Regulation - CliniGene comments on EU-centralised Guidelines (From March 2009)

All these documents are available on Clinisoft in the « WP1.5 – Overcoming regulatory hurdles »

Guideline Name and source	Type of documents (official source)	Consultation Starting date	Deadline for comments
Oncolytic viruses (EMEA/CHMP/GTWP/607698)	**ICH considerations** This document identifies general principles for the clinical development of OV regardless of the classification of such products in each region.	November 2008	28 February 2009
Quality, non-clinical and clinical issues relating specifically to recombinant Adeno Associated viral vectors (EMEA/CHMP/GTWP/587488/2007)	**CHMP-CTWP reflection paper** The aim of this reflection paper is to review the current status in the development of recombinant adeno-associated virus vectors, and raises regulatory points for consideration for pharmaceutical companies developing these products with the aim of submitting market authorisation applications (MAA).	March 2009	September 2009
The Provision of scientific recommendation on classification of advanced therapy medicinal products in accordance with article 17 of regulation (EC) N°1394/2007 (EMEA/99623/2009)	**CAT scientific recommendation** This document describes the roles and responsibilities, the required documentation and the evaluation process for the scientific recommendation on classification of advanced therapy medicinal products. This scientific recommendation is an optional procedure for applicants, which involves the CAT.	April 2009	8 June 2009
The EMEA Transparency policy (EMEA/232037/2009)	**EMEA Transparency policy** On 19 June 2009, the European Medicines Agency released for public consultation a draft transparency policy that sets out how the Agency intends to provide for greater clarity and openness in all areas of its operations.	June 2009	5 Octobre 2009
General principles to address virus and vector shedding (EMEA/CHMP/ICH/449035/2009)	**ICH considerations** The aim of the document is to provide recommendations for designing non-clinical and clinical shedding studies when appropriate. It is focused, in particular, on the analytical assays used for detection, and considerations for the sampling profiles and schedules in both non-clinical and clinical studies. The interpretation of non-clinical data and its use in designing clinical studies is also within the scope of this paper, as well as the interpretation of clinical data in assessing the need for virus / vector transmission studies.	July 2009	September 2009
Scientific Guideline on the minimum quality and non-clinical data for certification of advanced therapy medicinal products	**CAT scientific guidelines** The aim of this scientific guideline is to describe the minimum quality and non-clinical set of data that Small and Medium-size Enterprises (SMEs) developing	June 2009	31 Octobre 2009

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(EMEA/CAT/486831/2008)	Advanced Therapy Medicinal Products (ATMPs) should submit for scientific evaluation when seeking EMEA certification of quality, or quality and non-clinical data under Article 18 of Regulation (EC) No 1394/20072.		
Information on benefit-risk of medicines: patients', consumers' and healthcare professionals expectations (EMA/40926/2009)	**The EMEA together with the Patients' and Consumers' Working Party (PCWP), and the Healthcare Professionals' Working Group (HCP WG) report** The present document addresses the communication aspect in the light of society's need for transparent information on the benefits and risks of medicines. It has been prepared in association with patients' and healthcare professionals' organisations and the EMEA with the objective of making proposals to further fulfil patients' and healthcare professionals' expectations. It focuses on communication on benefits and risks of medicines provided in regulatory information, i.e. product information (summary of product characteristics, labelling and the package leaflet), public assessment report and product safety announcements.	June 2009	Document released for information only
Assessment of the functioning of the "clinical trials directive" 2001/20/EC (ENTR/F/2/SF D(2009) 32674)	**EC – Entreprise & industry directorate general - Public consultation paper** This assessment would consider, in particular, various options for further improving the functioning of the Clinical Trials Directive with a view to remedy shortcomings and unintended negative consequences while taking the global dimension of clinical trials into account.	July 2009	8 January 2010
Concept paper on the revision of the note for guidance on the quality, pre-clinical and clinical aspects of gene transfer medicinal products (EMA/CHMP/GTWP/BWP/234523/2009)	**EMEA-CHMP: revision of the Note for Guidance on the Quality, Preclinical and Clinical** Aspects of Gene Transfer Medicinal Products (CPMP/BWP/3088/99) that came into effect in 2001. This revision will address the issues identified from clinical experience and provision of Scientific Advice on GT medicinal products & will lay down detailed and updated requirements for the quality, non-clinical and clinical aspects of gene therapy medicinal products.	17 December 2009	31 March 2010
Questions and Answers document on Gene therapy (EMA/CHMP/GTWP/212377/2008)	**EMEA-CHMP document** This document will be regularly updated on the basis of received comments and questions.	19 January 2010	N/A (constantly updated) (CliniGene comments pending)
Draft Concept paper on the development of a guideline on the risk-based approach according to Annex I, Part IV of Dir. 2001/83/EC applied to ATMPs (EMA/CHMP/CPWP/708420/ 2009).	**CHMP concept paper** This concept paper is intended to provide the background and rationale of the guideline on the risk based approach and shall describe the approach and content of the future guideline.	27 January 2010	31 March 2010

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Draft paper setting out its vision for the strategic development of the Agency for the five years to 2015. (EMA/299895/2009)	**European Medicines Agency Roadmap** Building on the progress of its previous five-year strategy, the Road Map to 2015 charts the way forward for the Agency amid rapid developments in medical science and pharmaceutical research, as well as the continuing evolution of the European and international regulatory environments. With this strategy paper to guide it, the Agency will seek to consolidate its achievements to date and further strengthen its role as a guardian of human and animal health in the European Union.	27 January 2010	31 April 2010 (CliniGene comments pending)
Detailed guidelines on good clinical practice specific to advanced therapy medicinal products. (ENTR/F/2/SF/dn D(2009) 35810)	**EC – Entreprise & industry directorate general** These guidelines have been developed to address specific issues related to good clinical practice for clinical trials involving advanced therapy medicinal products. The final adoption of these guidelines by the College of Commissioners is foreseen once more practical experiences have been gained with the specificities of clinical trials involving advanced therapy medicinal products. Pending the final adoption of this guideline, it is recommended to apply the rules and principles set out in this text.	Not submitted for comment	**CliniGene has elected to forward comments on this paper and received acknowledgment from DG ENTR**
Reflection paper on stem cell-based medicinal products (EMA/CAT/571134/2009)	**EMEA-CAT reflection paper** The aim of this reflection paper is to cover specific aspects related to stem cell-based medicinal products, and is relevant to all medicinal products using stem cells as starting material.	31 March 2010	30 June 2010

Table 1: From May 2010 report