Chiesi

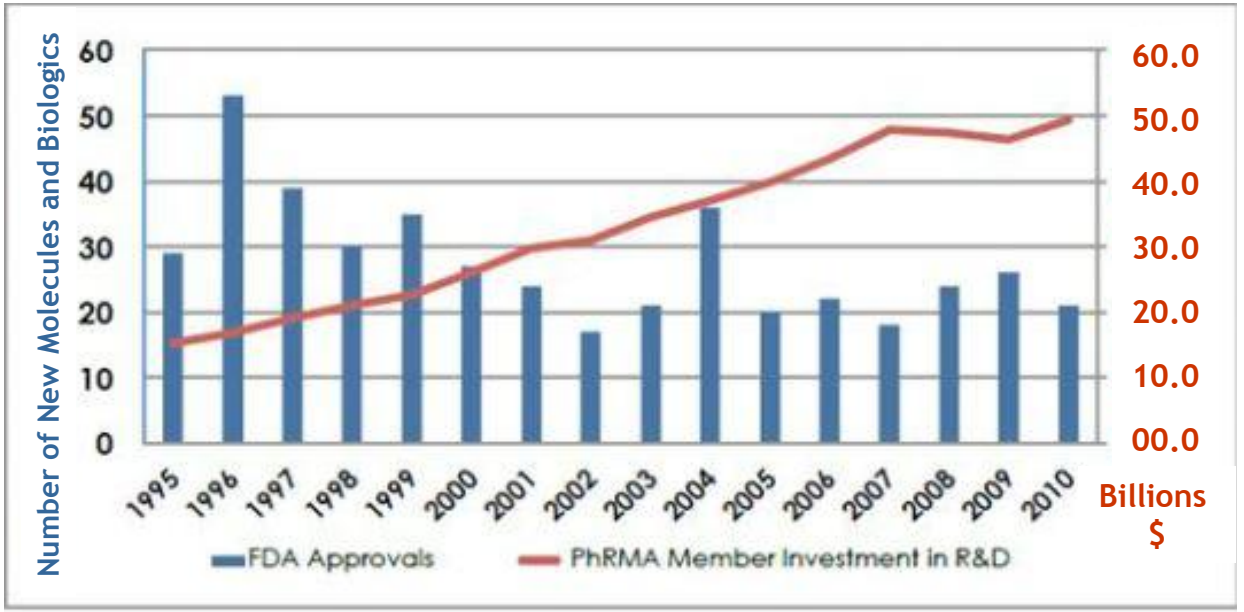
People and ideas for innovation in healtcare

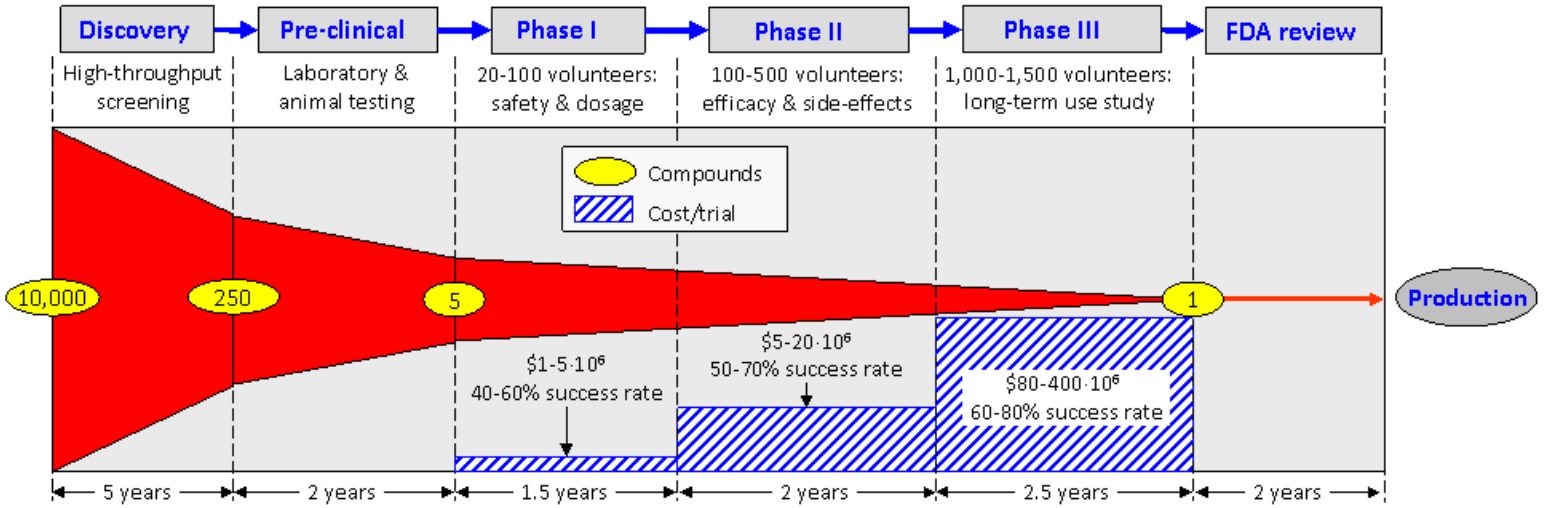
Collaborazione Industria-Università Luci ed Ombre

