

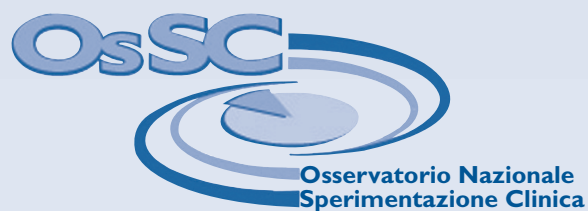


**AGENZIA ITALIANA DEL FARMACO**

**BULLETIN  
CLINICAL TRIALS OF DRUGS IN ITALY**

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**2006**



**Osservatorio Nazionale sulla Sperimentazione Clinica dei medicinali**  
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**2006 Bulletin**

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This Bulletin collects data from January 1<sup>st</sup>, 2000 to December 31<sup>st</sup>, 2005  
and is available on the web site <http://oss-sper-clin.agenziafarmaco.it>



## Clinical Trials (CT)

The clinical trials figures in this Bulletin refer to the National Monitoring Centre data entered by Sponsors and Ethics Committees and to Phase I trials evaluated by the Italian National Institute of Health, in the period January 1<sup>st</sup>, 2000 - December 31<sup>st</sup>, 2005.

All studies are classified according to the year in which the Ethics Committee of the coordinating site has evaluated them, as follows:

Year	CT
2000	560
2001	610
2002	565
2003	565
2004	607
2005	620
<b>Totale</b>	<b>3,527</b>

As showed in chart 1, in 2005 the Phase II clinical trials are 36.0% of the total, whilst the Phase III studies fall for the first time below 50.0%. Italy is still much involved in multicentre international researches, reaching 66.5% (chart 2) in the period 2000 - 2005.

Chart 1

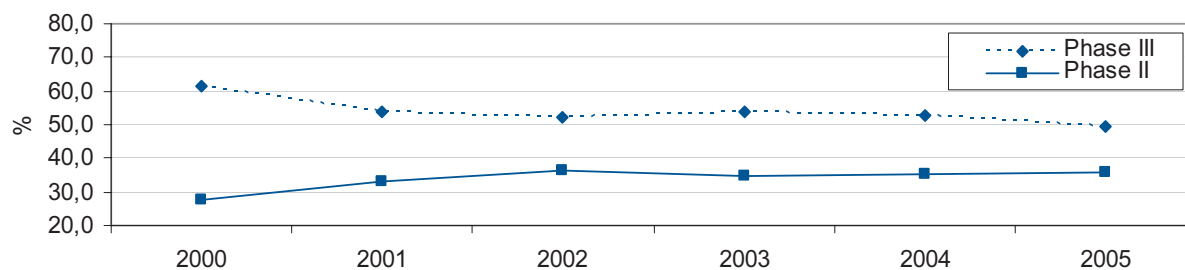
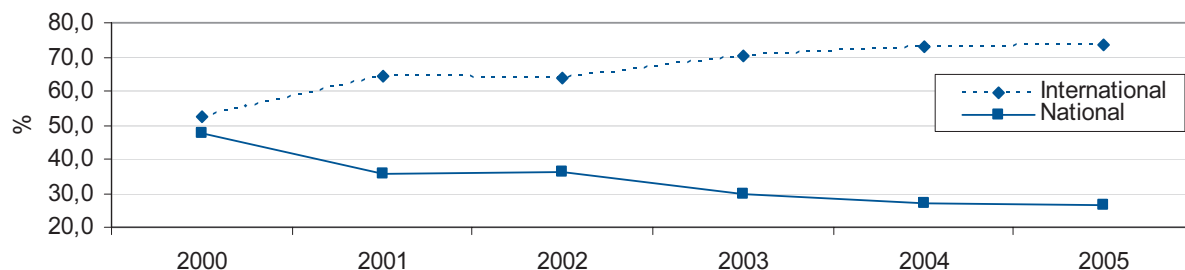


Chart 2



Antineoplastic and immunomodulating agents are still the most investigated category among the ATC (33.0%), followed by nervous system drugs (11.6%) and general antiinfectives for systemic use (10.0%).

Pharmaceuticals companies sponsor 73.7% of all Italian clinical trials, whilst the remaining 26.3% is coordinated by no profit entities (Hospitals, Local health units, Universities, etc.).

