EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 - Medical Products, quality, safety, innovation

Effectiveness and outcome measurement for blood, tissues and cells

In collaboration with GAPP Work Package 8

5th of February 2020, 10.00 to 17.00h

SANTE premises, Rue Froissart 101, Brussels

AGENDA

10.00-10.15	Welcome (*Stefaan van der Spiegel, DG SANTE*)	
10.15-10.30	Introduction	
10.30-10.45	Summary of WP8 Deliverables 8.1* and 8.2** (*WP8 Leaders*) • Summary of European-level BTC registries collecting clinical data • Comparison between risk-based criteria and clinical data in BTC registries	
10.45→	Drafting the Deliverable 8.3	
	Sub-group A "Clinical Data"	Sub-group B "Additional requirements of clinical evaluation protocols"
10.45-13.00	Defining minimum clinical data required	Defining additional requirements of clinical evaluation protocols
13.00-14.00 Lunch break		
14.00-15.30	Defining minimum clinical data required	Defining additional requirements of clinical evaluation protocols
15.30-16.00	Future actions, dividing the work between experts	Future actions, dividing the work between experts
16.00-17.00	Combining sub-group's ideas, agreeing on action plan	

* D8.1 - Catalogue of existing clinical data appropriate to provide information on the quality and safety of human blood, cell, and tissue therapeutics once applied to patients, under the conditions of current state-of-the-art processing and testing protocols

**D8.2 - Catalogue of risk-based set of criteria, appropriate to evaluate the established catalogue of clinical data for completeness and suitability in case of introduction of innovation to the current processing and testing protocols for human blood, cell, and tissue therapeutics