

eSubmission Gateway Project

Status Report

Project:	Electronic Application Form (02-004-00198)
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Project Sponsor:	Patrick Le Courtois
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Report Date:	June 2011 - Status Report

Current Summary of Project Status

- The scope of the work for the eSubmission Gateway Release 1 (1st production release) is to allow registered business partners from Pharmaceutical Industry to send eCTD submissions electronically to the EMA via the eSubmission Gateway. The eSubmission Gateway uses a well introduced secure transmission technology over the Internet from a software vendor called Axway. Many organisations are already familiar with this technology because it has been used for many years to transmit EudraVigilance ICSRs. These organisations which are already using the Axway Activator however need to re-register with the EMA for the eSubmission community. A draft SOP describing the registration process for the eSubmission Gateway community shall be published on the EMA website in July.
- The business requirements as well as the software architecture documentation for release 1 of this project are complete.
- The software development and development test phases are complete as well.
- System testing has started.
- Existing work instructions for the handling of incoming eCTD submissions will be modified to allow for the reception of eCTD submissions also via the eSubmissions gateway. It is expected that both methods to submit eCTDs (via CDs/DVDs and via eSubmission Gateway) will be supported for some time.

Reviewed/Updated Project Milestones

Milestone	Latest Estimate ¹
1. Review & finalize business requirements document for Release 1	complete
2. Review & finalize software architecture document	complete
3. Software development for Release 1	complete
4. Deployment documentation	complete
5. Development Testing	complete
6. Complete System Testing	June 2011
7. Draft UAT test scripts	complete
8. Start User Acceptance Testing	June 2011
9. Fix issues reported during UAT, retest and prepare 1 st production release	June/July 2011
10. Modify work instructions for incoming eCTD submissions	July 2011
11. Publish registration process for eSubmission Gateway (SOP)	July 2011
12. Start Pilot	July 2011
13. Start Production (eSubmission Gateway Release 1)	October 2011

¹ The dates reflect "the plan on the basis of which the eSubmission Gateway project team is working". There is no formal (budgetary) authorisation (from ED+HoU) for these projects yet.

Key success critical tasks

- Complete UAT and pilot
- Develop SOP for Industry for the eSubmission Gateway registration process
- Establish communications plan for the introduction of the new service

Top Project Issues & Risks

Issue/Risk	Owners	Status	Outcomes
eSubmission Gateway, Denial of service attack or SPAM (by technical errors/bugs)	Industry	open	
Insufficient Inbox capacity	EMA ICT	open	
Parallel operation (CDs/DVDs & eSubmission Gateway) is potentially resource intensive	EMA business	open	

Glossary

Abbreviation	Description
DES	Data Exchange Standards
RDM	Reference Data Model
EUTCT	European Union Telematics Control Terms
ICSR	Individual Case Safety Report
XML	Extensible Markup Language (Flexible way to create & share both format and data)
NCA	National Competent Authorities
DTD	Data Type Definition
XSD	XML Schema Definition (An XML schema provides a view of the document type at a relatively high level of abstraction).
UI	User Interface (form)
SAT	System Assurance Testing (IT Test Manager)
SOP	Standard Operating Procedure
UAT	User Acceptance Testing
eAF	Electronic Application Form
Pilot	Use of the candidate for the 1 st production release in production environment with a carefully selected limited number of users
Release 1.0	First Production Release