Riccardo Patacchini
Project Leader Drug Discovery
CHIESI Farmaceutici Parma

SCIENZA E INDUSTRIA: Ricerca e Innovazione in Biomedicina
Milano, 27 Novembre 2013, Università Bocconi

Decline in Pharmaceutical R&D efficiency





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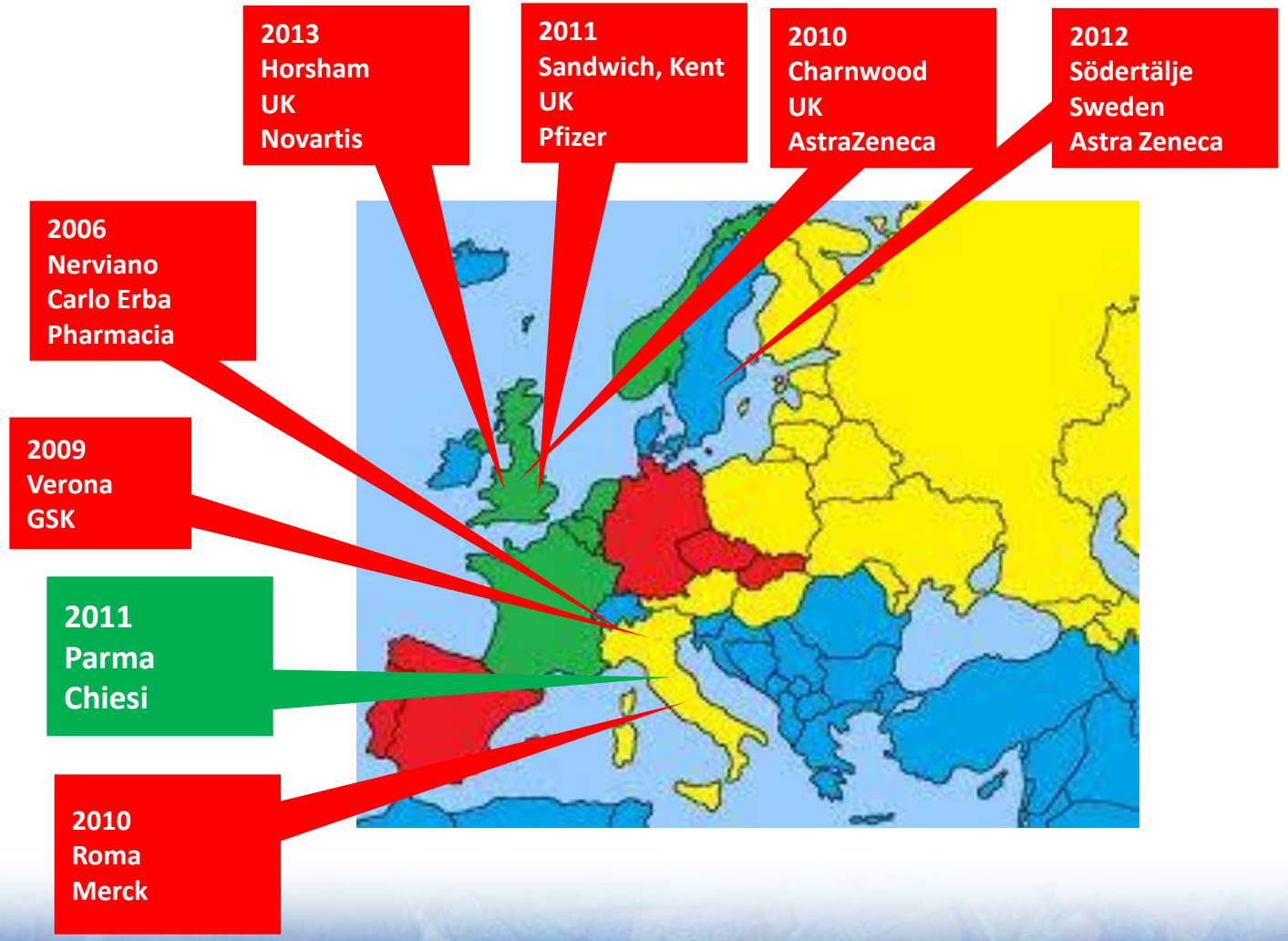
Collapse of R&D Sites of Pharma Industries



