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The challenges of conducting research in developing countries

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The Challenges of Conducting Research in Developing Countries

UNIVERSITY
OF MIAMI
ETHICS PROGRAMS



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Washington University in St. Louis
November 28th 2011



Panamerican
PABI
Bioethics
Initiative

Disclaimer

- The views provided in these slides are solely the opinions of the presenter are not meant to represent any group or organization.

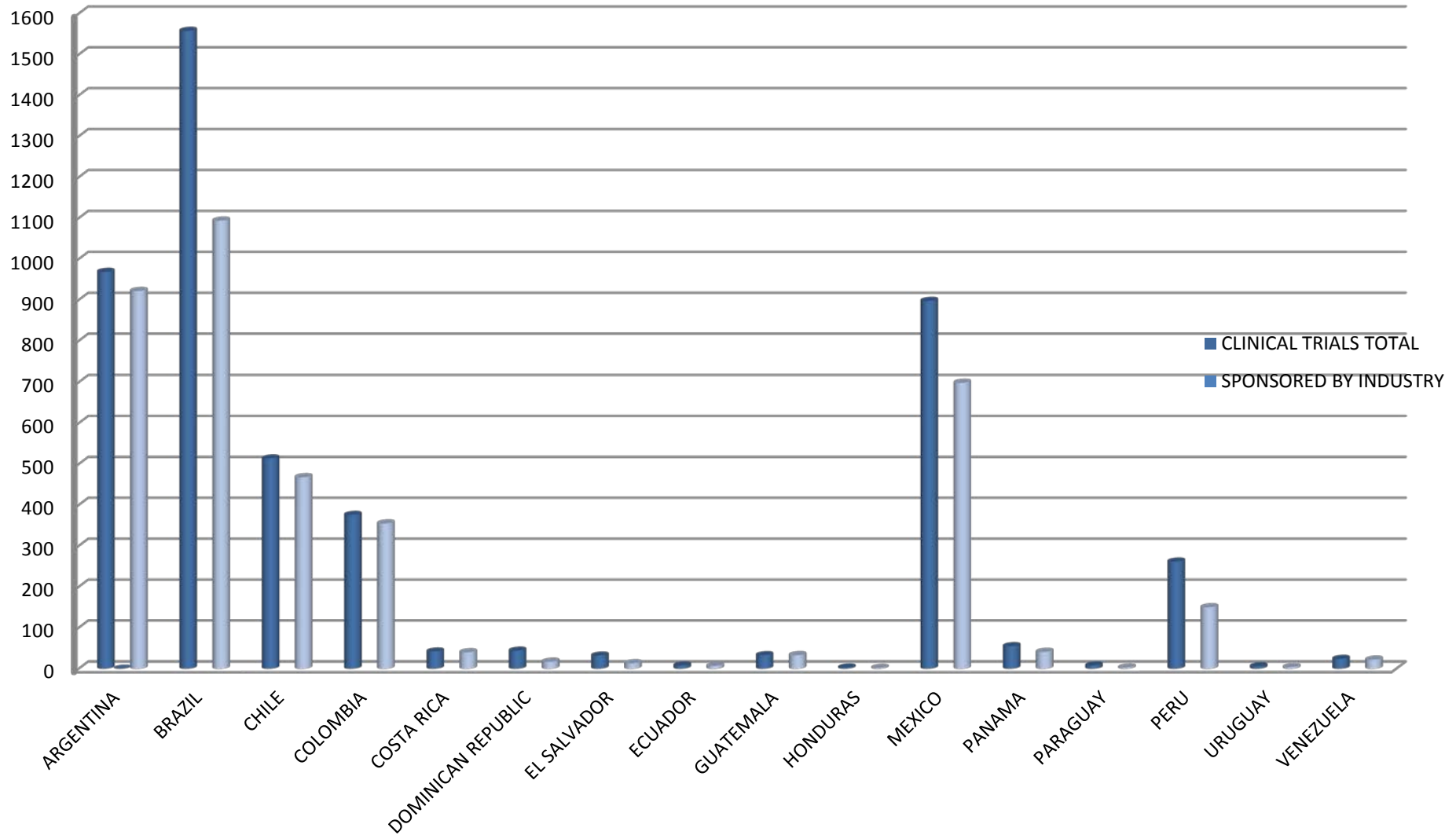
Challenges of a multicultural environment

