

# APPENDIX Competent Authorities

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Tables follow the order of the questionnaire.

**Table CA 1A: Year of creation of the institution and year of the first Clinical Trial Authorisation**

Agency	Creation	Year first CTA
A	2006	2006
B	2008	2004
C		1995
D	2004	2005
E	2008	1998
F	1998	
G	1992	1998
H		
I	1993	2006
J	1975	2004
K	1896	2004
L		
M	2008	1987
N	1996	1987

Agency	Creation	Year first CTA
O	2004	2004
P	1997	1993
Q	2004	2004
R	1994	1994
S	1993	2005
T	1950	1991
U		
V		1982
W	2008	1980
X	2008	2006
Y	2003	2004
Z non EU	2000	2000
ZZ non EU	1974	1985

**Table CA 2A: Competence of institutions for the 4 drug development phases**

Institution L did not answer question Q1.

Institution	Phase			
	I	II	III	IV
A	yes	yes	yes	yes
B	yes	yes	yes	yes
C	yes	yes	yes	yes
D	yes	yes	yes	
E	yes	yes	yes	yes
F	yes	yes	yes	yes
G	yes	yes	yes	yes
H	yes	yes	yes	yes
I	yes	yes	yes	yes
J	yes	yes	yes	yes
K	yes	yes	yes	yes
L				
M	yes	yes	yes	yes
N	yes	yes	yes	yes

Institution	Phase			
	I	II	III	IV
O	yes			
P	yes	yes	yes	yes
Q	yes	yes	yes	yes
R	yes	yes	yes	yes
S	yes	yes	yes	yes
T	yes	yes	yes	yes
U	yes	yes	yes	yes
V	yes	yes	yes	yes
W	yes	yes	yes	yes
X	yes	yes	yes	yes
Y	yes	yes	yes	yes
Z	yes	yes	yes	yes
ZZ	yes	yes	yes	yes

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**Table CA 3A: Competence of institutions for categories of CTs**

Institution L did not answer question Q1.

Institution	Biotech	Avd ther.	Med. Dev.	Surg. Proc.	Radiother.	Diagn. Proc.	Min. Inv. Proc.	Obs. studies
A	yes	yes	yes		yes	yes		
B	yes	yes	yes		yes	yes		
C	yes		yes			yes	yes	yes
D		yes						
E	yes	yes					yes	yes
F	yes	yes	yes					
G	yes	yes	yes	yes	yes		yes	yes
H	yes	yes	yes	yes	yes	yes	yes	
I	yes	yes	yes	yes	yes	yes		
J	yes	yes			yes	yes		yes
K	yes					yes		yes
L								
M	yes							
N	yes	yes	yes	yes	yes	yes	yes	yes
O		yes						
P								yes
Q	yes	yes						
R	yes	yes	yes					
S	yes	yes	yes	yes	yes			
T	yes	yes	yes					
U	yes	yes	yes					yes
V	yes	yes	yes					yes
W	yes	yes	yes	yes	yes	yes		yes
X	yes	yes	yes	yes	yes	yes	yes	yes
Y	yes	yes	yes		yes	yes	yes	yes
Z							yes	
ZZ	yes	yes						
Total number	22	21	16	7	11	11	8	12

Biotech: Biotechnological products

Avd ther.: Advanced therapy

Med. Dev.: Medical devices

Surg. Proc.: Surgical procedures

Radiother.: radiotherapy

Diagn. Proc.: Diagnostic procedures

Min. Inv. Proc.: Minimally invasive procedures

Obs. studies: Observational studies

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**Table CA 4A: Change in organisational structure (Q2) and change in the CT authorisation process (Q3) with the nature of change for those that changed their process**

Institution L did not answer questions Q2 and Q3.

Institution	Structural change	Process change	From no information to authorisation	From no info in phase I to authorisation	From notification to authorisation
A	yes	no			
B	yes	yes			yes
C	yes	yes	yes		yes
D	yes	yes	yes		
E	no	yes			
F	yes	no			
G	no	no			
H	yes	yes			
I	yes	yes			yes
J	yes	yes			yes
K	yes	yes			yes
L					
M	yes	no			
N	no	no			
O	no	no			
P	no	no			
Q	yes	yes	yes	yes	
R	yes	yes			yes
S	yes	yes			yes
T	no	yes			
U	no	yes			
V	no	no			
W	no	no			
X	yes	yes	yes		
Y	yes	yes		yes	
Z	no	no			
ZZ	no	yes			yes
Yes	15	16	4	2	8
No	11	10			

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**Table CA 5A: Number of CTAs submitted by commercial sponsors per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A										223	225		226		224	
B									267		529		523		573	
C							122									97
D							0		0		4		4		3	
E	293		265		293		247		297		317		359		391	
F							192		210		203		228		205	
G		54		59		57	69		82		74		89		90	
H			179		179		187		201		182		231		204	
I			960		896		780		917		784		861		760	
J					95		103		128		150		147		169	
K			1326		1316		1393		1735		1225		1264		1190	
L													185		205	
M	285		293		274		258		359		239		306		333	
N		110		111		85		93		130		95		98		91
O	464		474		410		404		445		442		488		486	
P	28		23		38		38		70		59		88		86	
Q									2		6		3		2	
R																
S			157		126		142		129		116		145		127	
T	109		111		148		161		110		196		146		151	
U	48		32		42		47		56		31		30		24	
V		402		415		453		470		473		528		494		560
W	375		358		343		289		307		300		332		354	
X							746		681		664		681		582	
Y		668		665		657		646		801		857		893		914
Z							13		15		12		19		5	
ZZ	240		220		193		201		214		182		173		179	

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**Table CA 6A: Number of CTAs submitted by commercial sponsors. Data used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	223	225	226	224
B	MV	MV	MV	MV	267	529	523	573
C	MV	MV	MV	122	MV	MV	MV	97
D	MV	MV	MV	0	0	4	4	3
E	293	265	293	247	297	317	359	391
F	MV	MV	MV	192	210	203	228	205
G	54	59	57	69	82	74	89	90
H	MV	179	179	187	201	182	231	204
I	MV	960	896	780	917	784	861	760
J	MV	MV	95	103	128	150	147	169
K	MV	1326	1316	1393	1735	1225	1264	1190
L	MV	MV	MV	MV	MV	MV	185	205
M	285	293	274	258	359	239	306	333
N	110	111	85	93	130	95	98	91
O	464	474	410	404	445	442	488	486
P	28	23	38	38	70	59	88	86
Q	MV	MV	MV	MV	2	6	3	2
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	157	126	142	129	116	145	127
T	109	111	148	161	110	196	146	151
U	48	32	42	47	56	31	30	24
V	402	415	453	470	473	528	494	560
W	375	358	343	289	307	300	332	354
X	MV	MV	MV	746	681	664	681	582
Y	668	665	657	646	801	857	893	914
Z	MV	MV	MV	13	15	12	19	5
ZZ	240	220	193	201	214	182	173	179

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**Table CA 7A: Number of CTAs on orphan diseases submitted by commercial sponsors per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A									3	17			17		17	
B																
C																
D																
E							1		2		2		2		3	
F																
G								0		0		1		1		
H																
I																
J								3		5		5		11		
K							5	4		41		50		48		
L																
M	1		1		1		2		1		1		2		2	
N																
O					2		1		13		33		32		32	
P																
Q									0		0		0		0	
R																
S													9		6	
T																
U																
V																46
W											17		17		20	
X																
Y																
Z																
ZZ		1		1		1		1		1		1		1		1

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**Table CA 8A: Number of CTAs on orphan diseases submitted by commercial sponsors. Data used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	3	17	17	17
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	MV	MV	MV	1	2	2	2	3
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	MV	0	0	1	1
H	MV	MV	MV	MV	MV	MV	MV	MV
I	MV	MV	MV	MV	MV	MV	MV	MV
J	MV	MV	MV	MV	3	5	5	11
K	MV	MV	MV	5	4	41	50	48
L	MV	MV	MV	MV	MV	MV	MV	MV
M	1	1	1	2	1	1	2	2
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	2	1	13	33	32	32
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	0	0	0	0
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	MV	9	6
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	46
W	MV	MV	MV	MV	MV	17	17	20
X	MV	MV	MV	MV	MV	MV	MV	MV
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	MV	MV	MV	MV	MV
ZZ	1	1	1	1	1	1	1	1

