

# Data Management in Non-commercial North-South Collaborative Clinical Research



## LESSONS LEARNED FROM SOME EDCTP TRIALS

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*European and Developing Countries Clinical Trials Partnership*



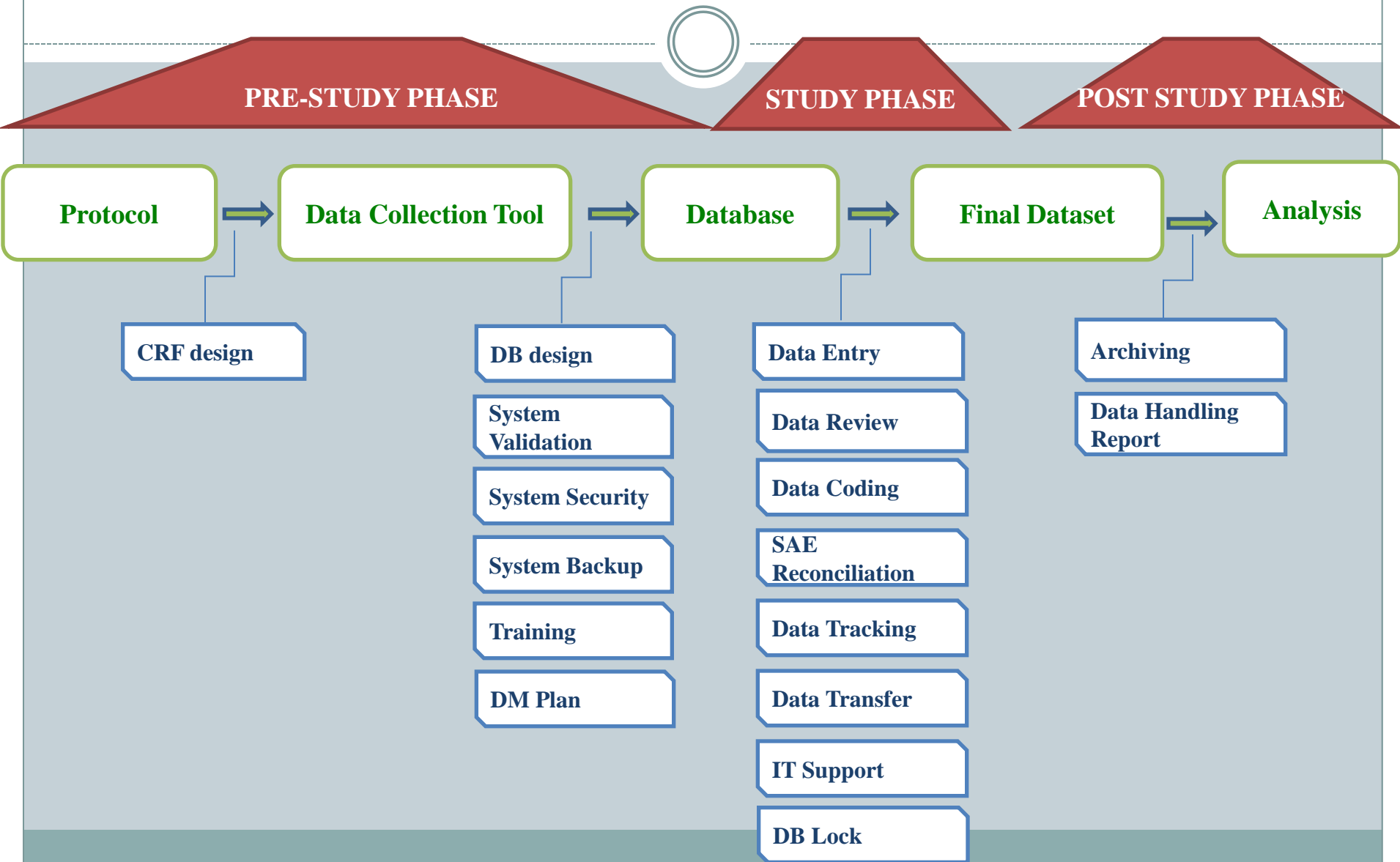
6th EDCTP Forum 9 – 12 OCT 2011 at Addis Ababa, ETHIOPIA

# 1. Understanding Data Management (DM) in Clinical Trials



- ... 5.1.3 “*Quality control should be applied at each stage of data handling to ensure that all data are reliable and have been processed correctly*”. (ICH-GCP)
- Behind an apparent simple CRF and database, there is a lot of preparation and work, to ensure quality at every step of DM!

