



Life Science Business, Partnering, Research And Discovery Opportunities Now Available in Italy

Michael G. Eckstein
President
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10-15 MINUTES OF FACTOIDS

Statistics and Background

Clinical Trials

Collaborative EU projects



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But no tech transfer or commercialization expertise!



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Aug 1 2009 (Vol. 29, No. 14)

BOOKMARK

Italian Biotech Revamps Old-World Mindset

Casting Off Traditional Business Customs Expected to Push the Industry Forward

Alberto Onetti, Ph.D.
Charles S. Versaggi, Ph.D.
Bruce F. Mackler, Ph.D., J.D.



click to enlarge

Proteogen Bio has patented a method that derivatizes active proteins and binds them on a support.

There are several main obstacles that prevent the Italian biotechnology industry from taking off. These hurdles are complex and rooted in cultural, as well as market infrastructural considerations. The "Life Science Innovation—From Vision to Commercialization" meeting held recently in Florence highlighted the realities facing Italian executives and sought to provide them with the fundamental strategies and skills to form, launch, and operate a life science company.

In 2008, the Italian biotechnology industry was composed of 260 companies involved in drug development, diagnostics, medical devices, and agbio. Based on the Blossom & Company-Assobiotech Report (2009), these are mostly small enterprises with less than 50 employees, collectively employing 41,000 people, with gross revenues of €15.3 billion, accounting for over 1% of GDP and 0.2% of overall country employment. This represents a fairly solid corporate base.

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Money

SECTION B

Tuesday, May 17, 2005

Costs, regulations move more drug tests outside USA

Other nations want drugs tested on their populations

By Julie Schmit
USA TODAY

The pharmaceutical industry is doing more human testing of drugs outside the USA in an effort to get drugs to market faster, lower costs and test drugs where they're likely to be sold.

Health care

The industry spent more than \$39 billion on research and development last year, with human drug testing accounting for the biggest cost, says the Pharmaceutical Research and Manufacturers of America. More than 21% of that was spent outside the USA, vs. 18% in 2000.

GlaxoSmithKline says 29% of its drug

trials last year were outside the USA and Western Europe. In two years, that will hit 50%, it says.

Last year, 50% of trials for Wyeth Pharmaceuticals were outside the USA. That'll be 70% in 2006, says Robert Ruffolo, Wyeth's head of research.

Merck's non-U.S. trials are at 50%, up from 45% five years ago, it says.

Cost is one factor. Trials in Eastern Europe, Asia and Central and South America might cost 10% to 50% less than trials in the USA and Western Europe, says Ronald Krall, GlaxoSmithKline's head of development.

Researcher and clinic/hospital costs are lower and patient recruitment is faster, which also lowers costs. Bigger populations more in need of medical treatment make faster recruitment possible, Wyeth's Ruffolo says.

The companies attempt to sell their drugs where tested, they say, and U.S. trials aren't declining as much as foreign ones are increasing. Also driving the trend:

► **Diseases.** "We have to go where the action is," says Henry Gabelnick of Conrad, a reproductive health agency. Next month, it plans to start a trial in four African countries and India to test a vaginal gel to prevent transmission of HIV/AIDS, which is more common in Africa and is rising in India.

► **Regulations.** Some nations, such as Japan, want drugs tested in their populations before approving them to be sold, says Fred Fiedorek, vice president of clinical research for Bristol-Myers Squibb.

Also, international standards for running clinical trials — including rules re-

garding consent — have been more widely adopted. The FDA expects companies to meet them, no matter where trials were done, to win approval to sell new drugs in the USA.

Unless there is a complaint, the FDA doesn't inspect ongoing trials, either in the USA or outside. There are too many: an estimated 50,000 worldwide in 2003, says Thomson CenterWatch, which keeps a drug-trial database. Companies are required to monitor trials.

Violations occur. Since 1998, the FDA has tried to disqualify about 30 U.S. researchers from running trials because the FDA said they violated regulations.

"With more foreign trials, 'They're further away from whatever scrutiny we have here,'" says Vera Hassner Sharav of the Alliance for Human Research Protection.



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Clinical Trials

In 2007 American pharmaceutical and biotechnology companies spent in excess of \$54 billion on drug discovery and development
(Source: PhARMA).

