Online ethics training programmes and standardisation of ethics training

Prof. Dominique Sprumont
Institut de droit de la santé
Université de Neuchâtel

OVERVIEW

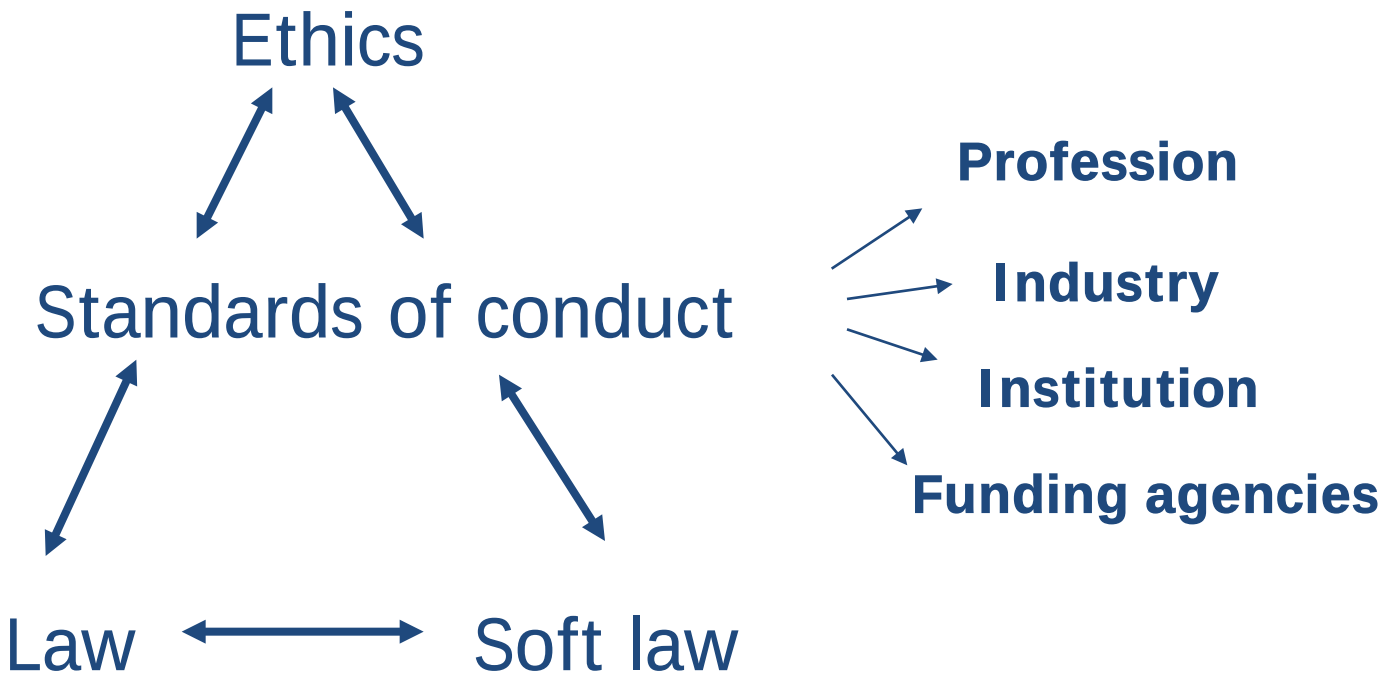
1. Introduction

2. Consensus Standards for Introductory e-Learning Courses in Research Ethics and Regulation

3. Introduction to the TRREE program (www.trree.org)

4. Q/A

1. Regulation of Biomedical Research: An Example of Internormativity



1. How to Handle this Complexity? A Question of Education

- “Education is a cornerstone for any meaningful attempt to construct a system of control of medical practice and experimentation. Once its importance is recognised, it has the virtue that something can be done about it. […] New rules and procedures are especially needed, but can only be promulgated after their purposes are clearly articulated. Here lessons from the past and present may serve as a guide to the future.”