# DM steps to be considered



## 2. EDCTP trials in our Network...

### 4 ABC malaria trial



### Pregact malaria trial



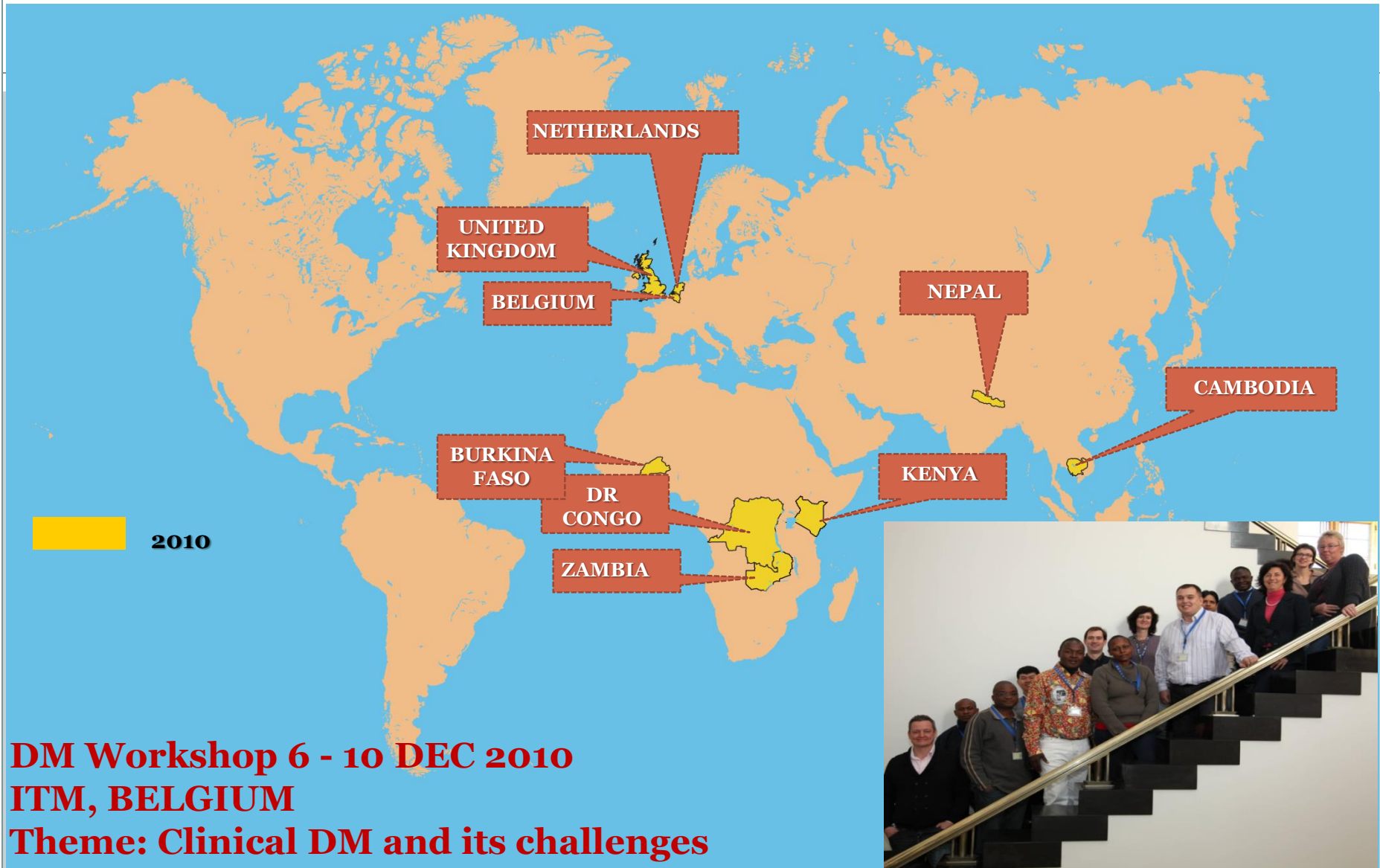
### Biomarkers study



## ...and its main DM challenges

- large, multi country, multi centre trials (big workload)
- academic environment (small DM teams)
- remote sites (no or bad internet)
- high quality and regulatory standards

