

Investigación y desarrollo de fármacos radical o incremental

Junio 21, 2015



Eliezer J. Barreiro

Profesor



Universidade Federal do Rio de Janeiro

Laboratório de Avaliação e Síntese de Substâncias Bioativas

<http://www.lassbio.icb.ufrj.br/>



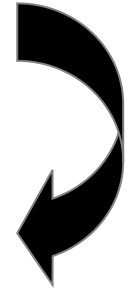
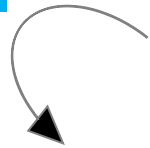
Summary

- ❖ *Prologue: The scientific research nowadays;*
- ❖ *The pharmaceutical innovation process;*
- ❖ *The role of the university in drug discovery (DD);*
- ❖ *The INCT-INOVAR;*
- ❖ *The process of technology transfer;*
- ❖ *Final remarks.*

The scientific research through the ages...



Galileo, Newton, Darwin, & Einstein

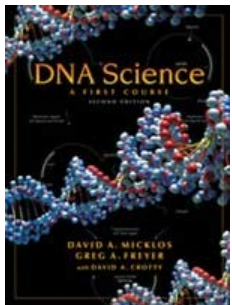


The physical Crick & the biologist Watson

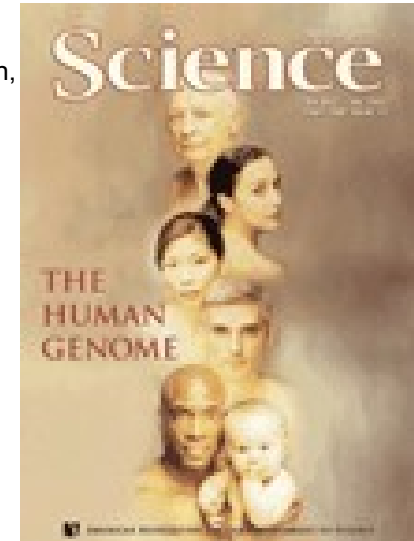
JD Watson & FHC Crick, A Structure for Deoxyribose Nucleic Acid, *Nature* 1953, 171, 737-738 .



