

Harmonization and strengthening of regulatory activities in Sub- Saharan Africa (focus on regulation of clinical trials)

Fifth EDCTP Forum

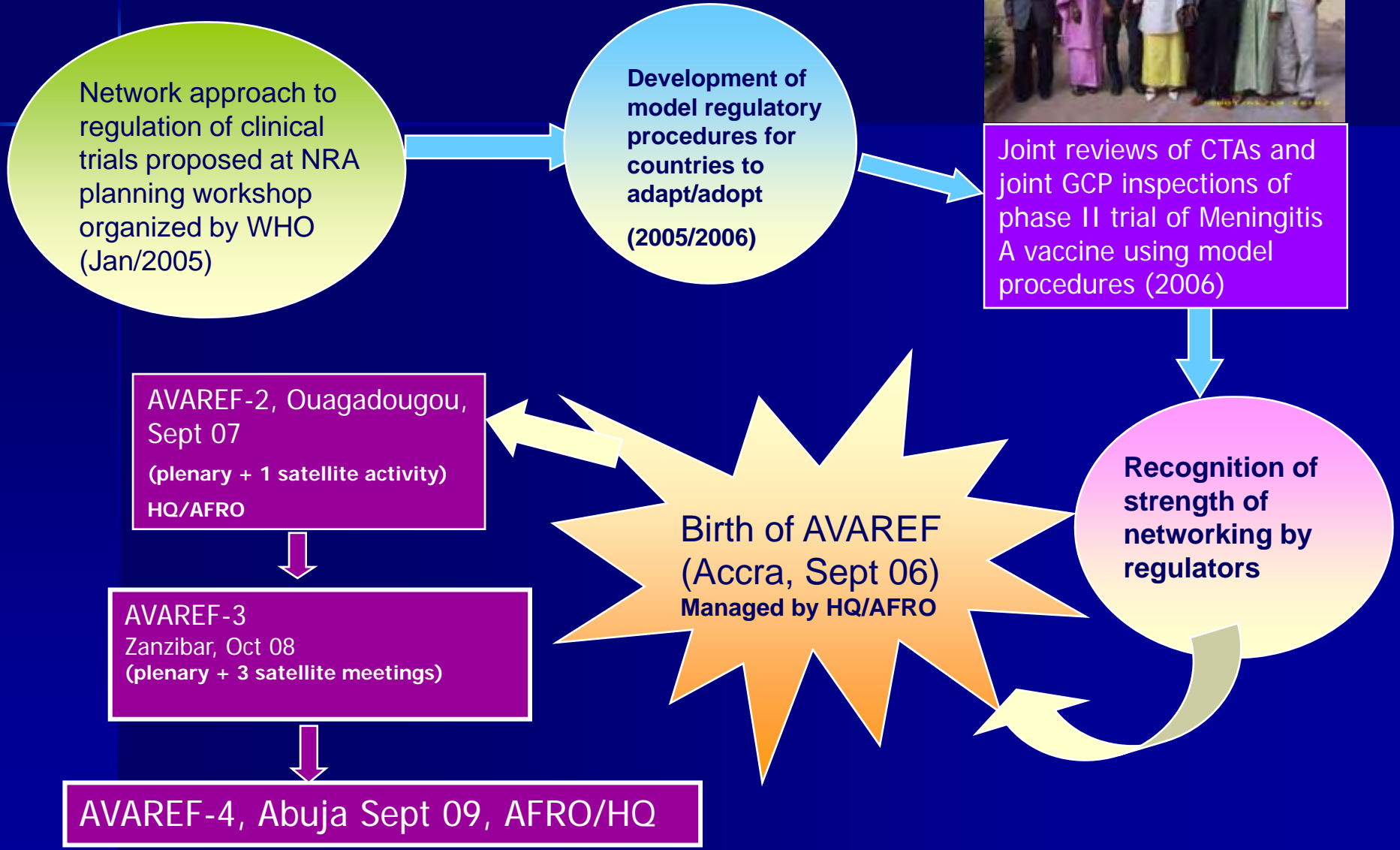
12-14 October 2009

Arusha, Tanzania

History of AVAREF



Joint reviews of CTAs and joint GCP inspections of phase II trial of Meningitis A vaccine using model procedures (2006)



Network approach to regulation of clinical trials proposed at NRA planning workshop organized by WHO (Jan/2005)

Development of model regulatory procedures for countries to adapt/adopt (2005/2006)

AVAREF-2, Ouagadougou, Sept 07
(plenary + 1 satellite activity)
HQ/AFRO

AVAREF-3
Zanzibar, Oct 08
(plenary + 3 satellite meetings)

