



Drug Portfolio Analysis

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June 18, 2008



Agenda

- Drug Development Industry Issues & Concerns in 2008
 - Fewer FDA Approvals
 - Blockbusters vs. Targeted Therapeutics
 - Drug Safety
 - Drug Development Costs
 - Political Landscape 2008
- Drug Development Approval Process Overview
 - Drug / Diagnostic: milestones & differences
 - FDA & EMEA
 - Companion Diagnostics & Targeted Therapeutics
 - Challenges (Regulatory / Reimbursement)
- Clinical Trials
- Deals & Alliances
- Portfolio Analysis – Resources by phase of development
- Drug Pipeline Databases
- Conclusion – Implications & Considerations



Drug Development Industry Issues & Concerns in 2008:

- Fewer FDA Approvals
- Blockbusters vs. Targeted Therapeutics
- Drug Safety
- Drug Development Costs
- Political Landscape 2008

Fewer FDA Approvals

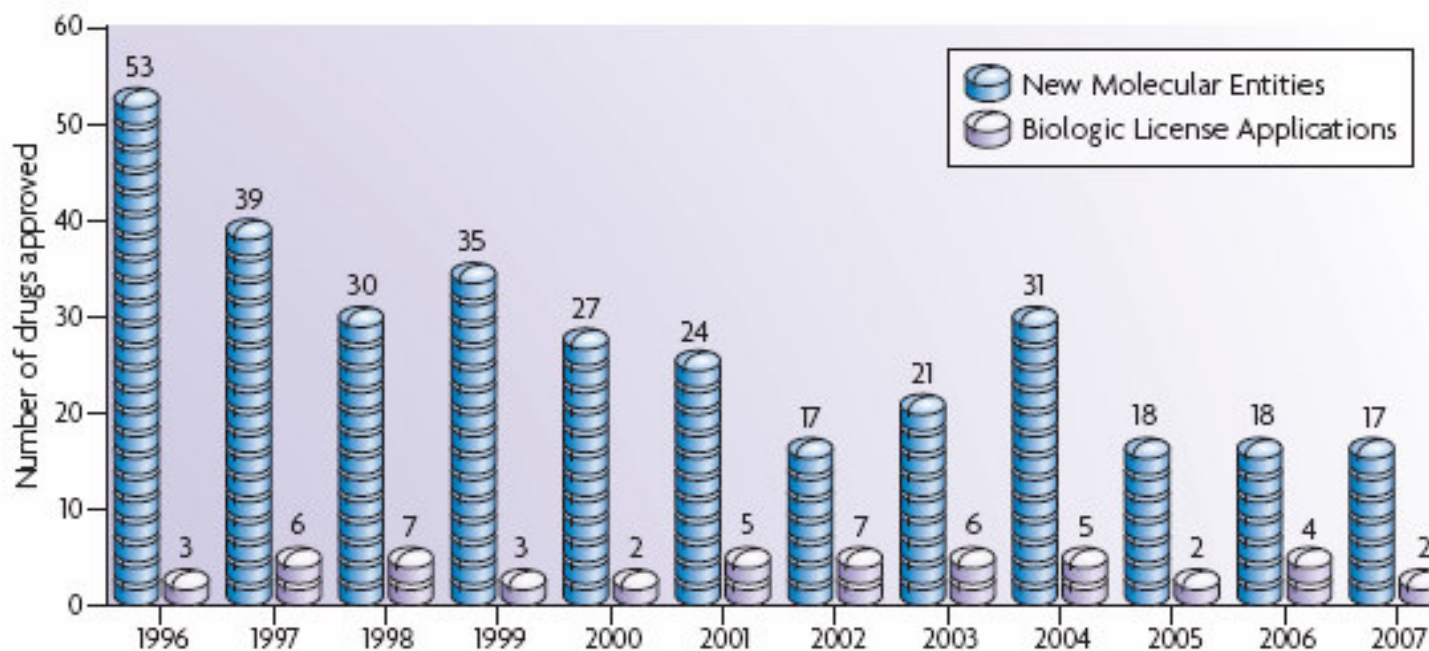


Figure 1 | FDA drug approvals. New molecular entities and biologic license applications approved by the US FDA by year.

Source: *Nature Reviews Drug Discovery* 7, 107-109 (February 2008)

Drug Approvals / Failures: Implication for Alliances

Table 1 | Drug development scorecard: January 2006 to December 2007

Source	FDA approvals	Phase III failures
Biotech industry	47 (45%)	68 (74%)
Biotech-pharma alliances	16 (16%)	18 (21%)
Acquisitions/licenses by pharma	4 (4%)	0
Pharma industry	36 (35%)	5 (5%)
Total	103	91

Source: Nature Reviews Drug Discovery 2008;7:197-8

Pipeline problems: Increasing the urge to merge

Box 1 | The great biotech buyout

The past few months have seen a spate of M&A deals in the biotechnology and pharmaceutical industry, as the current climate is forcing firms to plug the gaps in their product pipelines.

Company	Target	Price	Main purpose of purchase
Pfizer	PowderMed	≤US\$400 million*	Influenza vaccines
Genzyme	AnorMED	US\$580 million	Mozobil for haematopoietic stem-cell transplantation
Genentech	Tanox	US\$919 million	Improve returns on Xolair (omalizumab)
Merck	Sirna	US\$1.1 billion	Access to RNA interference technology
Lilly	ICOS	US\$2.1 billion	Full ownership of Cialis (tadalafil)
Gilead	Myogen	US\$2.5 billion	Bolster Gilead's pulmonary programme
Abbott	Kos	US\$3.7 billion	Acquire cholesterol treatments

*According to press reports.

Source: Nature Drug Discovery V.5 2006

2007-2008 Patent Expiry

Source: EvaluatePharma®

Report: Top 100 Drugs (WW Sales) - Ranked 2007

All Financial Data in US \$ (mln)

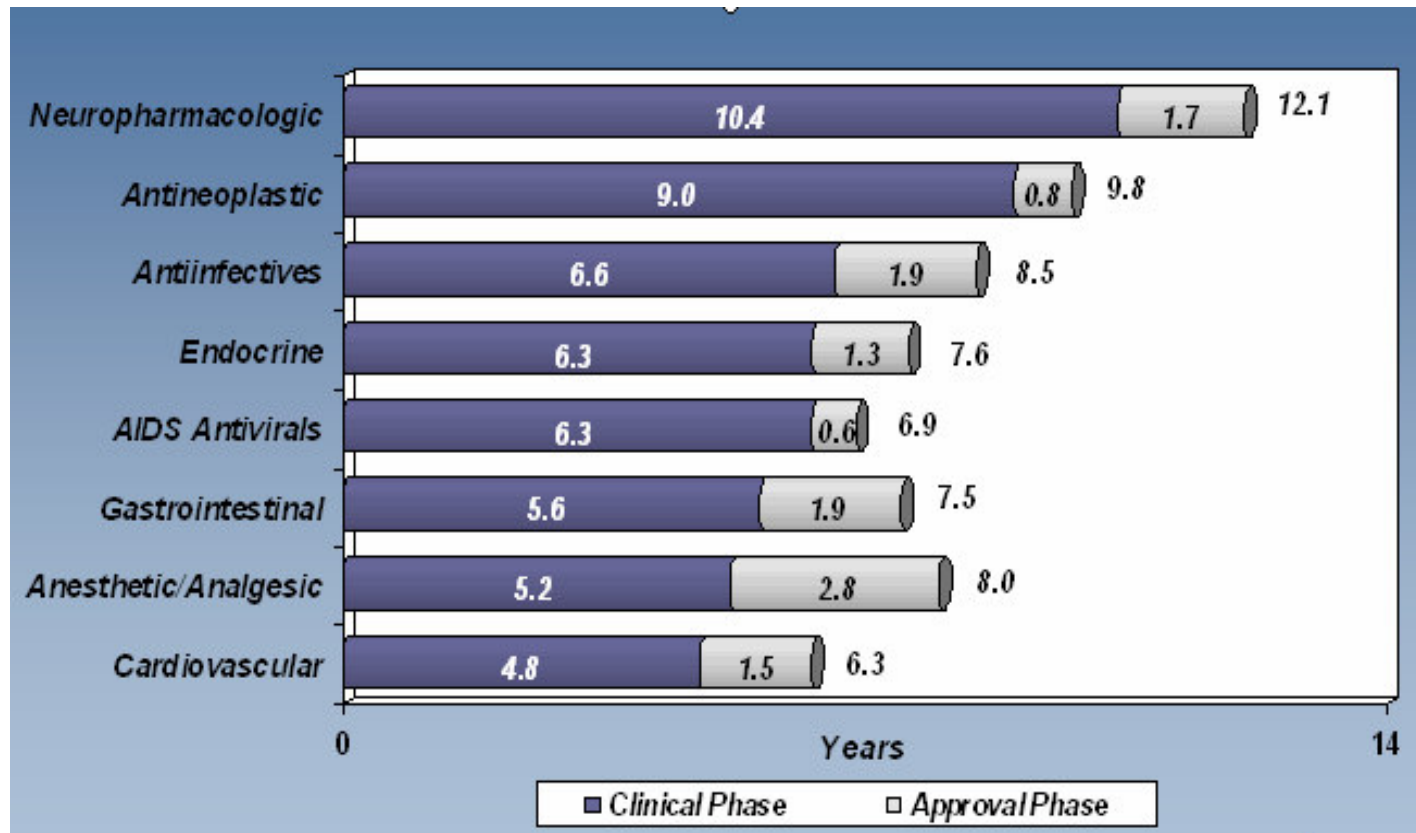
Rank	Product	Generic Name	Company	Therapeutic Subcategory	Annual Sales WW - Sales		Patent Expiry
					2006	2007	
93	Flixotide/Flovent	fluticasone propionate	GlaxoSmithKline	Corticoids	1,215	1,243	5/14/2004
91	NeoRecormon	epoetin beta	Roche	Anti-anaemics	1,233	1,282	12/31/2005
78	Seloken ZOK/Toprol XL	metoprolol succinate	AstraZeneca	Beta blockers	1,795	1,438	11/20/2006
20	Norvasc	amlodipine besylate	Pfizer	Calcium antagonists	4,866	3,001	3/23/2007
75	Pulmicort	budesonide	AstraZeneca	Corticoids	1,292	1,454	9/13/2007
71	Zyrtec/Reactine	cetirizine	Pfizer	Anti-histamines	1,569	1,541	12/25/2007
19	Fosamax	alendronate	Merck & Co	Bone calcium regulators	3,134	3,049	2/6/2008
58	Prograf	tacrolimus	Astellas Pharma	Immunosuppressants	1,455	1,724	4/8/2008
9	Effexor	venlafaxine	Wyeth	Anti-depressants	3,722	3,794	6/13/2008
13	Risperdal	risperidone	Johnson & Johnson	Anti-psychotics	3,338	3,437	6/29/2008
81	Keppra	levetiracetam	UCB	Anti-epileptics	956	1,407	7/14/2008
68	Depakote	divalproex sodium	Abbott Laboratories	Anti-epileptics	1,308	1,575	7/29/2008
33	Topamax	topiramate	Johnson & Johnson	Anti-epileptics	2,027	2,453	9/26/2008
86	Casodex	bicalutamide	AstraZeneca	Hormone therapies	1,206	1,335	10/1/2008
80	Betaferon/Betaseron	interferon beta-1b	Bayer AG	MS Therapies	672	1,410	12/31/2008
42	Lamictal	lamotrigine	GlaxoSmithKline	Anti-epileptics	1,836	2,196	1/22/2009
82	Imigran/Imitrex	sumatriptan	GlaxoSmithKline	Anti-migraine preparations	1,311	1,371	2/6/2009
60	CellCept	mycophenolate mofetil	Roche	Immunosuppressants	1,471	1,679	5/3/2009
40	Prevacid	lansoprazole	TAP Pharmaceutical Products	Antacids & anti-ulcerants	2,600	2,275	5/10/2009
49	Valtrex/Zelitrex	valacyclovir	GlaxoSmithKline	Anti-virals	1,558	1,870	6/23/2009

12

Source: EvaluatePharma 2008

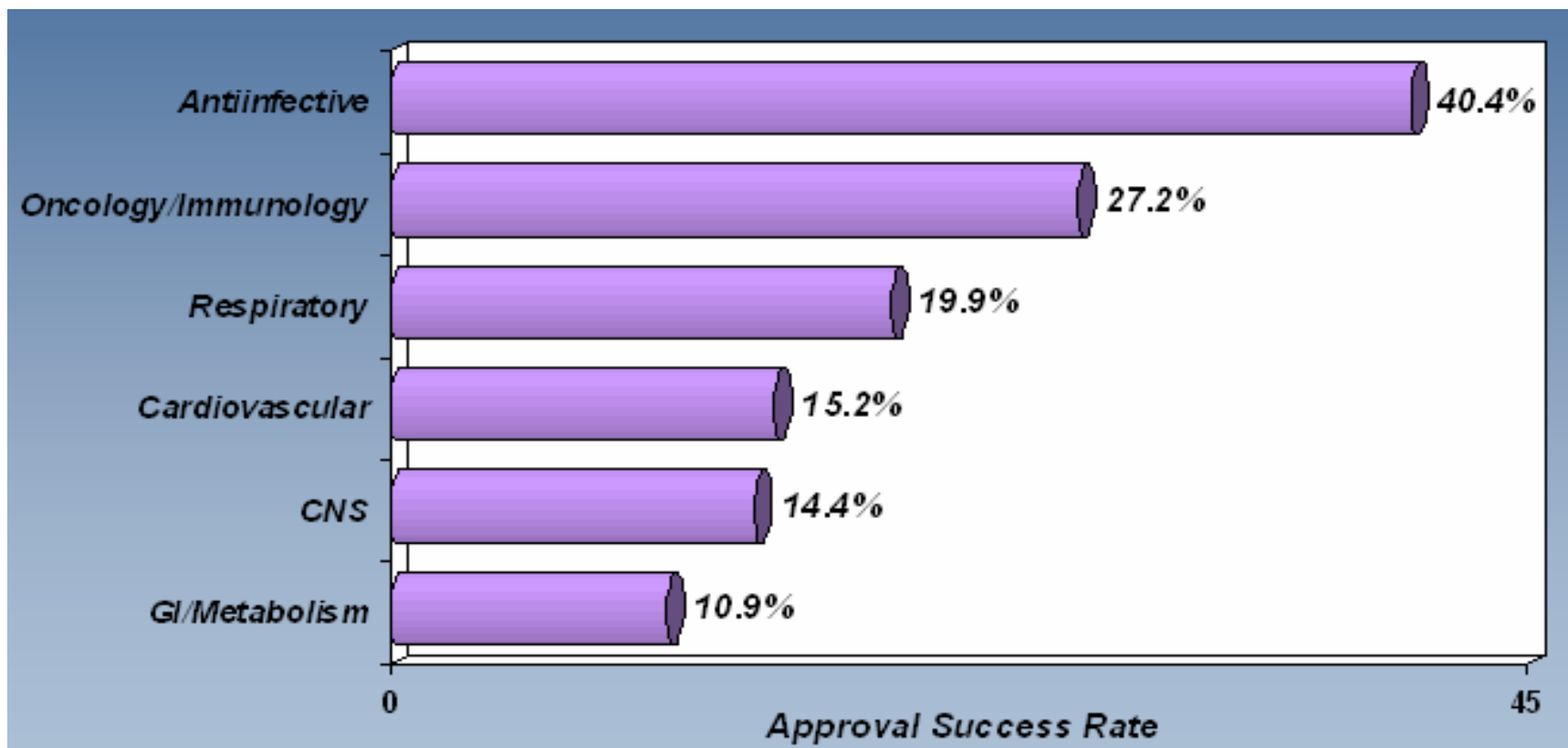
SLA 2008 – B. Gilmore-Halliwell & D. Webb

Clinical and Approval Times Vary Across Therapeutic Classes, 2002-04



Source: Tufts CSDD, 2006

Approval Success Rates for NCEs Also Vary by Therapeutic Class



Source: Tufts CSDD Impact Report, 8(3): May/June 2006

Blockbuster vs. Targeted Therapeutic:



- Segmented markets not as profitable as mass markets
- Goals of big pharma moving toward targeted therapeutics & personalized medicine

Blockbuster: Definition



- Blockbuster drugs defined as those with peak sales of \$1 billion annually.
- General population use
- Clinical trials large (\$\$\$)
- 79% IND's fail in clinical development
- Efficacious in 40-60% of the population

FDA Concerns: Safety & Efficacy Issues

The McGraw-Hill Companies
BusinessWeek
EUROPEAN EDITION / SEPTEMBER 5 & 12, 2005
DOUBLE ISSUE
www.businessweek.com

DRUGS GET SMART

How new medicines will more effectively target what ails you —and help prevent another Vioxx
BY RENEE CAPELL AND MICHAEL ARNDT (P. 38)

5th – 12th September 2005

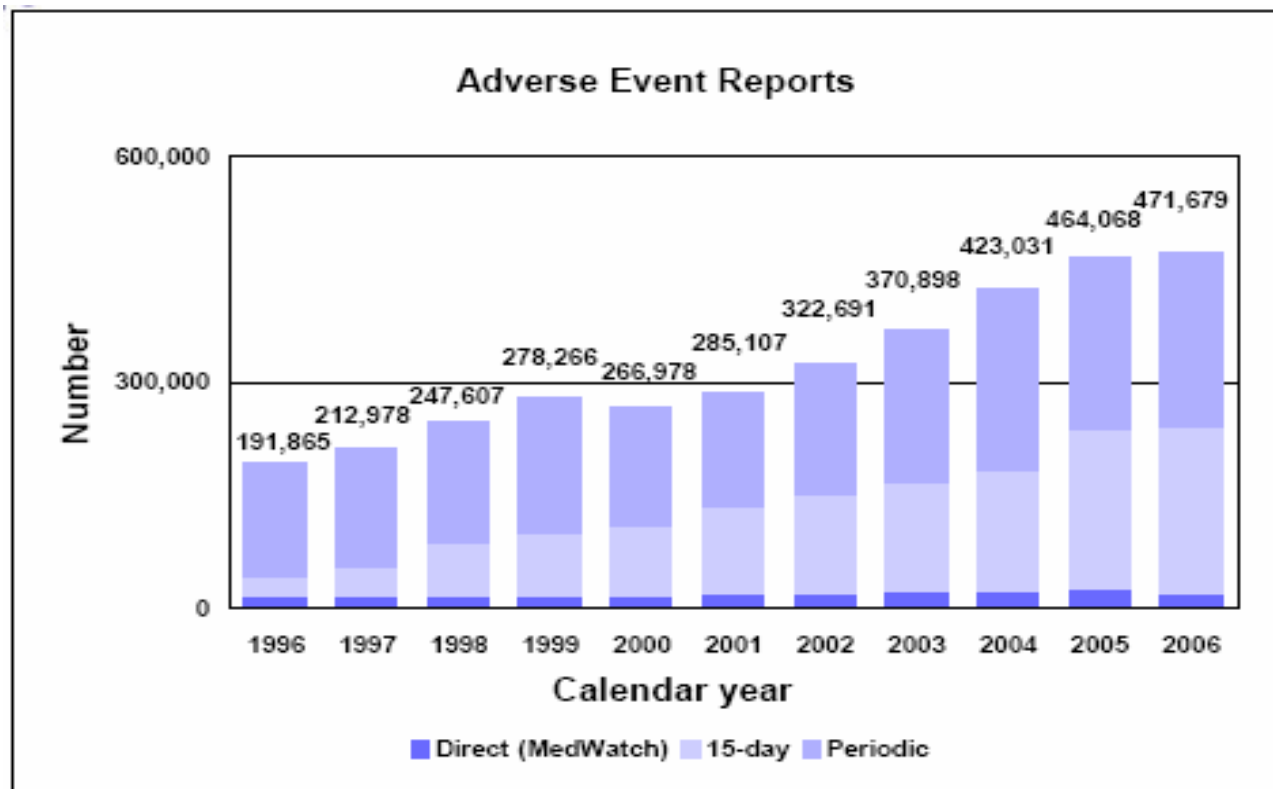
iml
Integrated Medicines Ltd

Keys issues with medicines today are

Safety and efficacy

FDA Safety Concerns

Post Marketing Adverse Event Reports --



Source: CDER *Report to the Nation* August 2007 (www.fda.org/CDER)