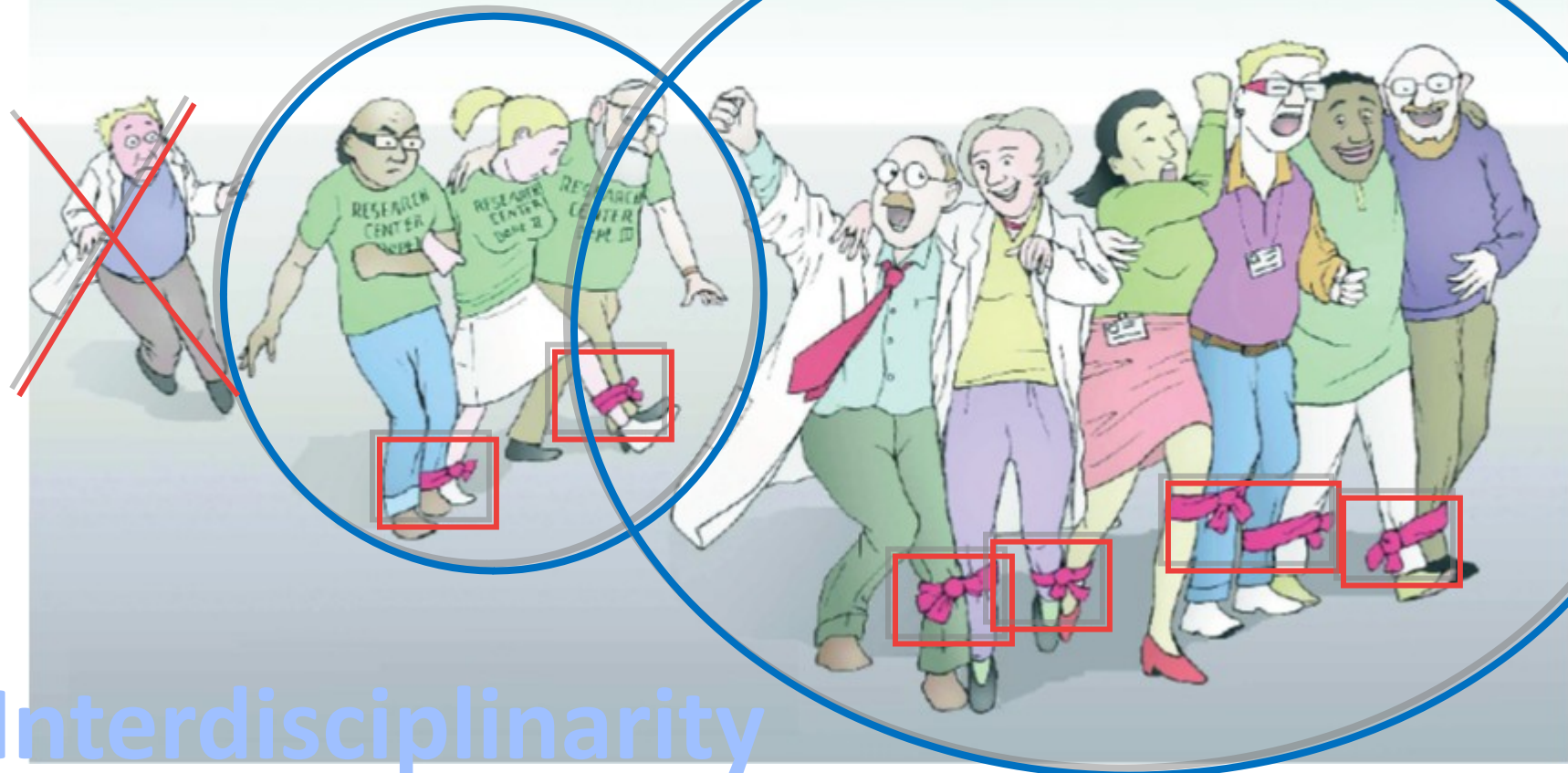
The human genome team



J. Craig Venter, Mark D. Adams, Eugene W. Myers, Peter W. Li, Richard J. Mural, Granger G. Sutton, Hamilton O. Smith, Mark Yandell, Cheryl A. Evans, Robert A. Holt, Jeannine D. Gocayne, Peter Amanatides, Richard M. Ballew, Daniel H. Huson, Jennifer Russo Wortman, Qing Zhang, Chinnappa D. Kodira, Xiangqun H. Zheng, Lin Chen, Marian Skupski, Gangadharan Subramanian, Paul D. Thomas, Jinghui Zhang, George L. Gabor Miklos, Catherine Nelson, Samuel Broder, Andrew G. Clark, Joe Nadeau, Victor A. McKusick, Norton Zinder, Arnold J. Levine, Richard J. Roberts, Mel Simon, Carolyn Slayman, Michael Hunkapiller, Randall Bolanos, Arthur Delcher, Ian Dew, Daniel Fasulo, Michael Flanigan, Liliana Florea, Aaron Halpern, Sridhar Hannenhalli, Saul Kravitz, Samuel Levy, Clark Mobarry, Knut Reinert, Karin Remington, Jane Abu-Threideh, Ellen Beasley, Kendra Biddick, Vivien Bonazzi, Rhonda Brandon, Michele Cargill, Ishwar Chandramouliswaran, Rosane Charlab, Kabir Chaturvedi, Zuoming Deng, Valentina Di Francesco, Patrick Dunn, Karen Eilbeck, Carlos Evangelista, Andrei E. Gabrielian, Weiniu Gan, Wangmao Ge, Fangcheng Gong, Zhiping Gu, Ping Guan, Thomas J. Heiman, Maureen E. Higgins, Rui-Ru Ji, Zhaoxi Ke, Karen A. Ketchum, Zhongwu Lai, Yiding Lei, Zhenya Li, Jiayin Li, Yong Liang, Xiaoying Lin, Fu Lu, Gennady V. Merkulov, Natalia Milshina, Helen M. Moore, Ashwinikumar K Naik, Vaibhav A. Narayan, Beena Neelam, Deborah Nusskern, Douglas B. Rusch, Steven Salzberg, Wei Shao, Bixiong Shue, Jingtao Song, Zhen Juan Wang, Aihui Wang, Xin Wang, Jian Wang, Ming-Hui Wei, Ron Wides, Chunlin Xiao, Chunhua Yan, Alison Yao, Jane Ye, Ming Zhan, Weiqing Zhang, Hongyu Zhang, Qi Zhao, Liansheng Zhong, Jie Zhong, Wenyan Zhong, Shiaoping C. Zhu, Shaying Zhao, Dennis Gilbert, Suzanna E. Lee, Gene Spier, Christine Carter, Anibal Cravchik, Trevor Woodage, Feroze Ali, Huijin An, Andrew Keane, Danita Baldwin, Holly Baden, Mary Barnstead, Ian Barrow, Karen Beeson, Dana Busam, Tommy Carver, Angela Center, Ming Lai Cheng, Liz Curry, Steve Danaher, Lionel Davenport, Raymond D. Miles, Susanne Dietz, Kristina Dodson, Lisa Doup, Steven Ferreira, Neha Garg, Andres G. Heistermann, Brit Hart, Jason Haynes, Charles Haynes, Cheryl Heiner, Suzanne Hladun, Damon Hostin, Jonathan Houck, Timothy Howland, Chinyere Ibegwam, Jeffery Johnson, Francis Kalush, Lesley Kline, Srinani Koduru, Amy Love, Felecia Mann, David May, Steven McCawley, Tina McIntosh, Ivy McMillen, Mee Moy, Linda Moy, Brian Murphy, Keith Nelson, Cynthia Pfannkoch, Eric Pratts, Vinita Puri, Jina Qureshi, Matthew Reardon, Robert Rodriguez, Yu-Hui Rogers, Deanna Romblad, Ben Runfel, Richard Scott, Cynthia Sitter, Michelle Smallwood, Erin Stewart, Renee Strong, Ellen Suh, Reginald Thomas, Ni Ni Tint, Sukyee Tse, Claire Vech, Gary Wang, Jeremy Wetter, Sherita Williams, Monica Williams, Sandra Windsor, Emily Winn-Deen, Keriellen Wolfe, Jayshree Zaveri, Karena Zaveri, Josep F. Abril, Roderic Guigó, Michael J. Campbell, Kimmen V. Sjolander, Brian Karlak, Anish Kejariwal, Huaiyu Mi, Betty Lazareva, Thomas Hatton, Apurva Narechania, Karen Diemer, Anushya Muruganujan, Nan Guo, Shinji Sato, Vineet Bafna, Sorin Istrail, Ross Lippert, Russell Schwartz, Brian Walenz, Shibu Yooseph, David Allen, Anand Basu, James Baxendale, Louis Blick, Marcelo Caminha, John Carnes-Stine, Parris Caulk, Yen-Hui Chiang, My Coyne, Carl Dahlke, Anne Deslattes Mays, Maria Dombroski, Michael Donnelly, Dale Ely, Shiva Esparham, Carl Fosler, Harold Gire, Stephen Glanowski, Kenneth Glasser, Anna Glodek, Mark Gorokhov, Ken Graham, Barry Gropman, Michael Harris, Jeremy Heil, Scott Henderson, Jeffrey Hoover, Donald Jennings, Catherine Jordan, James Jordan, John Kasha, Leonid Kagan, Cheryl Kraft, Alexander Levitsky, Mark Lewis, Xiangjun Liu, John Lopez, Daniel Ma, William Majoros, Joe McDaniel, Sean Murphy, Matthew Newman, Trung Nguyen, Ngoc Nguyen, Marc Nodell, Sue Pan, Jim Peck, Marshall Peterson, William Rowe, Robert Sanders, John Scott, Michael Simpson, Thomas Smith, Arlan Sprague, Timothy Stockwell, Russell Turner, Eli Venter, Mei Wang, Meiyuan Wen, David Wu, Mitchell Wu, Ashley Xia, Ali Zandieh, and Xiaohong Zhu



What makes a successful research team?

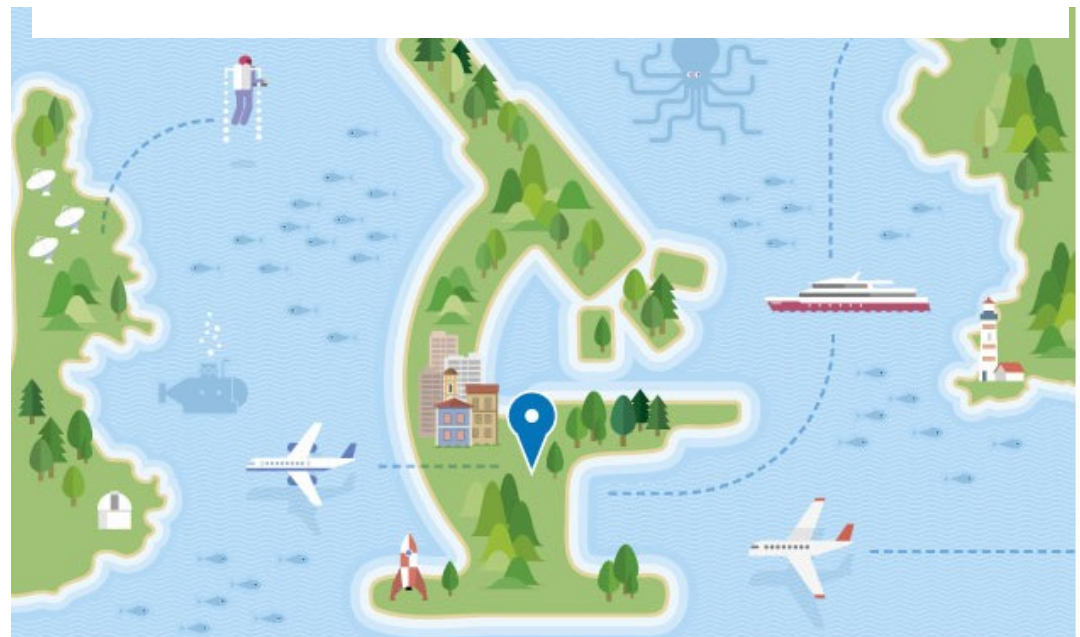


Interdisciplinarity

W Masona, D J Watts, Collaborative learning in networks, *PNAS* **2012**, 109, 764; M Williams, Productivity Shortfalls in Drug Discovery: Contributions from the Preclinical Sciences?, *JPET* **2011**, 336, 3; R Guimera, B Uzzi, J Spiro, L A N Amaral, Team Assembly Mechanisms Determine Collaboration Network Structure and Team Performance, *Science* **2005**, 308, 697.

The rise of research networks

New collaboration patterns are changing the global balance of science. Established superpowers need to keep up or be left behind, says **Jonathan Adams**.

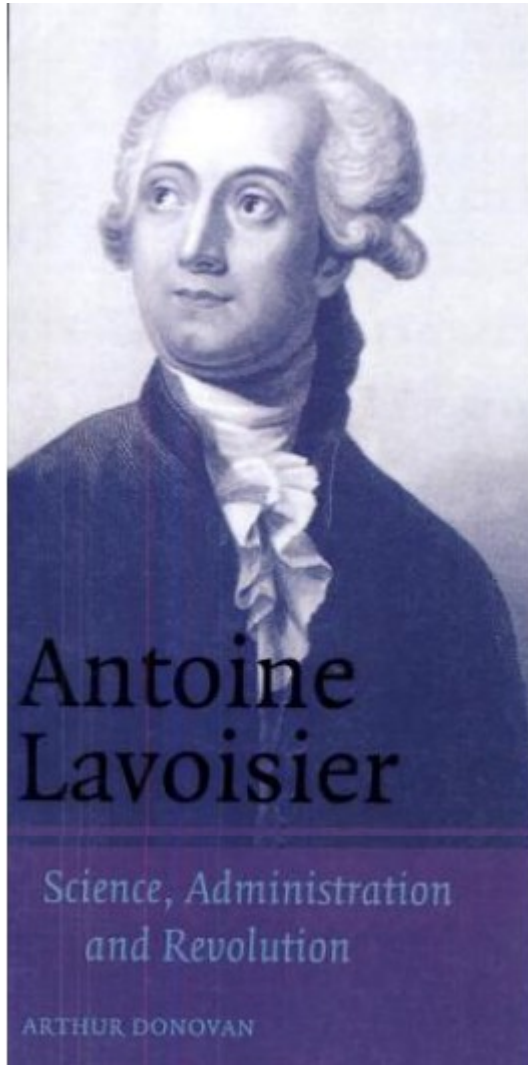


THE NEW MAP OF SCIENCE

Today more nations – from China and India to Singapore, Brazil and South Korea – are taking their place at the high table of research alongside the traditional science superpowers. At the same time national boundaries are being transcended through collaboration networks and 'brain circulation'. In this special issue *Nature* examines how the movement of people and ideas will change how science is done, how it is funded and the questions that it addresses.

