

Summary Tables

CLINICAL TRIALS

CEIC Statistics (Cumulative data until 31-12-2015)

Issued Opinion (CEIC's Time)

	Type of Request									
	PA					PP				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
1 st Trim.	37,5	35	24	79	31	21,5	22	6	48	123
2 nd Trim.	31,1	31	12	56	21	22,2	21	5	59	132
3 rd Trim.	29,1	26	13	57	33	21,1	20	8	44	105
4 rd Trim.	32,5	33	1	54	31	22,5	20	8	67	120
Total	32,8	31	1	79	116	21,8	20	5	67	480

Table 1: Statistics of time (days) for issuing the final opinion by type of request.

Validation

	Type of Request									
	PA					PP				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
Total	4,5	4	0	11	167	4,1	4	0	12	558

Table 2: Statistics of time (days) used for validation by type of request.

Time used by the Experts

	Type of Request									
	PA					PP				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
Total	24,3	21	0	80	116	11,4	8	0	73	480

Table 3: Statistics of time (days) used by the experts for the evaluation of the processes by type of request.

* The zero time means that the answers were given on the same day.

Time used for Additional Requests

	Type of Request									
	PA					PP				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
Total	24,2	20	1	248	119	14,8	9	0	163	163

Table 4: Statistics of time (days) used by the sponsor for the clarifications on the additional information, by type of request.

Issued Opinion (Total time)

	Type of Request									
	PA					PP				
	Average	Median	Min	Max	N	Average	Median	Min	Max	N
1 st Trim.	61,1	55	28	159	31	22,9	21	6	57	123
2 nd Trim.	66,2	55	29	182	21	28,9	23	9	148	132
3 rd Trim.	44,4	44	14	81	33	25,4	23	8	67	105
4 rd Trim.	38,9	29	23	115	31	27,6	23	8	114	120
Total	56,7	53	14	182	116	26,3	23	6	148	480

Table 5: Statistics of time (days) for issuing the final opinion by type of request, including the clock stops for additional information.