



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 May 2012
EMA/310155/2012 Noted

Update report on the Agency's EU Telematics: Operations report

Management Board meeting 7 June 2012

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 report covers the period from 1 January 2012 to 31 March 2012. Detailed information in the operation of the EU Telematics applications can be found in the annexed document.



EU Telematics Operations Report

Period from 1 January 2012 to 31 March 2012, unless otherwise stated

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Executive summary

This report covers the period from 1 January 2012 to 31 March 2012. All systems met and exceeded the agreed service levels. Call resolution by the service desk was also within specified targets. Operating costs remained within budget.

Systems availability

Over the three months, the totality of the EU Telematics systems were available on average for 99.8% of the required time (target 98.0%). Over the same period, a total of 4,048 calls to the service desk were received, equating to approximately 6 calls per hour. Of these calls, approximately 49% related to EudraLink, including calls to set up new accounts.

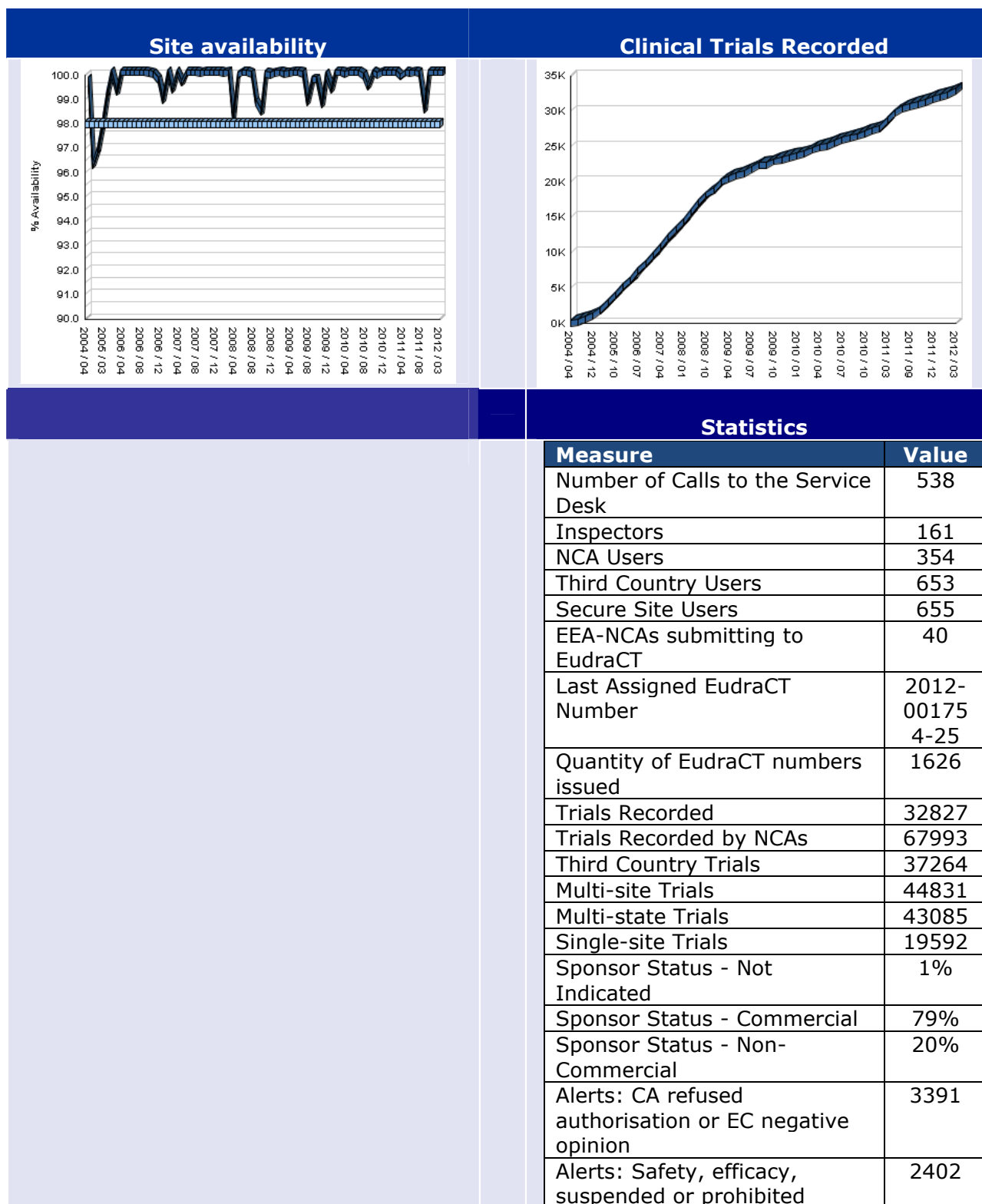
System	Value	Target	Achieved
EudraCT	100%	98%	YES
EudraGMP	99.98%	98%	YES
EudraLink	100%	98%	YES
EudraNet I	99.51%	98%	YES
EudraNet II	99.67%	98%	YES
EudraPharm	99.96%	98%	YES
EudraVigilance	99.54%	98%	YES
EURS	100%	98%	YES
EUTCT	99.58%	98%	YES

