



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EU Telematics Operations Report: 33rd report for period ending 31 December 2011

Management Board 22 March 2012

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Executive summary

This report covers up to 31 December 2011. 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 considering the schedule of payments for services.

Systems availability

Over the two months, the totality of the EU Telematics systems were available on average for 99.76% of the required time (target 98.0%). Over the same period, a total of 2,285 calls to the service desk were received, equating to approximately 4 calls per hour. Of these calls, approximately 51% related to EudraLink, including calls to set up new accounts.

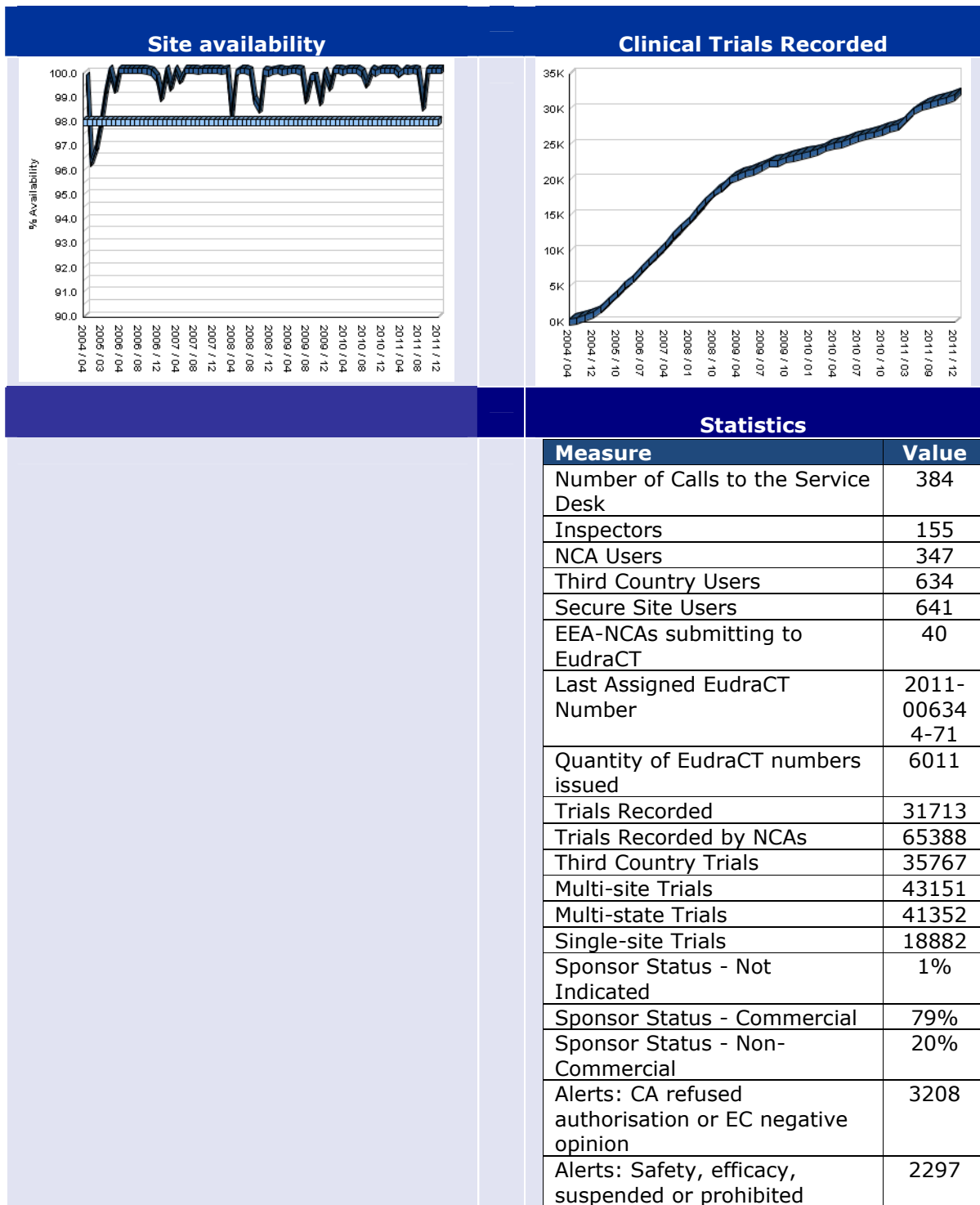
System	Value	Target	Achieved
EudraCT	100%	98%	YES
EudraGMP	99.99%	98%	YES
EudraLink	100%	98%	YES
EudraNet I	99.04%	98%	YES
EudraNet II	99.30%	98%	YES
EudraPharm	99.99%	98%	YES
EudraVigilance	99.61%	98%	YES
EURS	100%	98%	YES
EUTCT	99.93%	98%	YES