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**Table CA 9A: Number of CTAs on biotechnological products submitted by commercial sponsors per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A									27	84			91		79	
B																
C																15
D																
E							35	33		64		83		91		
F																
G								1		4		29		35		
H							17									36
I																
J					95		103		128		150		147		169	
K							0	0		67		108		98		
L																
M																
N																
O			1		5		9		61		89		132		138	
P																
Q											1		1		2	
R																
S													35		37	
T									11		23		31		31	
U									12		7		7		8	
V																
W											69		94		99	
X																
Y										204		188		242		227
Z																
ZZ		2		2		2		2		2		2		2		2

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**Table CA 10A: Number of CTAs on biotechnological products submitted by commercial sponsors. Data used for statistical purposes**

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	27	84	91	79
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	MV	MV	MV	MV	15
D	MV	MV	MV	MV	MV	MV	MV	MV
E	MV	MV	MV	35	33	64	83	91
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	MV	1	4	29	35
H	MV	MV	MV	17	MV	MV	MV	36
I	MV	MV	MV	MV	MV	MV	MV	MV
J	MV	MV	95	103	128	150	147	169
K	MV	MV	MV	0	0	67	108	98
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	MV	MV	MV
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	1	5	9	61	89	132	138
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	1	1	2
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	MV	35	37
T	MV	MV	MV	MV	11	23	31	31
U	MV	MV	MV	MV	12	7	7	8
V	MV	MV	MV	MV	MV	MV	MV	MV
W	MV	MV	MV	MV	MV	69	94	99
X	MV	MV	MV	MV	MV	MV	MV	MV
Y	MV	MV	MV	MV	204	188	242	227
Z	MV	MV	MV	MV	MV	MV	MV	MV
ZZ	2	2	2	2	2	2	2	2

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**Table CA 11A: Number of CTAs on advanced therapies submitted by commercial sponsors per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A															1	
B																
C																
D																
E						1		1		2		3				1
F																
G																
H								1								1
I	6		10		8		9		8		8		5		7	
J									0		7		6		12	
K							0		0		0		0		0	
L																
M																
N																
O									3		4		4		6	
P																
Q									0		0		0		0	
R																
S													0		0	
T																
U																
V																
W											3		1		4	
X															10	
Y										16		8		23		13
Z																
ZZ		2		2		2		2		2		2		2		2

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**Table CA 12A: Number of CTAs on advanced therapies submitted by commercial sponsors. Data used for statistical purposes**

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	1
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	MV	MV	1	1	2	3	0	1
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	MV	MV	MV	MV	MV
H	MV	MV	MV	1	MV	MV	MV	1
I	6	10	8	9	8	8	5	7
J	MV	MV	MV	MV	0	7	6	12
K	MV	MV	MV	0	0	0	0	0
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	MV	MV	MV
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	3	6	6	6
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	0	0	0	0
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	MV	0	0
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	MV
W	MV	MV	MV	MV	MV	3	1	4
X	MV	MV	MV	MV	MV	MV	MV	10
Y	MV	MV	MV	MV	16	8	23	13
Z	MV	MV	MV	MV	MV	MV	MV	MV
ZZ	2	2	2	2	2	2	2	2

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**Table CA 13A: Number of CTAs submitted by non-commercial sponsors per year.  
Raw data**

Institution X reported data for commercial and non-commercial sponsors (pooled)

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A									30	95		68		75		
B									15		68		86		90	
C																
D							0		0		0		1		0	
E			1		4		20		16		14		12		24	
F								96		105		101		107		63
G							1		1		4		1		3	
H			105		88		86		92		56		54		54	
I			240		331		318		306		261		287		240	
J					46		25		103		47		42		42	
K										30	146		266		108	
L													34		52	
M		5		3		4		4		7		5		6		8
N		21		28		21		23		32		23		24		23
O	97		141		155		167		184		219		281		270	
P							0						1		1	
Q									0		0		0		0	
R																
S							12		10		12		8		5	
T	4		3		4		3		1		1				1	
U	2		2		4		3		2		3		9		5	
V		181		187		86		118		111		108		94		95
W	119		126		124		161		114		91		93		79	
X							746		681		664		681		582	
Y		632		538		639		598		495		228		313		304
Z							7		5		6		6		4	
ZZ		65		62		50		50	50			46		60		53

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**Table CA 14A: Number of CTAs submitted by non-commercial sponsors. Data used for statistical purposes**

MV = Missing values. Institution X reported data for commercial and non-commercial sponsors (pooled).

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	30	95	68	75
B	MV	MV	MV	MV	15	68	86	90
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	0	0	0	1	0
E	MV	1	4	20	16	14	12	24
F	MV	MV	MV	96	105	101	107	63
G	MV	MV	MV	1	1	4	1	3
H	MV	105	88	86	92	56	54	54
I	MV	240	331	318	306	261	287	240
J	MV	MV	46	25	103	47	42	42
K	MV	MV	MV	MV	30	146	266	108
L	MV	MV	MV	MV	MV	MV	34	52
M	5	3	4	4	7	5	6	8
N	21	28	21	23	32	23	24	23
O	97	141	155	167	184	219	281	270
P	MV	MV	MV	0	MV	MV	1	1
Q	MV	MV	MV	MV	0	0	0	0
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	12	10	12	8	5
T	4	3	4	3	1	1	MV	1
U	2	2	4	3	2	3	9	5
V	181	187	86	118	111	108	94	95
W	119	126	124	161	114	91	93	79
X	MV	MV	MV	746	681	664	681	582
Y	632	538	639	598	495	228	313	304
Z	MV	MV	MV	7	5	6	6	4
ZZ	65	62	50	50	50	46	60	53

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**Table CA 15A: Number of CTAs on orphan diseases submitted by non-commercial sponsors per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A										0	3		5		1	
B																
C																
D																
E																
F																
G							0		0				0			
H																
I																
J									0		0		0		1	
K										1		6		10		4
L																
M																
N																
O							1		4		7		8		9	
P																
Q																
R																
S													0		0	
T																
U																
V																8
W												0		2		3
X																
Y																
Z																
ZZ		0		0		0		0		0		0		0		0

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**Table CA 16A: Number of CTAs on orphan diseases submitted by non-commercial sponsors. Data used for statistical purposes**

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	0	3	5	1
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	MV	MV	MV	MV	MV	MV	MV	MV
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	0	0	MV	0	MV
H	MV	MV	MV	MV	MV	MV	MV	MV
I	MV	MV	MV	MV	MV	MV	MV	MV
J	MV	MV	MV	MV	0	0	0	1
K	MV	MV	MV	MV	1	6	10	4
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	MV	MV	MV
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	1	4	7	8	9
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	MV	MV	MV
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	MV	0	0
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	8
W	MV	MV	MV	MV	MV	0	2	3
X	MV	MV	MV	MV	MV	MV	MV	MV
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	MV	MV	MV	MV	MV
ZZ	0	0	0	0	0	0	0	0

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**Table CA 17A: Number of CTAs on biotechnological products submitted by non-commercial sponsors per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A									4	34			29		30	
B																
C																
D																
E							1	1			1		1		1	
F																
G							0	0					0			
H							8									3
I																
J					46		25		103		47		42		42	
K									2		12		20		8	
L																
M																
N																
O			1		6		11		29		51		78		49	
P																
Q																
R																
S													3		2	
T																
U									0		2		2		3	
V																
W											25		33		23	
X																
Y									32		40		87		94	
Z																
ZZ		0		0		0		0		0		0		0		0

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**Table CA 18A: Number of CTAs on biotechnological products submitted by non-commercial sponsors. Data used for statistical purposes**

