



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 December 2012
EMA/777362/2012

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

Management Board meeting 13 December 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 September 2012 to 31 October 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 September 2012 to 31 October 2012

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Executive summary

This report covers the period from 1 September 2012 to 31 October 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.

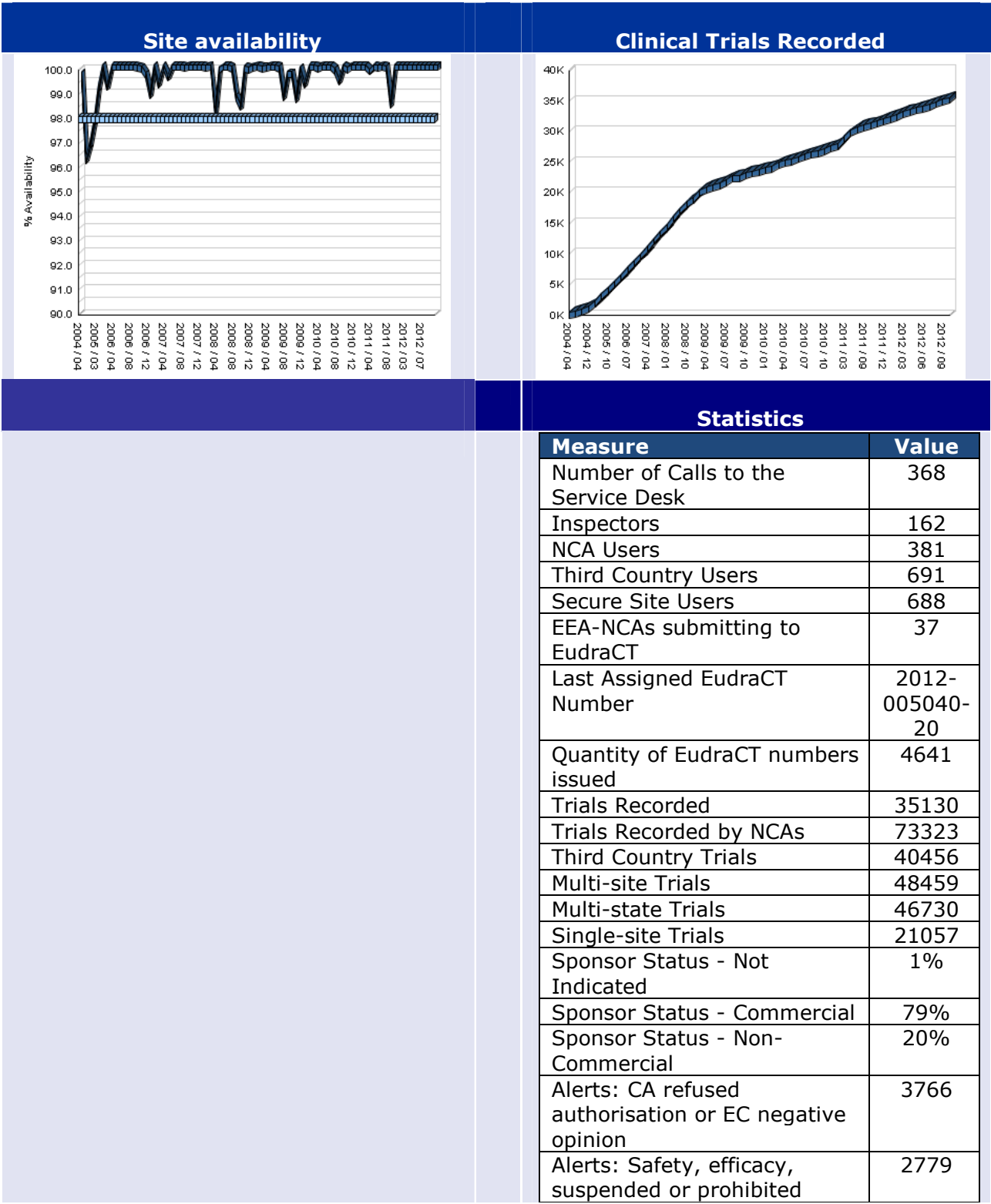
Systems availability

Over the two 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.

