Ricerca, innovazione e Competitività

Roma 15 novembre 2012

dott.ssa Nadia Storti

Azienda Ospedaliero Universitaria
OSPEDALI RIUNITI
Umberto I-G.M.Lancisi-G.Salesi
Ancona

Farmaci innovativi ed innovazioni terapeutiche: quali vantaggi per il paziente

- Possibili vantaggi terapeutici
- Controllo patologie orfane /non responders
- Studi clinici per la valutazione del ruolo del farmaco
- Valutazione dell'ammissione alla rimborsabilità
- Terapia e piano assistenziale personalizzata

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Farmaci innovativi ed innovazioni terapeutiche: vantaggi/svantaggi per l'Azienda

- Risposta terapeutica per i pazienti
- Aspetto economico
- Asincronia dei follow up/monitoraggi
- Complessità nella gestione delle schede di dati

Registri di monitoraggio AIFA

- Valutazione dell'appropriatezza prescrittiva farmaci innovativi
- Valutazione esiti post-marketing
- Schede di registrazione /dati epidemiologici
- Attuazione meccanismi di rimborso
  - ✓ Payment by results
  - ✓ Cost sharing
  - ✓ Risk sharing

Es. erlotinib, sorafenib, cetuximab, lenalidomide, ecc.

Competitività economica

- Riduzione finanziamento SSN
  - ~ 900 mil. 2012
  - ~ 1.800 mil. 2013
  - ~ 2.000 mil. 2014
- Riduzione FSR 2013 (177 mil.)

  farmaceutica ~ 47 mil. di cui ~ 5 mil. ospedaliera

AOU “Ospedali Riuniti” Ancona

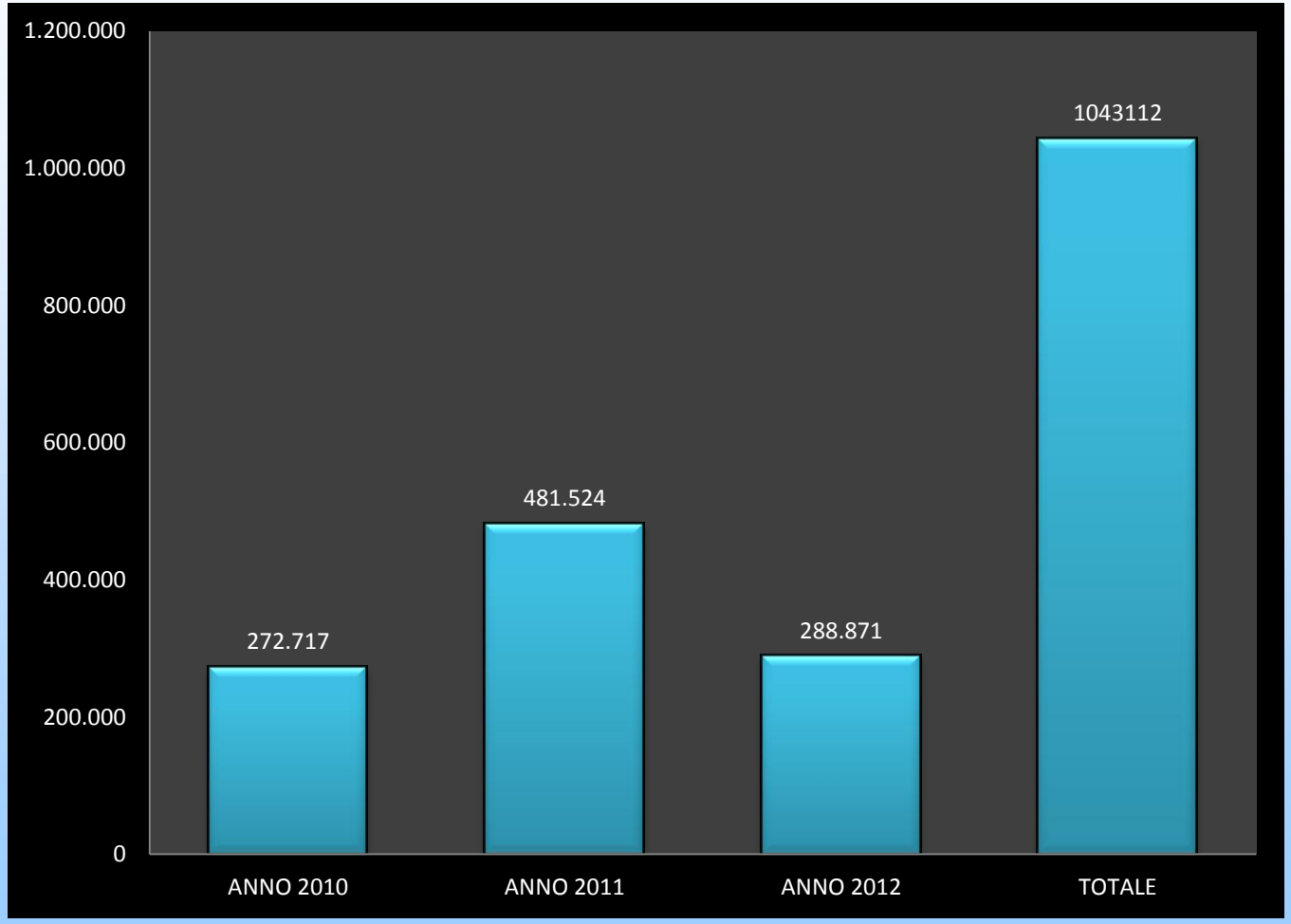
- 990 posti letto
- Bilancio 360 mil.
- 3.500 dipendenti
- 84 UOC
- Dipartimento oncoematologico (54 PL)
- 52.000 ricoveri totali azienda
- 2.250 ricoveri x tumori
- 180 ricoveri malattie rare pediatriche

