European Medicines Agency

EMEA/287743/2009
Management Board meeting 11 June 2009
Agenda point 23 For information[1]

Update on the implementation of the EU Telematics strategy

Background note

As agreed by the Management Board on 19 December 2002, the EMEA presents regular status and progress reports on Eudra Telematics implementation at each meeting.

Matters for Consideration

This is the 23rd report of this type. It covers the period from 01 January 2009 to 31 March 2009. An executive summary of the report is provided on page 2.

[1] This document presented for information will not be discussed at the meeting unless specifically requested by a member.

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Update on EMEA implementation of EU Telematics strategy

Executive Summary

Operation: Except for EudraNet 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 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, overdependence on external contractors, complexity of management structure 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 2009 is €13 615 000 of which € 8 947 000 is granted as Telematics fund by the European Commission. To date, € 3 368 000 have been committed and € 848 000 have been paid.

Contracts: New contracts and specific contracts were signed for hardware maintenance and support. Negotiations are under way with two software providers to establish new framework contracts.

Audits: An audit on data security and integrity of software, hardware and networks was carried out during the period.

TSC update: The TSC met in Brussels in March 2009. The principal topic was the Telematics Master Plan. The Committee expressed concern that (a) the funding assumption underlying the 2010 Master Plan would in all probability not hold; and (b) the further funding required over

the period 2011 to 2013 would not be available. It was accepted that EMEA would need to monitor the situation and manage the risk as necessary.

The TSC also discussed EudraPharm, noting that two NCAs raised issues that precluded the signature of the Memoranda of Understanding. The TSC agreed that a feasibility study should be commissioned by EMEA using existing budget appropriations. The study, to be completed before the end of 2009, should establish what users' requirements are, assess what is currently in place to meet these requirements, and derive the gap.

The European Commission introduced the new legislative package. The European Commission estimated that from a Telematics perspective, this would entail expenditure of M€ 3.8 to implement the pharmacovigilance aspects, and €500,000 to extend the EudraGMP database in support of the anti-counterfeit proposals. The Telematics master plan is to be updated to reflect these requirements.

Finally, the TSC discussed a proposal from the European Commission on the governance of EU Telematics: The Chair proposed that simplification of the governance structure be considered including the role, composition and chairmanship of the Telematics Steering Committee, such that the number of different groups currently involved would be reduced, the reporting lines rationalised, and the appropriate representation of the Regulatory Network in the structure confirmed. The Committee agreed, and the Chair undertook to make a concrete proposal to the next meeting of the Committee.

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 endorsed by the Telematics Management Committee at its last meeting and is expected to be published once accepted by the Telematics Steering Committee. Work is ongoing on version 3, which is aimed at resolving a number of issues raised by the proof of concept exercise carried out in connection with Version 2 whilst encompassing all information used in connection with the whole range of EU Telematics systems. The team will monitor international standardisation initiatives with a view to harmonisation. It is anticipated that full harmonisation will be achieved once the standards are themselves mature. 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

While this project has been behind schedule since inception, the team is working to complete the deliverables for the end of 2009. Development of the data exchange standards to reflect changes that have been agreed in the MAA application form is well advanced, and design work on the systems has commenced. 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 pilot production since December 2005.
The current roadmap towards full implementation of PIM details a start to the migration exercise in Q2 2009, with planning and analysis. This work is ongoing. This will be followed by a proof of concept migration in Q3/Q4, and the full migration will be carried out by EMEA and applicants/MAHs throughout 2010 and into 2011, to be completed at the latest by June 2011. This is considered a feasible timeframe in consideration of the significant dependencies and complexities of the project. In parallel, 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. The targeted date for moving into full production with PIM is June 2010. There is no direct dependency between completion of the migration exercise and exiting the pilot phase – the pilot phase can end while migration is ongoing.

Short/medium term development activities continue to concentrate on performance and stability issues for the PIM review system, and consolidation of system development. 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 Q2/Q3 2009, and the outcome of this analysis may necessitate a re-build of the application in order to meet performance and usability criteria for coming out of the pilot.

