European Medicines Agency

EMEA/MB/20870/2009
5 March 2009

Update on EMEA implementation of EU Telematics strategy

Executive Summary

Operation: Except for EudraNet, and EudraCT secure site, all agreed service levels have been attained; most of them are considerably above the threshold value of 98%. The number of users and the transaction volumes continue to increase. The total number of registered users of EU Telematics systems has now passed the 10,000 mark.

Project Progress: Project progress is presented in the section immediately following this summary. The key deviations from the 2008 Master Plan are that several projects are running a few months late, mainly because of the difficulties to attract and retain contractors. There are no major issues with quality, functionality and budget except for PIM where we continue to encounter performance issues and stability problems.

Risks: The four main risks to successful continuation of the programme are lack of human resources (EMEA staff and contractors), complications in procurement procedures, late definition of and significant changes to requirements, and funding. The funding risk has reappeared as a result of Commission proposals concerning EMEA budget and of the need to refocus EMEA resources towards improving IT systems in support of EMEA business processes. While it has been possible to plan project activities for 2009 in line with the Telematics Master Plan there is a significant funding issue in 2010 when the proposed Commission contribution will cover the operating costs and EMEA will only be able to contribute M€ 3 at most for development activities. The total development costs for 2010 derived from requests from Telematics Implementation Groups and other stakeholders amounted to €12 124 000, an increase of €7 921 000 over the budget figures contained in the version of the EU Telematics Master Plan 2008-2013. Following a review of the development requests, EMEA has proposed a prioritisation of requests leading to a total development budget of €6 622 000 for 2010. This can only be implemented if the Commission contribution is increased in 2010.

Resources: Human resources are assigned to the programme as agreed at 17 staff financed from the EU contribution and an additional 10 full time equivalents funded from EMEA fee income. The budget assigned to EU Telematics in 2008 was €12 631 000 of which €8 772 000 was granted as Telematics fund by the European Commission and €3 859 000 was covered from the EMEA budget. By the end of 2008, €12,721,905 was committed in respect of Telematics expenditure on IT maintenance and development whilst payments amounted to €5 490 730. The final budget assigned to EU Telematics will be known once final expenditure on meetings and staff costs have been reported.

The budget assigned to EU Telematics in 2009 is €13 615 000 of which € 8 947 000 is granted as Telematics fund by the European Commission.

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Contracts: A number of routine contracts for support and maintenance of software have been signed during this reporting period.

Audits: No audits were carried out during the reporting period.

TSC update: The TSC did not meet during the reporting period. The next meeting will be held as a stand-alone meeting to review and endorse the new version of the Telematics Master Plan.

Project Summary

Reference Data Model

Version 1 has been in production since November 2005. Version 2, which covers EudraPharm, EudraVigilance, EudraCT and M5 (Medicinal product identification) was completed at the end of 2008, in line with the revised planning, and has been made available for consultation via the Telematics Implementation Groups and the EU Telematics website[1]. Work on version 3 is aimed at resolving a number of issues raised by the proof of concept exercise carried out in connection with Version 2, at encompassing all information used in connection with the whole range of EU Telematics systems, and at harmonisation with international standardisation initiatives. While this scope is ambitious, Version 3 is currently planned for the end of 2009.

EudraPharm

This system has been in operation since 6 December 2006. In December 2008, the final development release containing the final version of the on-line data entry interface, full export and download facilities and the requested search by country feature was made available in the EudraNet version, where data made available by NCAs is currently accessible. The roadmap for the submission of data on national products by NCAs has been presented to HMA, and the Memoranda of Understanding for EU Telematics as a whole and EudraPharm specifically have not been signed. The development project was closed in December 2008 and EudraPharm is now being maintained rather than further developed. Key requirements including links to data fields from EudraCT (including those specifically related to paediatrics will be addressed in this context.

e-Application Forms

As discussed in the previous report, this project is behind schedule as it took longer than anticipated to put in place the necessary team to agree upon, and develop the data exchange standard and the related systems. The scope and requirements are agreed in some detail as documented in the project definition document and work has been initiated on developing the data exchange standards to reflect changes that have been agreed in the MAA application form. The key deliverables will be electronic data standards for the electronic submission of different kinds of application information to EMEA and regulatory authorities, and systems at EMEA that validate during data entry against controlled terminology lists and make available data for automatic uploading into tracking and case management systems. Veterinary and Human applications are within the scope of the development.