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	4	34	29	30
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	MV	MV	MV	1	1	1	1	1
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	0	0	MV	0	MV
H	MV	MV	MV	8	MV	MV	MV	3
I	MV	MV	MV	MV	MV	MV	MV	MV
J	MV	MV	46	25	103	47	42	42
K	MV	MV	MV	MV	2	12	20	8
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	MV	MV	MV
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	1	6	11	29	51	78	49
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MM	MV	MV	MV
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	M	MV	3	2
T	MV	MV	MV	MV	M	MV	MV	MV
U	MV	MV	MV	MV	0	2	2	3
V	MV	MV	MV	MV	M	MV	MV	MV
W	MV	MV	MV	MV	M	25	33	23
X	MV	MV	MV	MV	MV	MV	MV	MV
Y	MV	MV	MV	MV	32	40	87	94
Z	MV	MV	MV	MV	MV	MV	MV	MV
ZZ	0	0	0	0	0	0	0	0

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**Table CA 19A: Number of CTAs on advanced therapies submitted by non-commercial sponsors per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A															1	
B																
C																
D																
E							1		1				1			1
F																
G							0		0				0			
H							0									0
I	28		16		27		20		21		20		12		18	
J											5		7		5	
K							0		0		0		0		0	
L																
M																
N																
O					1		0		3		3		7		8	
P																
Q																
R																
S													0		0	
T																
U																
V																
W											4		1		1	
X															10	
Y									0		6		10			14
Z																
ZZ		0		0		0		0		0		0		0		0

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**Table CA 20A: Number of CTAs on advanced therapies submitted by non-commercial sponsors. Data used for statistical purposes**

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	1
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	MV	MV	MV	1	1	MV	1	1
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	0	0	MV	0	MV
H	MV	MV	MV	0	MV	MV	MV	0
I	MV	16	27	20	21	20	12	18
J	MV	MV	MV	MV	MV	5	7	5
K	MV	MV	MV	0	0	0	0	0
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	MV	MV	MV
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	1	0	3	3	7	8
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	MV	MV	MV
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	MV	0	0
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	MV
W	MV	MV	MV	MV	MV	4	1	1
X	MV	MV	MV	MV	MV	MV	MV	MV
Y	MV	MV	MV	MV	0	6	10	14
Z	MV	MV	MV	MV	MV	MV	MV	MV
ZZ	0	0	0	0	0	0	0	0

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**Table CA 21A: Total number of CTAs submitted by commercial sponsors and non-commercial sponsors**

(Sum of table CA6 and 14. institution X counted once since it was already the sum)

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	253	320	294	299
B	MV	MV	MV	MV	282	597	609	663
C	MV	MV	MV	122	MV	MV	MV	97
D	MV	MV	MV	0	0	4	5	3
E	293	266	297	267	313	331	371	415
F	MV	MV	MV	288	315	304	335	268
G	54	59	57	70	83	78	90	93
H	MV	284	267	273	293	238	285	258
I	MV	1200	1227	1098	1223	1045	1148	1000
J	MV	MV	141	128	231	197	189	211
K	MV	1326	1316	1393	1765	1371	1530	1298
L	MV	MV	MV	MV	MV	MV	219	257
M	290	296	278	262	366	244	312	341
N	131	139	106	116	162	118	122	114
O	561	615	565	571	629	661	769	756
P	28	23	38	38	70	59	89	87
Q	MV	MV	MV	MV	2	6	3	2
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	157	126	154	139	128	153	132
T	113	114	152	164	111	197	146	152
U	50	34	46	50	58	34	39	29
V	583	602	539	588	584	636	588	655
W	494	484	467	450	421	391	425	433
X	MV	MV	MV	746	681	664	681	582
Y	1300	1203	1296	1244	1296	1085	1206	1218
Z	MV	MV	MV	20	20	18	25	9
ZZ	305	282	243	251	264	228	233	232

## ICREL PROJECT

**Table CA 22A: Number of non-approvals by competent authorities**

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	0	0	1
B	MV	MV	MV	MV	6	5	57	74
C	MV	MV	MV	6	MV	MV	MV	MV
D	MV	MV	MV	MV	0	0	0	0
E	2	3	14	11	20	9	4	8
F	MV	MV	MV	5	9	3	2	4
G	MV	MV	MV	2	4	4	1	0
H	MV	MV	MV	0	MV	MV	MV	3
I	MV	MV	MV	MV	1	MV	MV	4
J	MV	MV	MV	0	0	4	7	6
K	MV	MV	MV	2	4	6	30	18
L	MV	MV	MV	MV	MV	MV	MV	MV
M	10	9	11	18	28	9	12	19
N	MV	MV	MV	MV	MV	MV	MV	MV
O	5	9	7	2	11	15	15	15
P	MV	MV	MV	0	MV	MV	MV	1
Q	MV	MV	MV	MV	0	0	0	0
R	MV	MV	MV	8	9	12	20	12
S	MV	MV	MV	MV	0	0	1	0
T	MV	MV	MV	MV	MV	MV	MV	MV
U	0	1	0	0	0	0	1	0
V	29	30	27	29	29	32	29	35
W	1	6	1	0	11	22	20	17
X	MV	MV	MV	MV	MV	MV	MV	0
Y	27	49	17	13	16	28	21	25
Z	MV	MV	MV	1	0	0	0	1
ZZ	1	1	1	1	1	1	1	2

# ICREL PROJECT

**Table CA 23A: Existence of an appeal system**

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	no	no	no	no	no	yes	yes	yes
B	no	no	no	no	no	no	no	no
C								
D					no	no	no	no
E								
F	yes	yes	yes	yes	yes	yes	yes	yes
G				yes	yes	yes	yes	yes
H				yes	yes	yes	yes	yes
I	yes	yes	yes	yes	yes	yes	yes	yes
J				yes	yes	yes	yes	yes
K	yes	yes	yes	yes	yes	yes	yes	yes
L								
M								
N								
O	no	no	no	no	no	no	no	no
P				yes	yes	yes	yes	yes
Q								
R				yes	yes	yes	yes	yes
S					yes	yes	yes	yes
T	no	yes	yes	yes	yes	yes	yes	yes
U	yes	yes	yes	yes	yes	yes	yes	yes
V	yes	yes	yes	yes	yes	yes	yes	yes
W	yes	yes	yes	yes	yes	yes	yes	yes
X								yes
Y	yes	yes	yes	yes	yes	yes	yes	yes
Z				no	no	no	no	no
ZZ	yes	yes	yes	yes	yes	yes	yes	yes

ICREL PROJECT

**Table CA 24A: Use of the appeal system**

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A						0	0	0
B								
C								
D								
E								
F								
G				0	0	0	0	0
H				0				
I					1			0
J				0	0	1	0	3
K				0	0	0	0	2
L								
M								
N								
O								
P				0				0
Q								
R								
S					0	0	0	0
T		6	4	3	1	1	2	10
U	0	0	0	0	0	0	0	0
V	no	no	no	no	no	no	no	no
W				0				
X								0
Y	0	0	0	0	0	0	0	0
Z				0				0
ZZ	0	0	0	0	0	0	0	0

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**Table CA 25A: Number of multi-national CTs submitted for approval per year.  
Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B																
C							87									
D											4		4		3	
E		280		255		284		255		300		310		360		400
F																
G							69		82		73		88		91	
H							172		184		162		199		169	
I																
J															126	
K																
L																
M	269		272		250		242		337		228		283		307	
N																
O	232		309		274		320		380		391		429		453	
P							36						87		85	
Q	0		0		0		0		2		5		3		2	
R																
S							120		110		110		110		120	
T							97								33	
U									34		28		34		25	
V		356		349		334		376		380		413		382		489
W											267		276		262	
X																
Y									677		535		775		935	
Z							10								4	
ZZ		120		120		120		120		120		100		100		100

