



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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

Management Board meeting 6 October 2011

### 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 31<sup>st</sup> report, covering the period from 1 January 2011 to 31 August 2011.

On this occasion, following the review by the Management Board Telematics Committee (MBTC), the reporting format has been changed in such that two reports are presented instead of one: The first report addresses the operational aspects and is attached below; the second report addresses projects and is presented for discussion under point 7bis.

The reason for this division is that the reporting period for projects will not necessarily be the same as the reporting period for operations. Consequently, this new approach provides the timeliest information on both topics.



## EU Telematics Operations Report

Period from 1 January 2011 to 31 August 2011, unless otherwise stated

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## Executive summary

This report covers the period from 1 January 2011 to 31 August 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 eight months, the totality of the EU Telematics systems were available on average for 99.38% of the required time (target 98.0%). Over the same period, a total of 10,888 calls to the service desk were received, equating to approximately 7 calls per hour. Of these calls, approximately 39% related to EudraLink, including calls to set up new accounts. The number of users of EudraLink increased by 1,673.

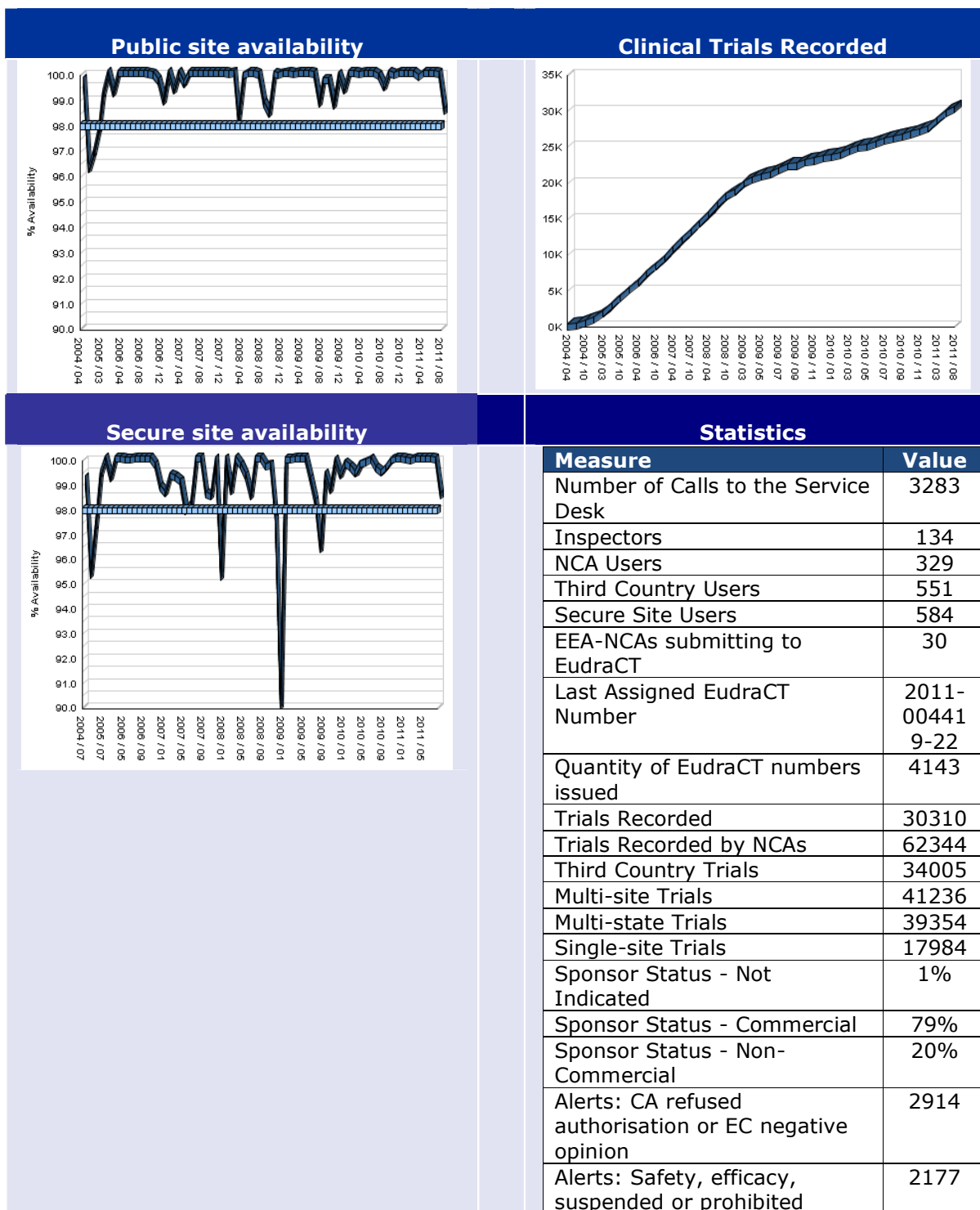
System	Value	Target	Achieved
EudraCT - Public Site	99.78%	98%	YES
EudraCT - Secure Site	99.79%	98%	YES
EudraGMP	99.59%	98%	YES
EudraLink	98.94%	98%	YES
EudraNet I	98.99%	98%	YES
EudraNet II	98.84%	98%	YES
EudraPharm	99.32%	98%	YES
EudraVigilance	98.89%	98%	YES
EURS	100.00%	98%	YES
EUTCT	99.69%	98%	YES