Operating budget

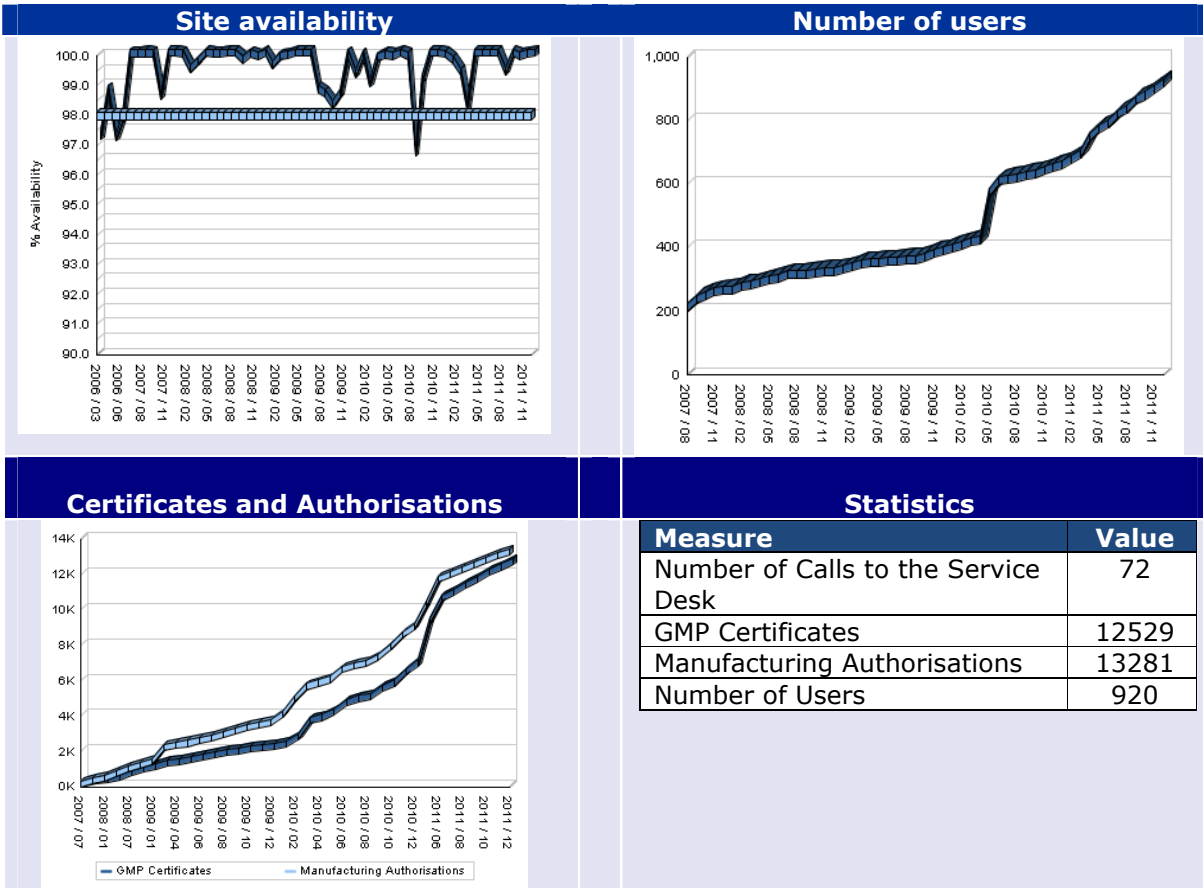
The comparison of actual and budgeted expenditure in the 2011 year is based upon the revised overall budget of €7.4 million. A saving of € 0.15 million was achieved on meetings' expenditure, as a consequence of a reduction in the number of meetings compared with previous years as systems come out of development and into production; abolition of the EURS Group and the fact that the PIM project is no longer in development.

