



## The NOTIFY project - general overview



Centro Nazionale Trapianti  
Italian National Transplant Centre



WHO Collaborating Centre  
on Vigilance and Surveillance for  
Human Cells, Tissues and Organs

## WORLD HEALTH ASSEMBLY RESOLUTION WHO 63.22

**Resolution 63.22** of the World Health Assembly was adopted in 2010 and gave WHO a mandate to **facilitate Member State access to appropriate informations** on donation, processing and transplantation of tissues, cells and organs, including data about serious adverse events and reactions.

# NOTIFY PROJECT



**Sharing vigilance experience and  
knowledge globally  
- the NOTIFY Project (WHO)**

## NOTIFY PROJECT: AIMS

**To provide professionals with relevant information helpful for determining the suitability of a potential donor.**

**To draft common guidelines supporting the implementation of effective vigilance and surveillance**

**To provide practical support to countries that are developing vigilance systems for Medical Products of Human Origin (MPHO)**

# NOTIFY PROJECT: TIMELINE

CNT nominated as WHO Collaborating Centre

2010

The  
NOTIFY  
Google  
Site

2011

BOLOGNA  
The  
Bologna  
Meeting

2012

GENEVA BIG  
V&S  
1° Global  
Consultation  
on V&S

ROMA  
2° Global  
Consultation

2013

BRASILIA  
MPHO

2014

BARCELONA  
Transfusion

2015

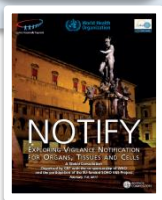
BARCELONA  
Technical  
Meeting

2016

ROME  
Second  
Technical  
meeting

2018

BRUSSELS  
Global  
Vigilance  
Networking  
NOTIFY and  
VISTART joint  
meeting



BOLOGNA  
Strategic  
meeting for  
the WHO  
MPHO  
INITIATIVE

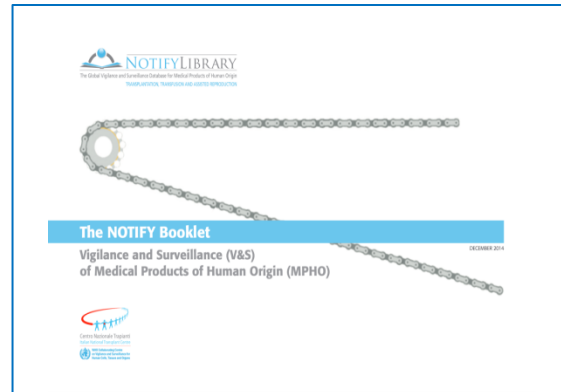
UPDATE OF THE NOTIFY BOOKLET!!

During this period more than 260 international Experts contributed to the content of the **NOTIFY Project**, its goals and in the improvement of the Notify Library

# NOTIFY PROJECT: MAIN COMPONENTS

1. NOTIFY website: <http://www.notifylibrary.org>

2. NOTIFY Booklet



3. NOTIFY Library



# NOTIFY WEBSITE



The Global Vigilance and Surveillance Database for Medical Products of Human Origin  
TRANSPLANTATION, TRANSFUSION AND ASSISTED REPRODUCTION



Centro Nazionale Trapianti  
Italian National Transplant Centre



WHO Collaborating Centre  
on Vigilance and Surveillance for  
Human Cells, Tissues and Organs

## THE NOTIFY PROJECT +

- History
- Who we are
- Interviews ▶
- Useful links
- Global consultation reports

## SEARCH LIBRARY +

- Search tutorial
- Adverse occurrence search
- Reference search
- Bibliographic list ▶
- Add or update record
- Editorial Group Guidelines ▶
- Database content analysis

