

# Preparing young scientists in the Developing World for facing Good Publication Practices

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# THE MAP OF THIS LECTURE:

- ❖ **A brief review of “Good Practices”**
- ❖ **Good Publication Practice: an emerging concept**
- ❖ **Two examples of what is being done: EQUATOR and MIBBI**
- ❖ **The challenge for scientists in developing countries working in biological sciences**
- ❖ **What can be done: some ideas**

# What are **Good Practices (GP's)**?

## A brief review of the concept

**GP's are guidelines that define:**

- ❖ **How things should be done (specifications and standard operating procedures)**
- ❖ **How to demonstrate their implementation (registries)**

**GP's** generally begin as guidelines ...and become compulsory as they get approved and introduced.

# **“Good Practices”** in the pharmaceutical industry: a one slide history

Source: Barbara Immel, The BioPharm Guide to GMP History, 2002.

**Laboratory  
Research**



**Good Laboratory  
Practices, GLP (1979)**



**The  
Industry**



**Good Manufacturing  
Practices, GMP (1963)**



**Clinical  
trials**



**Good Clinical  
Practices, GCP (1996)**

# “Good Publication Practice for pharmaceutical companies”

*Current Medical Research & Opinion* 2003;19(3):149-154

The Int. Soc. for Medical Publication Professionals

“...designed for use by  
pharmaceutical  
companies and other  
commercial  
organizations that  
sponsor clinical trials”

Updated in: BMJ,  
Dec. 2009, vol 339:  
“GPP2 Guidelines”

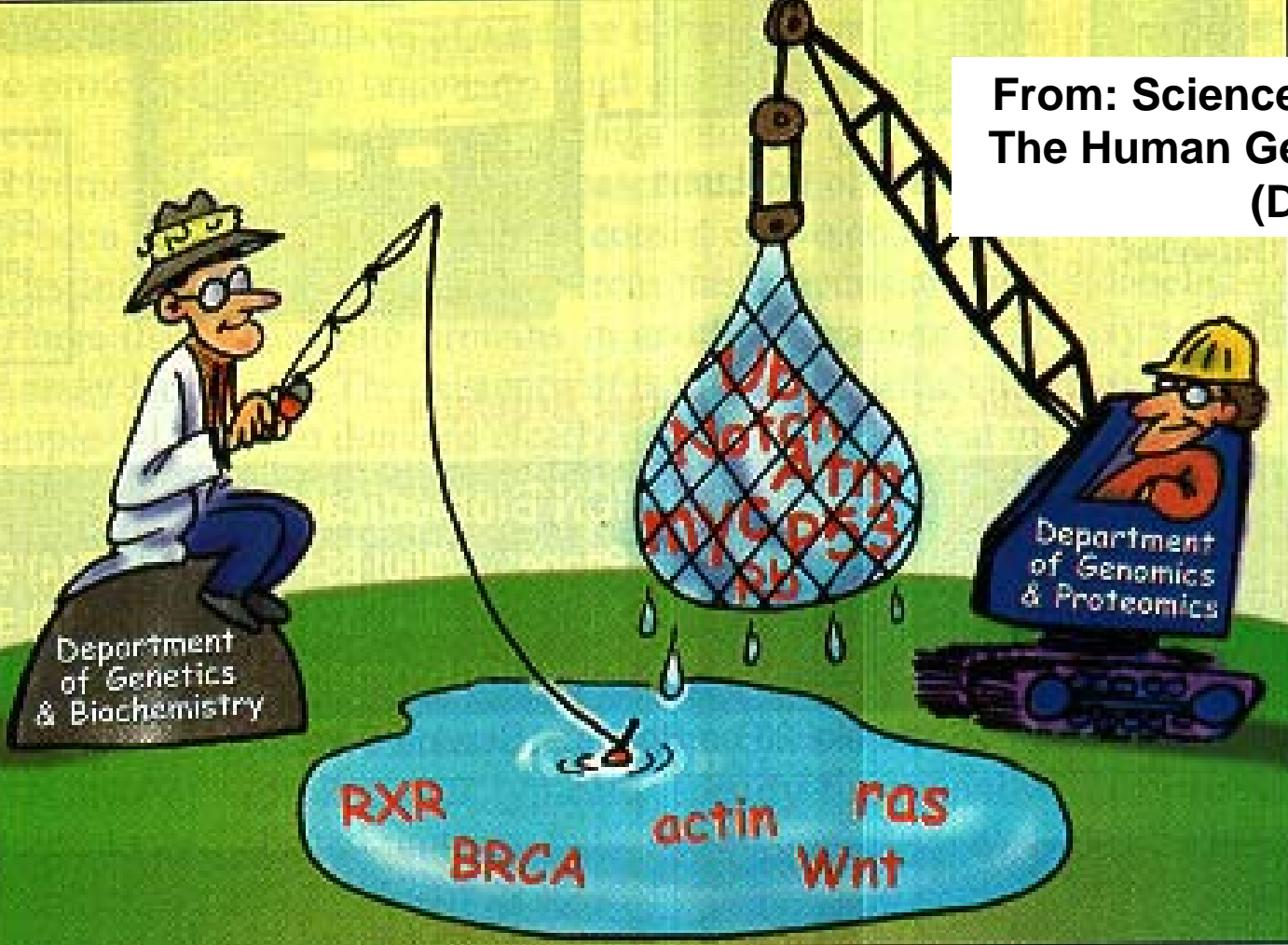


Both articles establishing Good Publication Practice addressed mainly **ethical aspects** in medical publications

