EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 November 2010
EMA/674449/2010

Update report on the Agency's implementation of EU Telematics strategy

Management Board meeting 16 December 2010

Background note

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

Matters for consideration

This is the 29th report of this type. It covers the period from 1 July 2010 to 30 September 2010. An executive summary of the report is provided on page 2.

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Update on the Agency's implementation of EU Telematics strategy

Executive Summary

Operation:

Agreed service levels have been attained except for EudraNet II; many 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 20,000 mark with more than 12,000 users of EudraLink and approximately 8,000 users of EudraVigilance.

Project Progress:

Project progress is presented in the section immediately following this summary. The key deviations from the 2010 Master Plan are that, on average, projects are running between 3 and 4 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. Version 8 of EudraCT, originally scheduled for release in June 2010, is delayed by at least six months.

Risks:

The main risks to successful continuation of the programme are lack of human resources (Agency 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 the Agency's budget and of the need to refocus the Agency's resources towards improving IT systems in support of the Agency business processes. The budget 2010 adopted by the Management Board during its meeting in December 2009 includes total project development costs of M€ 4.8 for EU Telematics. This already required some cuts to the development programme originally envisaged for 2010 and leaves little room for possible project overruns. M€ 2.2 was added to the development budget through the first amending budget 2010. Following an internal transfer the final total development spend for EU Telematics is expected to reach M€ 12.8 for 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 the Agency's fee income.

The original budget assigned to EU Telematics in 2010 was €13 691 000 of which € 10 000 000 is granted as Telematics fund by the European Commission. This amount has increased to € 20 574 000 following the budget monitoring exercises in August and October as well as the Amending budget in October 2010. The total amount committed to date in respect of Telematics in 2010 is € 17 291 420

Contracts:

The second specific contract was concluded for the EudraVigilance Data Management project. In addition, new specific contracts were concluded for software development with the FIT consortium (transactional systems), and with the Chronos consortium (business intelligence, on-line analytical processing)

Audits:

No audits were carried out during the reporting period specifically aimed at EU Telematics.

Management Board Telematics Committee (MBTC) update:

The MBTC met in April 2010, using Vitero, and face-to-face in June. The outcome of the two meetings was:

- Adoption of the "TIG Chair Appointment Procedure" document and agreement to circulate it to the Telematics Management Committee, to the Management Board and to the Heads of Medicines Agencies (HMA);
- Agreement that The "Role Description of the TIG Chair" and the "Current TIG Chairs, length of service and transitional arrangements" documents be finalised and adopted via written procedure after the June meeting;
- Agreement to consider the roles and compositions of existing TIGs and TMC sub-groups. when additional details of resource requirements, attendance patterns and the members' roles in the communication of Telematics matters had been further analysed; and
- Agreement that the Committee would encourage and promote the use of virtual meetings and alternative ways of communication throughout the European Medicines Regulatory Network.

In addition, the MBTC undertook an initial analysis of the interaction between the MBTC and the Heads of Medicines Agencies (HMA) at decision-making and advisory levels and refined the draft "Introduction to Telematics" document. The Committee was also updated on the status of the "Memoranda of Understanding" for EU Telematics (umbrella) and EudraPharm.

Project Summary

EU Telematics systems and standards: In production

Reference Data Model

Version 3 was approved by TMC in June 2010 following consultation by EMA, TIGs and NCAs. Version 3 has been extended with EudraGMP, CTS and eAF (MAA). In addition, this version also eliminates redundancies and inconsistencies between systems, partly as a result of issues identified by the proof of concept exercise carried out in connection with Version 2. The team has now completed the work according to plan and the project will now enter into maintenance mode where a Change Control Board (CCB) will deal with future change requests and monitor international standardisation initiatives. It is anticipated that full harmonisation will be achieved once the standards themselves are mature.

