EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Advanced Therapies (CAT)

Activities proposed by CAT-IP Focus group on non-clinical development of ATMPs

Action Plan

Activities proposed by the focus group and agreed by CAT:	Action plan
CAT, in cooperation with the Scientific Advice Working Party (SAWP), to explore generation of a living document tracking the experience gained with scientific advice on non-clinical questions for ATMPs. This document will provide CAT with an overview on the advice given, products types evaluated, POC models recommended, toxicology models agreed and, where used, disease models. As a second phase it will be determined if common elements can be extrapolated and transformed into mock-up case studies to be shared with stakeholders.	First phase (collection and analysis of SA): Completed. Second phase (extrapolation of common elements): Completed. Need for further actions to be discussed at the next meeting of the Focus Group.
To ensure that assessors in the NCAs have a consistent approach for the evaluation/request of non-clinical studies. CAT to include discussions on non-clinical development in ATMP assessors' training courses.	Already addressed in the programme of the forthcoming ATMP Assessors' training (5th-6th April 2011). Need for further actions to be discussed at the next meeting of the Focus Group.
Risk-based approach: CAT Working Parties and other CAT members to work on scenarios with different types of risks to be potentially included in the upcoming guideline. CAT to identify areas of risk relevant to	To be addressed via coordination between CAT and its WPs on the draft guidance on the risk-based approach. Completed.

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ATMPs (e.g. tumorigenicity, immunosuppression/immunomodulation, immunogenicity) to inform the discussions on the risk-based approach. Stakeholders to collect data on risks that have been already identified (e.g. tumorigenicity for embryonic stem cell products, insertional mutagenesis in gene therapy products) and on possible scenarios to address these issues in non-clinical studies, and to report back to CAT to inform the Committee's discussions.	To be addressed via coordination between CAT and its WPs on the draft guidance on the risk-based approach. Completed. Stakeholders in charge of this activity. Proposed scenarios to be presented at the next meeting of the Focus Group
To raise awareness of CAT on significant innovative approaches in non-clinical development (e.g. emerging animal models, new labelling techniques in biodistribution). This can be achieved, for example, by presenting these findings to CAT as scientific lectures given by relevant researchers.	Stakeholders to propose awareness sessions on significant innovative approaches in non-clinical development. 1st awareness session:11 Oct 2012
Further reflection could be: whether small animal models can substitute the need for large animal models and determination of the duration of such studies when using large animal models (i.e.; a life-long follow-up in large animal models might be difficult to put in practice).	Action plan to be further explored at the next meeting of the Focus Group.
To consider existing ISO standards used for medical devices to compare and gain experience on the risk-based approach used in the medical device field and see how certain elements can be used in the risk based approach used for ATMPs.	Done. Relevant ISO standards forwarded to CPWP and GTWP for their considerations.