Now, there is the need for **widening the concept**, to include **all aspects** related to **quality** when publishing biological, medical, and biomedical research

DUSTIN  
Toronto, Canada

From: Science, February 2001:  
The Human Genome Sequence  
(Draft)



In biomedical sciences there is **concern** about the **volume** of published data and the degree attained in their **validation** (and **interpretation**)



genomics



57,355 documents semantically analyzed



bioinformatics

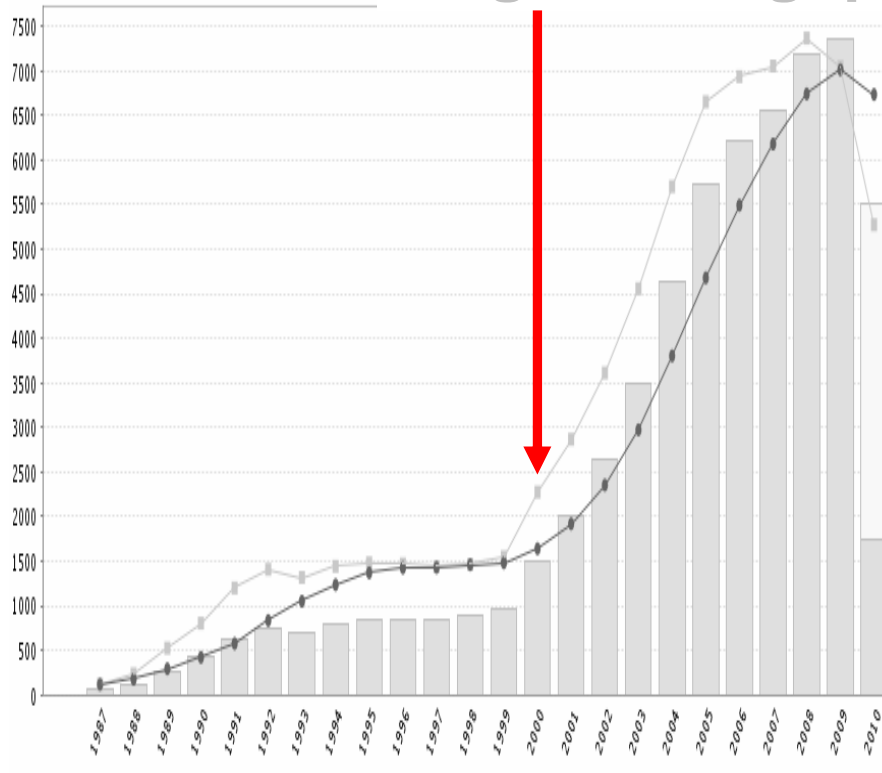


70,762 documents semantically analyzed

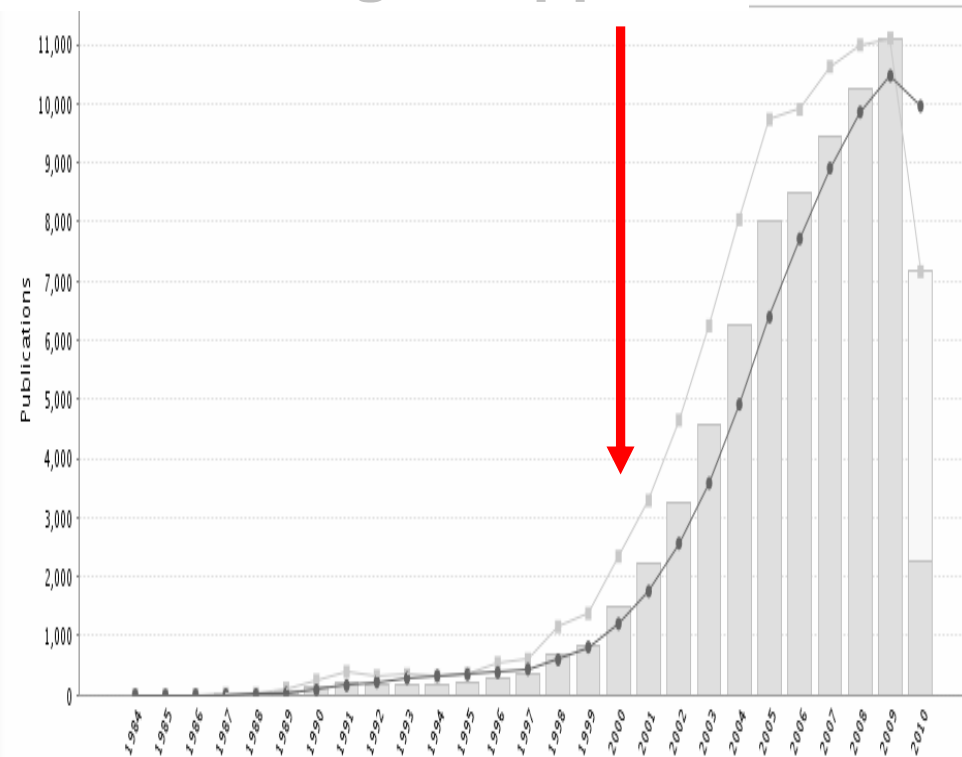


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## High Throughput Technologies appear