ICREL PROJECT

**Table CA 26A: Number of multi-national CTs submitted for approval per year.  
Data used for statistical purposes**

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	87	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	4	4	3
E	280	255	284	255	300	310	360	400
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	69	82	73	88	91
H	MV	MV	MV	172	184	162	199	169
I	MV	MV	MV	MV	MV	MV	MV	MV
J	MV	MV	MV	MV	MV	MV	MV	126
K	MV	MV	MV	MV	MV	MV	MV	MV
L	MV	MV	MV	MV	MV	MV	MV	MV
M	269	272	250	242	337	228	283	307
N	MV	MV	MV	MV	MV	MV	MV	MV
O	232	309	274	320	380	391	429	453
P	MV	MV	MV	36	MV	MV	87	85
Q	0	0	0	0	2	5	3	2
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	120	110	110	110	120
T	MV	MV	MV	97	MV	MV	MV	33
U	MV	MV	MV	MV	34	28	34	25
V	356	349	334	376	380	413	382	489
W	MV	MV	MV	MV	MV	267	276	262
X	MV	MV	MV	MV	MV	MV	MV	MV
Y	MV	MV	MV	MV	677	535	775	935
Z	MV	MV	MV	10	MV	MV	MV	4
ZZ	120	120	120	120	120	100	100	100

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**Table CA 27A: Number of multi-centre CTs submitted for approval per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B																
C							87									25
D																
E		10		10		10		20		10		9		10		12
F																
G									1		1		1		2	
H							24		11		20		15		15	
I																
J															169	
K																
L																
M									3		2				2	
N																
O	211		172		161		134		139		156		175		148	
P															1	
Q									0		0		0		0	
R																
S							25		30		25		10		10	
T							50								114	
U									1							
V		105		108		86		100		88		95		88		99
W																
X							435		392		344		367		328	
Y									89		78		105		74	
Z							0								0	
ZZ		30		30		30		30		30		30		30		30

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**Table CA 28A: Number of multi-centre CTs submitted for approval per year. Data used for statistical purposes**

MV = missing values

Institutions	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	87	MV	MV	MV	25
D	MV	MV	MV	MV	MV	MV	MV	MV
E	10	10	10	20	10	9	10	12
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	MV	1	1	1	2
H	MV	MV	MV	24	11	20	15	15
I	MV	MV	MV	MV	MV	MV	MV	MV
J	MV	MV	MV	MV	MV	MV	MV	169
K	MV	MV	MV	MV	MV	MV	MV	MV
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	3	2	MV	2
N	MV	MV	MV	MV	MV	MV	MV	MV
O	211	172	161	134	139	156	175	148
P	MV	MV	MV	MV	MV	MV	MV	1
Q	MV	MV	MV	MV	0	0	0	0
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	25	30	25	10	10
T	MV	MV	MV	50	MV	MV	MV	114
U	MV	MV	MV	MV	1	MV	MV	MV
V	105	108	86	100	88	95	88	99
W	MV	MV	MV	MV	MV	MV	MV	MV
X	MV	MV	MV	435	392	344	367	328
Y	MV	MV	MV	MV	89	78	105	74
Z	MV	MV	MV	0	MV	MV	MV	0
ZZ	30	30	30	30	30	30	30	30

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**Table CA 29A: Number of mono-centre CTs submitted for approval per year. Raw data**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A													88		86	
B																
C							38									8
D																
E		3		1		3		2		3		2		1		3
F																
G							1				4		1			
H							77		98		56		71		66	
I																
J															42	
K																
L																
M	16		21		28		16		22		14		23		26	
N																
O	89		110		114		117		110		113		165		155	
P							2						1			
Q									0		0		0		0	
R																
S							10		10		10		20		10	
T							14									4
U									21		6		5		4	
V		122		132		119		112		117		127		118		128
W											123		141		140	
X							311		289		320		314		254	
Y										516		476		322		204
Z							10								5	
ZZ		10		10		10		10		10		10		10		10

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**Table CA 30A: Number of mono-centre CTs submitted for approval per year. Data used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	88	86
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	38	MV	MV	MV	8
D	MV	MV	MV	MV	MV	MV	MV	MV
E	3	1	3	2	3	2	1	3
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	1	MV	4	1	MV
H	MV	MV	MV	77	98	56	71	66
I	MV	MV	MV	MV	MV	MV	MV	MV
J	MV	MV	MV	MV	MV	MV	MV	42
K	MV	MV	MV	MV	MV	MV	MV	MV
L	MV	MV	MV	MV	MV	MV	MV	MV
M	16	21	28	16	22	14	23	26
N	MV	MV	MV	MV	MV	MV	MV	MV
O	89	110	114	117	110	113	165	155
P	MV	MV	MV	2	MV	MV	1	MV
Q	MV	MV	MV	MV	0	0	0	0
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	10	10	10	20	10
T	MV	MV	MV	14	MV	MV	MV	4
U	MV	MV	MV	MV	21	6	5	4
V	122	132	119	112	117	127	118	128
W	MV	MV	MV	MV	MV	123	141	140
X	MV	MV	MV	311	289	320	314	254
Y	MV	MV	MV	MV	516	476	322	204
Z	MV	MV	MV	10	MV	MV	MV	5
ZZ	10	10	10	10	10	10	10	10

ICREL PROJECT

**Table CA 31A: Number of amendments submitted per year. Raw data**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	671	903
B	MV	MV	MV	MV	41	540	975	1219
C	MV	MV	MV	21	MV	MV	MV	67
D	MV	MV	MV	0	0	3	4	2
E	MV	MV	MV	MV	MV	793	1192	1586
F	MV	MV	MV	367	406	480	750	740
G	MV	MV	MV	MV	41	81	146	209
H	MV	274	303	558	161	361	385	401
I	MV	2034	1799	2329	2287	2897	2828	2855
J	MV	MV	MV	MV	3	112	273	499
K	MV	MV	MV	MV	4	594	1577	2528
L	MV	MV	MV	MV	MV	MV	629	544
M	320	332	317	340	351	461	915	1091
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	27	32	65	76	118	164
Q	MV	MV	MV	MV	MV	MV	5	11
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	8	52	262
T	MV	239	140	164	230	259	242	231
U	46	31	32	35	32	57	32	30
V	MV	MV	MV	MV	MV	MV	MV	MV
W	507	534	507	512	501	1025	765	901
X	MV	MV	MV	MV	MV	MV	MV	2200
Y	1429	1736	1837	1948	1497	3462	4208	4525
Z	MV	MV	MV	MV	MV	MV	MV	MV
ZZ	875	1023	862	903	500	500	500	590

## ICREL PROJECT

**Table CA 32A: Number of amendments submitted per year and not approved.**

**Raw data**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	0	0
B	MV	MV	MV	MV	MV	MV	MV	MV
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	MV	MV	MV	MV	MV	MV	MV	MV
F	MV	MV	MV	MV	MV	MV	MV	MV
G	MV	MV	MV	MV	MV	MV	MV	MV
H	MV	MV	MV	MV	MV	MV	MV	MV
I	MV	0	0	0	0	0	0	0
J	MV	MV	MV	MV	0	0	6	6
K	MV	MV	MV	MV	0	2	15	32
L	MV	MV	MV	MV	MV	MV	MV	MV
M	2	1	MV	2	MV	3	MV	2
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	MV	0	MV	MV	MV	3
Q	MV	MV	MV	MV	MV	MV	0	0
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	0	0	0
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	MV
W	MV	MV	MV	MV	MV	36	29	39
X	MV	MV	MV	MV	MV	MV	MV	0
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	MV	MV	MV	MV	MV
ZZ	0	0	0	0	0	1	2	1

ICREL PROJECT

**Table CA 33A: Average notification time for acknowledgement. Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B								
C				7				7
D						5	5	5
E					60	60	60	60
F				42	42	42	42	42
G								
H								
I							5	5
J				18.5				
K	5	5	5	5				
L								
M								
N								
O	10	10	10	10	7	7	7	7
P								
Q								
R				15				
S	5	5	5	5	5			
T								
U								
V								
W					2	2	2	2
X								11
Y								7
ZZ								
Z								26