### ***Operating budget***

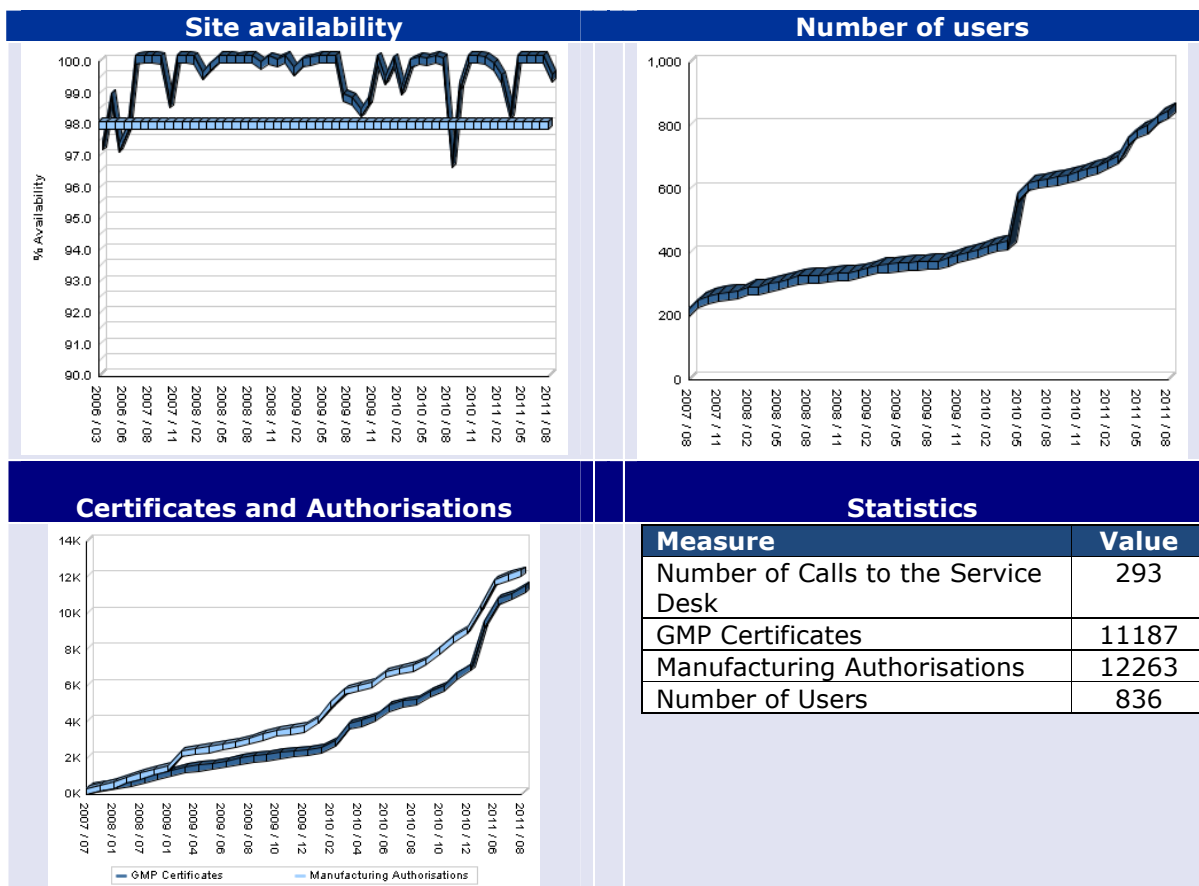
The operating budget for the year as a whole is €7.4 million, and expected expenditure year to date is €5.0 million. Actual expenditure in the year to date is €5.8 million, the difference reflecting the proportion of the annual support expenditure that is paid in the early part of the year. Expenditure on meetings is running below anticipated levels. There is 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.