GoPubMed Search for: **Genomics**



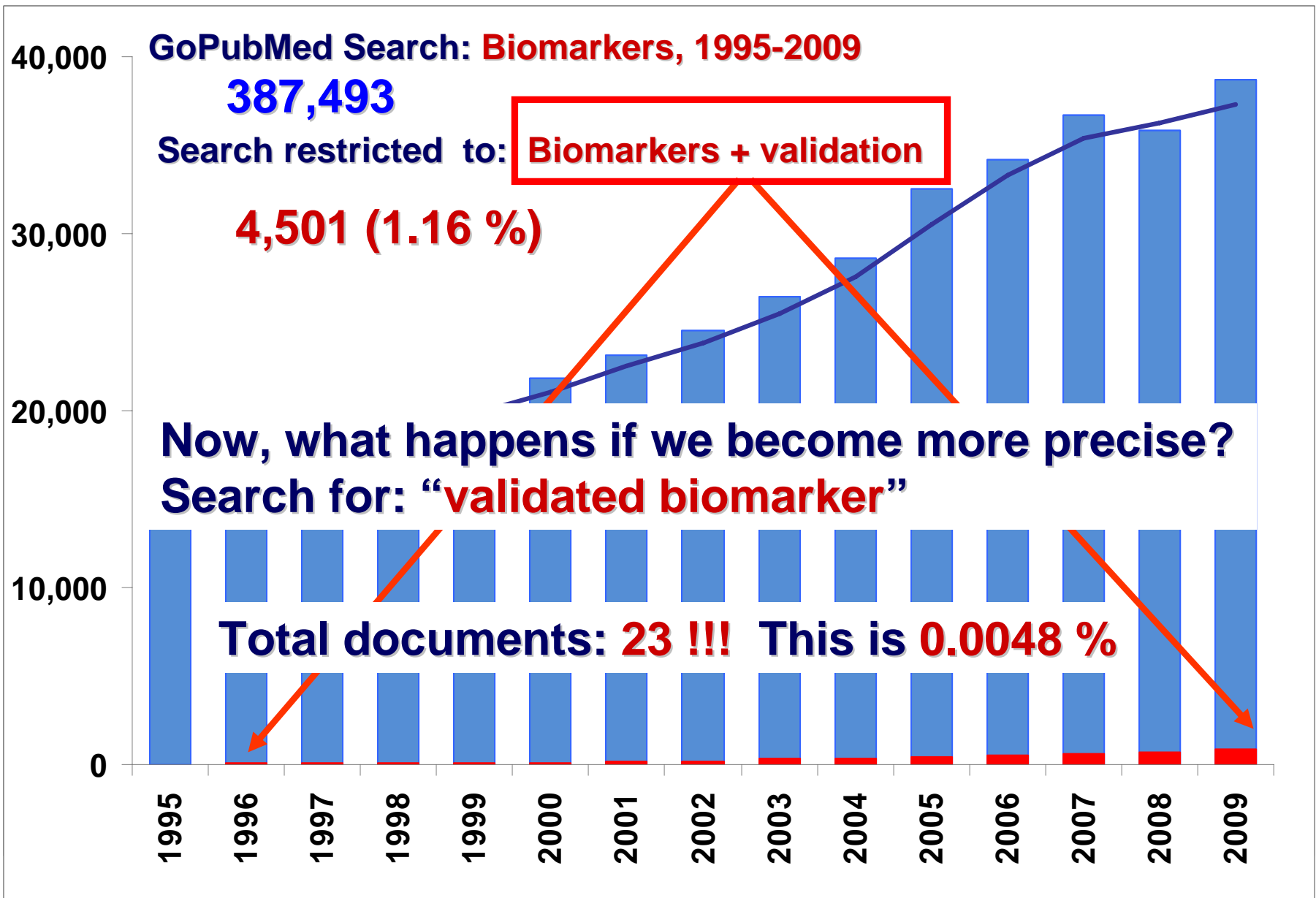
GoPubMed Search for: **Bioinformatics**



A grayscale microscopic image of cells, possibly fibroblasts, showing a grid-like pattern of cells. A white rectangular box is overlaid on the top half of the image, containing text. Another white rectangular box is overlaid on the bottom half of the image, also containing text. The background image shows a dense field of cells with some larger, more distinct cells visible.

**Let us explore the scientific  
production in one research subject:  
biomarkers**

**This is a field of confluence for medical,  
biological, pharmacology research and  
bioinformatics.**





In biological and biomedical research,

**high throughput technologies** are generating information at an **“industrial scale”**



...but data validation requires **“lab scale”** research, and is going slowly.

There is the need for an “external pressure” that imposes data validation as a requirement for publication **...and editors from biological journals are working on.**





# Guidelines for the next 10 years of proteomics

Marc R. Wilkins<sup>1</sup>, Ron D. Appel<sup>2</sup>,  
Angelika Görg<sup>5</sup>, Michael Hecker<sup>6</sup>,  
Young-Ki Paik<sup>10</sup>, Scott D. Patterson<sup>7</sup>,  
Richard J. Simpson<sup>14</sup>, Walter W.



## Molecular & Cellular Proteomics electronic submission

### Guidelines for Preparing Manuscripts Describing Research in Clinical Proteomics

The purpose of these guidelines is to provide sufficient information from which the reviewers/readers can evaluate, interpret, compare, and, reproduce the reported study. They contain both mandatory and recommended information. The former are underlined and marked with asterisks (\*).