EudraPharm

This system has been in operation since 6 December 2006 and is in maintenance mode. The latest release, in December 2009, addressed a number of change requests from NCAs in terms of the way in which data is presented, and the mandatory or optional nature of some fields. Further work on the publication of NCA data is contingent on the signing of the memoranda of understanding. As at the date of this report, 19 National Competent Authorities had signed the EudraPharm memorandum of understanding with EMA.

eCTD Implementation

The Agency implemented electronic-only submission of new applications for marketing authorisations on 1 July 2008 and since 1 January 2009, CHMP members are also no longer receiving paper submissions for Centralised Procedure applications. Since 1st January 2010, the eCTD format has been mandatory for all electronic Centralised Procedure applications. This was also the target date for all NCAs to be able to accept eCTD only applications. Since July 1st 2008, over 5,500 eCTD submissions have been received by the Agency, and 406 centrally-authorised products are managed in eCTD format (more than two thirds of the total number of centrally-authorised products).

EudraGMP

This system has been in production since 27 April 2007, and is in routine maintenance. Work is ongoing with the majority of NCAs (Germany and the Netherlands are testing the XML transfer) to facilitate the electronic submission of information via XML.

EU Telematics Controlled Terms (EUTCT)

EUTCT has been in production since March 2008 and currently version 5.2 is in production.

The system offers a central repository of controlled term lists for three audiences of stakeholders:

- The general public via the internet
- The European Regulatory Network via a virtual private network - EudraNet
- The EU Telematics applications via Web Services

During the remainder of 2010, it is planned to maintain and release a minimum of 10 CTLs into the production system under the Agency ICT Maintenance Budget.

EudraCT

The EudraCT system has been in production since 1 May 2004 and currently Version 7 is in production. It offers an EU register of Clinical Trials ongoing in EEA. It also offers alert mechanisms for the European Regulatory Network users for when trials are halted or changed in any one of the EEA countries. Currently all 30 NCAs in the EEA contribute information into this system.

EudraVigilance Human and the EudraVigilance Data Analysis System

This system has been in production since December 2001. The latest major release, EV Human 7.4, was deployed in production in July 2010. It provided additional and modified functionality including improved data cleaning tools, a modified approach to recoding, and improved duplicate detection in order to support data management activities.

EudraVigilance Veterinary

EudraVigilance Veterinary 2.x has been in production since 2005 and is now widely used by both Regulators and Industry.

Eudra Data Warehouse

This system has been in production since mid-2007 and currently version 01.06 is in production. It provides business intelligence functionality on veterinary PharmacoVigilance data.

EU Telematics systems: Projects

e-Application Forms

Issues raised during peer review and testing procedures coupled with changes in the staffing of the Team necessitate a re-planning exercise. An updated plan will be available mid November 2010

In parallel, operational and business plans will be developed so that appropriate UAT and pilot activities can be carried out in a coordinated manner prior to deployment of the eAF system in production.

Implementation of the PIM System (Centralised)

The current roadmap towards full implementation of PIM is under revision. The delivery times of the PIM systems have moved back from those planned when the migration project was initiated, and both the strategy and the timing of the migration project need to be revised in consequence. Delivery of the review system has been re-scheduled into 2011.

E-SPC Proof of Concept

The project is seeking funding in order to continue.

The Agency is providing minimum support to the project for the second half of 2010. Funding for 2011 is likely only to support one or two meetings.

The project is seeking alternative funding arrangements. Ongoing negotiations indicate a possibility of obtaining funding to resume detailed work in 2012.

Gateway and Central Repository for e-Submission

The timing of implementation of these functions is under review in the context of assuring seamless support across multiple systems for receipt and evaluation processes.. The immediate tasks are to:

- confirm that delivered software is of the required quality
- develop appropriate business processes and validate them with stakeholders
- ensure that operational infrastructures, processes and support are identified and planned for

The objective is to ensure that all the necessary preparation has been done, ready for delivery, for when EURS has been stabilised in production and accepted.

An updated plan will be available mid November 2010 .

Eudra Data Warehouse

A proof-of-concept to speed up the "folding-in" of the functionality for human pharmacovigilance analysis has successfully been concluded. A project is ongoing to evolve this proof-of-concept so that the Eudra Data Warehouse can provide business intelligence functionality on human pharmacovigilance data.