ICREL PROJECT

**Table CA 34A: Average time to issue approval letter concerning all applications.  
Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B								
C								60
D						50	40	35
E	72	68	109	60				
F								
G				40				50
H	37	40	41	43	40	36	40	42
I							33	36
J					30	30	30	30
K								
L								
M	60	60	60	60	60	60	60	60
N					57	51	50	53
O	120	120	120	120	90	90	90	60
P			66	65				60
Q								
R								68
S							46	45
T								
U	60	60	60	60	60	60	60	60
V								
W					42	45	47	47
X								
Y	35	35	35	35	24,5	24,7	24,8	23,9
Z								45
ZZ	19	20	17	19	20	20	22	25

ICREL PROJECT

**Table CA 35A: Average notification time for acknowledgement concerning phase 1. Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B								
C								
D								
E								
F								
G								
H								
I							5	5
J								
K	5	5	5	5				
L								
M								
N								
O	15	15	15	5	5	5	5	5
P								
Q								
R								
S								
T								
U								
V								
W								
X								
Y								3
Z								28
ZZ								

ICREL PROJECT

**Table CA 36A: Average time to issue approval letter concerning phase 1. Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B					15	15	15	15
C								60
D								
E	72	68	109					
F								
G								
H								
I							32	38
J					80	98	111	104
K					30	28	27	27
L								
M	60	60	60	60	60	60	60	60
N								
O	120	120	120	90	60	60	45	40
P								
Q								
R								
S								
T								
U								
V								
W								
X								
Y					15.1	15.7	17.2	26.6
Z								55
ZZ	19	20	17	19	20	20	22	25

ICREL PROJECT

**Table CA 37A: Average notification time for acknowledgement concerning phase 2 to 4. Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B								
C				7				
D						5	5	5
E								
F								
G								
H								
I								
J	5	5	5	5				
K								
L								
M								
N								
O								
P								
Q								
R								
S								
T								
U								
V								
W								
X								
Y								
Z								25
ZZ								

ICREL PROJECT

**Table CA 38A: Average time to issue approval letter concerning phase 2 to 4.  
Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B					28	28	28	28
C				60				60
D						50	40	35
E	72	68	109					
F								
G								
H								
I								
J					78	81	72	88
K					30	30	30	30
L								
M	60	60	60	60	60	60	60	60
N								
O								
P								
Q								
R								
S								
T								
U								
V								
W								
X								
Y	35	35	35	35	29.9	29	28	27
Z								40
ZZ	19	20	17	19	20	20	22	25

ICREL PROJECT

**Table CA 39A: Average time to issue acknowledgement letter concerning biological products. Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B								
C								
D								
E					60	60	60	60
F								
G								
H								
I								
J								
K	5	5	5	5				
L								
M								
N								
O								
P								
Q								
R								
S								
T								
U								
V								
W								
X								
Y								9
Z								
ZZ								

ICREL PROJECT

**Table CA 40A: Average time to issue approval letter concerning biological products. Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B					28	28	28	28
C								60
D								
E		68	109					
F								
G								
H								
I								
J								
K					30	30	30	30
L								
M								
N								
O								
P								
Q								
R								
S								
T								
U								
V								
W								
X								
Y					33	29	30	28
Z								
ZZ	19	20	17	19	20	20	22	25

ICREL PROJECT

**Table CA 41A: Average time to issue acknowledgment letter for xenogenic / somatic cell therapy. Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B								
C								
D								
E								
F								
G								
H								
I								
J								
K								
L								
M								
N								
O	15	15	15	5	5	5	5	5
P								
Q								
R								
S								
T								
U								
V								
W								
X								
Y								8
Z								
ZZ								

ICREL PROJECT

**Table CA 42A: Average time to issue approval letter for xenogenic / somatic cell therapy. Raw data in days**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B					148	148	148	148
C								180
D								
E					90	90	90	90
F								
G								
H								
I								
J								
K								
L								
M								
N								
O	120	120	120	90	60	60	60	60
P								
Q								
R								
S								
T								
U								
V								
W								
X								
Y					39	30	28	27
Z								
ZZ	19	20	17	19	20	20	22	25

ICREL PROJECT

**Table CA 43A: Number of full-time equivalents for scientific assessment of CTAs and amendments. Raw data**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	1	1	1	1	1	1	1.5	2.7
B					1	1	3	4
C				9				14
D								
E	5	4	1.5	3	3.5	4.5	4.5	4.5
F				5	5	5	5	5
G				0.5		1	1	1
H				3.25				3.25
I							8.8	9.6
J				2	10	10	10	12
K	1	1	3	3	8	10	16	18
L								
M	10	10	10	11	11	8	8	5
N				5.5				5.5
O	1	1	1	1	1.5	1.5	1.5	1.5
P	0.5			2				3
Q						0.25	0.25	0.25
R								
S	0.75	1.75	2	2.5	3	5	6.5	6.5
T	1	1	1	1	1	1	1	1
U	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
V								
W								
X							1	1
Y	3	3	3	4	5.8	6.5	7.5	7.9
Z				0.7				0.2
ZZ	2			2				2

ICREL PROJECT

**Table CA 44A: Number of full-time equivalents for administrative tasks concerning CTAs and amendments. Raw data**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	1	1	1	1	1	1	2	1.5
B					3	3	4	6
C				6				6
D								
E	2	2.5	2.5	3	3.5	4.5	4.5	4
F				2	2	2	2	2.5
G				0.5		1	1	1
H				1.9				2.75
I							6	6
J				1	1	1	1	2
K	1	3	3	3	6	7	9	12
L								
M	2	2	5	5	5	4	6	5
N				1				1
O	1	1	1	1	1.5	1.5	1.5	1.5
P	0.5			1.8				1.8
Q						0.25	0.25	0.25
R				3.25				8.38
S	0.25	0.25	1	1	1	1	1	1
T	1	1	1	1	1	1	1	1
U	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
V								
W								
X							1	1
Y	3	3	3	3	3.5	4	4	4
Z				0.5				0.3
ZZ	1			1				2

ICREL PROJECT

**Table CA 45A: Number of full-time equivalents for pharmacovigilance tasks and SUSAR reports. Raw data**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A								
B					0.5	0.5	0.5	0.5
C				6				9
D								
E	5	4	1.5	3	4	5	5	5
F				1.2	1.4	1.9	2	2.5
G				0.5		1	1	1
H				0.1				0.25
I							1.12	1.32
J				0.1	1	1	1	1
K	40	40	40	40	40	40	40	40
L								
M	3	3	3	3	3	5	5	5
N				1				1
O	1	1	1	1	1	1	1	1
P	0.2			0.2				0.2
Q						0.25	0.25	0.25
R								1
S								
T	1	1	1	1	1	1	1	1
U								
V								
W	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
X								
Y	0.1	0.1	0.1	0.1	0.2	0.2	0.6	0.5
Z				0.5				0.5
ZZ	0			0				1

ICREL PROJECT

**Table CA 46A: Number of SAEs / SUSARs received. Raw data**

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A							44	33
B						8	125	194
C								
D								
E								
F	502	286	320	407	465	1179	2101	2882
G	39	43	39	41	54	125	80	73
H								
I	41905	44214	55169	55392	70569	70664	68167	50378
J						562	1174	1695
K	13	13	48	119	386	2402	14646	19973
L								
M	498	650	647	623	629	402	410	301
N			307	157	190	127	62	46
O						320	375	405
P				10				12
Q								
R								16782
S								293
T				503				3281
U		31	34	43	30	35	21	16
V								
W		1880	2403	1360	3149	3877	3562	289
X								
Y	432	572	426	303	307	306	547	656
Z								
ZZ								250

**Table CA 47A: First year of entering data in EudraCT and EudraVigilance database, per institution**

Institution	EUDRACT	EudraVigilance
A	2004	
B	2005	2008
C	2007	2007
D	2005	2006
E	2004	2004
F	2004	2008
G	2004	2005
H	2004	2007
I	2006	
J	2004	2004
K	2004	2008
L		
M		2005
N	2004	2007