A statement of intent as regards the migration exercise, the pilot exit and the highly-recommended use of PIM is to be prepared by the EMEA Business Team and will be published at the end of Q2 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.

Work on the extension of PIM to MRP/DCP will resume in earnest once the approach is proven in production for the Centralised Procedure.

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, over 2000 eCTD submissions have been received by EMEA, and 385 centrally-authorised products are managed in eCTD format (more than two thirds 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, has been deployed in production early March 09. Parallel development activities are the inclusion of the EVDAS system (See Project 196 below) and clinical trials information (See also EudraCT below). The latter is scheduled to be available in July 09. A next iteration focussed on

providing data analysis functionality on EV Veterinary data, initially planned for 2012 as per the 2009 budget plan, has been brought forward to deal with duplicates detected in the transactional EV Vet system. 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 in the design phase. The planning indicates delivery in Q4 2009.

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 2.2 which will bring with it a pilot implementation of an automated business workflow (Oracle BPEL). This is now planned for end of Q2 2009.

Later in 2009 it is planned to deliver 2 further major versions of the application: Version 3, planned for Q3 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 future versions of EudraCT were 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.
The incorporation of clinical study results and coding of active substance/link to EVMPD will be addressed in Version 9 in 2010.

The pilot Data Warehouse reporting project is progressing. It includes 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 (EV Human 7.4) 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. This release is planned for delivery in October 09.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. The development of the tools for duplicate detection is now finished. User acceptance testing of this functionality is expected to start in May. Work on the next release has started. This next release has as objective to improve the EVWeb tool and is scheduled for user acceptance testing in August 09. 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 is currently on track to be complete, as regards the functionality for versions 1.4 and 2.0, in July 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

1.0 Operational Statistics

Systems availability:

System	Value	Target	Achieved
Central Repository	99.00%	98%	YES
EudraCT - Public Site	99.98%	98%	YES
EudraCT - Secure Site	99.96%	98%	YES
EudraGMP	99.81%	98%	YES
EudraLink	98.11%	98%	YES
EudraNet I	99.95%	98%	YES
EudraNet II	93.09%	98%	NO
EudraPharm	99.31%	98%	YES
EudraPIM	99.36%	98%	YES
EudraVigilance Data Analysis System	97.99%	98%	NO
EudraVigilance Human and Vet Production	99.92%	98%	YES
EudraVigilance Human and Vet External Compliance Testing	99.33%	98%	YES
EURS	99.00%	98%	YES
EUTCT	99.00%	98%	YES

*Table 1: Systems availability for the period **2009 / 01 to 2009 / 03** unless otherwise stated.*

EudraNet II:

The following issues affected EudraNet availability during this period:

Nokia Router Issues

Availability Stats with questionable accuracy

Internet Connectivity / Local NCA Problems

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 major service issues or outages have occurred. Please note that the availability figures for production are calculated on a 24h basis. In addition, there was an issue with the connection of the monitoring system during March 2009.

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.

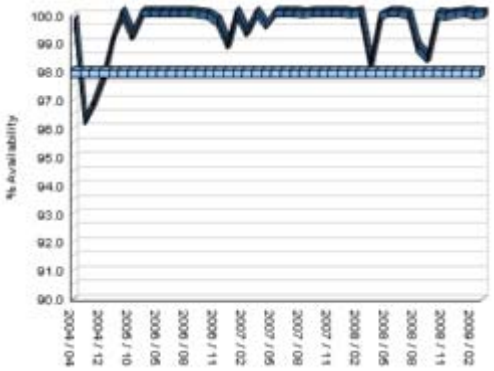
Central Repository:

No service issues or outages have occurred.