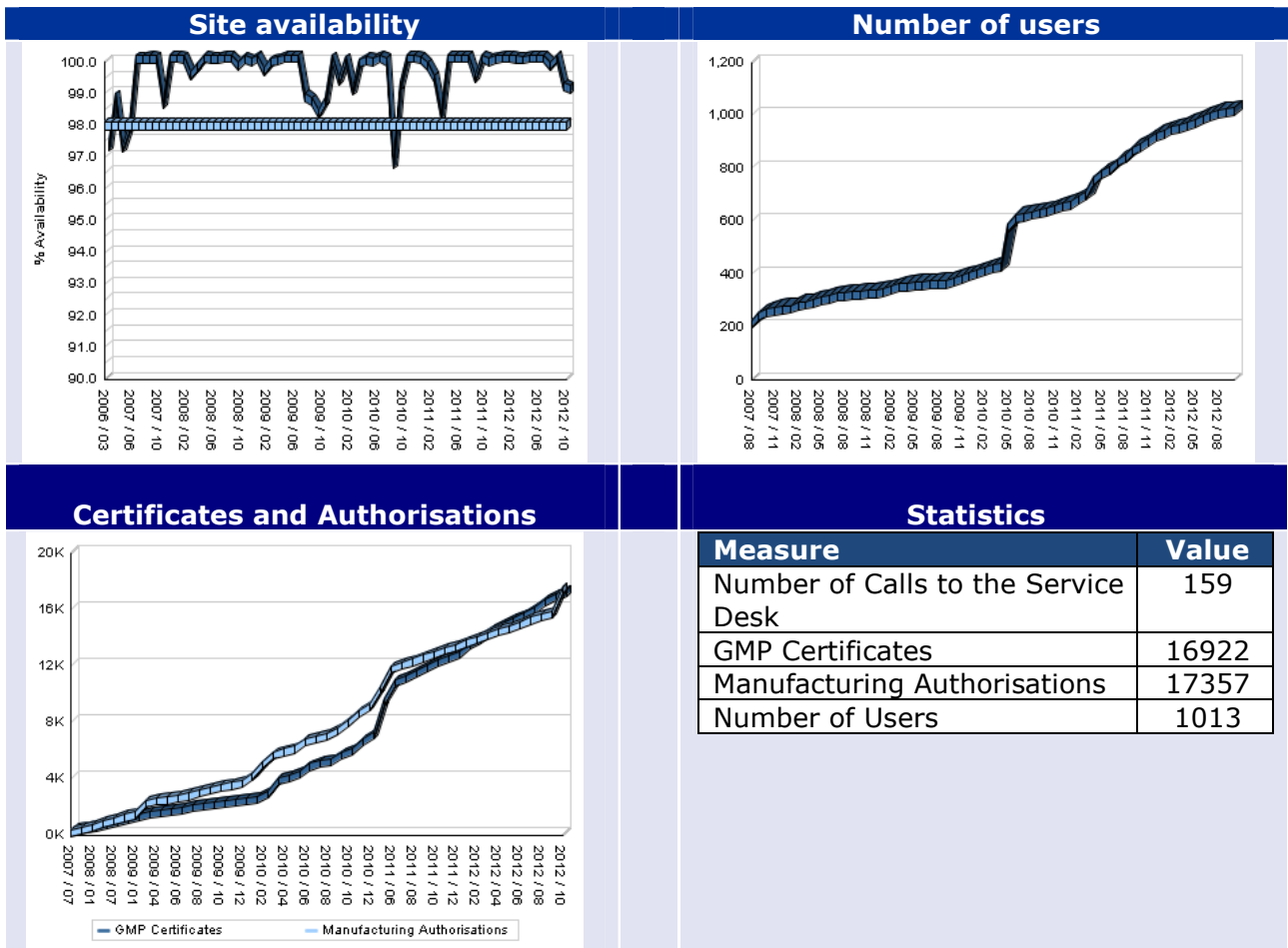
System	Value	Target	Achieved
EudraCT	100%	98%	YES
EudraGMP	99.07%	98%	YES
EudraLink	100%	98%	YES
EudraNet	99.10%	98%	YES
EudraPharm	99.90%	98%	YES
EudraVigilance	98.16%	98%	YES
EURS	100%	98%	YES
EUTCT	99.80%	98%	YES