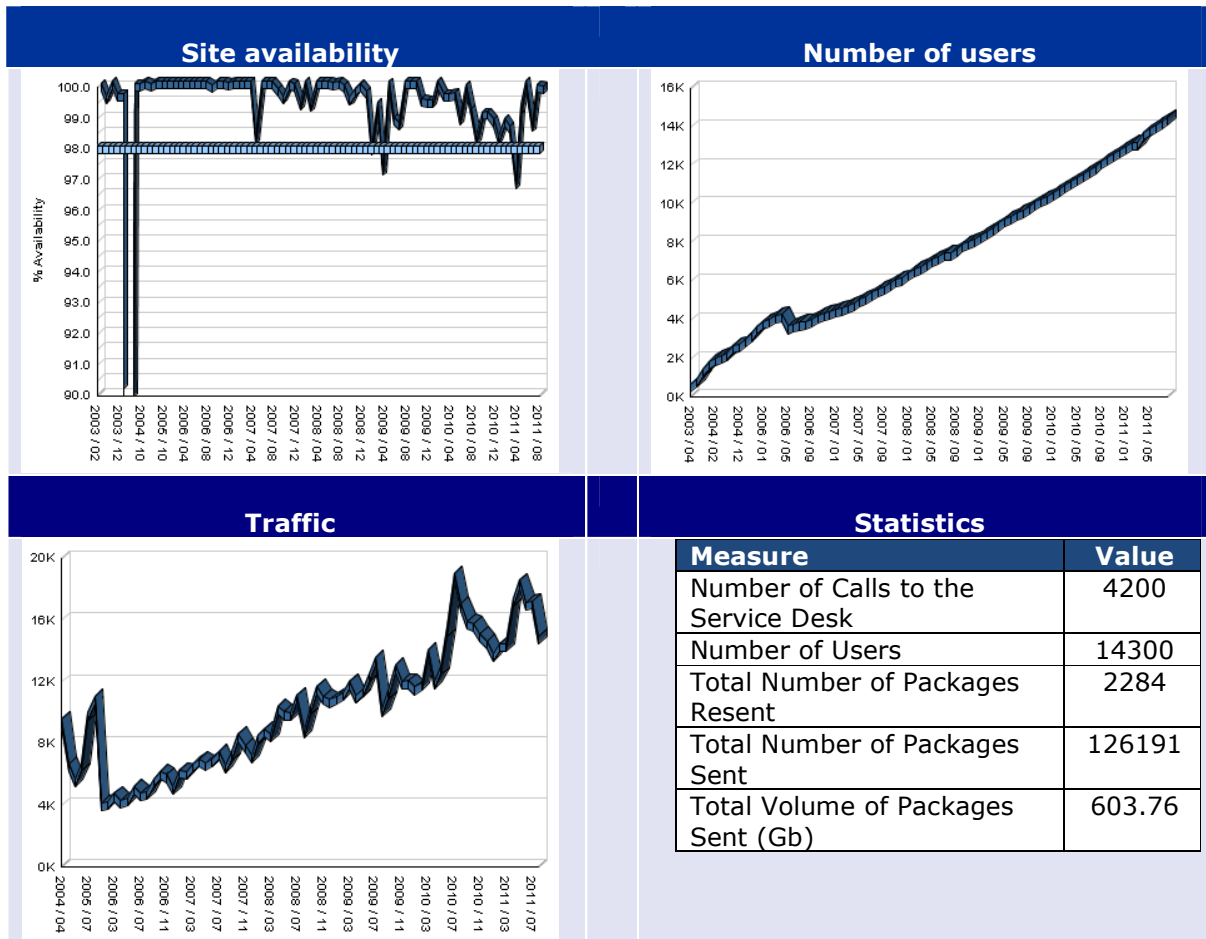
# System by system operational report

## EudraCT

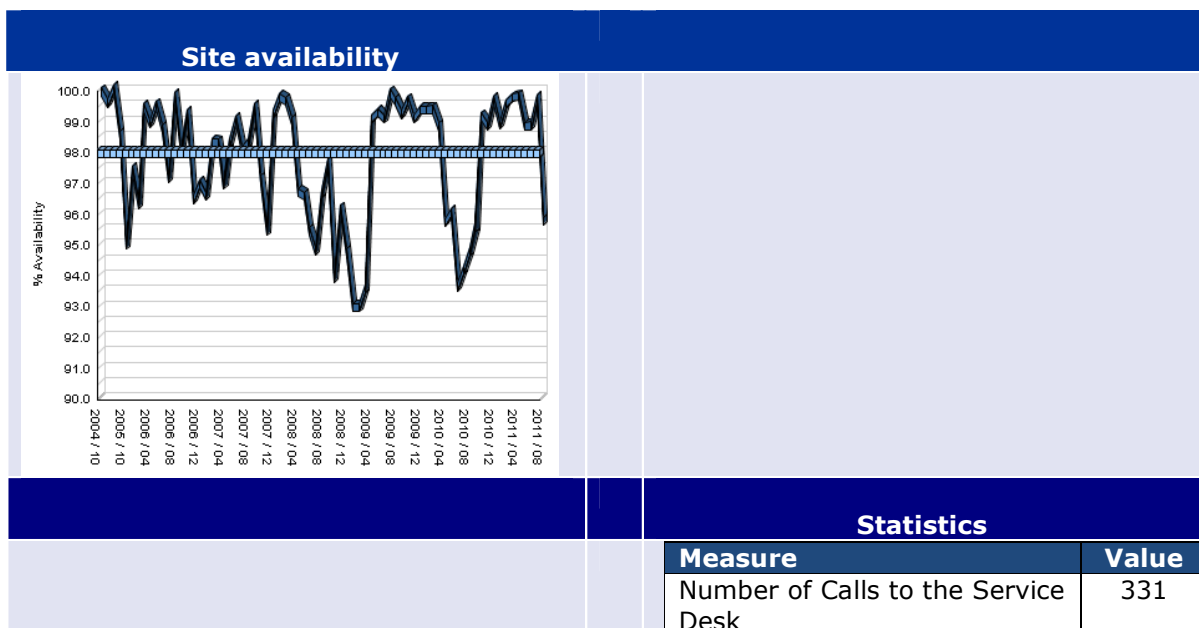


## EudraGMP

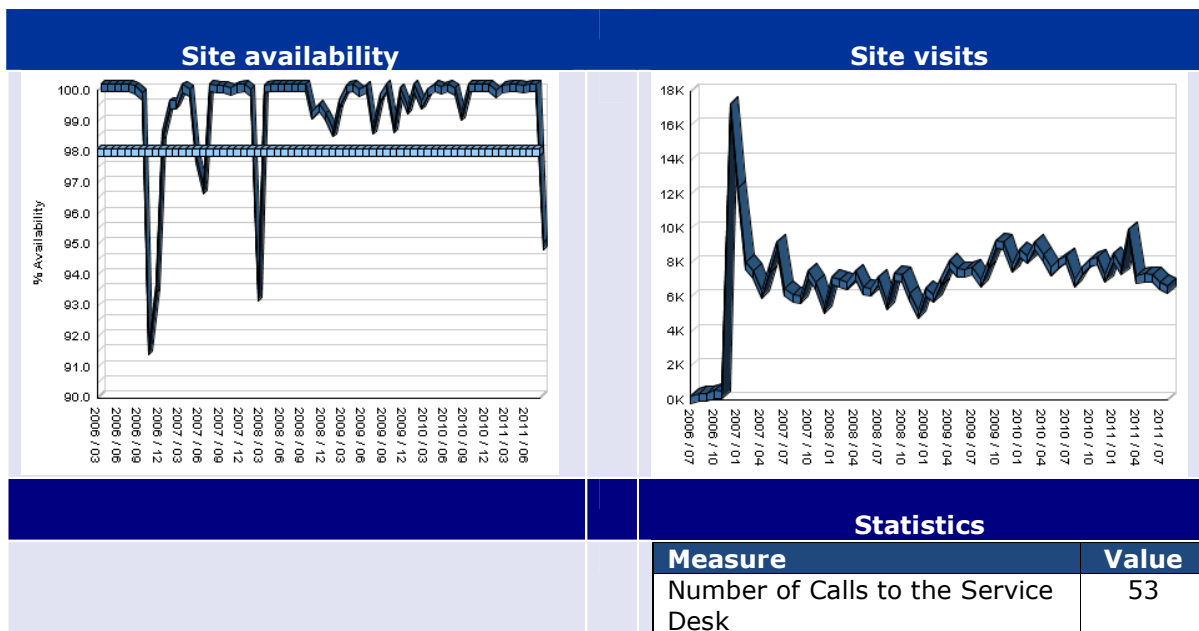


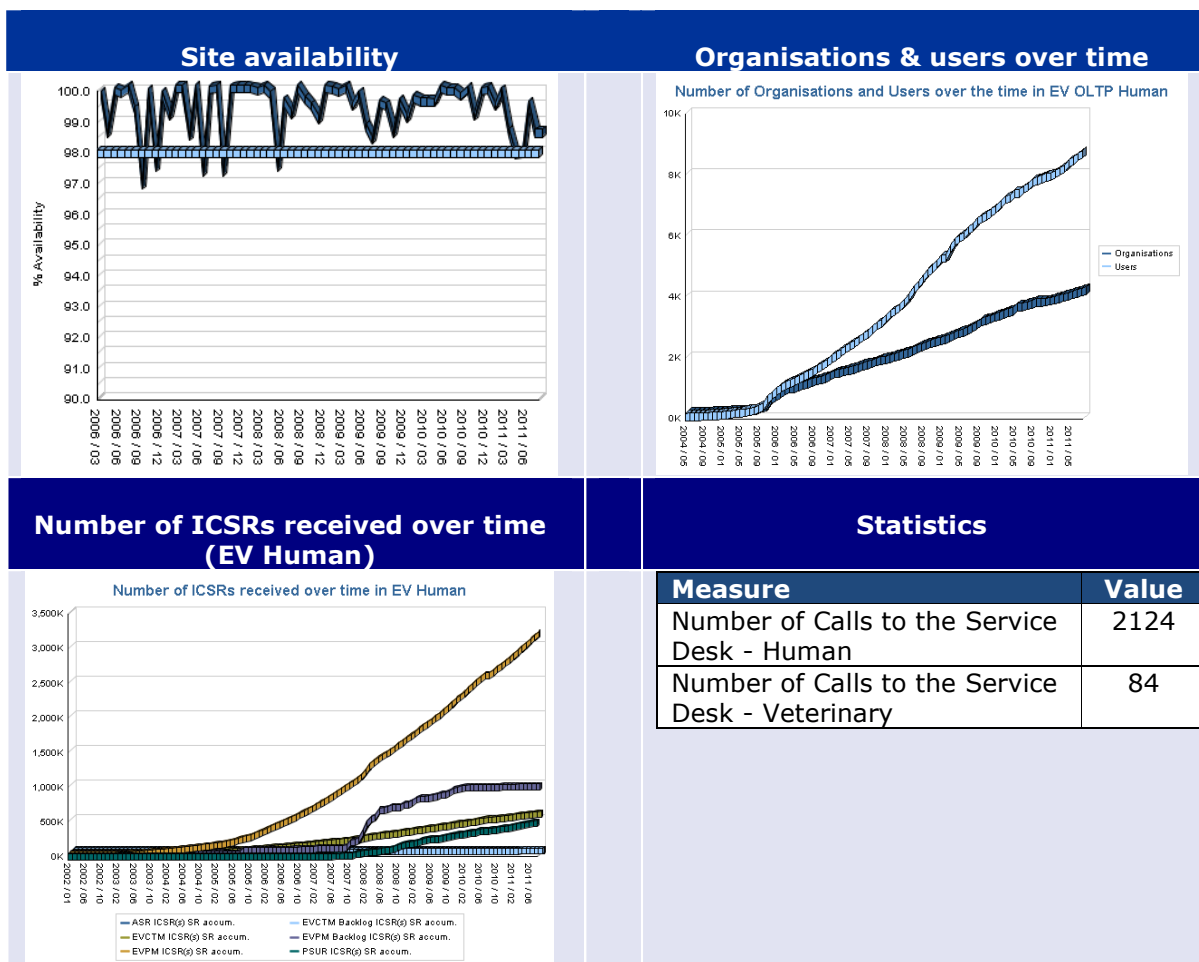


## EudraNet



## EudraPharm





## 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

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

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

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