Rimborsi

Totale 1/02/ 2010 - 9/11/2012

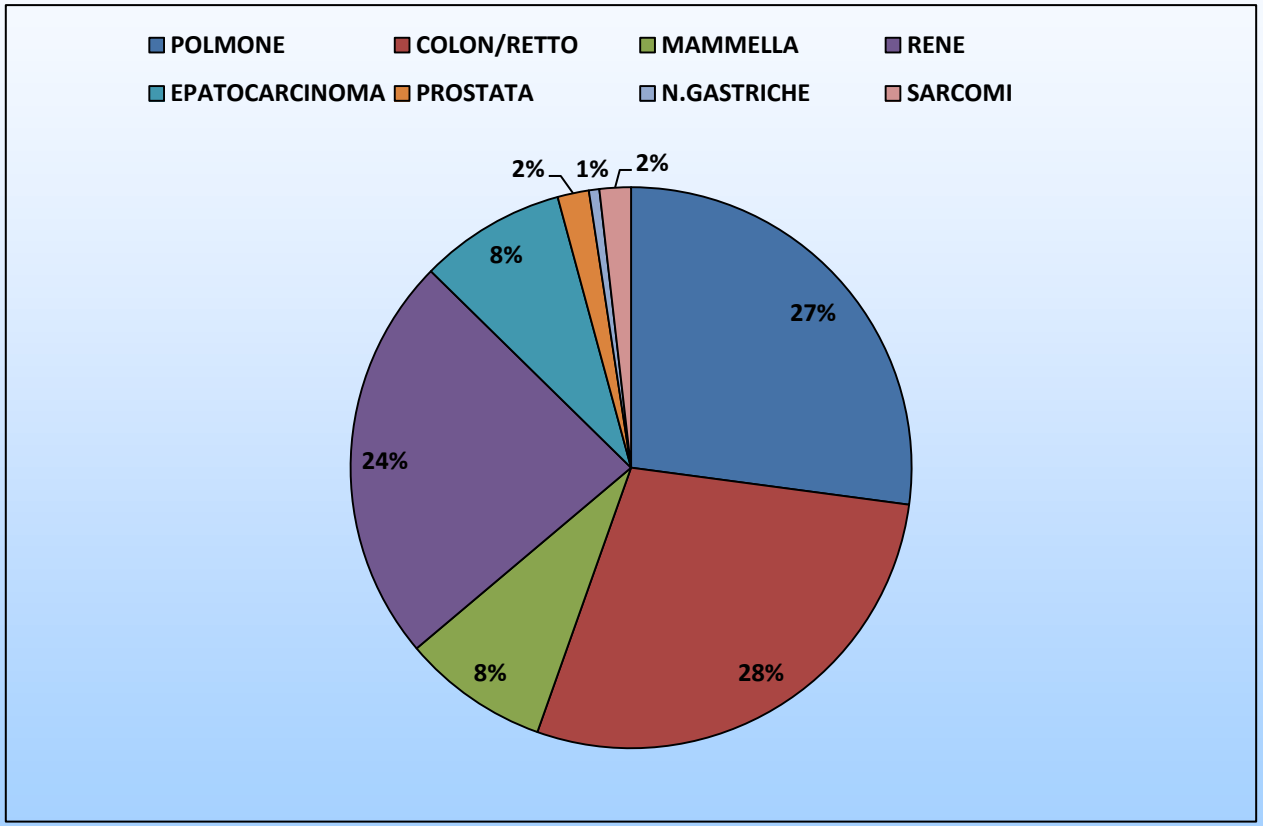
FARMACO	RIMBORSO	2012
AFINITOR	8.040	8.040
ERBITUX	6.712	6.712
YONDELIS	41.200	20.200
VELCADE	4.428	2.214
JAVLOR	10.950	8.518
TARCEVA	161.408	30.437
VECTIBIX	23.205	0
AVASTIN	277.562	108.739
NEXAVAR	129.421	67.825
TORISEL	7.830	7.830
HALAVEN	28.356	28.356
SUTENT	344.000	0
TOTALE	1.043.112	288.871