**Table 1**

**Monocentre / multicentre clinical trials per phase**

Total clinical trials: 3,527 (3,499 of which - 99.2% - with specified typology and phase)

Phase	Monocentre		Multicentre		Total	
	CT	%	CT	%	CT	%
Phase III	187	28.5	1,699	59.7	1,886	53.9
Phase II	290	44.3	898	31.6	1,188	34.0
Phase IV	85	13.0	220	7.7	305	8.7
Bioeq / Bioav	66	10.1	4	0.1	70	2.0
Phase I	27	4.1	23	0.8	50	1.4
<b>Total</b>	<b>655</b>	<b>100.0</b>	<b>2,844</b>	<b>100.0</b>	<b>3,499</b>	<b>100.0</b>

**Table 2**

**Monocentre / multicentre clinical trials per year**

Total clinical trials: 3,527 (3,499 of which - 99.2% - with specified typology)

Year	Monocentre		Multicentre		Total	
	CT	%	CT	%	CT	%
2000	89	16.2	460	83.8	549	100.0
2001	110	18.2	494	81.8	604	100.0
2002	118	21.2	438	78.8	556	100.0
2003	122	21.6	443	78.4	565	100.0
2004	107	17.7	498	82.3	605	100.0
2005	109	17.6	511	82.4	620	100.0
<b>Total</b>	<b>655</b>	<b>18.7</b>	<b>2,844</b>	<b>81.3</b>	<b>3,499</b>	<b>100.0</b>

**Table 3**

**National and international multicentre clinical trials per year**

Multicentre clinical trials: 2,844 (2,792 of which - 98.2% - with specified typology)

Year	National		International		Total	
	CT	%	CT	%	CT	%
2000	210	47.6	231	52.4	441	100.0
2001	170	35.9	304	64.1	474	100.0
2002	156	36.4	273	63.6	429	100.0
2003	131	29.6	311	70.4	442	100.0
2004	133	26.8	364	73.2	497	100.0
2005	134	26.3	375	73.7	509	100.0
<b>Total</b>	<b>934</b>	<b>33.5</b>	<b>1,858</b>	<b>66.5</b>	<b>2,792</b>	<b>100.0</b>

**Table 4**  
**Clinical trials per phase**  
Total clinical trials: 3,527

Phase	CT	%
Phase III	1,899	53.8
Phase II	1,198	34.0
Phase IV	306	8.7
Bioeq / Bioav	70	2.0
Phase I	54	1.5
<b>Total</b>	<b>3,527</b>	<b>100.0</b>

**Table 5**  
**Clinical trials per year and phase**  
Total clinical trials: 3,527

Year	Phase I		Phase II		Phase III		Phase IV		Bioeq / Bioav		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
2000	5	0.9	154	27.5	345	61.6	44	7.9	12	2.1	560	100.0
2001	5	0.8	203	33.3	328	53.8	55	9.0	19	3.1	610	100.0
2002	11	1.9	207	36.6	294	52.0	41	7.3	12	2.1	565	100.0
2003	11	1.9	198	35.0	304	53.8	45	8.0	7	1.2	565	100.0
2004	8	1.3	213	35.1	321	52.9	53	8.7	12	2.0	607	100.0
2005	14	2.3	223	36.0	307	49.5	68	11.0	8	1.3	620	100.0
<b>Total</b>	<b>54</b>	<b>1.5</b>	<b>1,198</b>	<b>34.0</b>	<b>1,899</b>	<b>53.8</b>	<b>306</b>	<b>8.7</b>	<b>70</b>	<b>2.0</b>	<b>3,527</b>	<b>100.0</b>

**Table 6**  
**Clinical trials per therapeutic classification**  
Total clinical trials: 3,473 (3,463 of which - 99.7% - with specified ATC drug)

ATC (1 <sup>st</sup> level)		CT	%
L	Antineoplastic and immunomodulating agents	1,142	33.0
N	Nervous system	400	11.6
J	General antiinfectives for systemic use	346	10.0
A	Alimentary tract and metabolism	290	8.4
C	Cardiovascular system	274	7.9
B	Blood and blood forming organs	245	7.1
M	Musculo-skeletal system	182	5.3
G	Genito urinary system and sex hormones	139	4.0
V	Various	121	3.5
R	Respiratory system	117	3.4
H	Systemic hormonal preparations, excl. sex hormones	82	2.4
S	Sensory organs	64	1.8
D	Dermatologicals	54	1.6
P	Antiparasitic products, insecticides and repellents	7	0.2
<b>Total</b>		<b>3,463</b>	<b>100.0</b>

**Table 7**

**Clinical trials per therapeutic classification**

Total clinical trials: 3,473 (3,463 of which - 99.7% - with specified ATC drug)

