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Regional Office of the World Health Organization

Report to the ACHR : Advances and challenges in the Clinical Trial Registration in Latin America & Caribbean

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Background:
High level advocacy

- XI World Congress of Public Health (2006)
  - BIREME reached an agreement among regional editors, raising awareness
  - HSS/RC promoting debate, raising awareness, and engaging with stakeholders
  - Participation in meetings organized by the Secretariat, Global and Regional ACHR, and others addressing technical cooperation for trial registration
  - PAHO sits in the Secretariat of the ICTRP

Advisory Committee on Health Research. (May 2007)
Recommendations

- "Continue work that enables the Member States to participate in the World Health Organization's International Clinical Trials Registry Platform (ICTRP). This includes evaluating the development of tools and strategies that facilitate the adoption and use of registries in the Region".

Detailed information on the deliberations, presentations, and recommendations can be found in the ***40th Meeting of the PAHO/WHO Advisory Committee on Health Research (ACHR), Report to the Director.*** (AHCR40/2007.10). Montego Bay, Jamaica, 29 April to 1 May 2007.

Advances since 40th ACHR Meeting
Leading from the front

- PAHO has systematically advocated for trial registration. For example:
  - Raising awareness (e.g. publications, presentations, interactions at various levels), funding activities with strategic partners and stakeholders
  - PJPH supported, adopting the trial registration requirement
  - Promoting registration among partners, researchers, and its grantees

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Advances since 40th ACHR Meeting
Building support

- Organizational support for the initiative
  - It is WHO's agenda as an important initiative to improve transparency and guide health research policies
  - It is highlighted as an important element of research governance for PAHO and its member countries
  - Asking grantees and project sponsors to register, when appropriate
  - Engaging Institutional Review Boards/Ethics Review Committees, and the networks that bring them together

Advances since 40th ACHR Meeting
Countries Reactions and WHO Developments

- WHO launched the ICTRP Search Portal of the Register Network (4 May 2007) and the first version of the Advanced Search function on the Search Portal (15 Aug 2007)
- Launch of the Countries have approached HSS/RC expressing interest in moving forward and asking for direction and some countries are now moving ahead developing their own registration tools (Example, Argentina, Brazil and Cuba)
- 27th Pan American Sanitary Conference took note of the ACHR Report

INTERNATIONAL CLINICAL TRIALS REGISTRY PLATFORM SEARCH PORTAL

http://www.who.int/trialsearch/

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INTERNATIONAL CLINICAL TRIALS REGISTRY PLATFORM SEARCH PORTAL

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Back to Search

Sort by Date of registration

69 trials found!

1 2 3 4 5 6 7

	Recruitment Status	Main ID	Public Title	Date of Registration
View details	Recruiting	NCT00543543	Broad Spectrum HPV (Human Papillomavirus) Vaccine Study in 16-to 26-Year-Old Women	12/10/2007
View details	Recruiting	NCT00539968	A Study to Evaluate the Safety, Tolerability, and Activity of Lonafarnib and Docetaxel (Study P04467)	04/10/2007
View details	Recruiting	NCT00525824	12-Week Open-Label, Phase IIIb Comparing Efficacy and Safety of Rosuvastatin (CRESTOR™) in Combination With Ezetimibe	05/09/2007
View details	Recruiting	NCT00517413	LATINO Study: A Study of Mircera for the Maintenance Treatment of Dialysis Patients With Chronic Renal Anemia.	16/08/2007
View details	Recruiting	NCT00495885	Efficacy and Safety of M100907 on Sleep Maintenance Insomnia With a Sub-Study in Stable Type II Diabetes Mellitus	02/07/2007
View				

