AFRICAN VACCINE REGULARY FORUM

In strengthening capacity of african ethical review committees and national regulatory agencies

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Stakeholder meeting,
Antwerp; 29 November 2013

E D C T P

World Health Organization
REGIONAL OFFICE FOR Africa

History of AVAREF

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

Development of model regulatory procedures (2005/2006)

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

Birth of AVAREF (AVAREF-I Accra, Sept 06

AVAREF-2, Burkina Faso, Sept 07

AVAREF-3, Tanzania, Oct 08

AVAREF-4. Nigeria, Sept 09

AVAREF-5 Kenya, Sept 10

AVAREF-6 Mozambique, Sept 11

AVAREF -7 Gabon, Sept 12

Potential of networking

TFI recommendation

RD's vision

AVAREF-8, Entebbe, Uganda 14-18 Oct 2013

Plenary presentations by product developers/regulators/researchers, Task team meetings, Joint reviews,.

Country members of AVAREF

- Botswana,
- Burkina Faso,
- Republic Democratic of Congo(RDC)
- Republic of Congo(Congo Brazza)
- Guinea equatoriale
- Ethiopia
- Ghana
- Kenya
- Malawi
- Mali
- Mozambique
- Niger
- Nigeria
- Republic of centrafic
- Senegal
- Sierra Leone
- South Africa
- Tanzania
- Uganda
- Zambia
- **Countries contacted to become AVAREF members : Ivory Coast, Benin, Guinea**

Partners and countries support AVAREF

- WHO/AFRO(secretariat)
- WHO/HQ
- GSK, Belgium
- Health Canada
- Gates Fondation/USA
- PATH Malaria Vaccine Institute/USA
- AERAS/USA
- EDCTP
- EMEA
- European Union
- African Union
- The list is not completed,
- During our meetings, we use 3 languages: French, Portugese, English, the documents published by AVAREF are also on 3 languages
- Website: www.avaref.net

African Vaccine Regulatory Forum (AVAREF)

A network approach to Capacity building and harmonization for regulation in the WHO AFR Region

Representation: 20 countries target for CT of HIV, Malaria, TB, meningitis vaccines

National Regulatory Authority

Ethics Committees

Scope

Regulation of medicines

Regulation of vaccines (registration, PMS etc.)

Regulation of clinical trials

Support from USFDA, Health Canada, European regulators

New vaccines in clinical development presented by sponsors/Vaccine developers

Recognized and supported by donors as an efficient platform

Informal structure allows rapid and dynamic response as per needs identified

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 (MenAfriVac and Malaria (RTS,S) vaccines
- Enthusiasm from countries for further developments:

  - integration of ethical review, regulation and registration of clinical trials

  - development of African Common Clinical Trial Document and other guidelines

Roles and Responsibilities

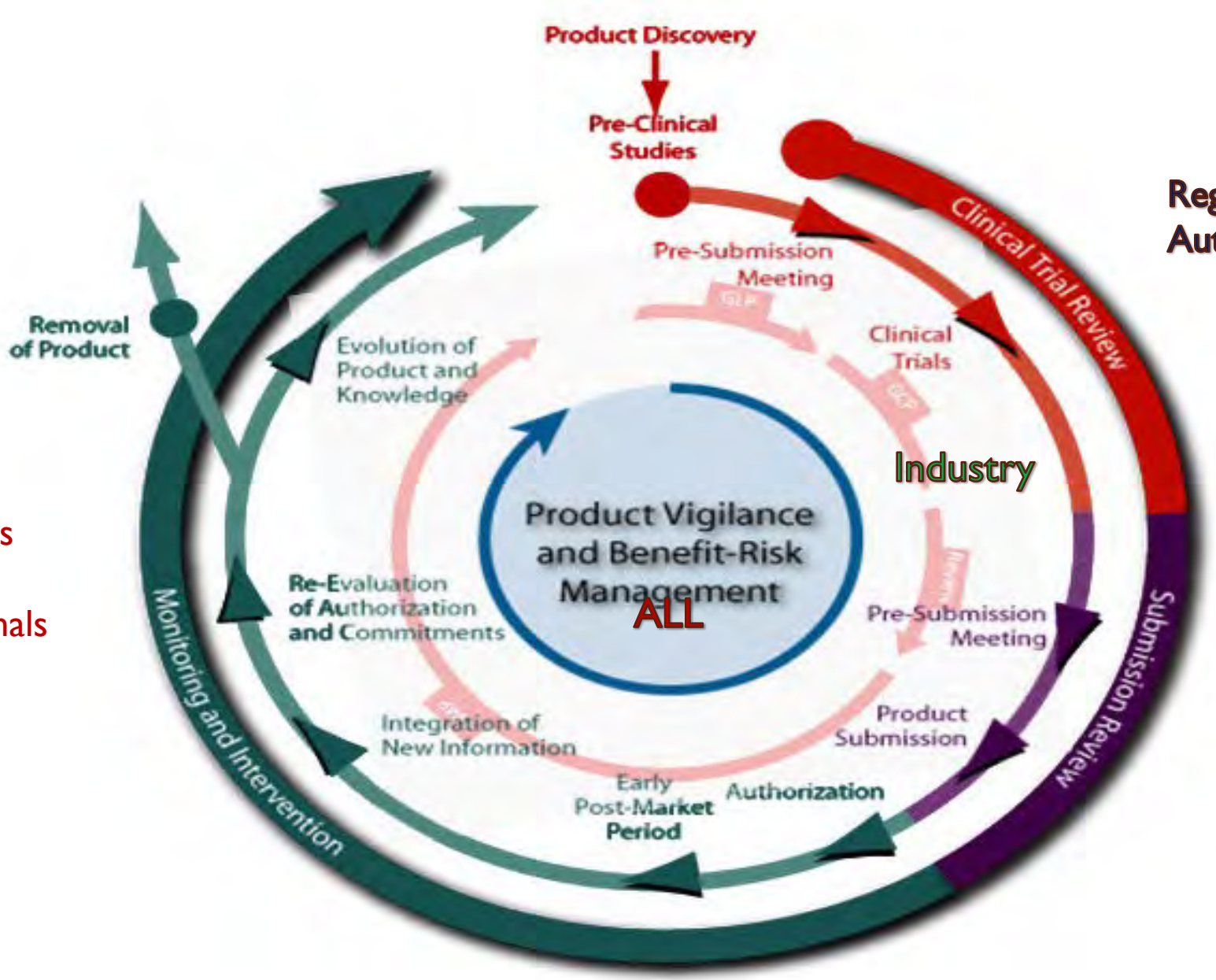
Ethics Committees

- Review and approve human research studies
- Audit sites to ensure compliance with GCP/GLP
- Review data

