European Medicines Agency

# 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 24th report of this type. It covers the period from 01 April 2009 to 30 June 2009. An executive summary of the report is provided on page 2.

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

# Update on EMEA implementation of EU Telematics strategy

## Executive Summary

**Operation:** All agreed service levels have been attained; most of them are considerably above the threshold value of 98%. Eudranet in particular was substantially improved since the previous report to the Management Board, achieving service availability greater than 99% over the period April – June 2009. 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 may be a significant funding issue in 2010 when the proposed Commission contribution will cover less than the operating costs of EU Telematics and EMEA will only be able to contribute M€5-6 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.If the current Commission proposals for the draft budget 2010 are maintained, further cuts have to be applied to the development programme.

**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, €9 688 000 have been committed and €2 816 590 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 EudraPharm was carried out during the period. The EudraPharm application was the last remaining Telematics application still to be audited. The focus of the audit was on application support and maintenance as further developments are on hold in 2009.

The Auditors found that EudraPharm operations appear to be compliant with all of the operation performance requirements that currently apply. There were no Opportunities For Improvement. Several positive points were raised concerning EudraPharm availability, response times and Service Desk.

**TSC update**: The TSC met in Stockholm in July 2009. The TSC:

- Made recommendations regarding the composition and mandate of its proposed successor, a sub-group of the EMEA Management Board;
- Agreed that the EU Telematics Master Plan 2009 – 2013 be endorsed by the HMA to be proposed to the Management Board of EMEA for adoption in October 2009 with its conclusion amended to retain the recommendation to implement the plan for 2009, but changing the recommendation with regard to subsequent years to the preparation of an adjusted plan taking into account the requirements of the proposed new pharmaceutical legislation and the risks of the identified funding gap;
- Agreed with the objectives and methodology of the EudraPharm Study proposed terms of reference, subject to four amendments; and
- Agreed that the fact of informal discussions between EMEA, EDQM and FDA in the context of international standardisation activities should be reported to the Heads of Agencies Joint meeting the following day[2].

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[2] The topic was introduced by the presentation at Annex B.

## 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 scheduled for quarter two, 2010.

## 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 a few of the Memoranda of Understanding for EU Telematics as a whole and EudraPharm specifically have 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

This project has been behind schedule since inception, and completion is anticipated in February 2010. 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 (also available to NCAs) 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 includes a start to the migration exercise in Q2 2009, with planning and analysis. This work is ongoing and is on track according to the revised plan, setting out the activities to carry out the full migration (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 being carried out, 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 Q3 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 $1^{st}$ 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 $1^{st}$ 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 ongoing are the implementation of a pilot for use by CMD and a small group of NCAs, and the implementation of the same system for downloading dossiers to local repositories for those NCAs wishing to use different review systems as is in place for those using EURS.. 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 a pilot for clinical trials information (See also EudraCT below). The latter is scheduled to be available in September 2009. 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. This iteration is now in test and is scheduled to be made available to the users in November 2009. Future development activities will encompass the inclusion of all other product-related information. A plan to converge all the different data warehouse activities is currently being drawn up as part of the ICT Master Plan.

## 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 development 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.
Version 2.2 was delivered into production on 10 July 2009 and Version 2.2.1 on the 16 July 2009 and brought with them the pilot implementation of an automated business workflow (Oracle BPEL) as planned.

October 2009 is the planned month for the delivery of Version 3 which will consist 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 and an additional 21 Controlled Term Lists.
Version 4 will be delivered by the end of 2009 and this version will involve the "making public" of the EUTCT site via Internet for the public and the continued exposure to the Regulatory Bodies via EudraNet and IntraNet for EMEA this together with additional Controlled Term Lists to service eAF and other EU Telematics systems.

Ongoing in 2010 and 2011 ICT 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.

For 2009, Versions 6.0.2, 7.0 and 7.0.1 of the system have been delivered into production. These versions provided bug fixes and new business functionality in Version 7 with the 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).
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.