Jay Katz 1969

1. Existing Elearning programs

- http://webcourses.amanet-trust.org/mod/resource/view.php?inpopup=true&id=116
- http://www.bioeticaweb.com/content/view/4197/91/
- http://www.bu.edu/online/programs/certificate-programs/clinical-investigationcourses.shtml
- http://BRANY.TrainingCampus.net
- http://www.ccac.ca/fr_/education/pnfiua
- http://www.csmls.org/CE/CE_course_details.cfm?ID=4658&&CFID=6835576-30697075
- https://www.citiprogram.org
- http://www.bioethicscolumbia.org/education/distance_learning.html
- http://www.epigeum.com/
- http://www.fhi360.org/resource/research-ethics-training-curriculum-retc-second-edition
- http://www.bioeticacs.org/?dst=curso_online
- http://www.menareti.net/
- http://www.estp.sci.eg/english/trainings/training_hretie
- http://www.kks-netzwerk.de/index,51,25,en,selten,x38hdt,,25.html
- http://www.thieme.de/viamedici/lernen/ethik/start.html
- http://www.cems.monash.org/online-ethics-training-course.html
- http://www.csl.uiuc.edu/ethics-center
- http://phrp.nihtraining.com/users/login.php
- http://ori.hhs.gov/education/products/montana_round1/research_ethics.html
- https://www.primr.org/Conferences.aspx?id=8523&ekmensel=297ded8b_421_0_8523_1
- http://ethique.msss.gouv.qc.ca/didacticiel/index.php?lang=fr_ca
- http://www.socra.org/html/education.htm
- http://www.redbioetica-edu.com.ar/
- http://www.fmv-uba.org.ar/cp/detallecurso.asp?idcurso=242
- http://www.onlinegcp.es/default.aspx?page=home
- **http://www.admin.ox.ac.uk/researchsupport/ctrg/gcponline/registration/**

University of Miami, Ethics Programs **Online Courses in Research Ethics World Health Organization Network of Collaborating Centres in Ethics,** December 2011

https://umshare.miami.edu/web/wda/ethics/documents/WHO/online_courses.pdf

2. Consensus Standards for Introductory e-Learning Courses in Research Ethics and Regulation

- Workshop at the Brocher Foundation, Hermance, Switzerland, January 16-18, 2013.

- 22 participants included developers and providers of e-learning programs from Africa, Europe and North America as well as funders and users of these programs

- Consensus standards for introductory e-learning courses in human participants research ethics,
  John R Williams, Dominique Sprumont, Marie Hirtle, et al., *J Med Ethics* published online August 19, 2013, doi:10.1136/medethics-2013-101572

JME Online First, published on August 19, 2013 as 10.1136/medethics-2013-101572

Consensus standards for introductory e-learning courses in human participants research ethics

John R Williams,[1] Dominique Sprumont,[2] Marie Hirtle,[3] Clement Adebamowo,[4,5,6] Paul Braunschweiger,[7] Susan Bull,[8] Christian Burri,[9] Marek Czarkowski,[10] Chien Te Fan,[11] Caroline Franck,[12] Eugenijus Gefenas,[13] Antoine Geissbuhler,[14] Ingrid Klingmann,[15] Bocar Kouyaté,[16] Jean-Pierre Kraehenbhul,[17] Mariana Kruger,[18] Keymanthri Moodley,[19] Francine Ntoumi,[20] Thomas Nyirenda,[21] Alexander Pym,[22] Henry Silverman,[23] Sara Tenorio[24]

For numbered affiliations see end of article.

Correspondence to
Professor John R Williams, Department of Medicine, University of Ottawa, 825 Grenon Avenue, Unit 19, Ottawa, ON, Canada K2B 6G1; jrewms@yahoo.com

Received 3 May 2013
Revised 15 July 2013
Accepted 30 July 2013

To cite: Williams JR, Sprumont D, Hirtle M, *et al*. *J Med Ethics*: Published Online First: [please include Day Month Year] doi:10.1136/medethics-

ABSTRACT

This paper reports the results of a workshop held in January 2013 to begin the process of establishing standards for e-learning programmes in the ethics of research involving human participants that could serve as the basis of their evaluation by individuals and groups who want to use, recommend or accredit such programmes. The standards that were drafted at the workshop cover the following topics: designer/provider qualifications, learning goals, learning objectives, content, methods, assessment of participants and assessment of the course. The authors invite comments on the draft standards and eventual endorsement of a final version by all stakeholders.