## NOTIFY BOOKLET +

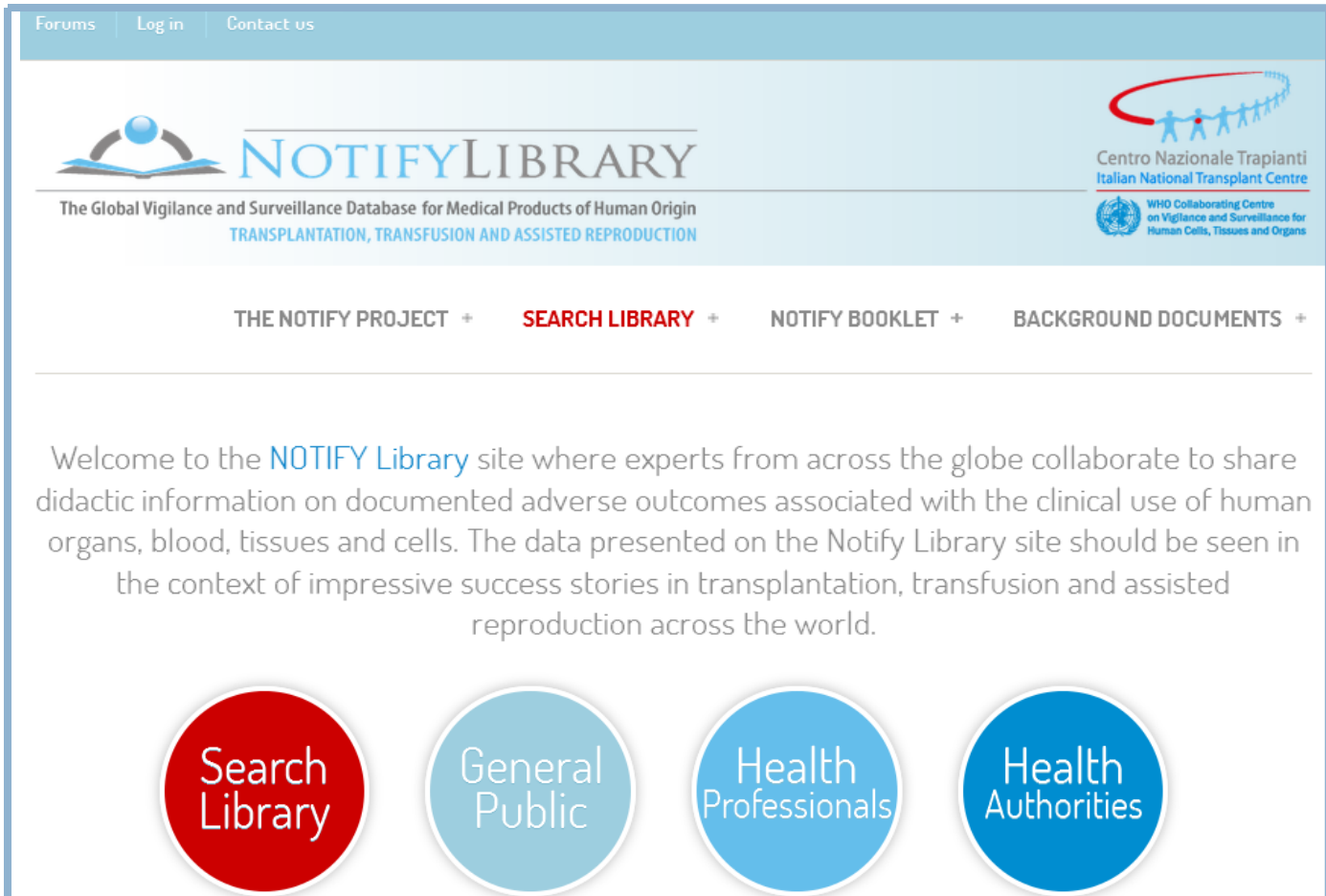
- 1 Introduction
- 2 The V&S Chain for MPHOs
- 3 History of Vigilance and Surveillance
- 4 Medical products of Human Origin (MPHO)
- 5 Towards a global governance of MPHO
- 6 The V&S system is primarily a responsibility for health authorities

## BACKGROUND DOCUMENTS +

- WORLD HEALTH ORGANISATION (WHO) AND WORLD HEALTH ASSEMBLY (WHA)
- RECOMMENDATIONS ▶ FOR EPIDEMIC DISEASE OCCURRENCE
- VIGILANCE GUIDANCE DOCUMENTS
- VIGILANCE AND SURVEILLANCE REPORTS


# NOTIFY WEBSITE


The website is maintained and updated on this platform and is intended as a **communication hub** for institutions and organisations worldwide collaborating in the facilitation of access to Vigilance and Surveillance information.




The screenshot shows the NOTIFYLIBRARY website interface. At the top, there is a navigation bar with links for 'Forums', 'Log in', and 'Contact us'. Below this is the main header area, which includes the NOTIFYLIBRARY logo on the left and the logo of the Centro Nazionale Trapianti (Italian National Transplant Centre) on the right. The logo of the WHO Collaborating Centre on Vigilance and Surveillance for Human Cells, Tissues and Organs is also present. Below the header, there is a horizontal menu with four items: 'THE NOTIFY PROJECT +', 'SEARCH LIBRARY +', 'NOTIFY BOOKLET +', and 'BACKGROUND DOCUMENTS +'. The main content area features a welcome message: 'Welcome to the NOTIFY Library site where experts from across the globe collaborate to share didactic information on documented adverse outcomes associated with the clinical use of human organs, blood, tissues and cells. The data presented on the Notify Library site should be seen in the context of impressive success stories in transplantation, transfusion and assisted reproduction across the world.' At the bottom, there are four circular buttons: 'Search Library' (red), 'General Public' (light blue), 'Health Professionals' (medium blue), and 'Health Authorities' (dark blue).