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How to discover innovative medicines more efficiently ?

Paul D. Leeson and Stephen A. St-Gallay**

NATURE REVIEWS | DRUG DISCOVERY
VOLUME 10 | OCTOBER 2011 | 749

under the control of scientists who are responsible for lead generation and optimization. Carrying excessive compound-based risk into clinical development, even with clinically attractive targets, will result in high attrition rates becoming even higher. It would be more efficient to invest additional time in the discovery phase to search for molecules with more appropriate properties.

It is becoming increasingly difficult to bring a new medicine to the market. Expensive late-stage clinical failures are becoming more common, and many pharmaceutical companies are currently undergoing restructuring and downsizing in response to the intense pressures to improve efficiency and reduce costs. De-risking preclinical-stage pipelines is one essential strategy for addressing these problems, because it will reduce the number of more expensive clinical failures at a later stage[1,2].

A successful drug candidate must possess absorption, distribution, metabolism, excretion and toxicity (ADMET) properties that result in a duration of exposure and disease-target occupancy that is sufficient for producing the desired functional response, as well as adequate safety margins[3]. If any of these compound-dependent properties remain in question when clinical concept testing is carried out, the disease hypothesis will not have been tested robustly, and a conclusion of efficacy failure will be insecure. The goal of substantially reducing compound-based attrition[2] is achievable because compound-dependent properties — biological potency, drug metabolism and pharmacokinetics, off-target selectivity and toxicity, receptor-binding kinetics, as well as pharmaceutical properties — are entirely

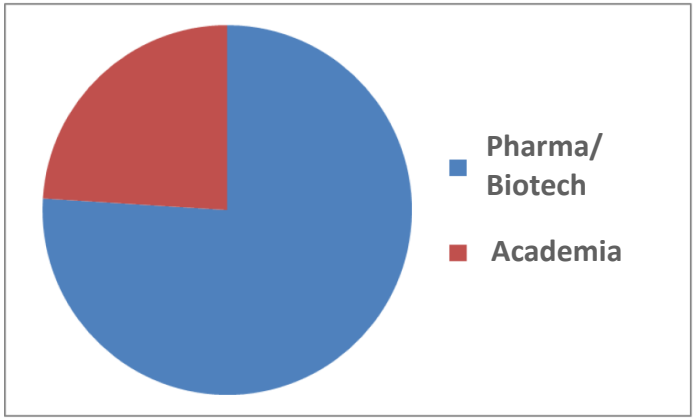
How to discover innovative medicines more efficiently ?