Operating budget

The comparison of actual and budgeted expenditure in the 2012 year is based upon the overall budget allocated to EU Telematics of €11.1 million. ICT is currently in the process of reviewing budget allocation, budget flow monitoring and identifying possible savings. The outcome of this review will be reported upon at the end of the next period.

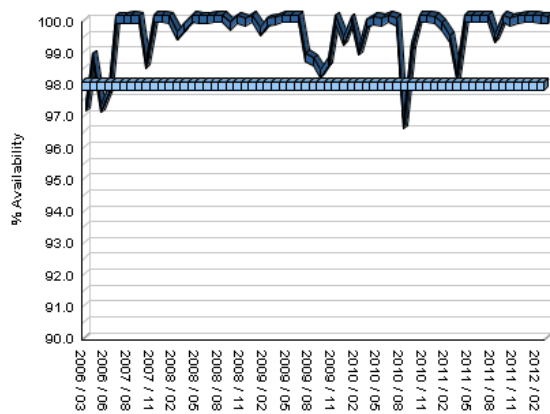
System by system operational report

EudraCT

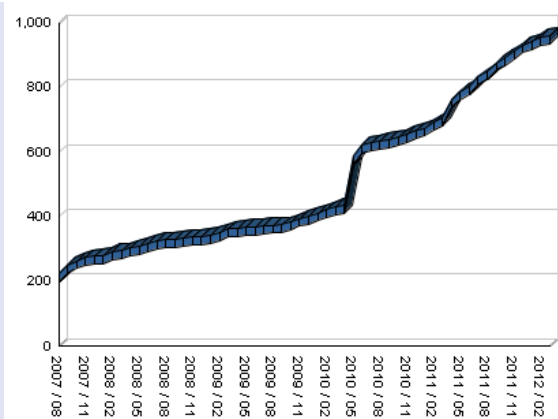


EudraGMP

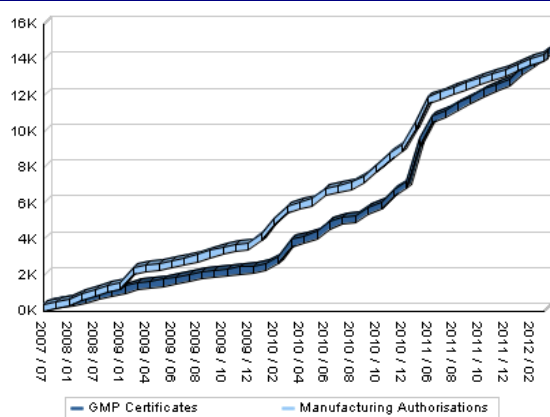
Site availability



Number of users