Implementation of the PIM System (Centralised)

The system has been in production since December 2005, but as a pilot. New versions of the PIM Review System and the Light Authoring Tool were made available in December 2008, together with guidance documentation for applicants. The plan to consolidate (i.e. maintain rather than significantly further develop) remains in place pending finalisation of analysis results. A set of criteria have been developed and published which, once met will permit the system to be moved forward out of pilot and into full production. Short/medium term development activities continue to concentrate on performance and stability issues for the PIM review system, and a new release of the PIM data exchange standard (v2.7, available for public consultation in December 2008). A detailed architectural/performance analysis of the PIM review system, including the use of Eudranet by National Competent Authorities working on the system, is planned for Q1 2009, and the outcome of this analysis may necessitate a re-build of the application in order to meet performance and usability

[1] http://euteleproj.eudra.org/

criteria for coming out of the pilot. EMEA's stated intention that all centrally authorised products will be converted to the PIM format is being planned in conjunction with work on the system, and marketing authorisation holders are being consulted, A statement of intent as regards the highly recommended use of PIM is to be prepared and published at the end of Q1 2009.

PIM: Extension to MRP/DCP

This project has the limited scope of defining the architecture and deriving an initial cost estimate for presentation to stakeholders, notably HMA. It is clear that construction work will not be authorised until such time as the system for centralised products is out of pilot. Work done to date has indicated that implementation for nationally authorised products is feasible. The major outstanding issue concerns the acceptability of a central system for MRP/DCP, where 4 NCAs have indicated a requirement for systems based on their own soil. The consequence of this, if the position is maintained, is a significantly more complex system, with attendant costs. Initial quantification of this is due to be presented in early 2009.

eCTD Implementation

This project is on track, in line with the announcement published on the EMEA website in February 2008. It is closely linked with the e-Application Form, the implementation of the EURS and the Central Repository. EMEA implemented electronic-only submission of new applications for marketing authorisations on 1 July 2008 and from 1 January 2009, CHMP members are also no longer receiving paper submissions for Centralised Procedure applications. EMEA published a new milestone in December 2008 for the strategy – from 1st January 2010, the eCTD format will be mandatory for all CP applications. Interim guidance on the expected format for any non-eCTD submissions received until that date has also been published, to facilitate handling and ease the transition to eCTD. Since July 1st 2008, 807 eCTD submissions have been received by EMEA, and 212 centrally-authorised products are managed in eCTD format (over half of the total number of centrally-authorised products).

Central Repository for e-Submission

This is in place, and initial testing has been completed. The results of these tests are under evaluation. After this has been completed, the central repository will be rolled out into production. Further activities planned are the implementation of a pilot for use by CMD and a small group of NCAs, and the development of an open applications programming interface for those NCAs wishing to use different review systems. Changes are currently pending to the central repository interface, based on initial feedback from testing. As for PIM, a statement of intent will have to be made by EMEA concerning future use of the central repository.

Eudra Data Warehouse

This system has been in production since mid-2007. The project has been hampered by the lack of availability of suitably qualified resources, and the contention for resources arising through the need to continue to work on the EVDAS that is in production. An initiative to speed up the "folding-in" of the functionality for human pharmacovigilance analysis is being taken forward through "Project 196" (See below). Release 01.04 of the Eudra Data Warehouse, offering data analysis functionality on EV Veterinary data, is nearing the end of the user acceptance testing and is expected to be deployed in production end February. Parallel development activities are the inclusion of the EVDAS system, clinical trials information. Future development activities will encompass the inclusion of all other product-related information.

Project 196: Incorporation of Human Medicinal products into the Eudra Data Warehouse

The objective of this project is to bring forward the "integration" of EVIDS into the Eudra Data Warehouse (EDWH). It is at an early stage – effectively mid-way through Inception – and therefore requirements gathering is not yet complete. Planning of what is to be delivered when has yet to be settled, but the first iteration in Q2 2009 will be very limited. Considerable progress has been made in improving performance of the current EudraVigilance data analysis system, EVDAS.

EU Telematics Controlled Terms

This system has been in production since March 2008. It currently contains 30 controlled lists of terms and is managed by the EUTCT Secretariat which is currently staffed by members of the Project Team together with support from the NCAs. These 30 lists include 3 standard term lists from EDQM and MedDRA and VedDRA.
Version 2.0 was delivered into production on 5 December 2008. The next major version will be Version 2.1 which will bring with it a pilot implementation of an automated business workflow (Oracle BPEL). This is planned for 31 March 2009 and is currently on schedule.

