What can we learn from innovative ways of monitoring health research?

WORLDWIDE ANTIMALARIAL RESISTANCE NETWORK

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UNIVERSITY OF OXFORD

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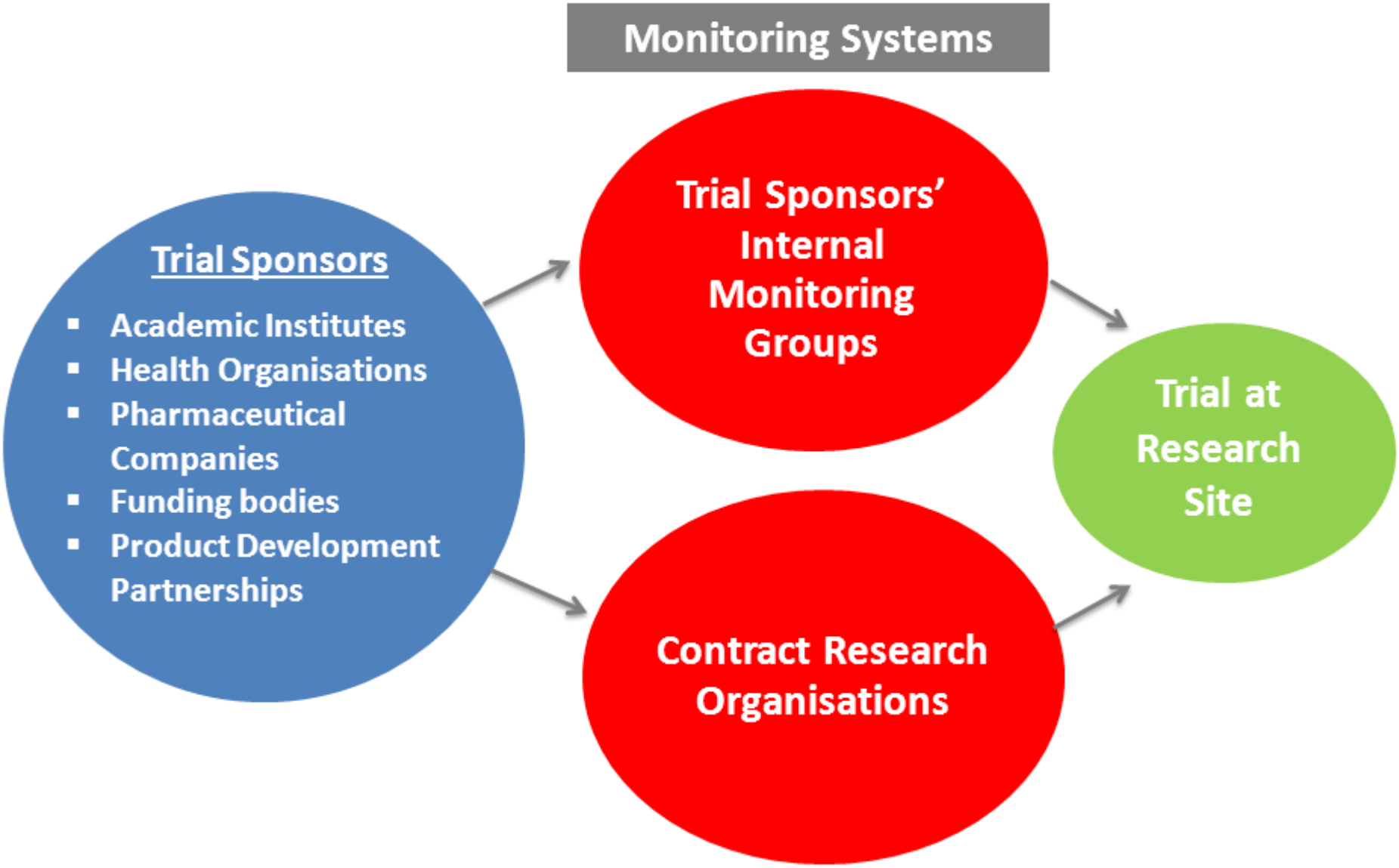
***WWARN is funding this research**