Industry
September 2005 to October 2005 and
the following: of 5,167 trials and 126,980 study
sites registered, North America accounted for 50.6% of all industry-
sponsored clinical trial sites globally, with the rest of the world at 49.4%
(Source: Clinical Trial Magnifier).

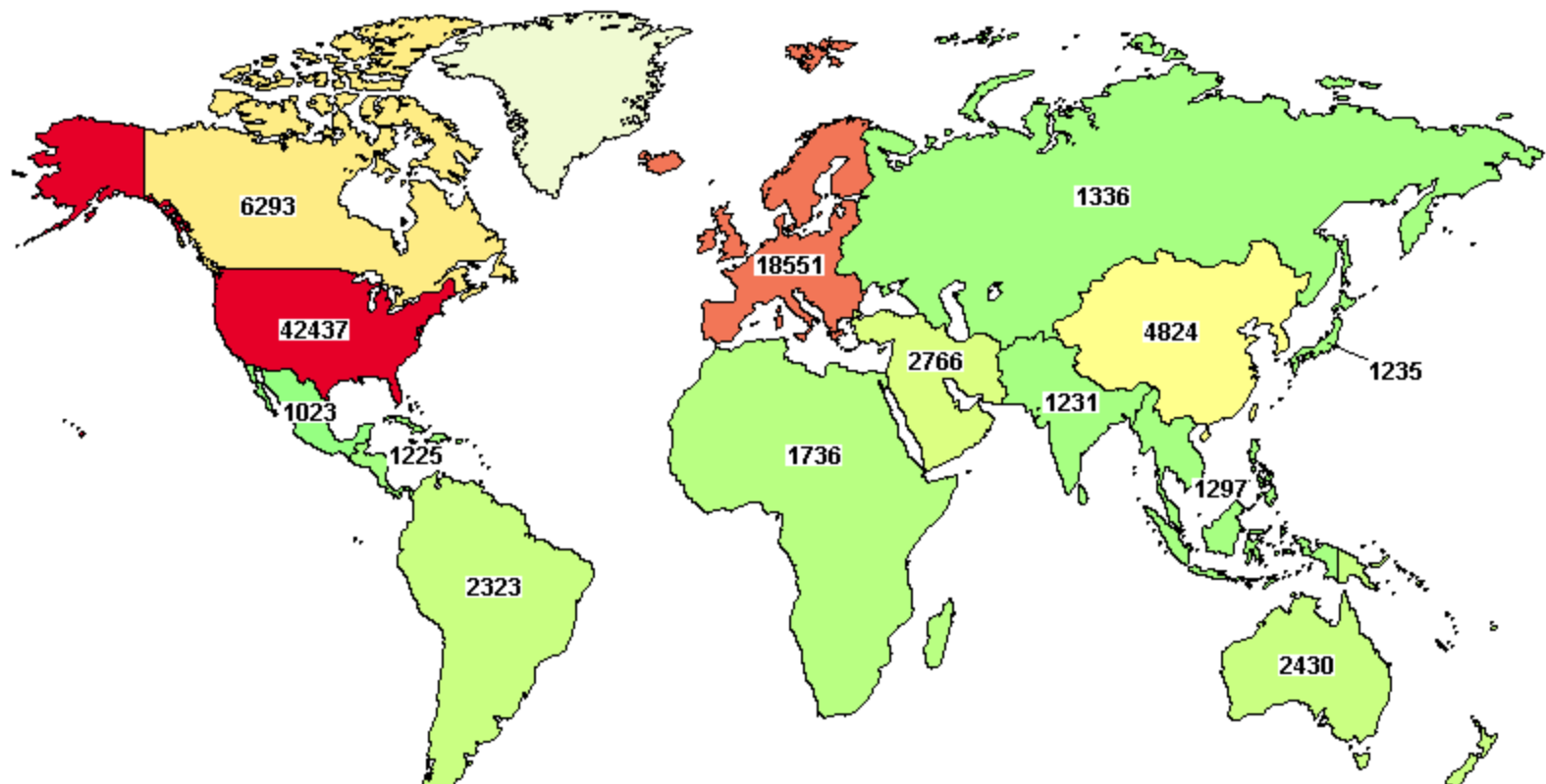
**By 2012 --- projections call for 60% of all
clinical trial sites to be located outside of the US**



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Map of All Studies in ClinicalTrials.gov

Click on the map below to show a more detailed map (when available) or search for studies (when map not available).