Forums | Log in | Contact us

 **NOTIFYLIBRARY**  
The Global Vigilance and Surveillance Database for Medical Products of Human Origin  
TRANSPLANTATION, TRANSFUSION AND ASSISTED REPRODUCTION

  
Centro Nazionale Trapianti  
Italian National Transplant Centre

 WHO Collaborating Centre  
on Vigilance and Surveillance for  
Human Cells, Tissues and Organs

THE NOTIFY PROJECT + **SEARCH LIBRARY** + NOTIFY BOOKLET + BACKGROUND DOCUMENTS +

Welcome to the [NOTIFY Library](#) site where experts from across the globe collaborate to share didactic information on documented adverse outcomes associated with the clinical use of human organs, blood, tissues and cells. The data presented on the Notify Library site should be seen in the context of impressive success stories in transplantation, transfusion and assisted reproduction across the world.

**Search Library** **General Public** **Health Professionals** **Health Authorities**



# NEW! NOTIFY CONSULTATION GROUP



NOTIFYLIBRARY

The Global Vigilance and Surveillance Database for Medical Products of Human Origin  
TRANSPLANTATION, TRANSFUSION AND ASSISTED REPRODUCTION



Centro Nazionale Trapianti  
Italian National Transplant Centre



WHO Collaborating Centre  
on Vigilance and Surveillance for  
Human Cells, Tissues and Organs

THE NOTIFY PROJECT +

**SEARCH LIBRARY** +

NOTIFY BOOKLET +

BACKGROUND DOCUMENTS +

Welcome to the [NOTIFY Library](#) site where experts from across the globe collaborate to share didactic information on documented adverse outcomes associated with the clinical use of human organs, blood, tissues and cells. The data presented on the Notify Library site should be seen in the context of impressive success stories in transplantation, transfusion and assisted reproduction across the world.

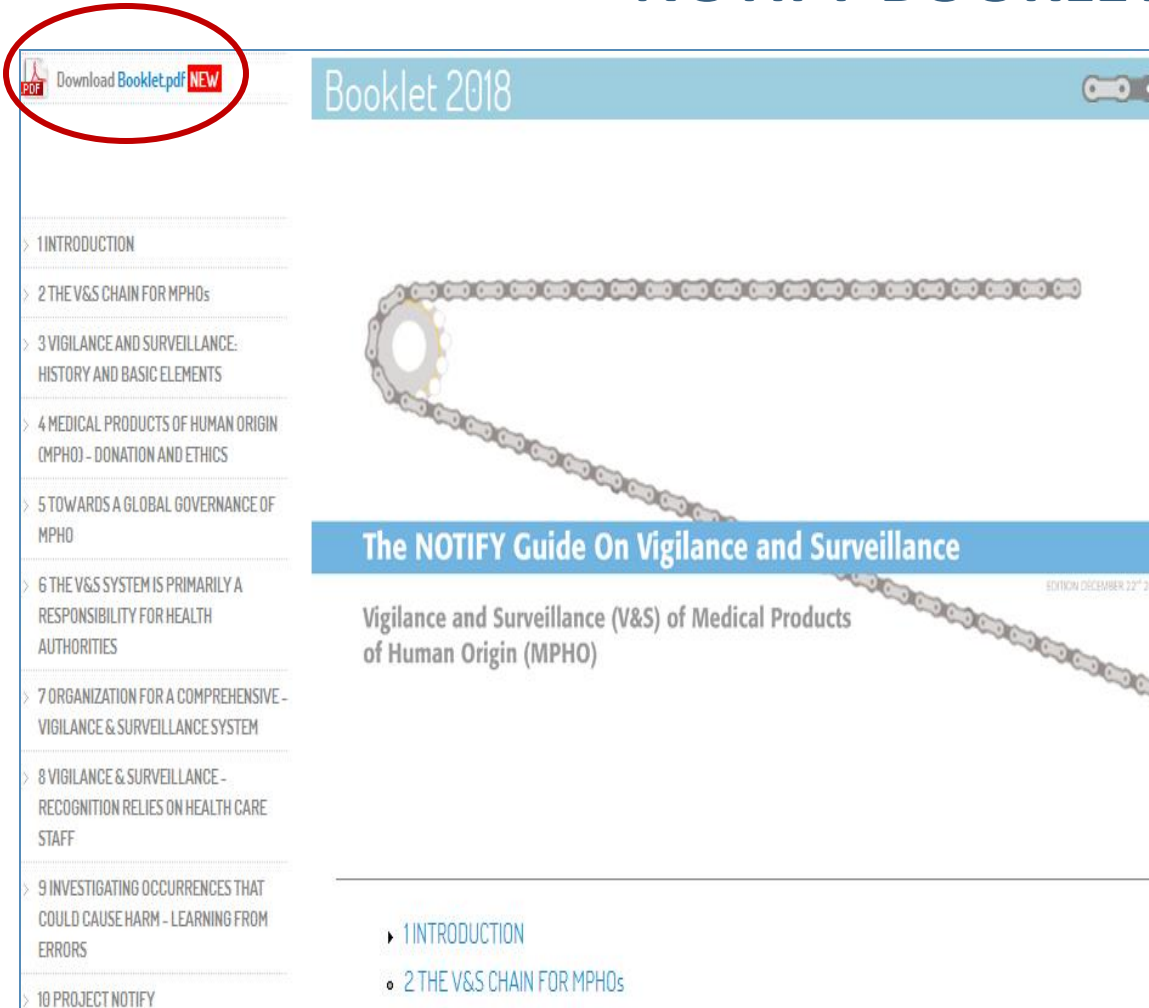


Ask our experts for advice on vigilance and surveillance



Inform us of a case/reference for the Library

# NOTIFY BOOKLET



**Booklet 2018**

[Download Booklet.pdf NEW](#)