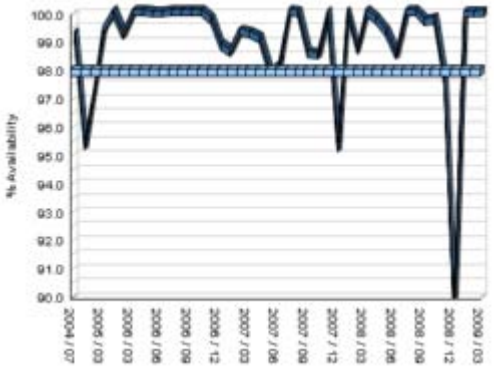
EUTCT:

No service issues or outages have occurred.

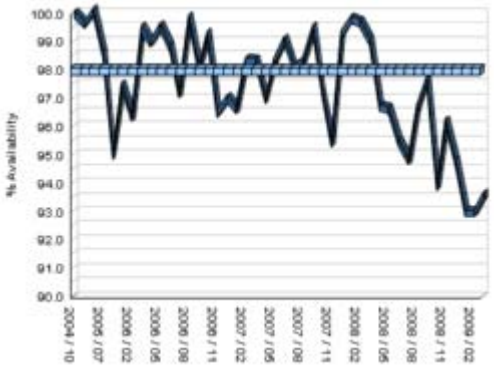
EudraCT – Public Site Availability



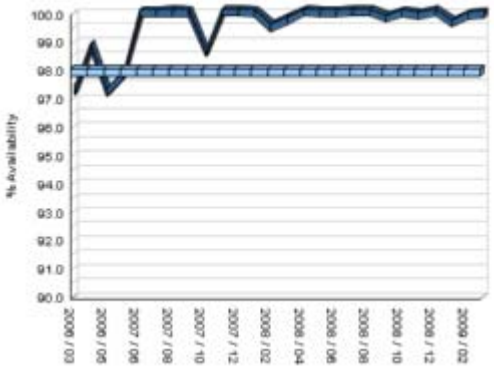
EudraCT – Secure Site Availability



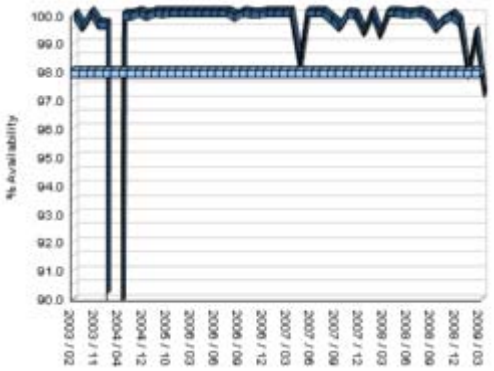
EudraNet II Availability



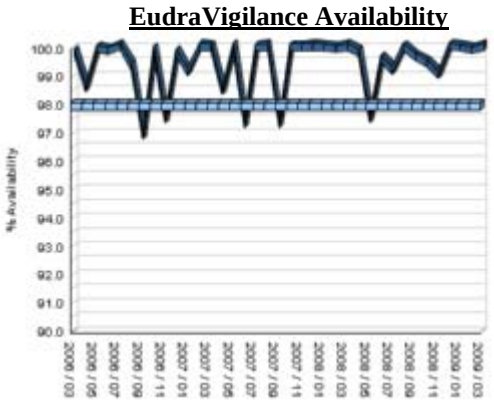
EudraGMP Availability



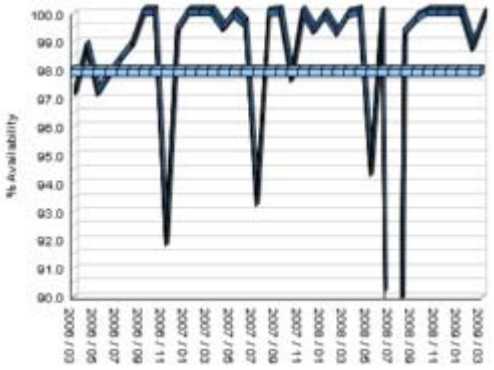
EudraLink Availability



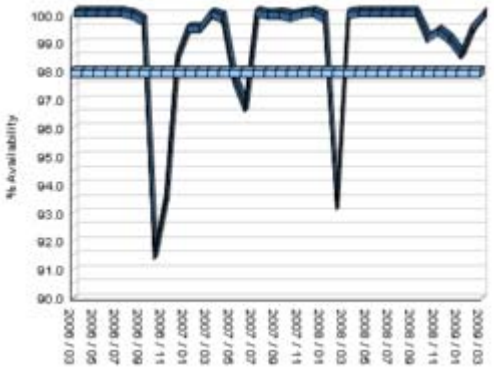
EudraVigilance Availability



EudraPIM Availability

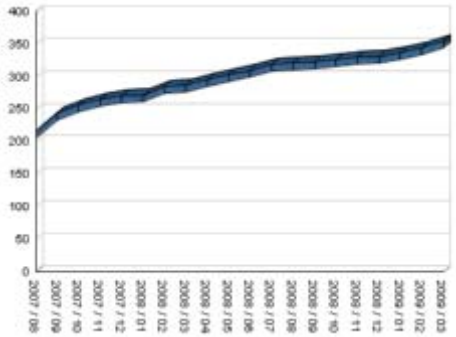


EudraPharm Availability

