PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

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Fundisa
African Academy of
Medicines Development

Education in Medicines Development and Regulation in Low and Middle Income Countries

Bernd Rosenkranz, MD PhD (Germany), FFPM

3rd Annual Regulatory Workshop:
New Developments in Drug Regulation

Pretoria, 08 – 09 September 2015

Pharmaceutical Industry in Africa

- Africa is one of the fastest growing economic regions –
  value of pharmaceutical industry increased
  from $ 4.7 billion in 2003 to $ 20.8 billion in 2013

- > 300 companies with manufacturing sites in Africa

- Clinical trials - Focus of pharmaceutical R & D in South Africa
  - Excellent medical qualification
  - € 1.3 - 2 billion generated annually through clinical trials in South Africa
    (Kahn, SAMJ 2008; SACRA, estimate 2008)
  - 550 active trials at any time

- Long and unpredictable review timelines by Regulatory Agencies

**Need for trained staff in industry,
clinical research groups/CROs and Agencies in Africa,
including LMICs**

Africa: Training Needs

- Pharmaceutical industry
- CROs
- Investigators and clinical site staff
- Regulatory agencies
- Pharmaceutical specialists:
  Preparation for accredited professional examinations

Education and Training of Specialists in Medicines Development and Regulation

What is Needed ?

Harmonization of Training Programmes in Medicines Development

- **Standard syllabus and learning outcomes**
- **Quality control**
- **Examinations**

SMD SPECIALIST IN MEDICINES DEVELOPMENT

MMD MASTER OF MEDICINES DEVELOPMENT

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MRA MASTER OF REGULATORY AFFAIRS

CLIC CLINICAL INVESTIGATOR CERTIFICATION

http://www.pharmatrain.eu/

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS

http://www.ifapp.org/

IFAPP

- Non-UK activities managed via International Committee
- 2011: "Export" of UK Faculty of Pharmaceutical Medicine (FPM) Diploma to South Africa (Stellenbosch University)

FACULTY OF PHARMACEUTICAL MEDICINE 1989

Accreditation

- Local University
- SA Department of Higher Education and Training
- SA Council on Higher Education (CHE)
- International and / or local accrediting specialist organisation, e.g., PharmaTrain, IRS

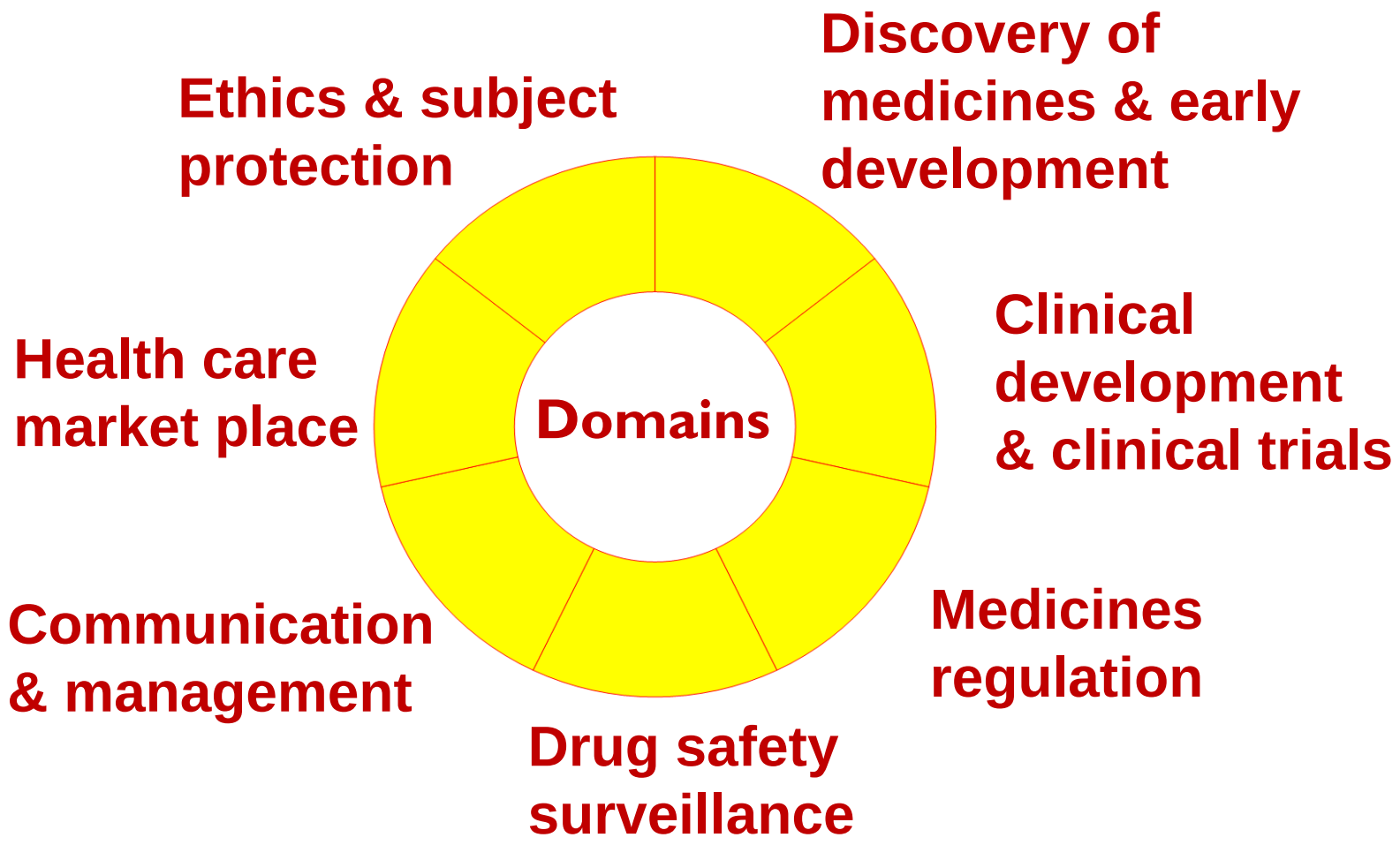
PharmaTrain Specialist in Medicines Development