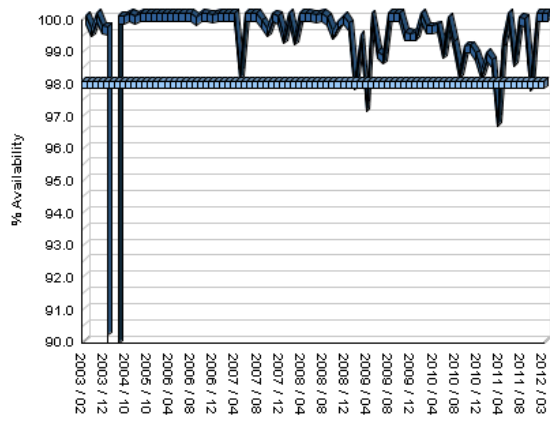
Certificates and Authorisations



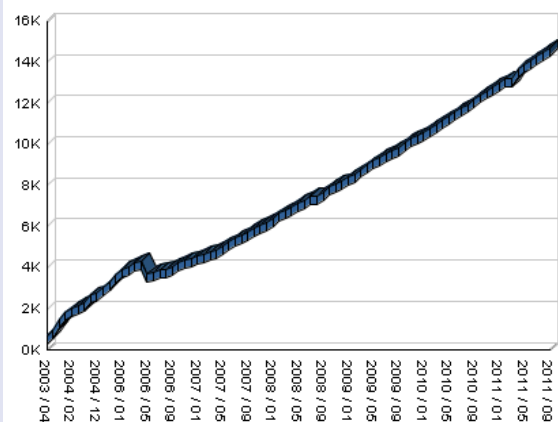
Statistics

Measure	Value
Number of Calls to the Service Desk	155
GMP Certificates	14153
Manufacturing Authorisations	14085
Number of Users	948

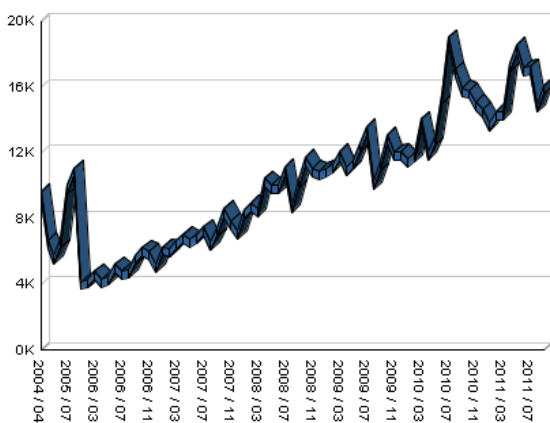
Site availability



Number of users



Traffic

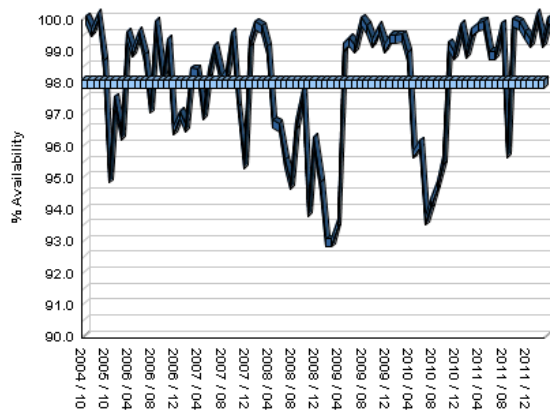


Statistics

Measure	Value
Number of Calls to the Service Desk	1972
Number of Users	14503
Total Number of Packages Resent	2587
Total Number of Packages Sent	142025
Total Volume of Packages Sent (Gb)	699.82

