EACCR Reciprocal Monitoring

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GHT workshop in Entebbe

Monitoring Definition (1)

The act of overseeing the progress of a clinical trial, and of ensuring that it is

- Conducted,
- Recorded,
- And reported

in accordance with

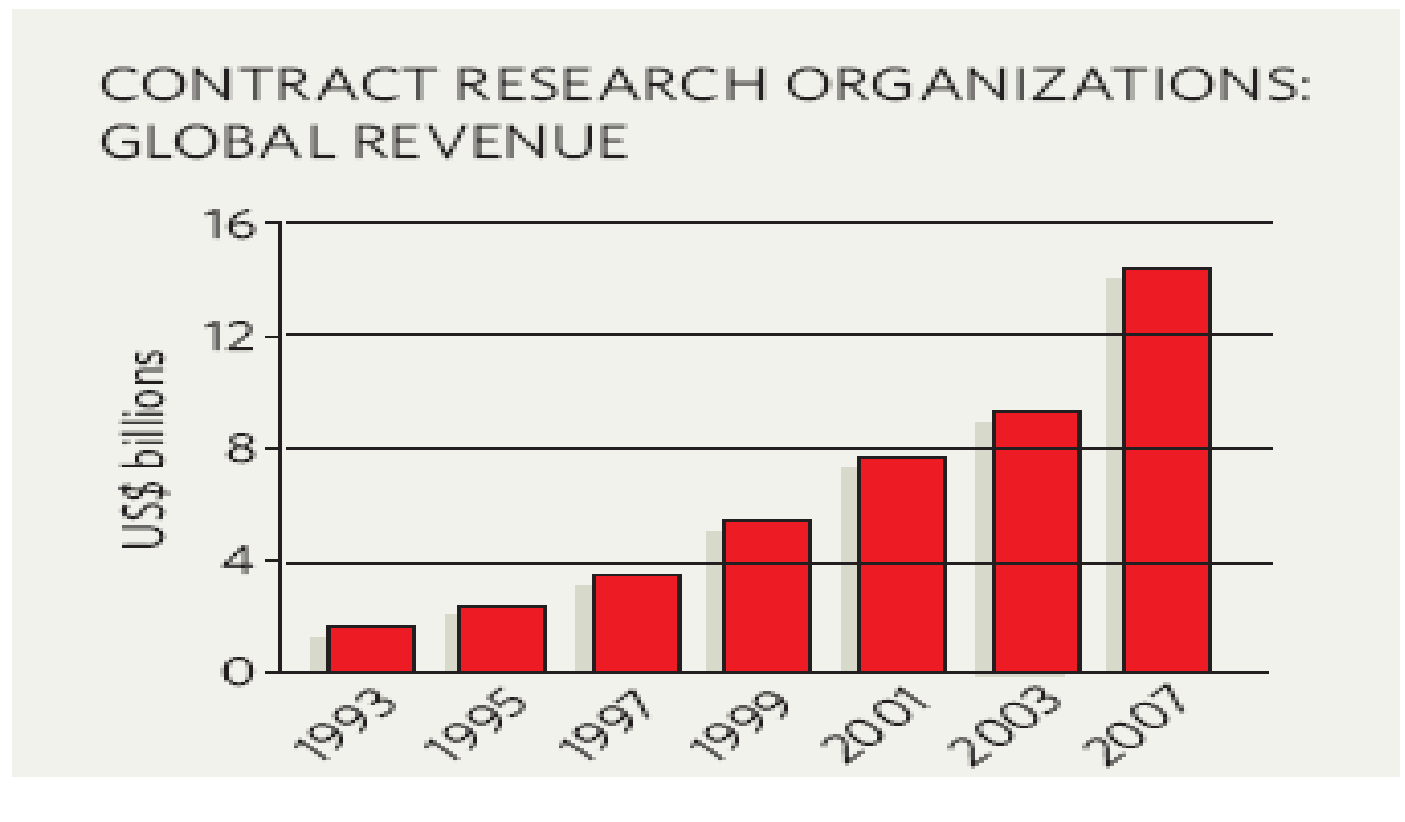
- Protocol,
- Standard Operating Procedures (SOPs),
- Good Clinical Practice (GCP),
- Applicable regulatory requirement(s).

