Bergen Summer
Research School
› Global Development Challenges

Global Health in Bio-medical, Social and Cultural perspectives
Bergen, 21 June - 2 July 2010

PhD-Research Course: Electronic mobile data in global health research: a hands-on course

Course leaders

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- **Jørn Klungsøyr**, Researcher, University of Bergen, Centre for International Health
- **Weiqin Chen**, Professor, University of Bergen, Department of Information Science and Media Studies
- **Peter Wakholi**, Researcher, University of Bergen, Centre for International Health / Department of Information Science and Media Studies

Invited guest lecturers

- **Bruce MacLeod**, Professor, University of Southern Maine, USA
- **Aamir Khan**, Center for Health Informatics, Interactive Research & Development & Indus Hospital, Karachi, Pakistan

Course description, goals and objectives

Contents
Implementation of measures to improve public health in most countries in the world requires good data either as a baseline or in the evaluation process. This course will give an in-depth coverage of new and emerging data collection and management tools using mobile telephones, handheld computers and web-based systems. The course will cover all steps required from designing a study, setting up systems and including immediate analysis using open source tools.

The course provides an update on current state-of-the-art ways of collecting and managing data collected in health research in different settings, highlighting the special challenges in low-resource settings.

- Principles of data management in health research
- Paper and double data entry
- Electronic data collection
- Data management and security

The course is a course focusing on increasing the quality of field research data collection and management through the usage of the **free and open source software packages** including:

- openXdata, mobile and web solution for data collection and management
  www.openxdata.org
- OpenMRS, a medical record system
  www.openmrs.org
- OpenClinica, a clinical trial system
  www.openclinica.org
- R, a statistical package
  www.r-project.org

The main topics covered are

- General principles of data collection and management
- Key regulations and requirements for clinical data management from e.g. FDA (www.fda.gov) , FDA 21 CRF Part 11, International Conference on Harmonization (ICH) on Good Clinical Practice and EMEA (www.emea.europa.eu)
- Challenges and possible pitfalls in field research data collection and management
- Study patterns (surveys, household surveys, follow-up studies, clinical trials) and selection of tools for different scenarios.
- Design of electronic forms including branching, validation, translation, user management, geographic information system (GIS) data and mapping and printing of forms.
- Data collection and field operation, focusing on the actual data collection using mobile devices and web forms for immediate electronic data entry.
- Data transmission / synchronization between sites and mobile devices
- Data management including handling of data inconsistencies and queries
- Preparation of datasets for reporting and analysis
- Analysis of data and report creation
- Visualization of data using GIS and mapping tools
- Setup, management and troubleshooting of solutions and mobile devices.
- Audit Trails, Electronic Signatures, Security and Standard Operating Procedures (SOPs)
- Open source networks and solutions and support options.
- Principles of health technology assessment, impact evaluation and cost-benefit analysis, including: validation, user acceptability testing and prototyping.

Objectives

At the end of the course students should:

- have key knowledge of how to design, deploy and manage electronic mobile data acquisition systems for various aspects of global health research, including surveillance, surveys, cohorts, clinical trials and medical records.
- have knowledge about free and open source tools they can use to meet the objective above.

- be capable of conducting training of end-users in key elements of this course once completed. Parts of this course is a Trainer of Trainers course (ToT)

Targeted students, prerequisites and ECTS

Prerequisites

- Interest in theory and practice of electronic field data collection and management.
- A technical training is not required for this course, but elementary knowledge of computer systems is required (e.g. file management, use of office tools, web pages and statistical analysis tools).
- The course is open to persons engaged in health research where electronic data collection is considered/used.
- Priority will be given to students admitted to a PhD or a Masters' Degree Programme.
- Proficiency in English at a level corresponding to TOEFL 300 or IELTS 5.0 is expected.
- Students are recommended to bring their own laptop and mobile telephone that is Java/J2ME enabled (see http://www.club-java.com/TastePhone/J2ME/MIDP_mobile.jsp)

General requirements

- Students are required to attend all the sessions of the course and participation is also mandatory in the plenary events of the overall programme of the Bergen Summer Research School 2010 (the programme will be published on the web in June 2010).

Teaching Methods
Interactive presentations by lecturers, computer sessions, demonstrations, student presentations, panel and group discussions.

Language of Instruction: English

Credits: 5.0 ECTS, 150 hours of student investment time

Assessment procedure
Assessment is divided in 2 parts.

- Part 1: During the course each student will design, setup, conduct, analyze and report on a small study based on prefilled material. Data will be entered using mobile and web, and a small paper written on the results of the study.
- Part 2: After the course, each students will independently in their home institutions analyze, design, setup and demonstrate a data collection and management system for a global health project based on the principles and technologies taught in this course. A short paper must be written that describes each step performed and evaluates the implementation and its use compared to the existing (paper/web based) solution.

Literature

- Scientific papers/reports (participants are given hard copies in booklets)
- Key references include:
    - FDA 21 CRF Part 11: http://en.wikipedia.org/wiki/Title_21_CFR_Part_11
    - EMEA/ICH Good Clinical Practice: http://www.emea.europa.eu/pdfs/human/ich/013595en.pdf
    - Rondell RK, Varley SA, Webb CF. Clinical Data Management 2nd ed., John Wiley & Sons, Chichester, 2000, ISBN: 0-471-98329-2.
- Handouts
- Manual and software (www.openXdata.org, www.openmrs.org, www.openclinica.org, www.r-project.org)
- Pre-reading material will be distributed electronically to all students prior to course start-up.