Costs of Drug Development

Key Facts

Research and Development

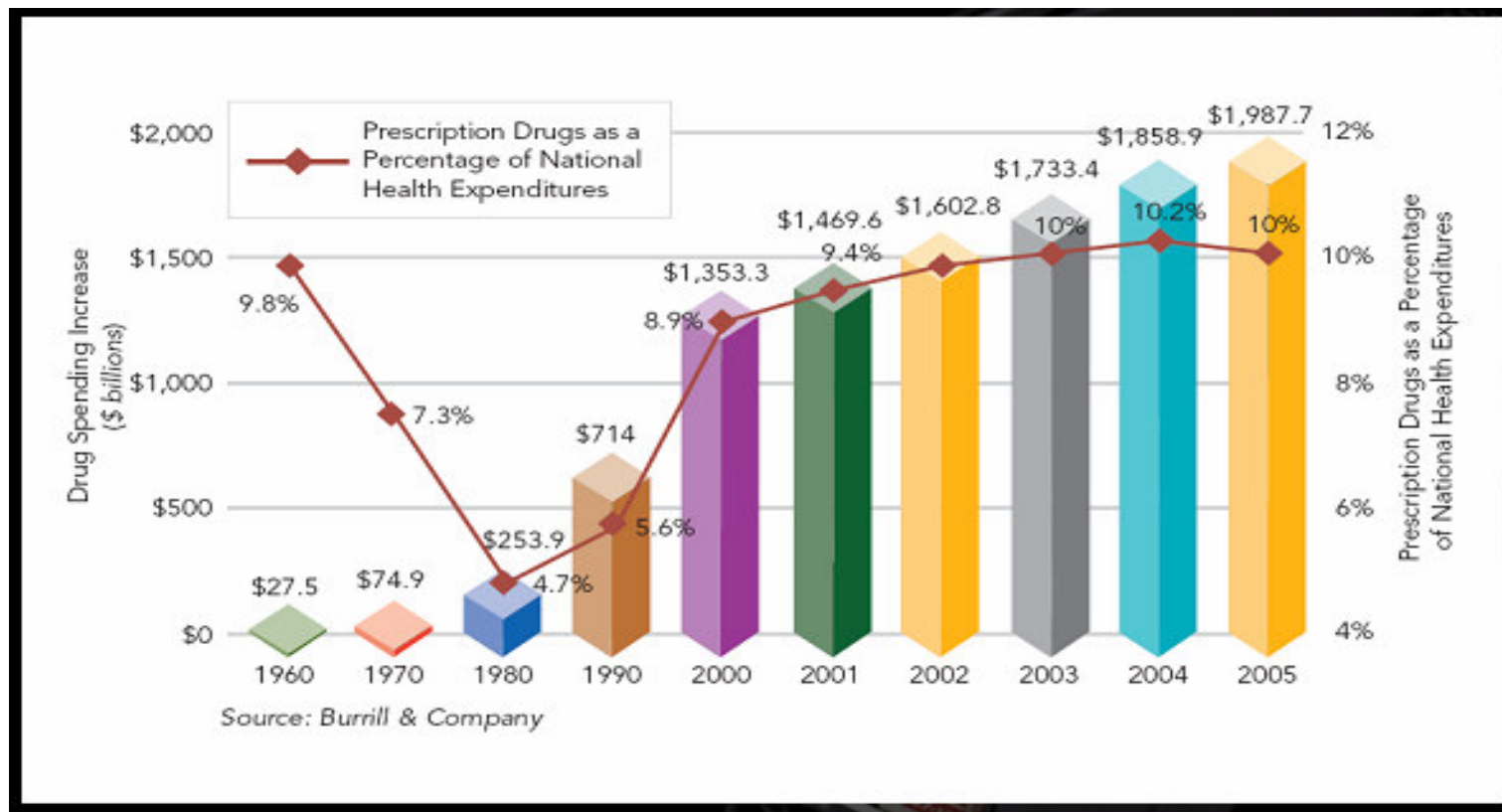
- Time to develop a drug = 10–15 years¹

Development Costs

- Cost to develop a drug
2001 = \$802 million²
1987 = \$318 million
1975 = \$138 million
- Cost to develop a biologic
2006 = \$1.2 billion³

- Development Cost
2010 → \$2.0 Billion
- Due to an increasing number of drugs being discontinued, forcing companies to write-off investment of failed products.

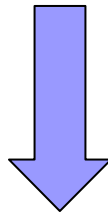
Prescription Drug Costs as a Percentage of Healthcare -



Healthcare Spend -

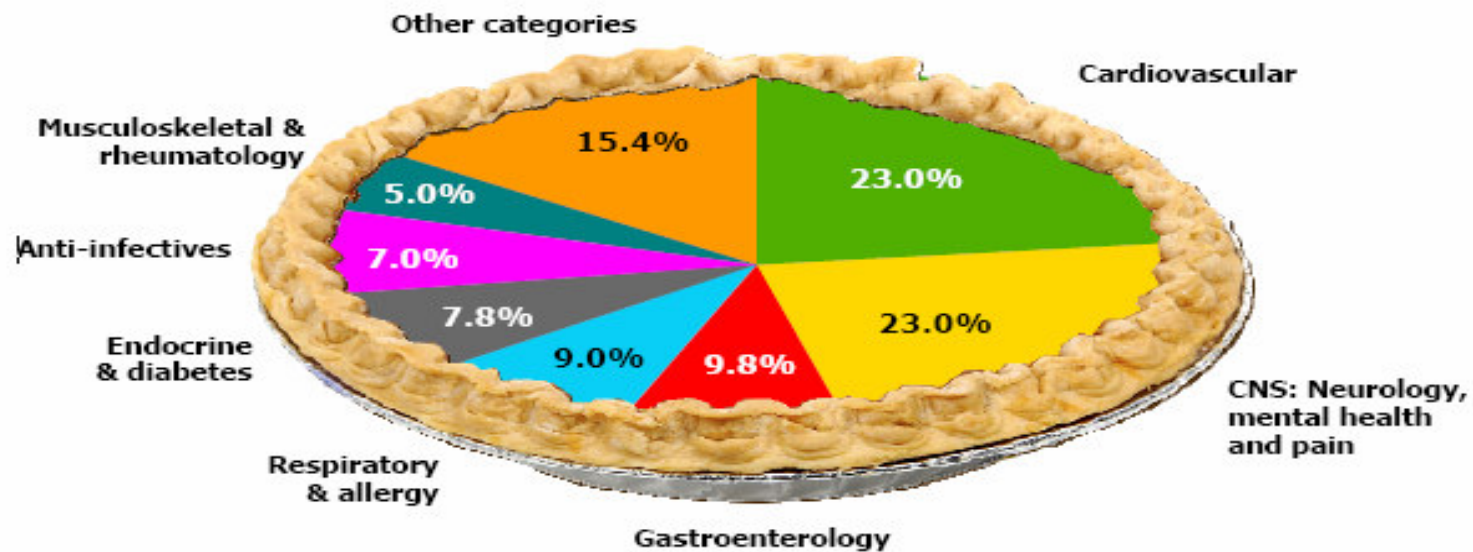
Current Spend –

- 8¢ of every \$1.00 on Diagnostics
- 92¢ of every \$1.00 on Therapy



Better use of diagnostics would decrease the costs of therapy.

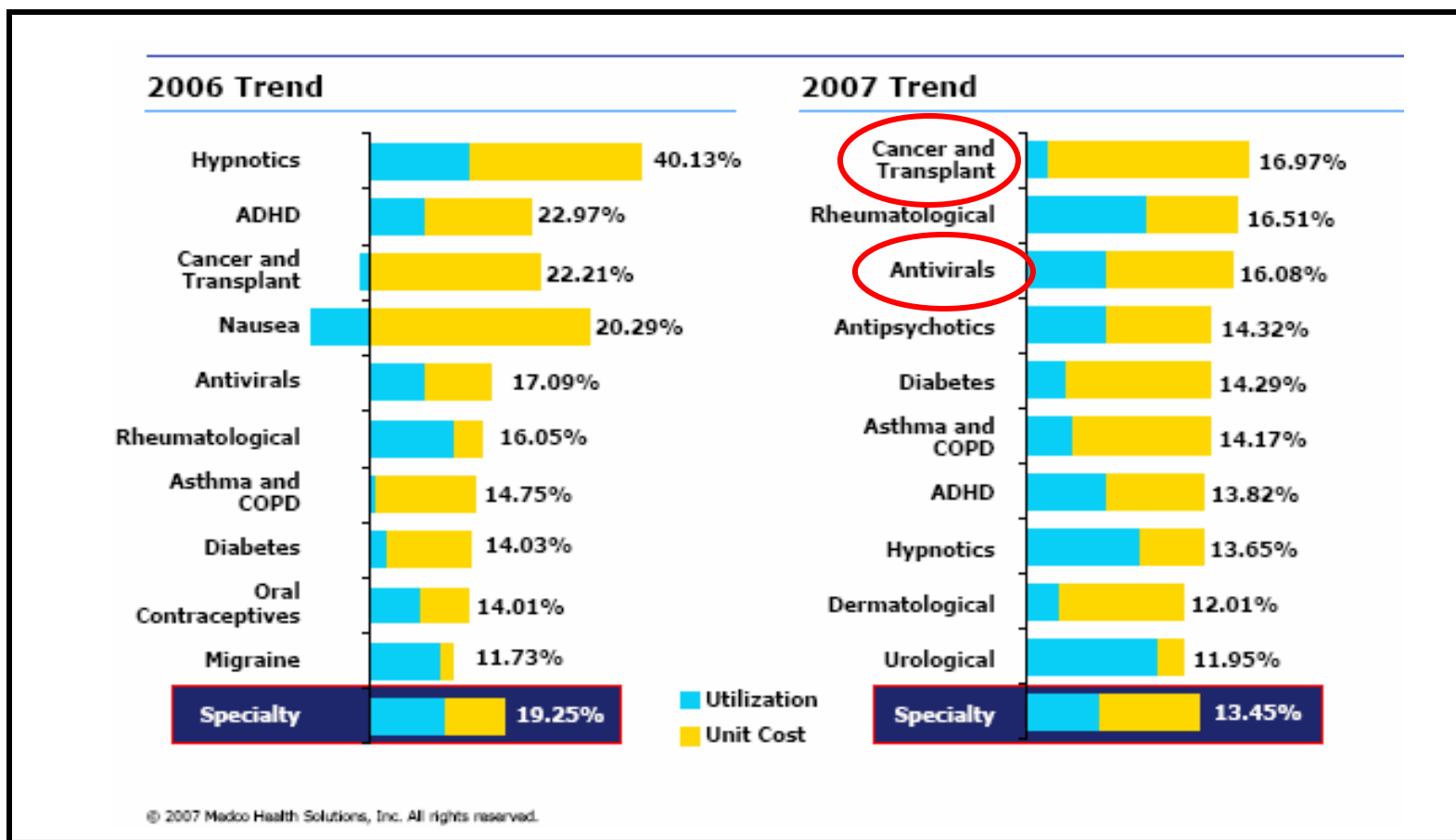
Top Contributors to RX Spend by Therapeutic Category (2007)



Sources: Medco data; *Drug Trend Report*, 2007, p. 15.

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Top RX Driver Trends – H1 2006 vs. H1 2007



Source: Medco Health Sciences (2007)



Political Landscape 2008

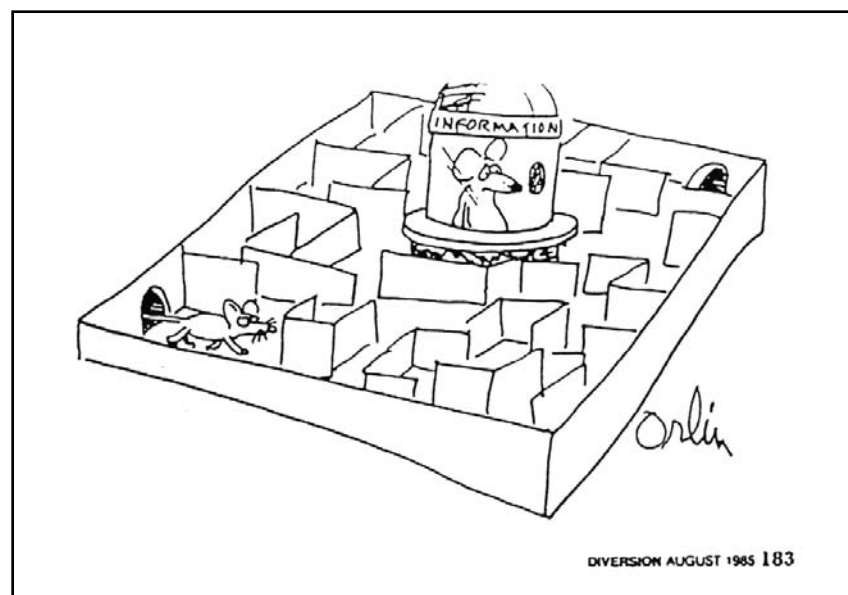
- August 2006 – Senator Barack Obama introduced the Genomics & Personalized Medicine Act
- January 2007 – Senators Kennedy & Enzi introduced the Genetic Information Nondiscrimination Act
- May 21, 2008 – GINA (Genetic Information Non-discrimination Act) signed into law

Planning is critical....



Drug Approval Process Overview: Information Maze

- Plethora of resources competing for those budget dollars
- What do you really need?
- What decisions are to be made?
- Organic development v. in-license?
- Drug / diagnostic combo?





Differences Between Small Molecules & “Targeted” Monoclonal Antibodies –

■ Small Molecules (Traditional Pharmaceutical Drugs)

- Oral or Intravenous
- Target multiple pathways**
- Cheaper to manufacture
- Short half-life
- Enter cytoplasm, therefore target any molecule or pathway regardless of location

■ Monoclonal Antibodies (Biotech drugs)

- Intravenous only
- Target specific protein**
- Expensive to manufacturer
- Inconvenient to administer but longer half-life
- Confined to proteins in extra cellular matrix



Balanced Equation

■ Biotech Strengths

- IP for novel products
- Distinguished products
- Niche technologies
- Innovative business cultures

■ Pharma Strengths

- Financial strength
- Development & commercial expertise
- Global reputation
- Recognized voice at regulatory agencies
- Marketing success

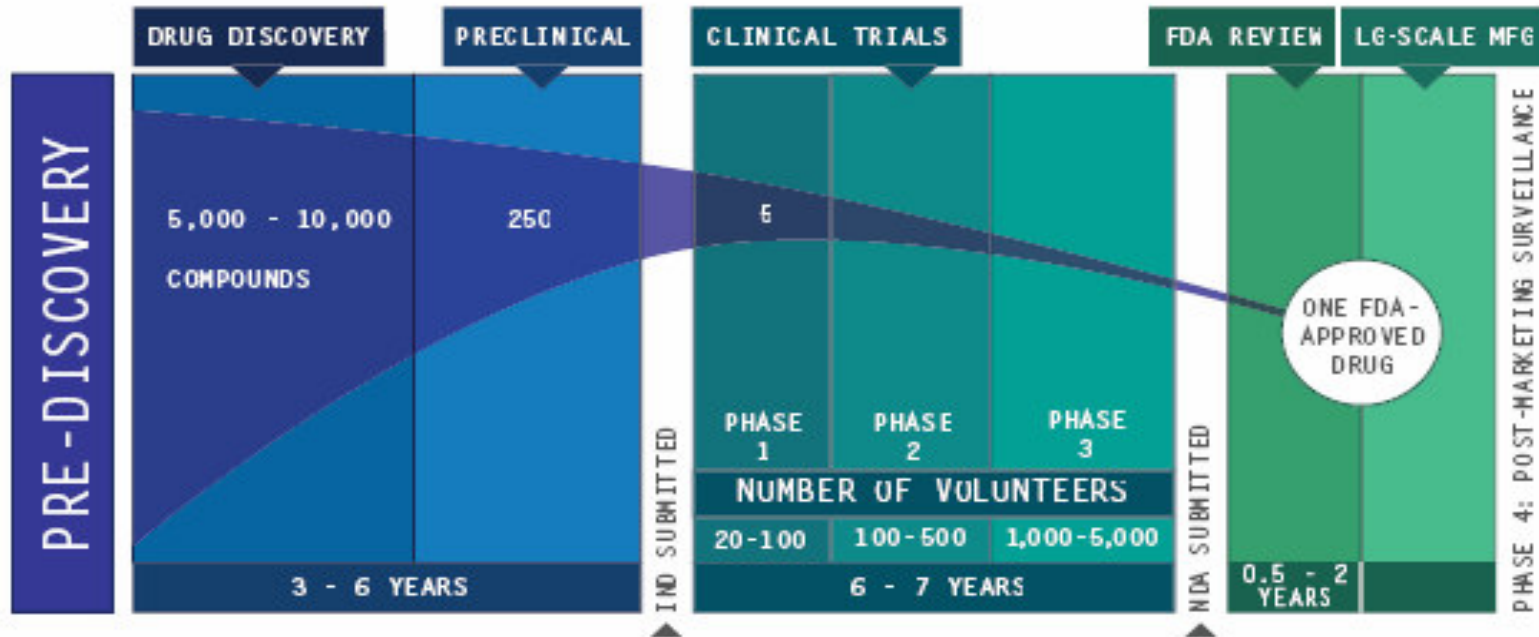


FDA & EMEA - Comparison

	FDA	EMA
Employees	12,000	440
Review Language	English	11 Languages
Countries Covered	1- United States	15 Member Nations
Communications with Companies	Extensive – Relate to phases, filings & pre-market	Does not communicate with companies until late in process.
Regulatory influence on drug pricing.	FDA not involved with pricing issues	Once approved, each country must price drug for marketing authorization of country

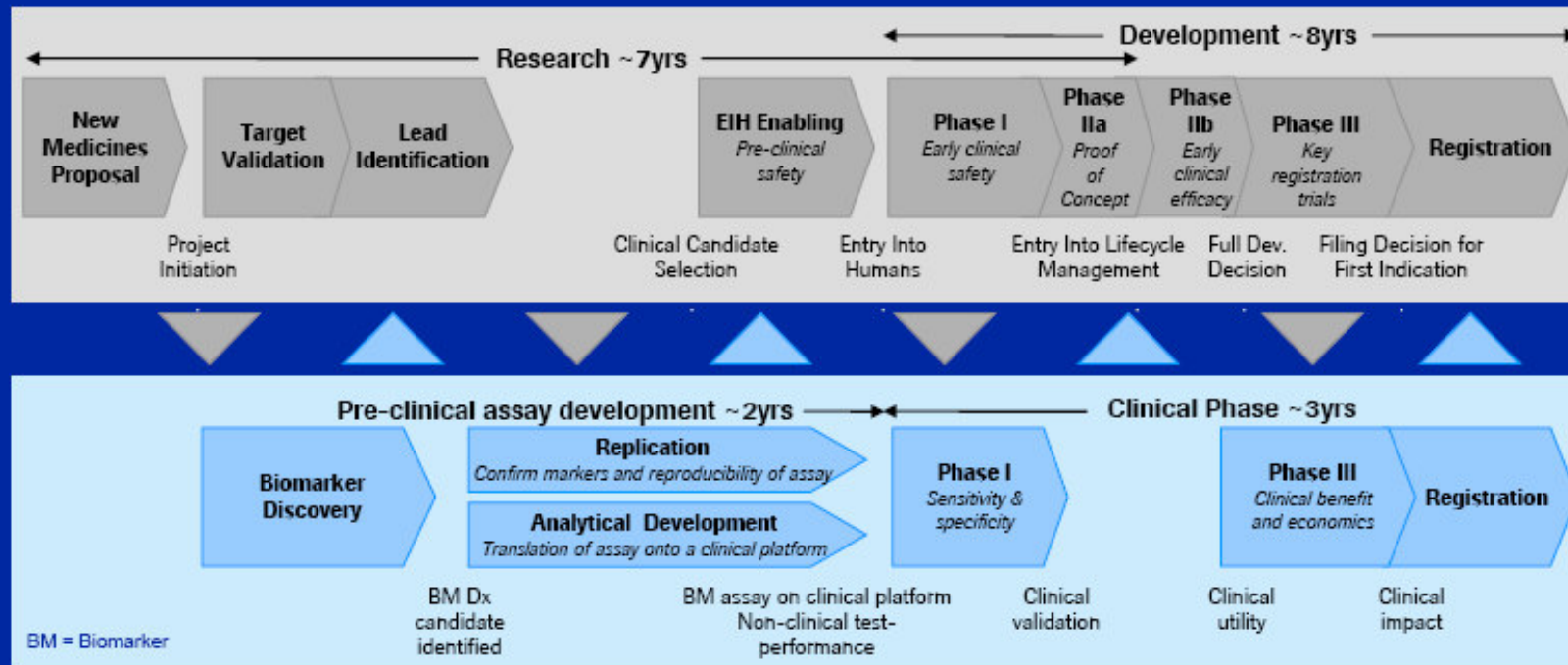
PHARMACEUTICAL RESEARCH & DEVELOPMENT

PROCESS



Source: 2007 PhRMA's Innovation.org

Pharma & Diagnostic Workflow Perspective -



- 1) **Coordinate joint launch (where feasible / sensible)**
- 2) **Manage interdependencies between Rx and Dx workflows**