- Global PharmaTrain Certification Board (gPCB) established
  - Chair: Peter Stonier (UK)
  - Membership: UK, Italy, Austria, Brazil, Japan, USA, South Africa
  - Responsibilities: Programme governance, curriculum, entry criteria for candidates, approval of individual programmes, quality management, equality & diversity compliance
  - Link to PharmaTrain Board

- Regional (country) programmes require:
- National PharmaTrain Certification Boards (nPCBs)
- PharmaTrain Regional Advisor
- Mentors for individual SMD participants

- Expected start: 2016 (Italy)

Specialist in Medicines Development: Core Competencies



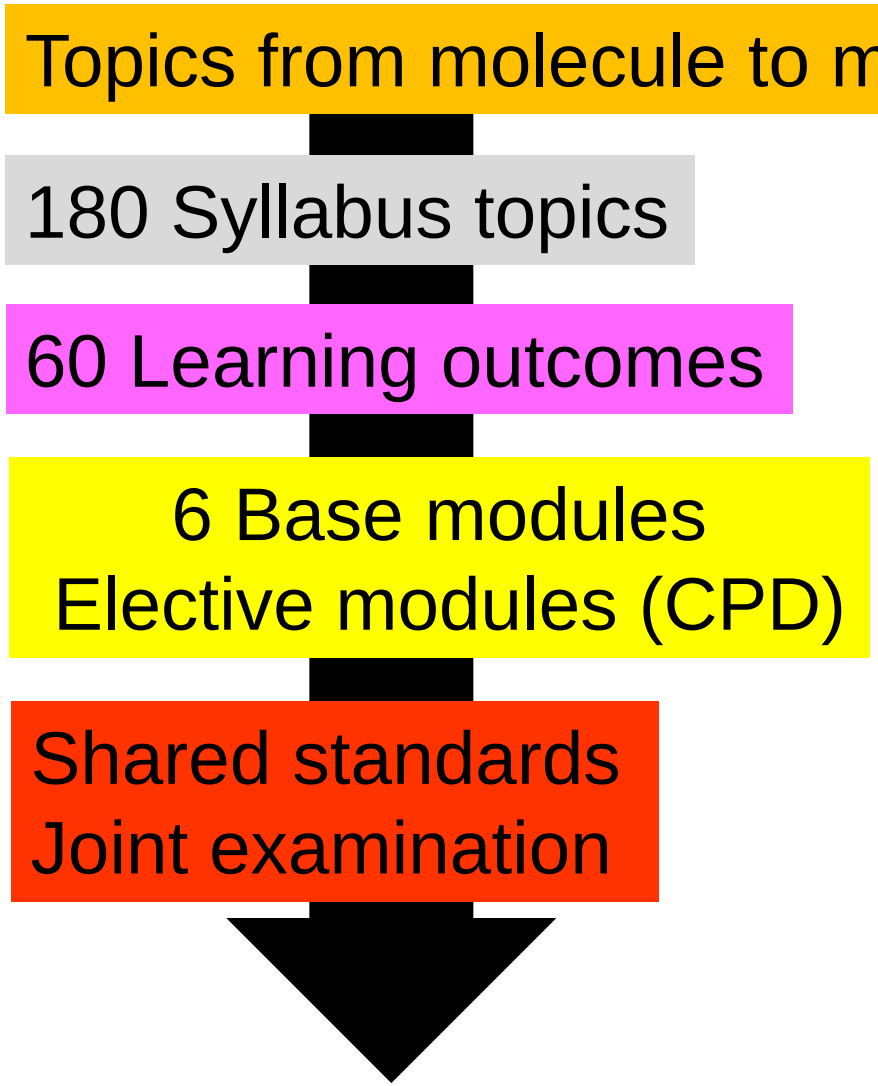
H. Silva et al. Frontiers in Pharmacology; doi: 10.3389/fphar.2013.00105