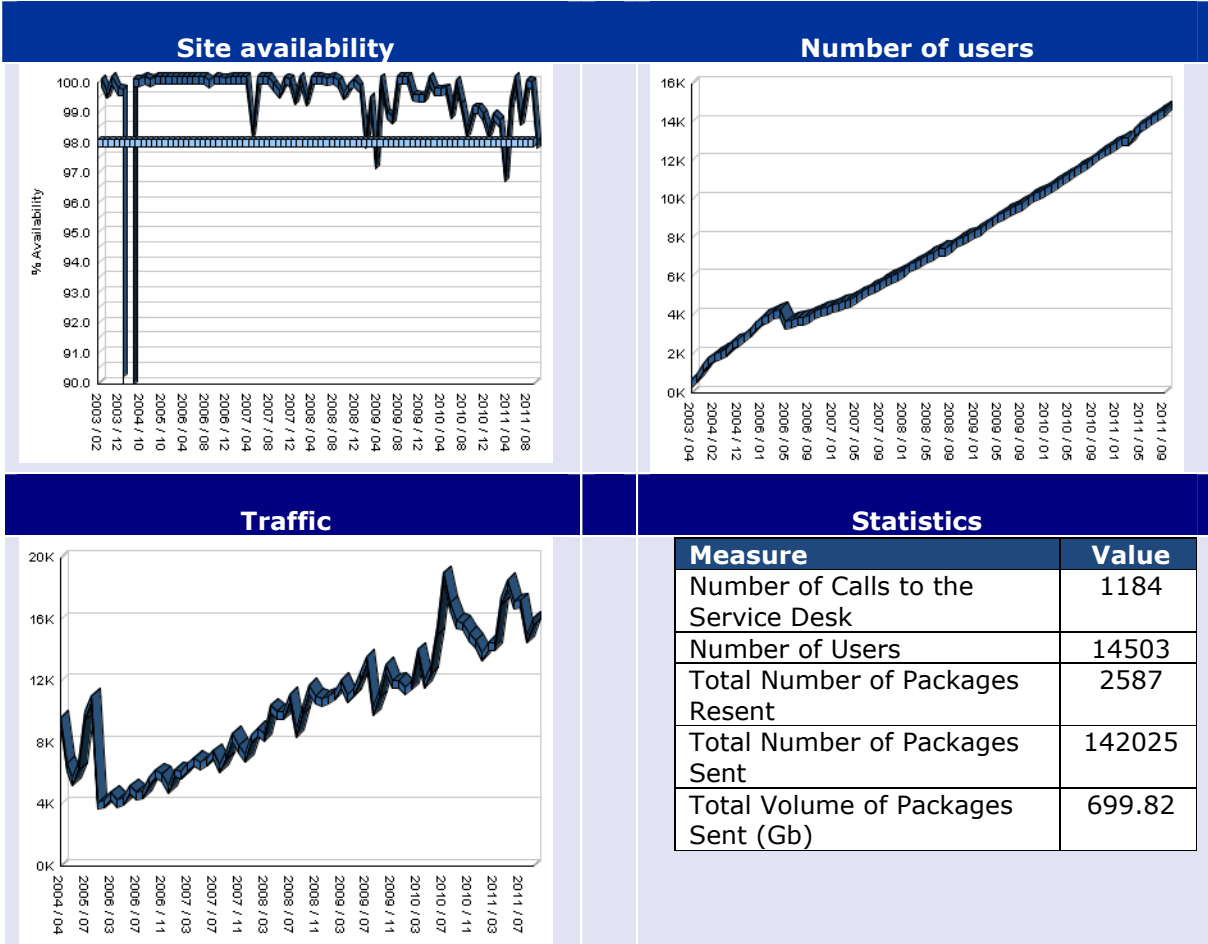
System by system operational report

EudraCT

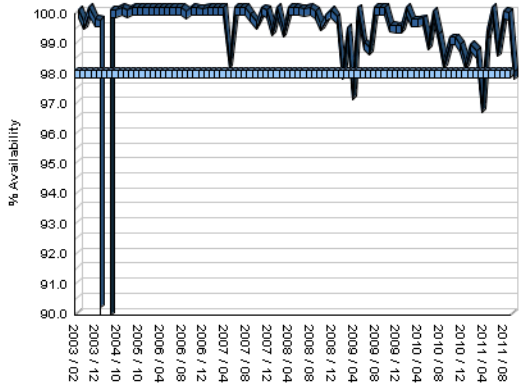


EudraGMP

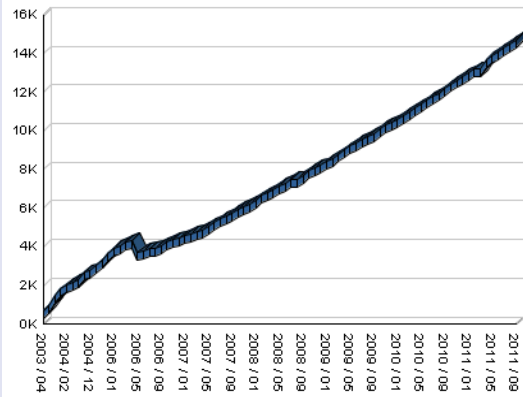