Ongoing development 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 will be addressed in Version 9 in 2010.

The **pilot** Data Warehouse reporting project is progressing and is planned for release in pilot at the end of September 2009.  It includes the implementation of the 6 report formats for use by the NCAs, EMEA and Commission in interrogating the EudraCT data as per Business Use Case 51. This is an important milestone in the development of the EudraCT project.

## 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 2009. At a later stage, technical measures will be put in place to implement the draft access policy.

Work is also ongoing to migrate the production environment to virtual servers and to the next version of the gateway.

## EudraVigilance Veterinary

This system has been in production since 2005. The development of the tools for duplicate detection is currently in user acceptance testing. Work on the next release has started. This next release has as objective to improve the EVWeb tool and is currently being tested before being released for user acceptance testing. At a later stage, technical measures will be put in place to implement the draft access policy.

Work is also ongoing to migrate the production environment to virtual servers and to the next version of the gateway.

## EudraGMP

This system has been in production since 27 April 2007.  Work on versions 1.4 and 2.0 is complete and this phase of the project is closed.  The key deliverables were Submission and Consultation of Non-Compliance Information, Improved Search Facility and Publication of Selected Data ("Public Access"). A core maintenance team has been retained.

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,.

## 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

A summary of the status, by project, is presented in tabular form below.

| Number | Project | Time | Quality | Risks |
|--------|---------|------|---------|-------|
| 00002 | Reference Data Model | -5 | 60% | 5 |
| 00010 | Electronic Application Form | -2 | 80% | 11.5 |
| 00014 | Product Information Management (PIM) | -4 | 70% | 25.4 |
| 00015 | eCTD Implementation | 0 | 70% | 29 |
| 00020 | Eudra Data Warehouse | -5 | 90% | 18.9 |
| 00024 | EudraVigilance MS Edition | 0 | 100% | 0 |
| 00027 | EU Telematics Controlled Terms (EUTCT) | -2 | 75% | 14.7 |
| 00035 | EU Telematics Strategy & Implementation | -1 | 80% | 25.6 |
| 00131 | PIM MRP/DCP Extension | -7 | 80% | 24 |
| 00133 | EudraCT | -1 | 85% | 10.8 |
| 00134 | Central Repository | -5 | 80% | 2 |
| 00144 | EudraVigilance v2.x (V) | -4 | 75% | 14.9 |
| 00145 | EudraVigilance v7.x (H) | -4 | 100% | 25.6 |
| 00148 | EudraGMP | 0 | 100% | 0 |
| 00157 | E-SPC Structure Proof of Concept | -2 | 90% | 6 |
| 00189 | EudraLink2 | -5 | 90% | 10 |
| 00196 | Incorporation of H PhV into EDWH | -9 | 90% | 21.6 |
| 00198 | Gateway for e-submissions | -6 | 90% | 2.5 |
| 00225 | PIM Information | 0 | 90% | 15.6 |
| 00226 | International Standardisation | -3 | 80% | 15 |
| 00227 | ICSR Testing | -2 | 95% | 10 |
| 00231 | EV Data Management | -7 | 85% | 7 |
| 00233 | Lincoln Technologies Pilot | -6 | 0% | 36 |
| 00234 | SAFE 2 Pilot | 0 | 95% | 0 |
| Programme | Averages | -3.5 | 81% | 13.8 |

*Notes:*

| Time | The number of months, in whole months, that the project is behind schedule (minus numbers), or ahead of schedule (plus numbers). Zero indicates the project is on schedule. |
|------|------|
| | 4 months or more behind schedule:          Red |
| | Between 1 and 4 months behind schedule       Amber |
| | One month or less late, or ahead of schedule    Green |
| Quality | An indication, expressed as a percentage, of the extent to which the requirements to date have been met. 100% is where all requirements have been met. |
| | Between 0 and 69%               Red |
| | Between 70% and 84%           Amber |
| | Over 84%                    Green |
| Risks | Expressed as a number between 1 and 36, from lowest to highest, this column indicates the perceived risk to successful com,pletion of the project. |
| | Between 17 and 36              Red |
| | Between 5 and 16               Amber |
| | Between 1 and 4                Green |
| Averages | These are calculated as simple averages for the column. |

