



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How to support regulatory capacity strengthening in Sub-Saharan Africa – EMA Perspective

EDCTP – Regulatory Affairs Stakeholder Meeting
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The European Medicines Agency

- The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.
- The European Medicines Agency is working with the Member States and the European Commission as partners in a European Medicines Regulatory Network
- Common training needs and challenges across network



Clinical trials - the respective roles of European Medicines Agency and the European Medicines Regulatory Network

- Responsibility for authorisation of Clinical trials is with Member States' national competent authorities (NCA)
- Responsible for GCP inspections of sites on their territories
- EMA is responsible for assessment of the results in the context of an application to market a medicine in Europe
- GCP inspections may be organised to verify the information in these trials
- No "own" CT inspectors – EMA acts as "coordinator" and inspectors come from NCAs as part of the EMRN



What is the European Medicines Regulatory Network?





What EMRN activities can be used to support regulatory capacity strengthening in Sub-Saharan Africa?

- General training activities organised for EMA–EU assessors/inspectors network
- Other International training activities
- Paediatric Medicines Regulatory Network activities
- Annual GCP and Pharmacovigilance Inspectors training workshops
- Observership possibilities at GCP and GMP inspections
- Article 58 assessment opportunities
- Support to capacity building organised by third party organisations e.g WHO, AVAREF etc.



Types of Training Activities/Regulatory Capacity at EMA

- **Type of Training**: Scientific and regulatory training for internal EMA and EU Network staff such as
 - “Awareness sessions” on dedicated new topics/topics update
 - Induction type sessions for “junior assessors”
 - Discipline specific training for more experienced assessors
- **Tools available**:
 - Integration into scientific activities of EMA (participation to working parties/Committee meetings)
 - Conferences/workshops involving learned societies on topic of scientific interests
 - Web-sharing and webinars
 - Public web streaming of conferences and workshops
 - EMA website/publicly available information e.g. EPARs



Other International training activities

- Specific activities organised within framework of collaboration agreements and in cooperation with **ICH** and the **International Pharmaceutical Regulators Forum (IPRF)**
- **“Visiting expert”** programme for regulators from outside the EU
- Development of **standard training packages** that can be provided **to EU and non EU regulators** e.g. On line basic GCP training course under development
- Promoting participation by video linkages
- EMA is building up a library of webcasts of workshops and training events that can be provided to (non-)EU regulators



Paediatric Medicines Regulatory Network

- Established by WHO in 2008 as part of initiative “Better medicines for children”
- Chaired by EMA
- Objectives include:
 - Promote capacity for development and assessment of paediatric medicines and paediatric formulations
 - Promote appropriate conduct of paediatric clinical trials
 - Meetings and webinars: 1 meeting in 2011 and 1 in 2013, webinar in 2013 (next in Feb 2014) – 26 countries participating
 - Guidance for paediatric trials assessors (WHO website)



GCP and Pharmacovigilance Inspector Training activities

- Annual GCP training event organised by EMA in collaboration with EU regulatory network
- Representatives from up to 40 non-EU countries typically invited:
Recent attendance from Africa
 - 2011 – Ghana, Kenya, Nigeria, Zambia
 - 2012 – Ethiopia, Ghana, Malaysia, Tanzania
 - 2013 – Ghana, Swaziland
- Opportunity for specific focussed GCP training as well as building up networks
- Similar annual training for Pharmacovigilance inspectors since 2010



Sample GCP Workshop Agenda

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH18 July 2013
EMA/INS/GCP/434131/2013
Compliance and Inspections

2013 EU GCP Inspectors Working Group Workshop PROGRAMME

14-16 October 2013, room 2A, EMA, London (UK)

Chair: Ana Rodriguez

Day 1 – Monday 14 October 9:00-17:30

Item	Topic
	Welcome
	Introduction with training purpose and objectives
1.	Risk based approach to inspection planning (national programmes)
1.1	How to develop a risk-based inspection programme; identification of triggers for routine and triggered inspections
2.	Risk based approach to GCP inspection preparation
2.1	General considerations when preparing an inspection
2.2	Review of data listings

Day 2 – Tuesday 15 October 9:00-18:30

Item	Topic
3.	Inspection of eTME and eSource Data
3.1	Practical steps/tips for conducting such inspections
3.2	Inspectors' expectations and common findings
4.	Categorisation and Impact of Inspection findings
4.1	Short presentations on inspection findings and their impact: questions after each presentation
5.	Safety Reporting in the context of a GCP inspection
5.1	Overview of the EU guidance requirements on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3')

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Item	Topic
5.2	Overview of PhV aspects to be reviewed during a GCP inspection

Day 3 – Wednesday 16 October 9:00-15:30

Item	Topic
6.	International cooperation on GCP inspections
6.1	Overview of EMA Action plan from the reflection paper on clinical trial data from 3 rd countries
6.2	EAMI collaboration network-Spain, Portugal and South America
6.3	The APEC initiative
6.4	Particularities of the informed consent process
6.4.1	EU/EEA inspectors' experience
6.4.2	Non EU/EEA inspectors' experience
7.	Inspection of Statistical Aspects of a marketing Authorisation Application (MAA)
7.1	Assessors' review of the statistical aspects of a marketing authorisation (MAA) application
7.2	How to look at practical aspects of statistical analysis whilst on inspection
General discussion and Conclusions of training course. Distribution of certificates.	



Article 58 as a tool for capacity building

- “Hands on” involvement of non-EU regulators as **expert or observers**, in specific scientific discussions on “Article 58” medicinal products opinions
- If funding available, would be possible to extend this to additional observers from countries where the product will be marketed
- Allows direct input/participation into the assessment/inspection process to enable familiarisation and speed uptake at National Level in Non-EU Countries, once review finalised.
- Limitation – number of relevant applications i.e. normally used for more innovative/complex medicines of public health need in non-EU Countries rather than generics



Capacity Building – other possibilities

- Limited support for capacity building outside the EU (see also training activities above).
- Pool of scientific expertise available through EMA's scientific committees and expert network
- EMA and EU inspectors invite local non-EU regulators to participate in (observe) GCP and GMP inspections when performed in their countries



Challenges

From a resource perspective, preferred EMA approach is to extend existing EU activities to non- EU Regulators (where possible)

However no funding available to support travel of non EU regulators (WHO has assisted in the past)

Conflicting priorities of experts due to multiple demands from multiple organisations



Conclusions

- EMA and EU regulatory network involved in large number of training and capacity building activities both within and outside EU
- Significant scientific experience within the network
- Experience in developing training approaches but may need to develop better tools to communicate/share
- Large range of public and non public training material
- Limited resources => important to adopt a coordinated and cost-efficient approach
- Awareness of different activities extremely important to avoid duplication and facilitate cooperation
- Potential to build on and adapt existing initiatives
- Need also to have a better understanding of non-EU Regulators Regulatory Capacity needs