Image credit: Jasiek Krzysztofak

J Adams,
Collaborations:
The rise of research
network,
Nature **2012**, 490, 335




“Most of the work still to be done in science and the useful arts is precisely that which needs knowledge and cooperation of many scientists and disciplines.

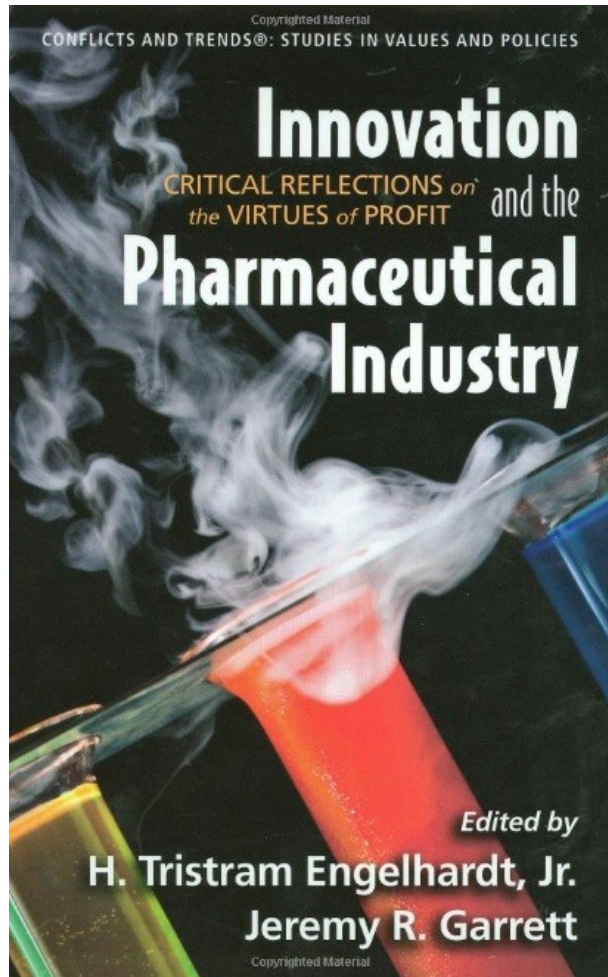
That is why it is necessary for scientists and technologists in different disciplines to meet and work together, even those in branches of knowledge which seem to have least relation and connection with one another.”

Interdisciplinarity

Antoine Lavoisier, 1793

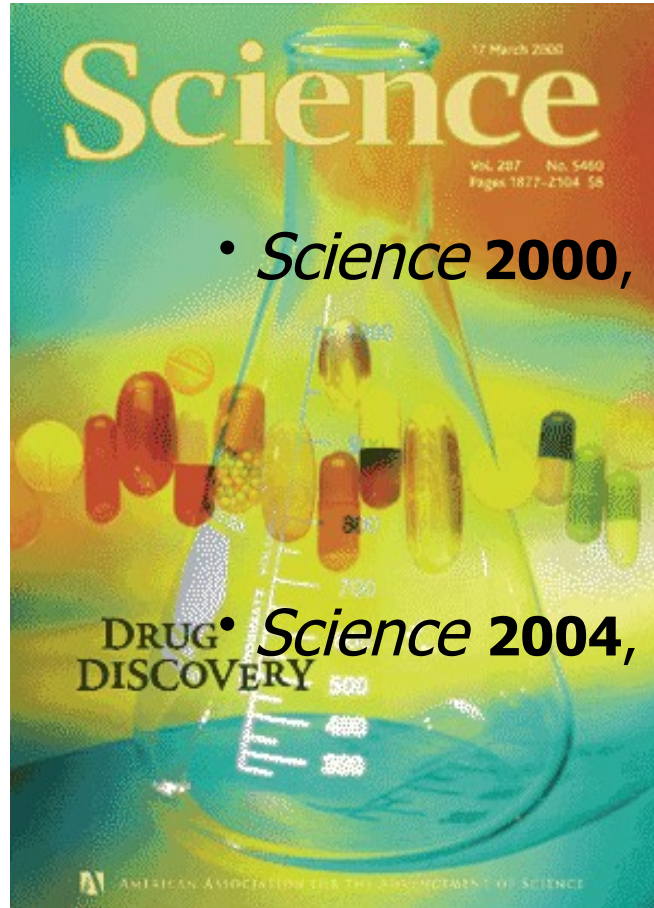


*The
pharmaceutical
innovation
process...*



Technological innovation is a process mostly dynamic in industrial activity.
This dynamism is accentuated in pharmaceutical innovation which, more than any other, depend on the effective and productive interaction between Science & Technology.

The drug discovery...



• *Science* **2000**, 287, 1951 (J. Uppenbrink, J. Mervis)



• *Science* **2004**, 303, 1713 (D. Kennedy)



...is science-based process!

The Nobel & drugs

• **165** researchers won the Nobel Prize in Chemistry from 1901 to 2013



<http://nobelprize.org>

■ **204** researchers won the Nobel Prize in Medicine from 1901 to 2013

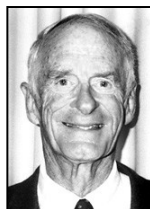
R Ganellin, W Duncan, Obituary James Black (1924-2010), *Nature* **2010**, 464, 1292; CP Page, J Schaffhausen, NP Shankley, The scientific legacy of Sir James W. Black, *TIPS* **2011**, 32, 181.



1990 - E. J. Corey



2001-R. Noyori



2001-W.S. Knowles

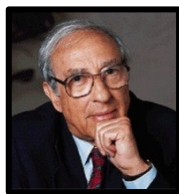


2001-K.B. Sharpless

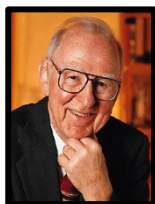


2012-R.J. Lefkowitz

2012-B.K. Kobilka



1992 -E.H. Fischer



1992 - E.G. Krebs



2013- M. Karplus



2013- M. Levitt



2013- A. Warshel

“for their discoveries of important principles for drug treatment”



1982 – S.B. Bergström



1982 – B.I. Samuelsson



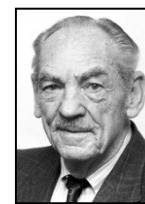
1982 – J.R. Vane



1988 - J.W. Black



1988 - G.B. Elion



1988 - G.H. Hitchings

inter-alia:

2013–M. Karplus
M. Levitt
A. Warshel

2012- R.J. Lefkowitz
B. K. Kobilka

2009-V Ramakrishnan
T. A. Steitz
A. E. Yonath

2002-J.B. Fenn
K. Tanaka
K. Hüthrich

1997-P.D. Boyler
J.E. Walker
J.C. Skou

1987 –D.J. Cram
J-M Lehn
C.J. Pedersen

1979 - H. C. Brown
G. Wittig


inter-alia:

AAS

Propranolol

Cimetidine

Acyclovir



*The role of
the university
in D2*

INCT



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Drug Discovery in an Academic Setting: Playing to the Strengths

Donna M. Huryl*

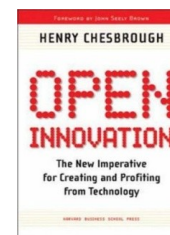
Department of Pharmaceutical Sciences, University of Pittsburgh, 712 Salk Hall, 3501 Terrace Street, Pittsburgh, Pennsylvania 1526, United States

 ACS Medicinal
Chemistry Letters


Inter-alia: CJ Tralau-Stewart et al., UK academic drug discovery, *Nature Rev. Drug Discov.* **2014**, 13,15; M Alvim-Gaston et al. Open Innovation Drug Discovery (OIDD): A Potential Path to Novel Therapeutic Chemical Space, *Curr Top Med Chem* **2014**, 14, 294; SP Forster et al. Virtual pharmaceutical companies: collaborating flexibly in pharmaceutical development, *Drug Discov. Today* **2014**, 19, 348; BS Slusher et al., Bringing together the academic drug discovery community, *Nature Rev. Drug Discov.* **2013**, 12, 811; H Wild, C Huwe, M Lessl, Collaborative Innovation — Regaining the Edge in Drug Discovery, *Angew. Chem. Int. Ed.* **2013**, 52, 2684; W L Jorgensen, Challenges for Academic Drug Discovery, *Angew. Chem. Int. Ed.* **2012**, 51,11680; S Frye et al., US Academic Drug Discovery, *Nature Rev. Drug Discov.* **2011**, 10, 409; C J Tralau-Stewart et al., Drug Discovery: New models for Industry-Academic partnerships, *Drug Discov. Today* **2009**, 14, 95; PG Wyatt, The emerging academic drug discovery sector, *Future Med. Chem.* **2009**, 1, 1013.