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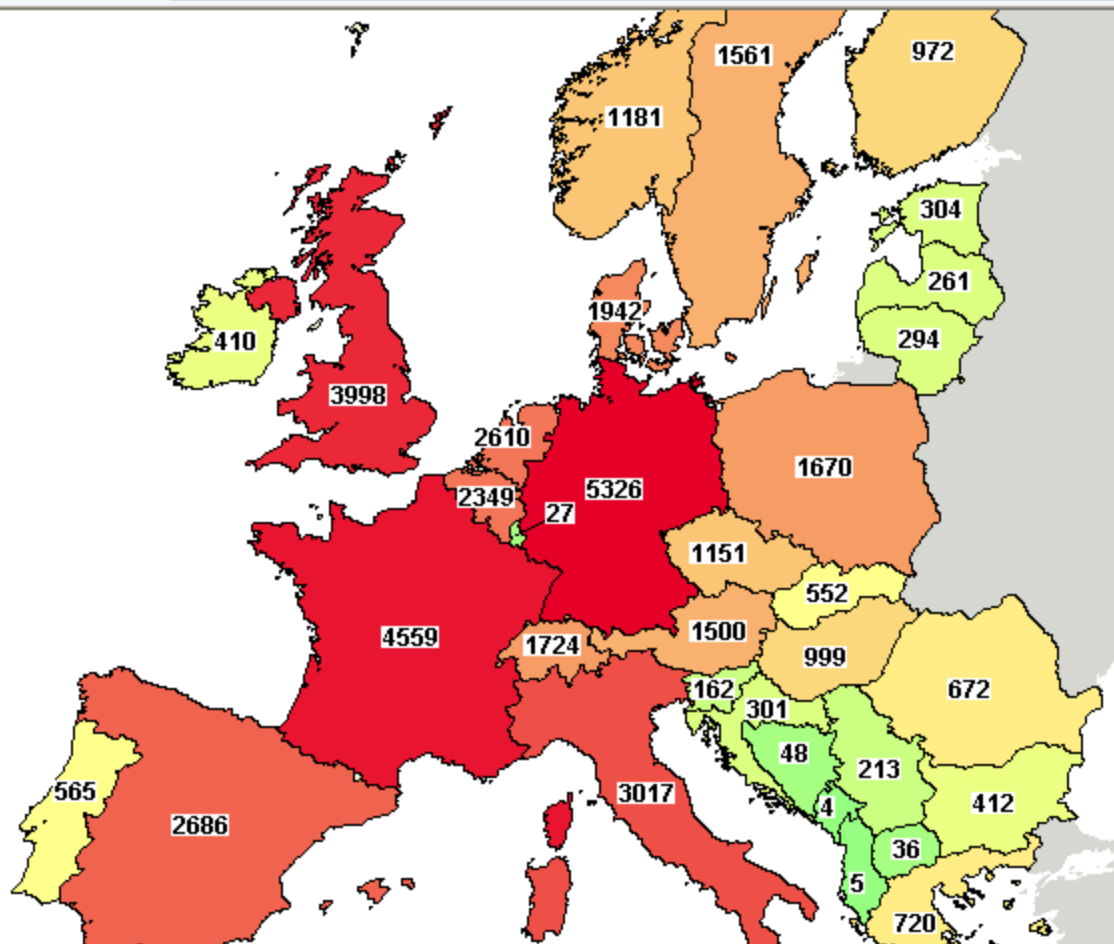
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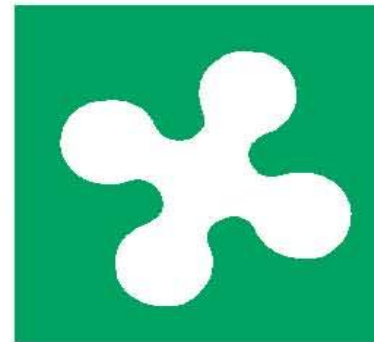
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Massachusetts and Lombardia: Biotechnology & Medical Research Agreement

Major Funding and Joint Project Development Opportunities for Researchers, Scientists, Institutions and Companies



Overview

Massachusetts and the Italian region of Lombardia have formally established a partnership to support collaborative biotechnology and medical research between the two regions. Lombardy - where nearly 50% of all Italian biotechnology companies are located, is an ideal gateway for Massachusetts firms interested in entering the European market, partnering with European research institutions, and identifying strategic alliances.

