



ANVISA
Agência Nacional de Vigilância Sanitária

Ministério da
Saúde



**World Health
Organization**



Centro Nazionale Trapianti

WHO Global Consultation on Vigilance and Surveillance for Medical Products of Human Origin

Draft programme of Work

v6.0

7-9 December 2013

Brasilia - DF – Brazil

Saturday 7 December

13:30 - 14:00 *Coffee - Registration*

Introduction

14:00	Welcome and Introduction of participants - Election of Chair and Rapporteurs	
14:15	Global V&S and the WHO initiative for Medical Products of Human Origin	Luc Noel
14:30	V&S a driver for excellence in transplantation , CNT and European experience	Alessandro Nanni-Costa
14:45	The focus of ANVISA on V&S: the example of Medical Products of Human Origin	Geni Neumann
15:00	Agenda and objectives of the third consultation	Deirdre Fehily

15:30 - 16:00 *Coffee Break*

The NOTIFY Library: Review and Resolution of remarkable cases Achievements Updates and orientations for the future

16:00 Editorial Group Workshops

Infections Editorial Group Meeting Room	Malignancy Editorial Group Meeting Room	Process Editorial Group Meeting Room	Living Donor Editorial Group Meeting Room	Genetic Editorial Group Meeting Room	Transfusion Meeting Room
Chair Paolo Grossi	Chair Beatriz Dominguez	Chair Marian Macsai	Chair Daniel Roberto Coradi de Freitas	Chair Laura Saint Martin	Chair Neelam Dhingra-Kumar

To work through unresolved rows agreeing to solutions

18:30 *Adjourn*

Sunday 8 December

08:30 - 9:00 Coffee

Reports of the Editorial Workgroups

09:00	Introduction and facilitation	Mike Strong
09:15	Infection - presentation + cases discussion	Paolo Grossi
09:45	Malignancy - presentation + cases discussion	Beatriz Dominguez
10:15	Process - presentation + cases discussion	Marian Macsai

10:45 - 11:15 Coffee Break

11:15	Living donor - presentation + cases discussion	Daniel Roberto Coradi de Freitas
11:45	Genetic - presentation + cases discussion	Laura Saint Martin
12:15	New scope with the extension to blood	Giuliano Grazzini
12:35	General discussion	

13:00 - 14:00 Lunch

Specificities and priorities by type of MPHO

14:00 Breakout groups

Organs Meeting Room	Cells Meeting Room	Tissues Meeting Room	ART Meeting Room	Blood Meeting Room
Chair Phil O'Connel	Chair Adrian Seber	Chair Ted Eastlund	Chair Chris O'Toole	Chair Giuliano Grazzini

15:00	Report in plenary
15:30	General discussion

15:45 - 16:00 Coffee Break

Future developments of the NOTIFY Library I

16:00	How to better capture, classify and use didactic adverse events in the NOTIFY Library	Stratos Chatzixiros
16:40	Presentation of an electronic tool for the insertion of new case types, or new information on existing case types (end of Google docs!)	Daniela Minutoli Deirdre Fehily
17:00	Towards using the NOTIFY Library as a medium of publication	Mike Strong
17:20	Terminology for V&S of MPHO constraints and necessities	Geni Neumann Paul Ashford Evi Petrisli
17:50	A place for ethics in the NOTIFY Library?	Marie-Charlotte Bouesseau
18:10	General discussion	

18:30 Adjourn

Monday 9 December

08:30 - 9:00 *Coffee*

09:00 - 09:15 Summary by Rapporteurs

Official launch of the NOTIFY website and library

09:15 **ANVISA, CNT, ISS, WHO PAHO, WHO HQ, MOH Brazil**

10:00 Language specific interfaces for the NOTIFY Library and website Jose Nuñez

10:20 General Discussion

10:40 - 11:10 *Coffee Break*

Promoting reporting systems and disseminating outcomes

11:10 Round table: National V&S systems, lessons learnt, impact on practices and perspectives

12:00 Round table: The roles of scientific and professional associations in V&S as support and complement of National V&S systems

12:40 Update on the EU vigilance tools Ioana Siska

13:00 *Lunch*

Global tools for the V&S of MPHO

14:00 The links of vigilance for MPHO Luc Noel

14:15 Horizon scanning , a role for a network of CDCs ? Matt Kuehnert,
Drago Domanovic

14:30 General discussion: priorities for Global vigilance

Conclusions and the way forward

15:30 Conclusions and the way forward Chair

16:00 *Meeting close*