Institution	EUDRACT	EudraVigilance
O	2004	
P	2004	
Q	2005	2005
R	2005	2005
S	2005	2005
T	2005	2005
U	2004	
V	2004	
W	2004	2006
X	2006	2006
Y	2004	2006
Z	2004	2005
ZZ	2004	2004

ICREL PROJECT

**Table CA 48A: Standard rate of CTAs for commercial sponsors. Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									2000		2000		2000		2850	
C							400								400	
D											171		171		171	
E	0		0		0		0		833		833		833		833	
F	806		826		848		867		885		904		919		941	
G							0		0		400		400		400	
H			1009		1010		1010		1350		1350		1350		1350	
I	0		0		0		0		0		0		2000		2000	
J							780		6250		6250		6250		6250	
K	770		770		770		770		770		3800		3800		3800	
L																
M	838		890		935		935		935		1683		1683		1683	
N																
O																
P	229		1144		1144		1144		1144		1144		1144		1144	
Q													1747		1747	
R																
S											1000		1000		1023	
T	327		327		327		327		327		327		327		327	
U											417		750		750	
V																3757
W									2728		2728		2728		2728	
X															0	
Y			0		0		0			1222		1254		1575		1825
Z								154							463	
ZZ							526								526	

## ICREL PROJECT

**Table CA 49A: Standard rate of CTAs for commercial sponsors. Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	2000	2000	2000	2850
C	MV	MV	MV	400	MV	MV	MV	400
D	MV	MV	MV	MV	MV	171	171	171
E	0	0	0	0	833	833	833	833
F	806	826	848	867	885	904	919	941
G	MV	MV	MV	0	0	400	400	400
H	MV	1009	1010	1010	1350	1350	1350	1350
I	0	0	0	0	0	0	2000	2000
J	MV	MV	MV	780	6250	6250	6250	6250
K	770	770	770	770	770	3800	3800	3800
L	MV	MV	MV	MV	MV	MV	MV	MV
M	838	890	935	935	935	1683	1683	1683
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	229	1144	1144	1144	1144	1144	1144	1144
Q	MV	MV	MV	MV	MV	MV	1747	1747
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	1000	1000	1023
T	327	327	327	327	327	327	327	327
U	MV	MV	MV	MV	MV	417	750	750
V	MV	MV	MV	MV	MV	MV	MV	3757
W	MV	MV	MV	MV	2728	2728	2728	2728
X	MV	MV	MV	MV	MV	MV	MV	0
Y	0	0	0	0	1222	1253	1575	1825
Z	MV	MV	MV	154	MV	MV	MV	463
ZZ	MV	MV	MV	526	MV	MV	MV	526

ICREL PROJECT

**Table CA 50A: Standard rate of CTAs for SMEs. Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									2000		2000		2000		2850	
C																
D																
E	0		0		0		0		833		833		833		833	
F	806		826		848		867		885		904		919		941	
G																
H			1009		1010		1010		1350		1350		1350		1350	
I	0		0		0		0		0		0		2000		2000	
J																
K	770		770		770		770		3800		3800		3800		3800	
L																
M	838		890		935		935		935		1683		1683		1683	
N																
O																
P																
Q													1747		1747	
R																
S											1000		1000		1023	
T																
U																
V																3757
W									455		455		455		455	
X															0	
Y																
Z								154								463
ZZ							526									526

ICREL PROJECT

**Table CA 51A: Standard rate of CTAs for SMEs. Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	2000	2000	2000	2850
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	0	0	0	0	833	833	833	833
F	806	826	848	867	885	904	919	941
G	MV	MV	MV	MV	MV	MV	MV	MV
H	MV	1009	1010	1010	1350	1350	1350	1350
I	0	0	0	0	0	0	2000	2000
J	MV	MV	MV	MV	MV	MV	MV	MV
K	770	770	770	770	3800	3800	3800	3800
L	MV	MV	MV	MV	MV	MV	MV	MV
M	838	890	935	935	935	1683	1683	1683
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	MV	1747	1747
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	1000	1000	1023
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	3757
W	MV	MV	MV	MV	455	455	455	455
X	MV	MV	MV	MV	MV	MV	MV	0
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	154	MV	MV	MV	463
ZZ	MV	MV	MV	526	MV	MV	MV	526

ICREL PROJECT

**Table CA 52A: Standard rate of CTAs for Orphan drugs. Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									2000		2000		2000		2850	
C																
D																
E	0		0		0		0		833		833		833		833	
F	806		826		848		867		885		904		919		941	
G																
H			1009		1010		1010		1350		1350		1350		1350	
I	0		0		0		0		0		0		2000		2000	
J																
K	770		770		770		770		770		3800		3800		3800	
L																
M	838		890		935		935		935		1683		1683		1683	
N																
O																
P																
Q													1747		1747	
R																
S											1000		1000		1023	
T																
U																
V																3757
W									455		455		455		455	
X															0	
Y																
Z								154								463
ZZ							526									526

ICREL PROJECT

**Table CA 53A: Standard rate of CTAs for orphan drugs. Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	2000	2000	2000	2850
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	0	0	0	0	833	833	833	833
F	806	826	848	867	885	904	919	941
G	MV	MV	MV	MV	MV	MV	MV	MV
H	MV	1009	1010	1010	1350	1350	1350	1350
I	0	0	0	0	0	0	2000	2000
J	MV	MV	MV	MV	MV	MV	MV	MV
K	770	770	770	770	3800	3800	3800	3800
L	MV	MV	MV	MV	MV	MV	MV	MV
M	838	890	935	935	935	1683	1683	1683
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	MV	1747	1747
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	1000	1000	1023
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	3757
W	MV	MV	MV	MV	455	455	455	455
X	MV	MV	MV	MV	MV	MV	MV	0
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	154	MV	MV	MV	463
ZZ	MV	MV	MV	526	MV	MV	MV	526

# ICREL PROJECT

**Table CA 54A: Standard rate of CTAs for non-commercial sponsors. Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									0		0		0		0	
C																
D																
E	0		0		0		0		833		833		833		833	
F	806		826		848		867		885		904		919		941	
G											400		400		400	
H			0		0		0		0		0		0		0	
I	0		0		0		0		0		0		200		200	
J																
K	770		770		770		770		770		3800		3800		3800	
L																
M																
N																
O																
P																
Q													699		699	
R																
S											0		0		0	
T																
U											417		400		400	
V																3757
W										2728		2728		2728		2728
X															0	
Y	0		0		0		0		349		568		448		492	
Z							154								463	
ZZ							0	0							0	0

ICREL PROJECT

**Table CA 55A: Standard rate of CTAs for non-commercial sponsors. Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	M	MV	MV	0	0	0	0
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	0	0	0	0	833	833	833	833
F	806	826	848	867	885	904	919	941
G	MV	MV	MV	MV	MV	400	400	400
H	MV	0	0	0	0	0	0	0
I	0	0	0	0	0	0	200	200
J	MV	MV	MV	MV	MV	MV	MV	MV
K	770	770	770	770	770	3800	3800	3800
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	MV	MV	MV
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	MV	699	699
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	0	0	0
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	417	400	400
V	MV	MV	MV	MV	MV	MV	MV	3757
W	MV	MV	MV	MV	2728	2728	2728	2728
X	MV	MV	MV	MV	MV	MV	MV	0
Y	0	0	0	0	349	568	448	492
Z	MV	MV	MV	154	MV	MV	MV	463
ZZ	MV	MV	MV	0	MV	MV	MV	0

ICREL PROJECT

**Table CA 56A: Standard rate of amendment for commercial sponsors. Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									250		250		250		250	
C							250								250	
D																
E	0		0		0		0		398		398		398		398	
F	0		188		193		197		201		205		209		213	
G																
H	0		0		0		0		0		0		0		0	
I	0		0		0		0		0		0		250		250	
J									780		780		780		780	
K											500		500		500	
L																
M											337		337		337	
N																
O																
P			169		169		169		169		169		169		169	
Q													93		93	
R																
S											100		100		102	
T																
U	0		0		0		0		0		0		250		250	
V																
W	91		91		91		91		0		0		0		0	
X															0	
Y																
Z							0								99	
ZZ							0								0	