National Regulatory Authorities

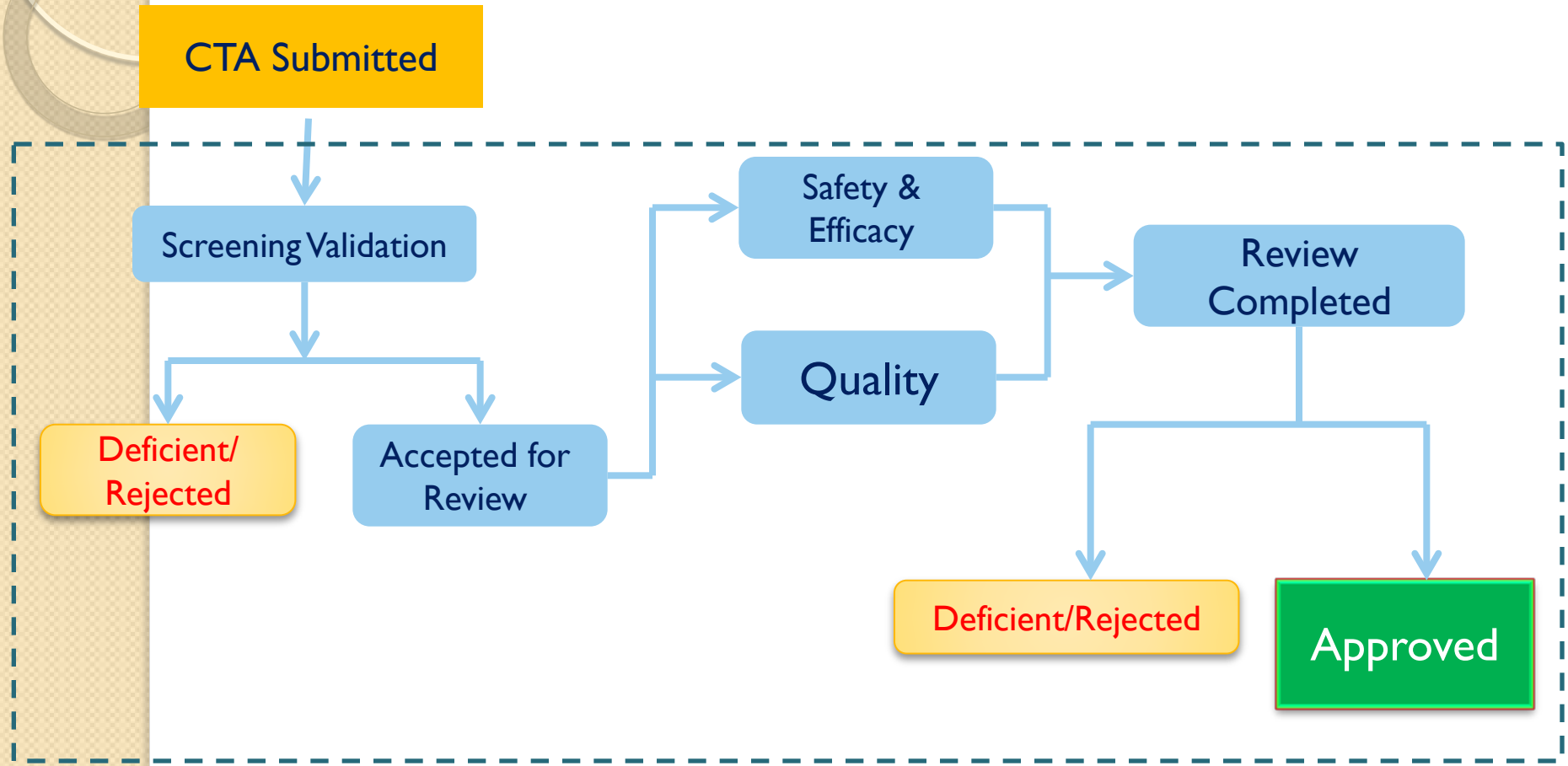
- Review CTAs for products for use in humans
- Approve importation of medicinal products for use in humans
- Inspect manufacturing facilities to ensure compliance with GMP
- Review CTDs and provide MA
- Review data and ensure PMS