“ ... a university has a number of unique characteristics that could contribute to making it an ideal environment where drug discovery & medicinal chemistry activities can thrive....There is no doubt that academia can play an important role in drug discovery”

ACS Med. Chem. Lett. **2013**, 4, 313



Henry
Chesbrough



Drug discovery: new models for industry-academic partnerships



Cathy J. Tralau-Stewart, Colin A. Wyatt, Dominique E. Kleyn and Alex Ayad

Drug Discovery Centre and Business Development, Imperial College London SW7 2AZ, UK

The re-focusing of pharmaceutical industry research away from early discovery activities is stimulating the development of novel models of drug discovery, notably involving academia as a 'front end'. In this article the authors explore the drivers of change, the role of new entrants (universities with specialised core facilities) and novel partnership models. If they are to be sustainable and deliver, these new models must be flexible and properly funded by industry or public funding. rewarding all partners for

A A Toole, The impact of public basic research on industrial innovation: Evidence from the pharmaceutical industry, *Res. Policy* **2012**, 41, 1; AJ Stevens *et al.*, The role of public-sector research in the discovery of drugs and vaccines. *N. Engl. J. Med.* **2011**, 364, 535; R Kneller, The importance of new companies for drug discovery: origins of a decade of new drugs. *Nature Rev. Drug Discov.* **2010**, 9, 867; MR Barnes *et al.*, Lowering industry firewalls: pre-competitive informatics initiatives in drug discovery, *Nature Rev. Drug Discov.* **2009**, 8, 701; PG Wyatt, The emerging academic drug-discovery sector. *Future Med. Chem.* **2009**, 1, 1013.

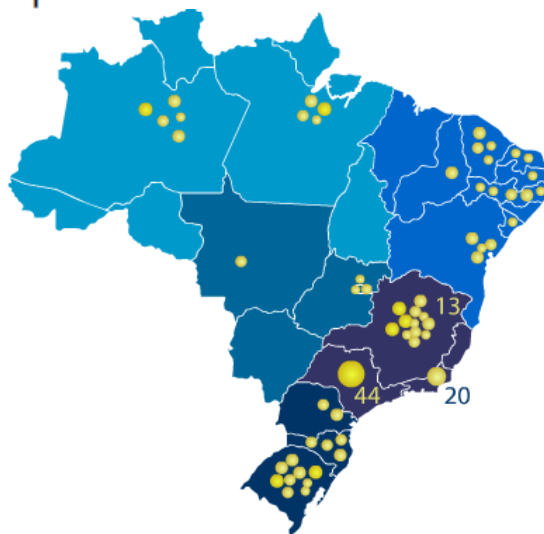


PROGRAMA INSTITUTOS NACIONAIS DE C&T

DOCUMENTO DE ORIENTAÇÃO APROVADO PELO COMITÊ DE COORDENAÇÃO

EM 29 DE JULHO DE 2008

Dentre os objetivos maiores do PACTI relativos ao Sistema Nacional de C,T&I (SNCTI) está a busca da excelência nas atividades em ciência e tecnologia em nível internacional, uma vigorosa integração do sistema de C&T com o sistema empresarial, a melhoria da educação científica, e a participação mais equilibrada das diferentes regiões do país no esforço produtivo com base no conhecimento.



**ENERGIA, EXATAS
AGRÁRIAS, MEIO-AMBIENTE
TECNOLOGIA DA INFORMAÇÃO
SAÚDE (>20)**



The mission...

- To organize the scientific capacity in an effective & productive drug discovery network ;
- Contribute to Brazil capacity on radical & incremental innovation in drugs ;



INCT-INOFAR...

Contribute to continuous qualification of students in drug discovery process (e.g. medicinal chemistry + pharmacology);



inofar

Instituto Nacional de Ciência e Tecnologia
de Fármacos e Medicamentos



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medicinal chemistry



Sede



LASSBio

Laboratório de Avaliação e Síntese de Substâncias Bioativas

Chemical Synthesis
For Lead Selection

Biological
Evaluation

Rational Design
& Lead Optimization

Molecular
Modeling

therapeutic
innovation

LASSBio
Laboratório de Avaliação e Síntese de Substâncias Bioativas

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The process of drug discovery & development

The current view

*fully integrated
pharmaceutical network*



DRUG DEVELOPMENT



medicinal chemistry

- Compound Design
- Compound Screening
- Assay Development
- In Vivo Experiments
- ADME/Tox Studies
- Translational Science

Clinical Assessment:

- Phase I: Safety
- Phase II: Efficacy
- Phase III: Registration

CLINICAL STUDY

Clinically Proven Molecule

Clinical Insights

Clinical Experiment

Competent Molecule

Innovation
Ideas Inspiration

Discovery Approaches:

Phenotypic → System Hypothesis

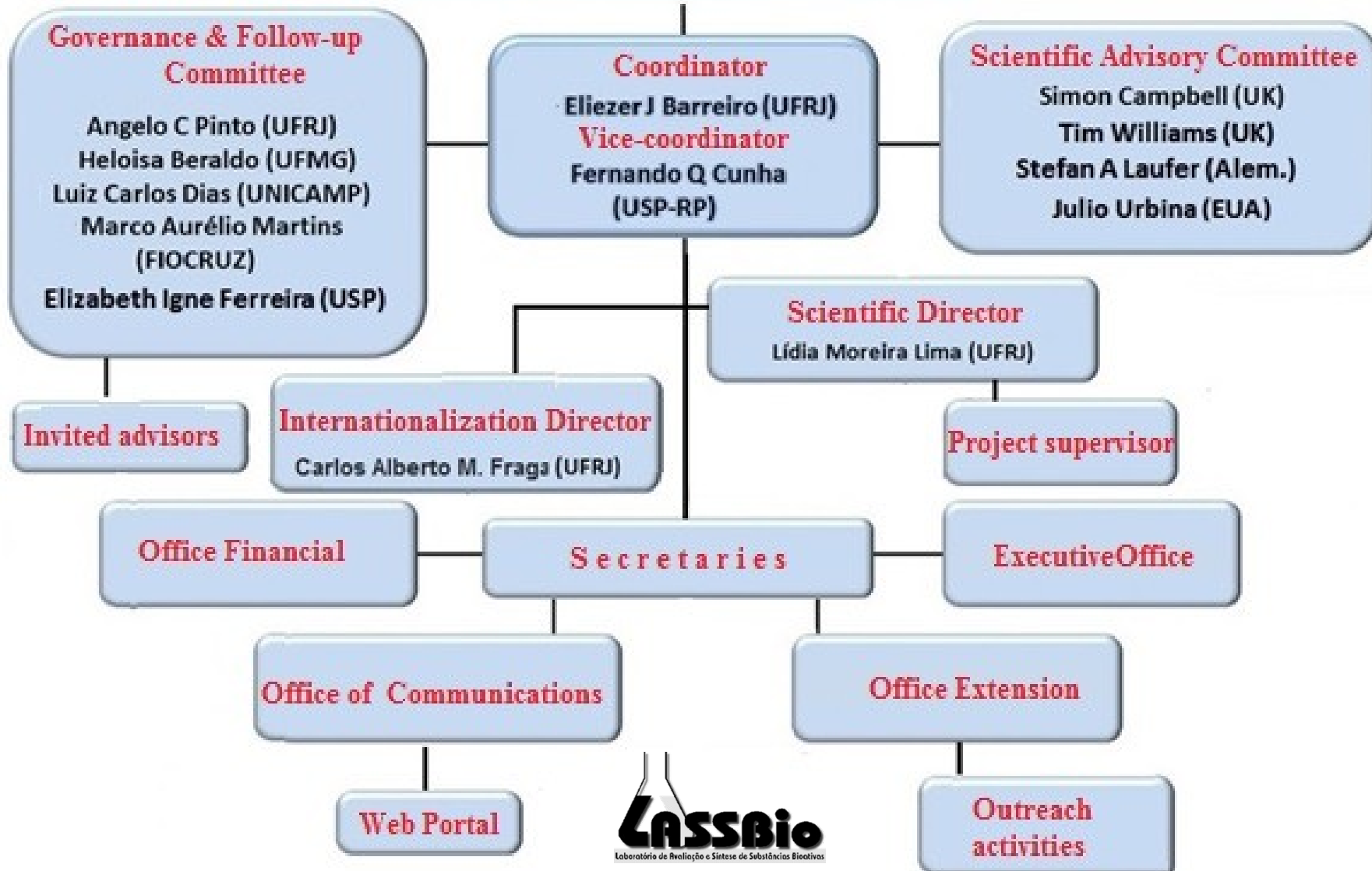
Target-based → Molecular Hypothesis

Ideas & Insights

DRUG DISCOVERY

Initiative

Governance committee

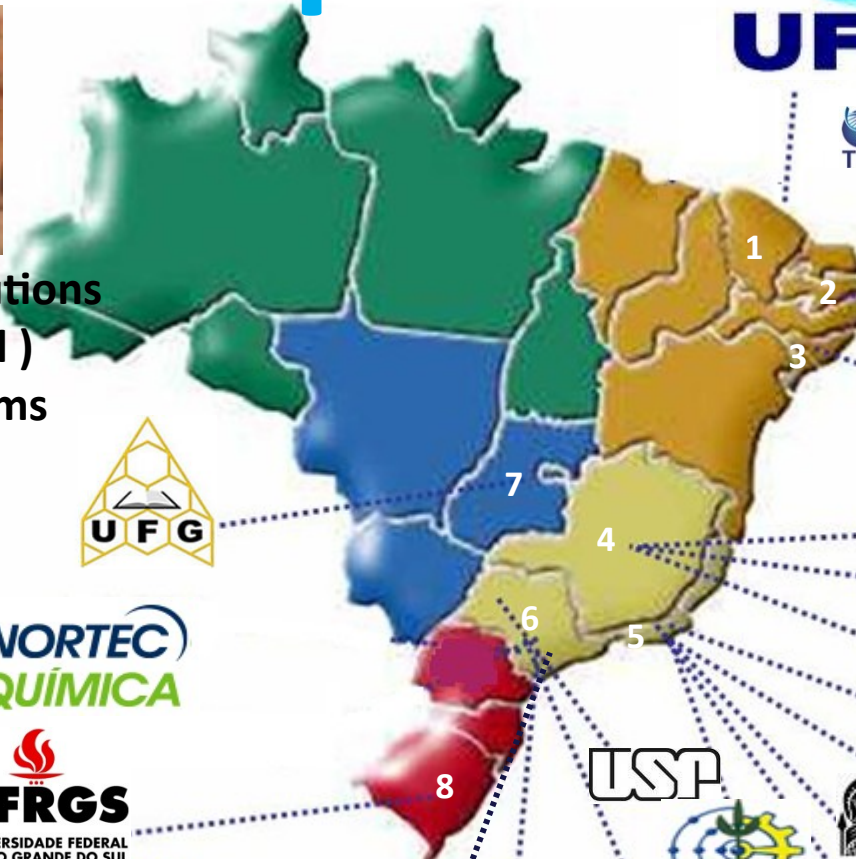




Partnerships



16 scientific institutions
(4 international)
30 research teams
6 companies



In Vitro Cells

UFMG



UFMG

USP



LNCC

CRISTÁLIA



NORTEC QUÍMICA



Universidade Federal do Pampa

UNIVERSITÄT TUBINGEN



UNICAMP

unesp



LNCC



becas

INTERNATIONAL ACTIVITIES



INCT-INOVAR established, on November 18, 2011, a cooperation agreement with the Interdisciplinary Center of Pharmacogenomics and Pharmaceutical Research (ICEPHA) of the University of Tübingen, Germany. Through this deal, we broaden the international scope of INCT-INOVAR and the bases for scientific exchange and the development of innovative research projects in new pharmaceuticals. On the other hand, the agreement establishes the organization of scientific and academic activities, like courses, conferences, seminars, symposiums, or lectures, and the exchange of researchers and/or students, as well as the exchange of materials and publications of mutual interest.

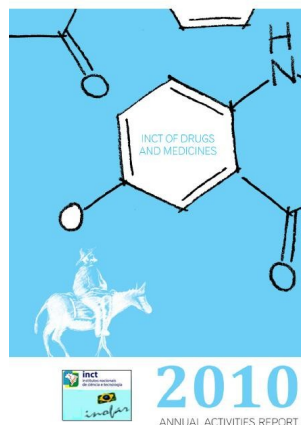
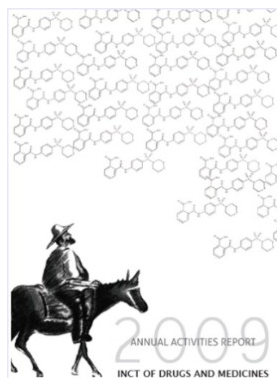


Professor Stefan Laufer (ICEPHA, University of Tübingen) & Professor Eliezer J. Barreiro (INCT-INOVAR, UFRJ, BR)

At the end of 2011, INCT-INOVAR through the Dean of the Federal University of Rio de Janeiro (UFRJ) signed a cooperation agreement with the Interdisciplinary Center for Pharmacogenomics and Pharmaceutical Research (ICEPHA) of the University of Tübingen, Germany, directed by Professor Stefan Laufer.

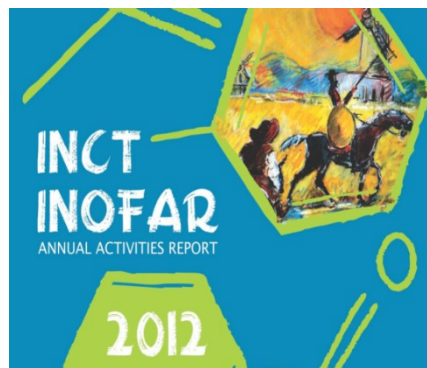
Annual Activities Report

www.inct-inofar.ccs.ufrj.br



Coordinator:
Eliezer J. Barreiro

INCT OF DRUGS
AND MEDICINES
ANNUAL
ACTIVITIES
REPORT



2014



www.inct-inofar.ccs.ufrj.br/download/aar/2014.pdf

Incremental *Innovation*



Generic drugs*



The market of
generic drugs in Brazil:
ca. US\$ 7.0 bi (2013)

**Active pharmaceutical ingredients
(API's)**



The INCT-INOVAR seeks to reverse the usual process in which API come from abroad, developing in ours laboratories a scalable synthetic route to generic & future generic drugs.

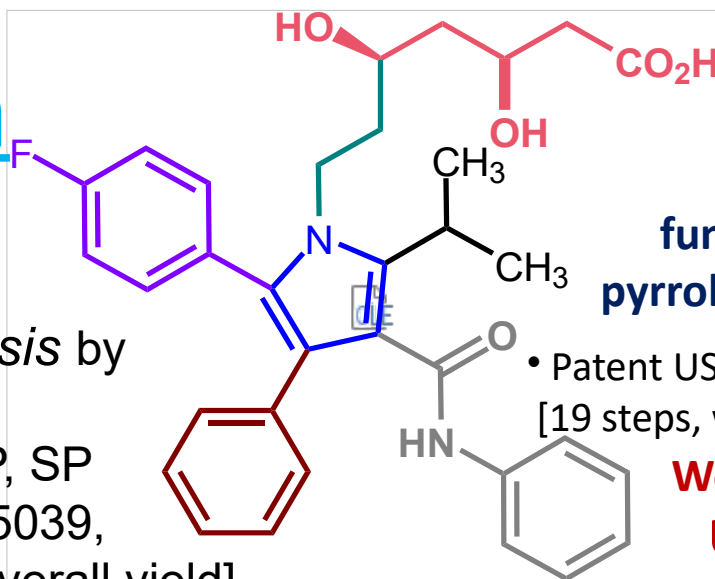




• Atorvastatin

1991

Lipitor™



functionalized
pyrrolheptenoic acid

- *New stereoselective synthesis* by Professor **Luiz Carlos Dias** & Dr **Adriano S. Vieira**, UNICAMP, SP (2010) – INPI Patent, 018110015039, 2011 (BR) [18 steps, with 19% overall yield]

