AIHA Internet Resources Digest

Supporting Access to High Quality Online Resources

December 2015

Spotlight on: CLINICAL TRIALS RESOURCES

Clinical trials are pre-planned studies of the safety, efficacy, or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices, or techniques selected according to predetermined criteria of eligibility and observed for predefined evidence of favorable and unfavorable effects. Depending on product type and development stage, investigators initially enroll volunteers and/or patients into small pilot studies, and subsequently conduct progressively larger scale comparative studies. Clinical trials can vary in size and cost, and they can involve a single research center or multiple centers, in one country or in multiple countries. Clinical study design aims to ensure the scientific validity and reproducibility of the results.

Data Bases

ClinicalTrials.gov

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. ClinicalTrials.gov currently lists 205,034 studies with locations in 191 countries. The submission of adverse event information was optional when the results database was first released but was required beginning in September 2009. Results information for registered and completed studies is submitted by the study sponsor or principal investigator in a standard, tabular format without discussions or conclusions. The results information that is submitted includes the following:

- **Participant Flow.** A tabular summary of the progress of participants through each stage of a study, by study arm or comparison group. It includes the numbers of participants who started, completed, and dropped out of each period of the study based on the sequence in which interventions were assigned.
- **Baseline Characteristics.** A tabular summary of the data collected at the beginning of a study for all participants, by study arm or comparison group.
- **Outcome Measures and Statistical Analyses.** A tabular summary of outcome

measure values, by study arm or comparison group.

- **Adverse Events.** A tabular summary of all anticipated and unanticipated serious adverse events and a tabular summary of anticipated and unanticipated other adverse events exceeding a specific frequency threshold.

https://www.clinicaltrials.gov/

The Pan African Clinical Trials Registry (PACTR)

This is a regional register of clinical trials conducted in Africa. The registry is an African initiative serving the needs of Africans. It provides an open-access platform where clinical trials can be registered free of charge. The PACTR aims to increase clinical trial registration in Africa by developing awareness of the need to register trials and supporting trialists during registration. Registration is free and may be done by mail and other alternative means

http://www.pactr.org

WHO International Clinical Trials Registry Platform

The mission of the WHO International Clinical Trials Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base. the Clinical Trials Search Portal provides access to a central database containing the trial registration data sets provided by the participating registries . It also provides links to the full original records.

http://www.who.int/ictrp/en/

The European Union Clinical Trials Register

The European Union Clinical Trials Register allows you to search for protocol and results information on:

- interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA);
- clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development. The EU Clinical Trials Register currently displays **27027** clinical trials with a EudraCT protocol, of which **3994** are clinical trials conducted with subjects less than 18 years old.

The register also displays information on **18612** older paediatric trials. ***https://www.clinicaltrialsregister.eu/ctr-search/search***

ISRCTN Registry

The ISRCTN registry is a primary clinical trial registry recognised by WHO and ICMJE that accepts all clinical research studies (whether proposed, ongoing or completed), providing content validation and curation and the unique identification number necessary for

publication. All study records in the database are freely accessible and searchable. ISRCTN supports transparency in clinical research, helps reduce selective reporting of results and ensures an unbiased and complete evidence base.

The registry was launched in 2000, in response to the growing body of opinion in favour of prospective registration of randomised controlled trials (RCTs). Originally ISRCTN stood for 'International Standard Randomised Controlled Trial Number'; however, over the years the scope of the registry has widened beyond randomized controlled trials to include any study designed to assess the efficacy of health interventions in a human population. This includes both observational and interventional trials.
http://www.isrctn.com/

Journals

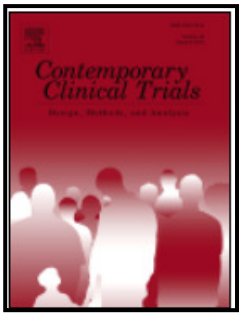
Clinical Trials

Clinical Trials: Journal of the Society for Clinical Trials is an international peer reviewed scholarly journal whose primary aim is the dissemination and development of knowledge about the design, conduct, analysis, synthesis, history, ethics, regulation and clinical or policy impact of all types of clinical trials and related medical research methodologies.

The journal's scope includes statistical methods for analyzing and designing all types of clinical trials, as well as methods to handle departures from randomization and quality of life assessment. It covers the use of economic outcomes, methods for handling missing data, sample size calculations for specific design features and methods for diagnostic tests.

Selected free full-text articles.
http://ctj.sagepub.com/

Contemporary Clinical Trials



Contemporary Clinical Trials is an international peer reviewed journal that publishes manuscripts pertaining to all aspects of clinical trials. The following topics are covered in the journal:

- Unconventional design features of specific trials and their rationale
- Preliminary or full results of clinical trials with unconventional design features
- Statistical methods for all aspects of clinical trials
- Methodologies for clinical trial operations including trial management and optimization; patient recruitment and retention; and trial quality monitoring and assessment
- Data management methodologies including data collection; database maintenance; data quality assurance; safety monitoring and risk management; and patient registries
- Regulatory requirements and their impact on clinical trials
- Ethical and legal considerations in clinical trials
- Risk-benefit, cost-effectiveness and decision analyses in clinical trials

Selected free full-text articles
http://www.sciencedirect.com/science/journal/15517144

Trials

Trials is an open access, peer-reviewed, online journal

that encompasses all aspects of the performance and findings of randomized controlled trials in health. We publish articles on general trial methodology as well as protocols, commentaries and traditional results papers - regardless of outcome or significance of findings.