System by system operational report

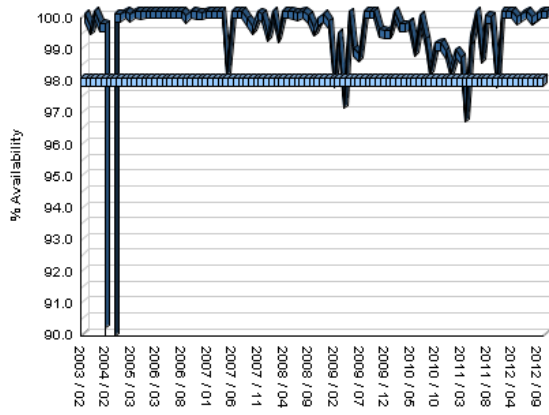
EudraCT



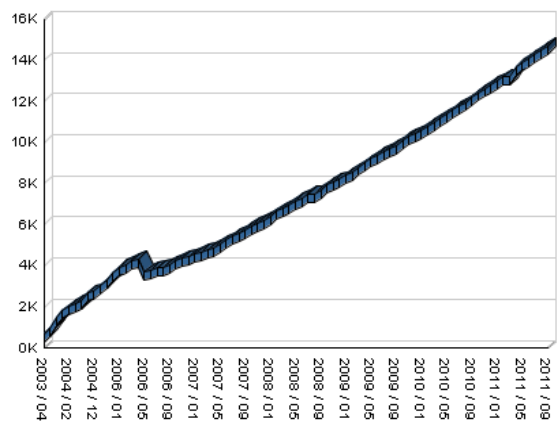
EudraGMP



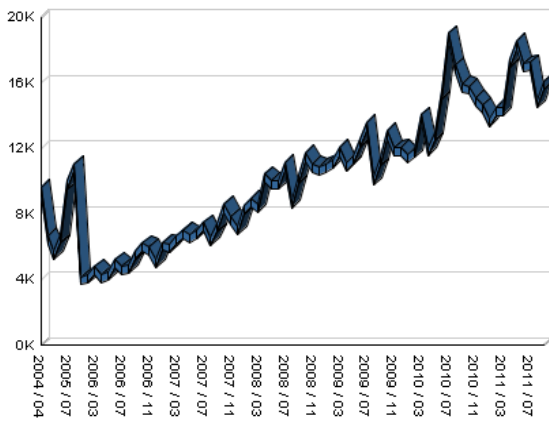
Site availability



Number of users



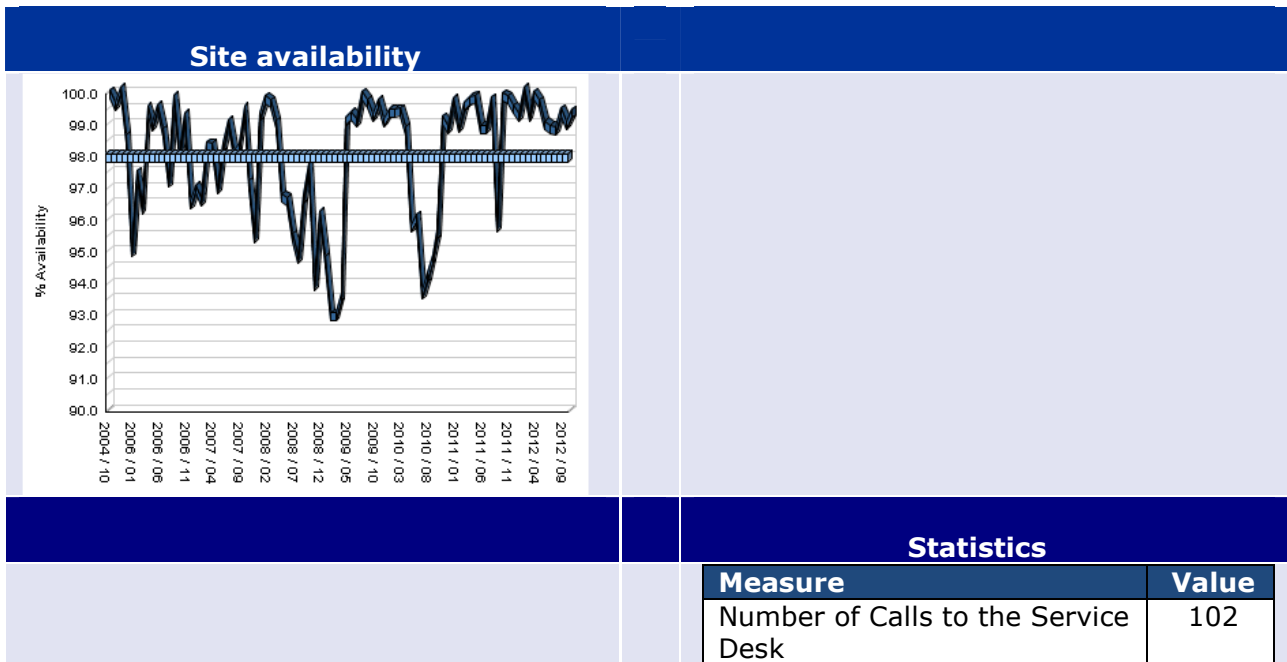
Traffic



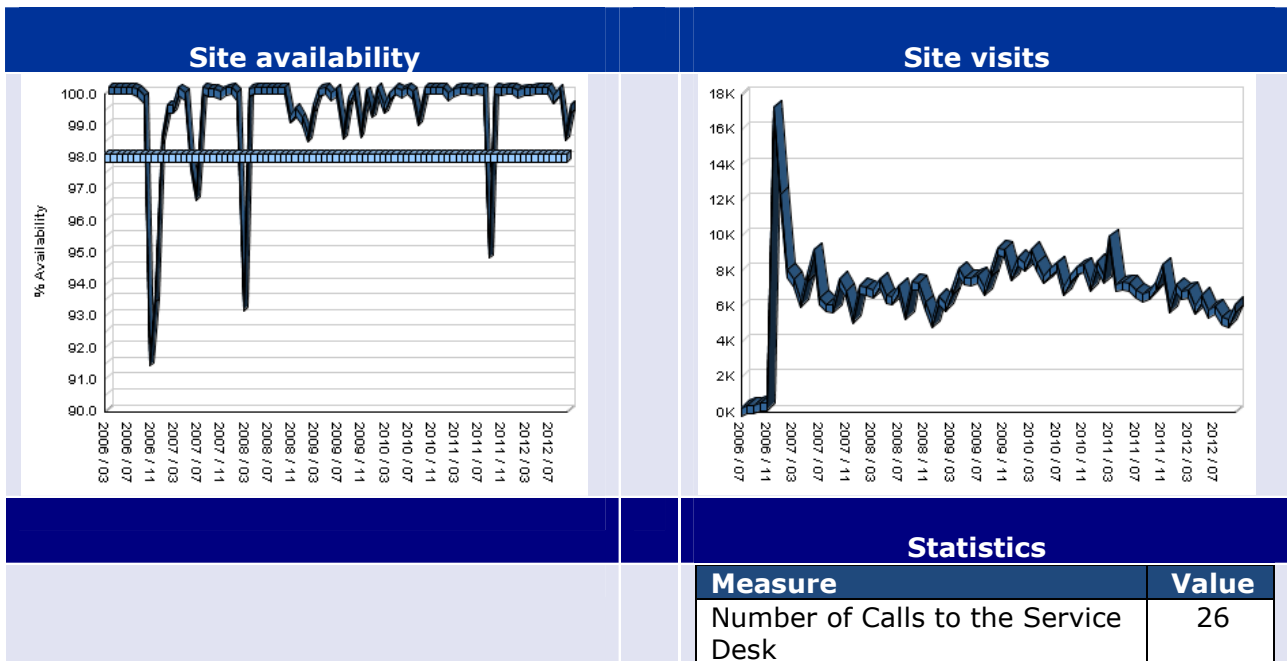
Statistics

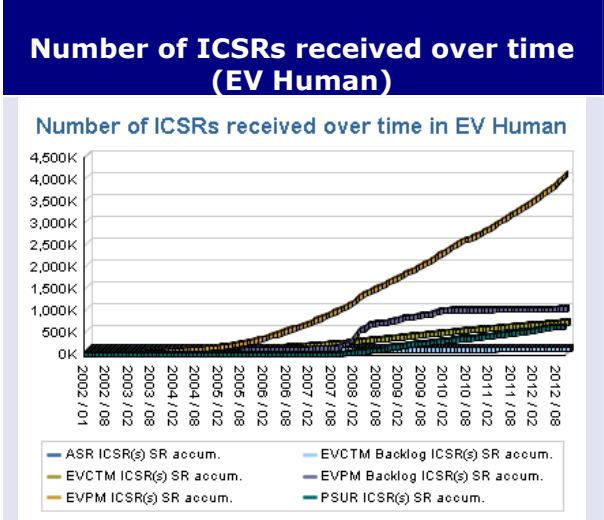