INTRODUCTION

This document is the output of a workshop that took place at the Brocher Foundation, Hermance, Switzerland, from 16–18 January 2013. The 22 participants included developers and providers of e-learning programmes from Africa, Europe and North America[1] as well as funders and users of these programmes.[2]

A writing committee, drawn from the participants at the meeting, produced this document. Two drafts were circulated to all other participants and their comments were incorporated in this version. It represents a consensus of those present at the workshop.

OBJECTIVES AND SCOPE

The overall goal of the workshop was to begin the process of establishing standards for e-learning programmes in the ethics of research involving human participants that could serve as the basis of their evaluation by individuals and groups who want to use, recommend or accredit such programmes. In recent years, there has been a proliferation of these programmes,[1] but to our knowledge, this workshop was the first occasion for developers, providers and users of programmes to meet for the purpose of establishing standards.

Preparations for the workshop included fund-raising, identification of and invitations to potential participants and development of a background paper and agenda. The three-day workshop was structured as follows: day 1—introductions, discussion and agreement on agenda, short presentations on the e-learning programmes represented at the workshop and round-table discussion of standards for such programmes; day 2—round-table discussions of specific standards: objectives, content, methods, evaluation and (briefly) technical aspects; day 3—review of earlier sessions; discussion and agreement on standards for introductory courses; agreement on next steps and who will be involved.

Given the complexity of research ethics and the diversity of e-learning programmes in this area, workshop participants agreed to focus on standards for the introductory course that all programmes offer. Standards for advanced and specialised courses that are tailored to the needs of specific groups (eg, Research Ethics Committee (REC) members, researchers, students, etc) or that treat in greater detail specific research topics or methods (eg, Good Clinical Practice (GCP), vaccine research, epidemiology, etc) may be developed at a later date.

THEORETICAL FRAMEWORK

Standards are consensus-based rules, guidelines or specifications to harmonise or formalise products, services and processes.[4] They are normally developed by associations of organisations that offer the products, services or processes, for example, industry or professional associations, or by organisations established specifically for producing standards, such as the International Organization for Standardization. Where there is no existing association of those who offer a specific product, service or process, as is the case with RECs[5] and e-learning programmes in research ethics, stakeholders can initiate the process of developing standards.

The distinction between standards and guidelines is not always clear. For example, one of the International Council on Harmonization's (ICH) guidelines states, "The objective of this ICH GCP *Guideline* is to provide a unified *standard*…".[6] We have chosen to use the term 'standard' to signify a minimum requirement for e-learning programmes in research ethics. In the future, guidelines can be developed for the implementation of the standards and for identifying best practices to which all programme developers can aspire.

The World Health Report 2013

Research for Universal Health Coverage

World Health Organization

2.1. OBJECTIVES AND SCOPE

- The overall goal of the workshop was to begin the process of establishing standards for e-learning programs in the ethics of research involving human participants **that could serve as the basis of their evaluation by individuals and groups who want to use, recommend or accredit such programs.**

2.2. Preliminary remarks

- Workshop participants agreed that:
  - To maintain the public's trust in the research enterprise, rigorous education stressing the need to protect individuals who participate in human research is essential.
  - Research ethics education programs to promote awareness and appreciation of human research protections must be provided to members of research ethics committees and to all members of the research team and must be included at the earliest possible stage of professional training.
  - Good Clinical Practice (GCP) training is essential for all clinical researchers and support staff. However, since GCP training is very process- and procedure-oriented, it does not provide sufficient instruction in the foundations of clinical research ethics. Thus, GCP courses should always be preceded or accompanied by an introductory course in research ethics.

