Cioms Iii Guidelines

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A User’s Guide World Health Organization
This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.
The Ways of Practical Reason in a Pluralist Society World Health Organization
This text aims to be a one-stop source for guidance and checking the rules for proper conduct of clinical trials, as well as providing a historical perspective of the clinical research landscape. Good Clinical Practice guidelines provide an international quality standard for the regulation of clinical trials. They include standards on how clinical trials should be conducted, provide assurance of safety and efficacy of newly developed drugs and protect human rights. Principles of Good Clinical Practice describes the ethical principles and regulatory requirements that influence the current and future conduct of clinical research. As well as providing essential information on clinical trial design and pharmacovigilance, coverage also includes: informed consent; investigator and sponsor responsibilities; site monitoring; institutional review boards and dependent ethics committees; clinical trial registration and reporting; quality assurance; and future implications for good clinical practices. Principles of Good Clinical Practice will be a definitive text for Clinical Development personnel at pharmaceutical companies, Contract Research Organizations (CROs), PharmD and postgraduate pharmacy students, and medical, pharmacy and drug company libraries
A Resource for Research Ethics Committees Government Printing Office
This 2009 text supersedes the 1991 International Guidelines for Ethical Review of Epidemiological Studies. Its core consists of 24 guidelines with commentaries. A section outlines the historical background and the revision process, and includes an introduction, an account of earlier instruments and guidelines and a statement of general ethical principles. An Appendix lists the items to be included in a research protocol to be submitted for

epidemiological research involving human subjects. Also included in the appendices is the World Medical Association's 2008 Declaration of Helsinki. [Ed.].

Science, Ethics, and Governance World Health Organization

v. 1. Research findings -- v. 2. Concepts and methodology -- v. 3. Implementation issues -- v. 4. Programs, tools and products.

Dictionary of Global Bioethics World Health Organization

This guide offers a practical step-by-step approach and algorithm to aid immunization professionals and decision-makers in determining the best course of action if additional vaccine safety data is needed. The guide provides a structured process for evaluating whether significant knowledge gaps exist, whether passive safety surveillance is adequate, and if not, methods for and practical aspects of conducting active vaccine safety surveillance. The guide also includes an essential vaccine information source list for evaluating the extent of data resources and several case studies for review. With more vaccine solutions available and opportunities for earlier availability of new vaccine products in resource-limited countries (e.g. vaccines against rotavirus, human papillomavirus or pneumococci) as well as new products that address diseases endemic in those countries only (e.g. malaria, dengue among others), generating reliable data about specific safety concerns is becoming a priority for all countries. This CIOMS publication--more than any other in recent history--has focused on the special needs of the country level organizations responsible for developing strategies and implementing new vaccination programs into resource-limited environments.

Drug-Induced Liver Injury World Trade Organization

This protocol covers the full range of research activities in the health field that involve interventions on human beings. It aims to protect the dignity and identity of everyone involved, without discrimination.

Principles of Good Clinical Practice AFRICAN SUN MeDIA

The purpose of this document is to present the case for the importance of pharmacovigilance, to record its growth and potential as a significant discipline within medical science, and to describe its impact on patient welfare and public health.

How to Develop and Implement a National Drug Policy Council of Europe

The idea for this manual came from Pfizer in the US, which provided the Clinical Trials Centre at The University of Hong Kong, Hong Kong SAR, PR China with a nonbinding grant for its development. The general project layout protocol was accepted by Pfizer in July 2009. Pfizer has not in any way interfered with the project, except for providing nonbinding comments to the final product. The entire text of this manual was written by Johan PE Karlberg. Marjorie A Speers provided considerable and essential comments on the contents and the first and subsequent drafts. A group of international human research protection experts mostly working in non-profit institutions or organisations - see Contributors for details - reviewed and provided important comments on the contents and final draft. It was solely created with the intention to promote human research protection of participants in clinical trials. This manual will be translated into numerous languages and is provided free of charge as an electronic file over the Internet (http://www.ClinicalTrialMagnifier.com) and offered in print for a fee. The objective beyond this project is to establish educational activities, developed around the manual, and jointly organised with leading academic institutions worldwide.