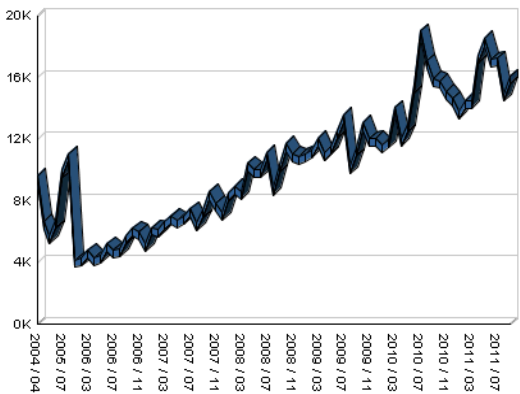
Site availability



Number of users



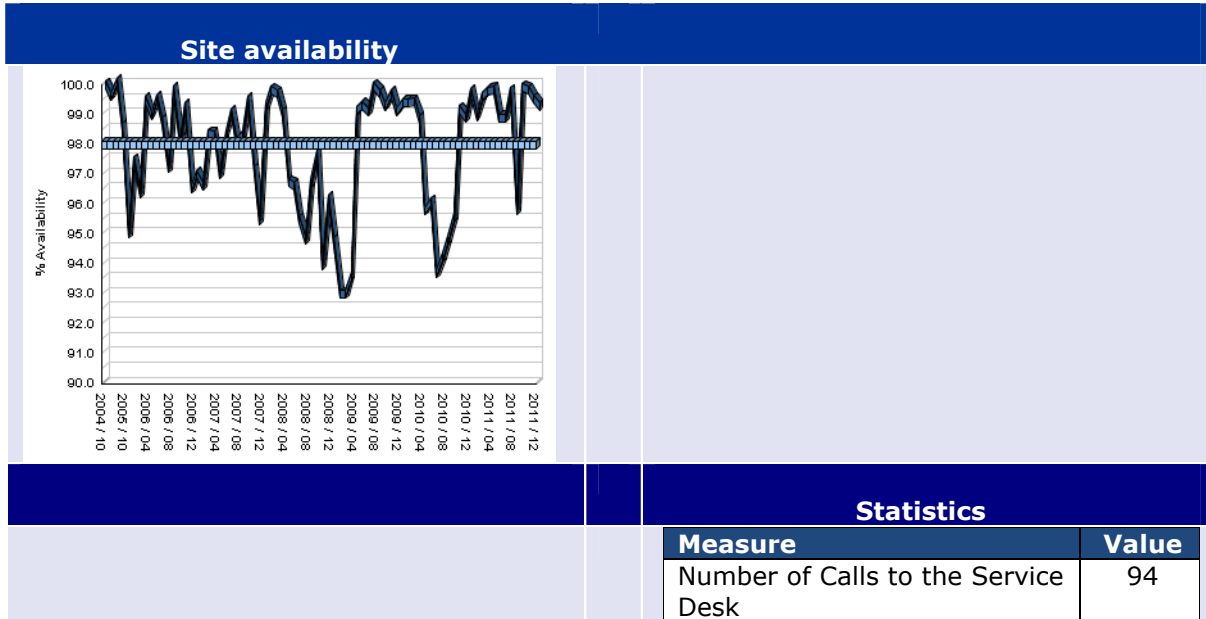
Traffic



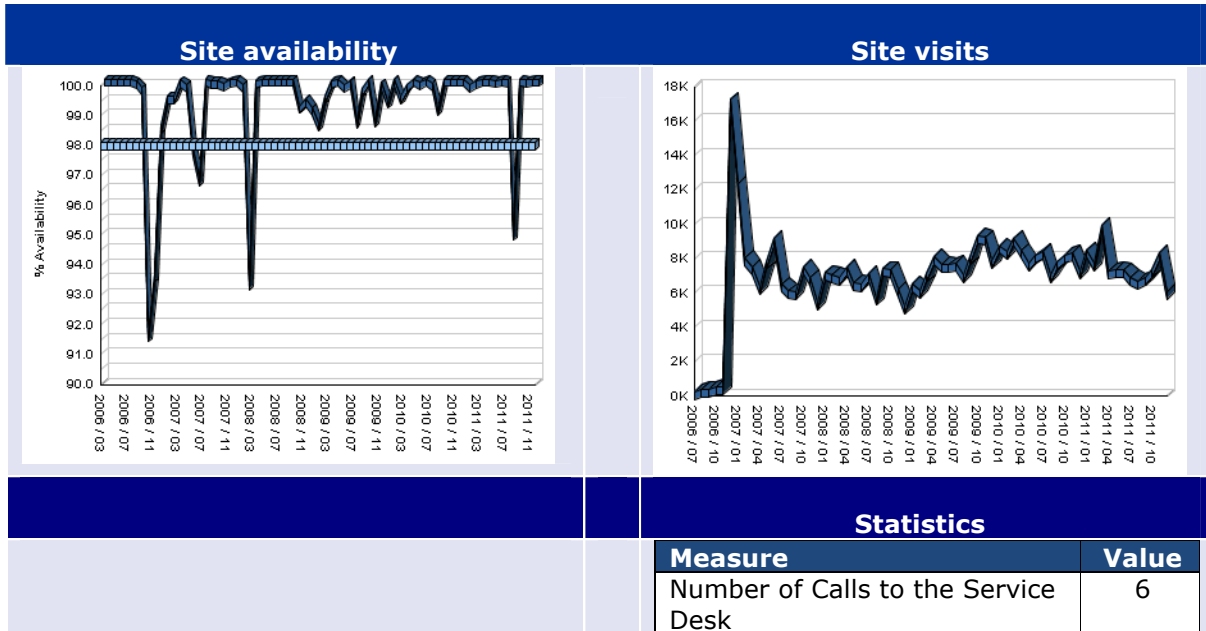
Statistics

Measure	Value
Number of Calls to the Service Desk	1184
Number of Users	14503
Total Number of Packages Resent	2587
Total Number of Packages Sent	142025
Total Volume of Packages Sent (Gb)	699.82