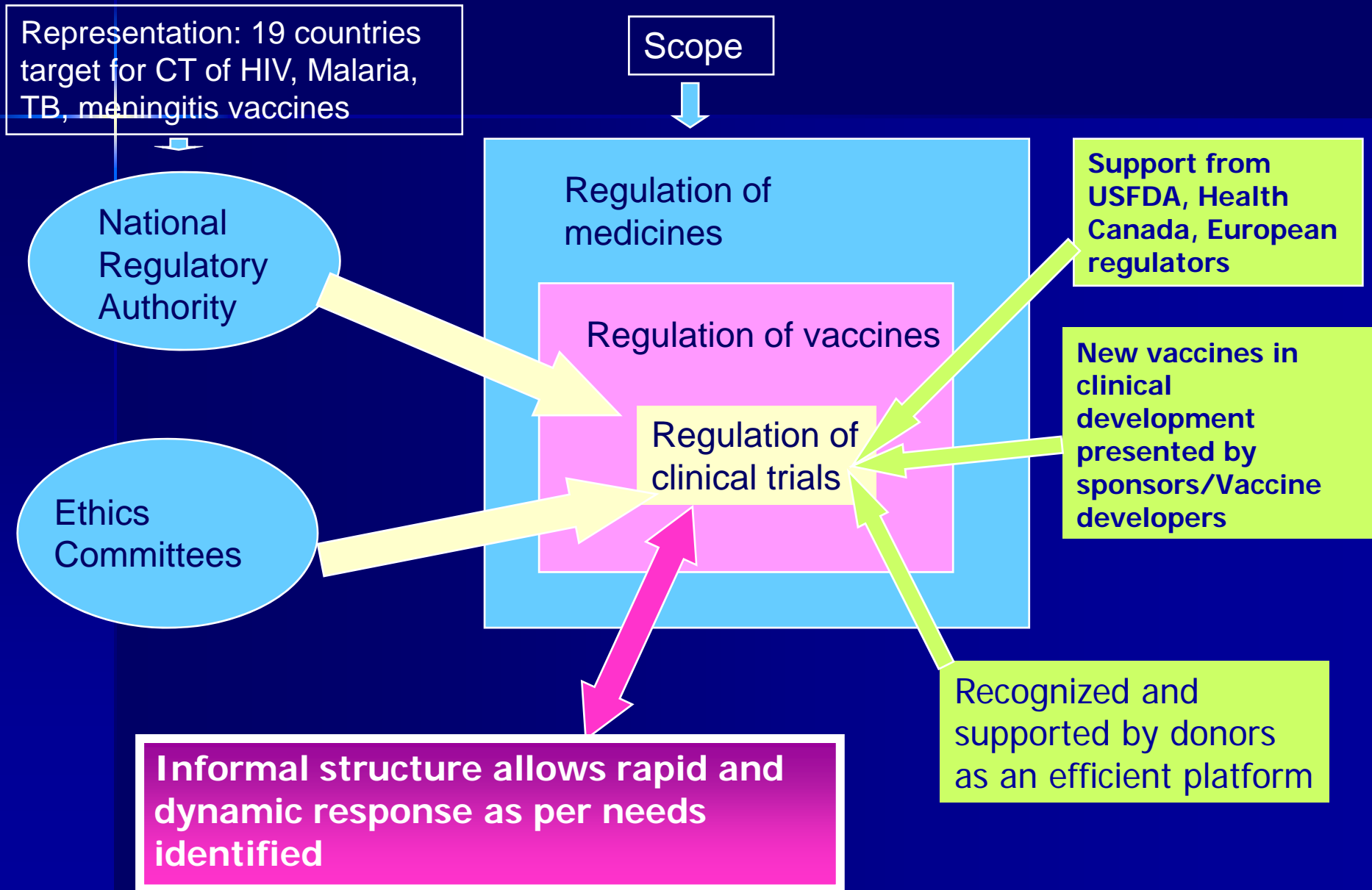
AVAREF-4, Abuja Sept 09, AFRO/HQ

Birth of AVAREF
(Accra, Sept 06)
Managed by HQ/AFRO

Recognition of strength of networking by regulators

AVAREF-African Vaccine Regulatory Forum

An informal network approach to regulation of clinical trials in Africa



AVAREF: an effective initiative to stimulate progress towards regulatory harmonization of clinical trials

- Channels of communication among African regulators and with regulators from developed countries have created confidence, strength and willingness to harmonize processes
- Model regulatory procedures developed and adopted by many Countries
- Joint reviews and joint inspections conducted (Conjugate meningitis A and Malaria vaccines)
- Enthusiasm from countries for further developments:
 - integration of ethical review, regulation and registration of clinical trials
 - development of African Common Clinical Trial Guidelines

Lessons learned

- High level of expertise, wisdom and commitment exists in countries – but gaps also recognized
- Mutual acceptance of these factors and recognition of common challenges provided the incentive to create a space to work together
- Capacity building activities (development of regulatory procedures for CTs, joint reviews and inspections) provided a foundation for:
 - a path towards harmonization
 - the design of "authentic learning" opportunities
- Increasing ownership by countries signalled by:
 - confidence to identify and propose future joint initiatives
 - between meeting implementation of activities