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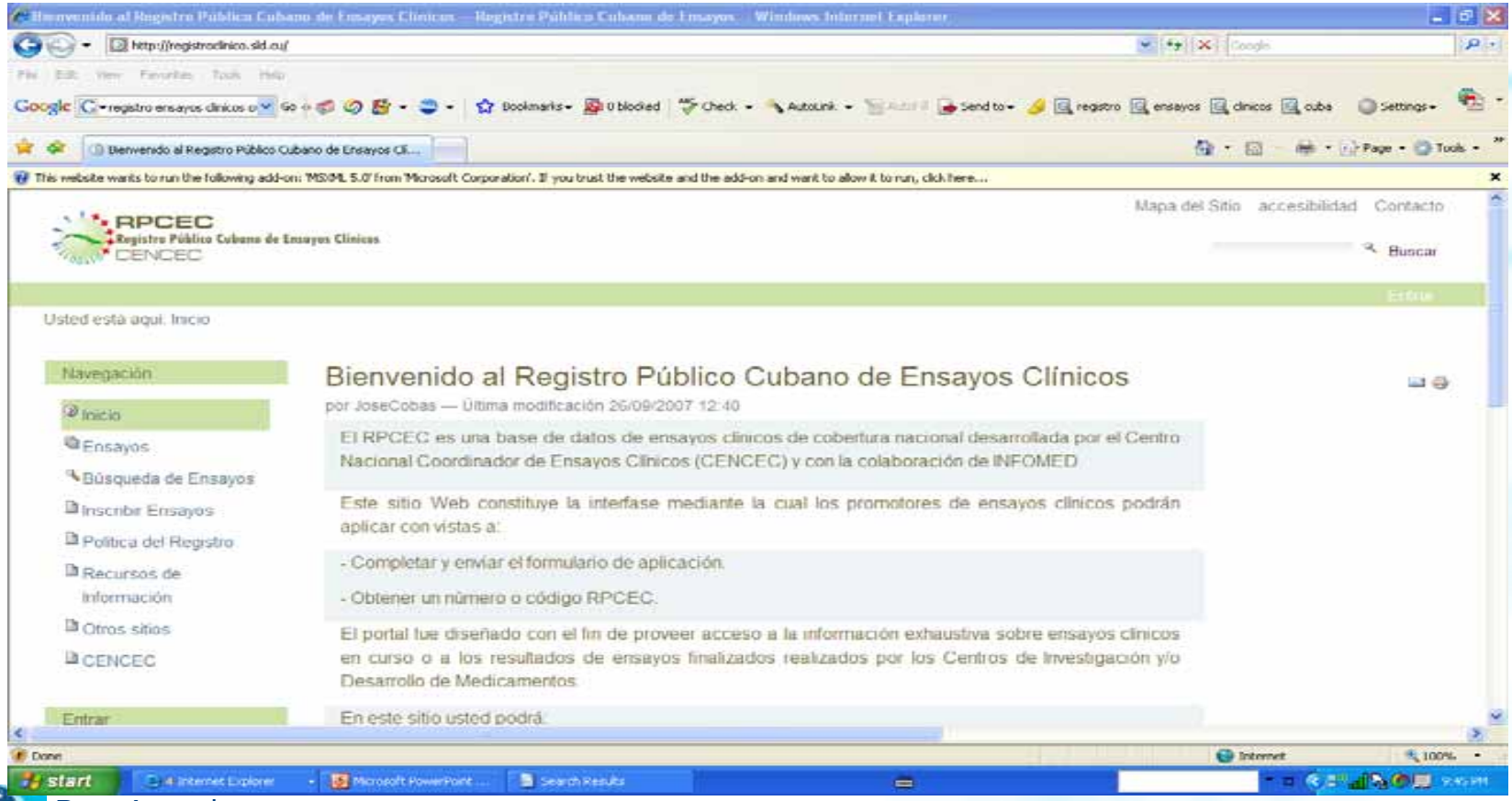
Registro Público Cubano de Ensayos Clínicos

http://registroclinico.sld.cu/



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27th Pan American Sanitary Conference note of Report of the Advisory Committee on Health Research (Document CSP27/INF/1)

…"83. The Committee's president, Dr. John Lavis, reported on the outcomes of the 40th Meeting of the PAHO Advisory Committee on Health Research (ACHR), held in Jamaica in May 2007. Key recommendations from the meeting included the drafting of a PAHO research policy, the reestablishment of the PAHO Research Grants Program, the establishment of a PAHO research registry, and the launching of the Evidence-Informed Policy Network (EVIPNet) initiative in the Region.