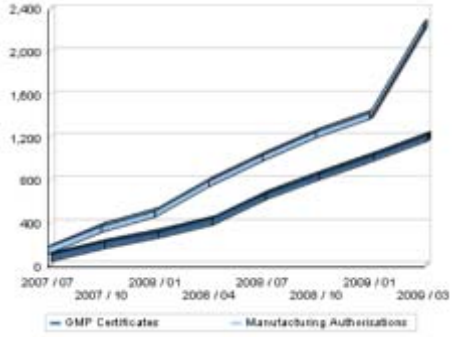


2.0 Utilisation Statistics

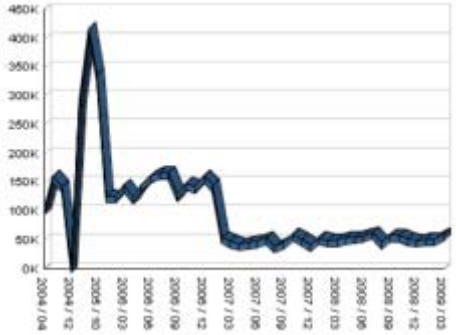
EudraGMP Users



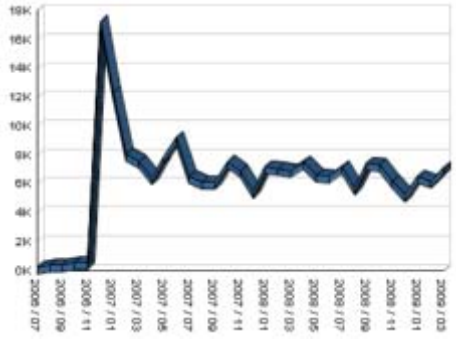
EudraGMP Statistics



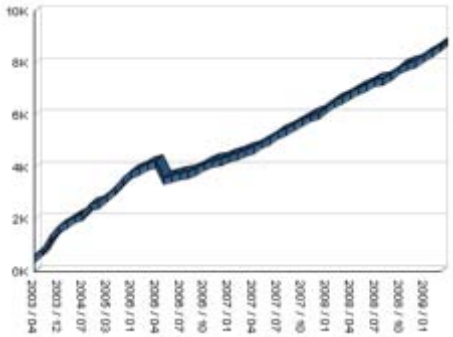
EudraMail Traffic



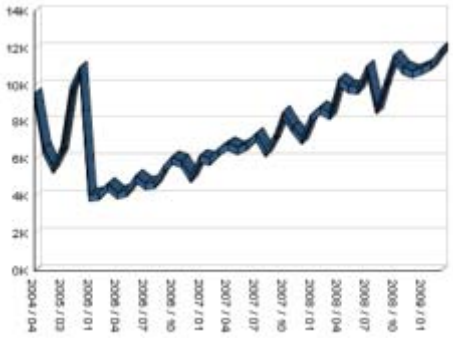
EudraPharm Site Visits



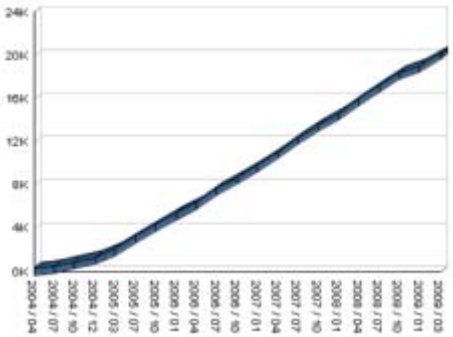
EudraLink Users



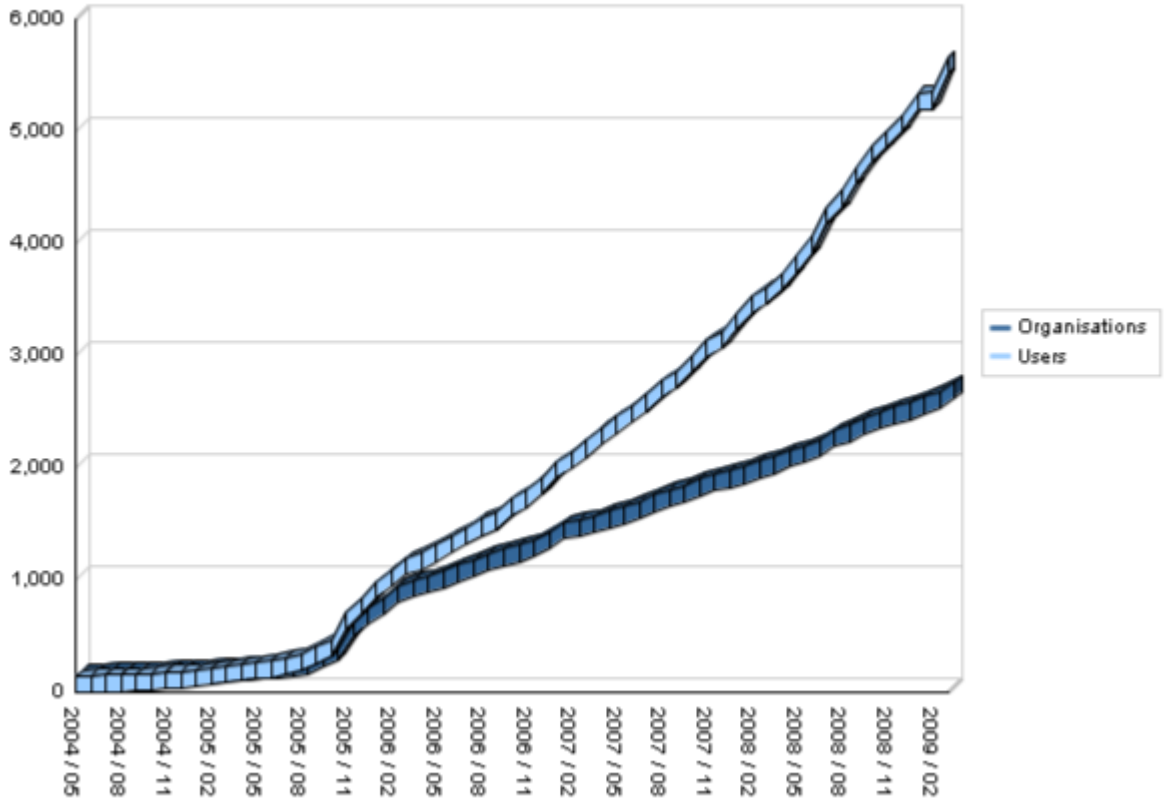
EudraLink Traffic



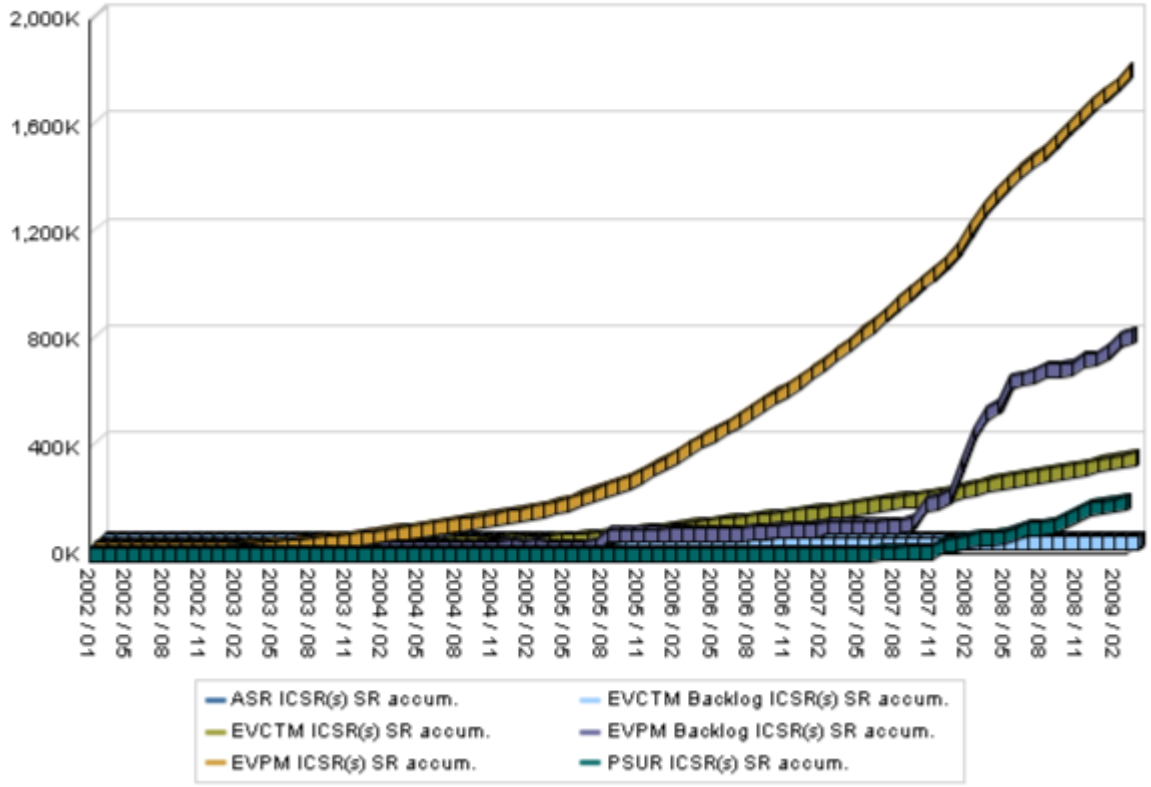
Clinical Trials Recorded



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



Number of ICSRs received over time in EV Human



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Financial resources

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Contracts

New contracts and specific contracts were signed for hardware maintenance and support. Negotiations are under way with two software providers to establish new framework contracts.

Audits

An audit on data security and integrity of IT soft/hardware and networks was carried out during the period, covering the following elements:

- The extent to which EMEA data security arrangements comply with relevant EU regulation and relevant standards.
- The effectiveness of, and compliance with, EMEA policies and procedures for maintaining the availability, confidentiality and integrity of information.
- The risk assessment process applied to identifying potential threats and the appropriate protective arrangements, including risks resulting from third party access.
- Information related asset inventory and management.
- Business continuity and IT disaster recovery arrangements.

C&N Unit made a decision to adopt the principles set out in ISO 27001:2005 for Information Security Management Systems (ISMS). A dedicated security role has been created in the organisation in order to implement the principles and develop the necessary arrangements.