## 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 | 99.72% | 98% | YES |
| EudraGMP | 100.00% | 98% | YES |
| EudraLink | 99.15% | 98% | YES |
| EudraNet I | 99.88% | 98% | YES |
| EudraNet II | 99.08% | 98% | YES |
| EudraPharm | 99.92% | 98% | YES |
| EudraPIM | 99.51% | 98% | YES |
| EudraVigilance Data Analysis | 98.42% | 98% | YES |
| EudraVigilance Production | 99.31% | 98% | YES |
| EURS | 99.00% | 98% | YES |
| EUTCT | 99.00% | 98% | YES |

*Table 1: Systems availability for the period **2009 / 04 to 2009 / 06** unless otherwise stated.*


### *EudraNet II:*

The following issues affected EudraNet availability during this period:

Nokia Router Issues

   Hungary (H)

Monitoring Issues

   Slovakia(V), Lithuania (V)

Internet Connectivity / Local NCA Problems

   Hungary (H), Romania (H), Ireland (H+V), Lithuania (H), Lithuania (V), France (H), Bulgaria (V), Portugal (H), Estonia (H+V)

### *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.

V7.0 successfully released to production on the 17th June 2009

*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.

*EudraGMP:*

No service issues or outages have occurred.
V2.0 successfully released to production 30th July 2009