The Path for Specialization
The PharmaTrain View

Specialist in Medicines Development: Medical and non-medical experts

S. Kerpel-Fronius, 2014

Harmonization of Training Programmes: PharmaTrain Concept



Learning outcomes are the main tools for harmonization

Joint examination & MCQ pool provide information on the uniformity of educational success

S. Kerpel-Fronius, 2014

PharmaTrain Working Group
Education of Medicines Development in LMICs

Medicines Development and Regulation –

IFAPP-PharmaTrain Working Group on Education in Low and Middle Income Countries

- Chairs: Sandor Kerpel-Fronius, Bernd Rosenkranz
- Membership: Hungary, Germany, UK, Belgium, Austria, Switzerland, USA, Singapore, South Africa (3 members)
- Objectives: Establish syllabus and standards for tailor-made accredited programmes in LMICs
  - Pilot countries in Africa: Zimbabwe, Ghana, Ethiopia


Education and training for medicines development, regulation, and clinical research in emerging countries

Sandor Kerpel-Fronius [1], Bernd Rosenkranz [2,3], Elizabeth Allen [4], Rolf Bass [5], Jacques D. Mainard [6], Alex Dodoo [7], Dominique J. Dubois [8], Mandisa Hela [9], Steven Kern [10], Joao Massud [11], Honorio Silva [12,13] and Jeremy Whitty [14]*

frontiers in Pharmacology

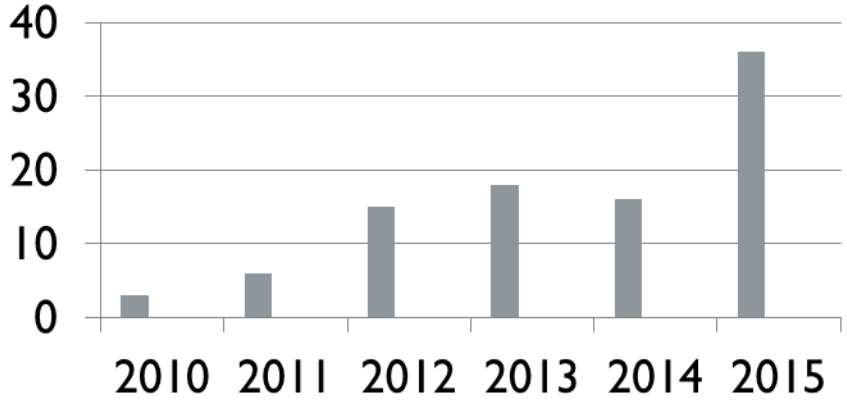
REVIEW
published: 14 April 2015
doi: 10.3389/fphar.2015.00080