Background

- Need for pragmatic, trial & context specific application of regulations[1]
- GCP hampered by bureaucracy and misapplication[2,3,4]
- Regulatory monitoring model presents GCP as complex & requiring huge resources
- Tick box mentality diverts attention away from key questions about ethical process, participant safety, study endpoints and data validity


Monitoring Systems
Trial Sponsors
Academic Institutes
Health Organisations
Pharmaceutical Companies
Funding bodies
Product Development Partnerships
Trial Sponsors' Internal Monitoring Groups
Contract Research Organisations
Trial at Research Site

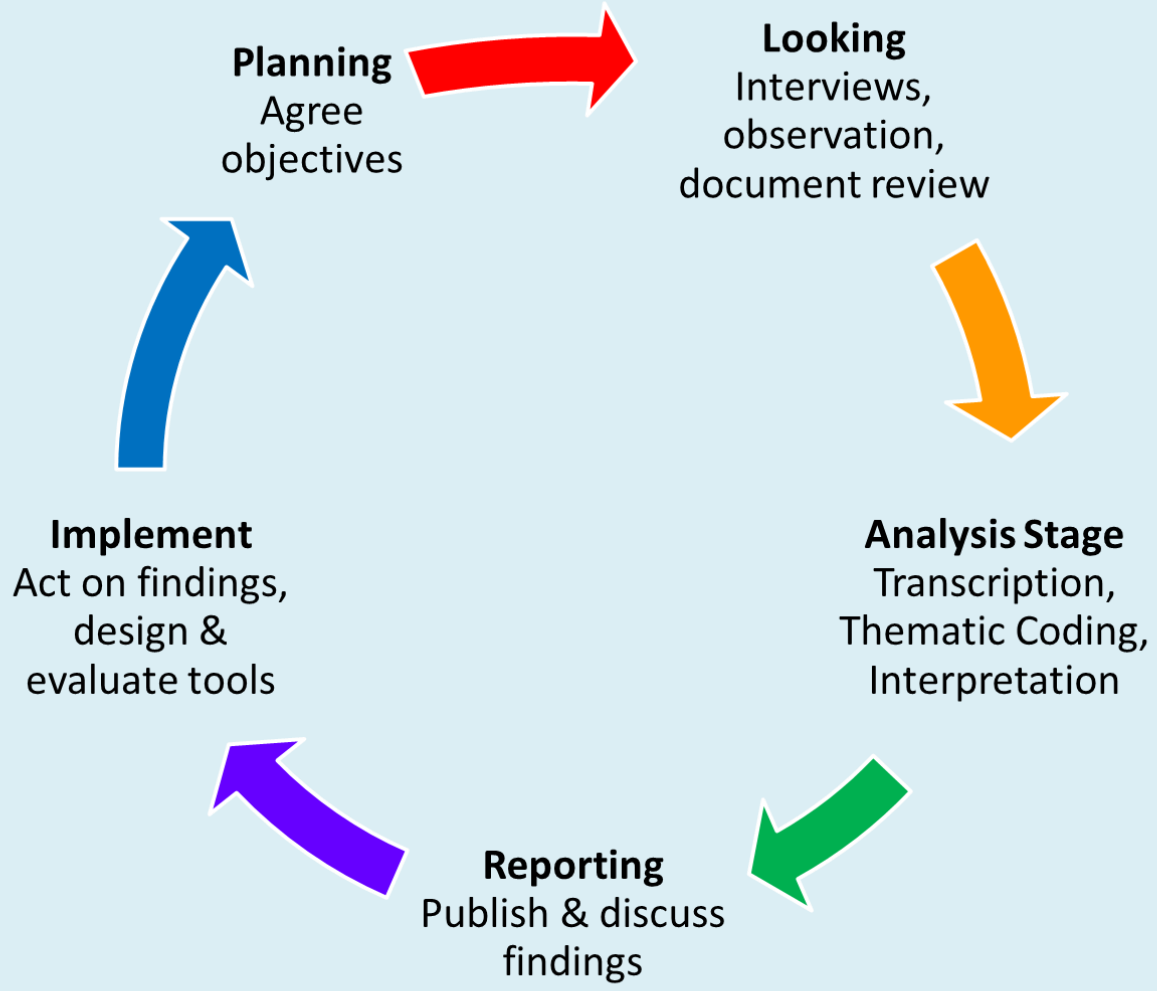
Research Question

What is the value of innovative quality management schemes (situated within international research networks) which are seeking to apply a shared learning style approach to trial monitoring, and how can this value be measured?