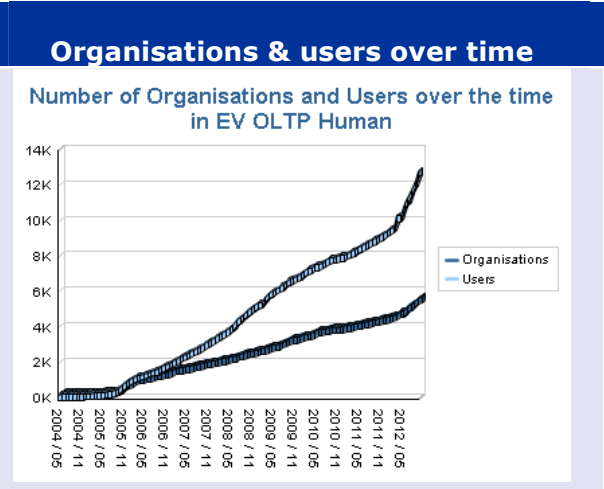
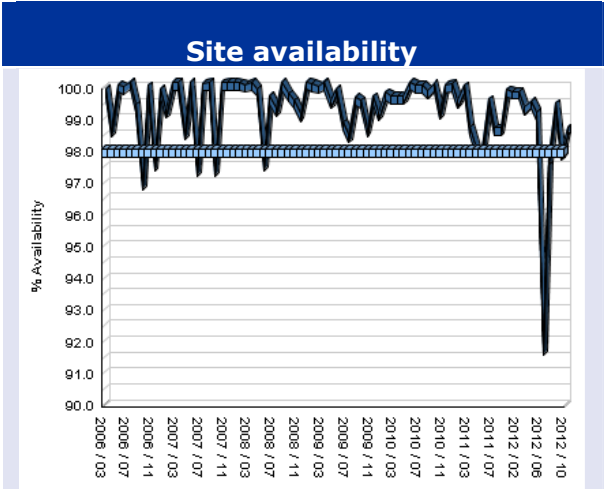
Measure	Value
Number of Calls to the Service Desk	1472
Number of Users	14503
Total Number of Packages Resent	2587
Total Number of Packages Sent	142025
Total Volume of Packages Sent (Gb)	699.82

EudraNet



EudraPharm





Statistics

Measure	Value
Number of Calls to the Service Desk - Human	855
Number of Calls to the Service Desk - Veterinary	16

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
2012 / 04	171	4622	632	10163
2012 / 05	0	4622	0	10163
2012 / 06	261	4883	716	10879
2012 / 07	112	4995	259	11138
2012 / 08	187	5182	469	11607
2012 / 09	165	5347	493	12100
2012 / 10	127	5474	576	12676