- A working definition of research. What is perceived by the society as research
 - Production of valid, reliable, and generalizable knowledge (Knowledge is ***organized*** information)
- Each community gives a special accent to the activity
- Influence of the dominant paradigms

Significant Concerns

- Lack of mandatory training on research ethics and responsible conduct of research
- Identification and management of conflicts of interest
- Enforcement of current regulations. Normative polyphony
- Research Ethics Committees (quorum, competence, independence, informed consent process, logistics and infrastructure)
- Weak or inexistent institutional accountability
- Economical disparities and access to healthcare
- Governance

Clinical Trials in Latin America
January 1st 2005- April 1st 2011
Source : Clinicaltrials.gov



Research misconduct and Human Subjects Protection

- Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
 - (a) Fabrication is making up data or results and recording or reporting them.
 - (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
 - (d) Research misconduct does not include honest error or differences of opinion.
- Office of Research Integrity, United States of America

Other definitions

- “All serious deviations from accepted ethical research practices in proposing, performing and reporting research”
 - Norwegian Council on Scientific Dishonesty
- “Behavior by a researcher, intentional or not that falls short of good ethical and scientific standards”
 - Joint Consensus Conference on Misconduct in Biomedical Research . Consensus statement , Edinburgh, October 28 & 29, 1999

Research misconduct in Latin American countries

- Magnitude and awareness of the problem (is there a problem?)
- Perception of scientific misconduct
- Environmental factors
 - Scientist, policy makers and the society
 - Lack of communication between media and scientists
 - Scientist may be perceived as “closed communities”
 - Latin American researchers , in many cases are working for governments (civil servants) working within a vertical and hierarchical system, not necessarily based in merits
 - Yriart M, Braginski R. The resurrection of the crotoxin case (1989-1996): Science, politics and media. *Redes*, Vol V, No 11; pp 113-139. National University of Quilmes, Argentina

Cultural and logistical challenges in the Latin American and Caribbean scenario

- Informed consent
 - Legal information may be excessive and confusing
 - Adequate disclosure of risks and eventual benefits
 - Risk of therapeutic misunderstanding
- IRBs
 - Definition of exempt studies
 - Lack of resources
 - Clinical Ethics Committees acting as Research Ethics Committees
 - Conflicts of interests- IRB independence
 - Deficiencies in assuring privacy and confidentiality
 - Oversight of clinical trials

Governance

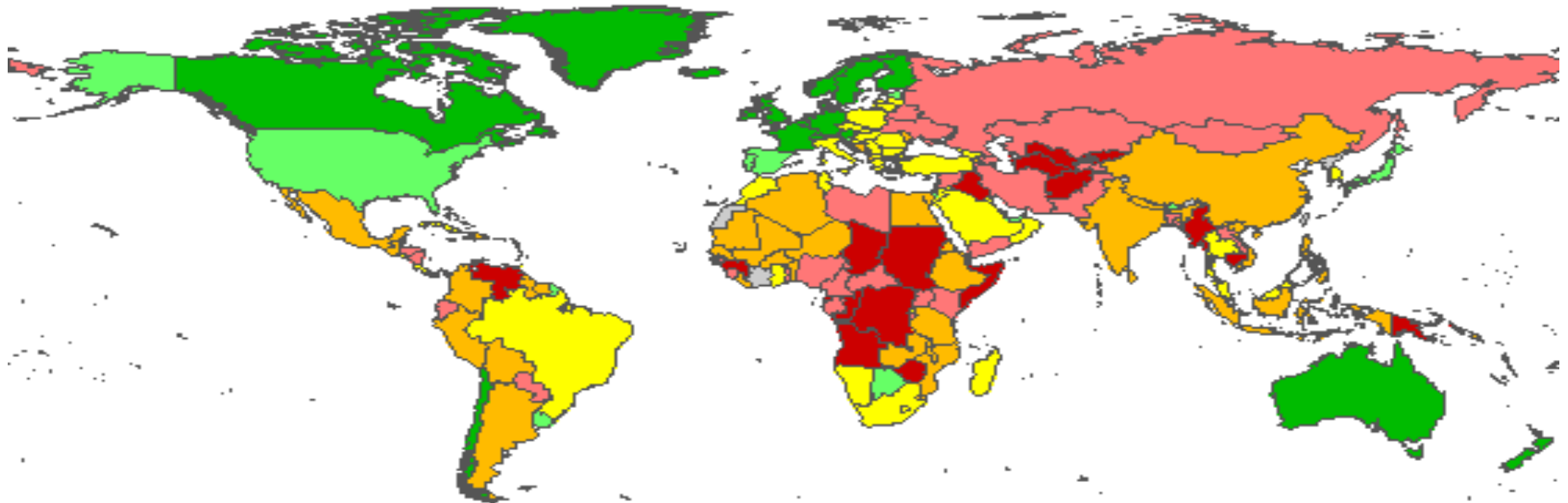
Traditions and institutions by which authority in a country is exercised