#### Ethics Approvals

- \* It is required to provide a statement of approval for use of human/animal biological material in the study including details of informed consent, participation and/or primary cell line derived from human subjects employed to protect human subject confidentiality and coding of biospecimens.

#### Study Goals and Design

A comprehensive description of the study design and objectives of the study, with specific attention to the following:

- \* The stage/phase of the study, e.g. discovery, validation, preclinical validation; etc.).
- \* the flow of subjects/samples through the study (number included in each stage of the study and reasons for exclusion in complex/larger studies) and reasons for

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DOI 10.1002/prca.200600771

Proteomics Clin. Appl. 2007, 1, 148–156



## Clinical proteomics: A need to define the field and to begin to set adequate standards

Harald Mischak<sup>1</sup>, Rolf Apweiler<sup>2</sup>, Rosamonde E. Banks<sup>3</sup>, Mark Conaway<sup>4</sup>, Joshua Coon<sup>5</sup>, Anna Dominiczak<sup>6</sup>, Jochen H. H. Ehrlich<sup>7</sup>, Danilo Fliser<sup>8</sup>, Mark Girolami<sup>9</sup>, Henning Hermjakob<sup>2</sup>, Denis Hochstrasser<sup>10, 11</sup>, Joachim Jankowski<sup>12</sup>, Bruce A. Julian<sup>13</sup>, Walter Kolch<sup>14</sup>, Ziad A. Massy<sup>15</sup>, Christian Neusuess<sup>16</sup>, Jan Novak<sup>17</sup>, Karlheinz Peter<sup>18</sup>, Kasper Rossing<sup>19</sup>, Joost Schanstra<sup>20</sup>, O. John Semmes<sup>21</sup>, Dan Theodorescu<sup>22</sup>, Visith Thongboonkerd<sup>23</sup>, Eva M. Weissinger<sup>24</sup>, Jennifer E. Van Eyk<sup>25</sup> and Tadashi Yamamoto<sup>26</sup>

<sup>1</sup> Mosaiques Diagnostics, Hannover, Germany\*

The aim of this manuscript is to initiate a constructive discussion about the definition of clinical proteomics, study requirements, pitfalls and (potential) use. Furthermore, we hope to stimulate proposals for the optimal use of future opportunities and seek unification of the approaches in clinical proteomic studies. We have outlined our collective views about the basic principles that should be considered in clinical proteomic studies, including sample selection, choice of technology and appropriate quality control, and the need for collaborative interdisciplinary efforts involving clinicians and scientists. Furthermore, we propose guidelines for the critical aspects

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<sup>5</sup> Department of Proteomics, Technische Universität München, München, Germany  
<sup>6</sup> Institut für Mikrobiologie, Ernst-Moritz Arndt-Universität, Greifswald, Germany  
<sup>7</sup> Biocenter, Div. Cell Biology, Medical University of Vienna, Vienna, Austria  
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<sup>10</sup> Yonsei Proteome Research Center and School of Life Science, Yonsei University, Seoul, Korea  
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<sup>12</sup> Proteome Research Centre, UCD College of Biomedicine, University College Dublin Belfield, Dublin, Ireland  
<sup>13</sup> Laboratoire d'immunochimie, DRDC, Ottawa, Canada  
<sup>14</sup> Ludwig Institute for Cancer Research, Parkville, Victoria, Australia

There is a concerted effort of publishers and experts for **enhancing the quality, transparency and confidence** of published results. Here are two examples:



## Medical research:

❖ **EQUATOR** (Web launched June 2008)

## Biomedical and Biological research:

❖ **M I B B I** (Web launched August 2008)



## Welcome to the EQUATOR Network website – the resource centre for good reporting of health research studies



Too often, good research evidence is undermined by poor quality reporting.

The EQUATOR Network is an international initiative that seeks to improve reliability of medical research literature by promoting transparent and accurate reporting of research studies.

[Find out how](#), or [get involved](#).

### Highlights

**EQUATOR Network at the Peer Review Congress 2009**

**Wednesday 9th September,**  
Vancouver, Canada.

Prior to the main [congress](#), the EQUATOR Network will run a

### Reporting guidelines



[Go straight to our 'Library for Health Research Reporting'](#)

### Authors



[Information for authors of research reports](#)

### Editors



[Resources for journal editors and peer reviewers](#)

### Developers



[Resources](#)



**Latest news** [more news](#)

### Research protocols in the Lancet journals

This new initiative will contribute to greater

# **Minimum Information for Biological and Biomedical Investigations (MIBBI):**

**<http://mibbi.org>**

**“To promote transparency in experimental reporting, enhance accessibility to data and support effective quality assessment, increasing the general value of a body of work”**

**From: Nature Biotechnology volume 26 number 8 AUGUST 2008**





## links

- Home
- The MIBBI Portal
- The MIBBI Foundry
- Foundry modules
- Related resources
- About us
- Project news
- Discussion
- MIBBI search

## search

Go

Search

## toolbox

- What links here
- Related changes
- Upload file
- Special pages
- Printable version
- Permanent link

article

discussion

view source

history

# MIBBI: Minimum Information for Biological and Biomedical Investigations

## Project News Highlights

- **OMICS: A journal of Integrative Biology recommends MIBBI use** in an editorial [↗](#)
- **BMC journals recommend MIBBI** in their 'Instructions to Authors' (example [↗](#))
- **Free download:** The MIBBI paper (*Nature Biotechnology*) [↗](#) & supplement

## Site navigation



### The MIBBI Portal

Access to Minimum Information guidelines for diverse bioscience domains



### Project news

Announcements relating to the project, such as new registrations, meetings, etc.