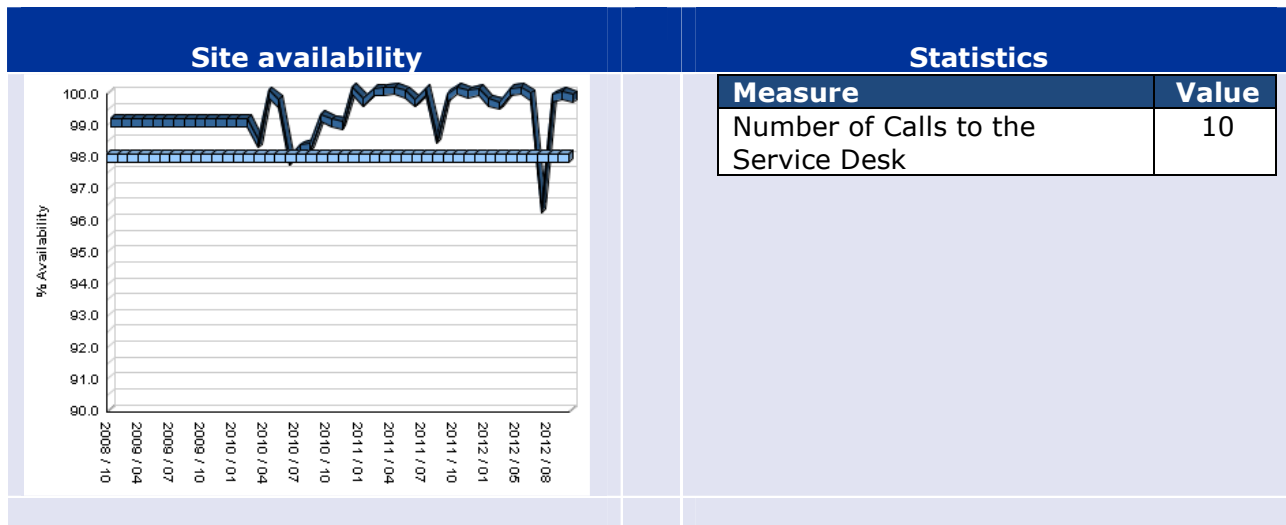
Period	EVPM ICSR(s) SR		EVPM Backlog ICSR(s) SR	
	Incremental	Cumulative	Incremental	Cumulative
2002	254	254	0	0
2003	49156	49410	0	0
2004	79901	129311	7932	7932
2005	178980	308291	43723	51655
2006	326241	634532	16276	67931
2007	447248	1081780	128413	196344
2008	588788	1670568	513464	709808
2009	564314	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
2012 / 04	60315	3637440	572	980925
2012 / 05	63829	3701269	130	981055
2012 / 06	62622	3763891	537	981592
2012 / 07	74551	3838442	5477	987069
2012 / 08	83255	3921697	3982	991051
2012 / 09	82877	4004574	294	991345
2012 / 10	85901	4090475	6680	998025

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
2012 / 04	6963	619974	1	12602
2012 / 05	7236	627210	5	12607
2012 / 06	6955	634165	17	12624
2012 / 07	7163	641328	88	12712
2012 / 08	7000	648328	21	12733
2012 / 09	6350	654678	1	12734
2012 / 10	7173	661851	21	12755

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
2012 / 04	95	9133	12068	585255
2012 / 05	99	9232	17051	602306
2012 / 06	103	9335	19462	621768
2012 / 07	92	9427	2250	624018
2012 / 08	34	9461	1125	625143
2012 / 09	1	9462	429	625572
2012 / 10	12	9474	924	626496

Users	Incremental	Cumulative
Affiliate: Human	78	2445
Affiliate: Vet	1	43
Commercial Sponsor: Human	22	741
Individual User: Human	1065	12714
Individual User: Vet	17	649
MAH: Human	180	2010
MAH: Vet	8	200
Non-Commercial Sponsor: Human	7	167
NCA: Human	0	40
NCA: Vet	0	30

EUTCT



Cost: use of the operational budget

The overall budget allocated to EU Telematics operations of €8.3M shows a reduction from €11.1, of €2.8M, found through rationalisation and cost saving techniques. 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	1,305.8	1,305.8
Training	9.8	8.2	-
Missions	62.0	51.7	15.5
Meetings	540.0	450.0	367.0
EMEA overhead	550.0	458.3	458.3
IT operations	5,583.0	4,652.5	4,515.0
Total	8,311.8	6,926.5	6,661.7

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.