ICH GCP 1.38

Monitoring Definition (2)

- Should be incorporated in a trial right from study design
- Be ongoing, helpful and fundamental
- Be proportional to the risk and complexity of the trial

Current Situation



Source: Wademan M. (Nature 2006)

The Need

- A practical and sensible approach to quality management through a system that would assure ethical and data standards whilst being appropriately tailored to the risk, complexity and nature of the study as well as being low cost and highly pragmatic.

- Cheaper but same quality options to support the conduct trials in Africa

Contract Research Organization (CRO) Vs Reciprocal monitoring (1)

CRO

- Costly -Not sustainable
- No accrued expertise in a particular research area
- Owned/contracted by the sponsor
- Minimal flexibility to tailor make applications to prevailing situation

Contract Research Organization (CRO) Vs Reciprocal monitoring (2)

Reciprocal Monitoring

- Involves staffs engaged in actual research trials
- Offers opportunity to share experience across the trials sites
- A lot less costly
- An opportunity for capacity building to better trials conduct

EACCR Reciprocal Monitoring scheme

- Coordination
  - The scheme is co-coordinated by:
    1. Annet Nanvubya-UVRI IAVI HIV Vaccine Program
    2. Elizabeth Ayuo-KEMRI/CDC
  - Financial coordination done from KEMRI/CDC Kisumu

Training at Kilifi

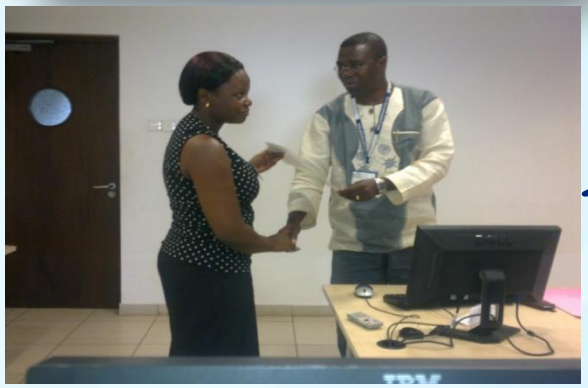
RMS Monitors- post training

Regional distribution of participating countries and institutions

Country	Institution	# of trials
Tanzania	•NIMR- Mwanza •NIMR-Dar le Salaam •KCRI	4
Uganda	•Makerere University •UVRI IAVI •UVRI-MRC •Nsambya Hospital	4
Kenya	•KEMRI-CDC •KEMRI-Wellcome Trust •KEMRI-WRP •KAVI	7
Ethiopia	•University of Gondar	None
Sudan	University of Khartoum	None