- Process by which governments are selected, monitored and replaced
 - Voice and accountability
 - Political stability and absence of terrorism/violence
- Capacity of a government to effectively formulate and implement sound policies
 - Government effectiveness
 - Regulatory quality
- Respect of the citizens and the state for the institutions that govern interactions among them
 - Rule of law
 - Control of corruption

Kaufmann D, Kraay A, Mastruzzi M. Global Economy and Development. Brookings Institutions. September 2010 www.govindicators.org

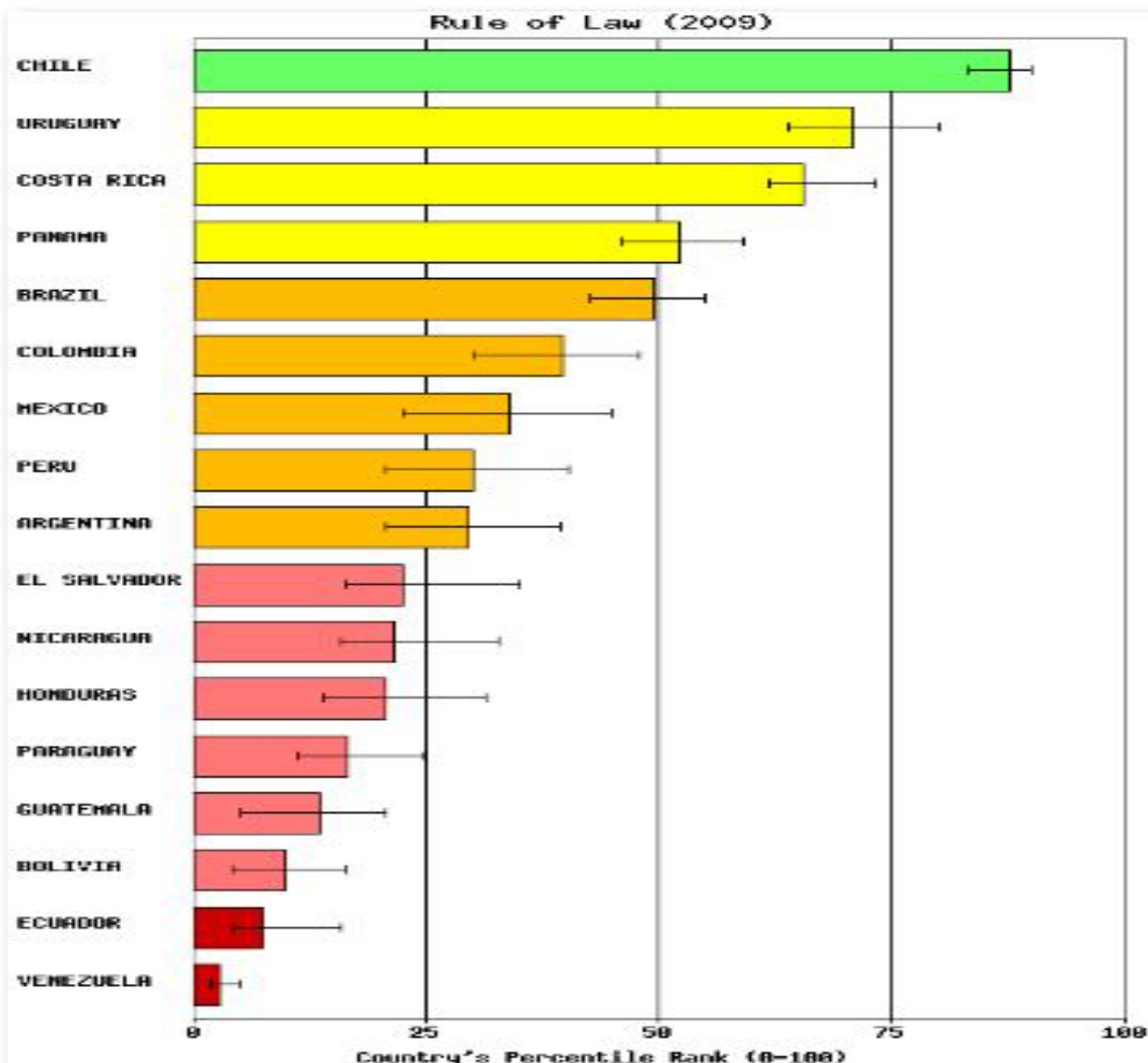
Worldwide Governance Indicators

Control of Corruption (2009)



