



Co-funded by
the Health Programme
of the European Union



VISTART - Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation Grant Agreement No. 676969



WP3-EXTERNAL ADVISORY BOARD MEETING – April 11th and 12th 2017

**BOVET Room - Address: Via del Castro Laurenziano 10 – 00161
Rome, Italy**

MINUTES

PARTICIPANTS

EXTERNAL ADVISORY BOARD

ASSOCIATED PARTNERS: RNDVCSH, ISS-CNS-CNT

EC REPRESENTATIVES

MEETING ATTENDEES:

11 April: Mauro Costa (EAB), Paula Bolton Maggs (EAB), Eoin McGrath (EAB), Aurora Dragomirișteanu (RNDVCSH), Laurian Arghisan (RNDVCSH), Paola Di Ciaccio (CNT), Maura Mareri (CNT), Claudia Carella (CNT), Stefan Van der Spiegel (DG SANTE); Ana-Maria Mancho-Rojo (CHAFEA)

12 April: Mauro Costa (EAB), Paula Bolton Maggs (EAB), Eoin McGrath (EAB), Aurora Dragomirișteanu (RNDVCSH), Laurian Arghisan (RNDVCSH), Paola Di Ciaccio (CNT), Maura Mareri (CNT), Cristina Pintus (CNT), Livia Canata (CNS), Ana-Maria Mancho-Rojo (CHAFEA)

EXCUSED:

Esteve Trias- Adroher (EAB), Rut Norda (EAB) Peter Flanagan (EAB), MD

DAY 1: 11 of April 2017

Meeting start: 16.30

Meeting end: 17:30

Chair: Aurora Dragomiristeanu



Discussed Issues	Decisions Taken	Date to be completed
<p>1. The meeting began with administrative issues. Travel expenses will be reimbursed according to the EC rules and Romanian regulations.</p> <p>For example in the case of the daily subsistence allowances the daily rate for Rome is 95Euro/day (EC). According with Romanian regulation, till the selling of 95Euro will be reimbursed the following: the daily allowance (is 35 EUR/day), the taxi fees or other cost of transportation (maximum 60 Euros/day). The funds for the expenses will be wired to the EAB members.</p>	<p>Reimbursement and Statement for mission forms were distributed to the EAB members.</p>	<p>At the return, the EAB members will mail to RNDVCSH the reimbursement forms signed accompanied by all the receipts and boarding pass and taxi receipts.</p>
<p>2. TORs for EAB members. Eoin McGrath and Paola Di Ciaccio (or Claudia Carella) will send the forms used in previous HP-JA projects</p>	<p>Forms for external evaluation to be created agreed and shared with EAB members.</p>	<p>end of April 2017</p>
<p>3. Resume/CV of the EAB members</p>	<p>To be sent to the WP3 to be included in the Intermediate Evaluation Report</p>	<p>end of April 2017</p>
<p>4. Affiliation of EAB members:</p> <ul style="list-style-type: none"> – Prof. Mauro Costa, M.D. - Member of task force on Quality and Safety on PMA techniques of European Society of Human Reproduction and Embriology (ESHRE) - Group leader of NOTIFY project; – Paula Bolton Maggs, M.D., - Serious Hazards of Transfusion; – Eoin McGrath - JACIE Operations Manager, EBMT Executive Office; – Esteve Trias- Adroher, M.D. - Medical Director of Transplant Services Foundation, Hospital Clínic Barcelona; – Rut Norda, M.D. Department of clinical immunology and transfusion medicine, Uppsala University Hospital, Uppsala Sweden 	<p>Will be brought up to date, according to the CV. In all the future documents will be used corrected affiliation.</p>	<p>Each EAB member will send their corrected affiliation up to date.</p>



<p>– Peter Flanagan, MD - President of International Society of Blood Transfusion (ISBT)</p>		
<p>5. Communication. The external evaluation board's role is to send the feedback on the final deliverable. Paula raised her concerns regarding deadlines for EAB member's contribution and consolidated external evaluation for each technical deliverables (WP4-WP10), to be included in the Evaluation Intermediate Report. When the EAB members agree with the quality of the content, they can write a maximum a paragraph. If comments are needed, they can be made with no limit of the contribution.</p> <p>Shared Comments. EAB members agree to share comments among the EAB members.</p>	<p>Deliverable will be sent when document is final or in advanced state, the WP leaders will send the deliverable to WP3. From WP3, deliverables will be sent them to EAB members. on e-mail.</p> <p>A plan of documents that are in preparation – to be sent to EAB members.</p> <p>WP3 will share the comments among the other EAB members. The WP leaders will receive a consolidated opinion from the EAB.</p>	<p>The turn-around time will be of around one month. For the inspection guideline, the turnaround time will be before end of April.</p>

DAY 2: 12 of April 2017

Meeting start: 13.00

Meeting end: 14:00

Chair: Aurora Dragomiristeanu

Discussed Issues	Decisions Taken	Date to be completed
<p>1. Administrative issues. Signature for travel expenses.</p>	<p>Reinbursement forms were signed by the present EAB members. All the available expenditure documents (hotel receipts, flight tickets, etc.) were collected by the RNDVCSH.</p>	<p>At the return, the EAB members will sent the return boarding pass and taxi receipts to RNDVCSH.</p>
<p>2. Paula Bolton Maggs suggested that the check-list for joint inspection from WP8 and joint audit from WP9 to be sent for information, without need to</p>	<p>It was agreed with that the check-list for joint inspections/audits will be sent to EAB members as</p>	<p>End of April 2017 As soon as available</p>



Co-funded by
the Health Programme
of the European Union



give feedback.	information materials.	
3. It was generally agreed by all the EAB present members, that the plenary meeting were very useful to have a full picture of progress of project and the	The pdf format of presentations from the first plenary meeting will be sent to EAB members after clearance from the WPs leaders (with disclaimer).	As soon as available from WP1
4. Common evaluation template.	Existing templates will be circulated and a format will be agreed. Claudia Carella and Eoin McGrath offered to provide the existing forms used in other JA-HP projects.	End of April 2017
5. AOB. Prof. Mauro Costa explained that is important to consider the need of ART in the field of inspections. The training of inspectors should take in consideration the need to raise competence in ART inspection. The clasification of the air quality must consider the result, not the mean. There need to have a uniformity of competent authorities among European Union. Aurora presented the process of development of inspection guidelines. Each competent authority have to have it's own quality system.	The main points to arise from these discussions were: the information transmission should be formalized.	Consider the aspects in the process of evaluation.
6. Call conference	It was agreed by the group that to set up a call confernce with all the EAB members.	April 27, 2017

The meeting closed with Aurora thanking everyone for attending the meeting and for their constructive contributions during the two days.

Minute taker: Laurian Arghisan