Pharmaceutical Medicine / Medicines Development

- Stellenbosch University Postgraduate Diploma course
  - Started in 2010
  - Also offered as Short Courses (Certificate, CPD)
  - 2 year programme (120 credits = 48 ECTS)
- Masters (MPhil) Medicines Development
  - Planned for 2016
  - Add-on to Diploma; Recognition of Prior Learning
  - 2 year programme (180 credits = 72 ECTS)

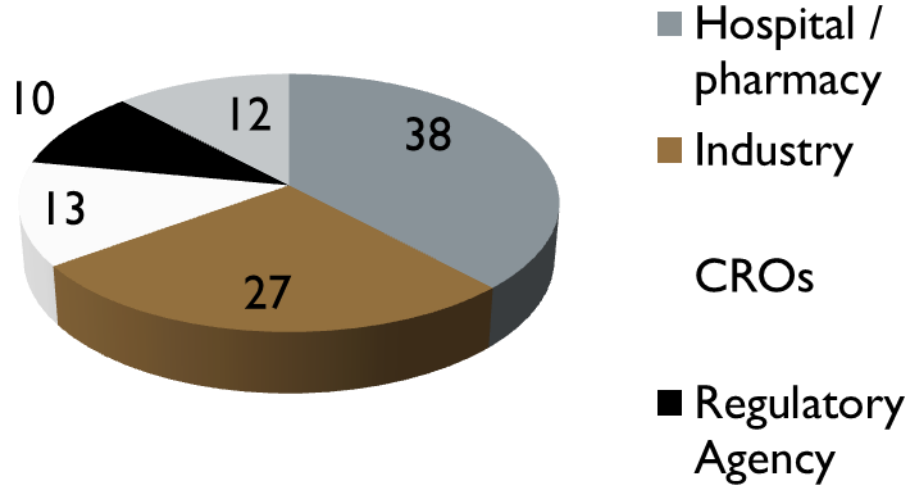
Students

Number of students in contact sessions

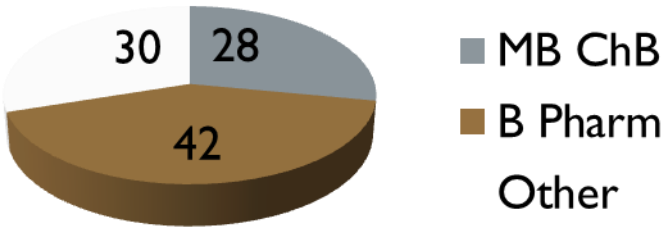


Graduated since 2012: 11 students

Professional background



Education



South Africa: Medicines Development Programmes

- University of Western Cape
  - MSc in Regulatory Science (with Hibernia)
- Rhodes University
  - MSc in Drug Development
- University of KwaZulu-Natal
  - M.Pharm. in Pharmacoeconomics and in Pharmacovigilance (on-line)
- University of Witwatersrand
  - MSc in Pharmaceutical Affairs
- Nelson Mandela Metropolitan University
  - M.Pharm., including Industry/Regulatory Affairs, Pharmaceutics and Drug Design (in conjunction with Aspen)
- Tshawane University of Technology
  - Bachelor in Pharmaceutical Sciences
- University of Pretoria
  - B.Sc. (Hons) with focus on clinical trials

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FUNDISA AFRICAN ACADEMY OF MEDICINES DEVELOPMENT

Fundisa African Academy of Medicines Development (FAAMD) is registered as a non-profit Company (Companies and Intellectual Property Commission of South Africa (CIPC), NPC 2014/104973/08), and is based in Cape Town, South Africa.

The aim of the Fundisa African Academy of Medicines Development is to provide leadership and capacity building in medicines development and regulation or related sciences by:

- Fostering and promoting teaching and training in South Africa and other African countries;
- Organising workshops and courses;
- Development of young scientists;
- Promoting communication and cooperation between teaching institutions, industry and regulatory agencies.

The Scientific Advisory Board (SAB) advises on strategic goals, specific teaching and training initiatives, and networking with professional organisations or regulatory agencies. Companies, regulatory agencies and other institutions are invited to join the Academy Support Organisation.

Fundisa African Academy of Medicines Development has been recognized as a Centre of Excellence by the European PharmaTrain Federation which provides an international training network. Together with the MCC, the Fundisa African Academy of Medicines Development organises the Workshop on New Developments in Drug Regulation held annually in Pretoria.