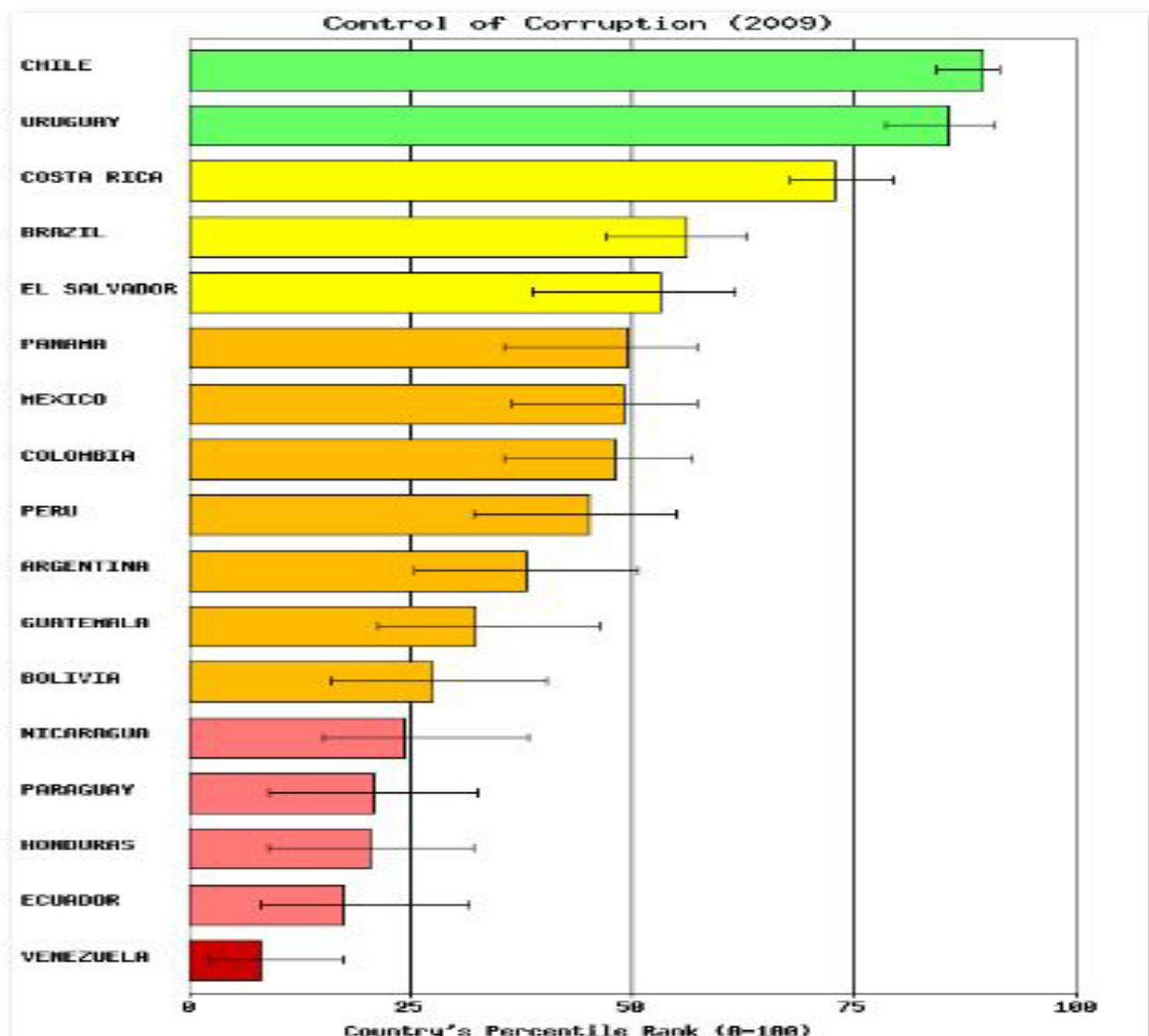
Source: Kaufmann D., A. Kraay, and M. Mastruzzi (2010), The Worldwide Governance Indicators: Methodology and Analytical Issues

Note: The governance indicators presented here aggregate the views on the quality of governance provided by a large number of enterprise, citizen and expert survey respondents in industrial and developing countries. These data are gathered from a number of survey institutes, think tanks, non-governmental organizations, and international organizations. The aggregate indicators do not reflect the official views of the World Bank, its Executive Directors, or the countries they represent. The WGI are not used by the World Bank Group to allocate resources.