Monitors' Training at Kilifi Feb 2011

Zewdu from Ethiopia



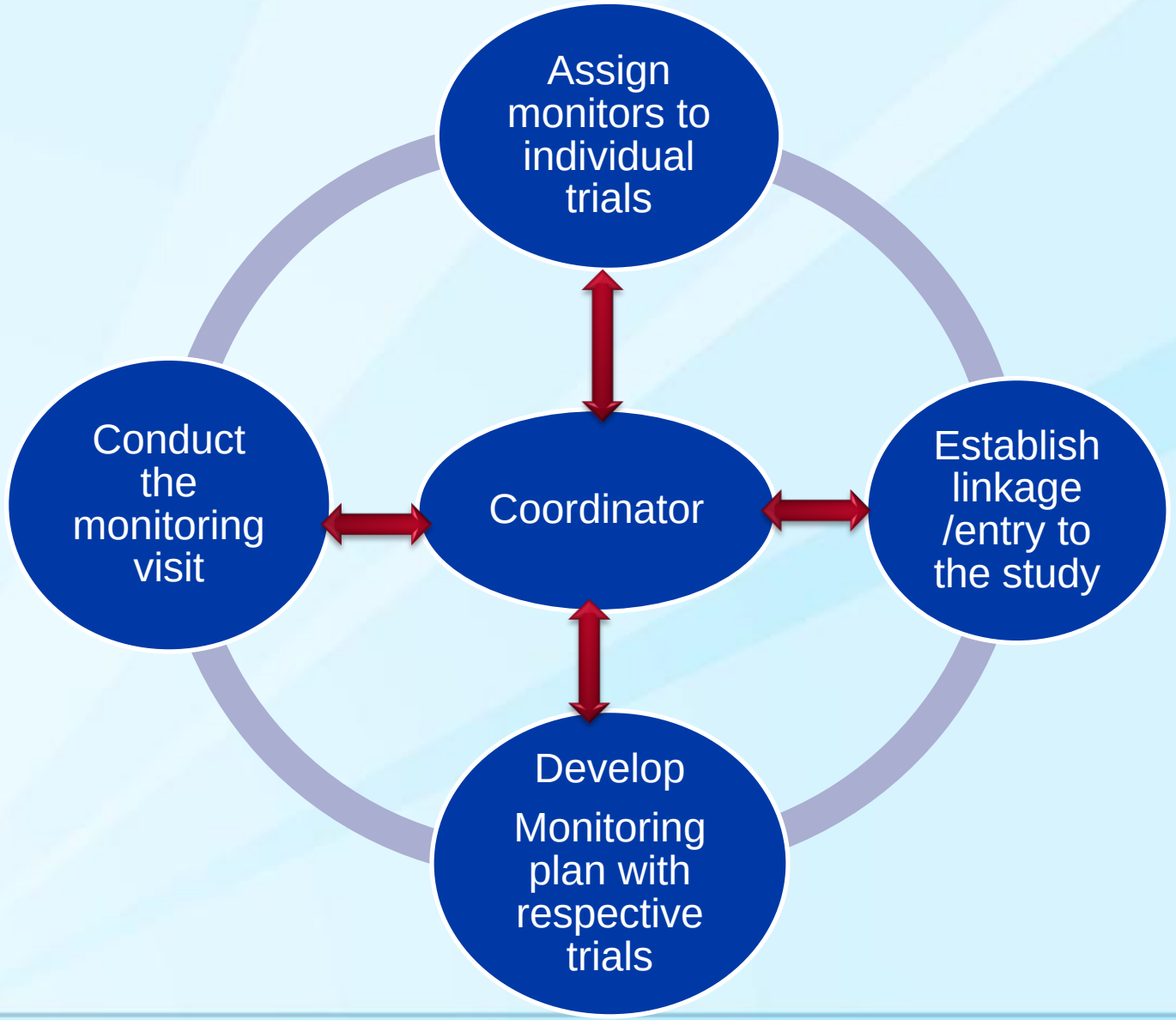
Annet from Uganda

Wanze from Tanzania

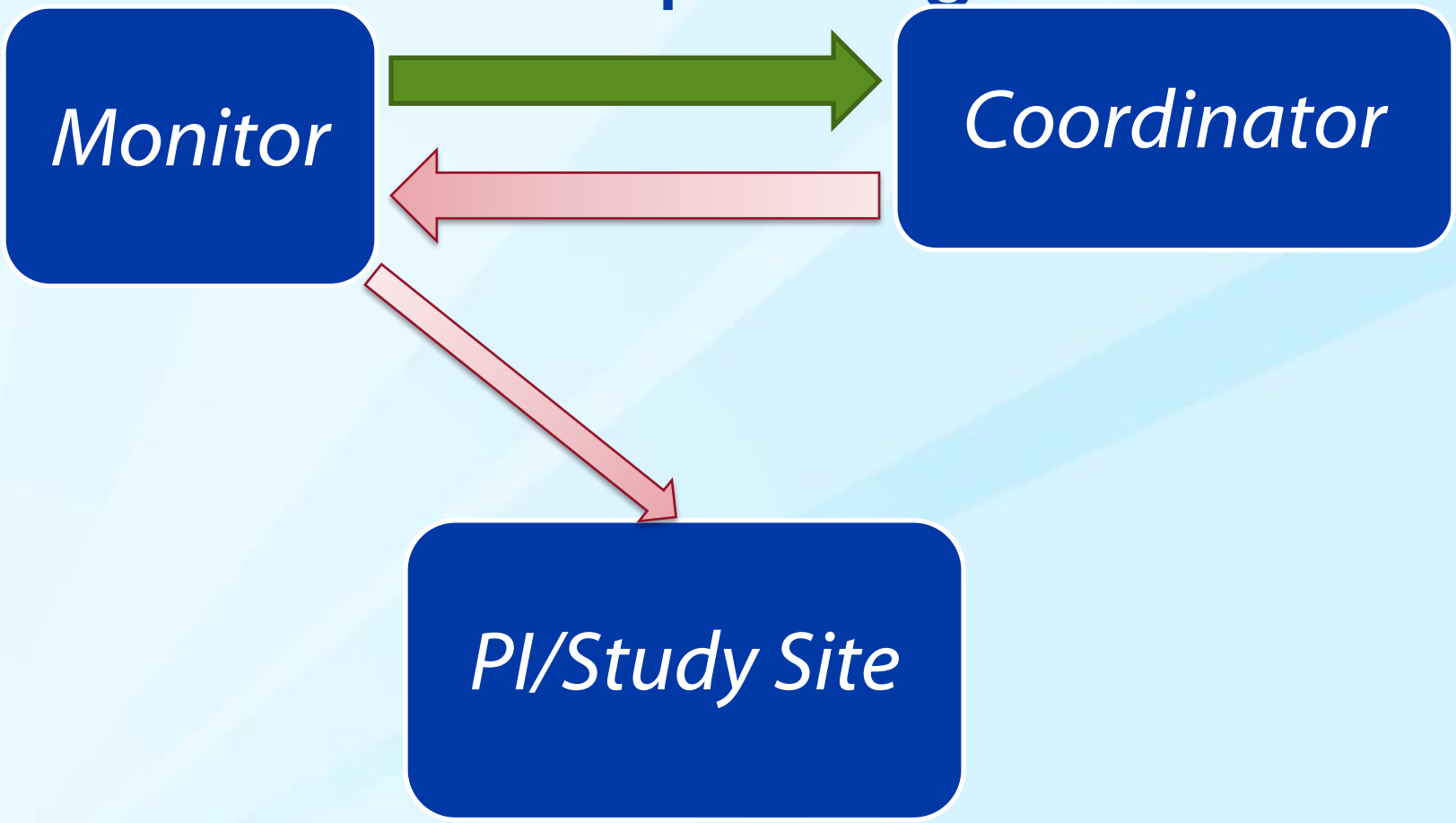
Tools being used

- Checklists
- Report templates
- Monitoring plans
- Note-to-file template
- Standard operating procedures
- Confidentiality Statement form
- Below are examples

Flow of activities



Flow of activities (1) - Reporting



To date

- RMS has a pool of 22 trained monitors
- 5 new monitors mentored
- 2 monitoring trainings conducted

- 11 studies monitored, 25 monitoring visits conducted so far across East Africa
- 3 consultative requests for services from PIs

- Evaluation of scheme conducted in May 2012

- 1 manuscript submitted "**A Global rethink of Clinical Trial Monitoring Practices: *Lessons from East African and South East Asian experience* "**

Success factors

- Cooperation from member institutions
  - Volunteering studies that can be monitored using this scheme
  - Allowing the monitors time out to conduct the monitoring visits and other related activities
- Commitment from the monitors to participate in this with professionalism

Challenges encountered

- Work load balancing for monitors between their primary duties and EACCR monitoring
- Uncertainty of finances for continuity
- Limited training opportunities to access internationally accredited courses
- Occasional communication breakdown due to non-response from PIs & a few monitors
- Fixing visit dates that are suitable for monitors and the study staff

Asanteni sana