Later in 2009 it is planned to deliver 2 further major versions of the application: Version 3, planned for 31 August 2009, consists of a full production implementation of an automated business workflow (Oracle BPEL) together with automation of terms availability for other Eudra systems and regulatory bodies. There will be more Controlled Term Lists available via the system.
In a proposed change to the currently published EU Telematics Master Plan a Version 4 is to be delivered at the end of 2009. This version will involve the “making public” of the site and the controlled terminology lists. IT development work for the project will be required beyond the end of 2009 to address, *inter alia*, the inclusion of the ISO Lists as detailed in the EU Telematics Master Plan.

EudraCT

This system has been in production since 1 May 2004. Further development as required in connection with Directive 2001/20/EC combined with the requirements proposed by the CTFG in 2007 and the functionality required by the Paediatrics Regulation have been combined in a single project as the EudraCT data is the foundation for both requirements.

Version 6 of the system was delivered into production on 8 December 2008.

The new guidelines which underpin the development of the further versions of EudraCT have just been published.

Version 7 will include automatic validation of CTA forms, automatic comparison of data content of CTA forms, and auto-generation of a CTA electronic document package (CTA form/XML/Validation report). Further development activities during 2009 will cover a major redesign of the CTA form, and publication of protocol-related data – Version 8, and incorporation of clinical study results and coding of active substance/link to EVMPD will be addressed in version 9 in the following year.

The pilot Data Warehouse reporting project has commenced including the implementation of 6 report formats for use by the NCAs, EMEA and Commission in interrogating the EudraCT data. This is an important milestone in the development of the EudraCT project, and is being carried out in parallel to Versions 6.0 and 7.0. Work on this project is still ongoing and is anticipated to be completed during 2nd quarter 2009.

EudraVigilance Human

This system has been in production since December 2001. A project has now been launched to provide additional and modified functionality including grouping of products and substances, improved data cleaning tools, a modified approach to recoding, and improved duplicate detection in order to support data cleaning activities. At a later stage, technical measures will be put in place to implement the draft access policy.

EudraVigilance Veterinary

This system has been in production since 2005. Work on duplicate detection is ongoing and expected to enter user acceptance testing at the end of February.. At a later stage, technical measures will be put in place to implement the revised data elements guideline (version 2.3) and the draft access policy.

EudraGMP

This system has been in production since 27 April 2007. Work on version 1.4 is complete. Work on version 2.0 is ongoing. The key deliverables over the next period are Submission and Consultation of Non-Compliance Information, Improved Search Facility and Publication of Selected Data ("Public Access"). A number of bug fixes are planned for deployment in builds 1.4 and 2.0.

The project will run into quarter two 2009. Following project closure, a core maintenance team will be retained.

Projects on hold

The following projects are either on hold or scheduled for initiation later in the programme

- Eudra User Management System (EUSM)
- PSURs in the eCTD

Operation

1.0 Operational Statistics

Systems availability:

System	Value	Target	Achieved
Central Repository	99.00%	98%	YES
EudraCT - Public Site	99.96%	98%	YES
EudraCT - Secure Site	95.62%	98%	NO
EudraGMP	99.83%	98%	YES
EudraLink	99.14%	98%	YES
EudraNet I*	99.87%	98%	YES
EudraNet II	94.54%	98%	NO
EudraPharm	98.97%	98%	YES
PIM	100.00%	98%	YES
EudraVigilance Data Analysis	98.49%	98%	YES
EudraVigilance Production	99.65%	98%	YES
EURS	99.00%	98%	YES
EUTCT	99.00%	98%	YES

*Table 1: Systems availability for the period **2008 / 11 to 2009 / 01** unless otherwise stated.*

* Represents the single remaining TESTA Connection between EMEA and the Commission – Outage due to move of TESTA Router.

EudraNet II:

The following issues affected EudraNet availability during this period:

Nokia Router Issues

Austria (AGES), France (H), Slovakia (V), Malta (H), Poland (GIF),

Availability Stats with questionable accuracy

Bulgaria (H - Jan = 0.0%), Lithuania (V), Portugal (V),

Internet Connectivity / Local NCA Problems

Bulgaria (H), Bulgaria (V), France (H), Greece (Demokritos), Lithuania (H), Portugal (V),

Notes:

1. There are several cases where the outage is assumed to be due to local LAN / Internet issues due to either poor or no communications with affected NCA
2. Several cases have been identified where the accuracy of the monitoring is called into question
3. The most recent availability figures of 94.66% (Dec) / 92.88% (Jan) are unrepresentative as a large number of sites were down due to the Monitoring System losing connectivity. Actual VPN connections were still operational.
4. There were (and continue to be) issues with the older Nokia boxes which require upgrades to their operating systems and to firewall settings.