EudraNet

Site availability

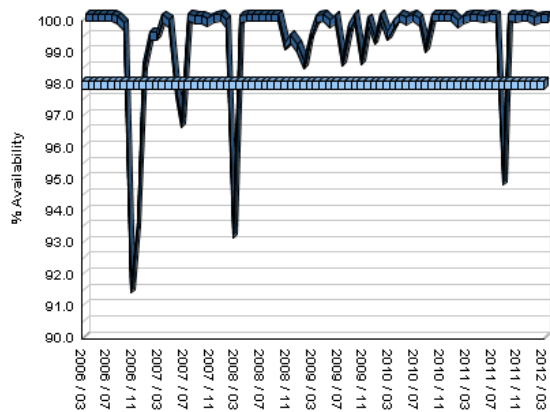


Statistics

Measure	Value
Number of Calls to the Service Desk	157

EudraPharm

Site availability



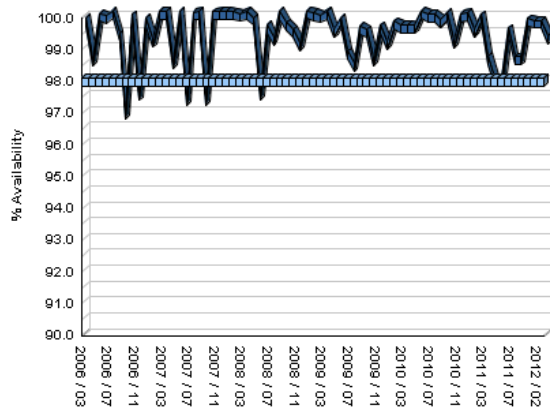
Site visits



Statistics

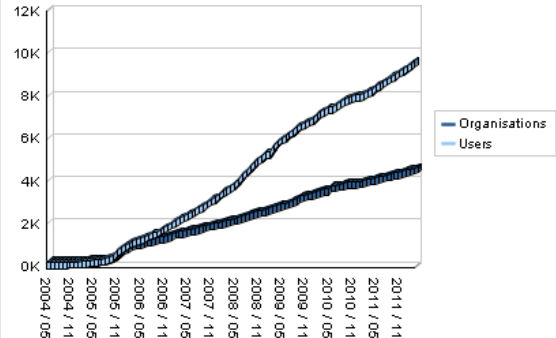
Measure	Value
Number of Calls to the Service Desk	22

Site availability



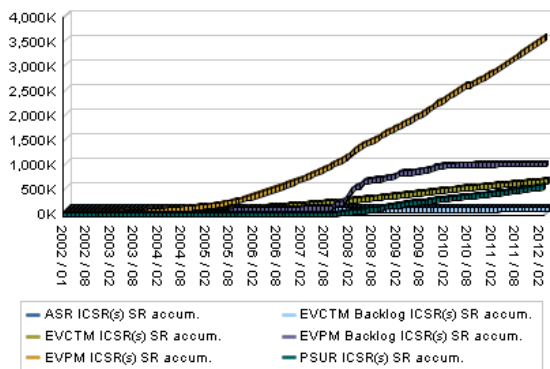
Organisations & users over time

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



Number of ICSRs received over time (EV Human)

Number of ICSRs received over time in EV Human



Statistics

Measure	Value
Number of Calls to the Service Desk - Human	1195
Number of Calls to the Service Desk - Veterinary	37

EudraVigilance Evolution statistics

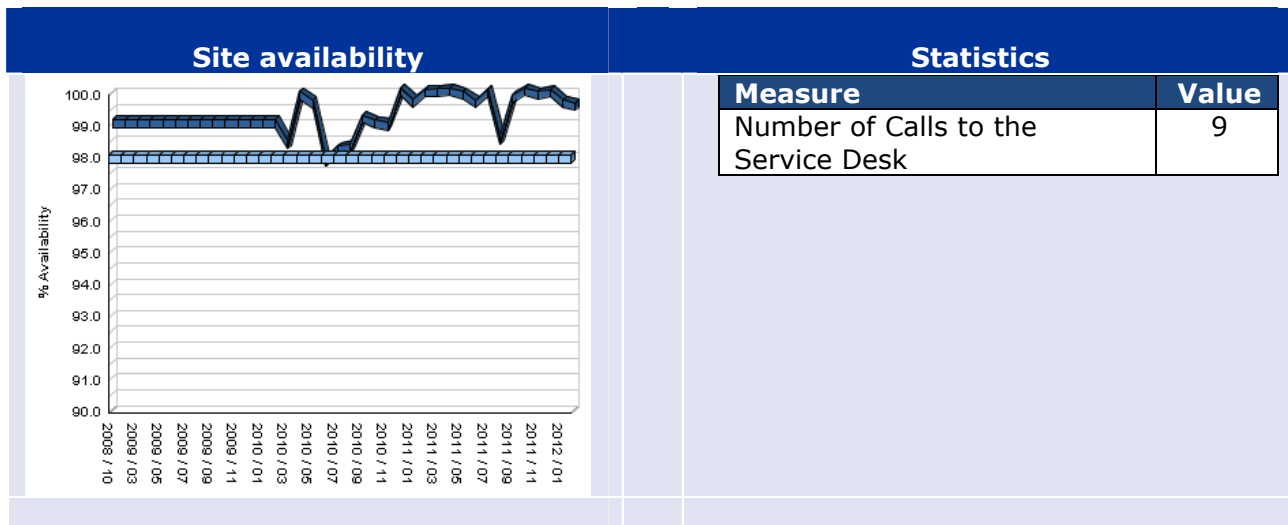
Period	Organisations		Users	
	Incremental	Cumulative	Incremental	Cumulative
2004	88	88	107	107
2005	523	611	655	762
2006	680	1291	1076	1838
2007	544	1835	1300	3138
2008	612	2447	1933	5071
2009	781	3228	1690	6761
2010	529	3757	1168	7929
2011	516	4273	1211	9140
2012 / 01	64	4337	170	9310
2012 / 02	49	4386	107	9417
2012 / 03	65	4451	114	9531