Source: TM Jaeger, Hoffmann-LaRoche, CHI Molecular Medicine TriConference, March 2008

Drugs with Companion Diagnostics

All Financial Data in US \$ (mln)

		Annual Sales WW - Sales						Growth per Year (%)				
	Company	2003	2004	2005	2006	2007	2008	2004	2005	2006	2007	2008
Angiomax/ Angiox	The Medicines Company	85	136	141	201	255	322	60%	4%	43%	27%	26%
Erbix	Bristol-Myers Squibb	-	357	684	1,075	1,337	1,757	n/a	92%	57%	24%	31%
Gleevec/Glivec	Novartis	1,128	1,634	2,170	2,554	3,050	3,430	45%	33%	18%	19%	12%
Herceptin	Genentech	876	1,156	1,723	3,134	4,046	4,833	32%	49%	82%	29%	19%
Iressa	AstraZeneca	228	389	273	237	238	224	71%	(30%)	(13%)	0%	(6%)
Nexavar	Bayer AG	-	-	-	163	370	583	-	-	n/a	127%	57%
Purinethol	Teva Pharmaceutical Industries	33	25	9	8	6	6	(24%)	(64%)	(14%)	(16%)	(7%)
Selzentry/ Celsentri	Pfizer	-	-	-	-	45	121	-	-	-	n/a	167%
Tarceva	Genentech	-	13	311	649	886	1,190	n/a	n/a	109%	37%	34%
Tykerb	GlaxoSmithKline	-	-	-	-	102	280	-	-	-	n/a	174%
Ziagen	GlaxoSmithKline	273	284	247	216	218	201	4%	(13%)	(13%)	1%	(8%)
Report Total		2,622	3,994	5,559	8,237	10,554	12,947	52%	39%	48%	28%	23%

Source: EvaluatePharma® 2008

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THERMACLEAR TEAMS UP WITH SEPHORA IN THE QUEST FOR CLEAR SKIN

SAN FRANCISCO, Calif. (September 14, 2007) - Therative announced today that ThermoClear, its innovative, hand-held acne treatment device, is now available at Sephora.com, the leading specialty beauty retailer in the U.S. ThermoClear will also be featured on the weekly Sephora show on HSN in late...

Agilent Technologies' Mass Spectrometry Software Platform to Support All...

DENVER, ASMS, June 2, 2008 -- Agilent Technologies Inc., (NYSE: A) chose the American Society of Mass Spectrometry meeting to announce that it is expanding its MassHunter Workstation software with many new functionalities, new modules and to support all Agilent mass spectrometers (MS). ...

Study: Dietary Ginger may work against cancer growth

Minneapolis/St. Paul - October 28, 2000 - The substance that gives ginger its flavor appears to inhibit the growth of human colorectal cancer cells, according to research at the University of Minnesota's Hormel Institute in Austin, Minn. Working with mice that lack an immune systems, research...

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Chembio Awarded NIH Grant for Rapid TB Test on DPP(TM) Platform

MEDFORD, NY, Jun 05, 2008 -- Chembio Diagnostics, Inc. (OTCBB: CEMI) ("Chembio" or the "Company") announced today that it has been awarded a \$298,000 one year, Phase One Small Business Innovative Research (SBIR) grant from the United States National Institutes of Health (NIH) to develop a simple,...

ZymoGenetics and Merck Serono Initiate Second Phase 2/3 Clinical Study of...

SEATTLE, Jun 05, 2008 -- ZymoGenetics, Inc. (NASDAQ:ZGEN) announced today that its partner Merck Serono, a division of Merck KGaA, Darmstadt, Germany, initiated a Phase 2/3 trial of atacept in patients with systemic lupus erythematosus (SLE). This study will evaluate the efficacy and safety of...

OFFICIAL SIGNING CEREMONY FOR WIBP STRATEGIC ALLIANCE

MONTREAL, QUEBEC, CANADA - June 5, 2008 - ProMetic Life Sciences Inc. (TSX:PLI) ("ProMetic") announced today that the official signing ceremony for the strategic alliance concluded earlier this year with the Wuhan Institute of Biological Products ("WIBP") a subsidiary of...

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Immunotoxins with Deletions in Domain II that Remove Immunogenic Epitopes...

Anti-CD22 immunotoxins consist of a disulfide-linked FV (VH/VL) antibody fragment recombinantly linked to a toxic moiety capable of killing cells. In particular, a 38-kDa active fragment of Pseudomonas exotoxin A (PE38) containing three specific domains (domain I, domain II and domain III) has...

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 **SUBMIT A PROFILE** - List your organization's profile for free.

- Past Month: 17 Techs Added. 0 Removed.
- 7,705 KE Technologies Available
- 339 KE Profiles Available

Data Resource	Last Updated
BioSpace Pipelines	Jun 8 2008
CW Clinical Trial Listings	Jun 8 2008
CW Drugs in Clinical Trials	Jun 8 2008
CW FDA Drug Approvals	Jun 8 2008
BioWorld Cardio Update	Jun 8 2008
BioWorld Medical Device Daily	Jun 8 2008
TechEx	Jun 8 2008
KE Profiles	Jun 8 2008
KE Technologies	Jun 8 2008
BioWorld International	Jun 8 2008
UVentures	Jun 8 2008
BioWorld Today Archive	Jun 7 2008
Biomedical NewsSearcher	Jun 6 2008

Tools & Solutions: BioPharm Insight



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Proprietary Pharmawire Intelligence

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Pharmawire

2008-06-10 [Cardium's diabetic foot ulcer gel Excellerate could compete on cost, but market moving away from biologics, doctors note](#) **Pharmawire**

2008-06-10 [Novartis says a third of 'cluster' of new Tekturna clinical trials is in response to demand for outcome data](#) **Pharmawire**

2008-06-10 [Sanofi study reassures on Lantus retinopathy issue](#) **Pharmawire**

2008-06-10 [TriZetto Group could close deal with Apax as soon as July, VP says](#) **Pharmawire**

2008-06-10 [Krka may raise EUR 1.4bn for acquisitions, but no specific target yet, chairman says](#) **Pharmawire**

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Clinical Trial Updates - Most Recent Week

Results 1 - 15 of 116 [Next Page](#) ([View All Results](#))

Date	Clinical Event	Trade Name	Company	Therapeutic Area	Indication
2008-06-10	Phase II Results	BXT-51072	SYNVISTA THERAPEUTICS (FKA ALTEON, INC.)	Hormonal Systems	Diabetes (General)
2008-06-10	Business Development News	FGFr Inhibitor	ASTEX THERAPEUTICS LTD (FKA: ASTEX TECHNOLOGY LTD)		Cancer (General)
2008-06-10	Phase III Results	Saxagliptin (DPP-IV inhibitor)	ASTRAZENECA	Hormonal Systems	Diabetes (Type 2)

Top Drugs by '08 Projections (\$Mil)

Trade Name	2008 FY E
Lipitor	12,477
Plavix	9,484
Insulin	6,351
Diovan / Co-Diovan	5,592
Nexium	5,159
Singulair	4,709
Zyprexa	4,685
Seroquel	4,609
Avastin	4,599
Humira / D2E7 (adalimumab)	3,952
1080 Other(s)	348,158

Tools & Solutions –HCUP Database

2004 National statistics

Outcomes by patient and hospital characteristics for

All discharges


	Total number of discharges	LOS (length of stay), days (mean)	Charges, \$ (mean)	Charges, \$ (median)	Costs, \$ (mean)	Costs, \$ (median)	Aggregate costs	Aggregate charges, \$ (the "national bill")	Admitted from emergency department	Admitted from other hospital	Admitted from long term care
All discharges	38,661,786 (100.00%)	4.6	20,455	10,754	7,632	4,274	294,775,758,011	790,119,407,815	16,672,068 (43.12%)	1,350,234 (3.49%)	571,345 (1.48%)
Age group											
<1	4,897,575 (12.67%)	3.6	8,859	1,966	3,364	777	16,370,920,602	43,127,730,488	272,339 (5.56%)	103,226 (2.11%)	8,110 (0.17%)
1-17	1,784,461 (4.62%)	3.6	14,443	7,445	5,787	2,985	10,389,681,314	25,957,747,399	869,453 (48.72%)	83,120 (4.66%)	15,831 (0.89%)
18-44	10,323,379 (26.70%)	3.7	15,064	8,698	5,674	3,400	58,513,722,924	155,385,805,594	3,625,159 (35.12%)	223,071 (2.16%)	101,324 (0.98%)
45-64	8,546,409 (22.11%)	5.0	25,687	14,960	9,603	5,809	82,212,571,586	219,945,930,235	4,445,928 (52.02%)	351,014 (4.11%)	134,657 (1.58%)
65-84	10,347,463 (26.76%)	5.7	27,445	16,206	10,102	6,320	104,697,650,596	284,404,611,069	5,621,332 (54.33%)	485,562 (4.69%)	220,776 (2.13%)
85+	2,711,697 (7.01%)	5.9	22,258	13,685	8,218	5,479	22,317,047,851	60,432,378,795	1,822,759 (67.22%)	102,200 (3.77%)	89,840 (3.31%)
Missing	50,802 (0.13%)	2.8	17,233	10,842	5,285	3,354	274,163,138	865,204,236	15,097 (29.72%)	2,041 (4.02%)	807 (1.59%)
Sex											
Male	15,773,422 (40.80%)	5.0	23,428	11,938	8,753	4,761	137,995,269,631	369,391,144,136	7,629,850 (48.37%)	666,715 (4.23%)	251,451 (1.59%)
Female	22,757,558 (58.86%)	4.4	18,405	10,101	6,865	4,013	156,047,181,005	418,365,417,777	8,994,183 (39.52%)	679,125 (2.98%)	317,812 (1.40%)
Missing	130,806 (0.34%)	2.7	18,532	12,837	5,523	3,861	733,307,375	2,362,845,903	48,035 (36.72%)	*	2,082 (1.59%)
Owner											
Government	5,194,845 (13.44%)	4.8	17,112	8,887	7,921	4,221	41,108,998,153	88,846,437,795	2,306,094 (44.39%)	165,808 (3.19%)	49,947 (0.96%)
Private, not-for-profit	28,023,511 (72.48%)	4.6	20,513	10,836	7,719	4,365	215,947,882,206	574,034,316,324	12,193,721 (43.51%)	1,023,436 (3.65%)	426,042 (1.52%)
Private, for-profit	5,004,831 (12.95%)	4.5	23,970	13,016	6,873	3,847	34,455,349,196	120,086,916,730	2,059,309 (41.15%)	115,098 (2.30%)	71,469 (1.43%)

- HCUPnet is a free, on-line query system based on data from the Healthcare Cost and Utilization Project (HCUP).
- It provides health statistics on hospital stays –
- National, State & regional .

Tools & Solutions – EvaluatePharma

Year	WW Rx Sales US \$ (Millions)	Market Share %
2003	8000	1.5
2004	10000	1.8
2005	12000	2.0
2006	14000	2.2
2007	14500	2.3
2008	14000	2.2
2009	14500	2.3
2010	15000	2.4
2011	16000	2.5
2012	17000	2.6

Tools & Solutions – 10K Wizard



Ticker Search :

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My Services
Regulatory
Client Tracking
About Us
10-K Classic
What's New

UPDATE : Peer Analytics - available from Feb 4 2008. [Learn more](#)

Basic

Advanced

Exhibits

10-K Items

8-K Search

Profile

Insider

Global Reports

SEC News Digest

SEC Comments

SEC NO Action

Financials

SC13 D/G

Ownership

Filing Agent

Mutual Funds

Registration Data

Custom Search

Advanced Search

Ticker OR CIK OR Company Name

Begins With Contains

File-Number OR Accession-Number

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Geographic Filter

Accelerated Status :

Exchange Index Period Ending

Financial Filters

Form Group **Form**

Industry (NAICS)

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Planning is critical.





Clinical Trials Databases

- ADIS Clinical Trials Insight (\$\$\$) – link with ADIS RDI
- Cancer Clinical Trials, NIH (free)
■ (www.cancer.gov/clinicaltrials)
- CenterWatch Clinical Trials Listing Service (\$) (www.centerwatch.com)
- CiteLine TrialTrove (Informa) (\$\$\$) – Link with PharmaProjects (www.citeline.com/trialtrove.html)
- ClinicalTrials.gov (NIH) (free) (www.clinicaltrials.gov)
- Inteleos (\$) (www.inteleos.com)

ADIS – Clinical Trial Insight

Clinical Trials Insight

Database | Home | Search | What's New | **Ongoing Trials** | Recent Meetings | Alerts | Preferences | Feedback | Perspectives | Help | Exit

Wolters Kluwer Health

Ongoing Trials Browse

Select category 1: Therapeutic Area (Active)

Select category 2: Lead Investigator

Please Select..
None
Drug Name
Indication
Companies
Trial Name
Lead Study Centre
Lead Investigator
Eisenmann J-C (1)
Eisenstat D (1)
Eisterer W (1)
Ek L (1)
Eklund J (1)
Ekman T (1)
El-Khoueiry A (11)
El-Khoueiry AB (1)
El-Rayes B (5)
Eldridge R (1)
Eleff M (1)
Elena A (1)
Elena DL (1)
Elena P (3)
Elena R (3)

Results

Page 1 of 1 Results Pages

SAVE AS ALERT | RESULTS PRINT / EXPORT | RESULTS CHART

Output	Ref	Article Title	Study Status	Study Endpoints
<input type="checkbox"/>	1	Gemcitabine + erlotinib +/- IMC-A12: therapeutic use Pancreatic cancer Phase III trial in patients with metastatic disease (Last Modified: 03/06/2008)	Recruiting	Complete clinical response, Objective clinical response, Partial clinical response, Progression-free survival, Recommended phase II dose, Survival
<input type="checkbox"/>	2	Cetuximab + irinotecan +/- brivanib alaninate: adverse reactions Various toxicities Phase III trial in patients with metastatic colorectal cancer (Last Modified: 22/05/2008)	Initiated	Biomarker levels, Disease progression, Pharmacokinetic parameters, Progression-free survival, Progression-free survival duration, Recommended dose
<input type="checkbox"/>	3	Paclitaxel + vandetanib: adverse reactions Various toxicities Regimen comparison in patients with solid tumours (Last Modified: 22/05/2008)	Recruiting	Clinical response, Maximum tolerated dose
<input type="checkbox"/>	4	Pertuzumab + cetuximab + irinotecan: therapeutic use Colorectal cancer Phase III trial of second-line therapy in patients with locally advanced or metastatic disease (Last Modified: 20/05/2008)	Initiated	Objective clinical response rate, Progression-free survival, Recommended phase II dose, Survival
<input type="checkbox"/>	5	Brivanib + cetuximab: adverse reactions Various toxicities Phase III trial in patients with metastatic	In process	Duration of objective clinical response, Maximum tolerated dose, Pharmacokinetic

ADIS – Clinical Trial Insight

Clinical Trials Insight



Database Home Search Set Scope Searches What's New Ongoing Trials Recent Meetings Alerts Preferences Feedback Perspectives Help Exit

Revise Search → Back to Results → Document

Reference Study Details Study History Descriptors & Links

Result 4 of 466 EMAIL PRINT

Bevacizumab +/- irinotecan: therapeutic use

Ongoing Trial

Last Modified: 09/06/2008

Glioblastoma

Phase II trial in patients with glioblastoma multiforme in first or second relapse

700017656

Location: USA
Endpoints: Duration of objective clinical response, Objective clinical response rate, Progression-free survival rate, Survival

SUBJECTS

Type	No. of Patients	Age
patients	167 (Actual)	adult

Patient Inclusion Criteria: Signed informed consent; age greater than or equal to 18 years; histologically confirmed glioblastoma multiforme in first or second relapse; radiographic demonstration of disease progression following prior therapy; bidimensionally measurable disease with a minimum measurement of 1 cm in one diameter on magnetic resonance imaging (MRI) performed within 14 days prior to first treatment; an interval of at least 4 weeks since prior surgical resection; prior standard radiation for glioblastoma multiforme; recovered from effects of prior therapy (including the following: 4 weeks from cytotoxic agents; 6 weeks from nitrosoureas; 3 weeks from procarbazine; 2 weeks from vincristine; 4 weeks from any investigational agent(s); 1 week from non-cytotoxic agents; 8 weeks from radiotherapy (or 4 weeks if a new lesion develops that is outside the primary radiation field relative to the pre-radiation MRI); Karnofsky performance status of at least 70 percent; life expectancy greater than 12 weeks; use of effective means of contraception (in males and females of childbearing potential); ability to comply with study and follow-up procedures.

Patient Exclusion Criteria: Prior irinotecan, bevacizumab or agent(s) that target the vascular endothelial growth factor pathway or vascular endothelial growth factor receptor; prior proleprospan 20 with carmustine wafer; prior intracerebral agents; need for urgent palliative intervention for primary disease; evidence of recent haemorrhage on baseline MRI of the brain (except presence of haemosiderin, resolving haemorrhagic changes related to surgery or presence of punctate haemorrhage in the tumour); received more than two treatment regimens for grade III and/or IV glioma; blood pressure reading greater than 150/100mm Hg; history of hypertensive encephalopathy; New York Heart Association (NYHA) grade II or greater congestive heart failure; history of myocardial infarction or unstable

National Cancer Institute – www.cancer.gov

The screenshot displays the National Cancer Institute website's search interface for clinical trials. At the top, the NCI logo and name are visible, along with a search bar and navigation tabs for NCI Home, Cancer Topics, Clinical Trials, Cancer Statistics, Research & Funding, News, and About NCI. The main heading is "Search for Clinical Trials: Advanced Search". Below this, there are sections for "Quick Links" (including Director's Corner, Dictionary of Cancer Terms, NCI Drug Dictionary, Funding Opportunities, NCI Publications, Advisory Boards and Groups, NIH Calendar of Events, and Español), "Questions about cancer?" (with phone and chat options), and "NCI Highlights" (listing treatment of metastatic breast cancer, long-term smoking cessation, and cuts in risk). The search options include "Basic Search" and "Advanced Search" (selected), with a "Help with Advanced Search" link. The search criteria are: "Type of Cancer" (All), "Stage/Subtype of Cancer" (select cancer type first), "Type of Trial" (All, Treatment, Supportive care), and "Status of Trial" (Active (currently accepting patients) selected, Closed (not accepting patients)).

