



Fundamentals of the registry

By *admin*

Created 31/01/2013 - 3:58pm

o Organizations and essential documents

[Ottawa Statement on trial registration.](#) [1]

- Krle?a-Jeric K, Chan A-W, Dickersin K, Sim I, Grimshaw J, Gluud C for the Ottawa Group. [The Ottawa Statement, Part One: Principles for international registration of protocol information and results from human trials of health-related interventions.](#) [2]
- Krle?a-Jeric K. [The Ottawa Statement, Part Two: Principles of operationalisation for international trial registration.](#) [3]
- [Part 3 about Principles of implementation of registration and results disclosure is under elaboration.](#)

[Declaration of Helsinki: Ethical Principles for Medical Research Involving human subjects \(principle 19\)](#) [4]

[The International Committee of Medical Journal Editors \(ICMJE\).](#) [5]

- [Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Publishing and Editorial Issues Related to Publication in Biomedical Journals: Obligation to Register Clinical Trials](#) [6]
- [Update on FDAAA from ClinicalTrials.gov: Basic Results Reporting at ClinicalTrials.gov and ?Prior Publication? \(2008\)](#) [7]
- [Clinical Trial Registration: Looking Back and Moving Ahead \(2007\)](#) [8]
- [Update on Trials Registration. Is This Clinical Trial Fully Registered?: A Statement from the International Committee of Medical Journal Editors \(2005\)](#)
- [Update on Trials Registration \(2004\)](#) [9]
- [Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors \(2004\)](#)

[International Clinical Trial Registry Platform \(ICTRP\) of WHO](#) [10]

- [Registration of EC Publications in international Registry Platform of WHO](#) [11]
- [FAQs WHO clinical trial registry](#) [12]
- [Glossary of WHO clinical trial registry](#) [13]

o Recommended articles

- [Krljević Jerić K, Chan AW, Dickersin K, Sim I, Grimshaw J, Gluud C, en nombre del grupo de Ottawa. Principios del registro internacional de protocolos y resultados de ensayos clínicos a base de intervenciones de salud en seres humanos: Declaración de Ottawa \(parte 1\). Rev Panam Salud Pública/Pan Am J Public Health 19\(6\), 2006: 413-6 \[14\]](#)
- [Cuervo LG, Valdés A, Clark ML. El registro internacional de ensayos clínicos \(editorial\). Rev Panam Salud Pública/Pan Am J Public Health 2006; 19\(6\):365-70 \[15\]](#)

o Hot topics

- [Zarin DA, Tse T, Williams RJ, Califf RM, Ide NC. The ClinicalTrials.gov results database--update and key issues. N Engl J Med 2011;364\(9\):852-60. \[16\]](#)
- [Krljević Jerić K, Lemmens T, Reveiz L, Cuervo LG, Bero LA. Prospective registration and results disclosure of clinical trials in the Americas: a roadmap toward transparency. Rev Panam Salud Pública. 2011 Jul;30\(1\):87-96. \[17\]](#)
- [Viergever RF, Ghersi D. The quality of registration of clinical trials. PLoS One. 2011 Feb 24;6\(2\):e14701. \[18\]](#)
- [Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases \(2010\) \[19\]](#)
- [Bian ZX, Wu TX. Legislation for trial registration and data transparency. Trials. 2010 May 26;11:64 \[20\]](#)
- [Tse T, Williams RJ, Zarin DA. Reporting 'Basic Results' in ClinicalTrials.gov. Chest 2009;136\(1\): 295-303. \[21\]](#)
- [Thomas KB, Tesch C. Clinical Trial Disclosure: The ongoing debate on public registers for clinical trials. The Journal of the European Medical Writers Association 2007;16\(2\). \[22\]](#)

o Communications

- [Clinical Trials Registry: BIREME announces LILACS and SciELO journals should follow WHO guidance. May 5, 2007. \[23\]](#)
- [Recommendation to the editors of indexed journals in LILACS and SciELO on Clinical Trials Registry. May 15, 2007. \[24\]](#)
- [eNote-release Distribution list of electronic notes of ICTRP \(in English\) \[25\]](#)

Equipo de Trabajo del RPCEC | CENCEC - MINSAP

rpcec@cencec.sld.cu

Calle 5ta A Edificio CECMED-CENCEC 2do piso e/ 60 y 62 Miramar, Playa.CP 11300. La Habana, Cuba

Telef: (537) 216-4126 | (537) 216-4218.

Copyright © 2014 All Rights Reserved.

Source URL (retrieved on 06/03/2021 - 10:08pm): <https://rpcec.sld.cu/en/fundamentals-of-the-egistry>

Links:

- [1] <http://ottawagroup.ohri.ca/>
- [2] <http://ottawagroup.ohri.ca/statement.html>
- [3] <http://ottawagroup.ohri.ca/statement2.html>
- [4] <http://ottawagroup.ohri.ca/statement3.html>
- [5] <http://www.icmje.org/>
- [6] http://www.icmje.org/publishing_10register.html
- [7] http://www.icmje.org/update_fdaaa.html
- [8] http://www.icmje.org/update_june07.html
- [9] http://www.icmje.org/update_may05.html
- [10] http://www.icmje.org/clin_trial.pdf
- [11] <http://www.who.int/ictrp/publications/en/index.html>
- [12] <https://www.who.int/ictrp/faq/en/>
- [13] <http://www.who.int/ictrp/glossary/en/index.html>
- [14] <http://www.scielosp.org/pdf/rpsp/v19n6/30528.pdf>
- [15] <http://www.scielosp.org/pdf/rpsp/v19n6/30516.pdf>
- [16] <http://www.nejm.org/doi/full/10.1056/NEJMsa1012065>
- [17] http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S1020-49892011000700013&lng=en&nrm=iso&tlng=en
- [18] <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0014701>
- [19] http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/EN/November_10_2009_Updated_Joint_Position_on_the_Disclosure_of_Clinical_Trial_Results.pdf
- [20] <http://www.trialsjournal.com/content/11/1/64>
- [21] <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2821287/>
- [22] <http://www.emwa.org/PastTWS/ClinicalTrialDisclosureThomasTesch.pdf>
- [23] <http://metodologia.lilacs.bvsalud.org/php/level.php?lang=es&component=17&item=9>
- [24] <http://metodologia.lilacs.bvsalud.org/php/level.php?lang=es&component=17&item=34>
- [25] http://www.who.int/ictrp/news/enote_subscribe/en/index.html