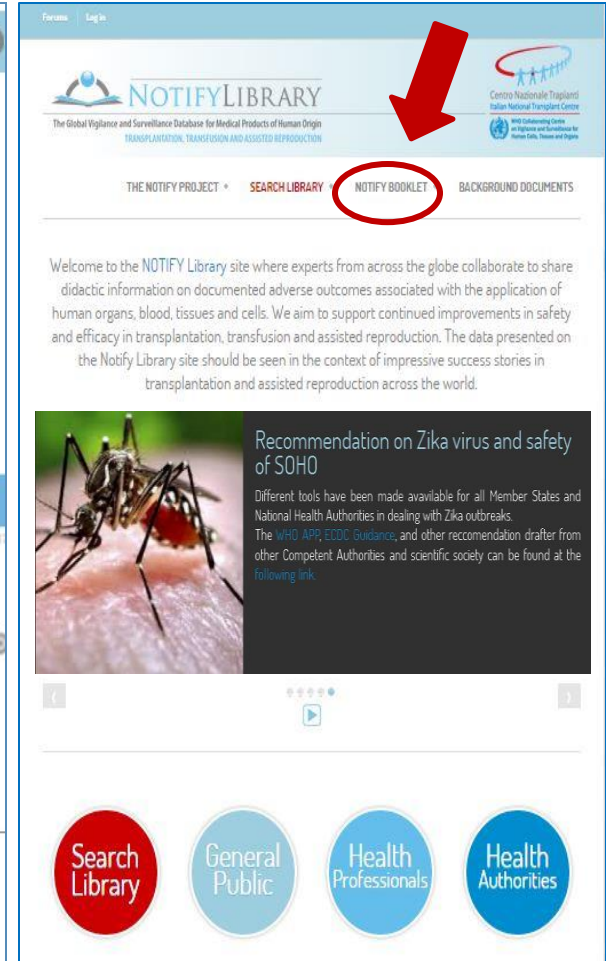
- > 1 INTRODUCTION
- > 2 THE V&S CHAIN FOR MPHOs
- > 3 VIGILANCE AND SURVEILLANCE: HISTORY AND BASIC ELEMENTS
- > 4 MEDICAL PRODUCTS OF HUMAN ORIGIN (MPHO) - DONATION AND ETHICS
- > 5 TOWARDS A GLOBAL GOVERNANCE OF MPHO
- > 6 THE V&S SYSTEM IS PRIMARILY A RESPONSIBILITY FOR HEALTH AUTHORITIES
- > 7 ORGANIZATION FOR A COMPREHENSIVE - VIGILANCE & SURVEILLANCE SYSTEM
- > 8 VIGILANCE & SURVEILLANCE - RECOGNITION RELIES ON HEALTH CARE STAFF
- > 9 INVESTIGATING OCCURRENCES THAT COULD CAUSE HARM - LEARNING FROM ERRORS
- > 10 PROJECT NOTIFY

**The NOTIFY Guide On Vigilance and Surveillance**

Vigilance and Surveillance (V&S) of Medical Products of Human Origin (MPHO)

- ▶ 1 INTRODUCTION
- 2 THE V&S CHAIN FOR MPHOs

**Interactive Booklet through an index**



Forums Login

**NOTIFYLIBRARY**  
The Global Vigilance and Surveillance Database for Medical Products of Human Origin  
TRANSPLANTATION, TRANSFUSION AND ASSISTED REPRODUCTION

Centro Nazionale Trapianti  
Italian National Transplant Centre  
WHO Collaborating Centre  
on Safety and Surveillance for Human Cells, Tissues and Organs

THE NOTIFY PROJECT • [SEARCH LIBRARY](#) • [NOTIFY BOOKLET](#) • [BACKGROUND DOCUMENTS](#)

Welcome to the NOTIFY Library site where experts from across the globe collaborate to share didactic information on documented adverse outcomes associated with the application of human organs, blood, tissues and cells. We aim to support continued improvements in safety and efficacy in transplantation, transfusion and assisted reproduction. The data presented on the Notify Library site should be seen in the context of impressive success stories in transplantation and assisted reproduction across the world.