Study Objectives

1. Describe EACCR & MORU monitoring schemes;
2. Explore/analyse the perspectives & experiences of those who developed and those who are coordinating schemes;
3. Explore /analyse the perspectives and experiences gained by trial investigators trial team being monitored;
4. Explore/analyse study participants' views about the nature, purpose and practice of trial monitoring
5. Develop ways of evaluating & measuring the quality, performance, costs, benefits and added value of the innovating schemes.

Participatory Action Research[8]

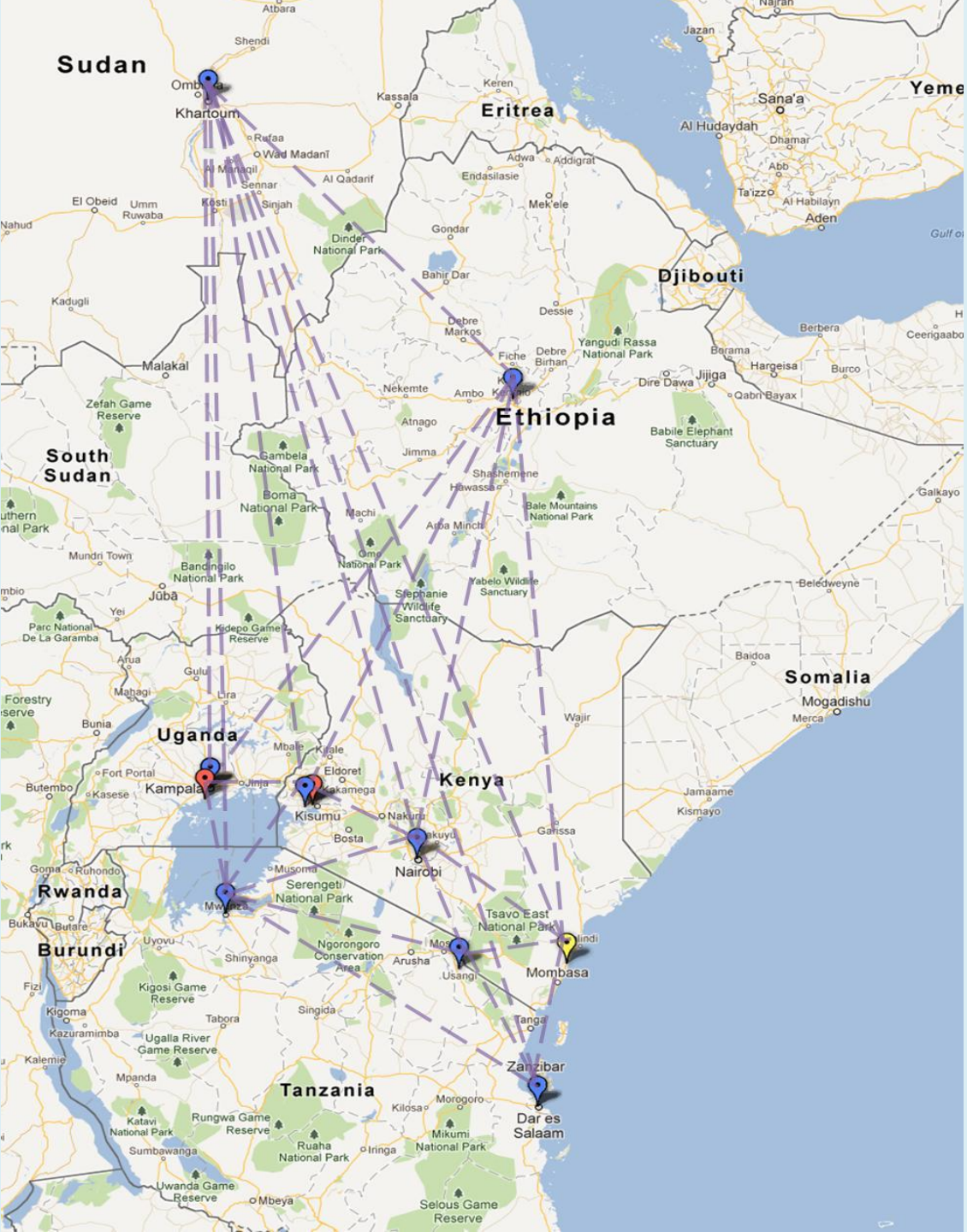


EACCR Scheme

- EACCR is an EDCPT funded network of excellence with the aim of increasing research capacity in the East African region
- Since 2010 EACCR has been piloting a reciprocal monitoring scheme to establish a pool of monitors who can undertake cross-site monitoring

Key Characteristics

- Two coordinators based in Kenya and Uganda provide oversight and logistical support
- Partner institutes nominate research staff for monitors training (currently 22 active)
- Experienced monitors are paired with less experienced monitors for mentoring
- Scheme coordinators consult with investigators to identify trials for monitoring
- Monitoring pairs are allocated trials taking place at partner institutes
- After an introduction visit the pairs develop a monitoring plan, conduct a series of site visits and compile reports for the investigators and scheme coordinators