NATIONAL CANCER INSTITUTE National Cancer Institute
U.S. National Institutes of Health | www.cancer.gov In English | [En español](#)

NCI Home Cancer Topics **Clinical Trials** Cancer Statistics Research & Funding News About NCI

Search for Clinical Trials: Advanced Search

[Quick Links](#)

- [Director's Corner](#)
- [Dictionary of Cancer Terms](#)
- [NCI Drug Dictionary](#)
- [Funding Opportunities](#)
- [NCI Publications](#)
- [Advisory Boards and Groups](#)
- [NIH Calendar of Events](#)
- [Español](#)

[Questions about cancer?](#)

- 1-800-4-CAICER
- [LiveHelp@online chat](#)

[NCI Highlights](#)

- [Treatment of Metastatic Breast Cancer](#)
- [Long-Term Smoking Cessation Cuts Risk](#)
- [Past Highlights](#)

[Basic Search](#) | [Advanced Search](#) [Help with Advanced Search](#)

Search NCI's list of 6,000+ clinical trials now accepting participants, or search the set of 17,000+ closed clinical trials.

Search Tip: Skip any items that are unknown or not applicable.

Type of Cancer: All

Stage/Subtype of Cancer: select cancer type first
(choose 1 or more)*

**Note: To choose multiple items:*
a) PC Users - Hold Ctrl key and click on items
b) Mac Users - Hold Command key and click on items

Type of Trial: All
Treatment
Supportive care
(choose 1 or more)*

Status of Trial:

- Active (currently accepting patients)
- Closed (not accepting patients)

CenterWatch: Clinical Trials

www.centerwatch.com

CenterWatchSM
Clinical Trials Listing ServiceTM

The Global Destination for
Clinical Trials Information

CenterWatch Bookstore | Tell A Friend About CW | CW WORLD

Go | [Advanced Search](#) | [Site Map](#) | [About CW](#) | [Contact Us](#) | [Your Privacy](#) | [Home](#)

Patient and General Resources

- Trial Listings
- About Clinical Research
- Notification Services
- Health Associations
- Drug Directories
- Patient Education

Additional Resources for Patients

Industry Professional Resources

- Site Identification Services
- Clinical Trial Results
- Product & Service Providers
- Drugs in Clinical Trials
- Jobs In Clinical Research
- Professional Bookstore

Additional Resources for Professionals

Welcome to the CenterWatch Clinical Trials Listing Service!

WHAT'S NEW
@ CenterWatch

Patient Notification Service

Clinical Trials Today
www.clinicaltrials.com

Online Survey | Press Releases | Awards & Articles | **Clinical Trials Today** | Clinical Trials Today | Industry News | Advertising Opportunities

Citeline - TrialTrove

The screenshot displays the Citeline TrialTrove website. At the top, there is a navigation bar with the Citeline TrialTrove logo, tabs for 'Categories', 'Search TrialTrove', and 'My Watch List', and a 'Submit Research Request' button. On the right side of the navigation bar, there are links for 'Other Citeline Services NEW!', 'My Preferences', 'Help', and 'Logout', along with a 'Citeline Demo' label.

The main content area is divided into a sidebar on the left and a main grid on the right. The sidebar includes a 'Home' tab, a 'Did You Know?' section with links for training, search results, and updates, a 'Support' section with links for Client Services, Research Support, and Account Services, and an 'Other Citeline Services NEW!' section with links for TrialScape, SiteTrove, and Pipeline. A yellow box at the bottom of the sidebar promotes 'Training is Free!' with a link to upcoming sessions.

The main grid is titled 'Clinical Trials By Therapeutic Category' and contains a table of categories and associated conditions:

Therapeutic Category	Associated Conditions
Autoimmune Inflammation	Allergic Rhinitis Anti-aging (dermatology) (Jun 30) Asthma Atopic Dermatitis Chronic Obstructive Pulmonary Disease Crohn's Disease
Cardiovascular	Acute Coronary Syndromes Arrhythmia Congestive Heart Failure
CNS	Alcohol Dependence Alzheimer's Disease Amyotrophic Lateral Sclerosis Anxiety Attention Deficit Hyperactive Disorder Autism Bipolar Disorder
Genitourinary	Benign Prostatic Hyperplasia Contraception Endometriosis
Infectious Disease	Bacterial Skin Infection HBV HCV HIV
Metabolic Endocrinology	Anemia Constipation Diabetic Complications Functional Dyspepsia
Oncology	Bladder Breast

Additional conditions listed in the grid include: Cystic Fibrosis, Irritable Bowel Syndrome, Lupus, Osteoarthritis, Other Inflammatory Arthritis, Psoriasis, Rheumatoid Arthritis, Sjogren's Syndrome, Transplantation, Ulcerative Colitis, Coronary Artery Disease, Dyslipidemia, Hemostasis/Hemophilia, Hypertension, Peripheral Arterial Disease, Thrombotic Disorders, Depression, Epilepsy (August 1), Insomnia, Migraine, Multiple Sclerosis, Pain (neuropathic), Pain (nociceptive), Parkinson's Disease, Restless Legs Syndrome, Schizophrenia, Smoking Cessation NEW!, Stroke (neuroprotection), Female Sexual Dysfunction, Infertility NEW!, Menopause (Sep 30), Overactive Bladder, Uterine fibroids (Jul 31), HPV, Intra-abdominal Infections, Onychomycosis NEW!, Otitis Media, Respiratory Infections, Sepsis, Urinary Tract Infections, Vaccines, GERD, Hyponatremia, Obesity, Osteoporosis, Renal Disease, Type 1 Diabetes, Type 2 Diabetes, Leukemia, Chronic Lymphocytic Leukemia, Chronic Myelogenous Leukemia, and Ovarian Pancreas.

Citeline TrialTrove

The screenshot displays the Citeline TrialTrove interface. At the top, there is a navigation bar with the Citeline logo, 'TrialTrove' text, and buttons for 'Categories', 'Search TrialTrove', and 'My Watch List'. On the right side of the navigation bar, there is a 'Submit Research Request' button and the text 'Citeline Demo'. Below the navigation bar, there are links for 'Other Citeline Services NEW!', 'My Preferences', 'Help', and 'Logout'. The main content area features a search bar with 'Search' and 'Search History' buttons. Below the search bar, there are buttons for 'New Search', 'Refine Search', 'Watch this Search', and 'Export'. A yellow banner indicates the search criteria: 'Epidermal growth factor receptor (EGFR) antagonist'. Below this, a grey banner states 'Viewing 312 ongoing trials out of a total of 533 in your subscription'. A row of filters shows trial counts: 'All Trials (533)', 'Ongoing Trials (312)', 'Planned (41)', 'Open Enrollment (211)', 'Closed Enrollment (59)', 'Temporarily Closed (1)', 'Terminated (26)', and 'Completed (195)'. The main table lists trial details with columns for Phase, Disease Type, Patient Segment, Sponsorship, Primary Drugs, Other Drugs, Protocol ID / Trial Identifier, Status, and Action.

Phase	Disease Type	Patient Segment	Sponsorship	Primary Drugs	Other Drugs	Protocol ID / Trial Identifier	Status	Action
I	Colorectal	III, IV	Merck KGaA	Erbix	fluorouracil , irinotecan (IV) , leucovorin	EMR 62202-045, TrialTroveID-016405	Open	View Watch
I	Colorectal, Head/Neck, Lung, Non-Small Cell, Pancreas, Renal	III, IV, Refractory/Relapsed	Institute for Drug Development, NCI	Avastin , Tarceva	Erbix	CTRC-IDD-0332, NCI-6588, NCT00101348, TrialTroveID-022079	Open	View Watch
I	Pancreas	III	NCI, Vanderbilt-Ingram Cancer Center	Erbix	gemcitabine , radiation therapy	NCT00467116, TrialTroveID-027092, VICC GI 0466, VICCIGI0466, VU-VICC-GI-0466	Closed	View Watch
I	CNS, Glioblastoma	N/A	Ludwig Institute for Cancer Research	ch806		TrialTroveID-032403	Open	View Watch
I	Colorectal, Gastric	III, IV, Refractory/Relapsed	BMS	brivanib alaninate	Erbix	05-112, 05453, 2939, 3G-06-1, BMS-CA182-003, CA182-003, CA182003, HS-06-00138, MCC#14449, NCT00207051, TrialTroveID-036297, UPCC 01205,	Closed	View Watch

ClinicalTrials.gov

The screenshot shows the ClinicalTrials.gov website. At the top left is the logo "ClinicalTrials.gov" with the tagline "A service of the U.S. National Institutes of Health". To the right are navigation links for "Home", "Search", "Study Topics", and "Glossary", along with a search input field and a "Search" button. The main content area is divided into two columns. The left column features three blue arrow icons pointing to the following sections: "Search for Clinical Trials" (with a description of the registry and a "Read more..." link), "Investigator Instructions" (with a description of registration instructions), and "Background Information" (with a description of how to use the site). The right column contains two sections: "Resources" with links for "Understanding Clinical Trials", "What's New", and "Glossary"; and "Study Topics" with links for "List by Condition", "List by Drug Intervention", "List by Sponsor", and "List by Location". At the bottom of the page, there are several small logos and links, including the U.S. National Library of Medicine (NLM) logo and the U.S. National Institutes of Health logo.

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

[Home](#) [Search](#) [Study Topics](#) [Glossary](#)

ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals. [Read more...](#)

▶ [Search for Clinical Trials](#)

Find trials for a specific medical condition or other criteria in the ClinicalTrials.gov registry. ClinicalTrials.gov currently has **57,256 trials** with locations in **156 countries**.

▶ [Investigator Instructions](#)

Get instructions for clinical trial investigators/sponsors about how to register trials in ClinicalTrials.gov.

▶ [Background Information](#)

Learn about clinical trials and how to use ClinicalTrials.gov, or access other consumer health information from the US National Institutes of Health.

Resources:

- [Understanding Clinical Trials](#)
- [What's New](#)
- [Glossary](#)

Study Topics:

- [List by Condition](#)
- [List by Drug Intervention](#)
- [List by Sponsor](#)
- [List by Location](#)

[U.S. National Library of Medicine](#), [Contact Help Desk](#)
[U.S. National Institutes of Health](#), [U.S. Department of Health & Human Services](#),
[USA.gov](#), [Copyright](#), [Privacy](#), [Accessibility](#), [Freedom of Information Act](#)

The footer contains three logos: the National Institutes of Health logo, the National Library of Medicine (NLM) logo, and the U.S. Department of Health & Human Services logo.

Inteleos – Clinical Trials Section

INTELEOS

Solutions for Drug Tracking+Analysis

Welcome Barbara Gilmore-Halliwell

[my workspace](#) | [my watch lists](#) | [my folders](#) | [my groups](#) | [my profile](#) | [user tips](#) | [logout](#)

SEARCH ANALYSIS CLINICAL TRIALS NEWS QUICK SEARCH for Recent Searches

Clinical Trials Search or Analysis

Select Field

Search Analysis

Drill-Down Analysis Comparison Analysis Pipeline Matrix

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Starting with Containing

- Brain Neoplasms
- Brain Neoplasms, Primary Malignant
- Brain Pathology
- Brain Stem Glioma,
- Brain Stem Neoplasms, Primary
- Brain Tumor
- Brain Tumor, Primary
- Brain Tumor, Recurrent
- Brain Tumors
- Branch Retinal Vein Occlusion
- BRCA1 Protein
- BRCA2 Protein
- Breakthrough Bleeding
- Breakthrough Pain
- Breast
- Breast Cancer**
- Breast Cancer Metastatic
- Breast Cancer With Bone Metastasis

ADD →

← DELETE

My Query

SEARCH: Select the field(s) you wish to search in from the drop-down menu; choose the term(s) from the associated lists and add them to 'My Query'. Combine fields and terms to create simple or complex queries.

Breast Cancer

Begin →



Deals & Alliance Resources Comparisons

- EvaluatePharma
- IDeals (Thomson Scientific)
- MedTrack
- Recombinant Capital's ReCap
- Windhover

EvaluatePharma: Search by Deal Type – In-licensed, Joint Venture, Company Acquisition, Product Acquisition, Out-licensed Technology

EvaluatePharma®
Helping you find value in the pharma & biotech sector

Home Peer Group Analyzer My Portfolio Reports Tools My Account Help & Support

Wednesday 11 June, 2008

Smart Search EP Vantage

NewsManager Search Only

Browse Categories

- Global Analysis (all companies) **NEW!**
- Company
- Product
- Generic Name
- Therapeutic Category
- EphMRA ATC Code
- Pharmacological Class
- Technology
- Indication
- Originator
- Market Status (Current)
- Deal Type**
- Deal Partner/Product Source

Comment

- ▶ ADA kicks off GLP-1 succession saga (10-Jun-2008)
- ▶ Glaxo seeking sharper research focus (09-Jun-2008)
- ▶ BTG predicting a rich vein of profits from Varisolve (08-Jun-2008)
- ▶ ASCO Interview - MolMed data should help deal talks (05-Jun-2008)

Analysis

- ▶ Event - The Medicines Company hoping for better treatment next time round (10-Jun-2008)
- ▶ ADA - DPP-IVs and GLP-1s steal the show (09-Jun-2008)
- ▶ ASCO EventAnalyzer - 2008's winners and losers (06-Jun-2008)
- ▶ Ipsen's attempt to enter US market met with scepticism (05-Jun-2008)

EventAnalyzer

- ▶ EventAnalyzer: Daily Market Movers (10 June 2008) (11-Jun-2008)
- ▶ EventAnalyzer: Weekly Market Movers (to 6 Jun 08) (09-Jun-2008)

EvaluatePharma®

You are here [Deal Type](#) | In-licensed | Overview

In-licensed

Overview By Company By Therapy

Reports

- ▶ Latest Product Deals (Since 1 JAN 2008) - By Date
- ▶ Largest Deals (Since 1 JUL 2007) - By Disclosed Deal Value**
- ▶ Product Deals - By Company & Year
- ▶ Product Deals - By Phase on Deal Date
- ▶ Product Deals - By Therapy Area
- ▶ Product Deals - By Technology
- ▶ Product Deals - By Indication
- ▶ Terminated Deals - By Date
- ▶ Count of Deals per Year & Type

Count of Deals per Year & Type

Deal Date	Product Count
In-licensed	
2008	116
2007	325
2006	396
2005	348
2004	447
2003	401
2002	431
2001	389
2000	335
Total (In-licensed)	3,188

EvaluatePharma – Top In-Licensed Drugs by Deal Value



Sample Deal Report from EvaluatePharma(R)

All Financial Data in US \$ (min)											
Rank	Company	Deal Type	Product	Deal Partner/ Product Source	Status on Deal Date	Deal Date	Upfront Payment	Deal Value	Deal Comment	Milestones (Development)	Milestones (Sales Related)
1	Genzyme	In-licensed	Mipomersen	Isis Pharmaceuticals	Phase III	1/7/2008	175	1,900	JAN08 In-licensed WW rights from Isis Pharmaceuticals (part of larger strategic alliance); Genzyme paid \$150m to buy 5m shares of Isis stock & will pay \$175m upfront fee, potential \$825m development & regulatory milestone payments plus up to \$750m in commercial milestone payments. Genzyme & Isis will share profits: initially 70/30 Genzyme/Isis split & reaching (on a sliding scale) 50/50 when annual WW revenues reach >\$2bn. Deal also gives Genzyme preferred access to future Isis drugs for CNS & certain rare diseases.	825	750
2	GlaxoSmithKline	In-licensed	TC-2696	Targacept	Phase II	7/27/2007	20	1,498	JUL07 Entered collaboration with Targacept covering pain, smoking cessation, addiction, obesity and Parkinson's disease; GSK to pay \$35m upfront including \$15m in equity investment, milestones up to \$1.5bn & tiered double-digit royalties on sales, in return for WW rights to develop & market candidatee from TRGT's neuronal nicotinic receptor program. GSK has option to assume development after PII. TRGT retains co-promotion option for pain to specialists & hospital based physicians in USA.	1,464	-
3	GlaxoSmithKline	In-licensed	OMP-21M18	OncoMed Pharmaceuticals	Pre-clinical	12/10/2007	-	1,345	DEC07 Research alliance with OncoMed for cancer stem cell antibody programme; GSK to pay upfront fees (comprised of cash as well as an equity investment), milestones up to \$1.4b, & double-digit royalties & also have option to invest in a future initial public offering by OncoMed.	1,345	-
4	GlaxoSmithKline	In-licensed	Elesclomol	Synta Pharmaceuticals	Phase II	10/8/2007	79	996	DEC07 GSK pays \$80m upfront to Synta. OCT07 In-licensed WW ex USA rights from Synta; GSK to pay upfront payments \$80m, milestone up to \$135m, regulatory milestones up to \$450m, commercial milestone payments up to \$300m & double-digit tiered royalties; GSK & Synta to share all development costs; GSK to purchase up to \$45m of Synta's common stock. GSK & Synta will co-promote in US; Synta to receive a tiered profit share based on levels of annual net sales.	577	296
5	Merck & Co	In-licensed	Deforolimus (MK-8669)	ARIAD Pharmaceuticals	Phase II	7/12/2007	75	927	JUL07 License WW rights from ARIAD in exchange for \$75m upfront, up to \$452m in development/regulatory milestones, up to \$200m in sales-based milestones, at least \$200m in estimated contributions by Merck to global development, up to \$200m in interest-bearing repayable development-cost advances from Merck (after ARIAD has paid \$150m in global development costs), WW ex US tiered double-digit royalties & US co-promotion (ARIAD books US sales & pays MRK 50% of income). Companies to each fund 50% of cost of US development, MRK to pay 100% of the cost of ex-US development. ARIAD to manufacture the API, & Merck will be responsible for formulation of the finished product.	452	200
6	Astellas Pharma	In-licensed	CTS-21166	CoMentis	Phase I	4/25/2008	79	746	APR08 WW rights in-licensed from CoMentis. CoMentis will receive an upfront payment of \$80m, an equity investment of \$20m & up to \$660m in milestones. In addition, CoMentis has the right to receive development milestones for next-generation beta-secretase inhibitors discovered under the terms of the research collaboration. Astellas will fund 100% of the pre-Phase III global development costs & CoMentis will share the Phase III development costs. Astellas has exclusive worldwide commercialisation rights while CoMentis retains the right to co-promote in the U.S., where profit will be shared. CoMentis will receive royalties on sales outside the U.S.	648	-
7	Sanofi-Aventis	In-licensed	IL-6 Trap	Regeneron Pharmaceuticals	Phase I	11/29/2007	93	707	NOV07 In-licensed WW rights from REGN. REGN to receive \$85m upfront payment, \$475m R&D funding over next 5 yrs, equity investment of \$312m & up to \$250m milestone payment for interleukin-6 receptor (IL-6R) MAb, Delta-like ligand-4 (Dl4) Inhibitor MAb & any other MAB therapeutics developed through collaboration. Sanofi-Aventis will have an option to extend the research agreement for up to an additional three years. Regeneron will have the right to co-promote any and all collaboration products worldwide. In US, profits will be shared equally. Ex. US, profits will be split on a pre-determined sliding scale with Sanofi-Aventis' share ranging from 65% to 55%. Payments include product lines: MAb Research Project & Dl4 Inhibitor.	-	273
8	Boehringer Ingelheim	In-licensed	Immunology Research Project	Abylnx	Research project	9/7/2007	-	656	SEP07 Abylnx & Boehringer Ingelheim collaborate jointly in the discovery of up to 10 Nanobody therapeutics against agreed targets across multiple therapeutic areas including immunology, oncology & respiratory. Boehringer expects to pay up to €75m during R&D term (including €15m in equity) plus up to €125m in development milestones per Nanobody & royalties. Abylnx has certain co-promotion rights in Europe.	649	-

Sample View of Peer Group Analyzer – Comparing Mid Cap Companies

Evaluate Pharma®
Helping you find value in the pharma & biotech sector

Home Peer Group Analyzer My Portfolio Reports Tools My Account Help & Support

Global Analysis (All companies)
Countries
Sectors
Create Peer Group

Pharmaceutical
Size
All Size
Large Cap (\$30bn+)
Mid Cap (\$2.5bn-\$30bn)
Small Cap (\$250m-\$2.5bn)
Micro Cap (\$100m-\$250m)
Nano Cap (<\$100m)
Private
Subsidiary
Joint Venture
Dead Company

NewsManager Search Only
Browse Categories
Global Analysis (all companies) NEW!
Company
Product
Generic Name
Therapeutic Category
EphMRA ATC Code
Pharmacological Class
Technology
Indication
Originator
Market Status (Current)
Deal Type
Deal Partner/ Product Source

Alpha Tools
NPV Analyzer NEW!
Calendar of Events NEW!
EP Vantage NEW!

