

Electronic Application Form Project

Status Report

Project: Electronic Application Form (02-004-00010)
Project Manager: Roger Blackburn
Programme Manager: Thomas Mauer
Project Sponsor: Patrick Le Courtois
Business Owners: Xavier Luria (Human). Melanie Leivers (Veterinary). Jean-Claude Brival (PDM).
Report Date: January 2011 - Status Report

Current Summary of Project Status

- Project has been delayed by up to 9 months due to the resignation of the project manager and subsequently the entire development and test team.
- The full project team comprising a project manager, a system architect, a business analyst, 2 - 3 developers and a test manager has been re-established by the 3rd of January 2010.
- The analysis and internal audit of the already existing implementation has been completed by the 14th of January 2011. Implementation guidelines for the development of Adobe forms using Adobe lifecycle server have been reviewed and updated.
- The eAF data model described in the DES document version 3.0 has been reviewed and the compliance with RDM 3.0 and the EUTCT implementation has been confirmed.
- The development work to fix the 400 reported defects in full compliance with the best practice implementation guidelines has started.
- The scope of the work for eAF Release 1.0 (1st production Release) is to implement the following four Adobe forms which are available on the EMA website for editing, validation, printing, generation and export of XML files, loading of XML files:
 - Marketing Authorization Application (Human)
 - Marketing Authorization Application (Vet)
 - Renewal of a MAA (Human&Vet)
 - Variation to a Marketing Authorization (Human&Vet)
- The basis for the development of the MAA Human form is the *Module 1: Administrative information Application form from May 2008*. The recent changes to the MAA Human (*Module 1: Administrative information Application form, June 2010*) form, which have been defined and which have been submitted to the Notice to Applicants Group for approval have been studied but are currently not in the scope of the eAF Release 1.0 delivery. Once the changes have been approved it will be decided if they are part of the eAF Release 1.0 delivery or of a subsequent Release.
- There are currently no formal plans for the completion of the EMA specific forms

Reviewed/Updated Project Milestones

Milestone	Latest Estimate ¹
1. Complete development and integration testing for MAA-H form	11 th of February 2011
2. Complete development and integration testing for MAA-V form	25 th of February 2011
3. Complete development and integration testing for Renewals form	4 th of March 2011
4. Complete development and integration testing for Variations form	11 th of March 2011

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

Milestone	Latest Estimate ¹
5. Complete Development Testing	25 th of March 2011
6. Complete System Testing	29 th of April 2011
7. Draft UAT test script and distribute to eAF user group for comments	11 th of March 2011
8. Receive all comments from eAF user group	8th of April 2011
9. Start User Acceptance Testing	3rd of May 2011
10. Report all UAT results	27 th of May
11. Prepare 1 st production Release (1.0)	24th of June 2011
12. Start Pilot	4 th of July
13. End Pilot	9 th of September
14. Start Production (eAF Release 1.x)	12 th of September 2011

Key success critical tasks

- Re-establish the eAF EMA core group
- Re-establish the eAF user group
- Business users (EMA & Industry) to define test cases for UAT
- Complete UAT for MAA (H & V), Variation and Renewal

Top Project Issues & Risks

Issue	Owners	Status	Outcomes
The changes to the MAA Human form (June 2010) may be adopted while the development & testing according to the existing form (May 2008) is still ongoing	NtA group	open	
eAF EMA core group may not have enough capacity to provide timely feedback to questions	EMA business	open	
eAF user group may be slow in providing feedback regarding the user acceptance tests	NcAs & Industry	open	

Glossary

Abbreviation	Description
DES	Data Exchange Standards
RDM	Reference Data Model
EUTCT	European Union Telematics Control Terms
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)
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