84. Member States expressed support for the recommendations, with Delegates of"Canada, Cuba, and Mexico commenting on the report. It was emphasized that PAHO's activities with regard to health research should be guided bye the research priorities of Member States."….

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Document available at:
http://www.paho.org/english/gov/csp/csp27-fr-e.pdf

Advances since 40th ACHR Meeting

Regional Primary Clinical Trial Register for LAC proposal

- PAHO sponsored a joint proposal that has been debated in São Paulo on the 26 October 2007
- The venue allowed bringing together strategic partners and experts in the field. The topic was high in the agenda of the meeting
- Successful workshop with about 25 participants including representatives from research and government institutions and national registers (Argentina, Brazil, Cuba, Colombia, Chile, India, Germany), Iberoamerican Cochrane and LATINREC, members of the ICTRP Scientific Board and the International Advisory Board, other technical experts, BIREME and PAHO HSS/RC

São Paulo Meeting: Objectives

- Inform about progress in Latin America & the Caribbean (LAC)
- Discuss the framework and model for a Regional Primary Clinical Trial Register for LAC, proposed by PAHO/BIREME
  - A portal and primary register
  - Common software that fulfills the WHO Criteria and a common communications protocol
- Identify the strategies to advocate, promote adherence, and monitor
- Identify challenges

São Paulo Meeting: Proposal

- The proposal prepared by BIREME & HSS/RC was well received and recommendations were made to now consult with existing registers and potential users of the software to ensure it addresses their needs
- Positive feedback and praise for conducting this consultation and demonstrating regional leadership
- Schema map: analysis of certified registers and fields

- Available in your folders or at http://reddes.bireme.org/documentacao-dos-projetos/clinical-trials-1/draft-reports/vision-report-0.5/

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DRAFT REPORTS

Up one level

- Vision Report 0.5 — by Milton Lapido — last modified 2007-11-19 11:00
- Vision Report 0.4 — by Milton Lapido — last modified 2007-10-22 15:25
- Vision Report 0.3 — by Milton Lapido — last modified 2007-10-22 15:25
- Vision Report 0.2 — by Milton Lapido — last modified 2007-10-22 15:24
- Vision Report 0.1 — by Milton Lapido — last modified 2007-10-22 15:23

São Paulo Meeting: Conclusions

- There is a shared interest in achieving coherent trial registration, and better understanding research production in our Region.
- Agreement in the Conceptual Framework for a Primary Register.
- Favorable context for development in the Region
- The register is not an end but a tool for adequate and timely access for access of information.
- Intellectual propriety rights: trade vs patent tradition

São Paulo Meeting: Recommendations

- Need of facilitation to debate ways of moving forward with the implementation of the ICTRP proposal in LAC
- The desire to plan ahead and reach constructive agreements; build on what has been already achieved, coordinate our work, avoid duplication, distribute responsibilities
- The need of an open source tool to facilitate coherent and standardized trial registration, and yet allows customization to meet local needs

São Paulo Meeting: Recommendations

- Allocation for technical cooperation including strategies for adherence and implementation
- Definition of the Universal Trial Registration Number
- Assess different implementation models
- Be aware of regulatory agencies' needs
- Mapping of countries, registers and partners characteristics and needs

PAHO's role and the PAHO Research Policy

- Promote trial registration in compliance with ICTRP
  - Advocacy, promoting adherence, monitoring progress, and defining strategies for implementation. For this we are propose three strategies:
    - Conceptual framework for a Primary Register
    - An open source tool to facilitate coherent and standardized trial registration
    - Technical cooperation including strategies for adherence and implementation
    - Research policy, good practices, PAHO Ethical Research Committee
    - Use trial registration as a tool to strengthen health research governance
    - Link to scientific production initiatives

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Discussion

- Listen to ACHR members on how to support this process, specifically:
  - The development of the Clinical Trials Register Platform for Latin America and the Caribbean
  - The software
  - The strategies to promote adherence and use