EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 December 2012
EMA/CAT/889316/2011
Committee for Advanced Therapies (CAT)

Report from CAT-IPs Focus group on incentives for Academia, hospitals, charities.

15th September 2011, 9:00 - 12:00 (UK time)

Chair: Paula Salmikangas

Item	Draft agenda/Summary of discussions
1.	**Introduction of participants** (see list of participants at the end of the document)
2.	**Scope of CAT-IPs Focus groups and objective of the meeting** A summary document (EMA/CAT/769749/2010) explaining scope, role, composition, duration of the CAT-IPs FG was distributed to all participant.
3.	**Brainstorming: Incentives for development of ATMPs** Participants heard a presentation by CAT secretariat on the regulatory, financial and technical incentives foreseen by the ATMP Regulation and the specific support provided by the Agency for the development of ATMPs As a general aspects IPs stressed the difficulty in Europe to translate basic research in products progressing to Phase I clinical studies. The main issue was identified in lack of investments in the field.
4.	**Wrap-up:** The following summary emerged from the discussions as a collection of significant points highlighted by interested parties to be reported to CAT. A number of correspondent actions were also proposed that could be further explored. <u>Summary of discussions</u> • At the start of the meeting, it was highlighted that CAT-IPs FGs aim at improving CAT's interaction with interested parties and propose shared solutions on some of the issues previously identified in general hearings with Interested Parties. Therefore the outcome of the meeting will be reported to CAT and the

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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	stakeholders for further considerations. • IPs stressed that actions directed to lowering uncertainty of regulatory outcome would increase confidence of capital venturist to invest in the ATMP field • In this respect the risk-based approach guideline was seen as a very useful document for developers. It was questioned whether the risk-based approach could be applied also for CTAs. • Clarification on GMP requirements in different clinical trial phases across European Member States would be crucial for developers in order to plan their clinical plan. • IPs acknowledged the need for training and dissemination of information in the Academic community: ways to reach this objective would be to establish dialogie with national reference bodies funding research (e.g. technology transfer offices).
5.	**Proposed actions:** • EMA/CAT to raise greater awareness on incentives available for Academia, Charities and Trusts • Explore possibility for developers to discuss with CAT/EMA their product development plan with a view to increase predictability of regulatory outcome • Engage in a 'simplification exercise' to reduce administrative burden for applicants and optimisation of resources by avoiding submission of the same data in different procedures (e.g. SA, PIP, ITF, Classification) • • Reflect on issue concerning EU harmonisation of criteria for moving to first in man clinical studies • Reflect on the current content of scientific guidelines to ensure that they are written not only to reach the MAA submission as milestone but also for intermediate clinical development stage.
6.	**Conclusions:** The summary of the discussions held and the proposed actions will be reported to CAT in October 2011 for endorsement. It was agreed that such focus group meetings, with more specific content, are a helpful addition to the usual meetings of the CAT with interested parties. The next meeting will be held when significant progress has been made on the majority of the proposed actions (not earlier than January 2012). The Chair thanked all participants for the fruitful discussions and closed the meeting.

LIST OF PARTICIPANTS	
Paula Salmikangas	CAT Vice-Chair
Alastair Kent	CAT member
Thierry Vandendriessche	CAT member
Lucia D'Apote	CAT Secretariat
Patrick Celis	CAT Secretariat
Elisa Pedone	EMA – H-QM Sector
Marie Helene Pinheiro	EMA – Regulatory adviser
Costantinos Ziogas	EMA - SME Office
Falk Ehmann	EMA ITF Secretariat
Odile Cohen-Haguenauer	Clinigene
Anton Ussi	EATRIS
Didier Caizergues	Genethon
Francesco Lanza	ISCT
Massimo Dominici	ISCT
Carla Paganin	Telethon