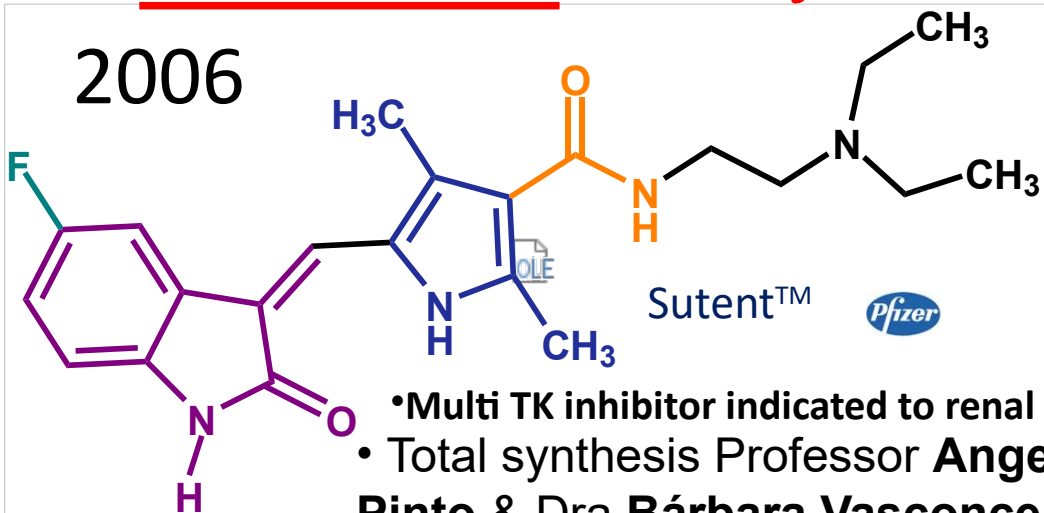
- Patent US 5273995 Pfizer (1991) [19 steps, with *ca.* 5% overall yield]

World total sales:
US\$ > 150 bi
(1991-2011)

• Sunitinib

super blockbuster-drug

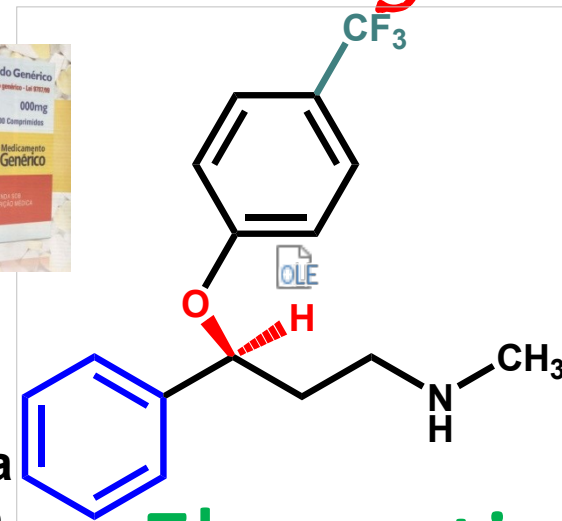
2006



Sutent™



- Multi TK inhibitor indicated to renal carcinoma
- Total synthesis Professor **Angelo da Cunha Pinto** & Dra **Bárbara Vasconcellos da Silva** IQ - UFRJ, **2011** (BR)



Fluoxetine

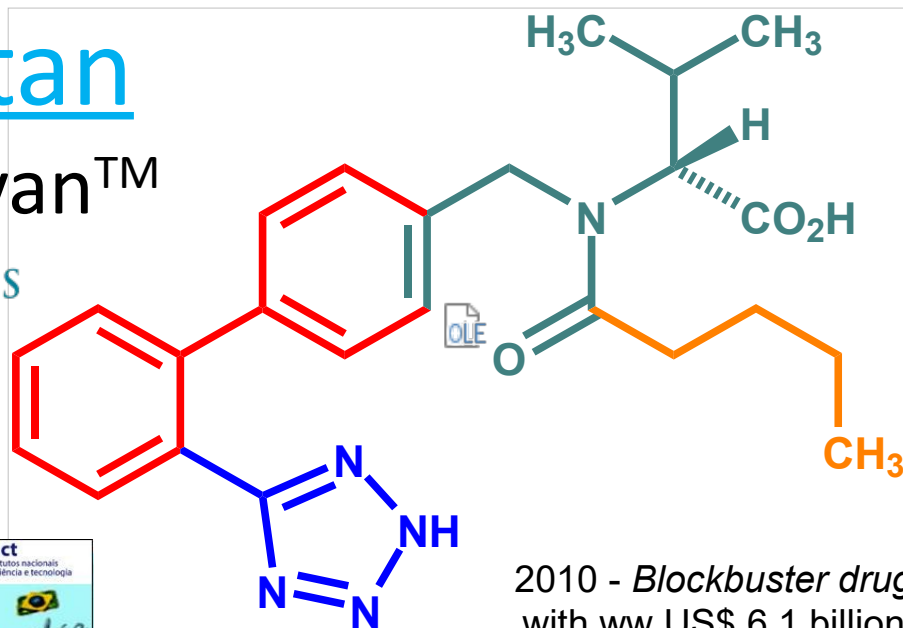
• Valsartan

1990 Diovan™

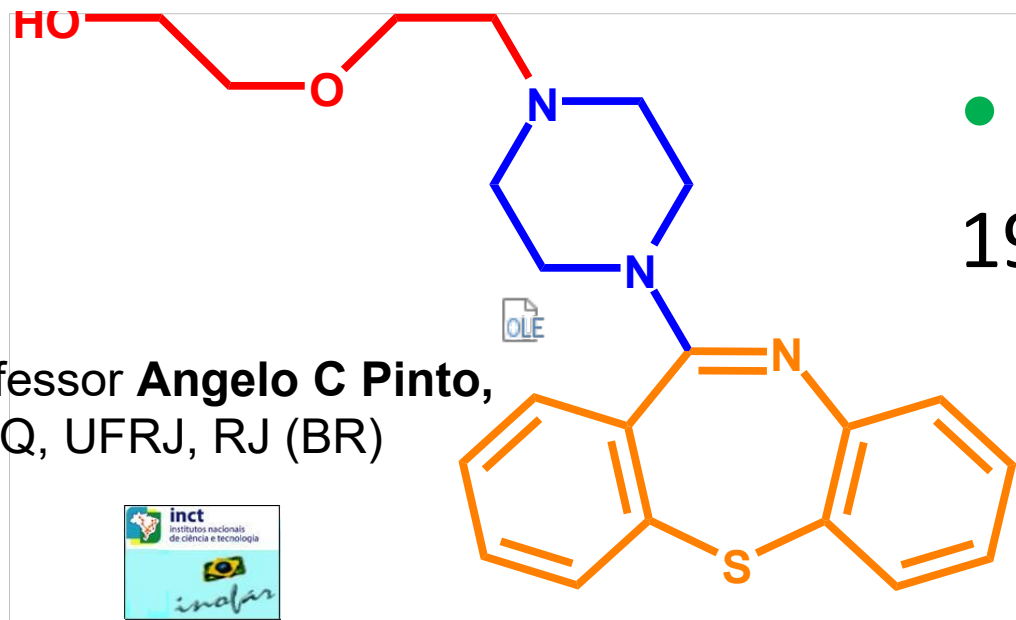


Angiotensin II receptor antagonist
or AT₁ receptor blocker (ARB)

- Professor **Luiz Carlos Dias**,
IQ, UNICAMP, SP (BR)



2010 - Blockbuster drug
with ww US\$ 6,1 billion



• Quetiapine

1996 Seroquel™



- Professor **Angelo C Pinto**,
IQ, UFRJ, RJ (BR)