Proceedings of the XVth CIOMS Round Table Conference, Manila, 13-16 September 1981 National Academies Press

As well as being a reference for the design, analysis, and interpretation of vaccine studies, the text covers all design and analysis stages, from vaccine development to post-licensure surveillance, presenting likelihood, frequentists, and Bayesian approaches.

Report of CIOMS Working Group X Cioms

In recent years public expectations for rapid identification and prompt management of emerging drug safety issues have grown swiftly. Over a similar timeframe, the move from paper-based adverse event reporting systems to electronic capture and rapid transmission of data has resulted in the accrual of substantial datasets capable of complex analysis and querying by industry, regulators and other public health organizations. These two drivers have created a fertile environment for pharmacovigilance scientists, information technologists and statistical experts, working together, to deliver novel approaches to detect signals from these extensive and quickly growing datasets, and to manage them appropriately. In following this exciting story, this report looks at the practical consequences of these developments for pharmacovigilance practitioners. The report provides a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical advice. But the report does not specify instant solutions. These will inevitably be situation specific and require careful consideration taking into account local needs. However, the CIOMS Working Group VIII is convinced that the combination of methods and a clear policy on the management of signals will strengthen current systems. Finally, in looking ahead, the report anticipates a number of ongoing developments, including techniques with wider applicability to other data forms than individual case reports. The ultimate test for pharmacovigilance systems is the demonstration of public health benefit and it is this test which signal detection methodologies need to meet if the expectations of all stakeholders are to be fulfilled.

Report by Topic Group 3 of the Cioms Working Group on Vaccine Safety Who Publications Centre USA

Examining the theoretical and empirical status of applied ethics, this volume demonstrates how a pluralistic and democratic society can deal with ethical issues in the light of its moral conscience. The volume first sets the stage for a conception of applied ethics as applications of transnational civil ethics, based both on a discourse theory of knowledge (Apel, Habermas), and on an activities and capabilities approach (Aristotle, Sen). It then examines how applied ethics relates to important theoretical discussions in philosophy such as constructivism, virtue ethics, hermeneutic and deliberative theory. The contributors discuss applied ethics in light of globalization and identify recurring dilemmas as well as the problem of universal norms. They close by considering two aspects of the institutional point of view - republicanism, and contractarianism and constitutional economics.

Clinical Trials in Developing Countries National Academies Press

The CIOMS Guide to Vaccine Safety Communication provides an overview of strategic communication issues faced by medicines regulators, those responsible for vaccination policies and programs and other stakeholders including: (1) the launch of newly-developed vaccines for the first time to market, (2) the introduction of current or underutilized vaccines into new countries, regions, or populations, and (3) the handling of any new safety issue arising during the life-cycle of a vaccine. The Guide sources from existing guidance documents and compiles recommendations relevant from a regulatory perspective, providing a common ground in a way that has not been achieved otherwise at a global level. It stresses the fundamental importance of regulatory bodies having a system in place with skilled persons who can efficiently run vaccine safety communication in collaboration with stakeholders. It presents information and examples with color-coding for quick access to three levels of guidance and offers a CIOMS template to use to create a Vaccine Safety Communication Plan.

Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research Who Publications Centre USA

This Dictionary presents a broad range of topics relevant in present-day global bioethics. With more than 500 entries, this dictionary covers organizations working in the field of global bioethics, international documents concerning bioethics, personalities that have played a role in the development of global bioethics, as well as specific topics in the field.The book is not only useful for students and professionals in global health activities, but can also serve as a basic tool that explains relevant ethical notions and terms. The dictionary furthers the ideals of cosmopolitanism: solidarity, equality, respect for difference and concern with what human beings- and specifically patients - have in common, regardless of their backgrounds, hometowns, religions, gender, etc. Global problems such as pandemic diseases, disasters, lack of care and medication, homelessness and displacement call for global responses.This book demonstrates that a moral vision of global health is necessary and it helps to quickly understand the basic ideas of global bioethics.