A pilot for clinical trials information (See also EudraCT below) has been made available in September 2009. The next version, aligned with EudraCT version 8, is in development, to be rolled out into production in 2011 as Version 2.0. This will deliver a fully supported production system with revised reports and power users from the NCAs and the Agency.

Future development activities will encompass the inclusion of all other product-related information, sourced from a wide variety of EU Telematics and other systems.

EU Telematics Controlled Terms (EUTCT)

EUTCT development for 2010 is planned to be completed by the end of the year with version 5.3.

This version will deliver improved performance and quality functionality of the system ready for the next stage development as per the EU Telematics Master Plan 2010-2014.

In parallel with these activities, a new EUTCT project has been started to incorporate in 2011 the ongoing ISO initiatives and to extend existing functionality of the system.

EudraCT

Version 8 is planned for delivery by the end of 2010. It will build on the requirements of Directive 2001/20/EC combing the ongoing business requirements of all stakeholders and include the functionality required by the Paediatrics Regulation and Regulation No (EC) 726/2004. In particular, Version 8 and its associated EU Clinical Trials Register will make public protocol-related information. These activities have been combined in a single project as data held in EudraCT is the foundation for both legislative requirements.

The new guidelines which underpin the development of the future versions of EudraCT were published on the Pharmacos site under Volume 10:

http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm.

Version 8 will also include a major redesign of the CTA form, as well as the publication of Protocol-related data.

In early 2011 in Version 8.1, it is planned to deliver a "standard" implementation of Gateway connectivity, business to business interface to allow the automatic data transfer from NCA systems to EudraCT.

Currently there is a requirements gathering exercise ongoing for 2010 involving not just the EU but also international harmonisation via the HL7 initiative – Clinical Trials Register and Results (CTR&R) workgroup to which project resources are committed, and via direct contacts with the US NIH ClinicalTrials.gov project in the context harmonisation.

EudraVigilance Human

Since the last major release, further enhancements are being made which include: infrastructure upgrades seeing the migration of the production environment to virtual servers migration to the 64bit version of Oracle and implementation of the revised safety report business rules into the external test environment allowing organisations to conduct compatibility testing.

Plans for 2011-2013 foresee putting in place technical measures to implement, amongst others, the draft access policy, the revised legislation and new international standards.

EudraVigilance Veterinary

Work on further extending the current version of EudraVigilance Veterinary (2.x) has been closed in favour of a new project. EudraVigilance Veterinary 3.x, has been started up to provide additional functionality, support new international standards and make the system more accessible for a broader user community. As part of this, technical measures will be put in place to implement the draft access policy, plans for which are currently being drawn up.

Work is also ongoing to migrate the production environment to virtual servers.

International Standardisation

This project aims to contribute to the delivery of six international standards in 2011/2012, and further standards following up on work within HL7.

The five draft International Standards making up the Identification of Medicinal Products (IDMP) project were released to the five month, Enquiry stage ballot of ISO on 23 September. Extensive work in support of testing in the frame of ICH has been undertaken during the period, and will continue through to the planned date for collation and submission of comments in January 2011. The new ICSR standard has been proposed for Final Draft International Standard ballot. This is anticipated to be released into formal ballot in February 2011.

Projects on hold

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

- PIM: Extension to MRP/DCP

  Work on the extension of PIM to MRP/DCP will resume once the approach is proven in production for the Centralised Procedure. One issue will be carried forward when the project re-opens, namely that four NCAs have indicated a requirement for systems based on their own soil, the consequence of which would be, if maintained as a position, a significantly more complex system, with attendant increased costs.

- Eudra User Management System (EUSM)

- PSURs in the eCTD

Operational Statistics

Systems availability

System	Value	Target	Achieved
Central Repository	100.00%	98%	YES
EudraCT - Public Site	99.76%	98%	YES
EudraCT - Secure Site	99.55%	98%	YES
EudraGMP	98.57%	98%	YES
EudraLink	98.77%	98%	YES
EudraNet I	99.67%	98%	YES
EudraNet II	94.76%	98%	NO
EudraPharm	99.63%	98%	YES
EudraPIM	99.78%	98%	YES
EudraVigilance Data Analysis	100.00%	98%	YES
EudraVigilance Production	99.86%	98%	YES
EURS	100.00%	98%	YES
EUTCT	98.51%	98%	YES

Table 1: Systems availability for the period 2010/07 to 2010/09 unless otherwise stated.