EACCR Partner Institutes involved in the RMS

wellcome trust

MORU

Mahidol Oxford

WELLCOME TRUST · MAHIDOL UNIVERSITY · OXFORD
TROPICAL MEDICINE RESEARCH PROGRAMME

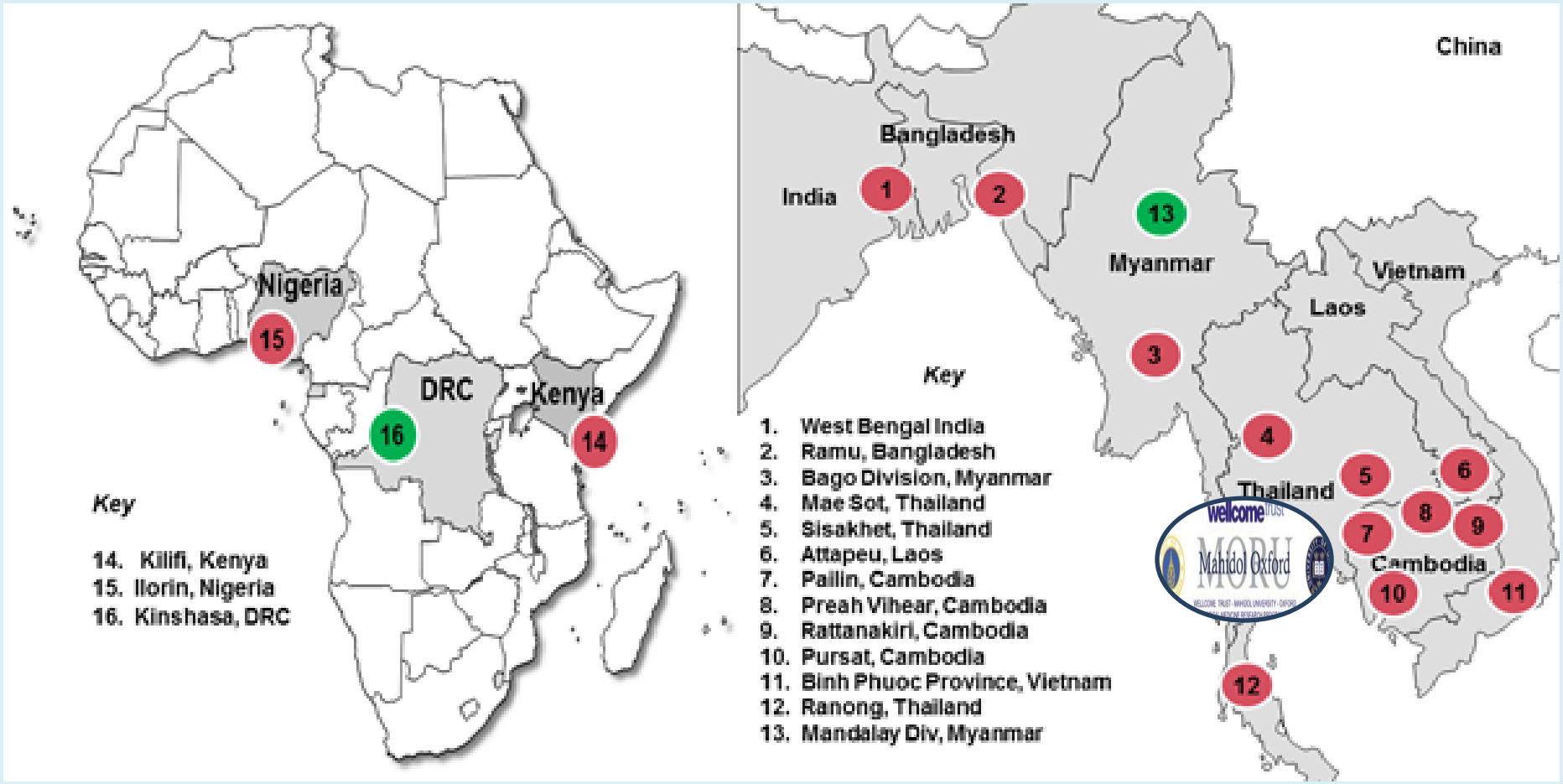
MORU Scheme

- MORU is a collaboration between Mahidol University and the University of Oxford and its main offices are located in Bangkok
- MORU has study sites in Thailand and other parts of developing world across Asia and Africa
- MORU established a Clinical Trials Support Group (CTSG) in 2008

Key Characteristics

- CTSG is embedded within MORU which promotes communication and transparency
- CTSG includes experienced clinical trial coordinators, data managers and statisticians
- Members of CTSG provide assistance in planning, managing and monitoring research activities to ensure compliance with ethical and regulatory requirements
- CTSG monitors focus on findings which will impact key trial outcomes and actively involve sites in problem solving

CTSG TRAC monitoring: Spatial Logistics



CTSG Monitors based at the Mahidol Research Unit in Bangkok

Core Findings

Monitoring Approach

- Value of shared learning & *'co-operative monitoring'*
- Value of *'observing research in practice'*
- Importance of prioritising errors which affect primary outcome and safety

Relationships

- The positioning of CTSG '*…creates the sense that monitoring is not policing but it is adding to the quality of this trial with a constant feedback loop.*'
- Positive interactions allay fears & increase importance attributed to monitoring

Challenges

- EACCR: Confidentiality, mandate authority, sustainability, infrastructure, focus
- MORU/CTSG: Workload, covering costs, incorporating an external perspective

Credibility

- Expertise of monitors: MORU (previous work), EACCR experienced researchers
- Detailed monitoring plans & reports, MORU involvement in protocol design