- Cercare convergenze tra Ricerca Industriale e mondo Accademico su temi di Ricerca specifici

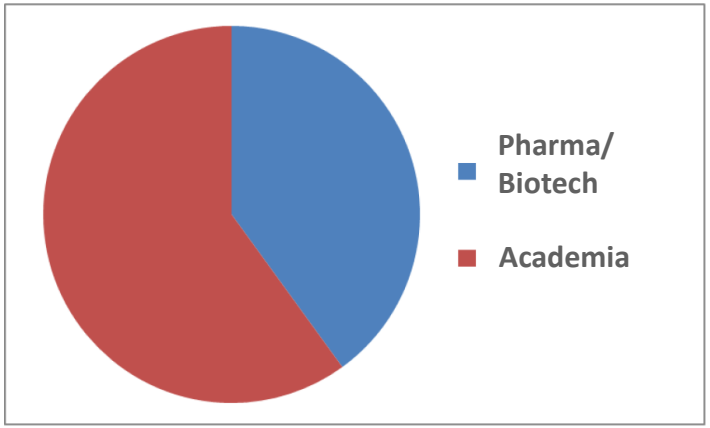
- Selezionando le eccellenze, e costruendo con esse un nuovo modello di collaborazione

L`iniziativa di GSK

Origin of new drugs approved by FDA during 1998-2007



Origin of "scientifically novel" new drugs approved by FDA during 1998-2007



Kneller et al, Nat Rev Drug Disc (2010), 9, 867

Your idea. Our resources.

Discovery Partnerships with Academia is a new approach to early drug discovery.

The concept is simple but powerful: bring together the insight and creativity of the academic world with the drug discovery expertise of GlaxoSmithKline (GSK) to establish truly integrated partnerships that can translate innovative research into medicines that benefit patients.

Each project will operate as a joint team, with both partners working towards shared goals with open sharing of information and data.

Industry–Academia Collaboration in Drug Discovery

….. a new approach

GSK, Shire & Telethon

- **October 2010** - Agreement between HSR-Telethon (Tiget) and GlaxoSmithKline for the development of gene therapy protocols for various genetic diseases
- Upfront payment (€ 10 million) and additional compensations according to the achievement of specific development milestones

- **October 2012** - Collaborative research agreement between Telethon (Tigem) and Shire for new therapies for lysosomal storage disorders and neurodegenerative diseases
- Five years financial support to Tigem research activities, with a licencing option for future clinical development

Chiesi - Università di Firenze

Progetto

FABER

un nuovo modello di collaborazione tra Industria ed Accademia

Copia da Cesare Zocchi, Michelangelo giovane scolpisce la testa di fauno, Studio Romanelli, Firenze

FABER: Sponsor & Budget

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People and ideas for innovation in healthcare

Chiesi Investment	**1.1 M€**
UNIFI Investment	**0.2 M€**
Regione Toscana	**1.5 M€**
Total	**3.8 M€**

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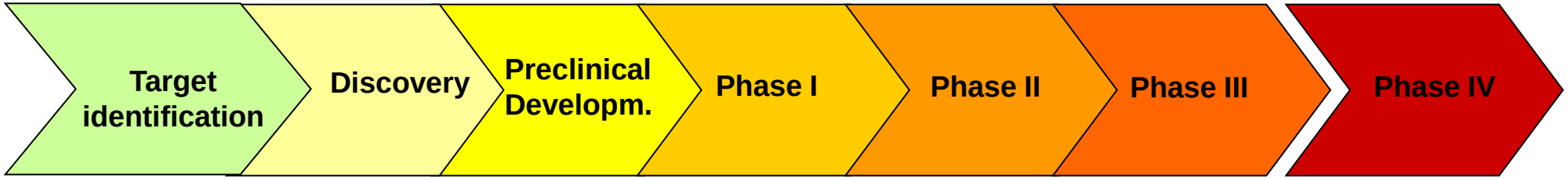
Sede Operativa Chiesi

Laboratori Congiunti presso Dipartimento di Farmacologia Preclinica e Clinica*, UniFi, Firenze

* Dipartimento Scienze della Salute, DSS, da Gennaio 2013



FABER

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IP Management

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UniFi

«….Chiesi sarà l'unico soggetto autorizzato a depositare domande di brevetto relative ai risultati del Progetto … e sarà tenuto a dare pronta comunicazione all'Università di Firenze di ciascun deposito.»

