology Testing

	Window Period (days)†	Incidence (no./100,000 person years)	Probability (no./100,000 donors)	Odds of missing infected eye donor
Anti-HIV	22	0.35	0.0211	<b>1 in 4,739,336</b>
HBsAg	59	1.29	0.2085	<b>1 in 479,613</b>
Anti-HCV	70	3.02	0.5792	<b>1 in 172,651</b>

†Dodd et.al., 2002

Odds comparison with  
other demographics

	Australian musculoskeletal donors	United States tissue donors
Anti-HIV	1 in 128,000	1 in 55,096
HBsAg	1 in 188,000	1 in 33,760
Anti-HCV	1 in 55,000	1 in 42,122



# Residual Risk Transmission

	Probability of infected donor (no./100,000)	Theoretical rate of transmission (%inoculated)	Probability of transmission (no./100,000)	Risk of transmission after serology testing
HIV	0.0211	0.3	0.0001013	<b>1 in 987,361,769</b>
HBV	0.2085	3-60	0.010-0.125	<b>1 in 799,360-9,992,006</b>
HCV	0.5792	1.8	0.0167	<b>1 in 5,994,858</b>

## Iatrogenic Transmission of Disease

Rabies	8 (5 donors)
CJD	1 (now thought unlikely)
Retinoblastoma	1
Adenocarcinoma of Iris	1
Hepatitis B	2 (2 donors)



# Microbiological Risk

Adverse Reaction	Percent for year 2011
Primary Graft Failures	0.043 ↓ (59% endothelial keratoplasty)
Endophthalmitis	0.015 ↓ (70% endothelial keratoplasty) ↓ (71% cut by surgeon)
Keratitis	0.009 ↓ (50% endothelial keratoplasty) ↓ (64% cut by surgeon)
Sclera	0

# Impact of Regulation (Australia)

- ***Cost increases***
  - Increased testing
  - Staff
- ***Difficulty accessing laboratory services***
  - Withdrawn services or not available
  - TGA license is expensive (time, effort and money) and difficult to maintain
- ***Withdrawal of some items***
  - amnion
  - More in tissue sector



- **Emphasise the unique nature of Eye Banking**
  - It is not Tissue Banking
- **Resist any manufacturing approach**
  - It is a clinical service
- **Base practice on Evidence and Outcome**
  - Monitor outcome and adverse events (yours and others)
- **Organise and Advocate**
  - EEBA, SIBO
  - Set standards