2.2. Preliminary remarks (cont'd)

- Workshop participants agreed that:
  - Ethics training should deal with all forms of research involving human participants, not just clinical research.
  - Although not the only appropriate method for providing foundational learning opportunities in research ethics, the on-line, e-learning presentation paradigm can be an extremely cost- and time-effective means of achieving this goal.

2.3. DRAFT STANDARDS FOR INTRODUCTORY RESEARCH ETHICS E-LEARNING COURSES

1. **Developer/provider qualifications**
2. **Learning goals**
   - To raise awareness and understanding of the role of research ethics in the protection of research participants and in the promotion of high-quality research that meets the needs of the concerned population. (**Research for universal health coverage**)
   - To educate those involved in the conduct of research involving human participants about their roles and responsibilities in the research process.
3. **Learning objectives**
   - Program participants will gain the knowledge, understanding and ability to apply basic concepts in research ethics in the evaluation of common ethical issues.
   - The introductory course will provide a common language and ethical framework for everybody involved in research.
   - A needs assessment will determine more precisely the objectives and content of the program.

2.3. DRAFT STANDARDS FOR INTRODUCTORY RESEARCH ETHICS E-LEARNING COURSES

4. Content

- The introductory course includes the following topics:
  - Basic concepts: what is ethics, what is research (different types of research), what is research involving human participants, what is ethics review of research
  - A brief history of research ethics
  - The roles and responsibilities of all those involved in research
  - Conflicts of interests and commitments
  - Ethics review by the competent REC
  - Fundamental principles and normative framework:
    - Scientific accuracy
    - Risk-benefit analysis
    - Autonomy/informed consent
    - Justice
    - Vulnerable populations
    - Confidentiality and privacy
    - Societal, religious and cultural factors
    - Local conditions
  - Monitoring post-REC approval

2.3. DRAFT STANDARDS FOR INTRODUCTORY RESEARCH ETHICS E-LEARNING COURSES

5. Methods

- The methods and training material are in line with the learning objectives and take into account any technical restraints (e.g., low band width) experienced by potential course participants.
- The introductory course is equivalent to a one-day seminar… Longer times might be expected if the learner follows all of the hyperlinks provided or explores all of the suggested additional readings… This limit might also be exceeded if the language of the course is not the learner's first language.
- The course provides participants with references and links for more in-depth study of the material, including resources in local languages where available. Participants are encouraged to make use of these materials and to regularly participate in other activities (seminars, workshops, refresher courses, and informal discussions) to increase their understanding and skills in research ethics.

2.3. DRAFT STANDARDS FOR INTRODUCTORY RESEARCH ETHICS E-LEARNING COURSES

6. Assessment of participants

- The course includes an assessment process to ensure that learners have a satisfactory understanding of the materials presented.

7. Assessment of the course

- All learners are given an opportunity to provide the course developers/providers written feedback about their online learning experiences (good and bad) with the course. This can be done by using open-ended questions or by a voluntary, anonymous online survey.
- When feasible, the course provider will seek recognition of the course for Continuing Professional Development (CPD) credit by the competent bodies.

3.1. TRREE: How ?

- Collaborative
- Collegial
- Multi - directional (North – South / South – North / South – South / North – North)
- African and European perspectives with in an international vision
- Based on universal ethical and legal principles

3.2. TRREE- Setting priorities (1)

Needs assessment Questionnaire

- Conceived, pre-tested and validated
- Approved by RECs in Cameroon, Mali, Tanzania and Switzerland
  - Submitted to ethics committee members in Cameroon, Mali & Tanzania
  - 109 contacted / 255 total in 3 countries
  - 68 % response rate (74/109)

Ateudjieu Jérome, Baume Cédric, Joyce Ikingura, Marie Hirtle, Alassane Niaré and Dominique Sprumont, Training Needs Assessment in Research Ethics Evaluation Among Research Ethics Committees Members in Three African Countries: Cameroon, Mali And Tanzania, in *Developing World Bioethics*, September 2009