«….i contributi dell'Università di Firenze, consistendo esclusivamente in ricerca scientifica primaria su meccanismi patogenetici di malattie respiratorie, sono suscettibili di dar luogo ad invenzioni brevettabili solo nell'ambito di nuovi modelli sperimentali e/o tecniche di laboratorio originali.

« L'Università di Firenze avrà il diritto di pubblicare i risultati del Progetto aventi valenza brevettuale una volta che Chiesi avrà provveduto a depositare una domanda di brevetto»

Shared Publications

OPEN ACCESS Freely available online

PLOS | ONE

Transient Receptor Potential Ankyrin 1 Channel Localized to Non-Neuronal Airway Cells Promotes Non-Neurogenic Inflammation

Romina Nassini[1,9], Pamela Pedretti[1,2,9], Nadia Moretto[2,9], Camilla Fusi[1], Chiara Carnini[2], Fabrizio Facchinetti[2], Arturo Roberto Viscomi[3], Anna Rita Pisano[2], Susan Stokesberry[4], Charlott Brunmark[5,6], Naila Svitacheva[5,7], Lorcan McGarvey[4], Riccardo Patacchini[2], Anders B. Damholt[5,8], Pierangelo Geppetti[1,9]*, Serena Materazzi[1]

1 Department of Preclinical and Clinical Pharmacology, University of Florence, Florence, Italy, 2 Pharmacology Department, Chiesi Farmaceutici SpA, Parma, Italy, 3 Department of Biochemistry and Molecular Biology, University of Parma, Italy, 4 Centre for Infection and Immunity, Queen's University Belfast, Belfast, United Kingdom, 5 AstraZeneca Research & Development Innovative Medicines Respiratory & Inflammation, Mölndal, Sweden, 6 Truly Translational Sweden AB, Lund, Sweden, 7 Disease Pharmacology LEO Pharma A/S, Ballerup, Denmark, 8 Department of Biology, University of Copenhagen, Copenhagen, Denmark, 9 Headache Center, University of Florence, Florence, Italy

The FASEB Journal article fj.10-162438. Published online August 18, 2010.

The FASEB Journal • Research Communication

Acetaminophen, *via* its reactive metabolite *N*-acetyl-*p*-benzo-quinoneimine and transient receptor potential ankyrin-1 stimulation, causes neurogenic inflammation in the airways and other tissues in rodents

Romina Nassini,*,[1] Serena Materazzi,*,[1] Eunice Andrè,*,[2] Laura Sartiani,* Giancarlo Aldini,[§] Marcello Trevisani,[‖] Chiara Carnini,[¶] Daniela Massi,[†] Pamela Pedretti,* Marina Carini,[§] Elisabetta Cerbai,* Delia Preti,[#] Gino Villetti,[¶] Maurizio Civelli,[¶] Gabriela Trevisan,* Chiara Azzari,[‡] Susan Stokesberry,** Laura Sadofsky,[††] Lorcan McGarvey,** Riccardo Patacchini,[¶] and Pierangelo Geppetti*,[3]

*Department of Preclinical and Clinical Pharmacology, [†]Department of Human Pathology and Oncology, and [‡]Department of Pediatrics, University of Florence, Florence, Italy; [§]Department of Pharmaceutical Sciences, University of Milan, Milan, Italy; [‖]Pharmeste Srl, Ferrara, Italy; [¶]Pharmacology Department, Chiesi Farmaceutici SpA, Parma, Italy; [#]Department of Pharmaceutical Chemistry, University of Ferrara, Ferrara, Italy; **Centre for Infection and Immunity, Queen's University Belfast, Belfast, UK; and [††]Division of Cardiovascular and Respiratory Studies, University of

Camphor, an Old Cough Remedy with a New Mechanism

To the Editor:

Author disclosures are available with the text of this letter at www.atsjournals.org.