EudraCT:

V6.0 was rolled out In December 2008. The rollout was successful, but there were 3 bugs found in the system after initial testing was completed.

- Part of the application that uses password authentication to start, was failing; this was fixed by changing the authentication method.
- PDF style sheets had changed from the previous version. This was not part of this update and had to be rolled back to the previous version's style sheets.
- There is also a bug where member state administrators are unable to manage their users. The fix of this issue has been rolled into a new release, which was tested and went into production the week beginning 26 January 2009.

All of these problems caused a small amount of down time and impacted user experience.

The issue fixed by the release of V6.0 is the duplicated alerts being sent to users. These emails are now sent in batch overnight, and no duplicate emails have been sent.

EudraVigilance:

No service issues or outages have occurred. Note that the availability figures for production are calculated on a 24h basis.

EudraVigilance Data Analysis System:

No service issues or outages have occurred. Please note that the availability figures for production are calculated on a 24h basis.

EudraGMP:

No service issues or outages have occurred

EudraPharm:

No service issues or outages have occurred

PIM:

Two new versions were rolled out during the reporting period leading to planned downtime.

EURS:

No service issues or outages have occurred

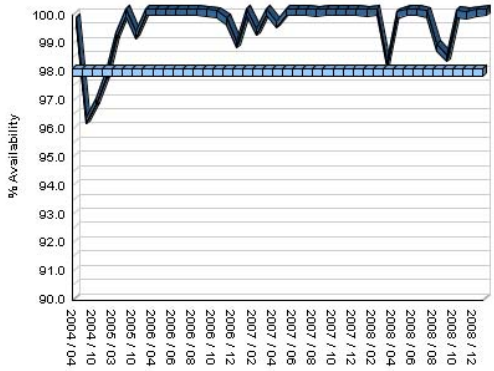
Central Repository:

No service issues or outages have occurred

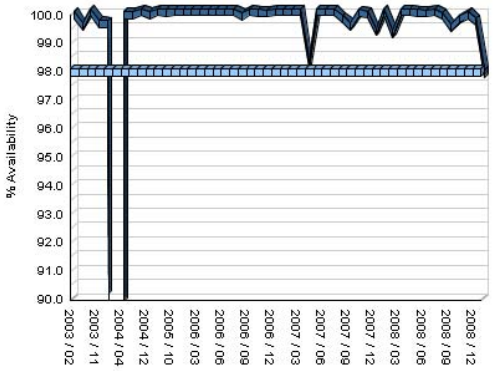
EUTCT:

No service issues or outages have occurred

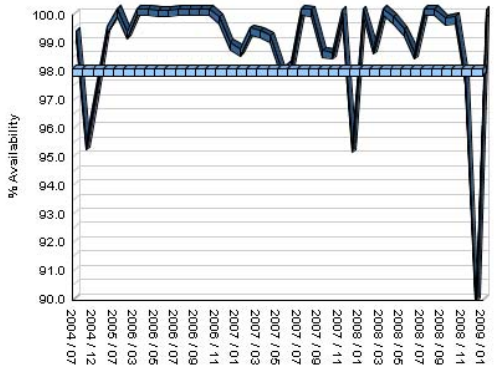
EudraCT – Public Site Availability



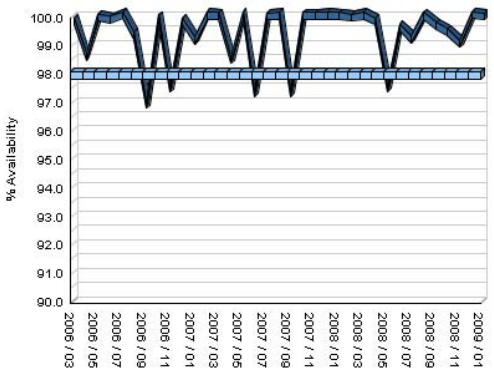
EudraLink Availability



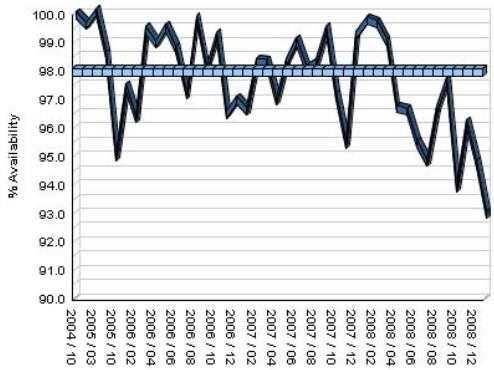
EudraCT – Secure Site Availability



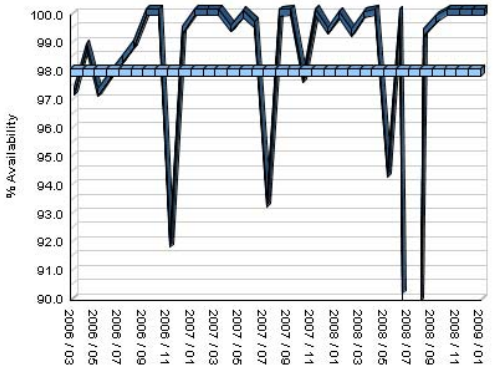
EudraVigilance Availability



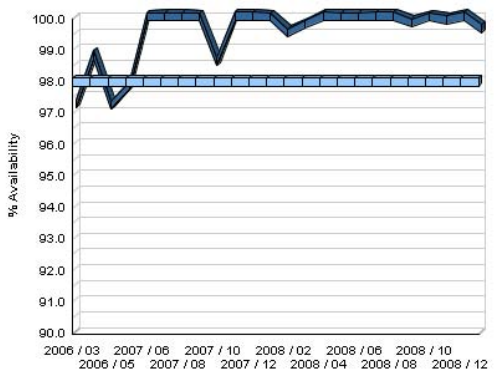
EudraNet II Availability



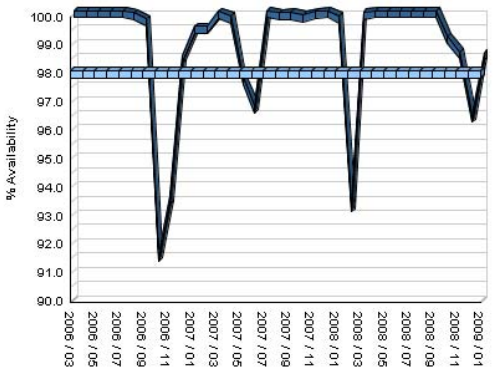
EudraPIM Availability



EudraGMP Availability



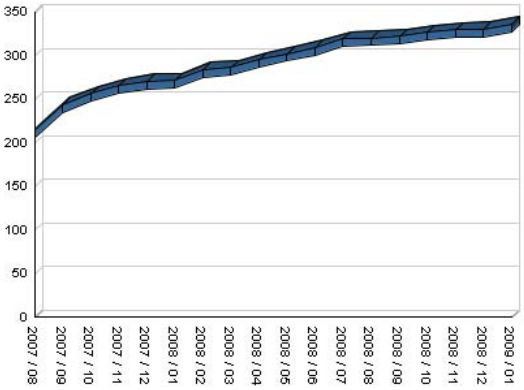
EudraPharm Availability



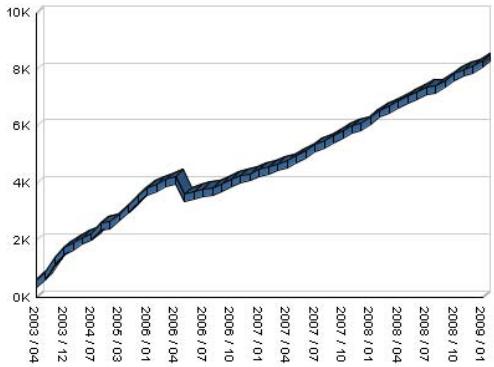
Please note that availability data displayed are calculated on a 24x7 basis and include planned downtime outside EMEA office hours.