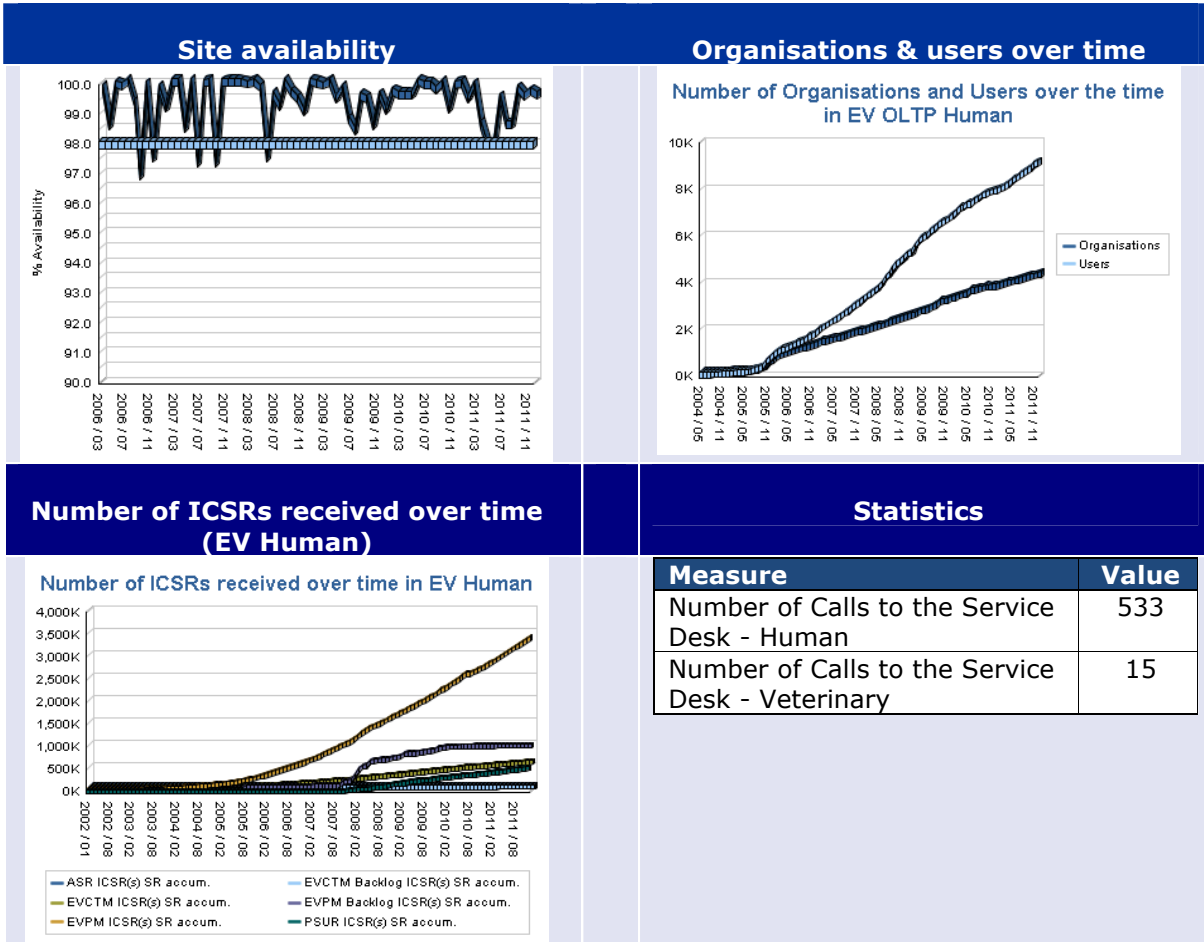
EudraNet



EudraPharm



EudraVigilance



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 / 01	35	3792	21	7950
2011 / 02	50	3842	77	8027
2011 / 03	41	3883	101	8128
2011 / 04	37	3920	81	8209
2011 / 05	58	3978	181	8390
2011 / 06	34	4012	71	8461
2011 / 07	52	4064	128	8589
2011 / 08	44	4108	100	8689
2011 / 09	44	4152	133	8819
2011 / 10	38	4188	93	8912
2011 / 11	57	4245	145	9057
2011 / 12	28	4273	83	9140