*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**
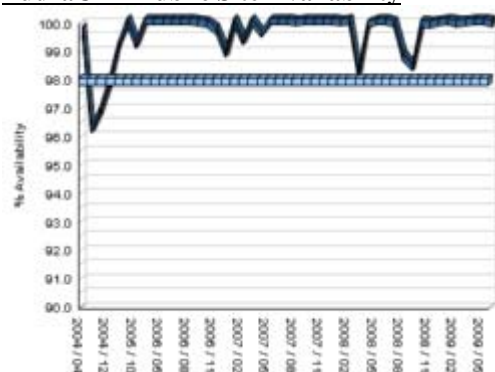
**EudraLink Availability**
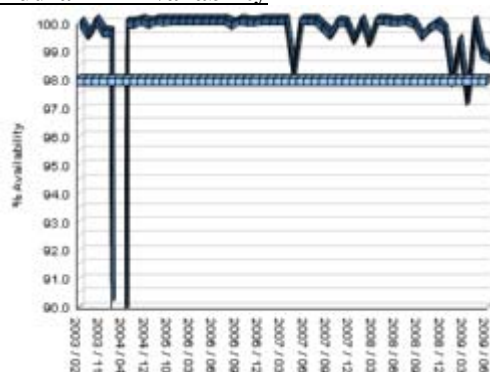
**EudraCT – Secure Site Availability**
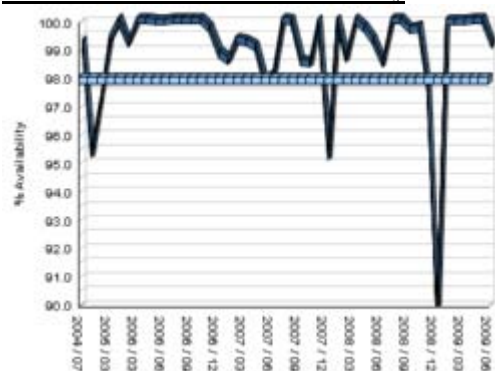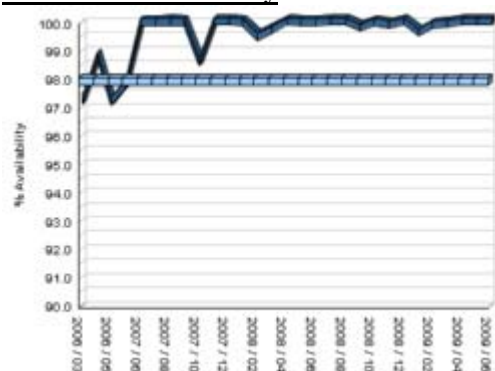
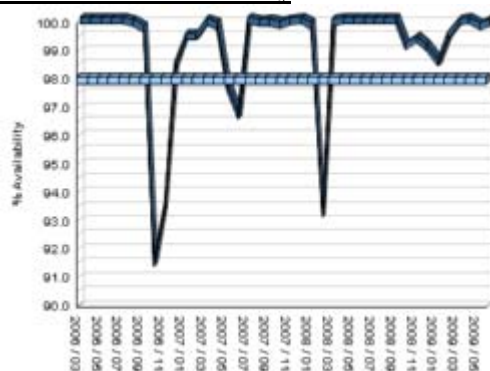**EudraVigilance Availability**
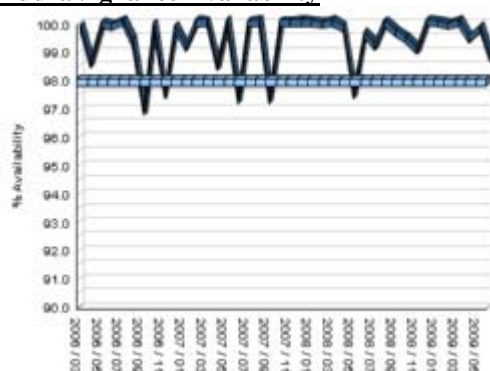
**EudraNet II Availability**
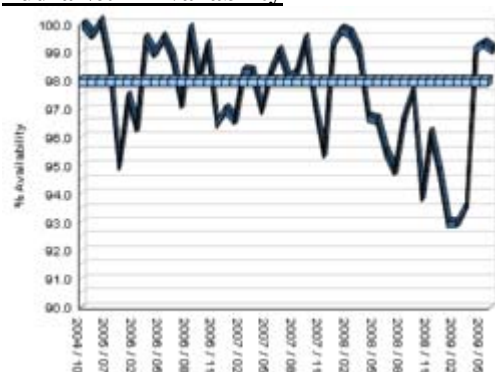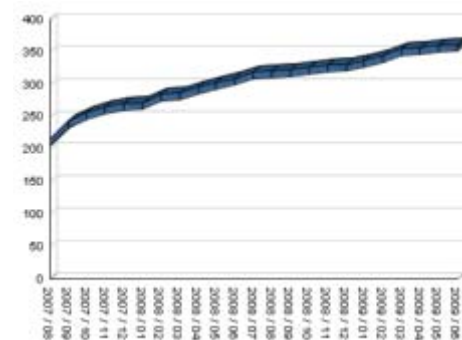
**EudraPIM Availability**
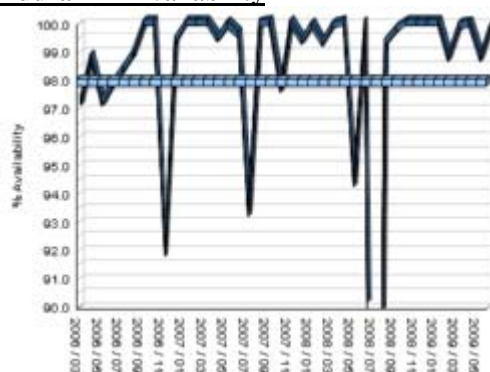
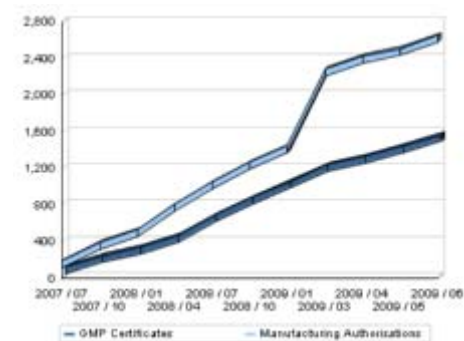**EudraGMP Availability**