This transfer of knowledge between Massachusetts and Lombardia will also support future discoveries through joint initiatives of vocational education and professional development. Massachusetts companies will now have access to the best-and-brightest scientific minds, companies, products and institutions.

Benefits

Available to Massachusetts based individuals, institutions, and companies. This collaborative relationship will provide:

Increased Access to Financing:

Massachusetts based entities have the ability to work and collaborate with Italian and European partners to apply for grant funding under the European Union (EU) Framework structure program, which financially supports research in EU Member States and joint research collaborations with international partners.

Entrée into the 25 member European Union:

In addition to the growth and business potential of Italy, this collaboration initiative can serve as a viable

Collaborative EU projects

EU Framework

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- Current program: Framework #7 (2007-2013)
- Total amount of funds --- € 50.5 BILLION
- Focuses on “collaborative company projects” for
the betterment of all EU citizens





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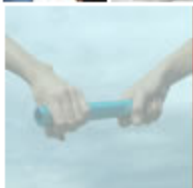
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Outside the EU

Can I participate in FP7 if I am based outside Europe?

The short answer is 'yes'. Organisations and researchers from more than 100 countries all over the world are already involved in EU research programmes.

The international dimension is no longer confined to a specific scientific and technological (S&T) cooperation programme but is now inherent in all European Community research activities. This international policy has three objectives:

- To support European competitiveness through strategic partnerships with third countries in selected fields of science and by engaging the best third country scientists to work in and with Europe.
- To enhance the production of knowledge and scientific excellence by enabling European universities, research institutions and firms to establish contact with their partners in third countries, thereby facilitating access to research environments outside Europe and promoting synergies on a global scale.
- To address specific problems that third countries face or that have a global character, on the basis of mutual interest and mutual benefit.

Participation is open to international organisations and legal entities established in third countries after the minimum conditions laid down in the 'Rules for participation' have been met, as well as any conditions specified in the specific programmes or relevant work programmes.

Can I receive EU research funding if I am based outside the EU?

Partners from Countries associated to FP7 (through international agreements that provide for a financial contribution of these countries to FP7 budget) can participate on similar terms (minimum conditions and funding) to participants from the EU Member States. Organisations and researchers from an international cooperation partner country (ICPC) may also receive funding. An ICPC is a third country which the European Commission classifies as a low-income, lower-middle-income or

- Public organisation
- Individual researcher
- Outside the EU

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Partners

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1 . [Ariadna Servicios Informaticos, S.L.](#)

Collaboration title: Mobile and internet applications, RFID, SW technologies,e-health, e-inclusion

Country: SPAIN

2 . [tebu-bio](#)

Collaboration title: tebu-bio - SME partner in Life Sciences, CRO outsourcing solutions for molecular biology, recombinant protein production, cell line engineering, cell culture and bioassays

Country: FRANCE

3 . [Palau Pharma S.A.](#)

Collaboration title: Palau Pharma S.A. is a biopharmaceutical company focused on the discovery and development of innovative, improved and safer medicines for the treatment of inflammatory and autoimmune diseases

Country: SPAIN

4 . [Universidad de Las Palmas de Gran Canaria](#)

Collaboration title: Optimization, development and application of new methodologies for the determination of traces of organic pollutants in marine and terrestrial environment

Country: SPAIN

5 . [BioEngineering Ltd](#)

Collaboration title: Environmental consulting for waste water treatment, development and production of microbial products for the natural treatment of environmental issues, biogas research as renewable energy source

Country: THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA



World Class Bench Science

Excellent regional and national economic-tax incentives

Strong university emphasis on science, research and discovery

Launching pad into the EU

Positive collaboration mentality

“Hidden Diamonds in the Rough”

Thank You !

Michael G. Eckstein

President

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