Users	Incremental	Cumulative
Affiliate: Human	35	1889
Affiliate: Vet	0	41
Commercial Sponsor: Human	27	628
Individual User: Human	578	8710
Individual User: Vet	20	579
MAH: Human	63	1367
MAH: Vet	4	166
Non-Commercial Sponsor: Human	6	140
NCA: Human	0	39
NCA: Vet	0	30

## EUTCT

Site availability		Statistics	
		Measure	Value
		Number of Calls to the Service Desk	34

### Cost: use of the operational budget.

Category	Budget €000	YTD Expected	YTD Actual
Staff Expenditure	1,567.0	1,044.7	1,144.3
Training	11.0	7.3	9.4
Missions	93.0	62.0	81.5
Meetings	673.0	448.7	324.9
EMEA overhead	550.0	412.5	412.5
IT operations	4,552.0	3,034.7	3,809.1
Total	7,446.0	5,009.9	5,781.7

As at the end of August 2011, the position was as set out above. Staff expenditure and overheads were 10% higher than expected because of a combination of extra costs incurred in covering for parental leave and salary increases, due in part to promotions. Missions were higher than anticipated due to a number of missions to India for Eudravigilance Data Management. Meeting expenditure is below anticipated levels. These savings are counterbalanced by the difference between actual expenditure and anticipated expenditure on IT operations. This figure will fall back to below the expected levels towards the end of the year as the expenditure in the early part of the year that covers the entire year evens out in comparison with expected expenditure.