**Recommendation on Zika virus and safety of SOHO**  
Different tools have been made available for all Member States and National Health Authorities in dealing with Zika outbreaks. The WHO APP, ECDC Guidance, and other recommendation drafted from other Competent Authorities and scientific society can be found at the following link.

[Search Library](#) [General Public](#) [Health Professionals](#) [Health Authorities](#)

# NOTIFY LIBRARY

- **publically accessible online database of didactic cases** of severe adverse reactions and events
- **from procurement and processing to clinical application** of blood, organs, tissues and cells used in transfusion, transplantation and assisted reproduction
- collected and analyzed by dedicated editorial groups of international experts, regulators and clinicians and **linked to their source reference:**
  - ✓ literature review (published articles in scientific journals and/or books)
  - ✓ case reports from regulatory or professional vigilance programs (grey literature)



# WHO WE ARE

**NOTIFY LIBRARY**  
The global vigilance and surveillance database for medical products of human origin (MPHO)  
**TRANSPLANTATION, TRANSFUSION, ASSISTED REPRODUCTION**

ITALIAN NATIONAL TRANSPLANT CENTRE  
(CNT)

WHO Collaborating Centre on  
Vigilance and Surveillance for  
Human Cells, Tissues and Organs

WORLD HEALTH ORGANISATION  
(WHO)

## STEERING GROUP

Alessandro Nanni Costa  
General Director - CNT, ROME

Jose Ramon Nunez  
Adviser - MPHO Service Delivery  
and Safety Department -  
WHO, GENEVE

Douglas Michael Strong  
SEATTLE

Deirdre Fehily  
DG SANTE - EC, Brussels

## EDITORIAL GROUP

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Eduard Muñoz-Díaz

## COLLABORATING PARTNER

Rafael Matesanz  
General Director -  
ONT, MADRID

Jaume Tort  
General Director -  
OCATT, BARCELONA

## NOTIFY OPERATIONAL TEAM

### Communication

Aurora Navarro  
OCATT - BARCELONA

### Clinical/Scientific Database Content

Evangelia Petrisli  
St. Orsola Malpighi Hospital - Bologna; CNT - ROME

### Project Assistant

Claudia Carella  
CNT - ROME

### Website and DB Development/Maintenance; Library Information Science support

Daniela Minutoli  
CNT - ROME

### Hardware and Software support

Pier Nicola Massimi  
CNT - ROME

# NOTIFY LIBRARY: ADVERSE OCCURRENCE DEFINITIONS

- 1. Severe Adverse Event (SAE):** any untoward occurrence, associated with the chain, from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalization or morbidity. *In the NOTIFY project these are referred to as cases of 'Risk of Harm'.*
- 2. Severe Adverse Reaction (SAR):** any unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalization or morbidity. *In the NOTIFY project these are referred to as cases of 'Harm to Donor', 'Harm to Recipient' or 'Harm to Fetus/Offspring'.*

# NOTIFY LIBRARY: SEARCH PAGE

## Adverse occurrence search

### Adverse occurrence type

(Expand all) (Clear)

Harm to a Recipient

Harm to a Donor

Harm to a Fetus or Offspring

Risk of harm

### Medical Products of Human Origin type - MPH0

(Expand all) (Clear)

Organs

Blood

Cells

Tissues

Reproductive

Derived medicinal products

Other

**FREE  
SEARCH**



#### Keywords

(searches keywords identified by the Notify editors)

#### Free text

(searches the text in the database cases and includes alerting signals, imputability and keywords)

#### Notify Library Record ID

(searches by Notify Library Record ID, for multiple records separated by commas)