### The MIBBI Foundry

Towards the next generation of MI guidelines for the biosciences



### MIBBI search

A Google™ Custom Search Engine covering a range of relevant web sites.



### Related resources

Links to other cross-domain projects, policy statements and sundry useful material



### Discussion

How to post to the MIBBI discussion forum, or join the Foundry developers' mailing list



### About us

A contextualisation of the



### MICheckout

Coming soon: browse and

**On April 4<sup>th</sup> 2010, 31 projects registered**





A large, brown, textured pyramid dominates the background under a clear blue sky. At its base, a modern building with a white roof and glass facade is visible on the left, and a smaller, ancient-style stone structure with columns is on the right. The text "Good Publication Practice in its wider significance is an emerging concept" is overlaid in the center.

**Good Publication Practice in its wider  
significance is an emerging concept**

## **THE LANGUAGE: Open Biomedical Ontology**

Defining controlled vocabulary  
for biosciences

## **THE DATA: WEB Accessibility of Experimental Raw Data**

Spectra, images, DB  
identifications...

## **THE REPORT: EQUATOR / MIBBI**

Guidelines for  
experimental reports

## **THE CONFIDENCE: Data Validation by confirmatory experiments**

## **GGP2**

Ethical aspects of  
clinical / biological  
research

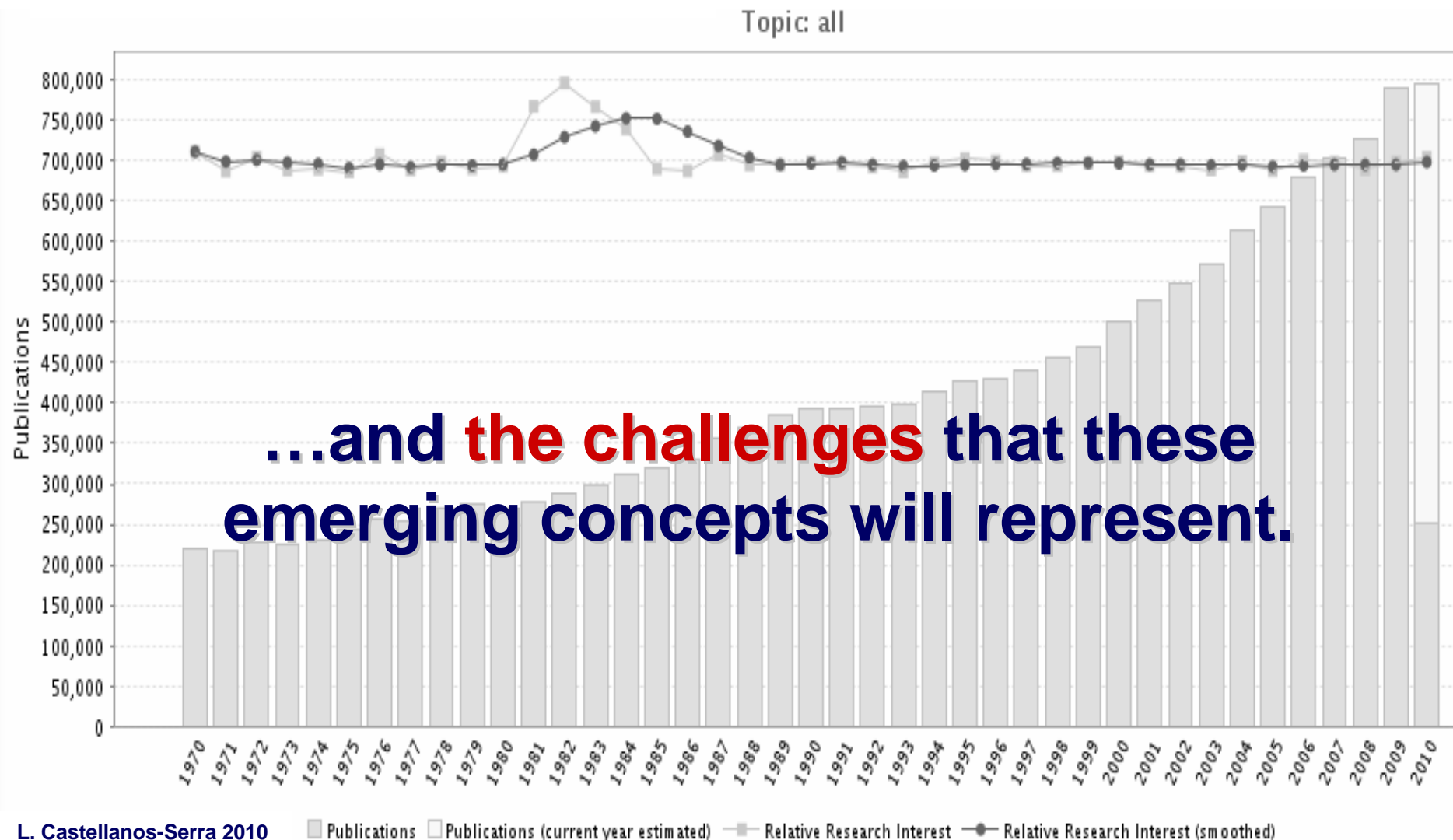
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graph TD; A[THE LANGUAGE: Open Biomedical Ontology] --> F[Quality and transparency standards for publishing biomedicine]; B[THE DATA: WEB Accessibility of Experimental Raw Data] --> F; C[THE REPORT: EQUATOR / MIBBI] --> F; D[THE CONFIDENCE: Data Validation by confirmatory experiments] --> F; E[GGP2 Ethical aspects of clinical / biological research] --> F;
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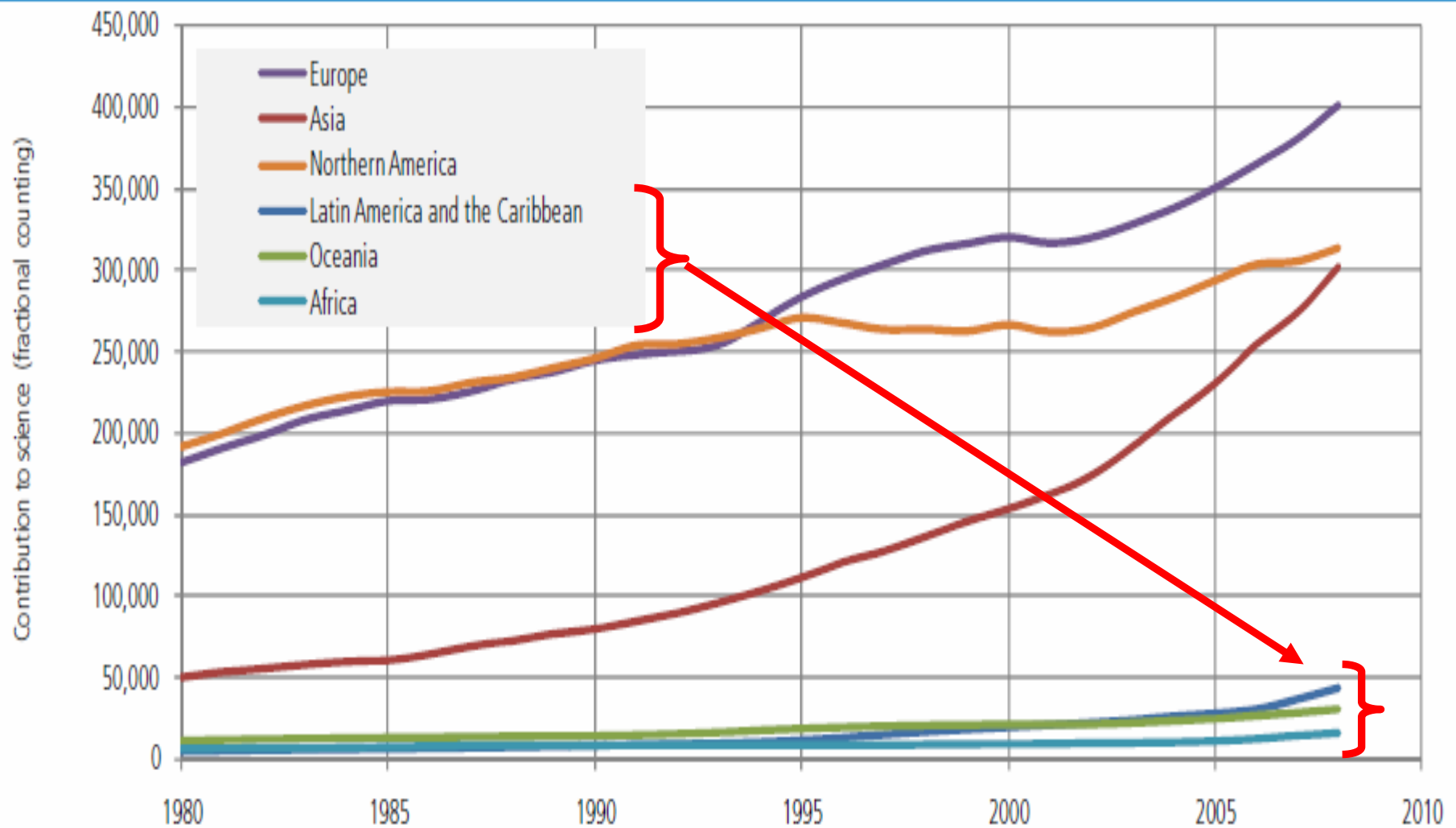
**Quality and  
transparency  
standards for  
publishing  
biomedicine**