Source: Kaufmann D., A. Kraay, and M. Mastruzzi (2010), The Worldwide Governance Indicators: Methodology and Analytical Issues

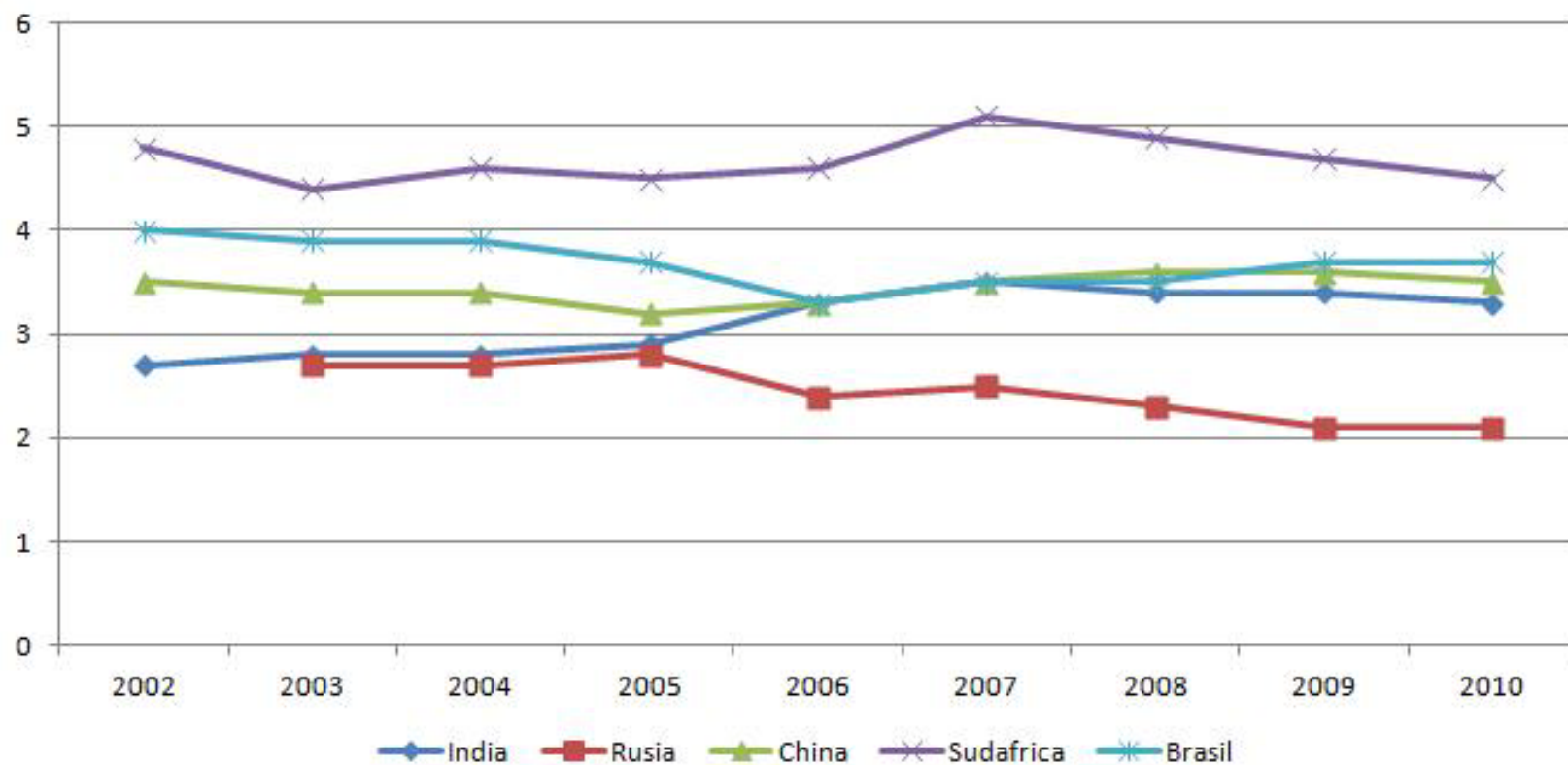
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Percepción de Corrupción en el grupo BRICS (Brasil, Rusia, India, China y Sudáfrica)
2002-2010 (Transparencia Internacional)