ANNO 2010	272.717
ANNO 2011	481.524
ANNO 2012	288.871
TOTALE	1.043.112


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1.000.000
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ANNO 2011
ANNO 2012
TOTALE

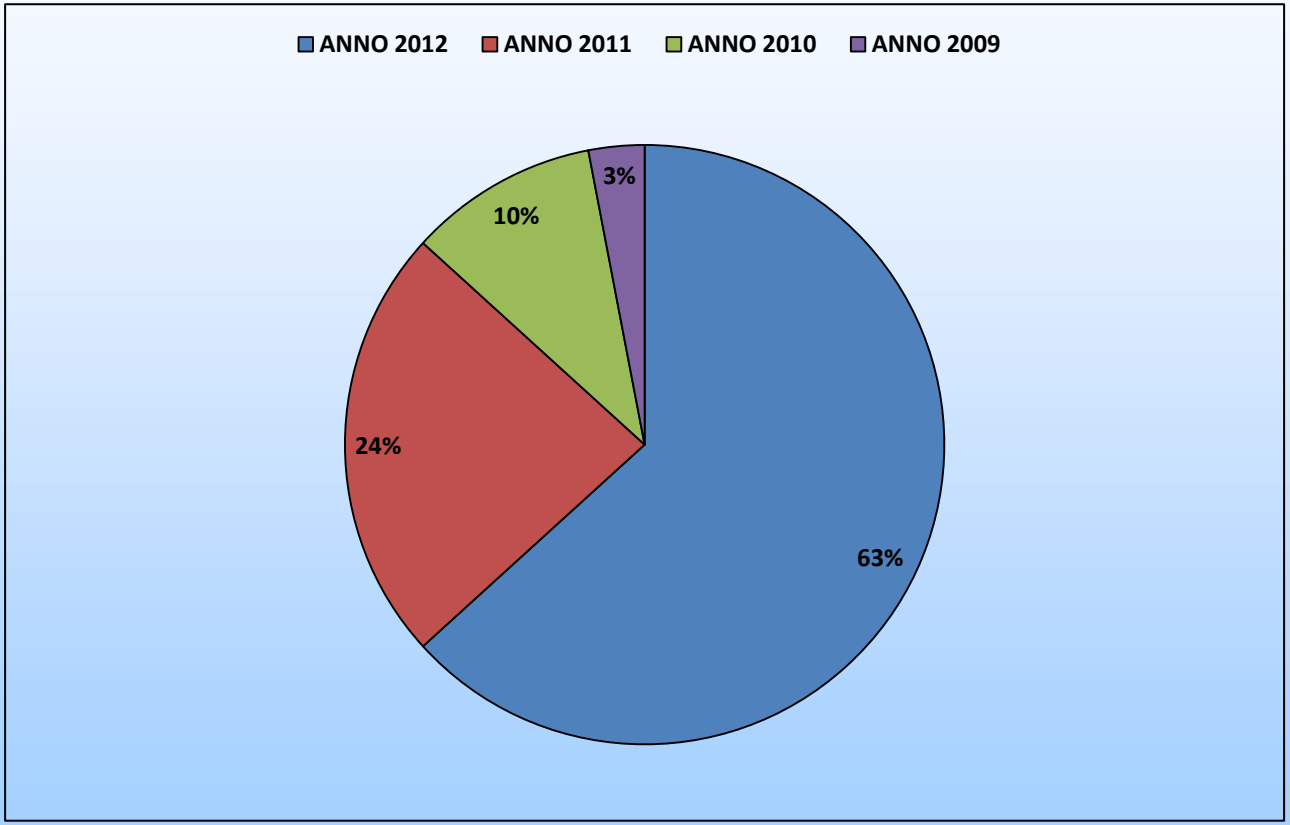
Pazienti tumori solidi attivi (1)