# **Publishing Biological, Biomedical and Medical Research **is changing.****

**Are we prepared in developing countries?**

# Now, a comment about the low presence of **developing countries** in high impact journals

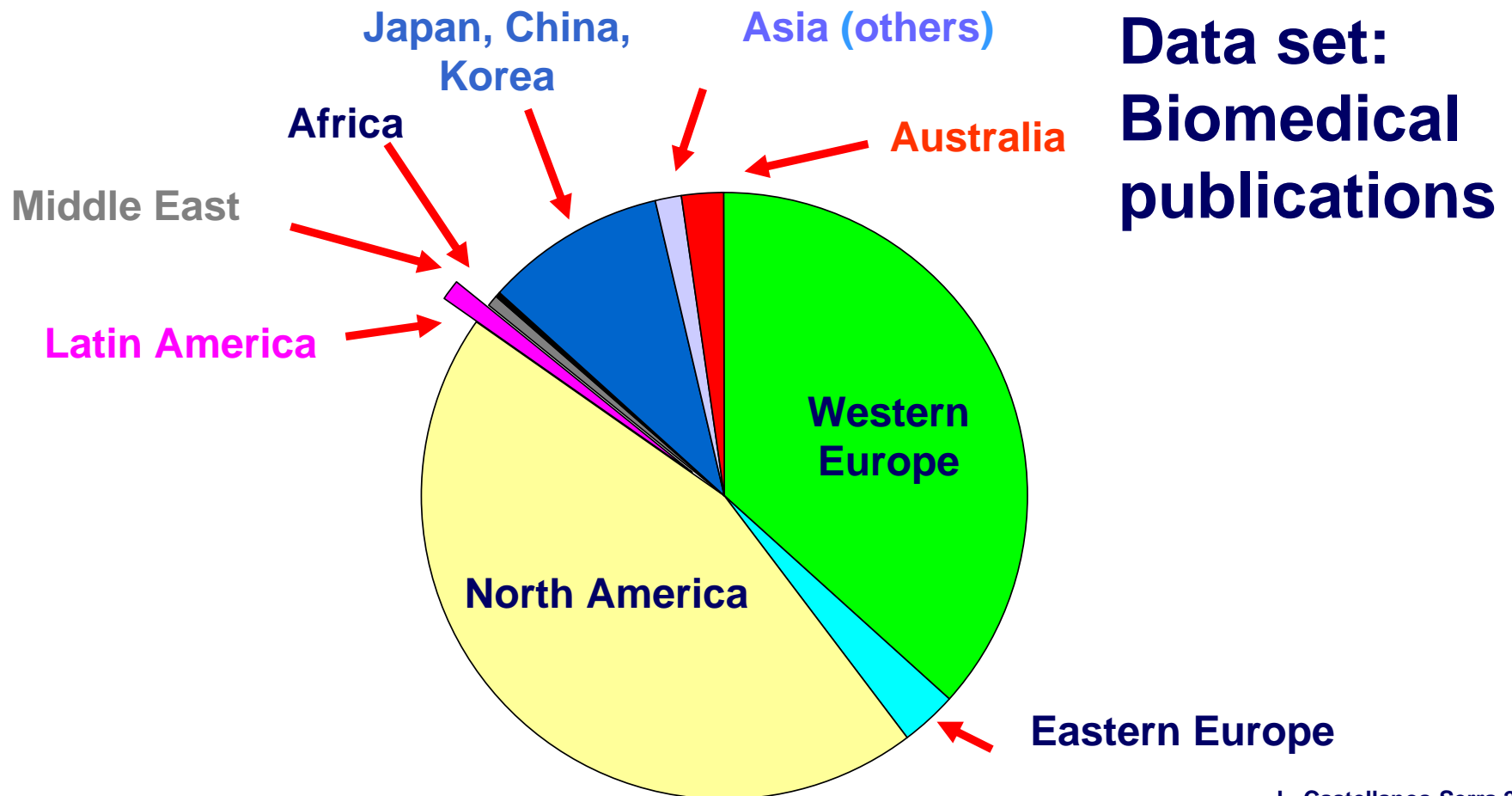




**Figure 9** Contribution to world science by region, in number of papers, 1980–2008

Source: Calculated by Science-Metrix using the Web of Science (Thomson Reuters)

**The low presence in main stream journals of papers originated in developing countries has several (and complex) reasons.**



## **Some are *economical* and *social*:**

- ❖ **Limited resources for science**
- ❖ **No innovative industry catalyzing national research**
- ❖ **Scientific agenda set mainly by academia in developed countries**

### **Consequences:**

**In many countries, science is mainly an exercise for a Bs. or M. Sc. degree**

**In fact, scientists are not socially demanded (no local consumption) ... and are not socially integrated**



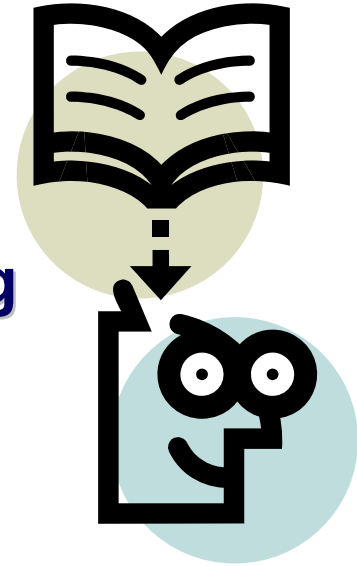
**Drain of clever minds from poor countries to developed countries reinforces the problem**

...And there are deficiencies in professional education. **Here we can influence.**

There is lack of training in writing / publishing skills, and there are linguistic barriers.....

but: frequently, there are **other problems:**

- ❖ The **Question** (the **Hypothesis**): unclear, irrelevant or can not be experimentally addressed
- ❖ A poor **experimental design**
- ❖ Lack of **rigorous controls**
- ❖ Poor **analysis / interpretation of results**





**Our education programs may help by developing skills for:**

**asking** (formulating) the important question

**organizing minds** (as experimentalists)

**critically** reading published information



**Briefly, preparing undergraduates and graduates as producers of knowledge.**

For **preparing Knowledge-producers (not only consumers)**, high education should play a key role.