Research misconduct in a multicultural environment

- Understanding differences in what is perceived as research misconduct
- Understanding that research misconduct might be embedded in other layers of misconduct, not necessarily linked to research activities
- Fostering education
- Promoting transparency

Pan American Bioethics Initiative

University Austral-
Argentina



Universidade de
Brasília- Brazil. No
current fellow

CENDEISS- Costa
Rica



SEPLAN Ministry of
Health- Honduras

MONA- UWI
Jamaica



National Institute of
Genomics, Mexico

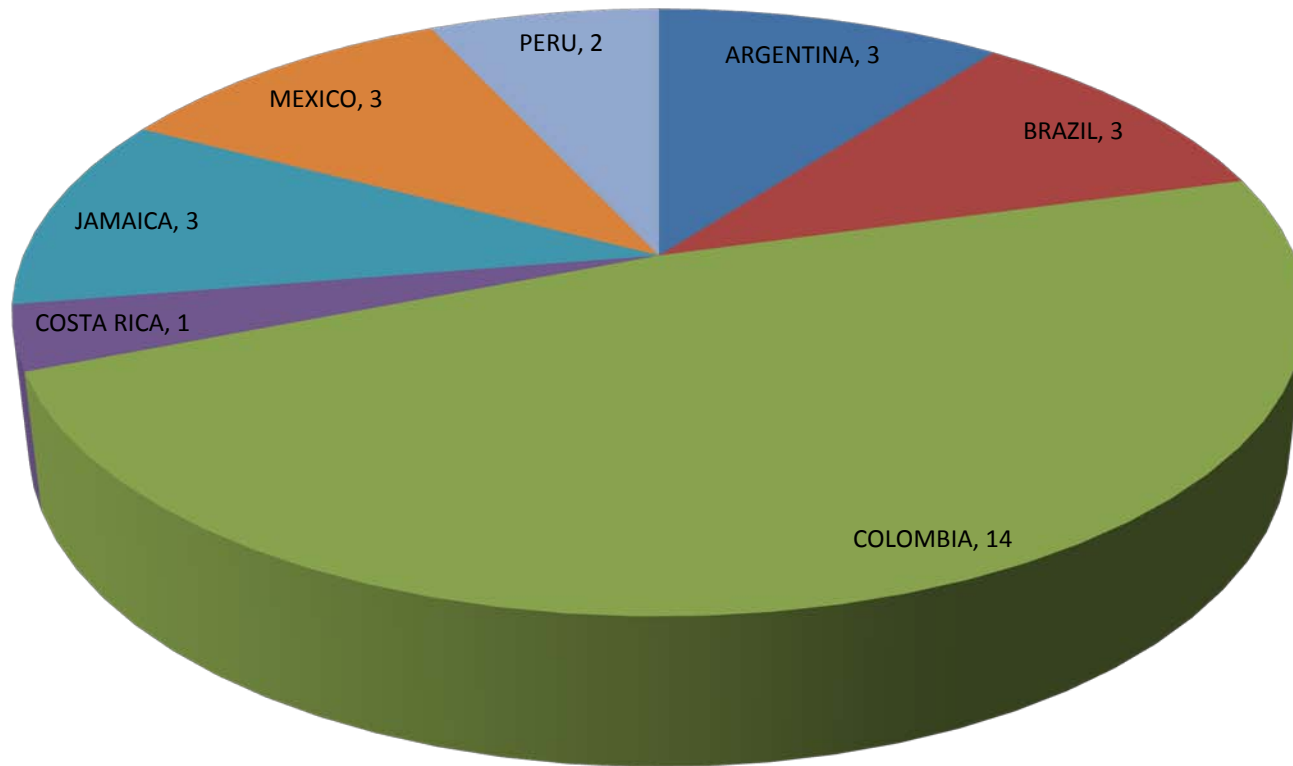
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Fogarty International Center (NIH-FIC)

New CITI Program modules by country (HSP and RCR)



Conclusions: Critical issues

- Ethical standards, laws and regulations
- Post trial access to benefits
- Placebo use
- Local capabilities
- Definition of vulnerability