Period	EVPM ICSR(s) SR		EVPM Backlog ICSR(s) SR	
	Incremental	Cumulative	Incremental	Cumulative
2002	254	254	0	0
2003	49156	49410	0	0
2004	79901	129311	7932	7932
2005	178980	308291	43723	51655
2006	326241	634532	16276	67931
2007	447248	1081780	128413	196344
2008	588788	1670568	513464	709808
2009	564314	2234882	218671	928479
2010	536859	2771741	39941	968420
2011	629645	3401386	10952	979372
2012 / 01	53293	3454679	603	979975
2012 / 02	57186	3511865	199	980174
2012 / 03	65260	3577125	179	980353

Period	EVCTM ICSR(s) SR		EVCTM Backlog ICSR(s) SR	
	Incremental	Cumulative	Incremental	Cumulative
2004	10607	10607	0	0
2005	43313	53920	616	616
2006	63754	117674	0	616
2007	78488	196162	668	1284
2008	108101	304263	3070	4354
2009	106878	411141	2259	6613
2010	95348	506489	1995	8608
2011	86737	593226	3974	12582
2012 / 01	6117	599343	19	12601
2012 / 02	6926	606269	0	12601
2012 / 03	6742	613011	0	12601

Period	ASR ICSR(s) SR		PSUR ICSR(s) SR	
	Incremental	Cumulative	Incremental	Cumulative
2005	1	1	0	0
2006	0	1	0	0
2007	536	537	32433	32433
2008	1374	1911	139888	172321
2009	913	2824	121477	293798
2010	2608	5432	105100	398898
2011	3011	8443	129215	528113
2012 / 01	225	8668	11362	539475
2012 / 02	138	8806	12659	552134
2012 / 03	232	9038	21053	573187

Users	Incremental	Cumulative
Affiliate: Human	70	2009
Affiliate: Vet	0	42
Commercial Sponsor: Human	32	692
Individual User: Human	410	9554
Individual User: Vet	9	614
MAH: Human	70	1503
MAH: Vet	8	180
Non-Commercial Sponsor: Human	6	150
NCA: Human	0	39
NCA: Vet	0	30



Cost: use of the operational budget

The overall budget allocated to EU Telematics operations of €11.1 million is currently being revised in view of potential savings that could be achieved. The total operational budget for the year, together with the anticipated costs for 2012 and the costs recorded for that period are set out in the table below.

Category	Budget €000	YTD Expected	YTD Actual
Staff Expenditure	1,567.0	391.8	391.8
Training	9.8	2.5	-
Missions	62.0	15.5	6.1
Meetings	540.0	135.0	142.4
EMEA overhead	550.0	137.5	137.5
IT operations	8,391.0	3,440.0	3,383.0
Total	11,119.8	4,122.2	4,060.7

The year to date IT operations costs include a number of items that cover the period following the quarter under review. All expenses incurred have been in line with the budget.

Missions expenditure has come in below budget as the number of delegates to international standardisation meetings has been reduced.