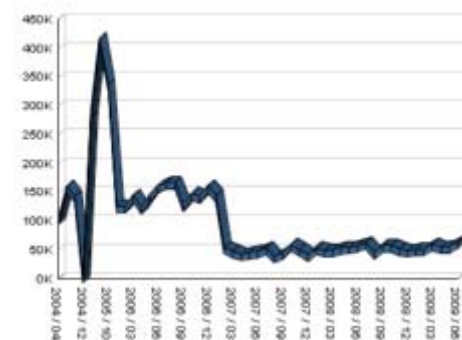**EudraPharm Availability**
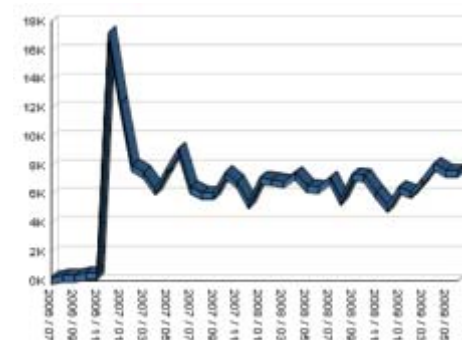
## 2.0 Utilisation Statistics

EudraGMP Users



EudraLink Users



EudraGMP Statistics



EudraLink Traffic



EudraMail Traffic
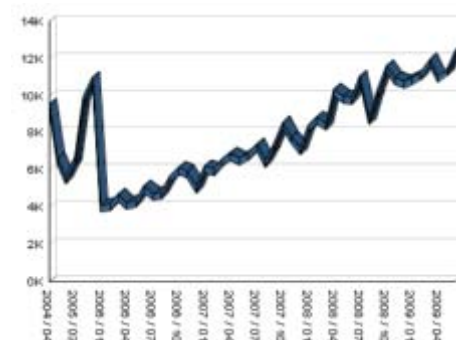