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**Table CA 57A: Standard rate of amendment for commercial sponsors. Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	250	250	250	250
C	MV	MV	MV	250	MV	MV	MV	250
D	MV	MV	MV	MV	MV	MV	MV	MV
E	0	0	0	0	398	398	398	398
F	0	188	193	197	201	205	209	213
G	MV	MV	MV	MV	MV	MV	MV	MV
H	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	250	250
J	MV	MV	MV	MV	780	780	780	780
K	MV	MV	MV	MV	MV	500	500	500
L	MV	MV	MV	MV	MV	MV	MV	
M	MV	MV	MV	MV	MV	337	337	337
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	
P	MV	169	169	169	169	169	169	169
Q	MV	MV	MV	MV	MV	MV	93	93
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	100	100	102
T	MV	MV	MV	MV	MV	MV	MV	MV
U	0	0	0	0	0	0	250	250
V	MV	MV	MV	MV	MV	MV	MV	MV
W	91	91	91	91	0	0	0	0
X	MV	MV	MV	MV	MV	MV	MV	0
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	0	MV	MV	MV	99
ZZ	MV	MV	MV	0	MV	MV	MV	0

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**Table CA 58A: Standard rate of amendment for small and medium enterprises.  
Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									250		250		250		250	
C																
D																
E	0		0		0		0		398		398		398		398	
F	0		188		193		197		201		205		209		213	
G																
H	0		0		0		0		0		0		0		0	
I	0		0		0		0		0		0		250		250	
J																
K																
L																
M											337		337		337	
N																
O																
P																
Q													93		93	
R																
S											100		100		102	
T																
U																
V																
W	91		91		91		91		0		0		0		0	
X															0	
Y																
Z							0								99	
ZZ							0								0	

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**Table CA 59A: Standard rate of amendment for small and medium enterprises.  
Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	250	250	250	250
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	0	0	0	0	398	398	398	398
F	0	188	193	197	201	205	209	213
G	MV	MV	MV	MV	MV	MV	MV	MV
H	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	250	250
J	MV	MV	MV	MV	MV	MV	MV	MV
K	MV	MV	MV	MV	MV	MV	MV	MV
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	337	337	337
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	MV	93	93
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	100	100	102
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	MV
W	91	91	91	91	0	0	0	0
X	MV	MV	MV	MV	MV	MV	MV	0
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	0	MV	MV	MV	99
ZZ	MV	MV	MV	0	MV	MV	MV	0

ICREL PROJECT

**Table CA 60A: Standard rate of amendment for orphan drugs. Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									250		250		250		250	
C																
D																
E	0		0		0		0		398		398		398		398	
F	0		188		193		197		201		205		209		213	
G																
H	0		0		0		0		0		0		0		0	
I	0		0		0		0		0		0		250		250	
J																
K																
L																
M											337		337		337	
N																
O																
P																
Q													93		93	
R																
S											100		100		102	
T																
U																
V																
W	91		91		91		91		0		0		0		0	
X															0	
Y																
Z							0								99	
ZZ							0								0	

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**Table CA 61A: Standard rate of amendment for orphan drugs. Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	250	250	250	250
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	0	0	0	0	398	398	398	398
F	0	188	193	197	201	205	209	213
G	MV	MV	MV	MV	MV	MV	MV	MV
H	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	250	250
J	MV	MV	MV	MV	MV	MV	MV	MV
K	MV	MV	MV	MV	MV	MV	MV	MV
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	337	337	337
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	MV	93	93
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	100	100	102
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	MV
W	91	91	91	91	0	0	0	0
X	MV	MV	MV	MV	MV	MV	MV	0
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	0	MV	MV	MV	99
ZZ	MV	MV	MV	0	MV	MV	MV	0

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**Table CA 62A: Standard rate of amendment for non-commercial sponsors. Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									0		0		0		0	
C																
D																
E	0		0		0		0		398		398		398		398	
F	0		188		193		197		201		205		209		213	
G																
H	0		0		0		0		0		0		0		0	
I	0		0		0		0		0		0		25		25	
J																
K																
L																
M																
N																
O																
P																
Q													93		93	
R																
S											0		0		0	
T																
U	0		0		0		0		0		0		200		250	
V																
W	91		91		91		91		0		0		0		0	
X															0	
Y																
Z							0								99	
ZZ							0								0	

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**Table CA 63A: Standard rate of amendment for non-commercial sponsors. Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV	MV	0	0	0	0
C	MV	MV	MV	MV	MV	MV	MV	MV
D	MV	MV	MV	MV	MV	MV	MV	MV
E	0	0	0	0	398	398	398	398
F	0	188	193	197	201	205	209	213
G	MV	MV	MV	MV	MV	MV	MV	MV
H	0	0	0	0	0	0	0	0
I	0	0	0	0	0	0	25	25
J	MV	MV	MV	MV	MV	MV	MV	MV
K	MV	MV	MV	MV	MV	MV	MV	MV
L	MV	MV	MV	MV	MV	MV	MV	MV
M	MV	MV	MV	MV	MV	MV	MV	MV
N	MV	MV	MV	MV	MV	MV	MV	MV
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	MV	MV	MV	MV	MV	MV
Q	MV	MV	MV	MV	MV	MV	93	93
R	MV	MV	MV	MV	MV	MV	MV	MV
S	MV	MV	MV	MV	MV	0	0	0
T	MV	MV	MV	MV	MV	MV	MV	MV
U	0	0	0	0	0	0	200	250
V	MV	MV	MV	MV	MV	MV	MV	MV
W	91	91	91	91	0	0	0	0
X	MV	MV	MV	MV	MV	MV	MV	0
Y	MV	MV	MV	MV	MV	MV	MV	MV
Z	MV	MV	MV	0	MV	MV	MV	99
ZZ	MV	MV	MV	0	MV	MV	MV	0

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**Table CA 64A: Funding: overall budget including staff salaries. Raw data in euros**

Insti- tution	2000		2001		2002		2003		2004		2005		2006		2007	
	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx	exact	approx
A																
B									141000		298500		304500		895050	
C								20000								50000
D																
E																
F										1020360		1047212		1114341		1221747
G																
H								371073							481464	
I															1994000	
J																
K		375000		375000		375000		375000		900000		1500000		1875000	2185500	
L																
M	238725		260765		256150		241193		335613		557323		822879		927526	
N							644746								812666	
O																
P								20395								69927
Q																
R																
S	26265		39612		41835		80153		112801		184041		211235		190098	
T																
U																
V																
W	819404		931719		1051311		1125430		1251387		1093599		1038578		1350516	
X																
Y	457650		485022		515678		754357		681002		896689		1170403		1274415	
Z																61687
ZZ																

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**Table CA 65A: Funding: overall budget including staff salaries. Data in euros used for statistical purposes**

MV = missing values

Institution	2000	2001	2002	2003	2004	2005	2006	2007
A	MV	MV	MV	MV	MV	MV	MV	MV
B	MV	MV	MV		141000	298500	304500	895050
C	MV	MV	MV	20 000	MV	MV	MV	50000
D	MV	MV	MV	MV	MV	MV	MV	MV
E	MV	MV	MV	MV	MV	MV	MV	MV
F	MV	MV	MV		1020360	1047212	11143418	1221747
G	MV	MV	MV	MV	MV	MV	MV	MV
H	MV	MV	MV	371073	MV	MV	MV	481464
I	MV	MV	MV	MV	MV	MV	MV	1994000
J	MV	MV	MV	MV	MV	MV	MV	MV
K	375000	375000	375000	375000	900000	1500000	1875000	2185500
L	MV	MV	MV	MV	MV	MV	MV	MV
M	238725	260765	256150	241193	335613	557323	822879	927526
N	MV	MV	MV	644746	MV	MV	MV	812666
O	MV	MV	MV	MV	MV	MV	MV	MV
P	MV	MV	MV	20395	MV	MV	MV	69927
Q	MV	MV	MV	MV	MV	MV	MV	MV
R	MV	MV	MV	MV	MV	MV	MV	MV
S	26265	39612	41835	80153	112801	184041	211235	190098
T	MV	MV	MV	MV	MV	MV	MV	MV
U	MV	MV	MV	MV	MV	MV	MV	MV
V	MV	MV	MV	MV	MV	MV	MV	MV
W	819404	931719	1051310	1125430	1251387	1093599	1038578	1350516
X	MV	MV	MV	MV	MV	MV	MV	MV
Y	457650.87	485022.34	515678.37	754357.54	681002.01	896689.15	1170403.8	1274415.35
Z	MV	MV	MV	MV	MV	MV	MV	61687
ZZ	MV	MV	MV	MV	MV	MV	MV	MV