Core Tools
Merge Companies
Company Rank
Peer Group Analyzer NEW!

What's New
EvaluatePharma's Coverage Continues to Grow
16 NEW Companies Available...
Q1 2008 Results: Company Analysis 02-Jun-2008
Increased Coverage: 22 NEW Companies Available 01-May-2008
More

Evaluate Pharma®
You are here Peer Group Analyzer | Mid Cap (\$2.5bn-\$30bn) | Worldwide | Overview

Mid Cap (\$2.5bn-\$30bn)

Worldwide Therapy Areas Generics USA News NPV NEW! Calendar of Events NEW! R&D Valuation Financials Patents Deals

Overview Archived Forecasts

Company Ranking Reports
WW Prescription (Rx) Sales
WW Prescription (Rx) plus Alliance & Royalty
WW Prescription (Rx) & OTC
Inline vs. Pipeline (2012)
WW Pharmaceutical Sales
Enterprise Value - Previous Close
WW Biotechnology Sales
2007 Pharma R&D Ranking

Worldwide Prescription (Rx) Sales: Top 15 in 2012

Company	Sales (US \$)
Astellas Pharma	9673
Daiichi Sankyo	9751
Eisai	6489
Genzyme	5815
UCB	5780
Mylan	5742
CSL	5336
Allergan	4832
Celgene	4451
Solvay	4387
Chugai	4083
Mitsubishi Tanabe Pharma	3771
STADA Arzneimittel	3544
Forest Laboratories	3369
Shire	3315

WW Rx Sales: US \$ (min)

Calendar of Events
Financial Results & Presentations: Next 12 Months (by date)
All Product Events: Next 12 Months (ranked by NPV as % of Mkt Cap)
Product Approvals: Next 12 Months (ranked by NPV as % of Mkt Cap)
PDUFA Dates: Next 12 Months (ranked by NPV as % of Mkt Cap)
Regulatory Filings: Next 12 Months (ranked by NPV as % of Mkt Cap)
Clinical Trial Initiation & Results: Next 12 Months (ranked by NPV as % of Mkt Cap)
Patents & Litigation: Ongoing & Next 12 Months (ranked by NPV as % of Mkt Cap)

Worldwide Prescription Rx Sales/ Ranking/ Market Share

Thomson's - IDEals





The Investigational Drugs database
ALERTS

Drug Alerts

QuickSearch:

SEARCH

Drug ▼

Posted on : 10th June 2008

Drugs: Priority Alert

Adolor and GSK launch Entereg for post-operative ileus in the US

Adolor Corp, June 10, 2008
News Release

Adolor and **GlaxoSmithKline** (GSK) have launched their mu opioid receptor antagonist, **Entereg** (alvimopan), in the US for post-operative ileus (POI).

The drug was approved by the FDA in May 2008 [**908026**].

Michael R Dougherty, President and CEO of Adolor, said: "Entereg is the only approved product with a demonstrated ability to accelerate gastrointestinal recovery following bowel resection surgery. POI is a serious condition that can have negative consequences for patients, and impose considerable expense on the healthcare system. We are working closely with GSK to enroll hospitals across the US to make Entereg available to bowel resection surgical teams and patients."

In April 2002, Adolor and GSK agreed to codevelop the drug [**447874**].

In February 2007, a Friedman Billings Ramsey analyst believed that the overall market opportunity was sufficiently large to accommodate both Entereg and its primary competitor, **Wyeth** and **Progenics Pharmaceutical's subcutaneous formulation of methylnaltrexone bromide**. The analyst expected Entereg to gain FDA approval for POI by early 2008 and commented that there was a possibility that Entereg's efficacy and safety profile would resonate more with doctors [**779552**], [**914770**].

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Avid Radiopharmaceuticals begins phase II Alzheimer's trial of 18F-AV-45
Avid Radiopharmaceuticals Inc, June 10, 2008

Radius selects RAD-140 as lead from androgen antagonist sarcopenia program
Radius Health Inc, June 10, 2008

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Thomson Scientific - IDEals

IDEals Create a new IDEals Analysis

STEP 2

home > Step1 > step 2

Select a general therapeutic area

Neoplasm

OR

Start by selecting a drug class by mode of action

Antimicrobial

cancel

Antimicrobial

- Antimicrobial
- Blood system agent
- CNS modulator
- Cardiovascular agent
- Cell control agent
- Dermatological agent
- Diagnostic agent
- Gastrointestinal system agent
- Gene target
- Genetic modulator
- Hormone modulator
- Immunomodulator
- Ion modulator
- Local hormone modulator
- Metabolic modulator
- Musculoskeletal system modulator
- Neurotransmitter modulator
- Ophthalmological agent
- Other actions
- Protein target
- Renal system agent
- Reproductive system modulator
- Respiratory system agent

Neoplasm

- Cardiovascular disease
- Degeneration
- Dermatological disease
- Endocrine disease
- Fatigue
- Gastrointestinal disease
- Genetic disorder
- Genitourinary disease
- Growth disorder
- Gynecology and obstetrics
- Hematological disease
- Immune disorder
- Infection
- Inflammation
- Injury
- Metabolic disorder
- Mouth disease
- Musculoskeletal disease
- Neoplasm**
- Neurological disease
- Nutritional disorder
- Ocular disease
- Otorhinolaryngological disease
- Prophylaxis
- Psychiatric disorder
- Respiratory disease
- Temperature disorder
- Toxicity & intoxication
- Ulcer
- Unidentified

Thomson-Pharma's Deal Search

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Quick Search Search as a Drug/compound name Search

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FORM SEARCHES

- General Text
- Clinical Trials →
- Drugs
- Intellectual Property →
- Literature and News
- Sequences
- Regulatory
- Deals**

Write your own

- Drugs

CUSTOM SEARCH

- Custom Form Request

MY SEARCHES

- Latest Searches
- Saved Searches

GUIDED SEARCHES

- Biology - ADMET
- Competitive Intelligence - Drugs
- Competitive Intelligence - Therapy Area
- Licensing and Business - Deal finder
- Cited Reference Search

Form search - Deals Help

Topic (Title, keywords, abstract) Title only

Company 1

Company 2

Organization type

Deal type

Territory
Enter territory names within "" for where the Deal is active. E.g "France" OR "Spain". Precede territory names with 'exclude' to search for territories not included. E.g. "world" exclude "Japan"

Drug

Therapy area

Technology

Action

Any text

Date

Added Date

- Current week
- Latest 2 weeks
- Latest 4 weeks
- Year to date
- Latest 5 years
- All years

Deal Status

- Any Status
 - Active Deals
 - Completed Deals
 - Terminated Deals
 - No Development Reported

Deal & Alliance - MedTrack

Basic Search ?

Search by

Search by Date ?

Time Period

No Restriction

Date Range

From:

To:

Geography

Select Region(s) or Countries:

- NORTH AMERICA
- USA
- Canada
- EUROPE
- Austria
- Belgium
- Czech Republic
- Denmark
- Finland
- France

Categories ?

Select Deal Categories based on

Product

Technology

Miscellaneous

Therapeutic Category

- All Areas
- Autoimmune and Inflammation
- Blood and Lymphatic System
- Cancer
- Cardiovascular and Circulatory System

Deal Parties

- All Parties
- Pharma/Pharma
- Pharma/Biotech
- Biotech/Biotech
- Drug Delivery

Deal Types

- All Deals
- Acquisition
- Co-development
- Co-Market
- Co-promotion

Clinical Trial Phase

- All Phases
- Research
- Preclinical
- Phase I
- Phase II

Area of Deal Focus

- All Areas
- Nutrition
- Devices
- Services
- Technology

Financial Terms ?

Payment Type	Min (in \$millions)	Max (in \$millions)
Total Deal Size	<input type="text"/>	<input type="text"/>
Development Fees	<input type="text"/>	<input type="text"/>
Equity	<input type="text"/>	<input type="text"/>
Funding	<input type="text"/>	<input type="text"/>
License fees	<input type="text"/>	<input type="text"/>
Milestone	<input type="text"/>	<input type="text"/>
Payments	<input type="text"/>	<input type="text"/>
Royalty	<input type="text"/>	<input type="text"/>
Termination Fees	<input type="text"/>	<input type="text"/>
Upfront cash	<input type="text"/>	<input type="text"/>
Upfront Equity	<input type="text"/>	<input type="text"/>

Note:
The Payment Types listed above are terms or conditions specified by the company or classifications determined from the public information evaluated. A specific Payment Type may not retrieve all possible deals from a search. For more accurate search results, Please try multiple criteria.

MedTRACK – Company Comparison



Selected Companies for Comparison

Biotechnology:

Amgen Inc. (AMGN)

Pharmaceuticals:

Bristol-Myers Squibb Co. (BMY)

Genentech Inc. (DNA)

Roche Holding AG (RHHBY)

Comparison by Multi Period Financials

Annual Income Statement

	2007			
	AMGN	BMY	DNA	RHHBY
REVENUES:				
Sales	14,311.0	19,348.0	11,724.0	42,977.2
Other Revenues	460.0	-	-	-
Total Revenues	14,771.0	19,348.0	11,724.0	42,977.2
EXPENSES:				
Cost Of Goods Sold	2,308.0	6,026.0	1,500.0	12,668.6
Cost Of Goods Sold, Total	2,308.0	6,026.0	1,500.0	12,668.6
GROSS PROFIT	12,463.0	13,322.0	10,224.0	30,308.7
Selling General & Admin Exp.	3,485.0	6,227.0	2,077.0	10,058.5
R & D Expense	3,247.0	3,080.0	2,293.0	7,214.7
Stock-Based Compensation	-	133.0	403.0	540.1
Selling Gen. & Admin Exp., Total	6,732.0	9,440.0	4,773.0	17,813.3
Amort. Of Intangible Assets	295.0	-	-	-
Depr. & Amortization, Total	295.0	-	-	-
OPERATING PROFIT	5,436.0	3,882.0	5,451.0	12,495.3
Interest Expense - Non Finance Div.	-328.0	-422.0	-76.0	-256.7
Interest Expense, Total	-328.0	-422.0	-76.0	-256.7
Interest And Invest. Income	309.0	241.0	270.0	959.5

MedTRACK – Un-partnered Deals?

SmartBar MedTRACK Japan -- Inside MedTRACK -- -- My Portfolio --

MedTRACK Disease Hub

Industry Hub | Drug Delivery | Deals & Alliances Usage Stats | Logout

April 22, 2007 Home Help ?

Search: Company Name

- Company Explorer
- Drug Classification
- Financial Tools
- Keyword Search
- Milestone Calendar
- Product Sales
- Extn. Product Profiles
- Research Tools
- News
- Special Items

MedTRACK Disease View

Pipeline Financial Both Product Sales Contact Patents Deals Milestones News Epidemiology

Your selected criteria:
Cancer >> Multiple Myeloma [\[Download All Tab Excel\]](#)

63 companies passed criteria in Category.

Search within results by

[Entire List](#) | [Result Pages : 1 2 3 4 5 6 7](#)


Product Partnering Filter >> [All Multiple Myeloma Products](#) | [Partnered](#) | [UnPartnered](#)

[Go to Full Pipeline](#) Page 1 of 7

= Updated in Last 7 Days = Global Private/NonUS Public

Company Name	Symbol	Total Products	Total Trials	PC	I	II	III	PA	A	MP	D	F	N	More Info
Abiogen Pharma S.p.A.	Private	39	0	1	--	--	--	--	--	--	--	--	--	- - - -
Affimed Therapeutics AG	Private	10	0	--	--	--	--	--	--	--	--	1	--	- - - -
<input type="checkbox"/> Amgen Inc	AMGN	76	1	--	1	--	--	--	--	--	--	--	--	Q C S G N
AmpliMed Corporation	Private	6	1	--	1	--	--	--	--	--	--	--	--	- - - -
Antyra, Inc.	Private	8	0	--	--	--	--	--	--	--	--	1	--	- - - -
Ascenta Therapeutics, Inc.	Private	7	0	1	--	--	--	--	--	--	--	--	--	- - - -
<input type="checkbox"/> AstraZeneca Plc	AZN	291	1	--	1	--	--	--	--	--	--	--	--	Q C S G N

Recombinant Capital's ReCap


RECOMBINANT CAPITAL

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ANALYST'S NOTEBOOK

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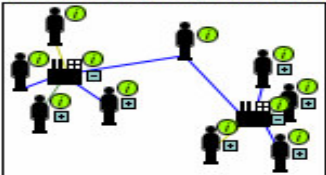
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.....

Take a peek inside the **Analyst's Notebook**. In this addition to our web services, we showcase a collection of material from Recap's consultants, including slide presentations, trend analyses, alliance discussions and much more. In the Notebook, you will find a couple of old favorites: the (newly updated) **Average Deal Terms** slide feature, and the **Daily Deal**. Also, don't miss the **Key Deals** discussion of a recent development in biotech partnering, or the page of slide **Presentations**, including our most recent presentation for the BIO 2006 conference.

Power Brokers of Biotech




Analyst's Notebook

Daily Deal	Signals Spotlight
Trends	Slides
Key Deals	

We continue to offer our **Power Brokers** visualization tool, utilizing our directors database to show the connections between 9,418 individuals who serve on biotech company boards of directors. Power

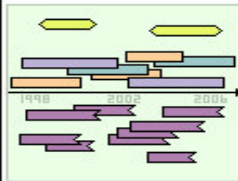
SIGNALS



Much Ado About Biologics
Most big pharmas have been slowly building their stores of protein- and antibody-based medicines, but they picked up the pace in 2007 with a series of clever acquisitions.

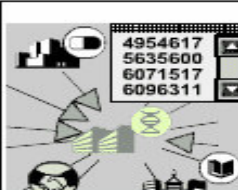
-----Currently On Signals Magazine-----

RECAPRX



RecapRx, is the answer to real world business questions surrounding clinical drug development. This new service features complete coverage of biotech clinical trials, with indication timelines, individual trial details, supporting regulatory documents & abstracts.

RECAPIP



RecapIP, a new way to explore & understand biotech intellectual property. Patents & patent applications, linked to their commercial agreements, reveal a world of 'partnered IP' that has been

Recombinant Capital's ReCap

RDNA RECOMBINANT CAPITAL		TEN DEALS THAT CHANGED BIOTECH					
ANALYST'S NOTEBOOK		This companion to the Signals Magazine article contains information available in ReCap's subscription data service, rDNA.com. For this special report, however, we've made the data available to all readers. To learn more about rDNA.com, check out the information site or call Recombinant Capital (925) 952-3870.					
Agreement	Date	Type	Size	Equity	Roy.	Subject	
1. Lilly / Genentech	8/78-7/80	D,L			8%	Humulin recombinant insulin	
2. Kirin Brewery / Amgen	5/84-10/89	CoD,JV,L	\$44.5		5%	EPO, G-CSF & GM-CSF in Japan	
3. GlaxoSmithKline / BioChem Pharma	1/90-6/99	E,JV,L,R	\$45.9	\$34.0	15%	Epiriv 3TC nucleoside analogue for AIDS & HBV	
4. Roche / Genentech	9/90	Acq	\$2014.0			60% acq. & governance agreement	
Roche / Genentech	6/95-7/99	CoD,L,O,S	\$0.0		22%	Ex-US products governance agreement	
5. Allergan / Ligand Pharmaceuticals	6/92-1/95	E,JV,Ter,W	\$39.0	\$24.0	50%	Screening via retinoid receptors	
Allergan / Ligand Pharmaceuticals	1/95-9/97	Ast,CoD,E,JV,O,Ter,W	\$56.0	\$6.0	50%	Allergan/Ligand JV based on retinoids	
6. Lilly / Centocor	7/92-6/96	CoD,Di,E,L,O	\$124.5	\$50.0	50%	Centoxin & ReoPro (CentoRx - abciximab) ex-Japan	

Windhover Business Intelligence

WINDHOVER HEALTH CARE BUSINESS INTELLIGENCE

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Search Deals

Use these selection lists or text fields to search. You may use *and*, *or*, *not*, *c* search for an exact phrase, place it in quote marks.

Company Name:

Deal Type:

Deal Industry: 

Potential Deal Value: to (\$m)

Deal Headline:

Deal Date: Anytime Month Day Year

Free Text:

Key Words:

(additional field)

Results Per Page:

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- All
- Biotechnology
- ADMET
- Antibodies
- Antisense, Oligonucleotides
- Drug Discovery Tools
- Gene Therapy, Cell Therapy
- Genomics-Proteomics
- Large Molecule
- Liposomes
- Nanotechnology, Chips, etc.
- Pharmacogenetics-Pharmacogenomics
- Synthesis Technologies, Production Processes
- Transgenics
- Contract Research
- Distributors
- In Vitro Diagnostics
- Biosensors
- Chemistry, Immunoassay
- Cytology
- Glucose Testing
- Hematology, Coagulation
- Molecular Diagnostics & Genetic Testing
- Saliva-based Testing
- Therapeutic Drug Monitoring
- Urine-based Testing
- Laboratory Testing Services
- Pharmaceuticals
- Chiral Chemistry
- Drug Delivery

Deals & Alliances - Comparison

	Coverage	Sources	Special Notes
Evaluate Pharma	Historic sales 1986 - present	SEC Filings, Annual & quarterly reports, presentations to analysts & investors, FDA, USPTO, equity analysts	<ul style="list-style-type: none"> ■ Benchmark “peer group’ companies & portfolios ■ NPV tools - Unique to EP – forecasts to 2028 ■ Gain insight into all sales at risk from patent expiry
IDeals	1998 - present	Investigational Drug Database (IDDB) records	<ul style="list-style-type: none"> ■ Subset of data from Investigational Drugs Database (IDDB) ■ Searchable by therapeutic area and mode of action
MedTrack	1998 – present (note: ownership change from LSA to DataMonitor in 2006)	<ul style="list-style-type: none"> ■ SEC filings ■ Press releases ■ Company websites ■ Meetings abstracts ■ Literature ■ News ■ Proprietary spiders to Company websites 	<ul style="list-style-type: none"> ■ Partnered & un-partnered search capabilities ■ Excellent export & share capabilities ■ Databases within include – D& A, Epidemiology, Pipeline profile, deal screener, trend analysis, price to news, venture finance, company explorer, company merger tool, patent expiry ■ Excellent customer service

Deals & Alliances - Comparison

	Coverage	Sources	Special Notes
ReCap	1988-present	SEC filings & exhibits Press Releases	<ul style="list-style-type: none"> ■ On-demand service for analysis of materials contracts (extra \$\$\$) ■ Comprehensive consulting services ■ Trend data available without subscription ■ Databases available from their website (valuation, alliances, clinical trials, IP) ■ Data difficult to export & share
Windhover (SIS)	1991-present	<ul style="list-style-type: none"> ■ SEC filings & exhibits ■ Press Releases ■ Company communications ■ Analyst reports ■ Secondary news sources ■ Editor's Meetings with Companies ■ Publication – Medtech Insight 	<ul style="list-style-type: none"> ■ Comprehensive deals, alliance and diagnostics database ■ Host analyst partnering conferences ■ New search & advanced search options ■ Links to companion Windhover products (Journals - In Vivo, Start-Up, RPM Report) – linked to deals db ■ Values deals by TA, company size, phase ■ Excellent customer service

Deals & Alliance Source Comparison

	Partnered/ Un- partnered Seachable?	Diagnostics	Inventor (person)
Evaluate Pharma	No	No	No
Ideals	No	No	No
MedTrack	Yes	Yes	No
ReCap	No	No	No
Windhover	No	Yes	No

Analysis: Requestor's role dictates info needed.