# The Importance of EEBA, SIBO and Eye Banks



Data



Surveillance  
& Vigilance



Epidemiology  
& Risk Management

***Bureaucracies are very poor in collating and interpreting meaningful data***

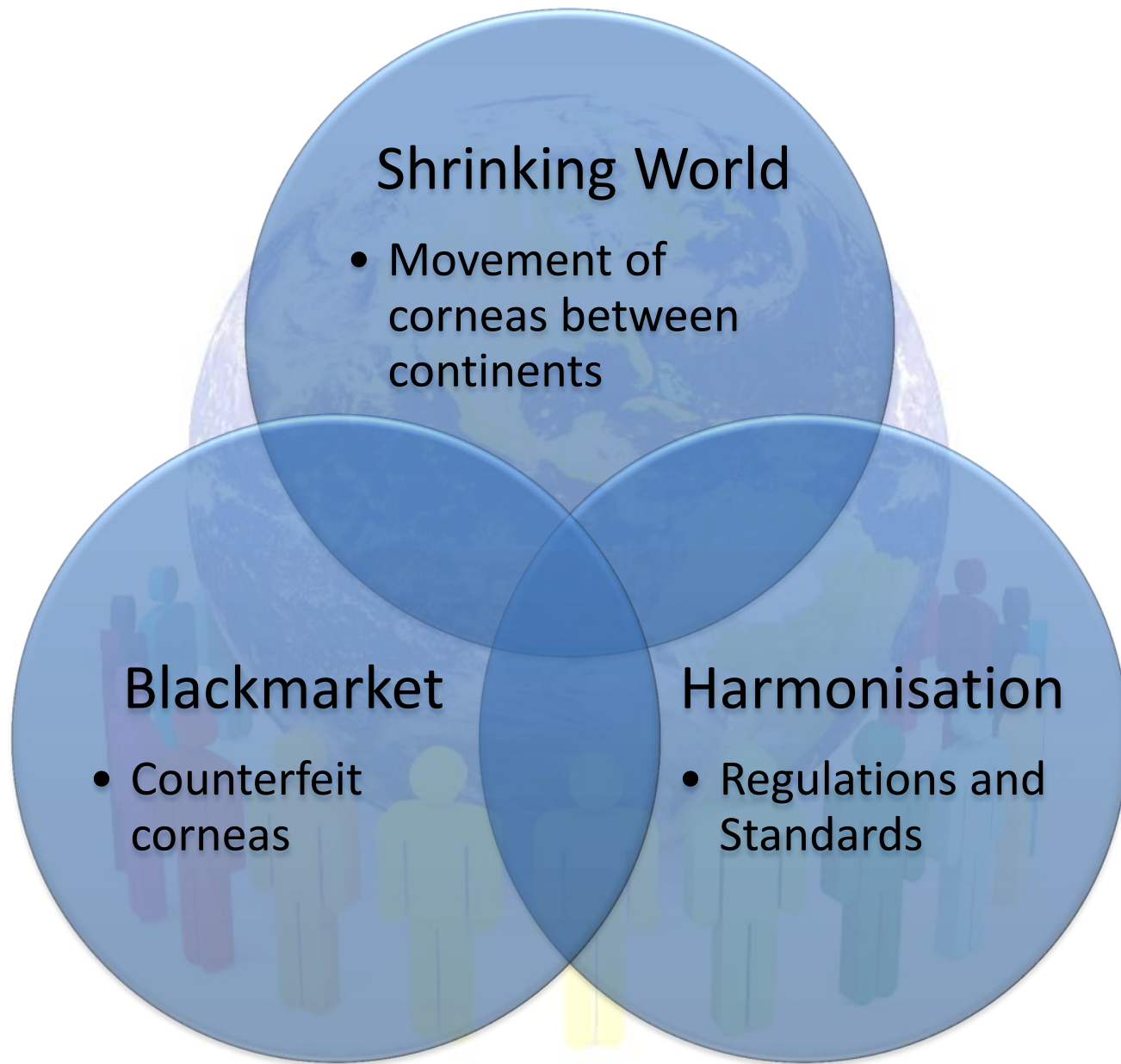
***Scientific and Professional Societies***

- ***Know what data needs to be collected***
- ***Can troubleshoot the data***
- ***Can interpret the data***



# Global Issues







**EYE BANK  
ASSOCIATION  
of AMERICA**

## **URGENT ALERT**

DATE: October 1, 2012

TO: EBAA Members

FROM: Kevin Corcoran, President & CEO  
Jennifer DeMatteo, Director of Regulations & Standards

RE: **POSSIBLE FALSIFICATION OF EXPORTED (OVERSEAS) U.S. TISSUE DOCUMENTATION**

Recently, EBAA received the following message from a member eye bank:

“We have recently had an (EBAA) member eye bank contact us regarding a tissue evaluation form they received from an international surgeon that seemed to have come from our eye bank. They contacted our Technical Director because they felt the form may have been tampered with. Our Technical Director had them forward us the form to check out. Upon receipt we realized the form was definitely not from us, seeing as how there were several rather severe discrepancies in the information on the form. The eye bank that had communication with the surgeon informed us that the surgeon had received this tissue from a Dr. Amr El Sheshtawy with forged paperwork with our name on it.”