Clinical Trials Recorded



EudraPharm Site Visits
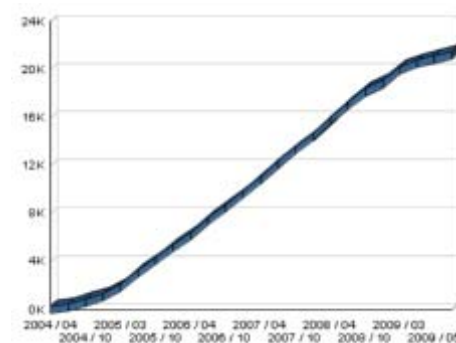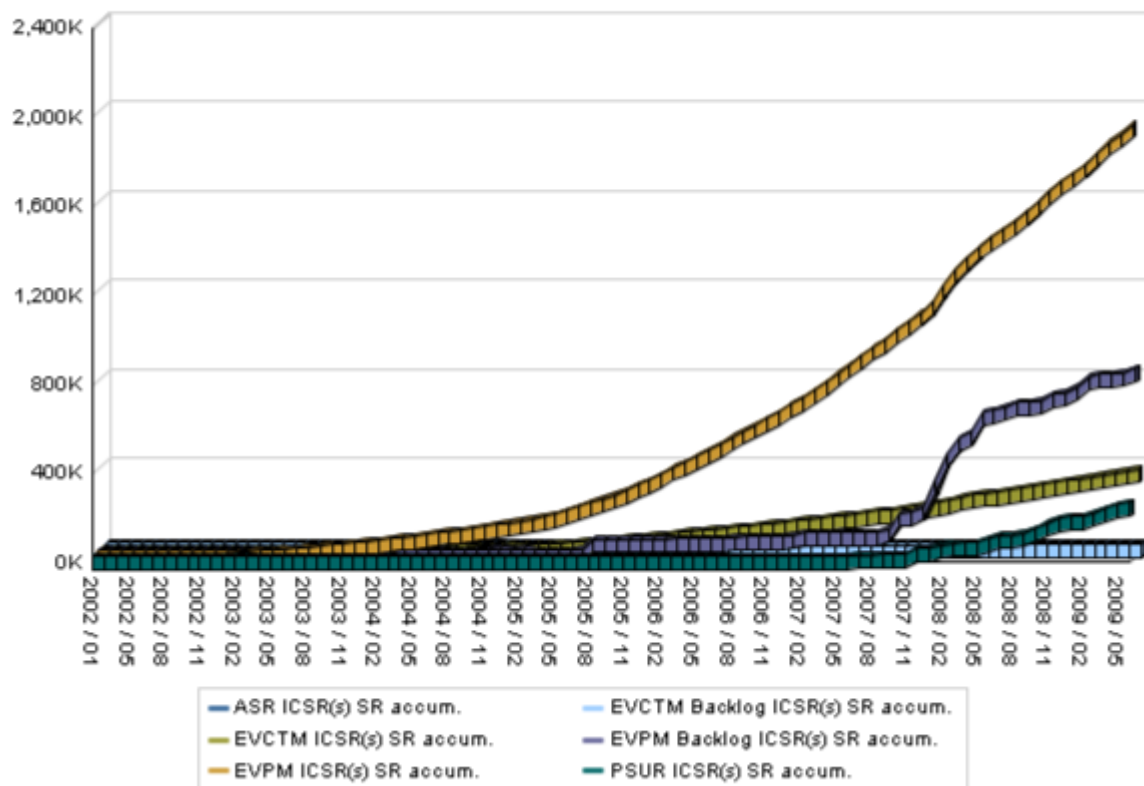
## Number of Organisations and Users over the time in EV OLTP Human
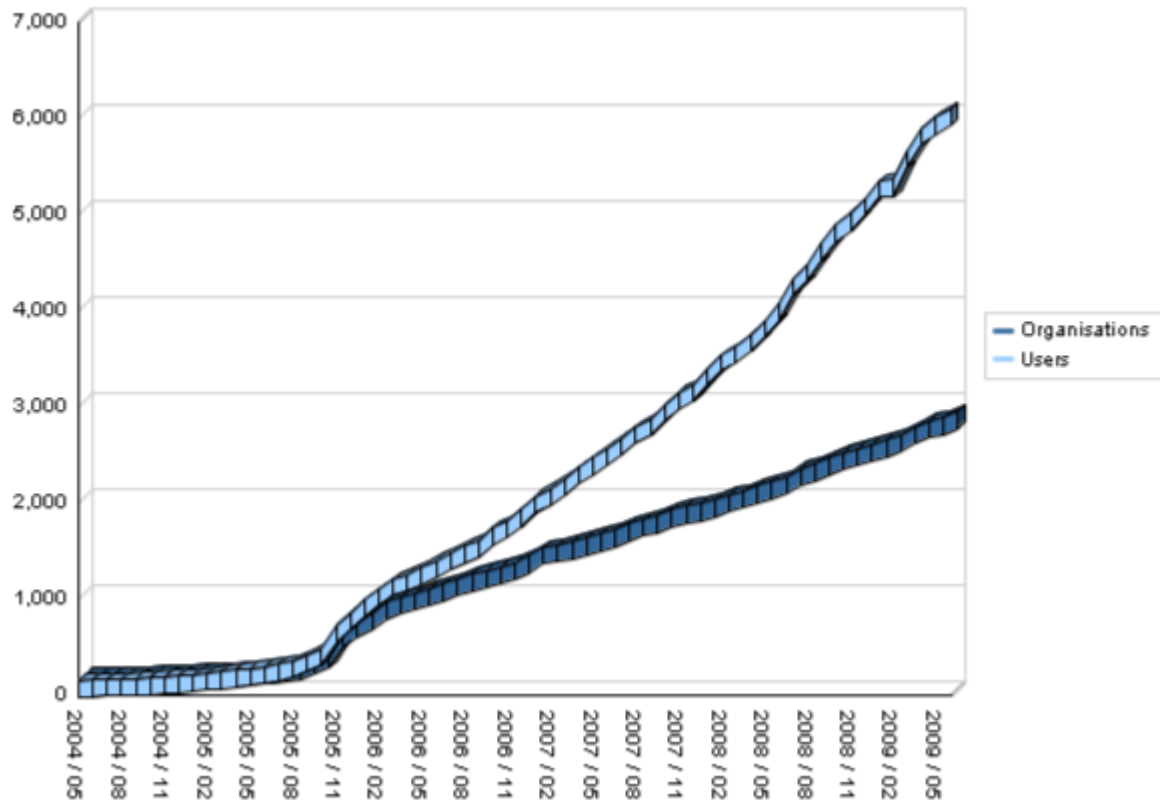