ATC (up to 2 <sup>nd</sup> level)		CT	% on group	% on total
<b>L</b>	<b>Antineoplastic and immunomodulating agents</b>	<b>1,142</b>	<b>100.0</b>	<b>33.0</b>
L01	antineoplastic agents	763	66.8	22.0
L04	immunosuppressive agents	183	16.0	5.3
L03	immunostimulants	151	13.2	4.4
L02	endocrine therapy	39	3.4	1.1
L	Antineoplastic and immunomodulating agents *	6	0.5	0.2
<b>N</b>	<b>Nervous system</b>	<b>400</b>	<b>100.0</b>	<b>11.6</b>
N06	psychoanaleptics	99	24.8	2.9
N05	psycholeptics	65	16.3	1.9
N03	antiepileptics	52	13.0	1.5
N04	anti-parkinson drugs	52	13.0	1.5
N07	other nervous system drugs	51	12.8	1.5
N02	analgesics	43	10.8	1.2
N01	anesthetics	38	9.5	1.1
<b>J</b>	<b>General antiinfectives for systemic use</b>	<b>346</b>	<b>100.0</b>	<b>10.0</b>
J05	antivirals for systemic use	158	45.7	4.6
J01	antibacterial for systemic use	96	27.7	2.8
J07	vaccines	64	18.5	1.8
J02	antimycotics for systemic use	18	5.2	0.5
J06	immune sera and immunoglobulins	10	2.9	0.3
<b>A</b>	<b>Alimentary tract and metabolism</b>	<b>290</b>	<b>100.0</b>	<b>8.4</b>
A10	drugs used in diabetes	116	40.0	3.3
A16	other alimentary tract and metabolism products	39	13.4	1.1
A07	antidiarrheals, intestinal antiinflammatory	34	11.7	1.0
A02	antacids, drugs for treatment of peptic ulcer	32	11.0	0.9
A05	bile and liver therapy	12	4.1	0.3
A04	antiemetics and antinauseants	11	3.8	0.3
A08	antiobesity preparations, excl. diet products	9	3.1	0.3
A11	vitamins	9	3.1	0.3
A03	antispasmodic and anticholinergic agents	8	2.8	0.2
A01	stomatological preparations	6	2.1	0.2
A09	digestives, incl. enzymes	5	1.7	0.1
A06	laxatives	4	1.4	0.1
A13	tonics	3	1.0	0.1
A12	mineral supplements	1	0.3	0.0
A14	anabolic agents for systemic use	1	0.3	0.0
<b>C</b>	<b>Cardiovascular system</b>	<b>274</b>	<b>100.0</b>	<b>7.9</b>
C09	agents acting on the renin-angiotensin system	80	29.2	2.3
C10	serum lipid reducing agents	60	21.9	1.7
C01	cardiac therapy	54	19.7	1.6
C02	antihypertensives	37	13.5	1.1
C08	calcium channel blockers	13	4.7	0.4
C07	beta blocking agents	9	3.3	0.3
C03	diuretics	8	2.9	0.2