EudraNet II

Eudranet II had service availability issues from April through August 2010. This was caused by an upgrade to the EMA Checkpoint firewalls which in turn led to system instabilities.

The first stage of the EudraNet II + migration was successful and is now in place and performing well.

In summary, EudraNet achieved reasonable availability levels in the recent 3 month period and successfully completed the first stage of the migration to EudraNet II+. Planning was also agreed and finalised for the deployment of the EudraNet upgrade at each of the NCAs. This deployment is to be completed by Q2 2011.

EudraCT

No service issues have occurred. The secure site was down for planned maintenance.

EudraVigilance

No service issues or outages have occurred other than planned and announced maintenance outages. Note that the availability figures for production are calculated on the basis of EMA working hours.

EudraVigilance Data Analysis System

No major service issues or outages have occurred.

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.

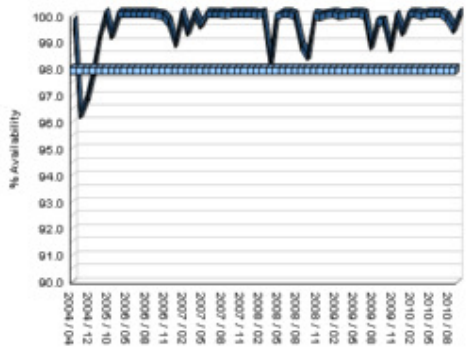
Central Repository

No service issues or outages have occurred.

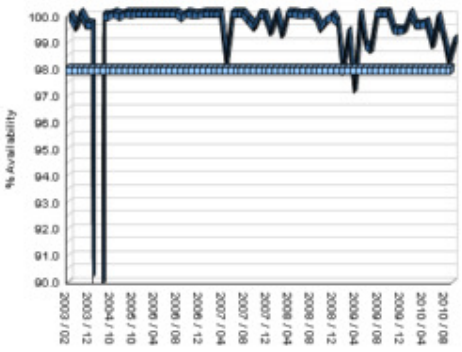
EUTCT

No service issues or outages have occurred.

