RegTrain-Project

Widening the scope of regulatory capacity building based on the VaccTrain I Pilot Project

Regine Lehnert

4th Biennial Scientific Conference on Medical Products Regulation in Africa,
30 Sept - 01 Oct 2019; Victoria Falls, Zimbabwe
Outline

• Introduction to the RegTrain project
• The NMRAs in Germany: Tasks and Networks
• International Partners of RegTrain
• Activities and Features
• Summary
RegTrain - Introduction

- Global Health Protection Programme (GHPP):
  - Funded by German Federal Ministry of Health
  - Since 2016
  - In total, today 24 projects (https://ghpp.de/en/about-ghpp/)
  - Extension with current project period: 2019-2020
  - Extends/builds on existing activities
  - First joint GHPP-project between the two German NMRAs
### PEI and BfArM - Tasks

<table>
<thead>
<tr>
<th>PEI</th>
<th>BfArM</th>
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<tbody>
<tr>
<td>Authorisation of clinical trials (CTO)</td>
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<td>Marketing authorisation (MA)</td>
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<td>Collection/evaluation of AE reports (PV)</td>
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<td>Inspections (GxP)</td>
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<td>Life cycle management</td>
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<td>Scientific and regulatory advice to industry and academic researchers</td>
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<td>“Advice” to health care professionals, to the public (patients),</td>
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<td>national and international bodies/stakeholders</td>
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<td>Research</td>
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<td>Official batch release</td>
<td>Opioid market oversight/control</td>
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<td>OMCL Lab</td>
<td>German Cannabis Agency</td>
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*Of note: Not in charge of food and cosmetics*
PEI and BfArM
Partners in the European and International Networks

National Medicines Regulatory Agencies of the European Member States

BfArM
PEI

Various bilateral MoU's

NEPAD

Committees and Working Parties, e.g. CHMP/PRAC/PDCO

EdQM

European Directorate for the Quality of Medicines & Health Care

World Health Organization

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RegTrain Partners

- NMRAs of
  - The Gambia
  - Ghana
  - Liberia
  - Sierra Leone
  - Zimbabwe

- SADC
- ECOWAS
- AU DA-NEPAD (AMRH)
- WHO AFRO
- WHO HQ
Focus Areas according to WHO Global Benchmarking Tool

- Clinical trials oversight (PEI: VaccTrain I)
- Marketing authorisation (BfArM: PharmTrain)
- Pharmacovigilance (PEI: VaccTrain II)
Features, Activities and Goals of RegTrain

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*GCFR: WHO draft Global Competency Framework for Regulators
Train the Trainer: Highlights

• Offers:
  – 8 - to 10-week fellowship
  – Per cycle: 1 fellow from MCAZ
    1 fellow from Ghana FDA

  – Lectures
  – Hands on: Case studies
  – Hands on: Evaluation
  – Insight into in house structures for knowledge sharing
  – Study visits between PEI and BfArM and WHO HQ
Train the Trainer: Highlights

• Expectations:
  – Active participation, commitment
  – Presentation of assessment processes at home NRA
  – Presentation of structures for sharing of newly gained knowledge and implementation at the home NRA/as RCORE
  – Preparation of training material for the follow-up training sessions at the home NRA/as RCORE
  – Follow-up on the trainings performed after completing the curriculum
Train the Trainer: Key features

- **Framework**
  - ✓ Curricula are tailored in line with feedback received from partner NRAs on their needs and priorities in the short and long term

- **Candidates’ profiles**
  - ✓ matching training contents (level of proficiency, WHO GCFR)
  - ✓ enabling knowledge transfer
  - ✓ ensuring continuity/sustainability

- **Entry evaluation**

- **End of training evaluation**
  - ✓ Assessment of knowledge/skill improvement in the given area

- **Sustainability**
  - ✓ Materials to be prepared by the fellows for their colleagues in the NRA and in RCORE trainings
  - ✓ Follow-up by GHPP on the impact of training
TtT: Pharmacovigilance (PV) of Vaccines and Biomedical Therapeutics (PEI), Q4 2019

I. The legal framework of PV

II. The organizational structure of the PV system according to international standards

III. Pharmacovigilance in the context of clinical trials and marketing authorization
   • The risk management plan
   • Adverse event reporting
   • Signal detection

IV. Preparation for the knowledge transfer (NMRA/RCORE)
TtT: Quality Assessment of Biomedical Therapeutics (PEI), Q1-2/2020

I. Medicinal Product Lifecycle

II. Regulation of Biologicals

III. Clinical Trial Application: Quality Assessment

IV. Models of Regulatory Reliance

V. Preparation for the Knowledge Transfer (NMRA/RCORE)
TtT: Training on Clinical Evaluation (BfArM); Q4 2019 and Q1-2 2020

I. Medicinal Product Lifecycle

II. Regulation of Pharmaceuticals (incl. Biosimilars)

III. Models of Regulatory Reliance

IV. Clinical Aspects of Bioequivalence Studies

V. Efficacy and Safety Studies

VI. Product Information

VII. Preparation for the Knowledge Transfer (NMRA/RCORE)
The Pillars of RegTrain

I
Strengthening structures of NMRAs

II
Supporting RCOREs Train the Trainers

III
Strengthening collaboration, harmonisation and networks
Thank you!

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