ATC (up to 2 <sup>nd</sup> level)		CT	% on group	% on total
C05	vasoprotectives	8	2.9	0.2
C04	peripheral vasodilators	5	1.8	0.1
<b>B</b>	<b>Blood and blood forming organs</b>	<b>245</b>	<b>100.0</b>	<b>7.1</b>
B01	antithrombotic agents	132	53.9	3.8
B03	antianemic preparations	62	25.3	1.8
B02	antihemorrhagics	34	13.9	1.0
B05	blood substitutes and perfusion solutions	9	3.7	0.3
B06	other hematological agents	8	3.3	0.2
<b>M</b>	<b>Musculo-skeletal system</b>	<b>182</b>	<b>100.0</b>	<b>5.3</b>
M01	antiinflammatory and antirheumatic products	95	52.2	2.7
M05	drugs for treatment of bone diseases	50	27.5	1.4
M03	muscle relaxants	21	11.5	0.6
M02	topical products for joint and muscular pain	13	7.1	0.4
M04	antigout preparations	2	1.1	0.1
M09	other drugs for disorders of the musculo-skeletal system	1	0.5	0.0
<b>G</b>	<b>Genito urinary system and sex hormones</b>	<b>139</b>	<b>100.0</b>	<b>4.0</b>
G04	urologicals	80	57.6	2.3
G03	sex hormones	46	33.1	1.3
G01	gynecological antiinfectives and antiseptics	7	5.0	0.2
G	Genito urinary system and sex hormones *	3	2.2	0.1
G02	other gynecologicals	3	2.2	0.1
<b>V</b>	<b>Various</b>	<b>121</b>	<b>100.0</b>	<b>3.5</b>
V08	contrast media	52	43.0	1.5
V03	all other therapeutic products	49	40.5	1.4
V01	allergenics	7	5.8	0.2
V09	diagnostic radiopharmaceuticals	6	5.0	0.2
V04	diagnostics	3	2.5	0.1
V06	general nutrients	3	2.5	0.1
V10	therapeutic radiopharmaceuticals	1	0.8	0.0
<b>R</b>	<b>Respiratory system</b>	<b>117</b>	<b>100.0</b>	<b>3.4</b>
R03	anti-asthmatics	74	63.2	2.1
R06	antihistamines for systemic use	15	12.8	0.4
R05	cough and cold preparations	14	12.0	0.4
R01	nasal preparations	8	6.8	0.2
R07	other respiratory system products	6	5.1	0.2
<b>H</b>	<b>Systemic hormonal preparations, excl. sex hormones</b>	<b>82</b>	<b>100.0</b>	<b>2.4</b>
H01	pituitary and hypothalamic hormones and analogous	57	69.5	1.6
H02	corticosteroids for systemic use	16	19.5	0.5
H05	calcium homeostatis	5	6.1	0.1
H03	thyroid therapy	3	3.7	0.1
H	Systemic hormonal preparations, excl. sex hormones *	1	1.2	0.0
<b>S</b>	<b>Sensory organs</b>	<b>64</b>	<b>100.0</b>	<b>1.8</b>
S01	ophthalmologicals	63	98.4	1.8
S	Sensory organs *	1	1.6	0.0
<b>D</b>	<b>Dermatologicals</b>	<b>54</b>	<b>100.0</b>	<b>1.6</b>
D05	antipsoriasis preparations	11	20.4	0.3
D06	antibiotics and chemotherapeutics for dermat. use	9	16.7	0.3
D07	corticosteroids, dermatological preparations	9	16.7	0.3
D11	other dermatological preparations	9	16.7	0.3

ATC (up to 2 <sup>nd</sup> level)		CT	% on group	% on total
D01	antifungals for dermatological use	6	11.1	0.2
D03	preparations for treatment of wounds and ulc.	5	9.3	0.1
D08	antiseptic and disinfectants	2	3.7	0.1
D02	emollients and protectives	1	1.9	0.0
D04	antipruritics, incl. antihistamines, anesthetics, etc.	1	1.9	0.0
D10	antiacne preparations	1	1.9	0.0
<b>P</b>	<b>Antiparasitic products, insecticides and repellents</b>	<b>7</b>	<b>100.0</b>	<b>0.2</b>
P01	antiprotozoan preparations	4	57.1	0.1
P03	ectoparasiticides, incl. scabicides	2	28.6	0.1
P02	anthelmintics	1	14.3	0.0
	<b>Total</b>	<b>3,463</b>		<b>100.0</b>

\* not further specified

**Table 8**  
**Clinical trials per therapeutic branch**  
Total clinical trials: 3,473

Therapeutic branch	CT	%
Oncology	917	26.4
Cardiology/Vascular diseases	405	11.7
Immunology and infectious diseases	334	9.6
Neurology	282	8.1
Gastroenterology	256	7.4
Endocrinology	203	5.8
Respiratory system diseases	151	4.3
Nephrology/Urology	123	3.5
Hematology	116	3.3
Psychiatry/Psychology	103	3.0
Musculo-skeletal system diseases	99	2.9
Ophthalmology	86	2.5
Dermatology/Plastic surgery	81	2.3
Rheumatology	71	2.0
Gynecology and obstetrics	67	1.9
Genito-urinary system	59	1.7
Anesthesiology	48	1.4
Pharmacology/Toxicology	29	0.8
Pediatrics/Neonatology	17	0.5
Otolaryngology	13	0.4
Traumatology and emergency medicine	7	0.2
Odontology and maxillofacial surgery	6	0.2
<b>Total</b>	<b>3,473</b>	<b>100.0</b>

