

4 December 2014
EMA/CAT/655614/2014

Dossier requirements for Pre-submission Procedure: ATMP Certification

Submission of application dossiers to the European Medicines Agency and members of the Committee for Advanced Therapies (CAT)

Application / Submission Type	Dossier Requirements for EMA, CAT Co-ordinator, Peer Reviewer and Members
Certification of ATMP	Completed Certification Request and Attachments sheet with relevant attachments in one package to be sent via Eudralink¹ (with password) to: EMA: pa-bus@ema.europa.eu CAT: the e-mail addresses are shown in the official list of members List of CAT members.

For submission purposes, only the e-mail addresses listed in the 'List of CAT members' should be used and only one submission per member is needed. Please mention the names of the relevant CAT members on the Eudralink submission package and/or cover letter.

¹ What is Eudralink?

EudraLink is a secure file transfer application provided by EMA. Drug companies and national medicine authorities need to be able to exchange highly sensitive documentation with the highest level of security. To use the service applicants must first register for a EudraLink account by sending an e-mail to Eudralink@ema.europa.eu. EudraLink allows for submissions up to 200MB in size. The cover message of your EudraLink package will be set by default on: 'The recipient(s) must have a Eudralink account to access the package'. All CAT members and EMA staff have their own EudraLink account and private login and password to open up EudraLink packages. Your submission may have an expiry date of up to 90 days.