EudraCT – Public Site Availability

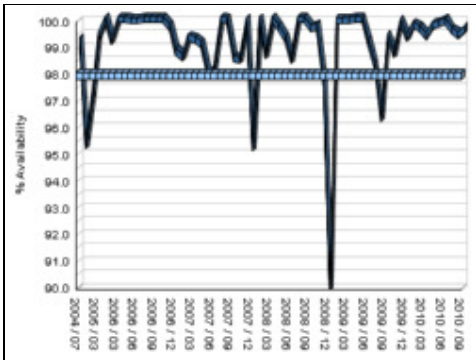


EudraLink Availability

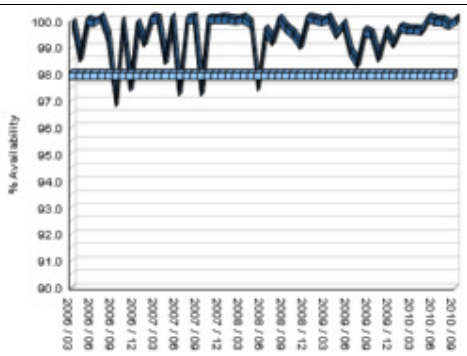


EudraCT – Secure Site Availability

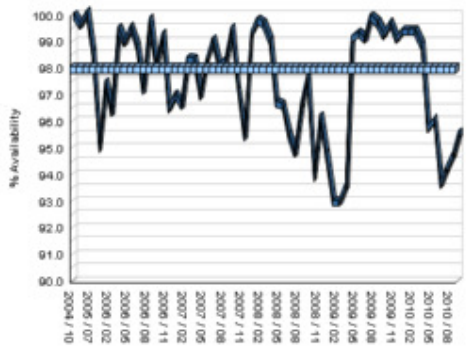
EudraVigilance Availability



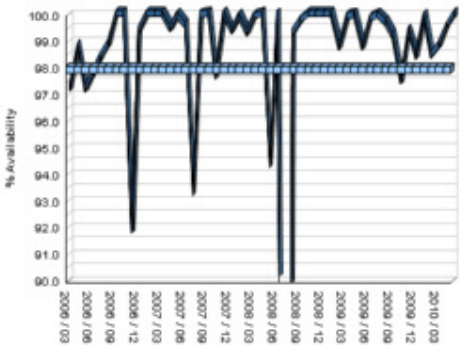
EudraNet II Availability



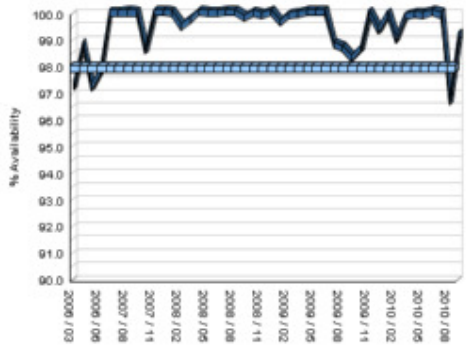
EudraPIM Availability

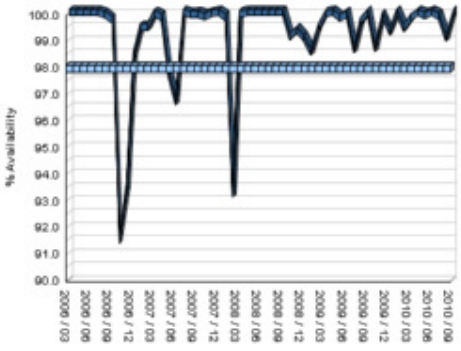


EudraGMP Availability



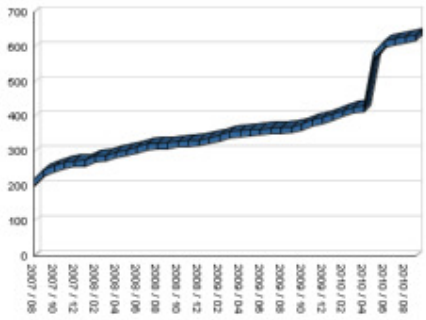
EudraPharm Availability



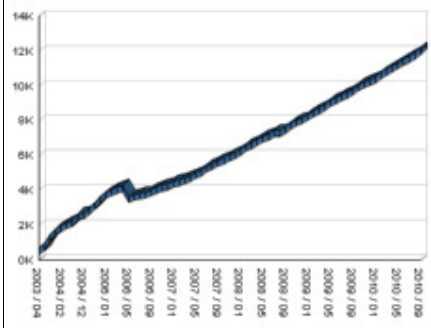


Utilisation Statistics

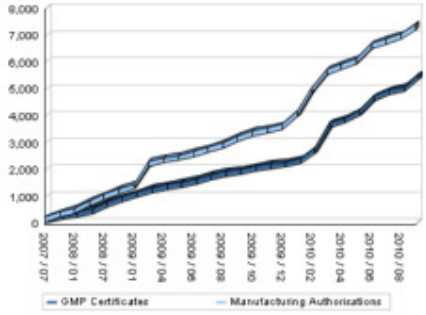
EudraGMP Users



EudraLink Users

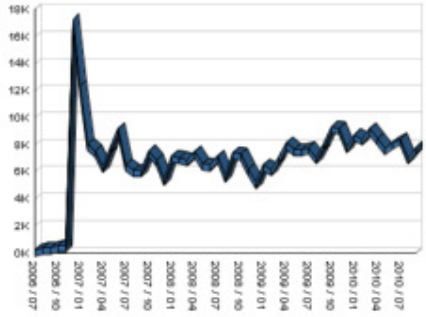


EudraGMP Statistics

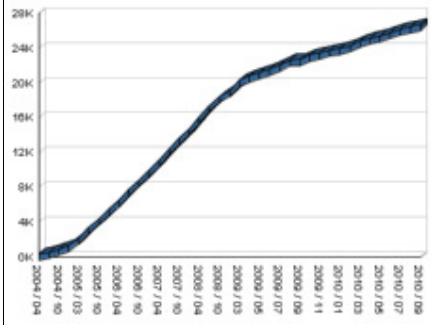


EudraLink Traffic

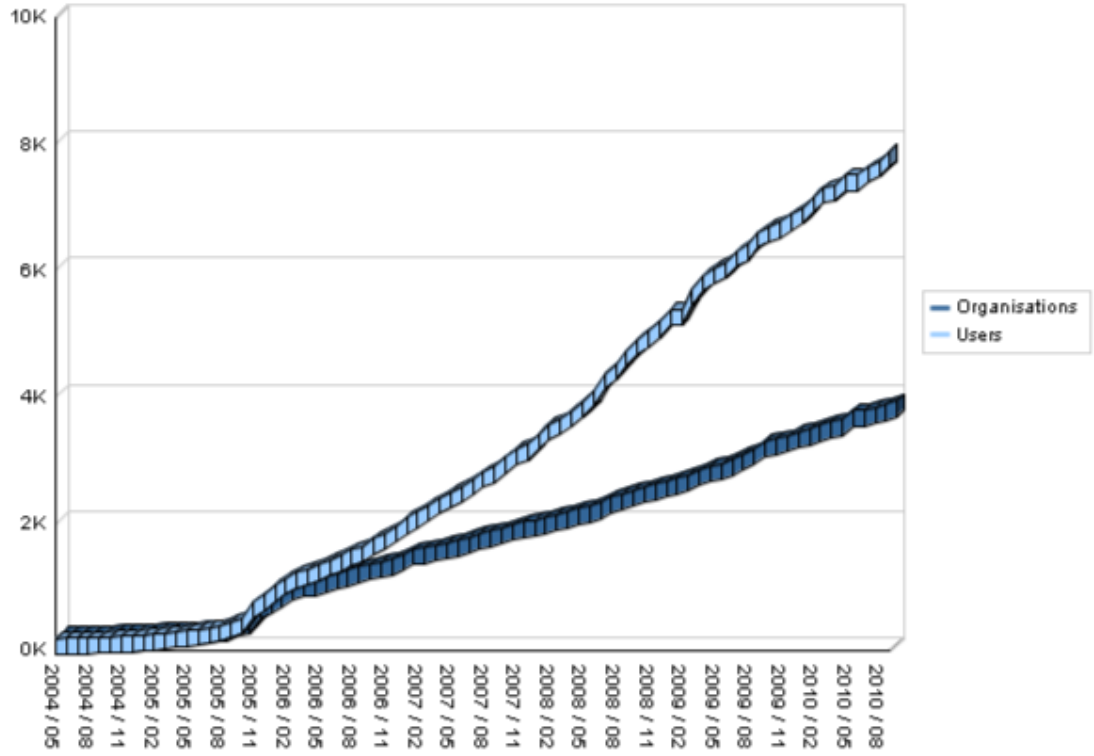
EudraPharm Site Visits



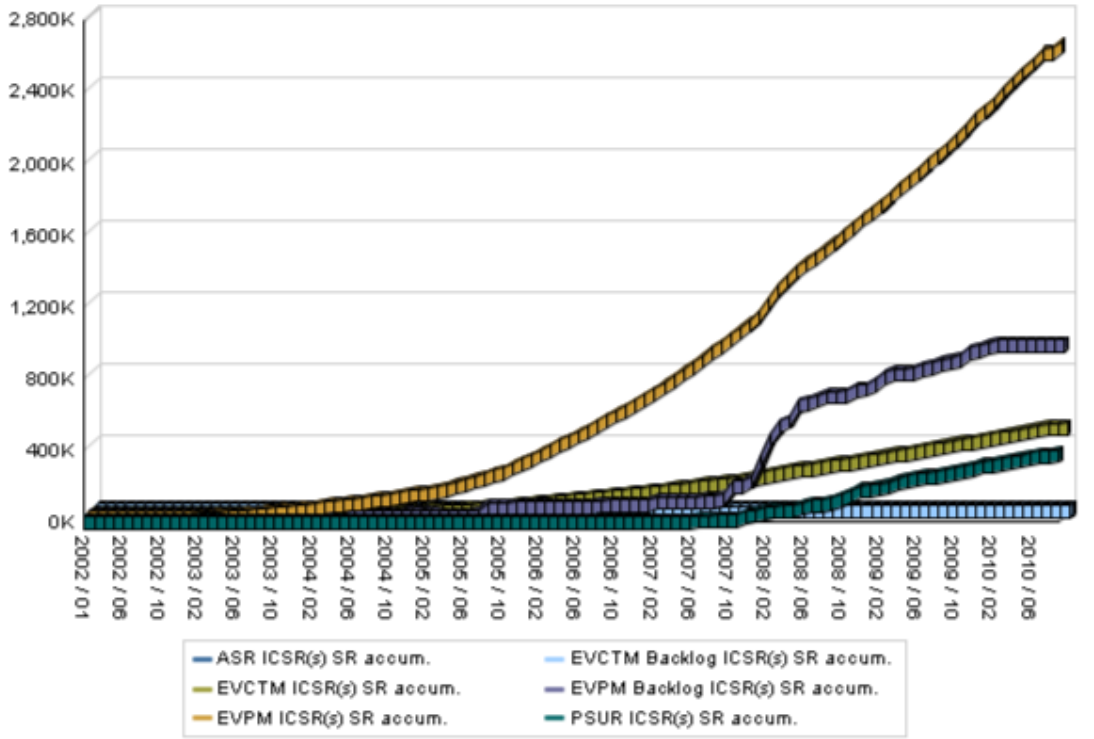
Clinical Trials Recorded



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 the Agency's fee income.

Financial resources

The budget assigned to EU Telematics in 2010 is €13 691 000 of which € 10 000 000 is granted as Telematics fund by the European Commission. This amount increased to € 16 430 000 following the budget monitoring exercise in August 2010 and is expexted to further increase to € 20,574,000. The total amount committed to date in respect of Telematics in 2010 is € 9 735 285