**Table 9**  
**Regional involvement in clinical trials**  
Total clinical trials: 3,473

Region	2000 – 2005					
	CT	% on total CT (3,473)	Health structures	Average CT per health structure	Coord. CT	% coord. CT/ total
Lombardia	2,032	58.5	143	34	1,098	54.0
Emilia-Romagna	1,396	40.2	76	35	454	32.5
Lazio	1,190	34.3	84	25	373	31.3
Toscana	1,133	32.6	74	25	334	29.5
Veneto	995	28.6	83	20	183	18.4
Piemonte	835	24.0	78	18	171	20.5
Liguria	798	23.0	30	34	229	28.7
Campania	690	19.9	77	16	116	16.8
Friuli-Venezia Giulia	641	18.5	30	28	103	16.1
Sicilia	602	17.3	83	12	56	9.3
Puglia	578	16.6	68	13	75	13.0
Umbria	465	13.4	29	21	118	25.4
Sardegna	425	12.2	34	18	28	6.6
Marche	371	10.7	29	17	48	12.9
Abruzzo	235	6.8	23	13	46	19.6
Calabria	181	5.2	35	7	3	1.7
Trentino-Alto Adige	140	4.0	12	14	14	10.0
Basilicata	110	3.2	7	18	2	1.8
Molise	83	2.4	11	8	20	24.1
Valle d'Aosta	9	0.3	2	5	0	0.0

The “CT” column total exceeds sample (3,473) as multicentre clinical trials are conducted in more than one health structure and therefore the same study can be counted in several Regions.

The “Health structures” column shows, for each Region, how many health structures participate in clinical trials – considered only once, even if involved in many different studies.

Figures in column “Average CT per health structure” represent, for each Region, the average number of trials conducted in every structure, obtained by adding up all studies carried out in that structure and then dividing by the number of involved structures of the Region itself.

The column “Coord. CT” indicates the number of trials for which the coordinating site is located in that Region (the total equals the sample size because there is always only one coordinating centre per trial).

**Table 10**  
**Clinical trials per involved structure**  
Total clinical trials: 3,473  
(Structures considered are those for which the competent EC approved the trial)  
First 30 structures out of 1,006

	Structure	CT	% on tot. CT (3,473)	Coord. CT	% coord. CT/ total
1	Ospedale Policlinico S. Orsola Malpighi (Bologna)	546	15.7	202	37.0
2	Istituto S. Raffaele (Milano)	498	14.3	237	47.6
3	Ospedale Policlinico S. Matteo (Pavia)	466	13.4	170	36.5
4	A.O. (Padova)	412	11.9	100	24.3
5	A.O. Universitaria Careggi (Firenze)	384	11.1	49	12.8
6	Policlinico Universitario Gemelli (Roma)	354	10.2	126	35.6
7	A.O. Universitaria Pisana (Pisa)	329	9.5	101	30.7
8	A.O. Ospedale Policlinico (Bari)	294	8.5	43	14.6
9	P.O. Spedali Civili (Brescia)	276	7.9	27	9.8
10	A.O. Policlinico (Modena)	265	7.6	40	15.1
11	Ospedali Riuniti (Bergamo)	265	7.6	46	17.4
12	Policlinico Universitario Umberto I (Roma)	255	7.3	56	22.0
13	A.O. Universitaria S. Martino (Genova)	251	7.2	53	21.1
14	Ospedale Niguarda Ca' Granda (Milano)	251	7.2	38	15.1
15	Arcispedale S. Maria Nuova (Reggio Emilia)	238	6.9	24	10.1
16	Policlinico Universitario (Udine)	219	6.3	45	20.5
17	P.O. Umberto I (Ancona)	216	6.2	30	13.9
18	Ospedale S. Giovanni Battista Molinette (Torino)	213	6.1	58	27.2
19	Ospedale Sacco (Milano)	207	6.0	48	23.2
20	P.O. Maggiore Policlinico (Milano)	200	5.8	79	39.5
21	DIMI dell'Università (Genova)	192	5.5	53	27.6
22	A.O. Arcispedale S. Anna (Ferrara)	178	5.1	7	3.9
23	A.O. (Perugia)	175	5.0	38	21.7
24	Ospedale S. Paolo (Milano)	172	5.0	20	11.6
25	Università (Perugia)	170	4.9	52	30.6
26	Ospedale S. Gerardo dei Tintori (Monza)	160	4.6	32	20.0
27	A.O. (Parma)	159	4.6	30	18.9
28	Ospedale Civile Maggiore (Verona)	151	4.3	30	19.9
29	Ospedale di Circolo e Fondazione Macchi (Varese)	151	4.3	5	3.3
30	A.O. Cardarelli (Napoli)	149	4.3	4	2.7

The "CT" column total exceeds sample (3,473) as multicentre clinical trials are conducted in more than one health structure and therefore the same study can be counted several times.  
The column "Coord. CT" indicates the number of trials for which the structure itself acts as coordinating site (the total equals the sample size because there is always only one coordinating centre per trial).