Limit results 100 per page ▼

SEARCH

Reset

Print/Save selected items

New search



# NOTIFY LIBRARY: SEARCH RESULTS

## Search criteria:

**Adverse occurrence:** Risk of harm

**Medical Product of Human Origin type - MPH0:** Tissues >> Ocular

Feedback questionnaire

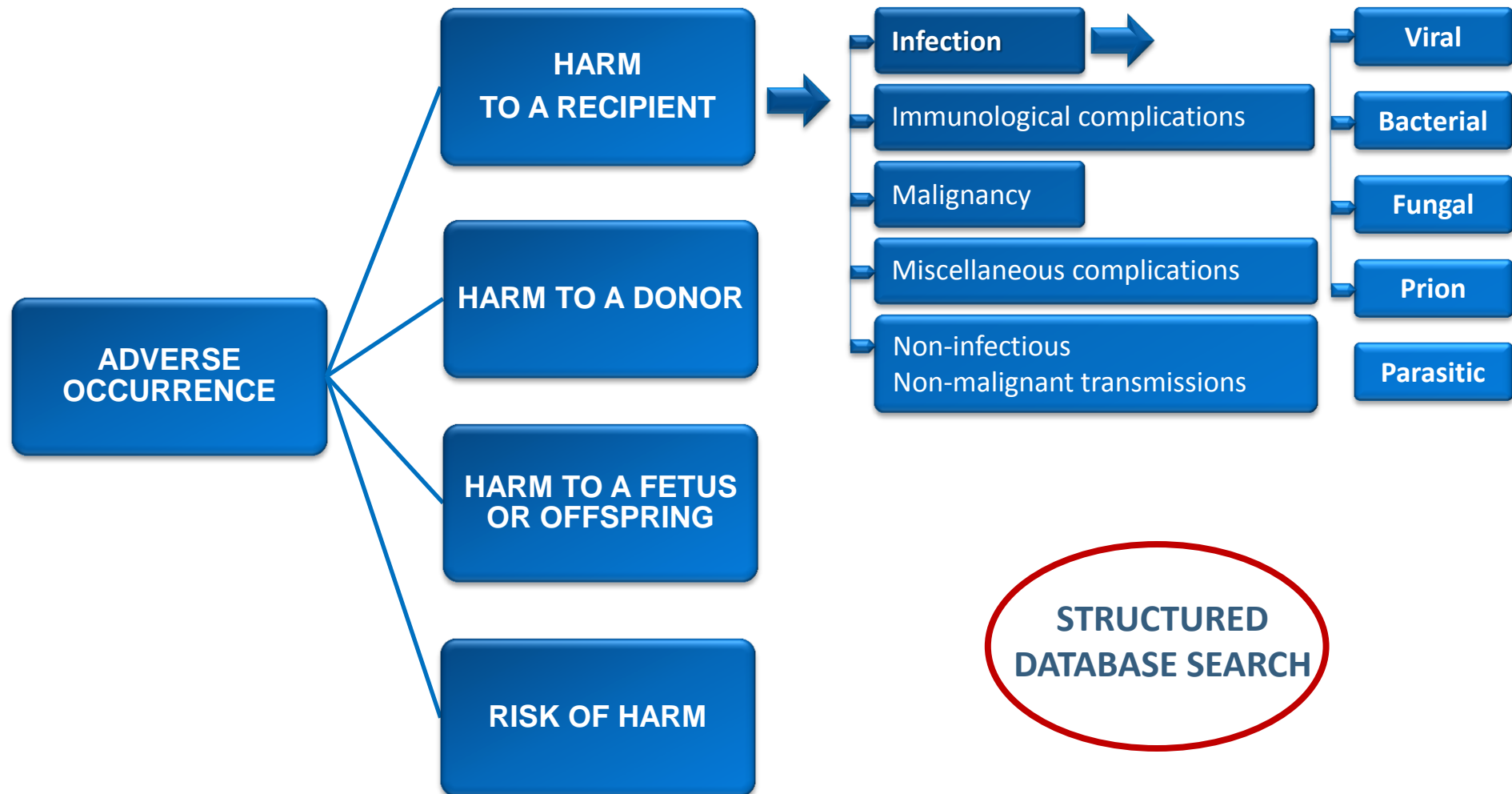
[4466] Li, J.Y.

[Donors with melanoma history: the risk to ocular tissue recipients](#)