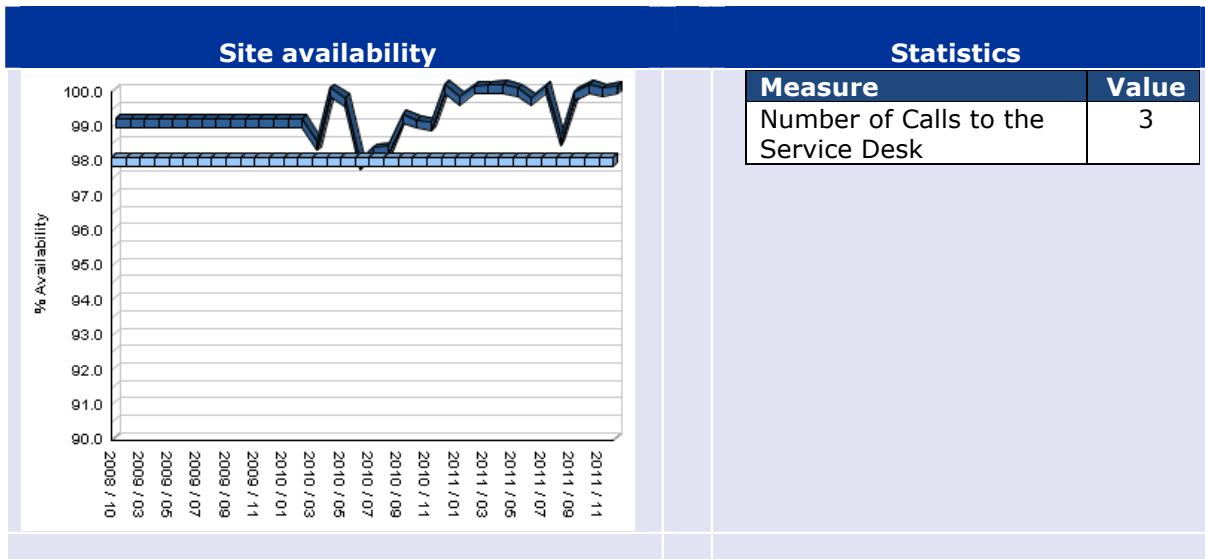
Period	EVPM ICSR(s) SR		EVPM Backlog ICSR(s) SR	
	Incremental	Cumulative	Incremental	Cumulative
2002	254	254	0	0
2003	49156	49410	0	0
2004	79901	129311	7932	7932
2005	178980	308291	43723	51655
2006	326241	634532	16276	67931
2007	447248	1081780	128413	196344
2008	588788	1670568	513464	709808
2009	564314	2234882	218671	928479
2010	536859	2771741	39941	968420
2011 / 01	46975	2818716	8	968428
2011 / 02	48155	2866871	3	968431
2011 / 03	56263	2923134	8136	976567
2011 / 04	51814	2974948	1386	977953
2011 / 05	54035	3028983	12	977965
2011 / 06	59789	3088772	673	978638
2011 / 07	50837	3139609	14	978652
2011 / 08	53538	3193147	196	978848
2011 / 09	52426	3245573	21	978869
2011 / 10	54223	3299796	222	979091
2011 / 11	52710	3352506	209	979300
2011 / 12	48880	3401386	72	979372

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 / 01	7807	514296	2	8610
2011 / 02	7543	521839	0	8610
2011 / 03	7769	529608	3728	12338
2011 / 04	7692	537300	12	12350
2011 / 05	7049	544349	0	12350
2011 / 06	7755	552104	0	12350
2011 / 07	6496	558600	39	12389
2011 / 08	6760	565360	0	12389
2011 / 09	7372	572732	15	12404
2011 / 10	6937	579669	129	12533
2011 / 11	6660	586329	42	12575
2011 / 12	6897	593226	7	12582

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 / 01	264	5696	8585	407483
2011 / 02	120	5816	11086	418569
2011 / 03	499	6315	11133	429702
2011 / 04	246	6561	10922	440624
2011 / 05	270	6831	9940	450564
2011 / 06	243	7074	15113	465677
2011 / 07	285	7359	10144	475821
2011 / 08	179	7538	8326	484147
2011 / 09	240	7778	12758	496905
2011 / 10	282	8060	8936	505841
2011 / 11	243	8303	11561	517402
2011 / 12	140	8443	10711	528113

Users	Incremental	Cumulative
Affiliate: Human	41	1939
Affiliate: Vet	2	42
Commercial Sponsor: Human	29	660
Individual User: Human	887	9144
Individual User: Vet	21	605
MAH: Human	36	1433
MAH: Vet	6	172
Non-Commercial Sponsor: Human	5	144

Users	Incremental	Cumulative
NCA: Human	0	39
NCA: Vet	0	30



Cost: use of the operational budget

The overall budget for EU Telematics operations of €8.1 million was reduced in June by €708,000 following a re-analysis of the allocation of costs between EU Telematics and the Agency’s administrative and business support systems. The total operational budget for the year, together with the anticipated costs for 2011 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	1,567.0	1,700.0
Training	11.0	11.0	11.0
Missions	93.0	93.0	90.9
Meetings	673.0	673.0	519.9
EMEA overhead	550.0	550.0	550.0
IT operations	4,552.0	4,552.0	4,586.3
Total	7,446.0	7,446.0	7,458.1

Staff expenditure was 10% higher than expected due to a combination of extra costs incurred in replacing staff on parental leave and various staff salary increases including promotions.

Mission costs were lower than anticipated due mainly to the cost of missions to India to audit the Eudravigilance Data Management activities being lower than the original budget.

Meeting expenditure ended the year below budget.

Year to date actual expenditure in respect of IT operations was on budget.