## ICREL PROJECT

**Table CA 66A: Reported strengths of the directive (verbatim)**

Strengths
Harmonisation
Two independent procedures for assessment
Clear deadlines for issuing authorisation
Harmonisation of regulatory requirements of the member states
Harmonisation of regulation of CTA in EU
Harmonisation of guidelines
Possibility to change information about CTA between CA= Member States= NAs
GCP for all clinical trials
Common harmonized standards
EudraCT and EudraVigilance CTM
Alerts for premature end and ban of clinical trials
Minimum criteria for protection of subjects
harmonization
Harmonisation of level of subjects protection/safety
Common procedures to start and conduct CTs in EU
Good practices (GMP, GCP)
Exchanges of information between NCAs
Better design of CT protocols
Improved Safety of participants of CT
Better conduct, monitoring and auditing of CT
Improved quality of CTs, especially for IIT studies
Higher reliability of CT results
Clear requirements, time lines, costs
Large increase of competent CT groups at non-commercial sponsors, especially universities
Improved scientific advise before and within the procedure
Documentation in most parts usable in many countries for multinational Trials
relatively harmonised interpretation and implementation
legislative basis for GCP
CTFG - useful resource
Clinical research conducted in Europe thanks to the CTD results in better evidence based medicine approach to science
safety of patients increased because of submission of IMPD as this guarantees quality of the IMP
One consistent CT approval system across EU
Access to EudraCT database for all Competent Authorities in EU
Increased protection of clinical trials subjects
Promotion of high standards / high quality research in EU
Opportunity for having more transparency on CT
Opportunity for increasing the quality of research in EU
Opportunity for getting harmonization in the requirements and assessments. Not everthing has been reached at the same level, but we are in the process
exchange of information
alert system
More sharing of information between EU countries
Established clear and specific provisions for the conduct of trials in all MS
EudraCT - electronic format is simple and efficient, online and offline use, allows MS to share information quickly and easily, automated rapid alerts

## ICREL PROJECT

<b>Strengths</b>
Eudravigilance - electronic format is simple and efficient, allows MS to share information quickly and easily, potential for analysis for safety signals
Substantial Amendments - regulatory requirements proportionate, non-substantial amendments not reported, sponsor identifies whether substantial or not, simple reporting form
Annual Safety Reports - regular and consistent reporting of safety profile of development drugs throughout development, format and content described in Vol 10 PvG guidance
More harmonisation between countries
More consistency in applications

**Table CA 67A: Reported weaknesses of the directive (verbatim)**

<b>Weaknesses</b>
Some items are not specified enough which contributes to different interpretation by the MS's
Unclear definition of "legal representative" of the sponsor
Burden in administration
No keeping general guidelines (despite of general guidelines, no keeping these ones by all member states)
CAs = NAs specificities
Lack of harmonization in practice
conducting trials has been made more difficult for academic/non-commercial researchers
more bureaucracy
databases difficult to use (at least for non-commercial researchers)
Too much room for implementation of guidances.
Need for a simplified system based on the risk of CTs.
Need for simplification of Susars reporting to Ethics Committees
Need for further coordination in CTA and safety data assessment by MS.
Increase in time (sponsor, EC and NCA) and costs (sponsor)
In few cases divergend decisions on the CTA by the member states
Lack of clear definition of the term "medicinal product" has caused problems with borderline products (medical devices, dietary supplements)
Additional national information required for minor parts of the CTA
Different intensity of assessment due to numbers of personnel
considerable burden remains for non-commercial investigators/sponsors
Non - commercial and non-interventional trials should be more specified.
harmonisation of requirements is difficult for sponsors conducting a multi national trial
A lot of double assessment is wasted assessing protocols/IMPdS by different member states
A lot of paperwork for CROs is required
Different ethical practises across Europe from MS to MS
the fact that different MSs have different practises means that certain research can proceed which could not happen if there is only 1 central approval system
Very significant increase in bureaucratic work-load
significant workload and bureaucracy involvement
Harmonization of some concepts interpretation, procedures and practices still to be fully achieved between EU member-States
National legislation sometimes differs from Directives (special requirements for documentation).
Guidance documents are not accepted by Ministry of Health and are not implemented in national legislation.

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<b>Weaknesses</b>
In our country we have two categories of clinical trials - biomedical reseach and clinical trial of medicinal products. Requirements for biomedical trials are sometimes more rigorous.
There is single database EudraCT. However we need our own database as all data in EudraCT are in English.
Some requirements should be simplified, specially for CT on authorised MP
There is a need for clarifying requirements with respect to applications referring to authorised CT (substantial amendments, safety reports and SUSAR reporting, deviations, etc)
We get information with very different format, criteria and quality from different sponsors for the same type of applications
not all member states complete all relevant fields, and some obvious errors in database
too complicated system/too many information points to complete for non-commercial sponsors
Quality of current data within Eudravigilance
Too many big, unclear forms for EudraCT, lack of clear version numbers on EudraCT forms influencing the quality of data within EudraCT
Not harmonised substantial amendment definition, CAs and RECs overloaded
SUSAR: Sponsors report all serious events instead of SUSARs, no IMP codes, different MS requirements
Annual Safety reports - huge workload for CAs to assess, significant duplication of effort by CAs, inconsistent formatting by sponsors, difficulty assessing paper line listings
EudraCT - lack of real time data entry by many CAs, poor current functionality re analysis, alternative public registries of CTs being built by several MS
Not clear enough in some areas - guidance on substantial amendments, penalties for GCP non compliance, responsibilities of investigators, use of inspection reports
Definition of Substantial Amendment

## ICREL PROJECT

**Table CA 68A: Reported suggestion of changes to the clinical trials directive and related legislation (verbatim)**

<b>Suggested changes to the Clinical Trials Directive and related legislation</b>
Mutual recognition only for the IMPD assessment
See "weakness" box.
Qualification of the sponsor and his legal representative has to be defined
SUSAR reporting needs cleared definitions: what to report (avoidance of unnecessary reporting, sponsors task to determine "relatedness")
Non- interventional trials should be regulated
All the SUSARs of the trial conducted in the EEA should only be submitted to the EMEA, Eudra Vigilance database. Subsequently, SUSARs originating in the country of a MS are automatically transmitted by the EudraVigilance database to the concerned MS
publicly accessible database of trials being conducted in EU would benefit patients/caregivers and healthcare professionals
mutual recognition for certain trials e.g. trials using orphan medicinal products or trials in rare diseases
Foster administrative simplification and maximize EU member-States harmonization of procedures and practices
Increase transparency and information exchange EU between member-States
Some requirements about CT should be differentiated on a risk-benefit balance approach (i.e. according to the authorisation status of the medicinal products).
would appreciate possibility to search for "indication"
further developed search function
Evaluation valueness and extensiveness of EudraCT application form
Clarify that MS legislation must require that all SUSARs are to be reported electronically to Eudravigilance
Simplify safety reporting to ethics committees, perhaps make CAs responsible for informing RECs of safety issues
Include Eudravigilance Medicinal Product Dictionary maintenance in legislation
Consider simplified approval processes for non-commercial researchers
Clarify guidance on notification requirements for substantial amendments
Standardized format and content of CT applications
Electronic submission of CT applications
Define Substantial Amendments (make a list that could be utilised when charging for SA)
A course in EudraCT (or updated guidelines) as there is a lack of information being updated
Define better the difference between Competent Authorities and ethics committees