The Auditors found that overall the information security arrangements in place are robust and largely meet the requirements of ISO 27001:2005.

The audit identified three opportunities for improvement related to the development and implementation process, which are being addressed at present in the form of Improvement Action Plans to be presented to the Auditors in June-09.

Telematics Steering Committee

The TSC met in Brussels in March 2009.

The principal topic was the Telematics Master Plan. The Committee expressed concern that (a) the funding assumption underlying the 2010 Master Plan would in all probability not hold; and (b) the further funding required over the period 2011 to 2013 would not be available. It was accepted that EMEA would need to monitor the situation and manage the risk as necessary.

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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
- Complexity of management structure (to be partially addressed through changes to TSC)
- Overdependence on external contractors (impossible to address root cause until more staff positions can be made available)
- Inadequate level of planning possible (risk mainly results from a combination of the other risks listed)

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	8604
	Total Number of Packages Resent	933
	Total Number of Packages Sent	33665
	Total Volume of Packages Sent (Gb)	135.66
EudraMail	Emails Sent to Eudra Subdomains	140057
	Emails Sent to Functional Mailing List	6497
	Total Number of Emails Sent	146554
	Total Traffic (Gbs)	21.82

*Table 2a: Systems user and usage statistics for the period **2009 / 01 to 2009 / 03** unless indicated.*

EudraCT

Measure	Value
EMEA/EC IDs	56
NCA Users	448
Responsible contacts in NCAs	50
EEA-NCAs submitting to EudraCT	30
Last Assigned EudraCT Number	20090011936
Quantity of EudraCT numbers issued	1776
Trials Recorded	19980
Trials Recorded by NCAs	39577
Multi-state Trials	24370
Multi-site Trials	26055
Third Country Trials	20746
Single-site Trials	11255
Sponsor Status - Non-Commercial	20.0%
Sponsor Status - Not Indicated	0.5%
Sponsor Status - Commercial	79.5%
Alerts: Safety, efficacy, suspended or prohibited	951
Alerts: CA refused authorisation or EC gave a negative opinion	1201

*Table 2b: Systems user and usage statistics for the period **2009 / 01 to 2009 / 03** unless indicated.*

EudraVigilance

Users	Incremental	Cumulative
Affiliate: Human Pre-production	65	1243
Affiliate: Human Production	68	1203
Affiliate: Vet Pre-production	1	9
Affiliate: Vet Production	2	10
Commercial Sponsor: Human Pre-production	24	439
Commercial Sponsor: Human Production	29	418
Individual User: Human Pre-production	600	5873
Individual User: Human Production	695	5625
Individual User: Vet Pre-production	22	254
Individual User: Vet Production	29	234
MAH: Human Pre-production	68	1032
MAH: Human Production	71	876
MAH: Vet Pre-production	15	87
MAH: Vet Production	18	75
Non-Commercial Sponsor: Human Pre-production	10	103
Non-Commercial Sponsor: Human Production	12	96
NCA: Human Pre-production	1	43
NCA: Human Production	1	38
NCA: Vet Pre-production	0	31
NCA: Vet Production	0	29

*Table 2c: Systems user statistics for the period **2009 / 01 to 2009 / 03** unless otherwise indicated.*

EudraGMP

	GMP Certificates	Manufacturing Authorisations	Number of Users (ECD)
EudraGMP	1180	2253	350

*Table 2d: EudraGMP user and usage statistics from **2009 / 01 to 2009 / 03.***

User support:

System	# of calls to help desk
EudraCT	257
EudraGateway	265
EudraGMP	65
EudraLink	1548
EudraNet II	60
EudraPharm	10
EudraPortal	71
EudraPIM	40
EudraVigilance - Human	520
EudraVigilance - Vet	19
Experts DB	4
EUTCT	4
MMD	54

*Table 3: Help desk statistics from **2009 / 01 to 2009 / 03.***