POLMONE	45
COLON/RETTO	47
MAMMELLA	14
RENE	39
EPATOCARCINOMA	14
PROSTATA	3
N.GASTRICHE	1
SARCOMI	3
TOT	166



Pazienti tumori solidi attivi (2)

ANNO 2012	105
ANNO 2011	39
ANNO 2010	17
ANNO 2009	5
TOT	166



Pazienti attivi 2011

Farmaco	N. Pazienti Eleggibili	N. Pazienti trattati o in trattamento	% Pazienti in trattamento / eleggibili	N. Pazienti con Fine trattamento	N. Pazienti con Fine trattamento per progressione o morte	% Pazienti con Fine trattamento per progressione o morte / eleggibili
AFINITOR	11	11	100.0	9	9	81.8
ALIMTA	16	16	100.0	14	13	81.3
AVASTIN	28	28	100.0	21	14	50.0
ERBITUX	12	12	100.0	5	4	33.3
IRESSA	10	10	100.0	4	4	40.0
JAVLOR	4	4	100.0	4	4	100.0
MABTHERA	187	187	100.0	173	19	10.2
MOZOBIL	1	1	100.0	1	0	0.0
NEXAVAR	36	36	100.0	19	17	47.2
REVLIMID	14	14	100.0	2	0	0.0
REVLIMID 648	8	8	100.0	3	1	12.5
SPRYCEL	8	8	100.0	3	3	37.5
SUTENT	20	20	100.0	17	15	75.0
TARCEVA	6	6	100.0	6	6	100.0
TASIGNA	6	6	100.0	1	0	0.0
THALIDOMIDE	1	1	100.0	0	0	0.0
THALIDOMIDE 648	12	12	100.0	6	1	8.3
TYVERB	10	10	100.0	7	7	70.0
VECTIBIX	5	5	100.0	1	1	20.0
VELCADE 648	1	1	100.0	0	0	0.0
VIDAZA	11	11	100.0	8	6	54.5
VOTRIENT	3	3	100.0	1	1	33.3
YONDELIS	3	3	100.0	3	2	66.7
	413	413	100.0	308	127	30.8