**Table 11**  
**Clinical trials per Sponsor type: profit / no profit**  
Total clinical trials: 3,473

Sponsor type	CT	%	Sponsors
Profit	2,559	73.7	285
No profit	914	26.3	172
<b>Total</b>	<b>3,473</b>	<b>100.0</b>	<b>457</b>

**Table 12**  
**Clinical trials per no profit Sponsor**  
Total clinical trials: 914

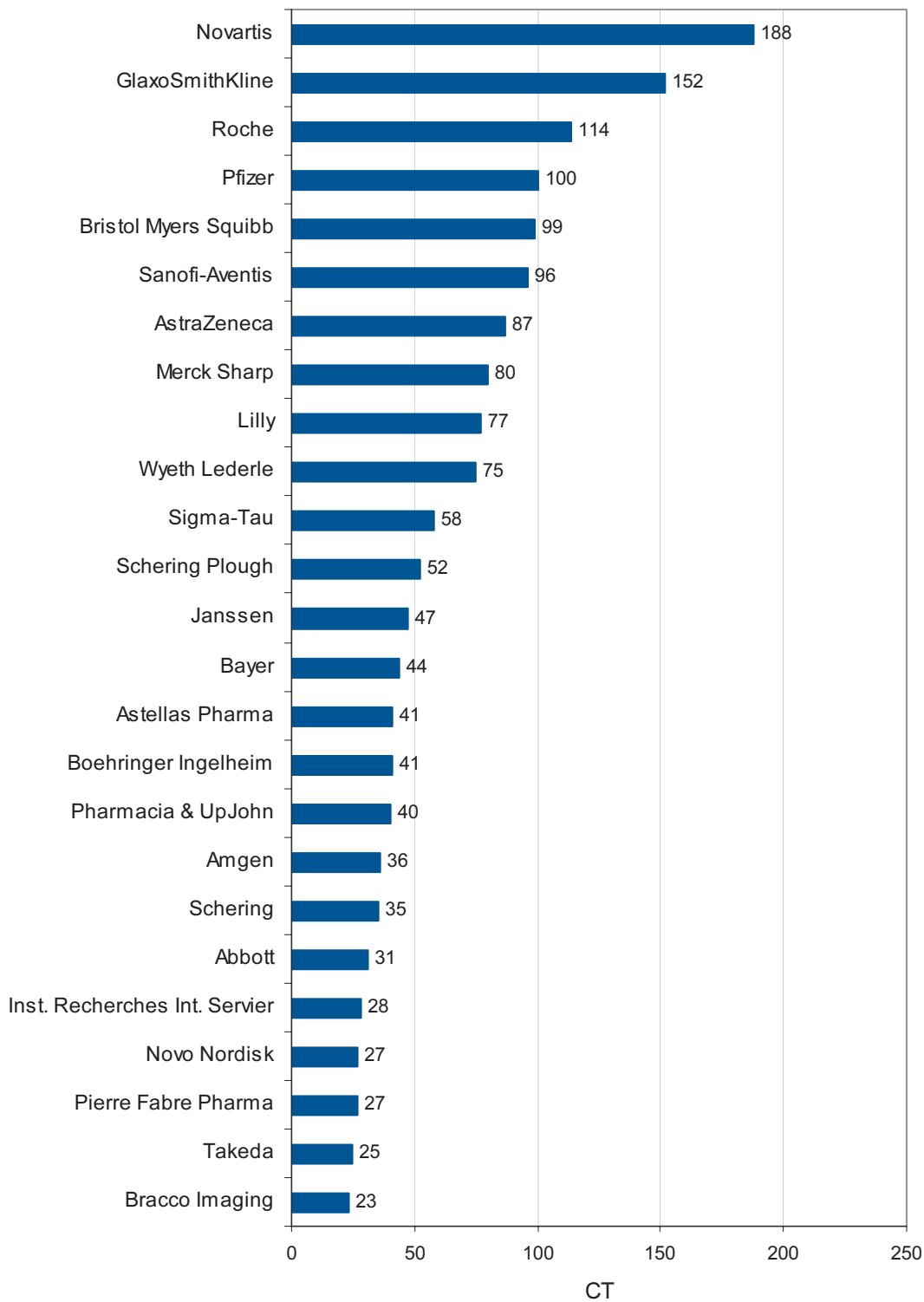
Sponsor type	CT	%	Sponsors
Local health unit or Hospital	344	37.6	70
Public/Private Institute of Research and Care	266	29.1	21
Scientific association	137	15.0	42
University	101	11.1	17
Other *	66	7.2	22
<b>Total</b>	<b>914</b>	<b>100.0</b>	<b>172</b>

\* Research organizations, Foundations, Governmental bodies

**Table 13**  
**Clinical trials per therapeutic classification and profit / no profit Sponsor**  
Total clinical trials: 3,473 (3,463 of which - 99.7% - with specified ATC drug)