Dominique Sprumont, Formation de base en éthique de la recherche : retour aux sources avec le projet TRREE, in *Bioetica Forum*, Décembre 2009

3.2. TRREE- Setting priorities (2)

Summary of Results of the NAQ

- 71% of respondents already had some sort of training in ethics (58 % in Switzerland)
- Priority in terms of content:
  - Fundamental principles of ethics
  - Applicable normative framework
  - How to conduct ethics review
  - Informed consent
- Audience
  - REC members & researchers

Ateudjieu Jérome, Baume Cédric, Joyce Ikingura, Marie Hirtle, Alassane Niaré and Dominique Sprumont, Training Needs Assessment in Research Ethics Evaluation Among Research Ethics Committees Members in Three African Countries: Cameroon, Mali And Tanzania, in *Developing World Bioethics*, September 2009

Dominique Sprumont, Formation de base en éthique de la recherche : retour aux sources avec le projet TRREE, in *Bioetica Forum*, Décembre 2009

3.3. Follow-up

- Elearning.trree.org (online since June 2009)
- New countries included every year (presently 12 with 6 more being drafted, and more for which funding has been requested)
- New languages available (Chinese and Polish being drafted / negociation starting for Spanish, Italian and Russian / GCP module available in Portuguese, dec. 2013)
- New Modules available: GCP (December 2012); HIV Vaccine Testing (March 27, 2013); HIV Research with Adolescents (December 2013)
- New Modules in the pipeline: Medical devices; Human and Social Sciences Health Research; etc.

Future development

- TRREE is preparing a full program in chinese in collaboration with Prof. Chien Te Fan, National Tsing Hua University, Hsinchu (Taiwan)
- TRREE intends to develop with AVAREF a new set of elearning tools and access to the regulation in the field of vaccines (and medicinal products) trials and regulation.
  - from ethics to regulation…

TRAINING AND RESOURCES IN RESEARCH ETHICS EVALUATION

TRREE

English (en)

WITH SUPPORT OF WMA

LOGIN

Username doms

Password

Remember username

Login

Create new account

Lost password?

LATEST NEWS

27 Nov, 22:28
Newsletter 16 - Two new national supplements for Lithuania and South Africa with a new layout
more »»»

10 Oct, 14:23
Newsletter 15- TRREE is recognized by the Nigerian National Health Research Ethics Committee
more »»»

2 Aug, 11:52
SARETI Masters Scholarships in Research Ethics 2014
more »»»

Older topics ...

PARTICIPANTS & STATISTICS

WELCOME to the TRREE on-line training programme on the ethics and regulation of health research involving human participants. Read more »»»

E-LEARNING MODULES

a web-based learning program and certification

LOG-IN REQUIRED

- Module 1 — **Introduction to research** [EN] [FR] [DE] [PT]
- Module 2.1 — **Research ethics evaluation** [EN] [FR] [DE] [PT]
- Module 3.1 — **Informed Consent** [EN] [FR] [DE] [PT]
- Module 3.2 — **Good Clinical Practice** [EN] [FR] [DE] [PT]
- Module 3.3 — **HIV vaccine trials** [EN] [FR] [DE] [PT]

LOG-IN
REGISTER NOW!

NATIONAL SUPPLEMENTS

local experts explain requirements in their country

NO LOG-IN

AFRICA

Burkina Faso [EN] [FR] [DE] [PT]

Cameroon [EN] [FR] [DE] [PT]

Côte d'Ivoire [EN] [FR] [DE] [PT]

Mali [EN] [FR] [DE] [PT]

Mozambique [EN] [FR] [DE] [PT]

Nigeria [EN] [FR] [DE] [PT]
New Quiz!

Senegal [EN] [FR] [DE] [PT]

South Africa [EN] [FR] [DE] [PT]
New!

Tanzania [EN] [FR] [DE] [PT]

EUROPE

Germany [EN] [FR] [DE] [PT]

Lithuania [EN] [FR] [DE] [PT] [LT]
New!