# 3. International Partnership on DM



**DM Workshop 6 - 10 DEC 2010**  
**ITM, BELGIUM**  
**Theme: Clinical DM and its challenges**

# Highlighting specific DM challenges

Trial Management



VS

Data Management



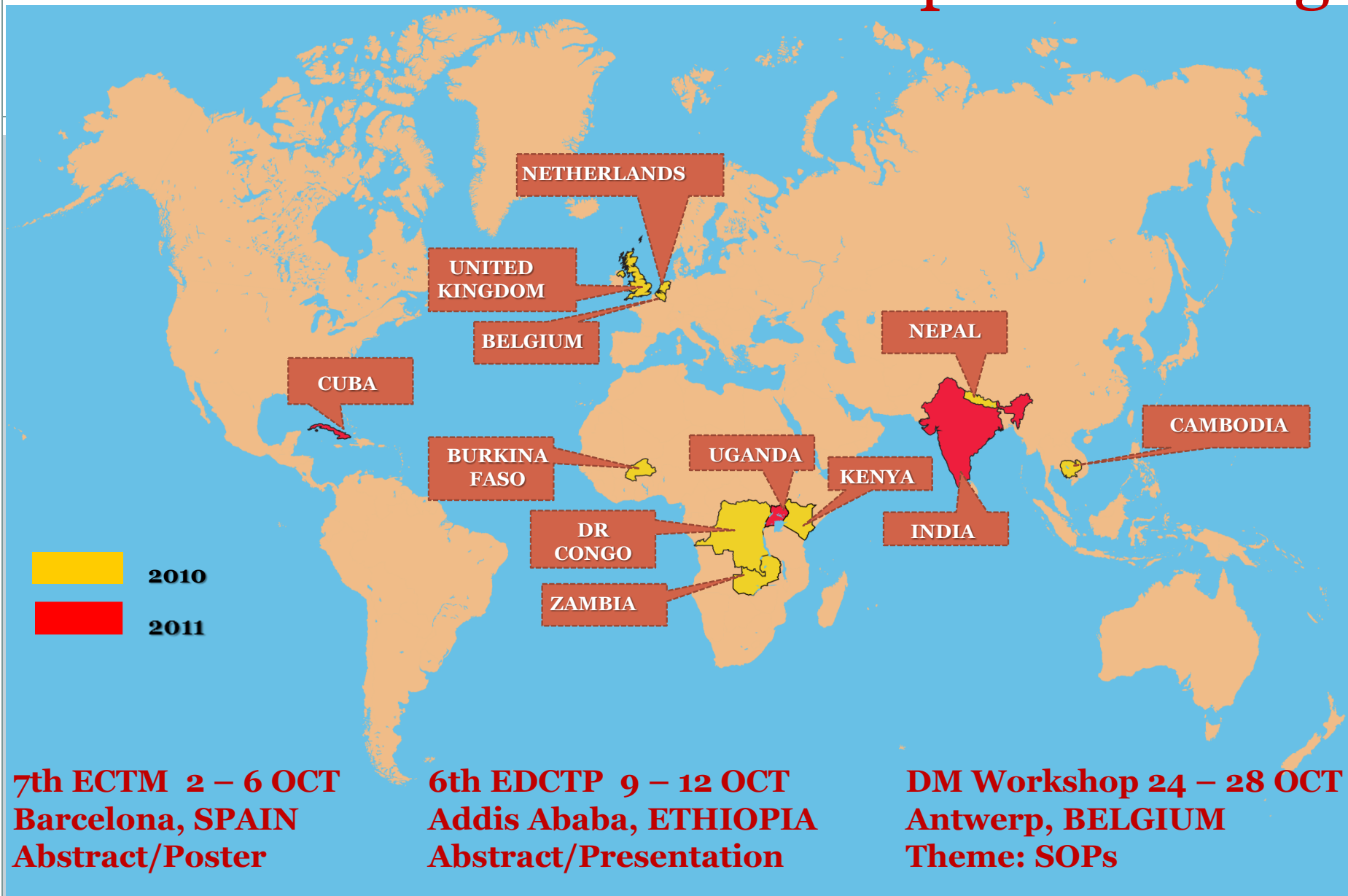
- Late involvement of Data Managers
- Workload under estimations & Unrealistic timelines
- Inadequate budget
- Low position of DM in Trial management