	Early Stage Company	Established Pharma / Large Biotech
Development	<ul style="list-style-type: none"> ■ Pipeline work ■ Complexity & cost of clinical trials ■ Development strategies ■ Manufacturing outsourcing 	<ul style="list-style-type: none"> ■ Availability of patients for clinical trials (based upon competitive landscape & other ongoing clinical trials). Both capture potential patients.
Regulatory & Legal	<ul style="list-style-type: none"> ■ Quality ■ Broad application of product (IP) for future 	<ul style="list-style-type: none"> ■ Fit with existing pipeline ■ IP value
Product Development & New Product Planning	<ul style="list-style-type: none"> ■ Market potential ■ Competitive landscape ■ Market entry possibilities ■ Marketing rights licensing 	<ul style="list-style-type: none"> ■ Market potential ■ Fit with existing pipeline ■ Fit with existing sales force ■ Competitive landscape
Management	<ul style="list-style-type: none"> ■ Track record of internal folks ■ Development & commercial competitors 	<ul style="list-style-type: none"> ■ Lead molecules / consolidation of pipeline

Analysis: Public vs. private company?

Data Needed	Public Company	Private Company
Product & Pipeline	<ul style="list-style-type: none"> ■ <u>Pipeline Databases</u> - <ul style="list-style-type: none"> □ ADIS R&D Insight □ IMS R&D Focus □ Thomson Pharma – IDDB □ Pharma Projects □ Prous Integrity □ Inteleos ■ www.drugname.com ■ Drugs @ FDA 	<ul style="list-style-type: none"> ■ <u>Pipeline Databases</u> - <ul style="list-style-type: none"> □ ADIS R&D Insight □ IMS R&D Focus □ Thomson Pharma – IDDB □ Pharma Projects □ Prous Integrity
Company Information & Manufacturing Capacity	<ul style="list-style-type: none"> ■ <u>Company</u> – BioScan, Coombs, Hoovers, IMS, VeriSpan ■ <u>Manufacturing Capacity</u> – analyst reports, 10K & news 	<ul style="list-style-type: none"> ■ <u>Company</u> –BioScan, Coombs, Hoovers, newspapers local to company location ■ Deals databases
Financials & Forecasts	<ul style="list-style-type: none"> ■ SEC Filings (Hoover, 10K Wizard) ■ D&B ■ Wall Street analysts ■ IMS, EvaluatePharma, BioPharm Insight 	<ul style="list-style-type: none"> ■ Local Press (http://newsdirectory.com) ■ D&B

Analysis continued.....

Data Needed	Is the company public ?	Is the company private ?
Business News	<ul style="list-style-type: none"> ■ <u>Subscription based news</u> - (BioCentury, BioWorld, SCRIP, Pink Sheet, IDRAC news etc.) ■ <u>News Alerts</u> (Factiva, Lexis Publisher, NewsEdge) ■ <u>Free</u> (Bio & FDLI Smart Briefs, Fierce Biotech, First Word, DMS Alerts, BioPharm Insight, PharmaVoice, DMS Alerts) 	<ul style="list-style-type: none"> ■ <u>Local press</u> where the company is located. Global news available at: www.newsdirectory.com ■ Deals & alliance databases under the “public” company the deal was done
Scientific News	<ul style="list-style-type: none"> ■ Scientific alerts (Commercially available or NCBI) ■ Prous Drug News Daily 	<ul style="list-style-type: none"> ■ Conference proceedings
Other	<ul style="list-style-type: none"> ■ Patents 	<ul style="list-style-type: none"> ■ Patents



Business News Sources:

Daily Biotech & Pharma Industry News Updates –

- AdvaMed SmartBrief** (no cost)
- BioCentury** - (subscription based)
- BioSpace Diagnostics** (no cost)
- BioSpace GenePool** (no cost)
- Biotechnology Industry Organization (BIO) SmartBrief** (no cost)
- BioWorld Today** (subscription based)
- Device Space Daily** (Medical Device & Diagnostics daily news (no cost)
- DMS Alerts**- (no cost) - Deals & Alliance News
- FDC Reports Pink Sheet** – (Subscription)
- Food & Drug Law SmartBrief (FDLI)** (no cost)
- FierceBiotech** (no cost) – RSS available
- First Word** (no cost & subscription based depending on level)
- Informa Healthcare –SCRIP** (subscription based) – RSS available
- Prous Drug News Daily** (subscription)

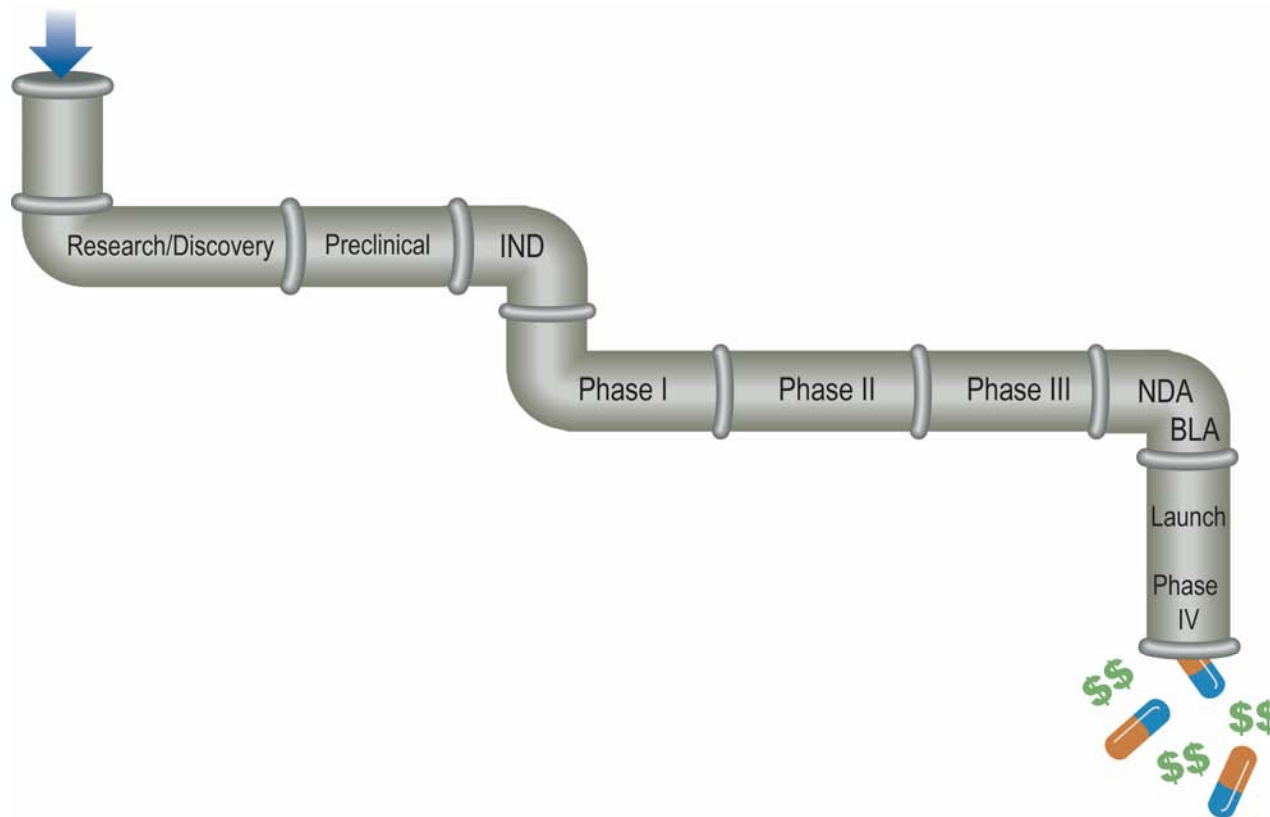
Weekly Biotech & Pharma Industry News Update(s)

- CHI Weekly Update (Cambridge Health Institute)** (no cost)

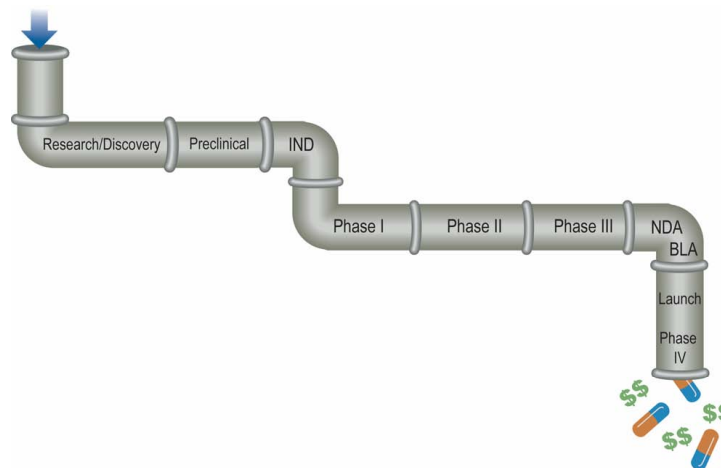
Monthly Biotech & Pharma Industry News Update(s) –

- BioPharm International** (no cost)
- IMS Health – World Market Summary** (no cost)
- PharmaVoice** (basic no cost, premium subscription available)

Pipeline – Focus by stage

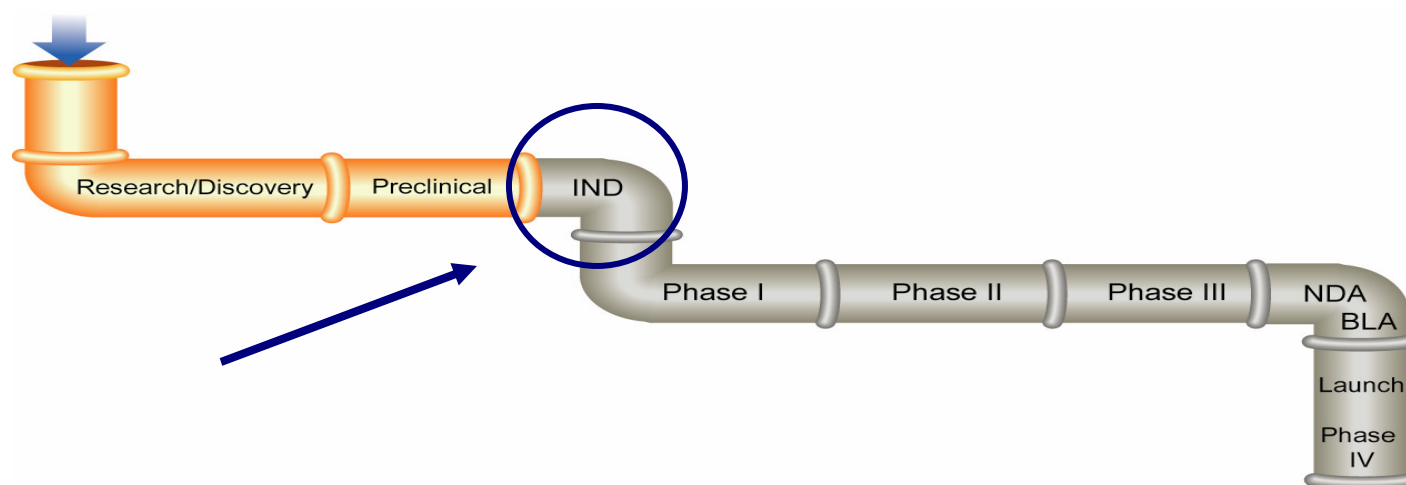


Where to look & what to look for will depend on phase of development -



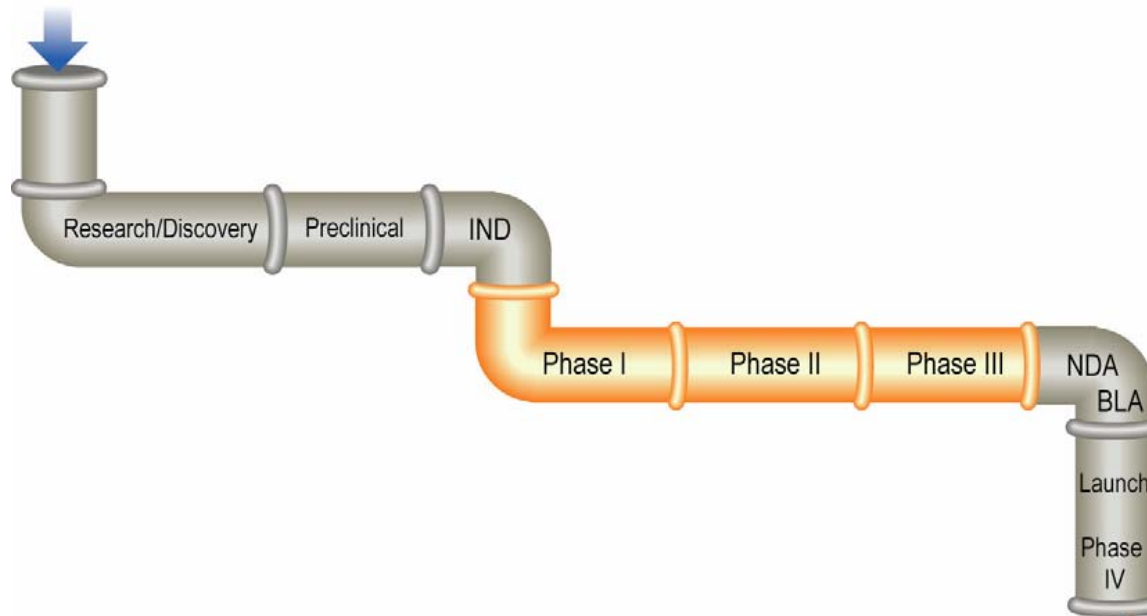
Pre-clinical	Phase I	Phase II	Phase III	Submission	Launch
<ul style="list-style-type: none"> ■ Scientific lit ■ Conference lit ■ Patents ■ Health Stats ■ Pipeline dbs ■ Business news 	<ul style="list-style-type: none"> ■ Pipeline dbs ■ Scientific lit ■ Clinical trials ■ Analysts ■ HCUP data 	<ul style="list-style-type: none"> ■ Pipeline dbs ■ Scientific lit ■ Conferences ■ Clinical trials ■ Business news ■ Analysts 	<ul style="list-style-type: none"> ■ Pipeline dbs ■ Scientific lit ■ Conferences ■ Clinical trials ■ Analysts ■ Business News ■ Deals dbs 	<ul style="list-style-type: none"> ■ Pipeline dbs ■ Regulatory (IDRAC) ■ FDA 	<ul style="list-style-type: none"> ■ Analysts ■ SEC filings ■ Business News ■ PDR/ GenRX ■ Redbook ■ IMS & Scott Levin Audits

Drug Development – Early Research



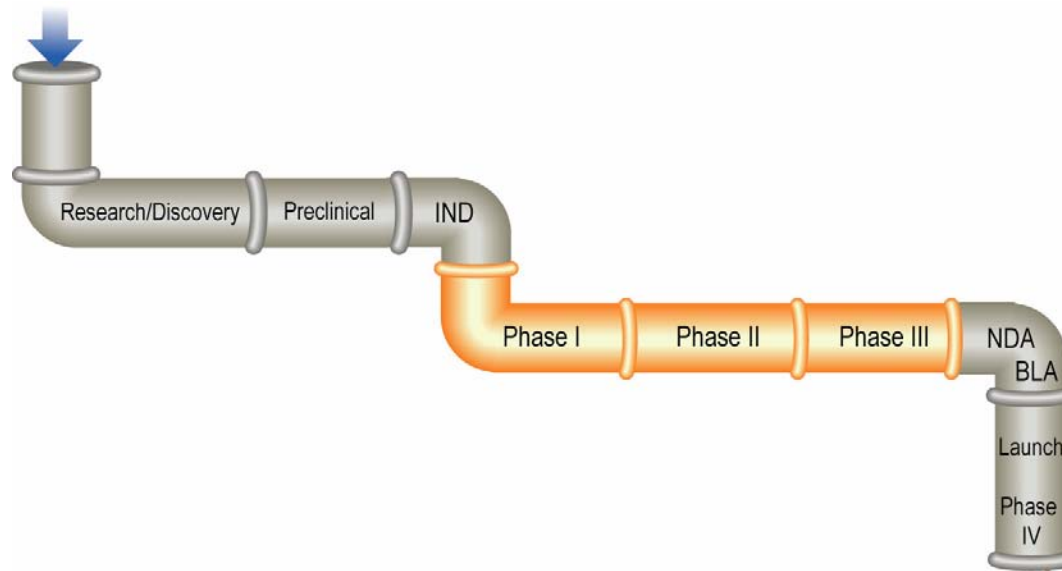
Nomenclature	Sources
<ul style="list-style-type: none">■ Chemical names■ Laboratory Codes■ CAS registry numbers	<ul style="list-style-type: none">■ Conference proceedings■ Patents■ Drug pipeline databases■ Scientific literature

Pipeline Development – Clinical Phases



Clinical Trials Questions	Studies that provide answers
<ul style="list-style-type: none">■ Safety & Efficacy■ Maximum tolerated dose■ Half-life■ Interactions with other drugs	<ul style="list-style-type: none">■ Formulation development■ Safety & efficacy■ Competitive products & their trials■ Don't ignore terminated trials■ Label considerations

Drug Pipeline Development – Clinical



Nomenclature	Sources
<ul style="list-style-type: none"> ■ Non-proprietary names ■ USAN (U.S. adopted names) ■ INN (International non-proprietary names) ■ In addition to the lab codes, CAS RN's and chemical names (previous phases) 	<ul style="list-style-type: none"> ■ Scientific literature ■ Meetings & conference proceedings ■ Pipeline databases ■ Clinical trial databases ■ Analysts & forecast resources

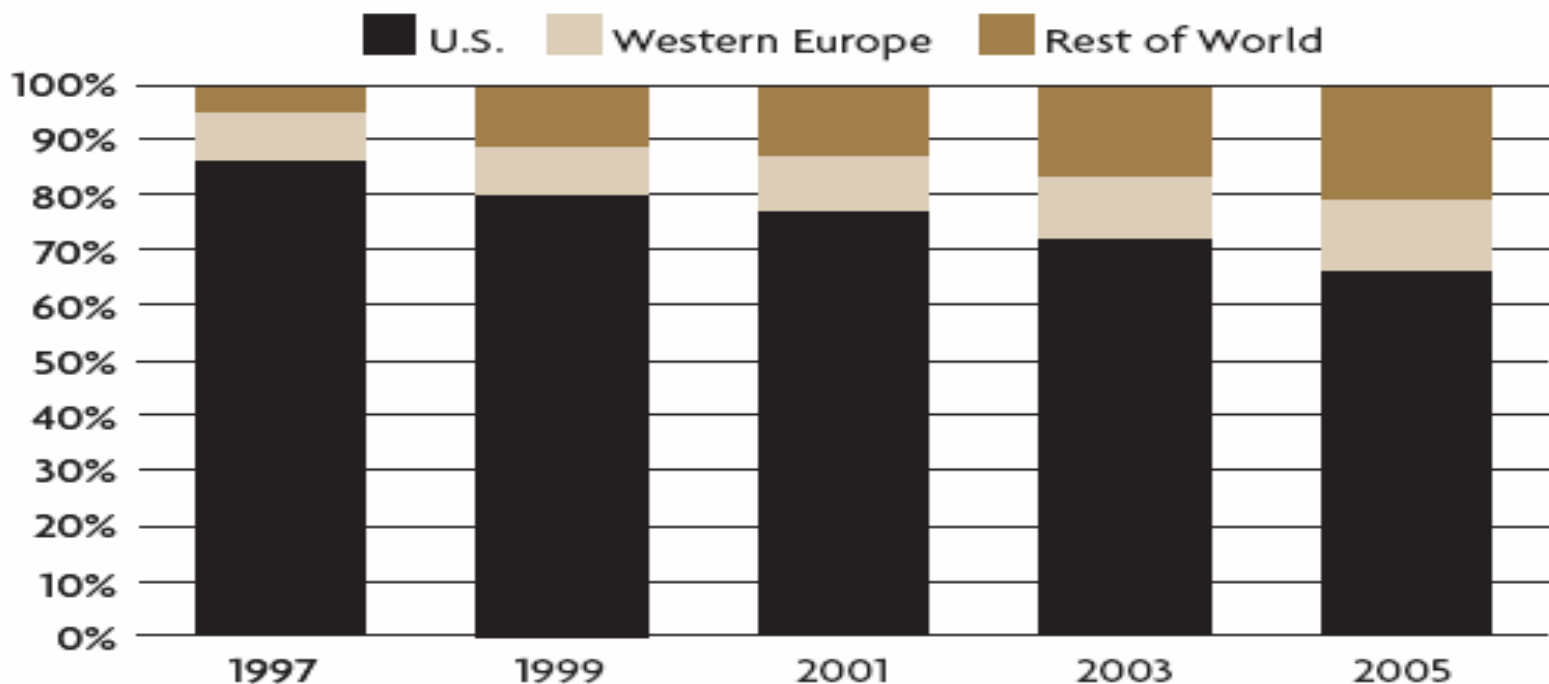


Changes in the Investigational Drug Research Process

- Increase in the number & size of clinical trials per New Drug Application
 - 1985 – 1988: Average # = 36 (3,200 patients tested/NDA)
 - 2000 - 2005: Average # = 70 (4,500-5,000 patients/NDA)
- Leading US Pharmaceutical companies increased # of new drug trials 52% since 2002
 - (Source: Outlook 2007 from Tufts Center for the Study of Drug Dev)
- Clinical testing phase gradually lengthening
 - Rise from mean time of 5.5 years in 1980's to 6.5 years in the 1990's/
 - In 2002 – 2004 duration extended 7 years
 - (Source: PhRMA 2007 Innovation.org)