Switzerland [EN] [FR] [DE] [PT]

TOOLS & RESOURCES

Glossary [EN] [FR] [DE] [PT]

Bibliography [EN] [FR] [DE] [PT]

SETTINGS

Course administration

Grades

My profile settings

Intended audience: The GCP module is relevant to anyone carrying out clinical trials and will be valuable for investigators, nurses, pharmacists, certain members of Ethics Committees, clinical trial monitors, staff working in pharmaceutical companies or in Contract Research Organization.

Pre-requisite: Modules 1, 2.1 & 3.1

Overview: Module 3.2 GCP: 32 questions & a Quiz with 25 questions. The system will automatically save completed material and allow you to continue at a later time.

Credits
Introduction
Objectives
Table of contents
Bibliography
Abbreviations

GCP Module

Module 3.2 ✔

GCP Quiz

GCP QUIZ ✔

GCP Training Certificate

Download Training Certificate

Printable material

Files

This module is sponsored by:

SwAPP | Swiss Association of Pharmaceutical Professionals

SwAPP: http://www.swapp.ch/about-us/

At the end of each module, a certificate is delivered to participants who got 70% of correct answers on thei
click (first try).

TRREE certificates are formally acknowledged by the following organizations:

FMH
Verbindung der Schweizer Ärztinnen und Ärzte
Fédération des médecins suisses
Federazione dei medici svizzeri
Swiss Medical Association

Foederatio Pharmaceutica Helvetiae
FPH
Programmes de formation postgraduée

COPYRIGHT

DISCLAMOR

Legal texts and policies are provided for reference purposes only – documents should not be considered offi
versions

ACKNOWLEDGMENTS

Credits

The TRREE GCP module meets Swissmedic requirements for investigator training.

Last modified: Thursday, 13 December 2012, 12:43 PM

The TRREE course is recognized by Nigerian National Health Research Ethics Committee as evidence of satisfactory training in informed consent and GCP (for clinical research) as required by the National Code for Health Research Ethics. All Nigerian researchers are required to complete training on Informed Consent and the Nigerian National Code for Health Research Ethics. Clinical researchers are, in addition, required to complete training in GCP.

These three training requirements can be met by completing the following TRREE modules:

1. Informed consent training: TRREE Modules 1 (Introduction), 2.1 (Research ethics evaluation), and 3.1 (Informed consent);
2. "Nigerian National Code for Health Research Ethics" training: Nigerian National Supplement Module;
3. "Good Clinical Practice" training: Module 3.2 GCP.

A completion certificate will be issued for each of these 3 modules separately upon completion. You will receive a copy of the certificate for each module you complete via e-mail ONLY from the office of the Coordinator of the TRREE programme in Nigeria, Ms. Busola Onasile (trree@westafricanbioethics.net). Please check your "SPAM" folder if you do not receive your certificates within a reasonable period.

General Introduction to National Supplements

Training Material

- Introduction to the legal system of Nigeria
- Nigerian Module
- Bibliography
- Reference documents [pdf]

Quiz

Quiz

This content is available only to logged-in users. *Login now »»*

Certificate of completion for Nigerian Participants

Not available until you achieve a required score in **Quiz**

Sponsored By

This module was realized with support of Fogarty International Center, West African Bioethics and EDCTP

Files

Files

- deutsch_10_040413.pdf
- english_10_040413.pdf
- francais_10_040413.pdf
- portugues_10_040413.pdf

TRREE

RESEARCH ETHICS EVALUATION

WITH SUPPORT OF WMA

HOME ABOUT TRREE CERTIFICATE TEAM CONTACT US

You are not logged in. (Login)

Home ► Login ► New account

Choose your username and password

Username*

Password* Unmask

More details

Email address*

Email (again)*

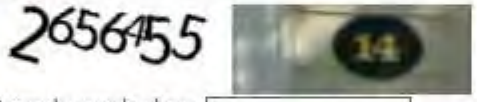
First name*

Surname*

City/town*

Country* Select a country

reCAPTCHA



Enter the words above

Get another CAPTCHA

Get an audio CAPTCHA

Create my new account Cancel

There are required fields in this form marked *.