# Recommendations



- Investing in quality for DM
- Designing common operating procedures & document templates
- Promote a North-South collaborative platform: providing individual knowledge/expertise available amongst the network
- Training and upgrading of the staff
  - Publications, upcoming ICT Software
- Better involvement of Data Managers in the research team

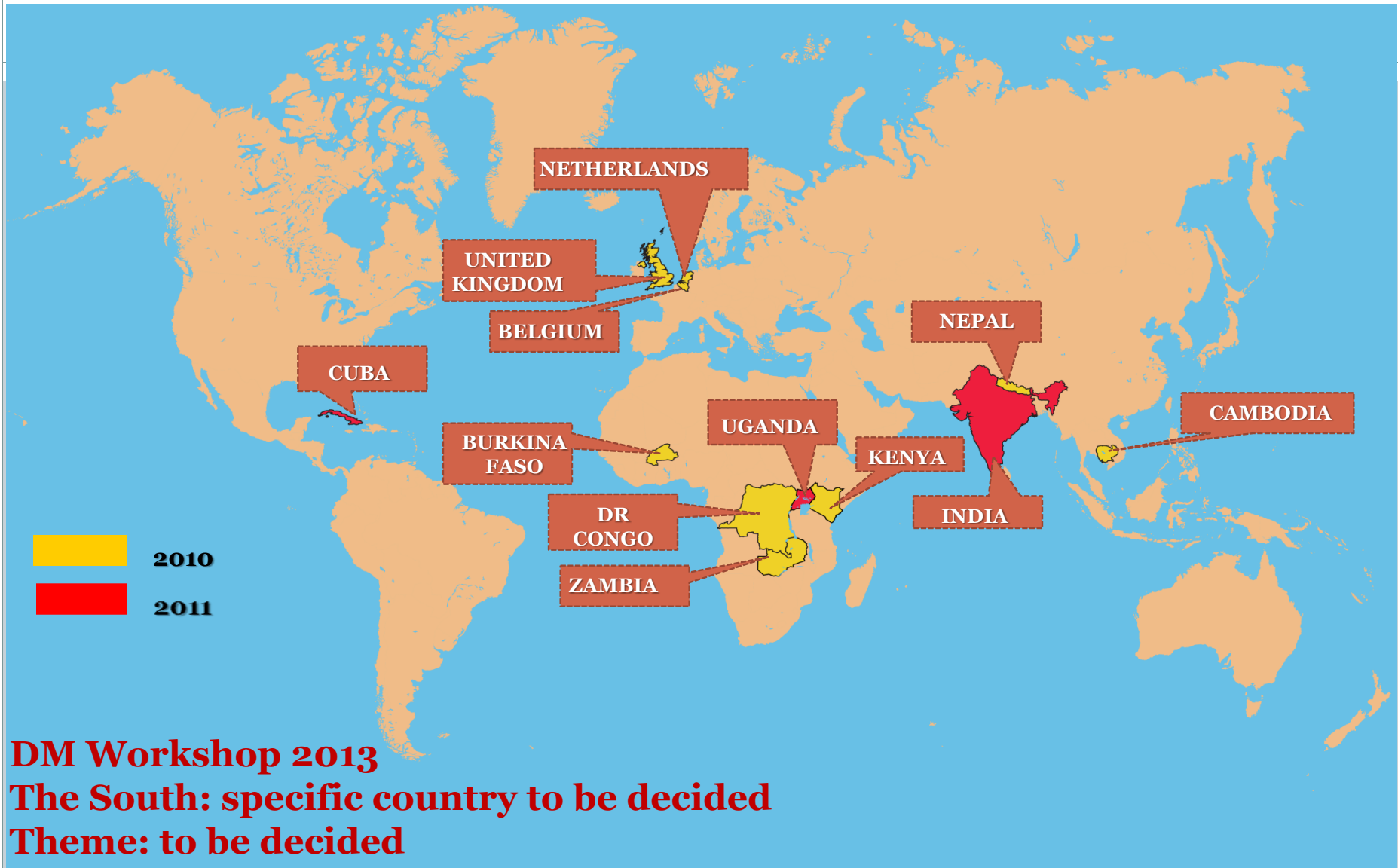
# 2011 International Partnership broadening...





# ...2012 onwards...

Training – Exchanging knowledge & expertise – Capacity building - Networking



# 4. Contact



- For more info on Data Management in Clinical Trials or on the DM network, contact:

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# 5. Acknowledgements



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