## Number of ICSRs received over time in EV Human

## 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 specific contract was signed for the provision of consultancy services partly for the Telematics programme. Negotiations are under way with two software providers to establish new framework contracts.

## Audits

An audit on EudraPharm was carried out during the period. The EudraPharm application was the last remaining Telematics application still to be audited. The focus of the audit was on application support and maintenance as further developments are on hold in 2009.

The Auditors found that EudraPharm operations appear to be compliant with all of the operation performance requirements that currently apply. There were no Opportunities For Improvement. Several positive points are raised concerning EudraPharm availability, response times and Service Desk as follows:

General Findings:
- EudraPharm is performing well against the service levels specified in the vision document. It fulfils the requirements of the legislation to provide a source of CAP data for the whole of Europe and continues to accept NAP data. The suggested evaluation and review of EudraPharm provides a logical step in the process of satisfying the legislation.

- EudraPharm was last formally released into production in August 2008. A further version had been released into test when development work on the project was stopped in December 2008.

- Since then one further production release has been agreed with the Head of the Project Management Sector in order to correct a number of outstanding issues in ClearQuest, including EudraCT and paediatric use data fields. Two performance issues, search speeds and a more recently discovered inability to cope with large amounts of data from NCAs are also addressed.

- The fixes for these problems were demonstrated to the TIG on Wednesday 24 June 2009 and the current aim is to carry out final testing in July with a release date in August/ September.

- Business continuity is managed using the same arrangements as other EMEA applications with offsite data replication. EudraPharm is due for test on the upgraded Citrix on 25th July.

Positive Points
- There is very little activity through the EudraPharm Service Desk. Three calls to the Service Desk were received in June but only one of these was ultimately attributable to EudraPharm and will be resolved during the last week of June. There are no calls outstanding from before June.

- The new tool Nimbus provides clear indicators of service level. EudraPharm is achieving 99.4 % availability on the public site (target 98%).

- The speed of response is averaging 0.5 – 0.6 of a second; the limit is 5 seconds.

## Telematics Steering Committee

The TSC met in Stockholm in July 2009. The TSC:
- Made recommendations regarding the composition and mandate of its proposed successor, a sub-group of the EMEA Management Board;
- Agreed that the EU Telematics Master Plan 2009 – 2013 be endorsed by the HMA to be proposed to the Management Board of EMEA for adoption in October 2009 with its conclusion amended to retain the recommendation to implement the plan for 2009, but changing the recommendation with regard to subsequent years to the preparation of an adjusted plan taking into account the requirements of the proposed new pharmaceutical legislation and the risks of the identified funding gap;
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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.

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[3] The topic was introduced by the presentation at Annex B.

## 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 well 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 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 and the Commission contribution to the EU Telematics budget may be significantly reduced.

# 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 | 59 |
| NCA Users | 499 |
| Responsible contacts in NCAs | 45 |
| 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**.*