2.0 Utilisation Statistics

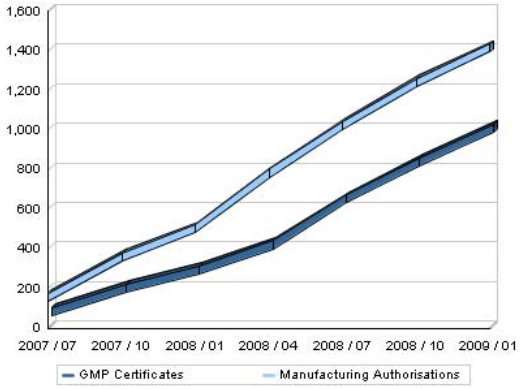
EudraGMP Users



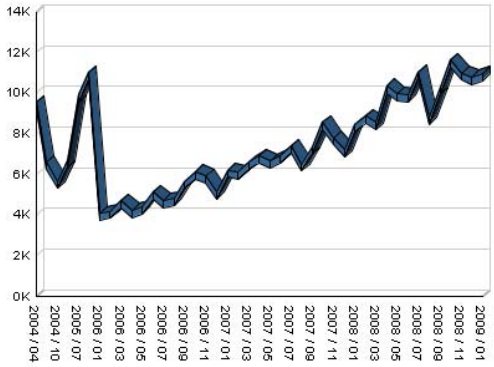
EudraLink Users



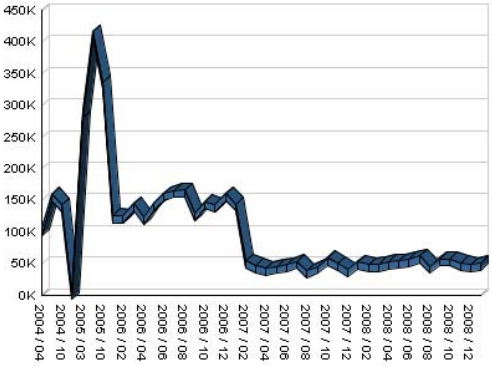
EudraGMP Statistics



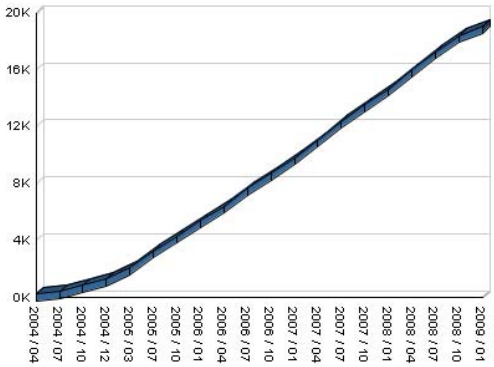
EudraLink Traffic



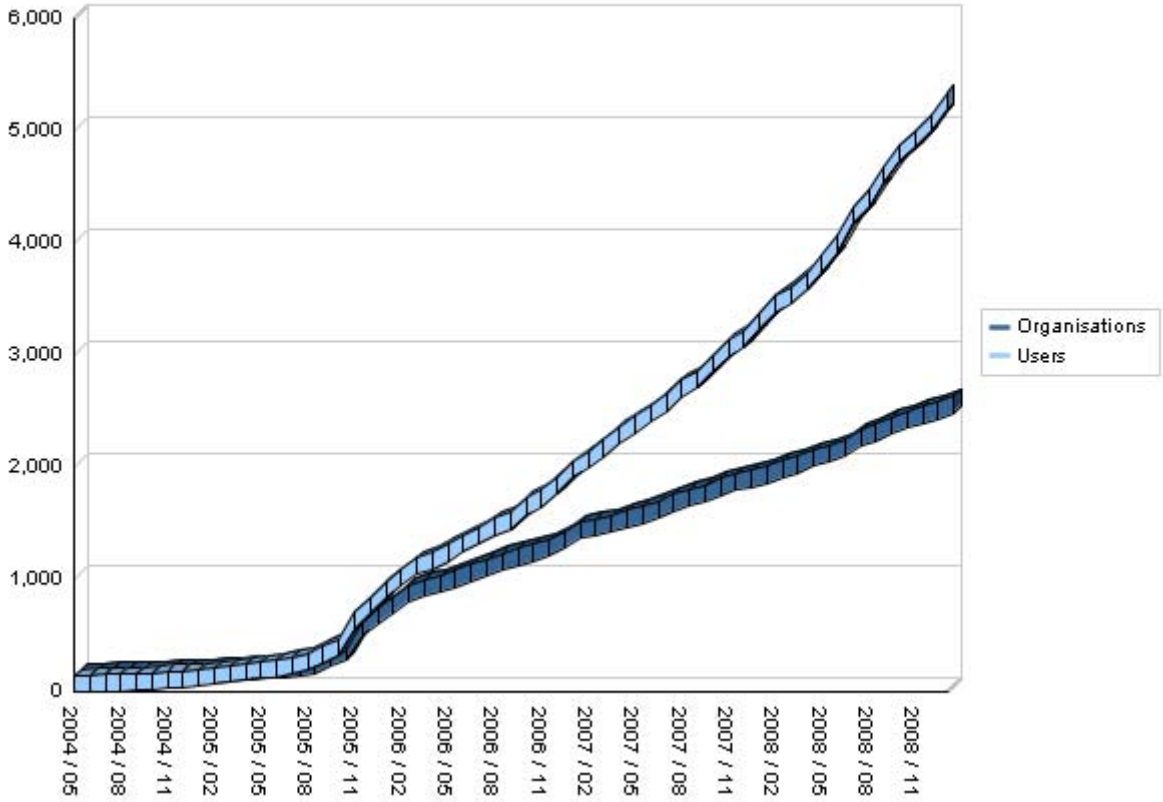
EudraMail Traffic



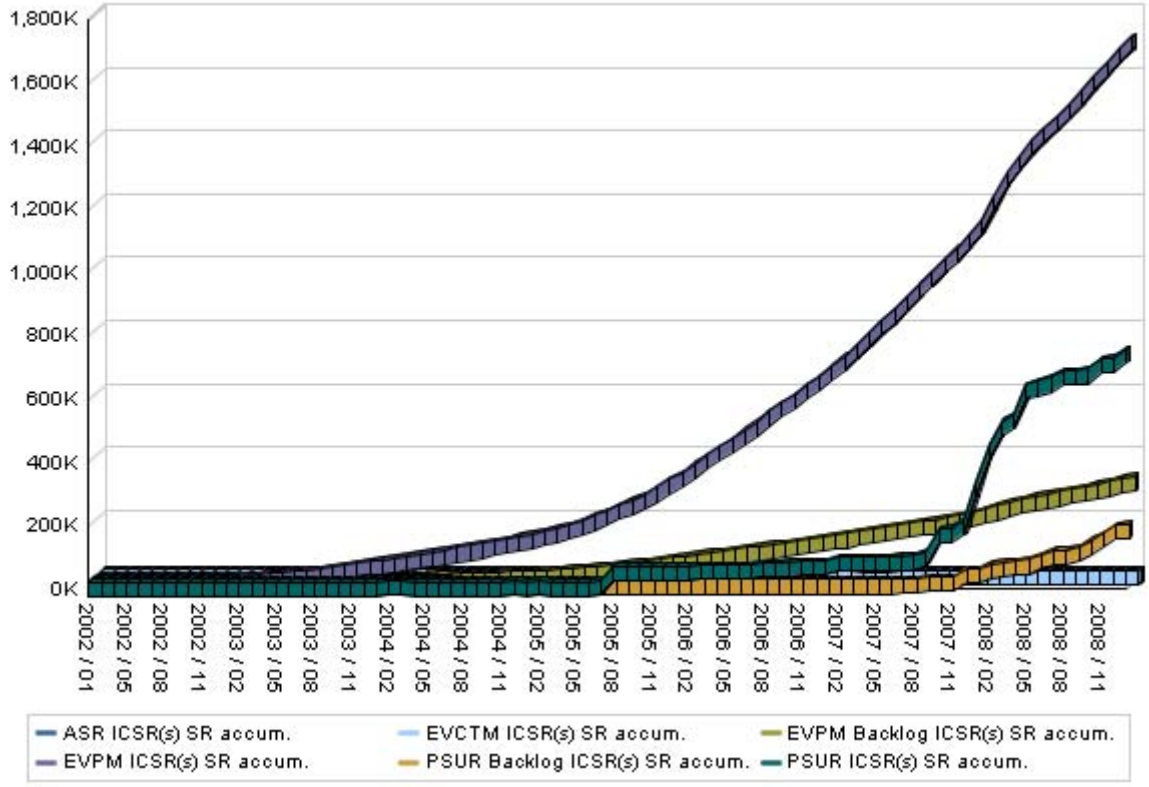
Clinical Trials Recorded



Number of Organisations and Users over the time in EV OLTP Human



Number of ICSRs received over time in EV Human



Human resources

Human resources are assigned to the programme as agreed at 17 staff financed from the EU contribution and an additional 10 full time equivalents funded from EMEA fee income.

Financial resources

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Contracts

A number of routine contracts for support and maintenance of software have been signed during this reporting period.

Audits

No audits have been carried out during the reporting period.

Telematics Steering Committee

The TSC did not meet during the reporting period. The next meeting will probably be held as a stand-alone meeting.