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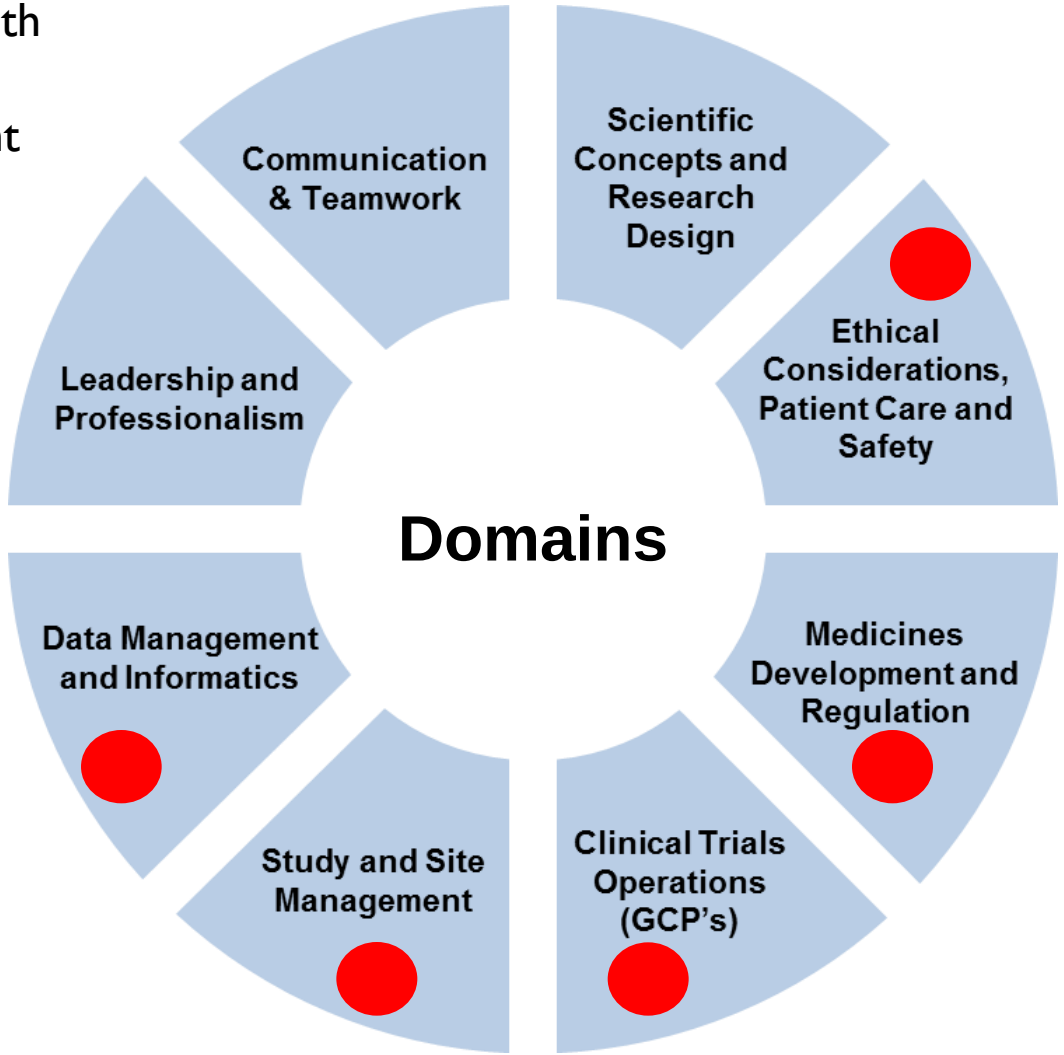
Clinical Research Professionals: Core Competencies

Several of the competencies overlap with

- Specialists in Medicine Development
- Clinical Pharmacologists



Related to drug development

Joint Task Force for Clinical Competency 2013, from S. Kerpel-Fronius, 2014

Training of Clinical Investigators

Goal: Training of planning, performing and organizing clinical trials at the investigator site

European Clinical Research Infrastructures Network

+

Alliance for Clinical Research Excellence and Safety

Clinical Investigator Certificate Course (CLIC)

Three levels of training related to distinct responsibilities in the performance of clinical trials:

- **Level 1:** site staff (CRA, CTA, study coordinator, study nurse)
- **Level 2**: (principal) investigator (responsibility for a clinical trial at a site)
- **Level 3:** sponsor-investigator (overall responsibility for a clinical trial)

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— CLIC —
Clinical Investigator (And Site Staff) Certification

CLIC Level 1: 23 - 24 March 2015
CLIC Level 2: 25 - 27 March 2015

Cassia Conference Centre, Nitida Wine Farm,
Tygervalley Road (M13), Durbanville, Cape Town

	OPTION 1: CLIC Level 1 2 days **R3200.00** **(Students R1800.00)**	OPTION 2: CLIC Level 1 & 2 5 days R8000.00 (Students R4200.00)	OPTION 3: Level 2 only (no CLIC certification) 3 days R4800.00 (StudentsR2400.00)
LEVEL 1	**Core knowledge in the preparation and conduct of studies at Investigational Sites** • *Medical: Sub / Co-Investigators* • *Non-Medical: Study Nurse, Study Coordinator*	**Core knowledge in the preparation and conduct of studies at Investigational Sites** • *Medical: Sub / Co-Investigators* • *Non-Medical: Study Nurse, Study Coordinator*	
LEVEL 2		**Knowledge in Regulatory and Managerial aspects required of Principal Investigator (and Clinical Trial Managers) according to ICH-GCP definition and National Legislation** • *Principal Investigator* • *Clinical Trial Manager/ Site Manager*	**Knowledge in Regulatory and Managerial aspects required of Principal Investigator (and Clinical Trial Managers) according to ICH-GCP definition and National Legislation** • *Principal Investigator* • *Clinical Trial Manager/ Site Manager*

South African Association of Pharmaceutical Physicians / Professionals (SAAPP) – History

- Special interest group formed in 1960s
  - PIMAG (Pharmaceutical Industry Medical Advisory Group)

- Replaced by SAAPP in early 1990s
  - Affiliate of Medical Association of SA (MASA)

- Member of IFAPP
  - SAAPP one of the 12 founder members of IFAPP
  - Currently not active, no formal contacts to IFAPP
  - Strong interest expressed by IFAPP Board members in re-establishment of SAAPP

South African Association of Pharmaceutical Physicians / Professionals (SAAPP)

http://www.ifapp.org/

Country organization: SAAPP

Contact: Michael Reid - Michael.Reid@pfizer.com

Other Initiatives in Africa – Examples

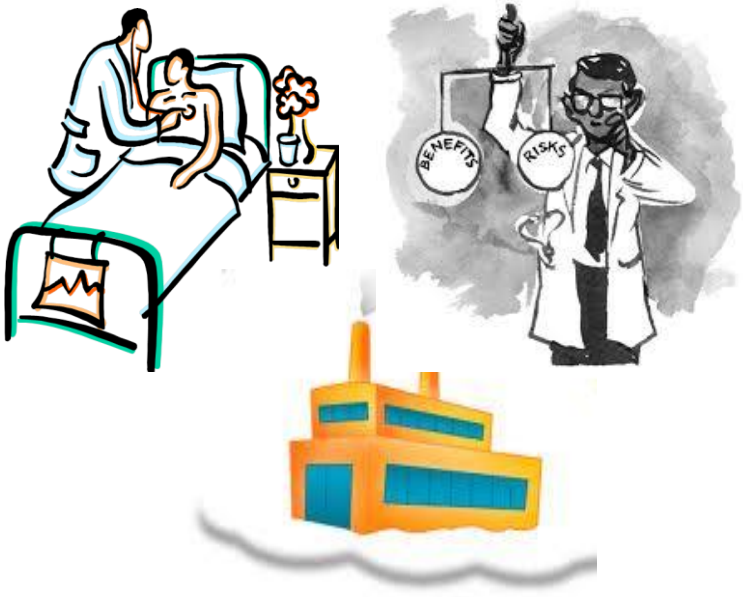
Continuous Professional Development (CPD): Meeting the challenge

How to develop further my competencies and professional career?

University

Post-graduate courses
Whom to teach ?
What to teach ?