You are not logged in. (Login)

Home

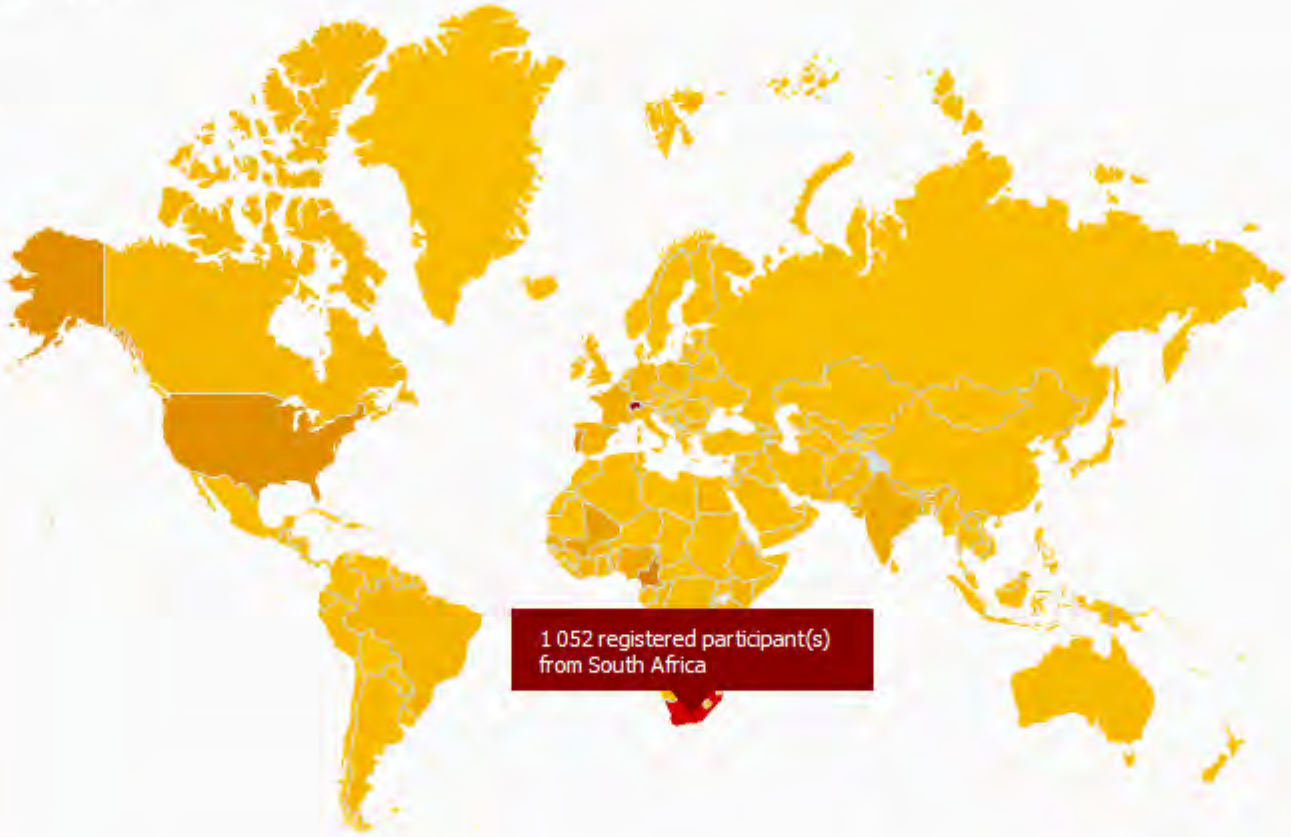
TRREE PARTICIPANTS & STATISTICS

TRREE is a growing community. You will find in this section our statistics with the main data concerning the number of visits, participation, origin of the participants and language distribution.