Lifecycle Approach Model

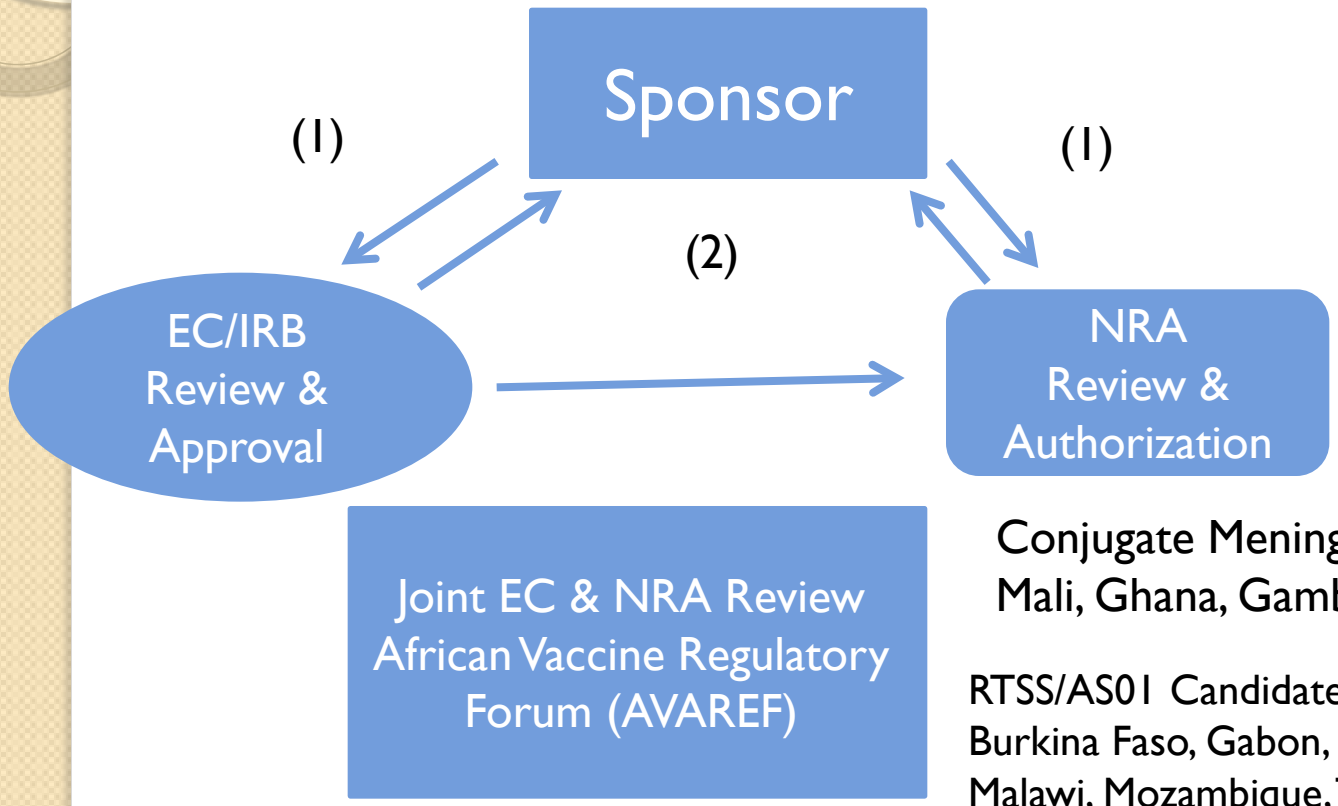


ALL
Regulators
Industry
Professionals
Public

CTA Review Process



Submissions & Reviews of CTAs



Conjugate Meningitis A vaccine
Mali, Ghana, Gambia, Senegal -

RTSS/AS01 Candidate malaria vaccine
Burkina Faso, Gabon, Ghana, Kenya,
Malawi, Mozambique, Tanzania

Review and approvals

Countries	Documents used	Duration for reviews	Type of submission	Require ments
Ghana, Tanzania, South Africa, Gambia, Uganda, Kenya, Nigeria	Adaptations of the African Common Clinical Trial Document	30-60 days for review and approvals	Online submissions Pre-registration on a WHO primary registry before submission	Ethics approval requirement before review by NRA
Senegal	Own SOPs integrating the african clinical trial document	30 -90 days	Physical submission, online submission (tests)	Ethics approval requirement before review by NRA

African Common Clinical Trials Guidance (ACCTG) documents

- Guidance to sponsors on clinical trial application procedure
- Guidance for evaluators
- Harmonized Guidance on "Good Clinical Practice" inspections
- Safety monitoring during Clinical Trials
- Importation & release of clinical batches
- Storage & exportation of clinical trials samples for testing
- Pre-selection of experts/reviewers
- Model Memorandum Of Understanding

African Common Clinical Trials Guidance (ACCTG) documents

Harmonized Good Clinical Practice (GCP) Guidelines for AVAREF countries

Aug 2009

Summary of 8th Meeting

- Regulatory pathway for submission of dossiers for RTS,S discussed with sponsors
- Update on malaria vaccine standards discussed
- Case study on causality assessment
- Case study on critical issues for evaluation of HIV vaccine CTAs
- Updates on CTAs reviewed and products registered

Lessons learned and perspectives

- High level of expertise and commitment exists in countries
- Mutual recognition and acceptance of common challenges provides incentive to create the space to work together: www.avaref.net (testing)
- 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
- Capacity building activities should feed into institutional developing plans (IDPs).
- Developing SPOs about fees for submission and administration of the protocols(ethical and regulatory review,: working groups are established and must share their results before the next meeting
- Developing e-learning by improving collaboration with for example TRREE, COHRED, and so on
- Increasing ownership by countries signalled by:

  - confidence to identify and propose future joint initiatives

  - between meeting implementation of activities


ETHIOPIA
ZAMBIA


8th Annual African Vaccine Regulator


GHANA
Rwenzori
acer


UGANDA
TOSHIBA
TOSHIBA
USAID
MALAWI

Thank you for your attention