29 November 2011
EMA/CAT/929342/2011
Committee for Advanced Therapies (CAT)

Draft agenda - CAT stakeholders workshop

Focus groups: a model for a fruitful interaction between the CAT and its stakeholders

Thursday, 12 January 2012, 9:00 -17:30

European Medicines Agency, conference room 2A (second floor)

~ Registration and Coffee ~

8.00 - 9.00

Chairperson: Dr. Christian K Schneider, CAT Chair

1	**Introduction**	**9:00 – 9:30**
1.1	**Welcome and opening remarks** *Christian K Schneider, workshop Chairperson*	
1.2	**CAT dialogue with its stakeholders** Topic: Focus Groups: a new model for a fruitful interaction between CAT and its stakeholders *Lucia D'Apote, CAT Scientific secretariat, EMA*	

2.	**Focus Group: non-clinical development of ATMPs**	**9:30 – 11:15**
2.1	**Objectives of the Focus group and outcome discussions in 2011**	
2.2	**Overview of Scientific Advices given on ATMPs - Non-clinical Issues** *Carla Herberts, PhD, Senior Non-clinical Assessor, CBG-MEB* *Henrik Tang Vestergaard, PhD, Non-clinical Assessor, DKMA*	
2.3	**Possible scenarios to address issues in non-clinical studies for ATMPs**	
2.4	**Panel Discussion** *Questions collected in advance of the workshop from participants*	

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2.	**Focus Group: non-clinical development of ATMPs**	**9:30 – 11:15**
	(preferably at the time of registration)	

~ Coffee Break ~

11:15-11:45

3.	**Focus Group: a better system to navigate guidelines for ATMPs**	**11:45 – 13:30**
3.1	**Objectives of the Focus group and outcome discussions in 2011**	
3.2	**Interactive flow-chart for Gene Therapy guidelines**	
3.3	**The way forward: action plan for 2012**	
3.4	**Panel Discussion** Questions collected in advance of the workshop from participants (preferably at the time of registration)	

~ Lunch ~

13:30-14:30

4.	**Focus Group: Incentives for Academia, hospitals and charities**	**14:30 – 16:30**
4.1	**Objectives of the Focus group and outcome discussions in 2011**	
4.2	**Raising awareness on available incentives (EMA)**	
4.3	**Improve certainty of regulatory outcome:** An identified incentive by stakeholders to foster translation of academic research into commercial products	
4.4	**Optimising resources:** Is it possible to have one set of data for different procedures (e.g. EMA scientific advice, CTA application, Proposal submission for FP7 research funding)? Can the criteria for assessment of data follow the same rationale during the entire product development?	
4.5	**The way forward: action plan for 2012**	
4.6	**Panel Discussion** Questions collected in advance of the workshop from participants (preferably at the time of registration)	

~ Coffee Break ~

16:30-16:45

5.	**Wrap-up**	**16:45 – 17:15**
5.1	**Objectives of the Focus group and outcome discussions in 2011**	

~ Closing remarks by chairperson ~

17:15-17:30