Pazienti attivi 2012

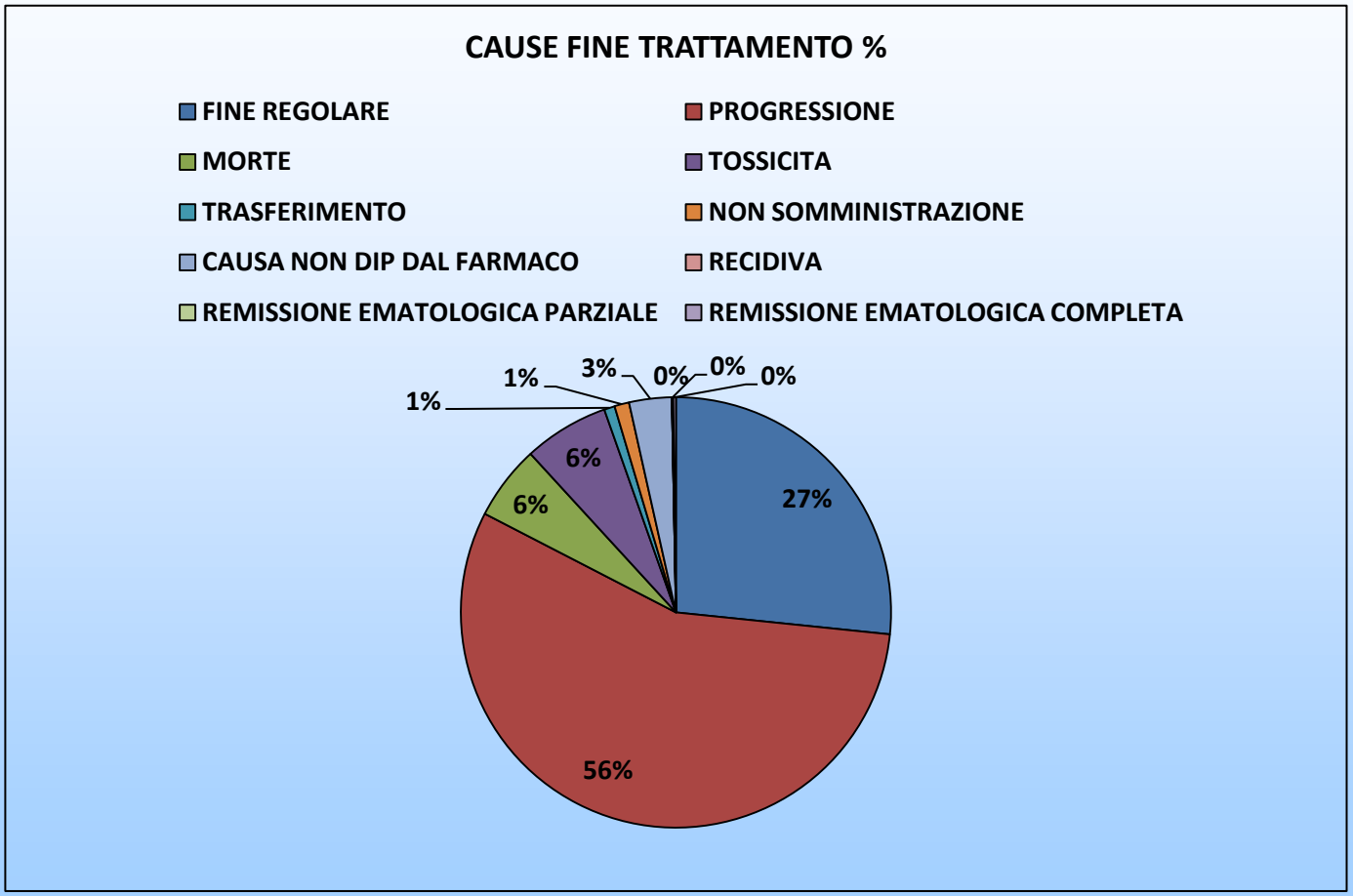
Farmaco	N. Pazienti Eleggibili	N. Pazienti trattati o in trattamento	% Pazienti in trattamento / eleggibili	N. Pazienti con Fine trattamento	N. Pazienti con Fine trattamento per progressione o morte	% Pazienti con Fine trattamento per progressione o morte / eleggibili
AFINITOR	12	12	100.0	7	7	58.3
ALIMTA	59	58	98.3	35	19	32.2
ARZERRA	1	1	100.0	1	1	100.0
AVASTIN	32	32	100.0	10	5	15.6
ERBITUX	11	11	100.0	1	0	0.0
HALAVEN	9	9	100.0	7	7	77.8
HERCEPTIN NEOPLASIE GASTRICHE	1	1	100.0	0	0	0.0
IRESSA	9	9	100.0	2	2	22.2
JAVLOR	3	3	100.0	2	1	33.3
JEVTANA	5	5	100.0	2	2	40.0
MABTHERA	71	68	95.8	25	3	4.2
MOZOBIL	4	4	100.0	3	0	0.0
NEXAVAR	35	35	100.0	12	11	31.4
REVLIMID	10	10	100.0	0	0	0.0
REVLIMID 648	9	9	100.0	2	1	11.1
SPRYCEL	4	4	100.0	2	1	25.0
SUTENT	10	10	100.0	1	1	10.0
TARCEVA	6	6	100.0	5	5	83.3
TASIGNA	4	4	100.0	0	0	0.0
THALIDOMIDE	3	3	100.0	0	0	0.0
THALIDOMIDE 648	2	2	100.0	0	0	0.0
TYVERB	7	7	100.0	2	2	28.6
VECTIBIX	8	8	100.0	3	2	25.0
VELCADE	4	4	100.0	0	0	0.0
VELCADE 648	9	9	100.0	2	1	11.1
VIDAZA	7	7	100.0	1	1	14.3
VOTRIENT	10	10	100.0	3	3	30.0
YONDELIS	5	5	100.0	2	1	20.0
	350	346	98.9	130	76	21.7