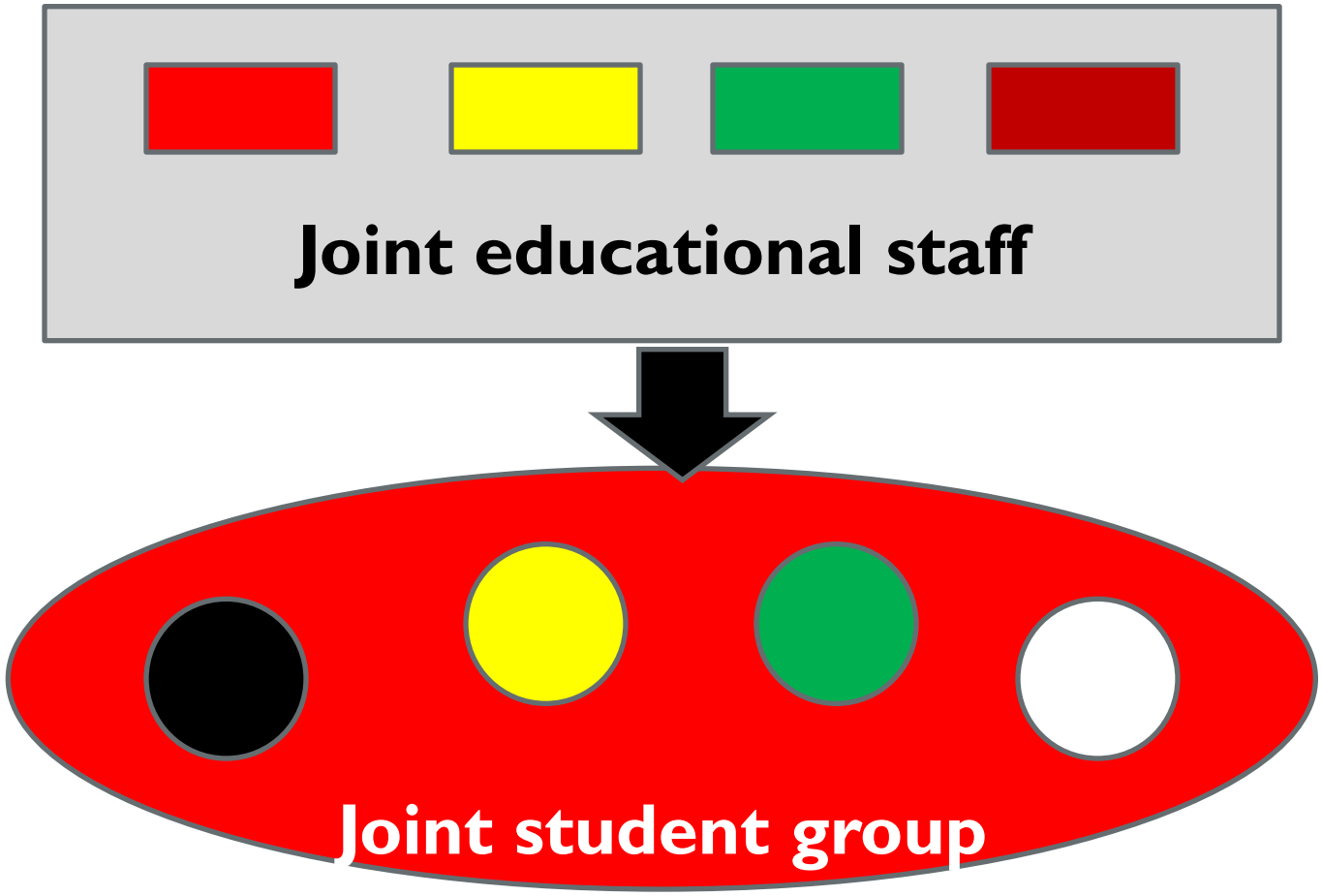
Workplace



How to train competent clinical investigators, regulators, and industry professionals ?

Needs cooperation between academic centers and various work places

Model for Cooperative Education in LMICs



All teaching activities managed jointly for all enrolled students by joint educational staff or coordinated by a central institution

Adapted from S. Kerpel-Fronius, 2014

Conclusions

- The management of life-long, comprehensive education and training of medicines development, regulatory sciences and clinical research is a major challenge for universities, industry and regulatory agencies
- Adequate cooperation between universities, other educational institutions and workplaces is mandatory
- Training in LMICs should be based on internationally accredited standards, tailored both in content and complexity to the local needs and
- Should be coordinated by local experts and organisations, preferably in regional cooperation and with international support