Prior to 2006, *Trials* was published as *Current Controlled Trials in Cardiovascular Medicine* (CCTCVM). All published CCTCVM articles are available via the *Trials* website. Articles are classified as one of the following types:

- Study protocols: describe proposed or ongoing research, providing a detailed account of the hypothesis, rationale, and methodology of the study.
- Research: Original studies rated as scientifically valid contributions to the field.
- Commentaries: short, focused and opinionated articles on any subject within the scope of the journal. These articles are usually related to a contemporary issue, such as recent research findings, and are often written by opinion leaders.
- Methodology articles: present a new experimental method, test or procedure. The method described may either be completely new, or may offer a better version of an existing method.
- Reviews: comprehensive, authoritative descriptions of any subject within the journal's scope, these articles are usually written by opinion leaders that have been invited by the Steering or Advisory Group, but can be submitted after acceptance of an author's proposal.

http://www.trialsjournal.com/

BMC Medical Research Methodology

BMC Medical Research Methodology

BMC Medical Research Methodology is an open access journal publishing original peer-reviewed research articles in methodological approaches to healthcare research.

Articles on the methodology of epidemiological research, clinical trials and meta-analysis/systematic review are particularly encouraged, as are empirical studies of the associations between choice of methodology and study outcomes.

http://bmcmedresmethodol.biomedcentral.com/

Guides and Toolkits

Clinical Trials Toolkit

NHS National Institute for Health Research

The Clinical Trials Toolkit provides practical advice to researchers in designing and conducting publicly funded clinical trials in the UK. Through the use of an interactive route-map, this site provides information on best practice and outlines the current legal and practical requirements for conducting clinical trials.

The Toolkit is primarily focused on Clinical Trials of Investigational Medicinal Products (CTIMPs) and the regulatory environment and requirements associated with these. However researchers and R&D staff working on trials in other areas will also find useful information and guidance of relevance to the wider trials environment.

http://www.ct-toolkit.ac.uk/

Test, Learn, Adapt: Developing Public Policy with Randomised Controlled Trials

GOV.UK

The paper argues that Randomised Controlled Trials (RCTs), which are now widely used in medicine, international development, and internet-based businesses, should be used much more extensively in public policy. ‘

Test, Learn, Adapt’ sets out nine separate steps that are required to set up any RCT. Many of these steps will be familiar to anyone putting in place a well-designed policy evaluation - for example, deciding in advance the outcome that we are seeking to achieve. Others are less familiar - for example, randomly allocating the intervention to control or intervention groups. Published by UK Cabinet Office Behavioural Insights Team – June 2012**.** 35 pp.
http://bit.ly/NGBz3Q

Global Health Trials

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

The Global Health Network is a hub joining together a collection of websites to support research by sharing knowledge and methods. Each has been established to create a subject specific online community of researchers who can build collaborations, develop documents, share resources and exchange information. This community shares templates, tools, resources, experience and knowledge about clinical research in global health. ***https://globalhealthtrials.tghn.org/***

ECRAN Project

ECRAN

Providing simple and independent information to patients in clinical trials is sometimes a difficult task for the investigators. The European Commission funded in 2012 the ECRAN project - European Communication on Research Awareness Needs - to improve the EU citizens’ knowledge about medical research, and to support their participation in independent and multinational clinical trials. The ECRAN project developed communication material and tools, including an animated film freely available, dubbed in 23 languages, and a website in six language, with some parts also in 23 languages. All the tools were designed to be simple and easy.

http://www.ecranproject.eu/

Identifying and Implementing Educational Practices Supported By Rigorous Evidence: A User Friendly Guide

ies INSTITUTE OF EDUCATION SCIENCES

Randomized controlled trials in education**.** This Guide seeks to provide educational practitioners with user-friendly tools to distinguish practices supported by rigorous evidence from those that are not. From the Institute of Education Sciences National Center for Education Evaluation and Regional Assistance (USA).

http://ies.ed.gov/ncee/pubs/evidence_based/evidence_based.asp

AIHA Internet Resources Digest Forthcoming Topics [Provisional]

- Knowledge Brokers
- Tropical Medicine

AIHA Related Resources

Critically Appraised Topics. *Internet Resources Digest, August 2015 http://www.healthconnect-intl.org/IRD_aug15.html*

Health Technology Assessment. *Internet Resources Digest, May 2012 http://www.healthconnect-intl.org/IRD_may12.html*

Translating Medical Knowledge into Practice. *Internet Resources Digest, January 2009 http://www.healthconnect-intl.org/FIRB_jan09.html*

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The *Internet Resources Digest* is compiled by Irina Ibraghimova, PhD, Library and Information Management Specialist HealthConnect International (www.healthconnect-intl.org). The contents are the responsibility of AIHA and do not necessarily reflect the views of PEPFAR, HRSA, or the United States Government.

If you have a suggestion for a Digest topic, or would like to contribute information about Internet resources, please contact ibra[at]zadar.net.

Back issues of the *Internet Resources Digest* for 2009-2015 are archived at www.healthconnectintl.org/resources.html.

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