- Strengthening QM across networks, professional exchange & development

The 'What' of trial monitoring?

- **Monitoring as a burden, policing -lack of credit given to investigator**

  '…initially scared…it took me a while to understand that they were working for the good of the trial'
- **Monitoring & regulation as a good discipline**
- **Critical elements:**

  The support role of monitoring & the scientific nature of monitoring

  'Monitoring as a concept or thing that will help you do your work better (an assurance for investigators)'
- **Success measures:**

  Trial improvements and increased site capacity

The 'How' of trial monitoring

- **The 'Who' of monitoring**
  - Ethos, nature, mandate, positioning of monitoring bodies (internal, external, network)
  - Accountability and organisational relationships
    'identifying with sponsor and site'
    'we are doing this together or…you are hiding something'
  - Credentials and origins of monitors
    Understanding of context, willingness to learn
- **What constitutes professional practice**
  - Monitoring and protocol development
  - The right balance *'paperwork and observation'*
  - The work approach/monitoring style
  - Relationships and interactions

Conclusions

The MORU & EACCR schemes represent viable alternatives for monitoring health research and their value needs to be recognised and developed.

- ✓ **They focus on research conduct and prioritise key outcomes and participants' safety**
- ✓ **They demonstrate the value of co-operative interactions between researchers & monitors**
- ✓ **They utilize existing scientific and monitoring expertise to build capacity and increase the quality of research**

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Thank you!

If you have any queries, please email them to tamzin@globalhealthtrials.org, and I will put you in contact with the research lead.