Cause fine trattamento

Farmaco	Pazienti Eleggibili	Pazienti in trattamento (almeno una richiesta farmaco effettuata)	Pazienti con fine trattamento (% su eleggibili)	Cause di fine trattamento Numero pazienti e Percentuale sul totale									
				Fine regolare del trattamento (%)	Progressione (%)	Morte (%)	Tossicità (%)	Trasferimento (%)	Non somministrazione (%)	Causa non dipendente dal farmaco(%)	Recidiva (%)	Remissione ematologica completa(%)	Remissione ematologica parziale(%)
AFINITOR	34	34	26 (76.5)	0 (0.0)	25 (96.2)	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
ALIMTA	94	93	68 (72.3)	12 (17.6)	46 (67.6)	1 (1.5)	2 (2.9)	0 (0.0)	0 (0.0)	7 (10.3)	0 (0.0)	0 (0.0)	0 (0.0)
ARZERRA	1	1	1 (100.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AVASTIN	148	148	118 (79.7)	12 (10.2)	92 (78.0)	0 (0.0)	7 (5.9)	2 (1.7)	1 (0.8)	4 (3.4)	0 (0.0)	0 (0.0)	0 (0.0)
ERBITUX	67	67	46 (68.7)	1 (2.2)	39 (84.8)	1 (2.2)	5 (10.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HALAVEN	9	9	7 (77.8)	0 (0.0)	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HERCEPTIN	65	65	65 (100.0)	59 (90.8)	1 (1.5)	0 (0.0)	4 (6.2)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
HERCEPTIN NEOPLASIE GASTRICHE	1	1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
IRESSA	19	19	6 (31.6)	0 (0.0)	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
JAVLOR	7	7	6 (85.7)	1 (16.7)	4 (66.7)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
JEVTANA	5	5	2 (40.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MABTHERA	279	276	217 (77.8)	180 (82.9)	19 (8.8)	7 (3.2)	9 (4.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.5)	0 (0.0)
MOZOBIL	5	5	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NEXAVAR	148	145	84 (56.8)	0 (0.0)	57 (67.9)	10 (11.9)	10 (11.9)	2 (2.4)	1 (1.2)	4 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)
REVLIMID	69	69	35 (50.7)	0 (0.0)	17 (48.6)	5 (14.3)	8 (22.9)	1 (2.9)	3 (8.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
REVLIMID 648	21	21	8 (38.1)	0 (0.0)	3 (37.5)	0 (0.0)	3 (37.5)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)
SPRYCEL	33	32	20 (60.6)	0 (0.0)	3 (15.0)	9 (45.0)	5 (25.0)	0 (0.0)	1 (5.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (5.0)
SUTENT	107	107	91 (85.0)	2 (2.2)	64 (70.3)	11 (12.1)	6 (6.6)	1 (1.1)	3 (3.3)	4 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)
TARCEVA	163	162	158 (96.9)	0 (0.0)	139 (88.0)	5 (3.2)	5 (3.2)	0 (0.0)	3 (1.9)	6 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
TASIGNA	17	17	4 (23.5)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	1 (25.0)
THALIDOMIDE	15	14	1 (6.7)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
THALIDOMIDE 648	14	14	6 (42.9)	4 (66.7)	1 (16.7)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TORISEL	1	1	1 (100.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TYVERB	32	32	24 (75.0)	0 (0.0)	24 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VECTIBIX	28	28	14 (50.0)	0 (0.0)	13 (92.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	0 (0.0)	0 (0.0)
VELCADE	13	13	4 (30.8)	3 (75.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VELCADE 648	21	21	6 (28.6)	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VIDAZA	24	24	11 (45.8)	0 (0.0)	4 (36.4)	5 (45.5)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VOTRIENT	13	13	4 (30.8)	0 (0.0)	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
YONDELIS	17	17	14 (82.4)	0 (0.0)	11 (78.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (21.4)	0 (0.0)	0 (0.0)	0 (0.0)
Totale %	1470	1460	71.2	26.6	55.9	5.6	6.4	0.8	1.1	3.2	0.0	0.1	0.2

