COMMENT ON Implementation of the Advanced Therapies Regulation: public consultation on the Revised Clinical Trial Application Form as regards advanced therapy investigational medicinal products

COMMENT FROM Roche, October 15th 2008
Comment on points D.3.11.2 to D.3.11.4 and D4 to (pages 9-11) Is it expected that at the time of the first clinical trial the sponsor knows what the classification of the future ATMP is? The regulatory classification of these products (borderline products and subclasses of the ATIMPs) is complex, the definitions in the legislation are not comprehensive and the confirming case-be-case classification procedure via CAT to be established takes in practice more than 60 days. Since the formal definition for e.g. gene therapy product is currently under reconsideration, it is not possible to fully evaluate if the proposal is appropriate