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AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE

VOL 185 2012

Research article

Cigarette smoke–induced neurogenic inflammation is mediated by α,β-unsaturated aldehydes and the TRPA1 receptor in rodents

Eunice Andrè,[1] Barbara Campi,[1] Serena Materazzi,[2] Marcello Trevisani,[1] Silvia Amadesi,[3] Daniela Massi,[4] Christophe Creminon,[5] Natalya Vaksman,[3] Romina Nassini,[2] Maurizio Civelli,[6] Pier Giovanni Baraldi,[7] Daniel P. Poole,[3] Nigel W. Bunnett,[3] Pierangelo Geppetti,[1,2] and Riccardo Patacchini[6]

[1]Center of Excellence for the Study of Inflammation, University of Ferrara, Ferrara, Italy. [2]Clinical Pharmacology Unit, Department of Critical Care Medicine and Surgery, University of Florence, Florence, Italy. [3]Departments of Physiology and Surgery, UCSF, San Francisco, California, USA. [4]Department of Human Pathology and Oncology, University of Florence, Florence, Italy. [5]CEA, Institut de Biologie et Technologies de Saclay (iBiTec-S), Service de pharmacologie et d'immuno analyse (SPI), Gif sur Yvette, France. [6]Pharmacology Department, Chiesi Pharmaceuticals, Parma, Italy. [7]Department of Pharmaceutical Chemistry, University of Ferrara, Ferrara, Italy.

The Journal of Clinical Investigation

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Ostacoli principali

- vincere i pregiudizi del mondo universitario sulla ricerca industriale

- vincere i pregiudizi dei ricercatori dell`industria sulla ricerca pubblica in Italia

- vincere le resistenze della burocrazia

- trovare un compromesso per lo sfruttamento della proprietà intellettuale dei risultati

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Benefici per l`Università

- Giovani laureati con alta specializzazione sono avviati verso il mondo del lavoro

- Il confronto con l`Industria stimola la ricerca primaria a scoprire nuovi meccanismi patogenetici utili a sviluppare soluzioni terapeutiche innovative

- Si acquisiscono fondi per la ricerca in cambio di trasferimento tecnologico delle conoscenze

- si può concorrere alla assegnazione di grants (nazionali, CE etc) riservati a progetti di collaborazione/ consorzi

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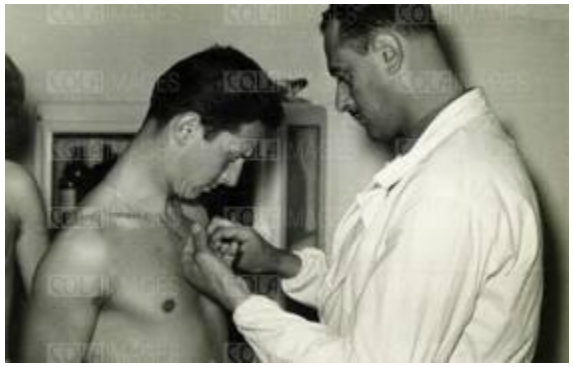
Benefici per l`Azienda

- Possibilità di accedere ad un know-how ed a «facilities» difficilmente reperibili altrove, evitando la lievitazione di centri di ricerca propri

- si può concorrere alla assegnazione di grants (nazionali, CE etc) riservati a progetti di collaborazione /consorzi



- Possibilità di valutare i giovani ricercatori in un lungo periodo di tempo, consentendo la selezione dei più adatti a cui offrire una posizione permanente in azienda

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Incentivi Fiscali per R&D

2012

Credito d'imposta del 90% dell'importo che eccede la media degli investimenti effettuati nel triennio 2008-2010 per attività commissionate ad Università ed Enti Pubblici.

2013-2016*

Credito d`imposta per attività commissionate ad Università ed Enti Pubblici oppure realizzate direttamente dalle Imprese: 50% incrementale rispetto all'anno precedente con credito d'imposta massimo annuale di € 2.500.000

Proposta: elevare il Credito di Imposta a carico delle Aziende al 30% sulle spese sostenute (fino ad un massimale di 100 M €) per Progetti di Ricerca Condivisi con Università ed Enti di Ricerca Pubblici

* proposto nella Legge di Stabilità

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Grazie !