Contracts

A Framework contract and the first specific contract were concluded for the Eudravigilance Data Management project.

Audits

No audits were carried out during the reporting period specifically aimed at EU Telematics.

Management Board Telematics Committee

The MBTC met for the sixth time on 6th September 2010 via Vitero.

The committee discussed drafts of the documents dealing with the role of a TIG member and meeting streamlining proposals, with a view to adopting them at its next meeting. The MBTC also reviewed the preliminary budget proposals for EU Telematics and committed to detailed discussion of updated proposals the following month.

The Committee agreed the composition of the core group that will take forward the EudraPharm Implementation Study with the appointed contractor.

The MBTC met for the fifth time on 9th June 2010.

The Committee adopted the TIG Chair Appointment Procedure document and agreed to circulate it to the Telematics Management Committee, to the Management Board and to the Heads of Medicines Agencies (HMA).

The Role Description of the TIG Chair and the Current TIG Chairs, length of service and transitional arrangements documents were further discussed, before being finalised and adopted via written procedure on the 8th July 2010.

There was an initial discussion of the roles and compositions of existing TIGs and TMC sub-groups. The Committee decided to reconsider the subject when additional details of resource requirements, attendance patterns and the members' roles in the communication of Telematics matters had been further analysed.

There was an initial analysis of the interaction between the MBTC and the Heads of Medicines Agencies (HMA) at decision-making and advisory levels. This subject will be further discussed at the October meeting of the MBTC.

The Committee also refined the "Introduction to Telematics" document and requested that the document be worked on further over the summer. The Chair of the TMC gave an update on the status of the Memoranda of Understanding for EU Telematics (umbrella) and EudraPharm.

The Committee agreed to encourage and promote the use of virtual meetings and alternative ways of communication throughout the European Medicines Regulatory Network.