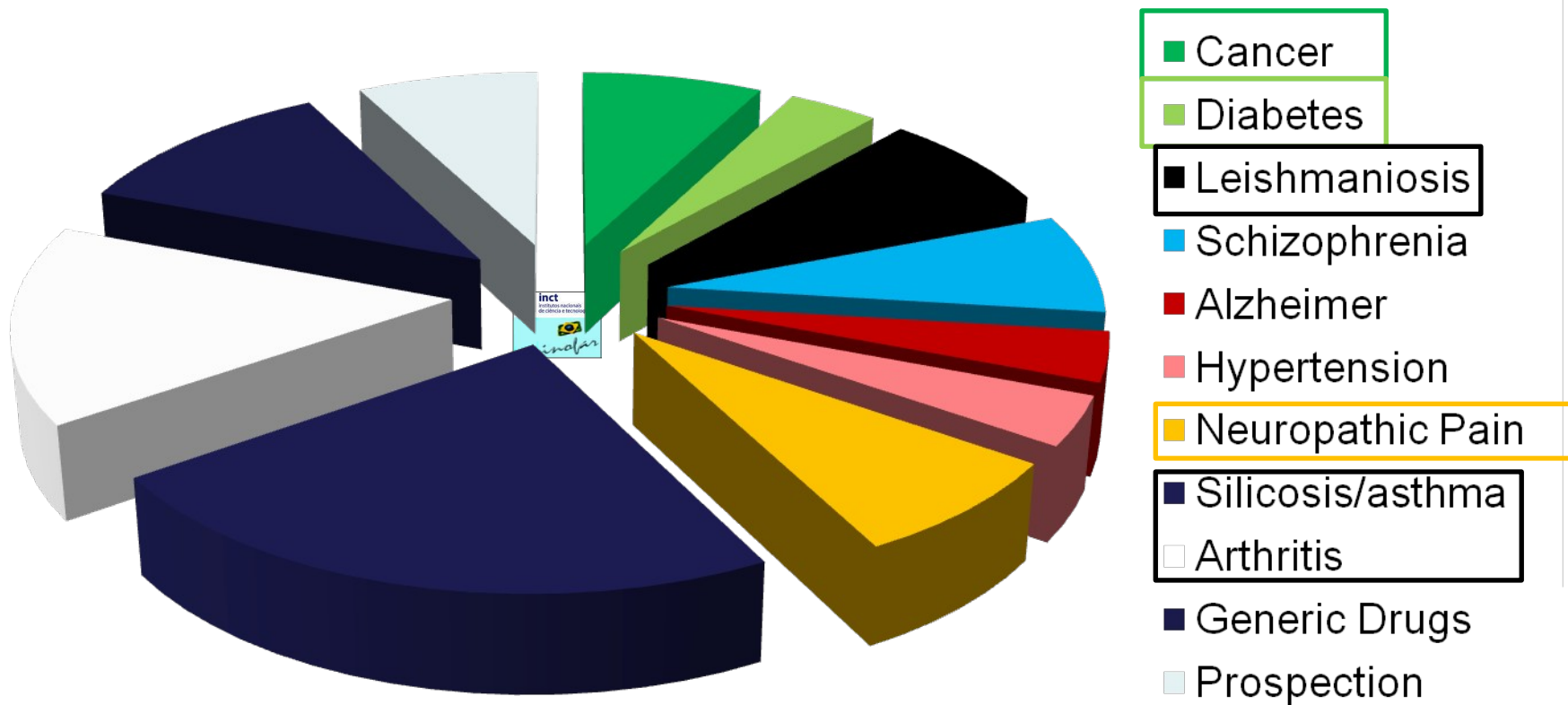


5-HT₂ & D2 receptors blocker
(multitarget drug)

2011 - Blockbuster drug
US Sales = US\$ 4,6 billion

Radical *Innovation*

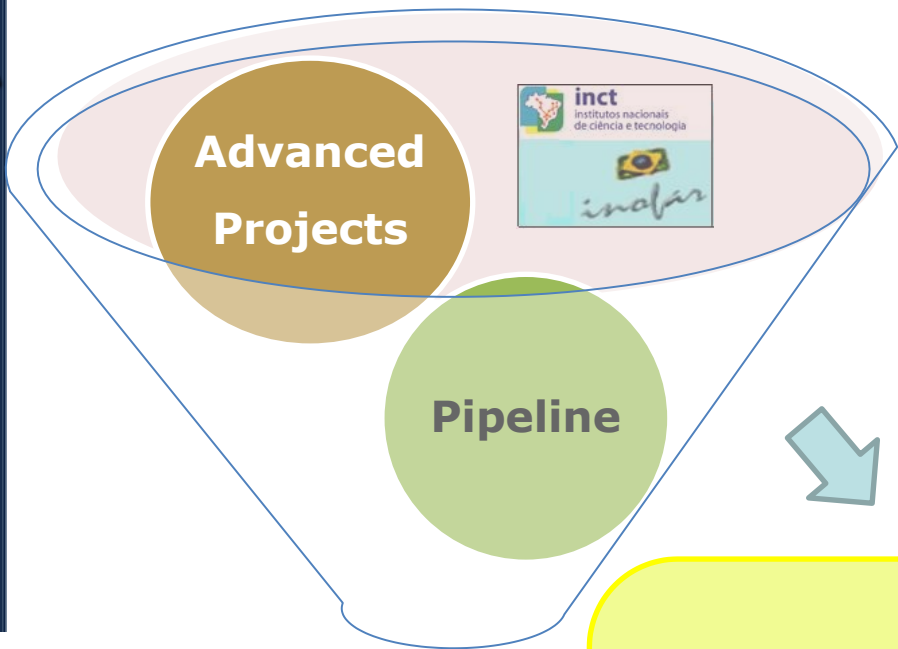
Projects*



* At right **colors** squares the principal's research projects



Radical Innovation



Antileishmanial activity of new N-acylhydrazone derivatives and analogues
 ICB-UFAL / LASSBio-
 UFRJ

Studies on design & discovery of new antidiabetes drug candidates.
 LASSBio-UFRJ
 BR102013012646-2

Studies of new oncolytic agent, dual inhibitor of kinases
 LASSBio-UFRJ
 WO2014113859
 WO2013142935

Studies of anti-inflammatory & analgesic effect of LASSBio-591, a new candidate of AIA drug.
 LASSBio-UFRJ/FM-USP,RP

Studies on new drug candidate useful for neuropatic pain
 LASSBio-UFRJ / FM-USP,RP
 WO2012054996

Novel 2-chloro-4-anilino-quinazoline derivatives as EGFR and VEGFR-2 dual inhibitors

Maria Leticia de Castro Barbosa^{a,b}, Lídia Moreira Lima^{a,b}, Roberta Tesch^a, Carlos Mauricio R. Sant'Anna^c, Frank Totzke^d, Michael H.G. Kubbutat^d, Christoph Schächtele^d, Stefan A. Laufer^e, Eliezer J. Barreiro^{a,b,*}

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^bGraduate Program of Chemistry (PGQu), Chemistry Institute, Federal University of Rio de Janeiro, Rio de Janeiro, RJ, Brazil

^cDepartment of Chemistry, Federal Rural University of Rio de Janeiro (UFRRJ), Seropédica, RJ, Brazil

^dProQinase GmbH, Freiburg, Germany

^eDepartment of Pharmaceutical/Medicinal Chemistry, Institute of Pharmacy, Eberhard-Karls-University Tübingen, Tübingen, Germany

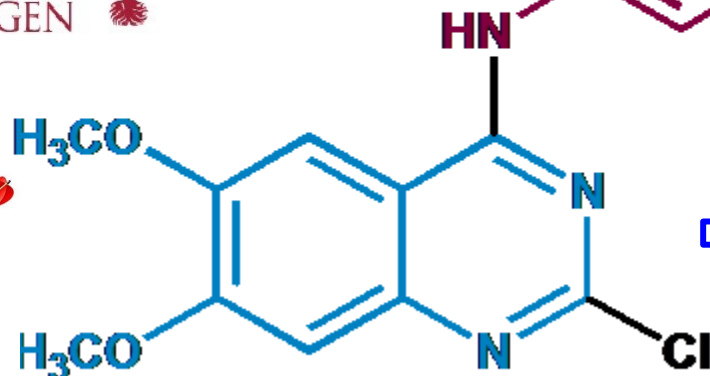
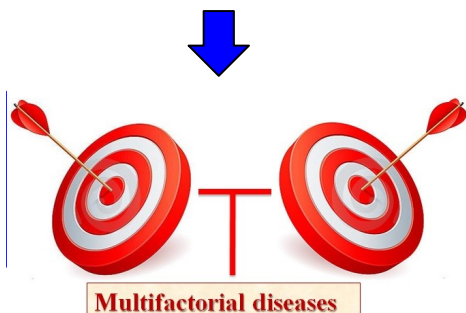
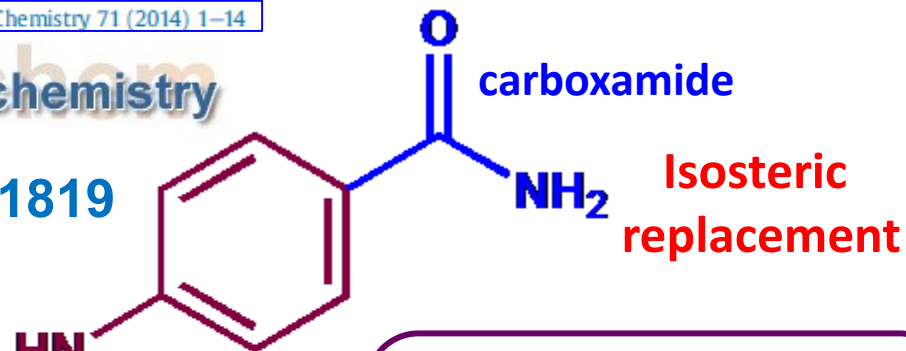


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medicinal chemistry

LASSBio-1819



Dual kinase activity
 IC_{50} (EGFR) = 0,90 μ M
 IC_{50} (VEGFR) = 1,17 μ M

Dual
 Inhibitor
 Dual

MLC Barbosa, Novos derivados quinazolínicos funcionalizados inibidores duais das tirosina cinases receptoras EGFR & VEGFR-2, PhD Thesis, Instituto de Química, UFRJ, 2013.