Advantages of joint reviews

- Enhances the quality of the review
- Ultimate learning experience by summing up findings from all countries plus expertise from advanced NRA
- Encourages harmonization of procedures and decision criteria
- Optimizes timeframes for review process
- Adds reliability to the clinical data resulting from those studies

Pan African Clinical Trial Alliance (PACTA)

AVAREF



PACTA (Pan African Clinical Trial Alliance)

EC/IRBs



PACTA

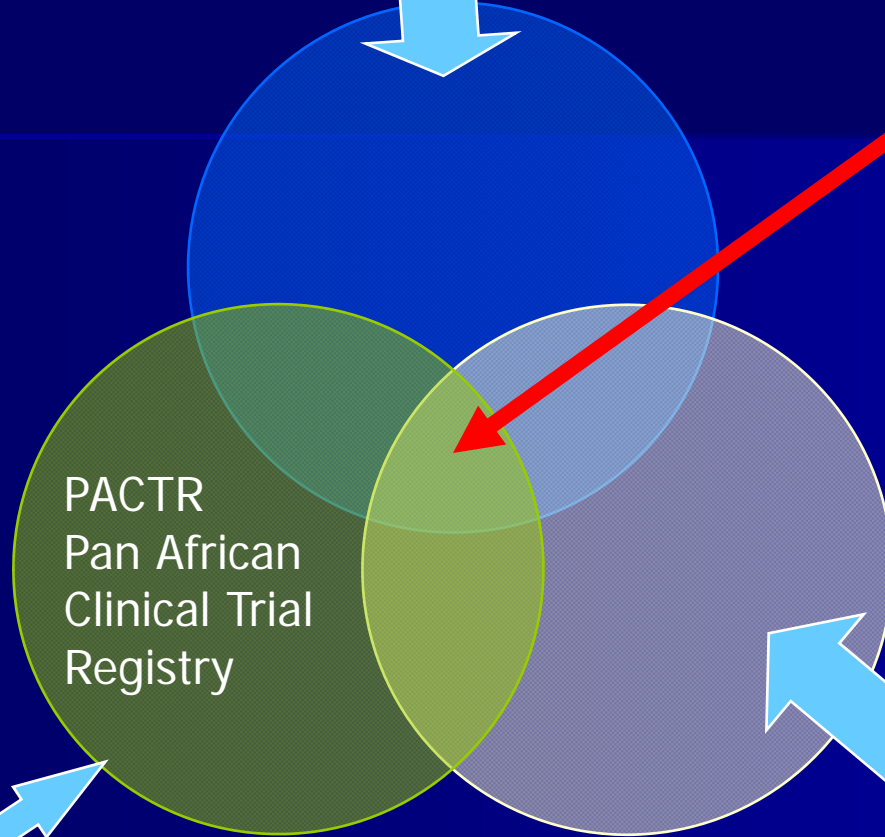
Sharing

+

Strengthening

+

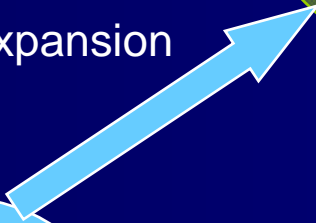
Harmonization



PACTR
Pan African
Clinical Trial
Registry

NRA

expansion



ATM
registry

Key elements

1. Responsibility to research participants
2. Address the challenges posed by the continuously evolving research environment
3. Capacity building
4. Compliance with international standards
5. Improve link between EC/IRBs and NRAs
 - A regional registry is the link (PACTR)
6. Information exchange
7. Harmonized regulatory guidelines, a common clinical trial registry, co-operation on oversight of clinical trials, transparency and continual effort to build mutual trust are most important instruments to achieve the vision.

Integration of regulation, registration and ethical approval of clinical trials

- Creation of functional collaborative network for approval and oversight of medicines/vaccines interventional clinical trials in Africa.
 - Work towards compliance with international ethical and regulatory standards to assure the safety and well being of clinical trial participants and the validity of generated data
 - Promote good research and regulatory practices
 - Work towards harmonized regulatory guidelines, greater transparency and improved collaboration and co-operation

New recommendations

AVAREF-4

- Revised concept paper to be presented to all Heads of Agencies and ECs to implement recommendations of the Ministers at the last RC meeting
- Pilot countries will include requirement of registration of trials submitted for authorization
- Harmonized guidelines for submission of CTA to be implemented
- New points will be proposed for primary registries to include proof of submission to NRAs and outcome of the review
- NRAs and ECs to agree on common set of data for national databases of CTs and "dialogue" with PACTR
- Pilot countries to use Heath Research Web (COHRED) and assess potential use as an information sharing platform

PACTA team

Liliana Chocarro, IVB, WHO/HQ

Samvel Azatyan, Medicines. WHO/HQ

Davina Gherzi, ICTRP; WHO/HQ

Doris Chou, ICTRP, WHO/HQ

Marie Charlotte Bouessau, ETH, WHO/HQ

Prof. Dicky Akanmori, WHO/AFRO

AVAREF members