International Journal of Eye Banking 2016; 4 (1) :1-4

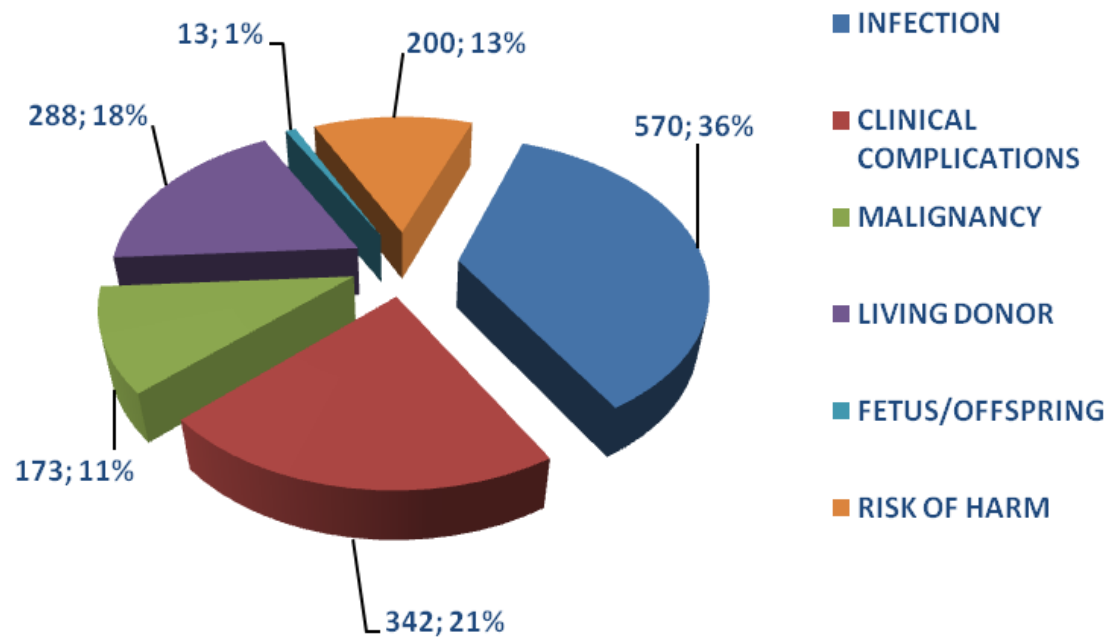
<input type="checkbox"/> Record ID	Adverse occurrence	
<input type="checkbox"/> 1683	<p><b>Adverse occurrence description:</b> Subject review: Donors with melanoma history and risk to ocular tissue recipients</p> <p><b>Adverse occurrence type:</b> Risk of harm =&gt; Other</p> <p><b>MPH0 type:</b> Tissues =&gt; Ocular =&gt; Cornea</p> <p><b>Time to detection:</b> 2 months</p> <p><b>Alerting signals, symptoms, evidence of occurrence:</b> Recipient developed ocular melanoma within two months of surgery.</p> <p><b>Estimated frequency:</b> Rare; Review article written in response to single case report of melanoma transmission following keratolimbal allograft. No existing reports in literature documenting melanoma transmission from corneal transplant. Based on the case report a moratorium on use of ocular tissue from donors with melanoma (restricted from all use) and donors with metastatic solid tumors (not to be released for use of vascular components) was issued in February 2016 to be reviewed by the Eye Bank Association of America in October 2016.</p> <p><b>Demonstration of Imputability or Root cause:</b> Donor had history of malignant melanoma.</p> <p><b>Imputability grade:</b></p> <p><b>Expert comments for publication:</b> Article was written as a review at the time of active discussion regarding the appropriate response to the cited case report. It is pointed out that donors with solid tumors constitute 30-40% of the ocular donor pool. In the case of melanoma, micrometastases raise concern for the possibility of transmission, but in practice this has not been seen. Possible factors contributing to the absence of known transmissions include the avascular nature of cornea and absence of immunosuppressive drugs. It is also noted that vascularized ocular components (such as keratolimbal allografts) also require immunosuppression and may have tumor transmission risks more similar to solid organ transplants. The article discusses the need to balance restoring sight and patient safety in the difficult setting of limited available evidence.</p> <p><b>Keywords:</b></p> <p>cornea transplantation   cornea   melanoma   subject review   keratolimbal   metastasis   exclusion criteria</p>	<p>1 reference</p>