Risk and Issue Management

Programme and project risk registers are being regularly updated at the Agency. The major risks and issues may be categorised into those that are short-term (mainly relating to (1) the ability of the Agency to meet the human resource requirements through staff or contract means due to the specificity of skills needed, and the time frame available, and (2) the constant increase in requirements requested through the development process and medium term. The medium term risks are structural in nature, and relate to a degree of uncertainty regarding the adequacy of funding going forward, the complexity of the stakeholder relationships that need to be managed, and the imbalance between external contractors and Agency staff, leaving a degree of over-dependence on the one hand, and a capacity shortage for support activities, including procurement activities, on the other.

With regard to the short-term risks, the Agency is recruiting staff on a limited scale with precise specifications, and putting as much emphasis as possible on recruiting to time and specification with its suppliers. The effect of specification changes is being addressed through clear communication of the both the fact of the specification change, and the impact in terms of time and cost.

The medium term issues and risks are being addressed following escalation.

The funding issue identified during the preparation of the budget 2010 persists. While short term problems in 2010 were (partially) addressed through the first amending budget, there are question marks over budget 2011 which will not be finally resolved until European Parliament and Council have reached agreement on the EU budget 2011.

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 above agreed thresholds, and that significant additional resources over and above the agreed amounts are being assigned to further developments within the programme by the Agency. The structural funding problem originally identified in 2005 and temporarily resolved through the assignment of significant additional budget by the Agency and the Commission has reappeared in 2010 and will continue into 2011 and beyond as the Agency will have to focus on modernising its 'corporate' IT systems and the Commission contribution to the EU Telematics budget will be reduced.

Annex 1

Systems users and usage

System		
EudraLink	Number of Users	12019
	Total Number of Packages Resent	864
	Total Number of Packages Sent	51305
	Total Volume of Packages Sent (Gb)	180.01

Table 2a: Systems user and usage statistics for the period 2010/07 to 2010/09 unless indicated.

EudraCT

Measure	Value
Agency/EC users	80
NCA Users	592
Responsible contacts in NCAs	48
EEA-NCAs submitting to EudraCT	30
Last Assigned EudraCT Number	2010-023192-26
Quantity of EudraCT numbers issued	4479
Trials Recorded	53504
Trials Recorded by NCAs	26440
Multi-state Trials	33414
Multi-site Trials	28741
Third Country Trials	35471
Single-site Trials	15363
Sponsor Status - Non-Commercial	79%
Sponsor Status - Not Indicated	1%
Sponsor Status - Commercial	20%
Alerts: Safety, efficacy, suspended or prohibited	2046
Alerts: CA refused authorisation or EC negative opinion	1567

Table 2b: Systems user and usage statistics for the period 2010/07 to 2010/09 unless indicated.

EudraVigilance

Users	Incremental	Cumulative
Affiliate: Human Pre-production	24	1302
Affiliate: Human Production	52	1761
Affiliate: Vet Pre-production	0	21
Affiliate: Vet Production	0	37
Commercial Sponsor: Human Pre-production	30	354
Commercial Sponsor: Human Production	33	539
Individual User: Human Pre-production	327	4935
Individual User: Human Production	593	7634
Individual User: Vet Pre-production	10	386
Individual User: Vet Production	13	421
MAH: Human Pre-production	41	925
MAH: Human Production	59	1232
MAH: Vet Pre-production	6	132
MAH: Vet Production	6	126
Non-Commercial Sponsor: Human Pre-production	2	63
Non-Commercial Sponsor: Human Production	3	120
NCA: Human Pre-production	0	42
NCA: Human Production	0	39
NCA: Vet Pre-production	0	51
NCA: Vet Production	0	30

Table 2c: Systems user statistics for the period 2010/07 to 2010/09 unless otherwise indicated.

EudraGMP

	GMP Certificates	Manufacturing Authorisations	Number of Users (ECD)
EudraGMP	5383	7339	628

Table 2d: EudraGMP user and usage statistics from 2010/07 to 2010/09

User support

System	# of calls to service desk
EudraCT	277
EudraGateway	410
EudraGMP	42
EudraLink	1586
EudraNet II	68
EudraPharm	15
EudraPortal	25
EudraPIM	115
EudraVigilance - Human	758
EudraVigilance - Vet	51
Experts DB	8
EUTCT	28
MMD	33

Table 3: Service desk statistics from 2010/07 to 2010/09.