Clinical Investigations are going global -

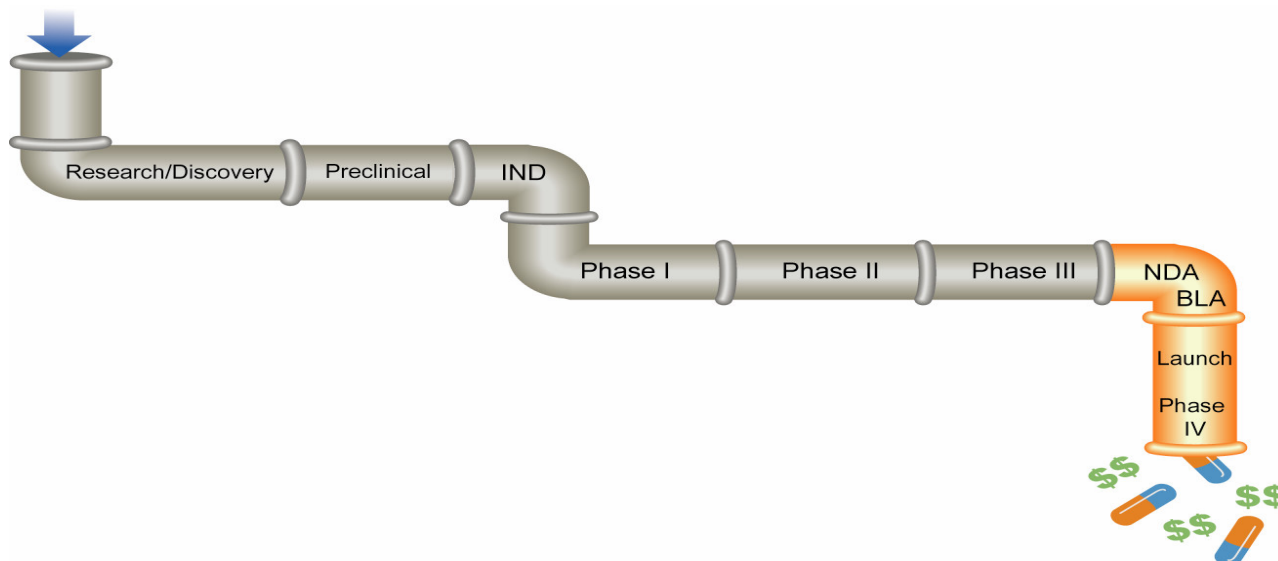
Distribution of 1572 Forms by Location of Investigative Site



Note: A 1572 form must be submitted to the FDA by a clinical investigator prior to initiating a study in human subjects.

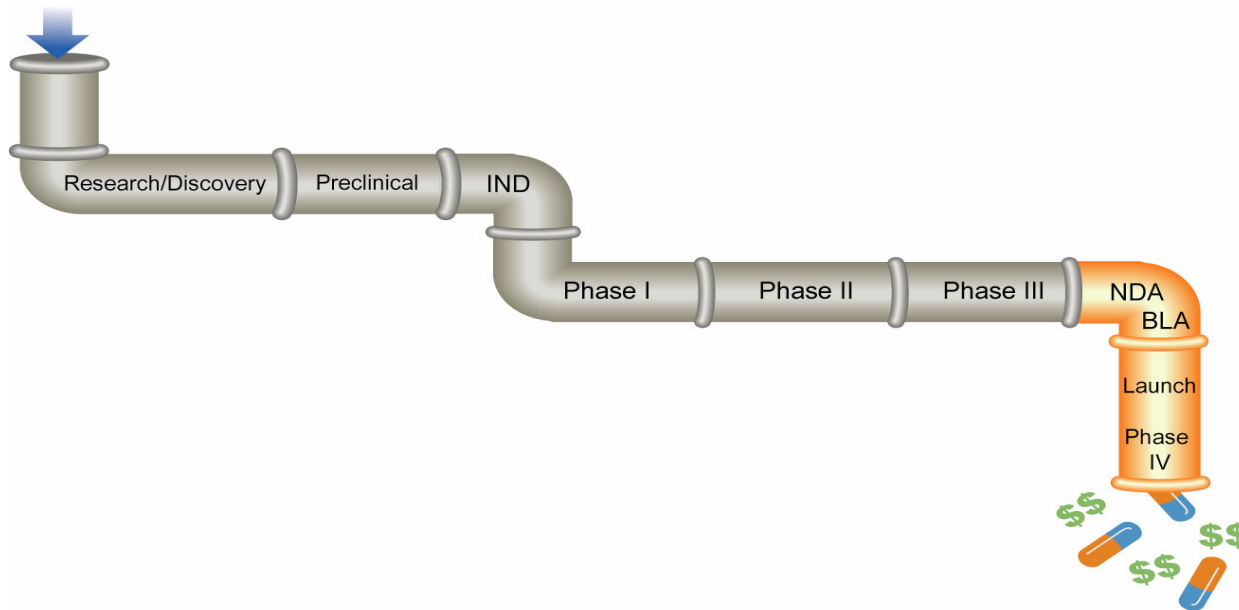
Source: Tufts Center for the Study of Drug Development

NDA Preparation & Filing



NDA Filing	Approval /Launch Prep
<ul style="list-style-type: none"> ■ Follows clinical trials ■ Clinical trial data analysis phase ■ NDA / BLA electronic submissions ■ Manufacturing / CRM inspection ■ Label reviews ■ Publication planning ■ MD / RN Educations 	<ul style="list-style-type: none"> ■ FDA has 6 months for standard review; priority reviews are shorter ■ In most cases, FDA review time exceeds 6 months. Average is 2 years. PDUFA purpose is to shorten time to approval ■ Once NDA approved, drug marketable

Pipeline Development – NDA/Launch/Post Marketing



Nomenclature	Sources
<ul style="list-style-type: none"> ■ USAN/USP (established name) ■ Proprietary names / Chemical names ■ Generic names ■ Brand names 	<ul style="list-style-type: none"> ■ Patent literature ■ Business literature ■ Clinical literature ■ Analysts & Forecasts ■ FDA & internet regulatory sites (IDRAC)



Drug Pipeline Databases

- ADIS - R&D Insight
- IMS R&D Focus – IMS Health (IMS Global Services)
- Investigational Drugs Database (IDDB) – Thomson Scientific
- Inteleos (Elsevier)
- Pharmaprojects – (Informa Healthcare)
- Prous Integrity
- Others Portals Containing Pipeline Data: BioPharm Insight / MedTrack

Revise Search Back to Results Document

At A Glance Organisations Phase Overview Properties Adis Evaluation Scientific Summary History References Result 1 of 1 EMAIL


Epoetin alfa - Kirin-Amgen

Epoetin - Amgen; Epoetin- α ; Epoetin-alpha; Epogen[®]; Epoimmun[®]; Eprex[®]; Erypo[®]; Espo[®]; KRN 5702; Procrit[®]; recombinant human EPO; recombinant human erythropoietin; rHuEPO

LEHMAN MARKET ANALYSIS

Company	Indication / Class	Region	Patent Expiry	Launch Date	Probability Of Success	Licensed Status	Peak Sales	Year Of Peak Sales	Cycle
Amgen	Anaemia, dialysis only / Red blood cell stimulation	US	Jun-2012	1989	100%		\$3300m	2011	
Amgen	Anaemia, non dialysis / Red blood cell stimulation	ex-US	Dec-2004	1990	100%	Royalty	\$1235m	2002	
Amgen	Anaemia, non dialysis / Red blood cell stimulation	US		1989	100%	Royalty	\$3030m	2002	
Chugai	Anaemia / Red blood cell stimulation	Japan		1990	100%	In licensed	\$750m	2012	

IMS R&D Focus -



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24 October 2006

- [R&D FOCUS >>](#)
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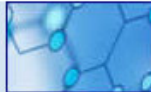
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Investigational Drug Database "IDdb"

The screenshot shows the 'ALERTS' section of the IDdb website. The header includes the IDdb logo and the text 'The Investigational Drugs database'. Below the header, there is a 'QuickSearch' field with a search button and a dropdown menu set to 'Drug'. The main content area displays a 'Drugs: Priority Alert' posted on June 10, 2008. The alert title is 'Adolor and GSK launch Entereg for post-operative ileus in the US'. The text of the alert describes the launch of Entereg (alvimopan) by Adolor Corp. and GlaxoSmithKline (GSK) for post-operative ileus (POI). It mentions that the drug was approved by the FDA in May 2008 [908026]. A quote from Michael R. Dougherty, President and CEO of Adolor, is included. The alert also mentions that in April 2002, Adolor and GSK agreed to codevelop the drug [447874]. In February 2007, a Friedman Billings Ramsey analyst believed that the overall market opportunity was sufficiently large to accommodate both Entereg and its primary competitor, Wyeth and Progenics Pharmaceutical's subcutaneous formulation of methylnaltrexone bromide. The analyst expected Entereg to gain FDA approval for POI by early 2008 and commented that there was a possibility that Entereg's efficacy and safety profile would resonate more with doctors [779552], [914770]. At the bottom, there are links for 'Other Drug Alerts' and a 'SHOW CHECKED' button. A list of other alerts is visible, including 'Avid Radiopharmaceuticals begins phase II Alzheimer's trial of 18F-AV-45' and 'Radius selects RAD-140 as lead from androgen antagonist sarcopenia program'.

The screenshot shows the 'SEARCH center' section of the IDdb website. The header includes the IDdb logo and the text 'The Investigational Drugs database'. Below the header, there is a 'QuickSearch' field with a search button and a dropdown menu set to 'Drug'. The main content area displays 'Advanced Search' options. A list of indexes is provided: ACTIONS, COMPANIES, STRUCTURES, INDICATIONS, DEVELOPMENT STATUS, WORD/PHRASE, TECHNOLOGIES, DRUG NAMES, and COUNTRIES/REGIONS. There are also options for 'WRITE YOUR OWN' and 'EDIT/SAVE SEARCHES'. The page also includes a 'Text Search' and 'Guided Search' section. At the bottom, there is a 'Need help?' link to a tutorial and a 'TUTORIAL' button. The footer contains the text 'Click HERE for help' and '© 1997-2008 Thomson Scientific Ltd Terms of Use'.

Investigational Drug Database "IDdb"

IDdb ³ THOMSON FINANCIAL INTELLIGENCE DATA The Investigational Drugs database **INVESTEXT PharmaSelect**

IDdb Portal > Current Opinions > Investext

QuickSearch: **Investext PharmaSelect** Reports added: 16th May 2008 Previous Latest

SEARCH Drug

IDdb Alerts

Browse Database

Browse Indexes

Search Center

IDdb Portal

CP Gazette

Current Opinions

Investext Select

Patent Analysis

PubMed

Derwent Drug File

Derwent WDA

Personal

IDeals

BIOTECHNOLOGY - 2008 ASCO PLANNER AND ABSTRACT HIGHLIGHTS
(15 pages)
LI, HAN
16th May 2008

NOVO-NORDISK A.S.
Novo Nordisk A/S (13 pages)
ANON
16th May 2008

OSCIENT PHARMACEUTICALS CORP
Oscient Pharmaceuticals Corp (13 pages)
ANON
16th May 2008

PHARMACEUTICALS - APR OUTPATIENT PRESCRIPTION DRUGS CONTINUED
(8 pages)
HONG, YOUNA, ET AL
16th May 2008

Nabi Attractive Target as NicVAX Progresses - NicVAX Patent Upheld
Nabi Biopharmaceuticals (10 pages)
DUNN, STEPHEN M.
16th May 2008

OSTEOLOGIX INC
Osteologix A/S (4 pages)
KAPLAN MATTHEW L.
16th May 2008

Perrigo Co PRGO Raising Estimates and Price Target for PRGO
L Perrigo Co (5 pages)
LECKOW, DEREK WILHELM
16th May 2008

ValuEngine Detailed Valuation Report for AMGN
Amgen Inc (13 pages)
ANON
16th May 2008

ValuEngine Detailed Valuation Report for ALTH
Allos Therapeutics Inc (13 pages)
ANON
16th May 2008

ValuEngine Detailed Valuation Report for BRL
Barr Pharmaceuticals Inc (13 pages)
ANON
16th May 2008

Type of report

IDdb Companies

Industry Reports

Search Investext

Last 7 days

All

SEARCH

Text search

IDdb ³ NLM On DrugNet **PUBMED**

Pubmed > Results Summary

QuickSearch: **Search Results**

SEARCH Drug

Your search for **EGFR in Title** found **164** results.

Results Summary

Category	No. of results
Pubmed	164

IDdb Alerts

Browse Database

Browse Indexes

Search Center

IDdb Portal

CP Gazette

Current Opinions

Investext Select

Patent Analysis

PubMed

Derwent Drug File

Derwent WDA

Personal

IDeals

Pubmed [1-20] [21-40] [41-60] [Next] **SHOW CHECKED**

Epidermal growth factor receptor (EGFR) targeted therapies in non-small cell lung cancer (NSCLC)
Rev Recent Clin Trials
2006 Jan;1(1):1-13

The use of xenograft models for the selection of cancer treatments with the EGFR as an example
Crit Rev Oncol Hematol
2008 Mar;65(3):200-11

EGFR inhibitors for the treatment of squamous cell carcinoma of the head and neck
Curr Oncol Rep
2008 Mar;10(2):176-84

Mutations in the epidermal growth factor receptor gene and effects of EGFR-tyrosine kinase inhibitors on lung cancers
Gen Thorac Cardiovasc Surg
2008 Mar;56(3):97-103

EGFR antagonists in cancer treatment
N Engl J Med
2008 Mar 13;358(11):1160-74

EGFR inhibitors as first-line therapy in advanced non-small cell lung cancer
J Thorac Oncol
2008 Mar;3(3):303-10

THOMSON-Pharma



Thomson-Pharma Sources:

- Biosis
- Conference Fast Track
- Current Chemical Reactions
- Current Contents
- Current Opinion Journals:
 - Drug Discovery Development
 - Investigational Drugs
 - Molecular Therapeutics
- Current Patents Gazette
- Data Stream
- Delphion
- Derwent Biotechnology Resource
- Derwent Chemistry Resource
- Derwent Drug File
- Dolphin
- DrugDex
- GENESEQ
- GENESEQ FASTAlert
- GlobalTOPIC
- IBES
- IDdb
- IDeals
- IDrac
- Index Chemicus
- INPADOC
- Investext
- Medstat
- NewsEdge
- Orange Book
- Patent Citation Index
- Patent Fast Alert
- Patents Preview
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- PubMed
- SDdb
- Sharewatch
- SwissProt
- Thomson Patent Store
- Web of Science
- World Drug Alerts
- World Patent Index
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DRUG REPORT

CONTENTS

- Drug summary
- Breaking news
- Overview
- SWOT Analysis**
- Sales market share
- US Rx Profiles
- DRUGDEX overview
- Therapeutic use
- Development status
- Dev. status: history
- Licensing
- Patent position
- Orange book
- Chemistry
- Drug names
- US generic forecast
- SPC**
- First Marketing Auth.
- API Manufacturing
- Regulatory Filings
- Import Data
- Literature evaluation
- Scientific data

DRUG SUMMARY

Drug name: epoetin alfa
 Company: Amgen Inc
 Highest dev status: Launched
 FDA approved: Anemia, In Patients With Non-Myeloid Malignancies - Antineoplastic Adverse Reaction (Adult, Pediatric), Anemia Of Chronic Renal Failure (Adult, Pediatric), Surgical Procedure - Transfusion Of Blood Product, Allogeneic; Prophylaxis (Adult), Anemia - Zidovudine Adverse Reaction (Adult, Pediatric)
 Therapy areas: Anemia; Cerebrovascular ischemia; Brain injury
 Actions: Erythropoietin ligand; Neuroprotectant; Hematopoietic stimulant
 Technologies: Subcutaneous formulation; Intravenous formulation; Glycoprotein; Protein (recombinant)
 Update date: 17 April 2007
 Reason for update: 2 references added [782372, 782382]

BREAKING NEWS FROM NEWSEDGE

Defined Potential Time and Cost Savings of Once-Monthly Anemia Treatment 23/04/2007; Amgen's First Quarter 2

OVERVIEW

Developed and launched by [Amgen](#) and marketed with various licensees, epoetin alfa (marketed as Epogen by Amgen and as Procrit®/Forex by Johnson & Johnson J&J) is an iv recombinant form of erythropoietin (482636). It is

SWOT ANALYSIS

Strengths	Weaknesses
<ul style="list-style-type: none"> Treatment achieves target hemoglobin levels in >80% of patients [605043] Greater increases in hemoglobin levels seen in chemotherapy-induced anemia cancer patients, compared to Amgen Inc's Aranesp (darbepoetin alfa, qv); patients also require fewer blood transfusions [603321] Results of a large, retrospective database analysis suggested Procrit had a lower drug cost in the inpatient hospital setting compared to Aranesp [734810] 	<ul style="list-style-type: none"> Dosed three times a week; sc administration not recommended [605669], [606057] Associated with erythropoietin antibody-positive pure red cell aplasia (PRCA) [606057] Being a first-generation erythropoietin, it competes with newer second-generation products [606059] Clinical trials have raised concerns over tumor progression and patient survival [606059]
Opportunities	Threats
<ul style="list-style-type: none"> Data from the ongoing CHOIR study to investigate anemia as a modifiable risk factor for cardiovascular disease in chronic kidney disease (CKD) [605639] Recombinant therapeutic protein market is set to increase by two thirds by 2010. Erythropoietins are expected to lead the market [605639] In October 2006, the US Federal District Court denied Roche's motion to dismiss Amgen's patent infringement lawsuit against Roche. Amgen continued to believe that Roche's peg-EPO product (R-744) violates Amgen's patents [733583] Amgen has agreed to exclusively supply epoetin alfa and darbepoetin alfa until the end of 2011 to Fresenius for use in the latter's dialysis patients. This may protect market share prior to the possible launch of Roche's R-744 (CERA) [733065], [733428] In a study examining biweekly dosing in patients with anemia related to CKD who were not receiving dialysis, 88% of patients achieved target hemoglobin levels [743591] 	<ul style="list-style-type: none"> A regulatory process to prove bioequivalency of biogeneric products in the US [605639] Competition from Amgen Inc's Aranesp and Transkaryotic Therapies Inc's Dynepo (epoetin delta, qv) in the oncology market [606029] Patent coverage expired in the EU; biogeneric entry in the EU expected [606029] True generic versions of Procrit are available outside the US and Europe [605639] Roche's second-generation EPO R-744, filed with the FDA and the EMEA for the treatment of renal anemia in April 2006 [662745], [666975]

SUPPLEMENTARY PROTECTION CERTIFICATES

Displaying page 1 | [Show Full Results](#)

Active Ingredient(s)	Patent Details	SPC Holder	SPC Country	SPC Number	SPC Status	SPC Expiry
epoetin alfa	LV0010506	Kirin-Amgen Inc	Latvia	040041M	Rejected	19-Jun-2005
epoetin alfa	EP0148605	Kirin-Amgen Inc	Italy	920376M	Granted	02-May-2007
epoetin alfa	EP0148605	Kirin-Amgen Inc	UK	930156M	Withdrawn	11-Dec-2004
epoetin alfa	EP0148605	Kirin-Amgen Inc	Netherlands	930128M	Rejected	11-Dec-2004
epoetin alfa	EP0148605	Kirin-Amgen Inc	Luxembourg	930338M	Withdrawn	12-Dec-2004
epoetin alfa	EP0148605	Kirin-Amgen Inc	France	920481M	Granted	20-Nov-2007
epoetin alfa	EP0148605	Kirin-Amgen Inc	France	920482M	Granted	20-Nov-2007
epoetin alfa	EP0148605	Kirin-Amgen Inc	Belgium	930106M	Withdrawn	12-Dec-2004
epoetin alfa	DE3482828	Kirin-Amgen Inc	Germany	930092M	Withdrawn	12-Dec-2004

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NEWS

Elsevier's Inteleos Poised to Launch Integrating Technology for Drug Tracking and Analysis

The Universal Integrator™ Enables Quick and Easy Comparison of Data From Multiple Sources

Amsterdam, 7 June 2007 - Elsevier, a world-leading healthcare and scientific publisher, announced today, that it has renewed its agreement with AdvantTechnologies (aTi) paving the way for the launch of the Inteleos Universal Integrator™ (UI) a revolutionary tool to integrate information on drug pipeline research from multiple sources.