Yes, Knowledge as a finished product (the paradigms, the state of the art)

....**but also,**

presenting Knowledge as a building-up process

**Teaching the dynamics of knowledge is:**

- ❖ How knowledge is built from the bench (the key experiments and their interpretation)
- ❖ The conflicts, the unclear zones of knowledge, the borders....

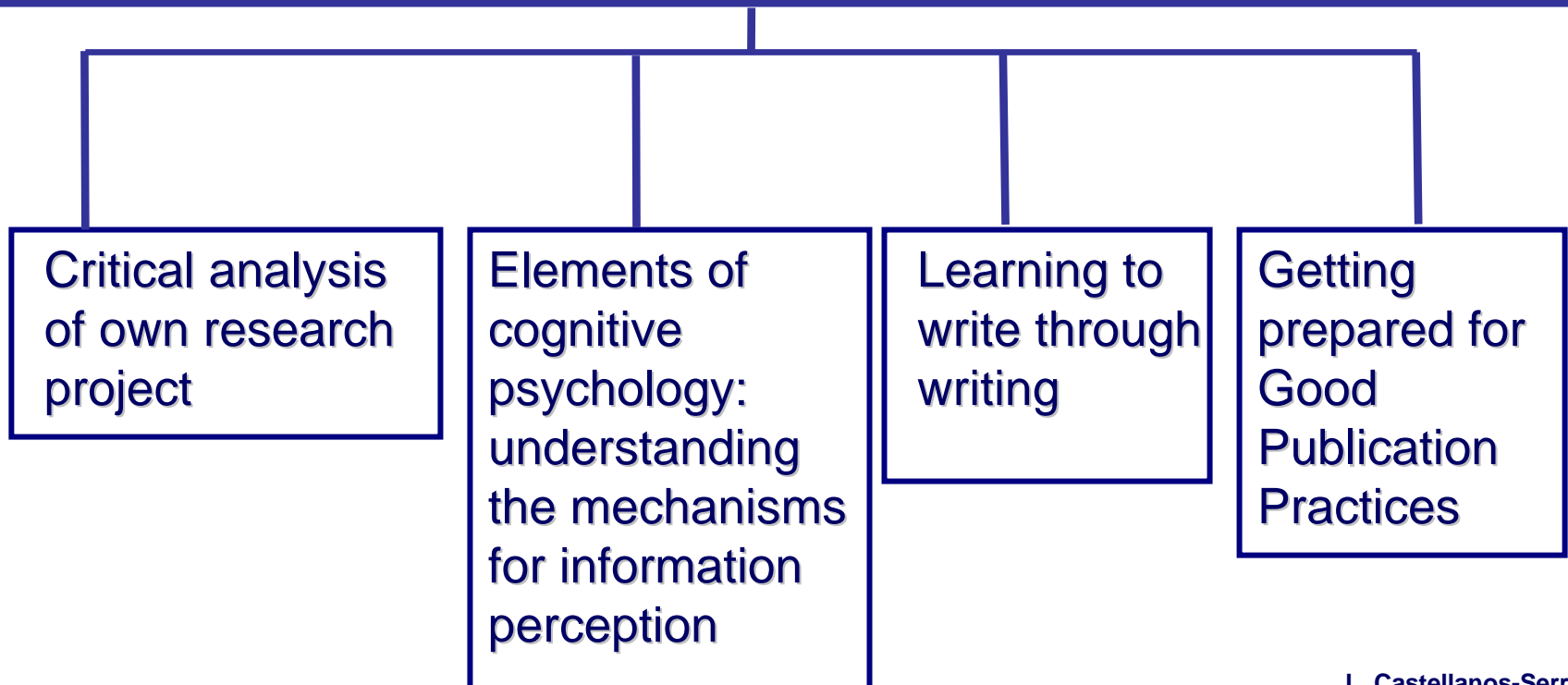


# Our experience in helping young scientist for publishing

Starting on 2004, as a component of  
graduate formation



## Communicating biomedical, biological and medical information: from research design to research report

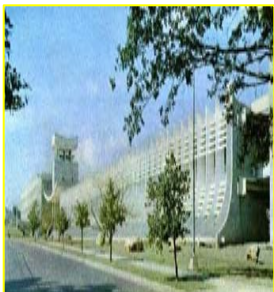


# Communicating biomedical, biological and medical information: from research design to research report

## An interactive workshop

- ❖ It is not conducted by an specialist in (only) scientific writing, **but by a scientist working on the field**, with experience as editor and reviewer
- ❖ Flexible design: yearly update of contents
- ❖ Participants work on their research project, optimizing daily the document
- ❖ Certificate of approval: when a paper in a main stream journal is accepted

L. Castellanos-Serra 2010



# Four points that may contribute to increase developing countries publications

1. Persuade young researchers **that the main benefit from publishing** is their own professional formation
2. Increase local (national) **recognition** for scientists that publish
3. Incorporate in **under-graduate and graduate formation** Research Methodology and basic elements for scientific publishing
4. Create an **efficient publication support** for scientists, accessible all over the country

# FIVE “TAKE-HOME” MESSAGES

- ❑ As **bioinfo producers**, we are living in a rapidly changing environment.
- ❑ **The standards** for publishing biomedical sciences are becoming more exigent.
- ❑ With more stringent standards, the presence of developing countries in main stream journals **risks to even decrease**. This is a trend to be stopped.
- ❑ Young scientists in developing countries **can be prepared and should be prepared**.
- ❑ This is **a challenge** for academic education and for experienced scientists, working all together.