PEDIDO INTERNACIONAL PUBLICADO SOB O TRATADO DE COOPERAÇÃO EM MATÉRIA DE PATENTES (PCT)

(19) Organização Mundial da Propriedade Intelectual
Secretaria Internacional



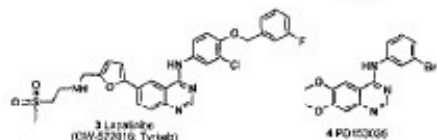
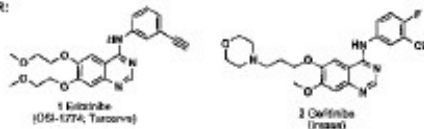
(10) Número de Publicação Internacional
WO 2014/113859 A1

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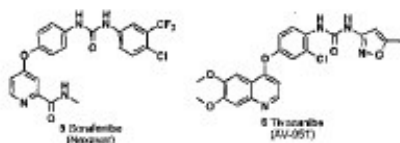
(54) Title : 2-CHLORO-4-ANILINO-QUINAZOLINE COMPOUNDS INHIBITING PROTEIN TYROSINE KINASES, PHARMACEUTICAL COMPOSITIONS COMPRISING THE SAME, METHOD FOR PRODUCING THE SAME AND TYROSINE KINASE INHIBITION METHOD

(54) Título : COMPOSTOS 2-CLORO-4-ANILINO-QUINAZOLINICOS INIBIDORES DE PROTEÍNAS TIROSINA CINASES, COMPOSIÇÕES FARMACÊUTICAS COMPREENDENDO OS MESMOS, PROCESSO PARA SUA PRODUÇÃO E MÉTODO PARA INIBIÇÃO DE TIROSINA CINASES

EGFR:



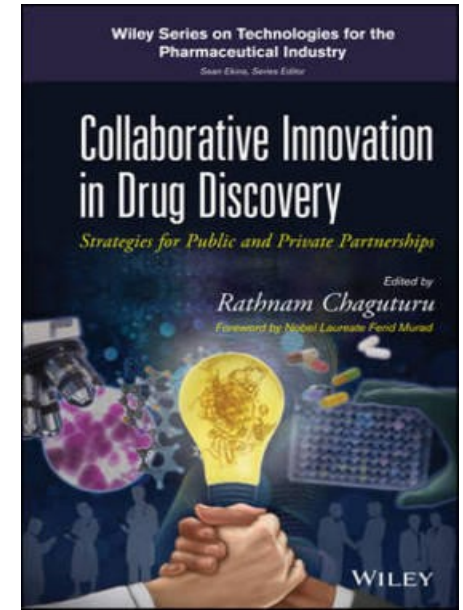
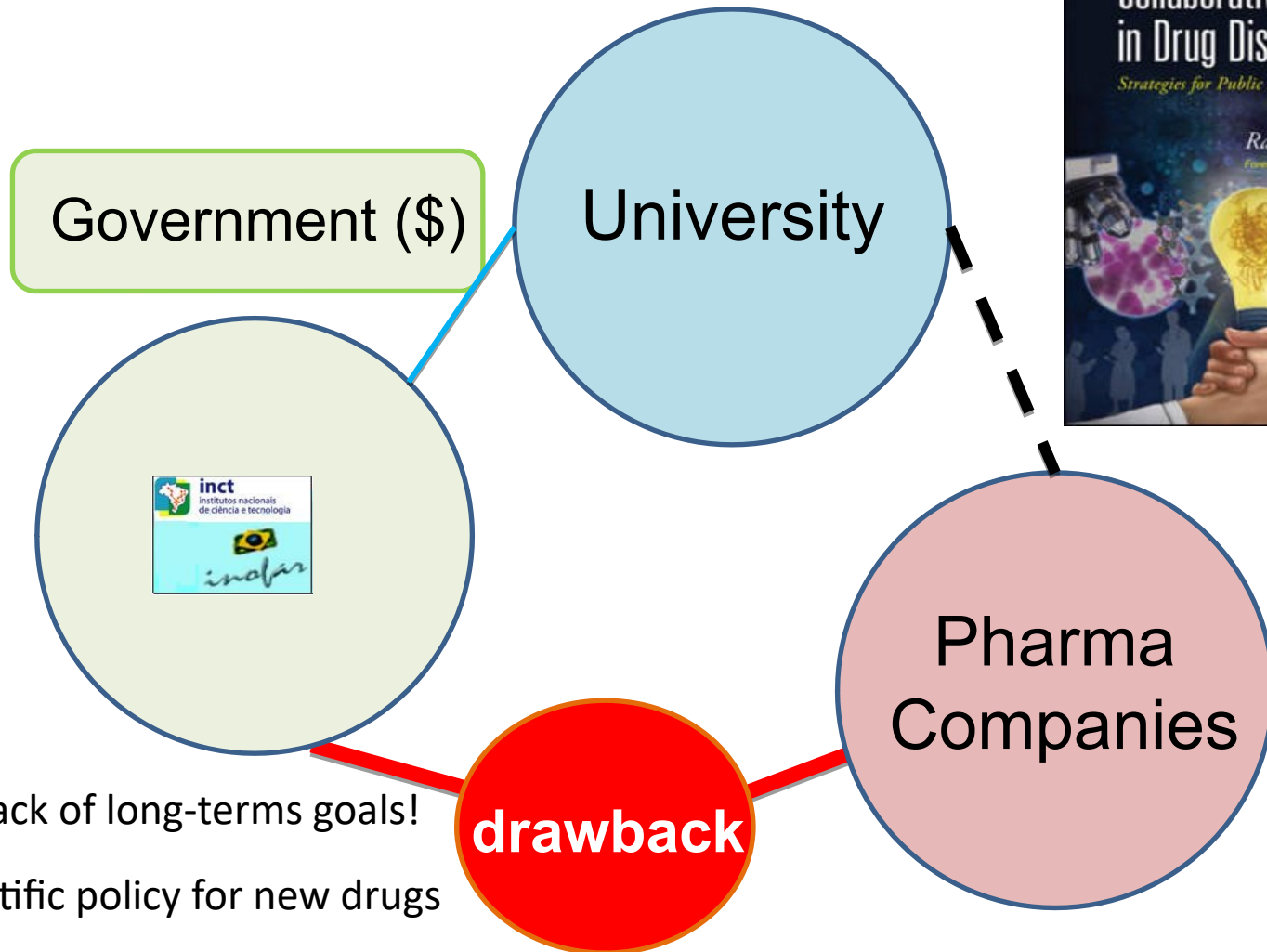
VEGFR-2:

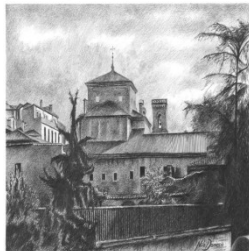


(57) Abstract : The present invention relates to 2-chloro-4-anilino-quinazoline derivatives with EGFR and/or VEGFR-2 protein tyrosine kinase inhibiting activity, to anti-tumour pharmaceutical compositions that comprise said compounds, and to methods for producing the same. The present invention further provides a method for treating solid tumours by inhibition of tyrosine kinases.

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TESCH, Roberta;

Process of technology transferring





Opportunities and Challenges for Innovation in Pharmaceuticals: Now or Never!

Barreiro, E. J.;* Pinto, A. C.

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<http://www.uff.br/rvq>

[Rev Virtual Quim 2013, 5, 1059](#)

Abstracts

The article describes the discovery of new drugs and presents some of the pioneer scientists of these findings. It also shows the innovation in pharmaceuticals and the contributions of INCT-INOVAR that will help Brazil to be one of the players in drug development.

Keywords: Pharmaceutical innovation; new drugs; process of drug discovery.

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Muchas Gracias!