



# EUSTITE FINAL CONFERENCE

## Final Draft Programme

December 1st – December 4<sup>th</sup> 2009

Warsaw, Poland

This conference incorporates the 2nd Exploratory Workshop (WP 5), the final meeting of the V&S Medical Advisory Committee (WP 4b) and the final Project Partners Meeting (WP1) of the EUSTITE project.

1st December 13.00 – 16.00 - EUSTITE Project Partners meeting – Part I

## 2nd December

### Inspection of Tissue Establishments and Tissue and Cell Procurement

9.00 – 9.15 Official Opening of the Conference - Artur Kaminski,

9.15 – 9.30 The EUSTITE Project - Aims and Objectives - Deirdre Fehily, CNT, Italy

#### Session 1: A Common Approach to Inspection in the European Union - Chair: Artur Kaminski

9.30 – 10.10 EUSTITE Inspection Guidelines – Deirdre Fehily, CNT, Italy

10.10 – 10.50 EUSTITE Training of Tissue and Cell Inspectors – Johann Kurz, Ministry of Health, Austria

10.50 - 11.00 NorPEP - The Nordic Partnership for the EUSTITE Project - Mike Cox, Danish Medicines Agency

11.00 – 11.30 Coffee

#### Session 2: Challenges of Implementation in Decentralised Inspectorates - Chair Jacinto Sanchez Ibañez

11.30 – 11.40 Introduction – Jacinto Sanchez Ibañez, Competent Authority, Galicia, Spain

11.40 – 12.00 Case Study 1: Spain – Harmonising regulation by the Autonomous Communities – Gregorio Garrido, ONT

12.00 – 12.20 Case Study 2: Germany – Harmonising regulation by the Länder – Isabel Astner, Braunschweig

12.20 – 12.40 Case Study 3: France – Harmonising ART regulation nationally – Dr Philippe Fourchtein, ABM

12.40 – 13.00 Open Discussion

13.00– 14.00 LUNCH

Session 3: Challenges of Implementation in Small Member States - Chair: Jan Koller

14.00- 14.10 Introduction - Jan Koller, Slovakia

14.10 - 14.25 Case Study 1: Malta – Richard Zammit, Ministry of Health, Malta

14.25 - 14.40 Case Study 2: Cyprus – Carolina Stylianou, Tissue and Cell Inspectorate, Cyprus

14.40– 14.55 Case Study 3: Estonia - Svetlana Orlova, State Agency of Medicines, Estonia

Session 4: Challenges of Implementation of Certain Technical Requirements - Chair: Patrick Costello

15.00 - 15.15 Case Study 1: ART – facilities and testing – Trish Davies, HFEA, UK

15.15 - 15.30 Case Study 2: Interpretation of air-quality requirements (A in D) for processing of non-reproductive tissues – Patrick Costello, IMB, Ireland

15.30 - 15.45 Case Study 3: Inspecting Procurement – Emyr Harries, HTA, UK

15.45 - 16.00 EuroGTPS - developing technical guidance for tissue establishments - Esteve Trias, TSF, Spain

16.00 - 16.30 Coffee

Session 5: International Tissue and Cell Distribution - Chair: Johann Kurz

16.30 - 16.45 Tissues – Scott Brubaker, American Association of Tissue Banks

16.45 - 17.00 Gametes and embryos - Angela Sutherland, HFEA, UK

17.00 - 17.15 Haematopoietic stem cells - Per Llungman, EBMT

17.15 - 17.30 Ensuring equivalent safety of imported/exported tissues and cells: the US perspective – Anita Richardson, FDA

17.30 - 17.45 Ensuring equivalent safety of imported/exported tissues and cells: the EU perspective – Patrick Costello, IMB

3rd December

## Vigilance and Surveillance of Tissues and Cells

### Session 6: Reporting Serious Adverse Events and Reactions - Chair: Izabela Tyszkiewicz

- 08.30 – 8.50 EUSTITE Vigilance and Surveillance Tools - Luc Noel, WHO
- 8.50 - 9.40 The EUSTITE V&S Pilot - Stephanie Sullivan, EUSTITE Pilot Co-ordinator
- 9.40 - 10.00 Rapid Alerts in the EU – Mike Cox, Danish Medicines Agency
- 10.00 - 10.20 Horizon Scanning for Risk - Richard Tedder, Public Health Agency, UK
- 10.20 - 10.40 Responsive Safety Measures - Reacting to Risk – Mike Strong, USA

11.00 - 11.30 Coffee

### Session 7: Engaging clinical users in vigilance and surveillance - Chair: Trish Davies

- 11.30 – 11.50 The Experience with Haemovigilance - Renè de Vries, International Haemovigilance Network
- 11.50 - 12.10 Tissue and Cell Vigilance at the Hospital Level in France - Fewzi Teskrat, AFSSAPS
- 12.10 – 12.30 A new US initiative (Hospital Tissue Management) – Scott Brubaker, AATB
- 12.30 - 13.30 Round Table - Scientific and Professional Societies
- Engaging tissue users in vigilance - Ruth Warwick (EATB)
  - Engaging ART clinicians in vigilance - Luc Gianaroli (ESHRE)
  - Engaging ocular surgeons in tissue vigilance - Esteve Trias (EEBA)
  - Engaging HPC transplanters in vigilance - Carolina Stylianou (EBMT)

13.30 - 14.30 LUNCH

### Session 8: Electronic Vigilance Reporting - Chair: Ewa Olender

- 14.30 - 14.50 Simultaneous reporting to professional and regulator system - David Mold, Serious Hazards of Transfusion (SHOT), UK
- 14.50 - 15.10 US Transplant Transmitted Sentinel Network (TTSN) Project - Matt Kuehnert, US CDC
- 15.10 - 15.30 Tissue and Cell Vigilance reporting to the FDA - Laura St Martin, FDA
- 15.30 - 15.50 V&S Annual Reporting to the EC - long term trending and monitoring - Deirdre Fehily, CNT, Italy

Session 9: Developing key recommendations for effective V&S in the EU and globally (Coffee during session) - Chair: Deirdre Fehily

16.00 - 17.00 – 5 working groups

Facilitators: Jacinto Sanchez, Caterina Delvecchio, Richard Zammit, Dagmar Doerman, Arnaud Deguerra

17.00 – 18.00 Working group feedback

4th December

Where to from here?

Session 10: Measuring Success - Chair: Samuel Arrabal

09.00 – 09.10 Introduction - Samuel Arrabal, ABM, France

09.10 - 09.30 Impact – EUSTITE indicators of V&S and inspection performance - Anne Cathrine Bollerup, Danish Medicines Agency

09.30 – 10.30

5 working groups:

Facilitators: Jacinto Sanchez, Caterina Delvecchio, Richard Zammit, Dagmar Doerman, Arnaud Deguerra

Are there indicators that are inappropriate or missing?

How should we prioritise the indicators?

Group feedback

10.30 – 11.00 COFFEE

Session 11: Looking to the future - Chair: Artur Kaminsky

11.00 – 11.20 Looking to the Next EU Project - 'SOHO V&S' - Deirdre Fehily, CNT, Italy

11.30 – 11.50 Looking to the future – Harmonised European Tools in the Global Context - Luc Noel, WHO

11.50 - 12.00 Conference Closing Remarks

12.00 Conference Close

4th December 13.00 – 16.00 - EUSTITE Project Partners meeting – Part II – Project Close (apart from Work Package 7, Training, which it is hoped will be extended for a further 6 – 12 months).