Cause fine trattamento

FINE REGOLARE	26,6
PROGRESSIONE	55,9
MORTE	5,6
TOSSICITA	6,4
TRASFERIMENTO	0,8
NON SOMMINISTRAZIONE	1,1
CAUSA NON DIP DAL FARMACO	3,2
RECIDIVA	0
REMISSIONE EMATOLOGICA PARZIALE	0,1
REMISSIONE EMATOLOGICA COMPLETA	0,2



Durata media trattamento

N. pazienti eleggibili: 1470

N. Pazienti con inizio e fine trattamento: 1025

Farmaco	N. Pazienti	N. medio di somministrazioni ricevute	Media (gg)	Minimo (gg)	Massimo (gg)
AFINITOR	26	5	193.69	6	580
ALIMTA	68	5	120.97	4	459
ARZERRA	1	8	58	58	58
AVASTIN	116	8	176.34	0	775
ERBITUX	46	12	187.89	0	1355
HALAVEN	14	8	89.86	56	183
HERCEPTIN	65	16	352.02	0	483
IRESSA	6	8	263.33	77	341
JAVLOR	6	4	70.5	0	183
JEVTANA	2	3	66	55	77
MABTHERA	214	6	124.71	0	868
NEXAVAR	82	9	125.2	5	597
REVLIMID	31	7	245.55	8	657
REVLIMID 648	7	3	90	21	267
SPRYCEL	19	5	305.11	14	1244
SUTENT	88	6	265.82	6	1331
TARCEVA	152	7	150.26	0	1308
TASIGNA	4	6	198.5	131	250
THALIDOMIDE	1	7	317	317	317
THALIDOMIDE 648	6	6	85	18	145
TORISEL	1	8	63	63	63
TYVERB	24	7	195.88	78	330
VECTIBIX	14	6	111.5	14	328
VELCADE	4	20	128.75	88	178
VELCADE 648	6	16	143.5	17	343
VIDAZA	11	7	209.18	2	466
VOTRIENT	4	6	164	25	311
YONDELIS	14	6	197.21	37	770
Totale	1025	7	175.34	0	1355

Dosaggi medi

Farmaco	Uomini			Donne			Totale		
	N. trattati (*)	N. Richieste farmaco	Dosaggio Medio (mg)	N. trattate (*)	N. Richieste farmaco	Dosaggio Medio (mg)	N. trattati (*)	N. Richieste farmaco	M+F Dosaggio Medio (mg)
AFINITOR	25	128	201.64	9	34	225	34	162	206.54
ALIMTA	53	259	842.72	40	191	693.33	93	450	779.31
ARZERRA	0	0	0	1	8	1787.5	1	8	1787.5
AVASTIN	67	562	437.65	81	561	548.57	148	1123	493.07
ERBITUX	42	509	453.97	25	254	415.77	67	763	441.25
HALAVEN	0	0	0	9	108	1.54	9	108	1.54
HERCEPTIN	0	0	0	65	1023	404.55	65	1023	404.55
HERCEPTIN NEOPLASIE GASTRICHE	0	0	0	1	1	408	1	1	408
IRESSA	3	29	7250	16	102	7428.92	19	131	7389.31
JAVLOR	7	20	479.25	0	0	0	7	20	479.25
JEVTANA	4	9	46.11	1	1	40	5	10	45.5
MABTHERA	155	933	694.95	121	689	610.4	276	1622	659.04
MOZOBIL	1	1	60	4	16	23.61	5	17	25.75
NEXAVAR	118	484	18643.73	27	90	18018.21	145	574	18545.65
REVLIMID	37	369	418.56	32	244	426.27	69	613	421.63
REVLIMID 648	12	55	181.36	9	68	168.31	21	123	174.15
SPRYCEL	16	144	3141.53	16	172	3782.44	32	316	3490.38
SUTENT	79	451	1149.55	28	153	896.1	107	604	1085.35
TARCEVA	119	566	4066.7	43	249	4226.31	162	815	4115.46
TASIGNA	10	115	19464.35	7	124	20106.45	17	239	19797.49
THALIDOMIDE	5	24	2712.5	9	12	2975	14	36	2800
THALIDOMIDE 648	8	16	2581.25	6	10	2240	14	26	2450
TORISEL	1	8	25	0	0	0	1	8	25
TYVERB	0	0	0	32	244	28857.87	32	244	28857.87
VECTIBIX	18	131	439.31	10	63	313.41	28	194	398.43
VELCADE	5	18	8.97	8	20	7.73	13	38	8.32
VELCADE 648	12	47	8.76	9	42	7.94	21	89	8.38
VIDAZA	19	195	832.84	5	61	847.46	24	256	836.33
VOTRIENT	6	32	9794.47	7	30	12004.6	13	62	10863.89
YONDELIS	11	75	2.05	6	26	1.71	17	101	1.96
Totale	833	5180	3268.24	627	4596	3429.67	1460	9776	3344.13