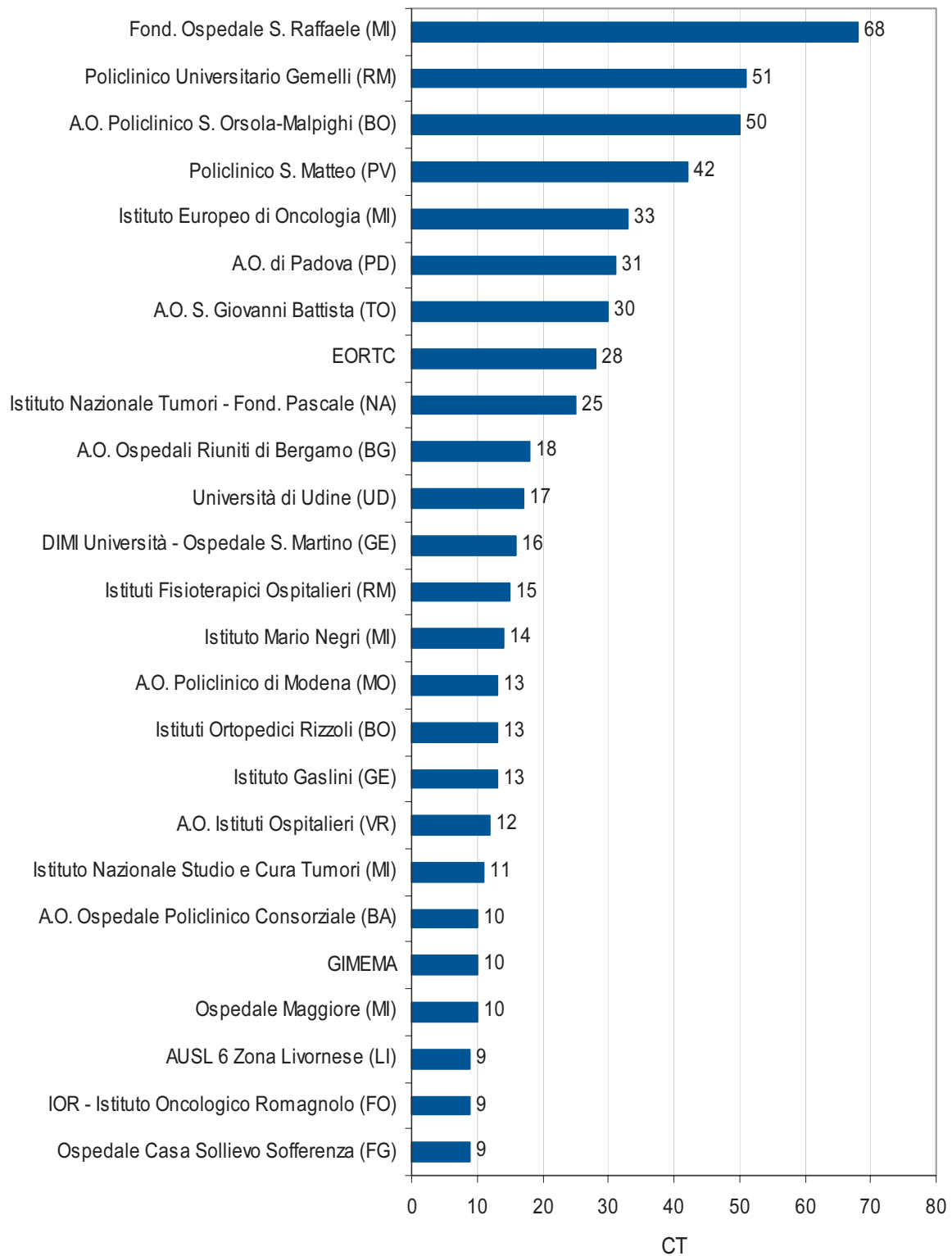
ATC (1 <sup>st</sup> level)		Profit		No profit	
		CT	%	CT	%
L	Antineoplastic and immunomodulating agents	619	24.2	523	57.7
N	Nervous system	325	12.7	75	8.3
J	General antiinfectives for systemic use	290	11.3	56	6.2
A	Alimentary tract and metabolism	261	10.2	29	3.2
C	Cardiovascular system	221	8.6	53	5.8
B	Blood and blood forming organs	195	7.6	50	5.5
M	Musculo-skeletal system	138	5.4	44	4.9
G	Genito urinary system and sex hormones	130	5.1	9	1.0
V	Various	101	3.9	20	2.2
R	Respiratory system	106	4.1	11	1.2
H	Systemic hormonal preparations, excl. sex hormones	55	2.2	27	3.0
S	Sensory organs	61	2.4	3	0.3
D	Dermatologicals	51	2.0	3	0.3
P	Antiparasitic products, insecticides and repellents	4	0.2	3	0.3
	<b>Total</b>	<b>2,557</b>	<b>100.0</b>	<b>906</b>	<b>100.0</b>