Practical Approaches to Risk Minimisation for Medicinal Products World Health Organization

CIOMS, in association with the World Health Organization, started its work on ethics in health-related research in the late 1970s. Accordingly, CIOMS set out, in cooperation with WHO, to prepare guidelines to indicate how the ethical principles set forth in the Declaration of Helsinki of the World Medical Association, could be effectively applied, particularly in low-resource settings, given their socio-economic circumstances, laws and regulations, and executive and administrative arrangements. Since then revised editions of the CIOMS ethical guidelines were published in 1993 and 2002. New developments in research have prompted CIOMS to again revise their ethical guidelines. The result is now available in this new publication. In the new 2016 version of the ethical guidelines, CIOMS provides answers to a number of pressing issues in research ethics. The Council does so by stressing the need for research having scientific and social value, by providing special guidelines for health-related research in low-resource settings, by detailing the provisions for involving vulnerable groups in research and for describing under what conditions biological samples and health-related data can be used for research. Progress towards a world where all can enjoy optimal health and health care is crucially dependent on all kinds of research including research involving humans. Involving humans in medical research is necessary to improve the knowledge base on which medicine should be based. At the same time, individuals participating in health-related research have individual human rights and have a right to be protected against the risks that research may bring to them. The tension between these two considerations has led the medical community to endorse ethical guidelines for health-related research. Research Ethics Committees can use these guidelines to evaluate whether a given research protocol is ethically acceptable or not.

International Reporting of Periodic Drug-safety Update Summaries Cioms Publication

A drug policy is a crucial ingredient in every country's national health strategy as it provides a strategic framework to identify goals and commitments. This publication discusses the key components of such a policy. Issues covered include: the selection of essential drugs, affordability; finance and supply; regulation and quality assurance; rational use; research; human resources; monitoring and evaluation.

Ethical Conduct of Clinical Research Involving Children National Academies Press

Guidelines for Preparing Core Clinical-safety Information on DrugsReport of CIOMS Working Groups III and V : Including New Proposals for Investigator's BrochuresWorld Health OrganizationGuidelines for Preparing Core Clinical-safety Information on DrugsReport of CIOMS Working Group III.Who Publications Centre USAInternational Ethical Guidelines for Health-Related Research Involving HumansCioms Publication

Maximizing Benefits, Minimizing Risk World Health Organization

The definitive reference guide to designing scientifically sound and ethically robust medical research, considering legal, ethical and practical issues.

Cioms Guide to Vaccine Safety Communication National Academies Press

The aim of this book is to provide research ethics committee members with a resource that focuses on research ethics issues in Africa. The authors are currently active in various aspects of research ethics in Africa and the majority have been trained in the past by either the Fogarty International Center or Europe and Developing Countries Clinical Trial Partnership (EDCTP) sponsored bioethics training programmes .

Guidelines for Preparing Core Clinical-safety Information on Drugs Pharmaceutical Press

Drug-Induced Liver Injury, Volume 85, the newest volume in the Advances in Pharmacology series, presents a variety of chapters from the best authors in the field. Chapters in this new release include Cell death mechanisms in DILI, Mitochondria in DILI, Primary hepatocytes and their cultures for the testing of drug-induced liver injury, MetaHeps an alternate approach to identify IDILI, Autophagy and DILI, Biomarkers and DILI, Regeneration and DILI, Drug-induced liver injury in obesity and nonalcoholic fatty liver disease, Mechanisms of Idiosyncratic Drug-Induced Liver Injury, the Evaluation and Treatment of Acetaminophen Toxicity, and much more. Includes the authority and expertise of leading contributors in pharmacology Presents the latest release in the Advances in Pharmacology series

International Ethical Guidelines for Health-Related Research Involving Humans Springer Nature

The Handbook is a detailed manual giving a step by step approach to undertaking the pharmacovigilance of antimalarials. It is intended to be a source of practical advice for pharmacovigilance centres. It provides information on spontaneous reporting of adverse drug reactions as a complement to other WHO publications. In addition, it provides details on how to conduct cohort event monitoring, which is a method of active safety surveillance collecting information on all adverse events occurring after treatment. It also details how to perform causality assessment and signal identification, applicable to both methods of surveillance.