Stima spesa anno 2010

Farmaco	N. confezioni	Spesa ex factory stimata
AFINITOR	32	100.080
ALIMTA	162	231.778
AVASTIN	560	656.073,8
ERBITUX	881	175.319
HERCEPTIN	75	50.305,5
IRESSA	2	4.854
MABTHERA	808	1.120.445,23
NEXAVAR	82	292.084
REVLIMID	639	4.092.522
REVLIMID 648	10	52.920
SPRYCEL	58	244.009,12
SUTENT	193	511.916,1
TARCEVA	196	412.096,44
TASIGNA	23	95.312
THALIDOMIDE	26	9.973,6
TYVERB	28	34.300
VECTIBIX	173	294.100
VELCADE	108	140.400
VELCADE 648	143	185.900
VIDAZA	11	3.894
YONDELIS	108	158.256
Totale	4318	8.866.538,79

Stima spesa anno 2011

Farmaco	N. confezioni	Spesa ex factory stimata
AFINITOR	64	183.060
ALIMTA	265	382.925
AVASTIN	586	459.406,1
ERBITUX	498	99.102
IRESSA	75	182.025
JAVLOR	34	41.650
MABTHERA	931	1.291.967,32
MOZOBIL	3	18.645
NEXAVAR	161	573.482
REVLIMID	1696	10.883.418
REVLIMID 648	68	365.946
SPRYCEL	80	338.039,44
SUTENT	147	451.950
TARCEVA	118	229.142,61
TASIGNA	52	212.380
THALIDOMIDE	10	3.836
THALIDOMIDE 648	38	14.576,8
TYVERB	132	161.700
VECTIBIX	46	78.200
VELCADE 648	46	59.800
VIDAZA	1187	420.198
VOTRIENT	9	11.218,35
YONDELIS	66	92.076
Totale	6312	16.554.743,62

Stima spesa anno 2012

Farmaco	N. confezioni	Spesa ex factory stimata
AFINITOR	59	201.480
ALIMTA	299	432.055
ARZERRA	15	36.165
AVASTIN	548	370.770,95
ERBITUX	447	88.953
HALAVEN	204	81.600
HERCEPTIN NEOPLASIE GASTRICHE	3	2.012,22
IRESSA	49	118.923
JAVLOR	13	7.105
JEVTANA	9	39.600
MABTHERA	613	849.839,83
MOZOBIL	11	68.365
NEXAVAR	149	530.738
REVLIMID	136	817.803
REVLIMID 648	48	263.340
SPRYCEL	83	350.814,44
SUTENT	78	232.557
TARCEVA	54	107.831,49
TASIGNA	66	248.640
THALIDOMIDE	15	5.754
THALIDOMIDE 648	6	2.301,6
TYVERB	110	135.693,95
VECTIBIX	70	119.000
VELCADE	4	5.200
VELCADE 648	84	109.200
VIDAZA	945	334.530
VOTRIENT	88	121.675,95
YONDELIS	30	42.252
Totale	4236	5.724.200,43

GRAZIE PER L'ATTENZIONE