# NOTIFY LIBRARY: ADVERSE OCCURRENCE TYPE TAXONOMY (extract)



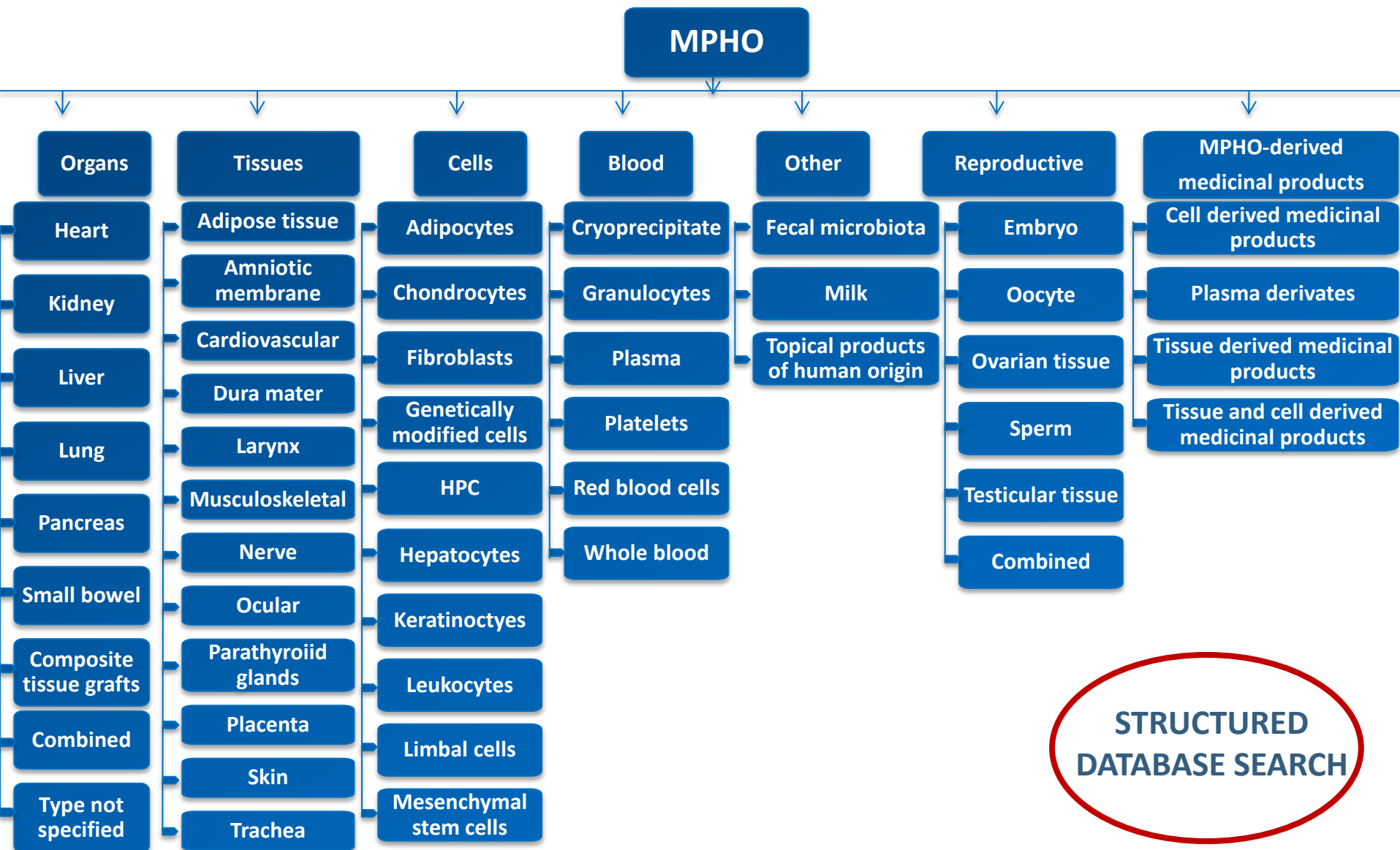


## NOTIFY LIBRARY: UPLOADED RECORDS BY ADVERSE OCCURRENCE TYPE (n=1,586)

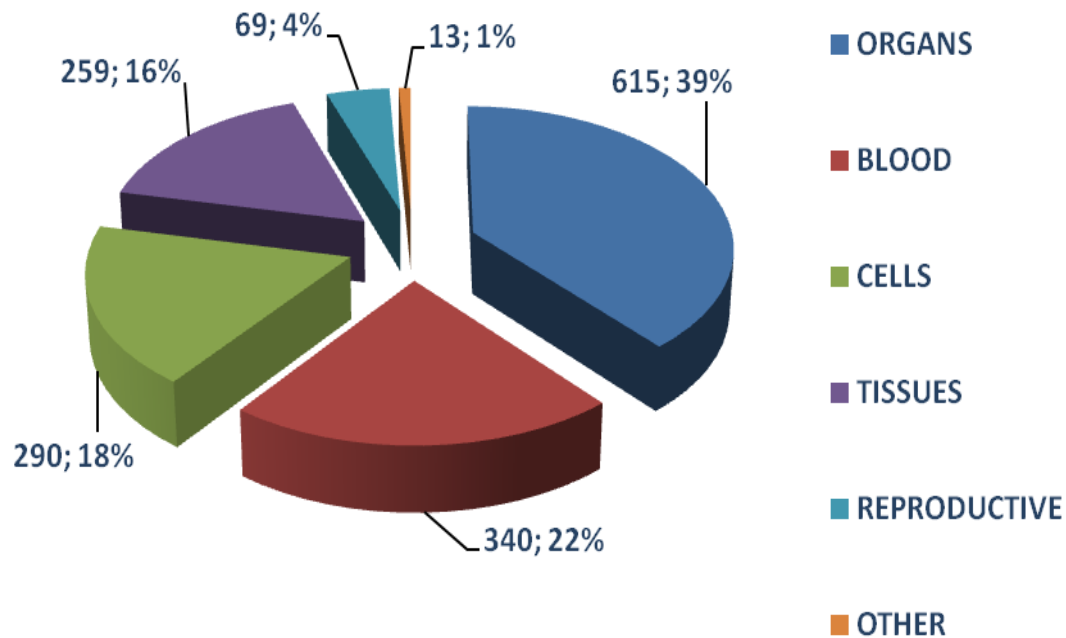


**2,472 REFERENCES INDEXED**

# NOTIFY LIBRARY: MPHO TYPE TAXONOMY



## NOTIFY LIBRARY: UPLOADED RECORDS BY MPHO TYPE (n=1,586)



**2,472 REFERENCES INDEXED**

## CONCLUSION

Notify is a joint Global initiative that **supports the sharing of published vigilance information** for teaching purposes and greater public transparency on the use of Medical Products of Human Origin.

The Notify Library is the first database that aims to **organize the current knowledge** about serious adverse events and reactions of organs, blood, tissues, cells and ART available globally **in a single, publically accessible database.**



***THANK YOU***

[notifylibrary@iss.it](mailto:notifylibrary@iss.it)



Centro Nazionale Trapianti  
Italian National Transplant Centre



WHO Collaborating Centre  
on Vigilance and Surveillance for  
Human Cells, Tissues and Organs