- Download TRREE Aggregated Statistics *(Updated on November 1, 2013)*

For a direct access to the number of participants per country, please consult the interactive map below.

Number of participants per country
(updated every hour)



Use mouse wheel to zoom in on a particular area.

TRREE PARTICIPANTS & STATISTICS

TRREE is a growing community. You will find in this section our statistics with the main data concerning the number of visits, participation, origin of the participants and language distribution.

- Download TRREE Aggregated Statistics *(Updated on November 1, 2013)*

For a direct access to the number of participants per country, please consult the interactive map below.

Number of participants per country
(updated every hour)

Use mouse wheel to zoom in on a particular area.

TRREE PARTICIPANTS & STATISTICS

TRREE is a growing community. You will find in this section our statistics with the main data concerning the number of visits, participation, origin of the participants and language distribution.

- Download TRREE Aggregated Statistics *(Updated on November 1, 2013)*

For a direct access to the number of participants per country, please consult the interactive map below.

Number of participants per country
(updated every hour)

Use mouse wheel to zoom in on a particular area.

South-African module

Written by
Nivedhna Singh

Expert advice
Adv. Ann Strode, (UKZN) & Dr. Joanna Bourke-Martignoni (UNINE)

Supervised by Prof. Douglas Wassenaar (UKZN)

Sponsored and Funded by a Medical

Bibliography

1. CIOMS International Ethical Guidelines for Epidemiological Studies. Council for International Organization of Medical Sciences (CIOMS) and World Health Organization (WHO) Feb 2008

2. World Health Organization: Good Clinical Laboratory Practice. Special Program for Research and Training in Tropical Disease (TDR), 2009

3. World Medical Association: Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants 59th WMA General Assembly, Seoul, Korea, October 2008; [HL:

4. ICH International Conference on Harmonisation (ICH)

- **ICH E1-E2F:** Clinical safety
- **ICH E3:** Clinical study reports
- **ICH E4:** Dose response studies
- **ICH E5:** Ethnic factors
- **ICH E6:** Good clinical practice
- **ICH E7:** Special populations: Geriatrics
- **ICH E8:** General considerations for clinical trials
- **ICH E9:** Statistical principles for clinical trials
- **ICH E10:** Choice of control group and related issues in clinical trials
- **ICH E11:** Clinical investigation of medicinal products in the pediatric population
- **ICH E12:** Principles for clinical evaluation of new antihypertensive drugs
- **ICH E14:** Clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs
- **ICH E15:** Definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics: Genomic data and sample coding categories
- **ICH E16:** Biomarkers related to drug or biotechnology product development: context, structure and format of qualification submissions
- **ICH S1A-S1C:** carcinogenicity studies
- **ICH S2:** genotoxicity studies
- **ICH S3A-S3B:** toxicokinetics and pharmacokinetics
- **ICH S4:** toxicity testing
- **ICH S5:** reproductive toxicology
- **ICH S6:** biotechnological products
- **ICH S7A-S7A:** pharmacology studies
- **ICH S8:** immunotoxicology studies
- **ICH S9:** nonclinical evaluation for anticancer pharmaceuticals
- **ICH S10:** photosafety evaluation

5. EU REGULATIONS

- Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures
- EU EMEA/CHPM/SWP/28367/07, guideline on strategies to identify and mitigate risks for first-inhuman clinical trials with investigational medical products
- European Union "The rules governing medicinal products in the European Union": Volume 10 - Clinical Trials Regulations
- Volume 10 contains guidance documents applying to clinical trials.
  Chapter II: Monitoring and Pharmacovigilance
  - Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (June 2011
  - ICH guideline E2F - Note for guidance on development safety update reports (September 2010)

Thank you for your attention and see you soon on www.trree.org

Institut de Droit de la Santé
Av. du 1er Mars 26
CH-2000 Neuchâtel
Dominique.Sprumont@unine.ch
www.unine.ch/ids