Risk management

Programme and project risk registers are being regularly updated at the EMEA. The major risks remaining are

- the shortage of human resources, both for EMEA staff and contractors
- late input or significant changes to user requirements (scope creep)
- procurement procedures running late
- funding issues which have reappeared as a result of Commission proposals and the need to reassign EMEA budget to systems supporting EMEA business processes

While it has been possible to plan project activities for 2009 in line with the Telematics Master Plan there is a significant funding issue in 2010 when the proposed Commission contribution will cover the operating costs and EMEA will only be able to contribute M€ 3 at most for development activities. The total development costs for 2010 derived from requests from Telematics Implementation Groups and other stakeholders amounted to € 12 124 000, an increase of € 7 921 000 over the budget figures contained in the most recent version of the EU Telematics Master Plan. Following a review of the development requests, EMEA has proposed a prioritisation of requests leading to a total development budget of € 6 622 000 for 2010. This can only be implemented if the Commission contribution is increased in 2010.

Conclusions

The EU Telematics programme continues to run largely on course. Like any programme of its size, complications in governance, and interdependencies with systems running at NCAs, it encounters delays, most of them minor but a few significant, budget overruns and gaps between functionality desired by the user communities and that which can be delivered. It is important to point out that all systems required by legislation have been in production for some time, that service levels are mostly well above agreed thresholds – except for EudraNet, and that significant additional resources over and above the agreed amounts are being assigned to further developments within the programme by the EMEA. The structural funding problem originally identified in 2005 and temporarily resolved through the assignment of significant additional budget by EMEA and the Commission will reappear in 2010 and 2011 when EMEA will have to focus on modernising its ‘corporate’ IT systems.

Annex 1: Systems users and usage

System		
EudraLink	Number of Users	8211
	Total Number of Packages Resent	657
	Total Number of Packages Sent	32245
	Total Volume of Packages Sent (Gb)	124.96
EudraMail	Emails Sent to Eudra Subdomains	127685
	Emails Sent to Functional Mailing List	7367
	Total Number of Emails Sent	135052
	Total Traffic (Gbs)	20.04

*Table 2a: Systems user and usage statistics for the period **2008 / 11 to 2009 / 01** unless indicated.*

EudraCT

Measure	Value
NCA Users	470
Responsible contacts in NCAs	52
EMEA/EC IDs	53
EEA-NCAs submitting to EudraCT	30
Quantity of EudraCT numbers issued	6677
Last Assigned EudraCT Number	2008009334
Trials Recorded by NCAs	37027
Trials Recorded	18824
Multi-state Trials	22731
Third Country Trials	19282
Multi-site Trials	24358
Single-site Trials	10534
Sponsor Status - Commercial	79.5%
Sponsor Status - Not Indicated	0.5%
Sponsor Status - Non-Commercial	20.0%
Alerts: Safety, efficacy, suspended or prohibited	455
Alerts: CA refused authorisation or EC gave a negative opinion	704

*Table 2b: Systems user and usage statistics for the period **2008 / 11 to 2009 / 01** unless indicated.*

EudraVigilance

Users	Incremental	Cumulative
Affiliate: Human Pre-production	51	1224
Affiliate: Human Production	43	1158
Affiliate: Vet Pre-production	2	8
Affiliate: Vet Production	1	8
Commercial Sponsor: Human Pre-production	26	429
Commercial Sponsor: Human Production	31	403
Individual User: Human Pre-production	433	5696
Individual User: Human Production	489	5329
Individual User: Vet Pre-production	25	259
Individual User: Vet Production	30	218
MAH: Human Pre-production	75	1009
MAH: Human Production	63	836
MAH: Vet Pre-production	12	76
MAH: Vet Production	14	62
Non-Commercial Sponsor: Human Pre-production	9	99
Non-Commercial Sponsor: Human Production	7	88
NCA: Human Pre-production	3	44
NCA: Human Production	1	37
NCA: Vet Pre-production	0	32
NCA: Vet Production	0	29

*Table 2c: Systems user statistics for the period **2008 / 11 to 2009 / 01** unless otherwise indicated.*

EudraGMP

	GMP Certificates	Manufacturing Authorisations	Number of Users (ECD)
EudraGMP	994	1415	332

*Table 2d: EudraGMP user and usage statistics from **2008 / 11 to 2009 / 01.***

User support:

System	# of calls to help desk
EudraCT	297
EudraGateway	216
EudraGMP	63
EudraLink	1278
EudraNet II	38
EudraPharm	9
EudraPortal	60
EudraPIM	31
EudraVigilance - Human	612
EudraVigilance - Vet	30
Experts DB	8
EUTCT	4
MMD	40

*Table 3: Help desk statistics from **2008 / 11 to 2009 / 01.***