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SEARCH ANALYSIS CLINICAL TRIALS NEWS QUICK SEARCH for Drugs [Recent Searches](#)

Drug Search ?

Select Field

Brand Name
Generic Name
Code Name
Clinical Phase [+]
Therapy Area [+]
Drug Class [+]
Mechanism Of Action [+]
Country/Region [+]
Company [+]

Advanced Search
- New Molecular Entity
- Fixed-Dose Combination
- FDA/EMEA orphan designation
- Product Type [+]
- Method of Delivery [+]
- Special Age Population
- FDA Approval Type and Criteria

afelimomab
aflibercept

My Query

Include subcategories

Visudyne
Macugen
Lucentis
aflibercept

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SEARCH ANALYSIS CLINICAL TRIALS NEWS QUICK SEARCH for Drugs Recent Searches

Search Results Visudyne; Macugen; Lucentis; aflibercept | Edit Search Query | ← Displaying records 1 - 4 of 4 → 

Drug Name	Originator/ Developer/ Marketer	Therapy Areas	Drug Classes	Indications	Highest Phase	Key Regions
<input type="checkbox"/> aflibercept AVE-0005 VEGF Trap VEGF Trap- Eye	(O) Regeneron Pharma..	advanced cancer	Antineoplastics	First-line treatment of hormon...	Phase III	US; Brazil; Canada
	(D) Regeneron Pharma..	ascites	Ophthalmics			
	Sanofi-Aventis	cancer		First-line treatment of pancre...	Phase III	US; AUS; Canada
	Bayer Healthcare	colorectal cancer				
	(M) Regeneron Pharma..	diabetic macular edema		Second-line treatment of color...	Phase III	US; AUS; Brazil
	Sanofi-Aventis	lung adenocarcinoma		Second-line treatment of local...	Phase III	US; Canada; China
	Bayer Healthcare	lung non small cell cancer		Third-line treatment of advanc...	Phase III	US; Canada; Spain
		metastasis		Treatment of patients with neo...	Phase III	US; EU; JP
		nonhodgkin lymphoma		Treatment of cancer (VEGF Trap...	Phase I	JP
		ovary cancer		Treatment of diabetic macular ...	Phase I	US
<input type="checkbox"/> pegaptanib sodium Macugen EYE-001	(O) Gilead Sciences	diabetic macular edema	Ophthalmics	Treatment of neovascular (wet)...	Phase IV	US; EU
	(D) OSI Pharmaceutic..	ocular histoplasmosis	Vascular endothelial growth factor (VEGF) antagonists	Treatment of diabetic macular ...	Phase III	US
	Pfizer	retina exudate		Treatment of macular edema due...	Phase III	US
	(M) OSI Pharmaceutic..	retina macula age related degeneration		Treatment of age-related macul...	Discontinued - III	US
	Pfizer	retina macula cystoid edema		Treatment of chronic, post-ope...	Discontinued - I	US
		retina macula edema		Treatment of subfoveal choroid...	Discontinued - I	US
		retina neovascularization				

Pharmaprojects



Pharmaprojects - Classic

The screenshot displays the Pharmaprojects V5.2 (Web) interface. The top navigation bar includes buttons for 'New', 'Open', 'Save', 'Save As', and 'Delete'. A 'Quick Search' box is on the left, and 'Print', 'Copy', 'Export', and 'Help' buttons are on the right. The main content area is titled 'Drug Profile Search - W/C 8 Jun 2008 [280]'. On the left sidebar, the 'Search' menu is expanded, with 'Target Data' and its sub-item 'Primary Target Name' circled in green. An arrow points from this menu item to the 'Find:' search results. The 'Find:' results list various target names, including 'hepatocyte nuclear factor 4, alpha', 'hepatocyte stimulatory factor', 'hepatoma transmembrane kinase', 'hepatopoietin A', 'hepatorenal tyrosinaemia', 'hepsin (transmembrane protease, serine 1)', 'HER1', 'HER2', 'HER2/NEU', 'HER3', 'HER4', 'hereditary angioedema', 'hereditary nonpolyposis colon cancer, type 6', 'hereditary prostate cancer 2', 'heregulin alpha', 'HERG', 'HERG1', 'Hertz junctional epidermolysis bullosa', 'Hermes antigen', 'Hers disease', 'herstatin', 'HERV-7q', 'HERV-7q envelope protein', 'HERV-tryptophan envelope protein', 'HERV-W', 'HERV-W Env glycoprotein', 'HERV-W-ENV', 'HERV-W{7q21.1} provirus ancestral Env polyprotein', 'hEST2', and 'HEVnn10_hepatitis-E virus'. On the right side of the results, there are buttons for 'Add', 'Delete', 'Clear', 'Replace', '(...)', '(..X..)', 'Search', 'Results', 'Profile', and 'Graph'. At the bottom, there is a 'Standard Search' section with 'View' and 'Web' options.

Pharmaprojects - Pipeline

The screenshot shows the home page of the Pipeline Informa Healthcare website. The header includes the logo, navigation tabs for Home, Search Pipeline, and My Watch List, and a Submit Research Request button. The main content area is titled 'Home' and features a 'Welcome to Pipeline' message. The message states that the user's company has purchased a corporate-wide subscription and provides instructions on how to use the service. A 'Search Pipeline Now' button is prominently displayed. On the left side, there are several service categories: 'Did You Know?' (with links for training, research support, and search results), 'Support' (with links for Client Services and Research Support), and 'Related Services' (listing TrialTrove, TrialScope, SiteTrove, and Expert Opinion).

The screenshot shows the search interface of the Pipeline Informa Healthcare website. The header is identical to the home page. The main content area is titled 'Search' and features a 'Search History' tab. The search criteria are organized into several rows, each with a dropdown menu and a search button:

- Drug Name:** Includes a checked 'Any' option and a 'Select from a list of choices' dropdown.
- Disease:** Includes a checked 'Any' option and a 'Select from a list of choices' dropdown.
- Status:** Includes a checked 'Any' option and a grid of buttons for 'Pipeline', 'Launched', and 'Inactive'. Below these are buttons for 'P', 'I', 'II', 'III', 'PR', 'R', 'L', 'S', 'NDR', 'D', and 'W'.
- Company:** Includes a checked 'Any' option, a 'Select from a list of choices' dropdown, and radio buttons for 'OR' and 'AND'.
- Therapeutic Class:** Includes a checked 'Any' option and a 'Select from a list of choices' dropdown.
- Mechanism Of Action:** Includes a checked 'Any' option and a 'Select from a list of choices' dropdown.
- Biological Target:** Includes a checked 'Any' option and a 'Select from a list of choices' dropdown.

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- Genomics **New!**
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- Experimental Pharmacology
- Pharmacokinetics/Metabolism
- Clinical Studies
- Disease Briefings
- Companies & Research Institutions
- Literature
- Patents

Quick Access to Key Drugs & Biologics Information
Drug Name Search Index go

Quick Access to Pipeline Information
Gateways to Development Status Condition Lookup

Highlights June 9 - 15, 2008

Today's News

Company News

- UCB and Otsuka to codevelop and copromote Keppra and Cimzia in Japan

Gastrointestinal Drugs

- Amitiza filed for chronic idiopathic constipation in Switzerland
- Entereg available for postoperative ileus

Metabolic Drugs

- Radius selects preclinical SARM candidate for sarcopenia

Neurologic Drugs

- Epix initiates second trial in phase IIb Alzheimer's disease program

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27th Congress of the European Academy of Allergy and Clinical Immunology (EAACI) (June 7-11, Barcelona) 2008
CITATIONS

PREDICTIVE PHARMACOLOGY module

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Prous Integrity – Target Search

The screenshot displays the Prous Integrity web application interface. The main search area is titled "Advanced Search" and includes a "Target" section with a "Target Name" dropdown menu. A red circle highlights the "Target Name" dropdown, and a red arrow points from it to a secondary window showing a "List of Values" selection interface. This secondary window contains a search input field, a "Lookup" button, and a list of search terms. A red circle highlights the term "MEK" in the list, and another red arrow points from it to the search results table below.

The search results table, titled "Records Retrieved 7 in Targets", shows the following data:

Target Name	Links	Conditions
MAP2K1 (MEK1)		Cancer
<input type="checkbox"/> MAP2K1 (MEK1)		
<input type="checkbox"/> Mitogen-activated protein kinase kinase 1 gene; MAP2K1	Entrez Gene: 5604	
MAP2K2 (MEK2)		Cancer
<input type="checkbox"/> MAP2K2 (MEK2)		
<input type="checkbox"/> Mitogen-activated protein kinase kinase 2 gene; MAP2K2	Entrez Gene: 5605	
MAP2K4 (MKK4)		
<input type="checkbox"/> MAP2K4 (MKK4)		
<input type="checkbox"/> Mitogen-activated protein kinase kinase 4 gene; MAP2K4	Entrez Gene: 6416	
MAP2K5 (MEK5)		
<input type="checkbox"/> MAP2K5 (MEK5) isoform A		
<input type="checkbox"/> MAP2K5 (MEK5) isoform B		
<input type="checkbox"/> MAP2K5 (MEK5) isoform C		
<input type="checkbox"/> Mitogen-activated protein kinase kinase 5, transcript variant A, gene; MAP2K5 variant A	Entrez Gene: 5607	
<input type="checkbox"/> Mitogen-activated protein kinase kinase 5, transcript variant B, gene; MAP2K5 variant B	Entrez Gene: 5607	
<input type="checkbox"/> Mitogen-activated protein kinase kinase 5, transcript variant C, gene; MAP2K5 variant C	Entrez Gene: 5607	

The interface also includes a sidebar with "Conditions" and "Product" categories, and a "Filter by Statistics" panel on the right with options like "Target Condition" and "Target Mechanism of Action".

Prous Integrity – BioMarker Kit Development



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Knowledge Areas Quick Search go Home Support/Help Query Manager/Alert Center Reports

Records Retrieved Records 1 to 5 of 5 retrieved Options

Kit Development Status Search Results

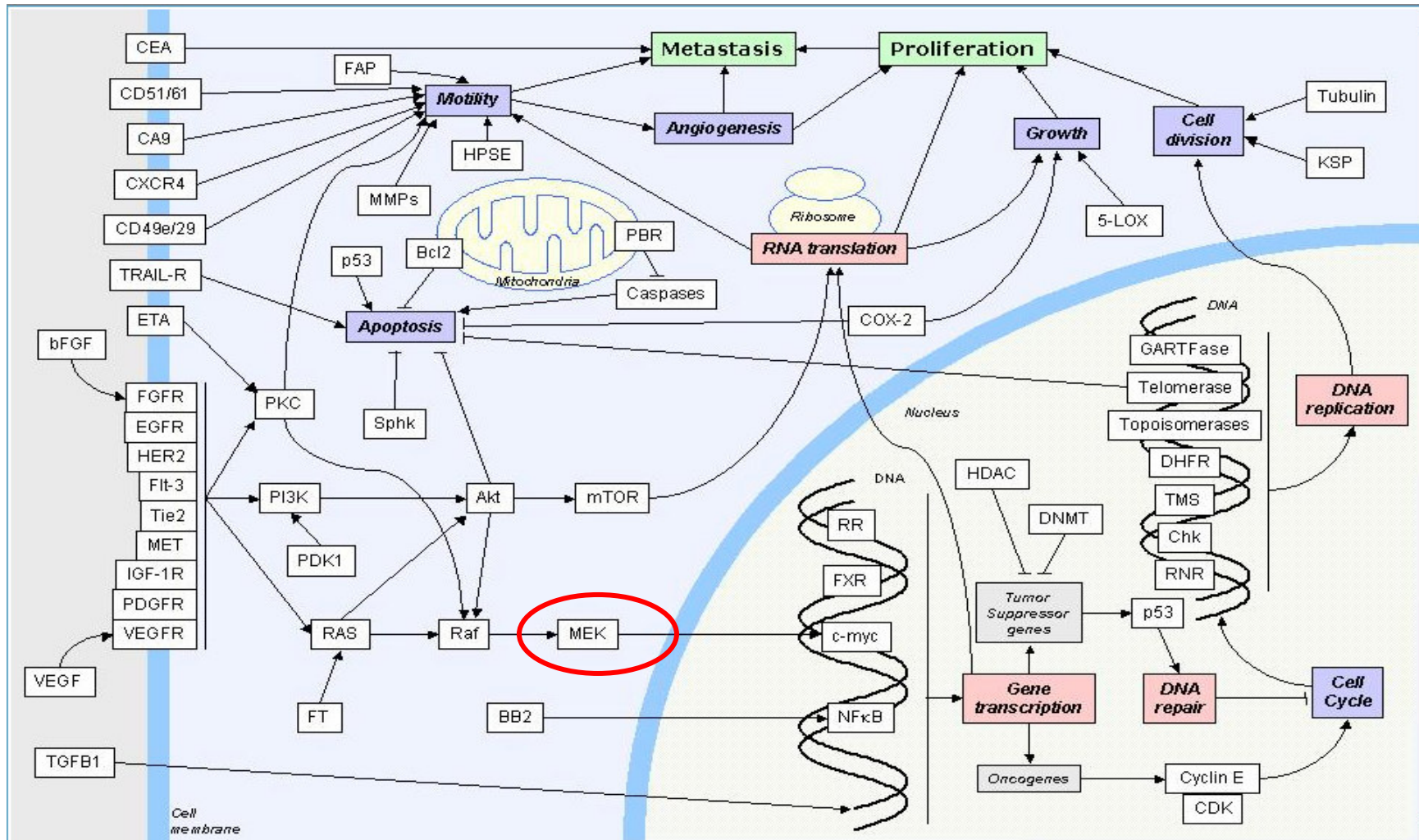
1

Kit	Use	Organization	Status	Country / Area	Reg. Auth.	Date	Source
<input type="checkbox"/> Inform HER-2/NEU	<ul style="list-style-type: none"> Biomarker: HER2 Indication: Cancer, breast Population: Primary - Lymph Node Negative Role: Prognosis - Risk Stratification Technique (Substrate): FISH (DNA) Authority: ASCO 	Ventana Medical Systems, Inc.	Approved	US	FDA	30-12-1997	Ref. (1) / Pat. (0)
<input type="checkbox"/> Dako Herceptest	<ul style="list-style-type: none"> Biomarker: HER2 Indication: Cancer, breast Population: Not Determined Role: Selection for Therapy Technique 	Dako Denmark A/S	Approved	US	FDA	25-09-1998	Ref. (1) / Pat. (0)

Filter by Statistics

- ▶ Indication
- ▶ Condition
- ▶ Role
- ▶ Population
- ▶ Type
- ▶ Biological Process
- ▶ Technique
- ▶ Substrate
- ▶ Organization

Prous Integrity –Targetscape Lung Cancer



Smart Charts - Data Integration Tool

Create Combined Chart Wizard

Step 2 - Select charts to be combined:

- EGFR - Prous
- EGFR - ADIS
- EGFR - Pharmaprojects
- EGFR - Thomson-Pharma

Key chart: Mechanism = EGF receptor inhib

Charts to be combined:

Next >

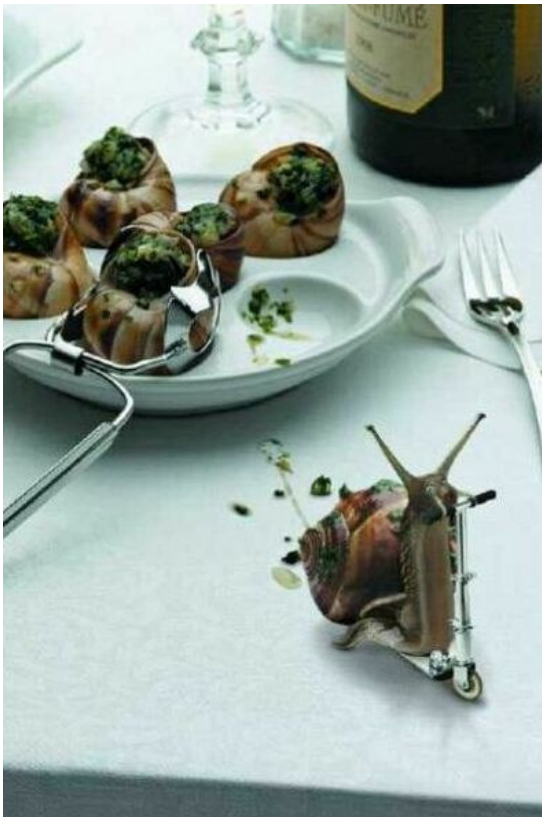
< Back

Identify unique compounds

Combined: EGFR Combined - (ADIS, IMS, IDDB, Pharmaprojects, Thomson -Pharma)

	Drug	Common Drug Name	Synonyms	Database	Company	Status
47	BMS-599626	BMS-599626	HER kinase inhibitor, Bristol-Myers Squibb pan HER kinase inhibitor, BMS	Thomson Scientific IDdb	Bristol-Myers Squibb Co	Phase 1 Clinical
48	Pan-HER kinase inhibitor, Bristol-Myer Squibb	BMS-599626	BMS 599626	IMS R&D Focus	Bristol-Myers Squibb	Phase I
	BMS-599626	BMS-599626	HER1/2 inhibitors, BMS	PJB Pharmaprojects	Bristol-Myers Squibb (USA)	No Development Reported

Conclusion -



- There are several avenues to success when collecting information.
- Who are your customers?
- Where are budget dollars best spent?
- Where did the information in the database/portal come from? Was it a synthesis of existing data or purchase of an independent source?



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- John Willmore, BizInt Solutions

Up Next: Case studies using pipeline dbs.