# Worldwide Data (Activity)

**Donors**

**Transplants**

**Movement**



**EBAA vs Eurocet?**

# Data and Coding



- Standardised terminology and coding for Eye Banking – **counting the same thing**

- ICCBBA



- Developed and supported by:





# Surveillance and Vigilance

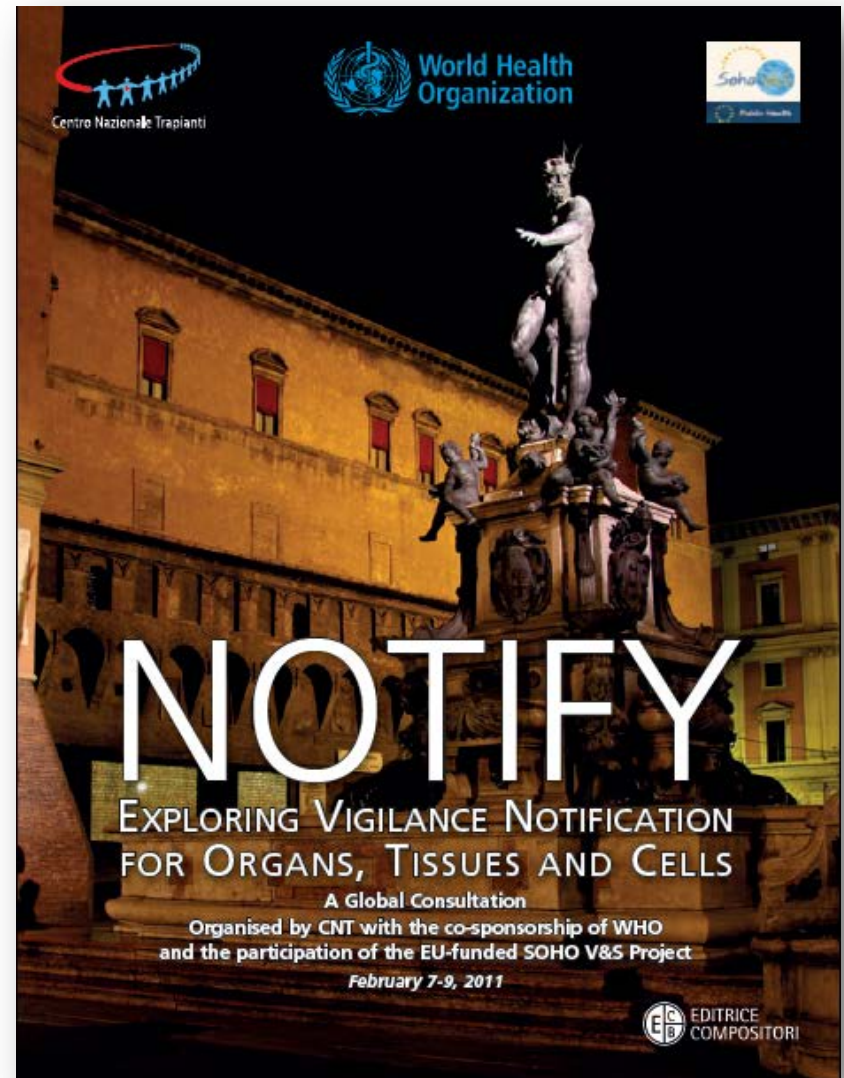
Surveillance of severe adverse reactions and events

- **Globally**

Participation and advice of Scientific and Professional Societies



Relevance – base practice on evidence and outcome





# Global Alliance of Eye Bank Associations



**Share Best Practices and Guidelines**



**Establish a Worldwide Register of Eye Banks**



**Develop & Promote Global Coding, Traceability Efforts and Bio-Vigilance Systems for Ocular Tissue**

**Provide Global Advocacy for Eye Donation and Eye Banking**



**Share of Information on Scientific Meetings / Conferences / Workshops**



# Global Alliance of Eye Bank Associations



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## MEMORANDUM OF UNDERSTANDING

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Global Alliance of Eye Bank  
Associations

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2012

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RIO DE JANEIRO  
8-9 AUGUST 2013

Grazie per la vostra  
attenzione e pazienza

Accolgo con favore  
tutte le domande