**Chart 3**  
**Distribution of clinical trials per profit Sponsors**  
The first 25 out of 285 sponsor 63.4% of clinical trials



**Chart 4**

**Distribution of clinical trials per no profit Sponsors**  
The first 25 out of 172 sponsor 60.9% of clinical trials



### Ethics Committees (EC)

All the recent legislation on clinical trials and mostly the legislative decree no. 211 dated June 24<sup>th</sup>, 2003 (implementation of Directive 2001/20/EC in Italy) enforces the Ethics Committee central role and responsibility in the clinical trials evaluation process.

A trial can start only after the EC motivated opinion has been released. The EC has to take into account, while evaluating the study, the importance of the trial and its design, the protocol, the investigator's and his team curricula, the procedure to obtain the informed consent from the subjects to be enrolled and the written information to be communicated to them.

Waiting for a specific decree on ECs (foreseen by the legislative decree no. 211/2003), it is important to point out the high number of ECs operating in Italy: 309. This number is a warranty for the citizens involved in clinical trials, but it also highlights the need of a procedures' and methods' harmonization.

Local ECs work mainly for Local health units (49.2%) and Hospitals (32.4%) and have been instituted mostly by the Director General of the health structure (78.3%).

On average, each EC is made of 14 members and, even if some differences exist from one Region to another, the 53.9% of them are employed by the structure in which the Committee works.

The Clinicians are still the more represented category (25.8%).

In Italy there is an EC every 185,000 inhabitants. In Valle d'Aosta, Piemonte and Lombardia a regional EC sides the local ones in evaluating the trials, while in Umbria there is only a regional EC acting as a central authority.

**Table 14**  
**Ethics Committees per Region**  
Ethics Committees: 309

Region	EC	%	<i>cumulative</i> %	No. inhabitants *	No. inhab. / EC
Lombardia **	61	19.7	19.7	9,032,554	148,075
Lazio	35	11.3	31.1	5,112,413	146,069
Sicilia	30	9.7	40.8	4,968,991	165,633
Veneto	24	7.8	48.5	4,527,694	188,654
Campania	23	7.4	56.0	5,701,931	247,910
Emilia-Romagna	18	5.8	61.8	3,983,346	221,297
Puglia	18	5.8	67.6	4,020,707	223,373
Calabria	15	4.9	72.5	2,011,466	134,098
Toscana	14	4.5	77.0	3,497,806	249,843
Marche	13	4.2	81.2	1,470,581	113,122
Friuli-Venezia Giulia	10	3.2	84.5	1,183,764	118,376
Liguria	10	3.2	87.7	1,571,783	157,178
Sardegna	10	3.2	90.9	1,631,880	163,188
Piemonte **	8	2.6	93.5	4,214,677	526,835
Abruzzo	5	1.6	95.1	1,262,392	252,478
Basilicata	4	1.3	96.4	597,768	149,442
Trentino-Alto Adige	4	1.3	97.7	940,016	235,004
Molise	4	1.3	99.0	320,601	80,150
Valle d'Aosta **	2	0.6	99.7	119,548	59,774
Umbria **	1	0.3	100.0	825,826	825,826
<b>Total</b>	<b>309</b>	<b>100.0</b>		<b>56,995,744</b>	<b>184,452</b>

\* data provided by Istat, Italy's National Statistical Institute (resident population according to the October 21<sup>st</sup>, 2001 census - table published in the Official Journal of the Italian Republic no. 81 dated April 7<sup>th</sup>, 2003)

\*\* active regional EC

### Private Sites (PS)

Private sites recognised eligible to conduct clinical trials, by the Ministry of Health from 1998 to 2003 and then by the Italian Medicines Agency, are 36. Most of them are located in central and northern Italy.

Examining data in details, we find out that clinical trials in PS can be conducted in many branches, especially in Cardiology (36.1%), General Medicine, Oncology and Orthopaedy and Traumatology (30.6%), Neurology and Urology (27.8% both).

Bronchopneumology, Dermatology, Pediatrics and Psychiatry are among the less representative branches (2.8%).

**Chart 5**  
**Private Sites per Region**



