



EDCTP: partnerships in tuberculosis vaccines research and development

TB Vaccines A Second Global Forum

23 September 2010
Sokos Hotel Viru, Tallinn, Estonia

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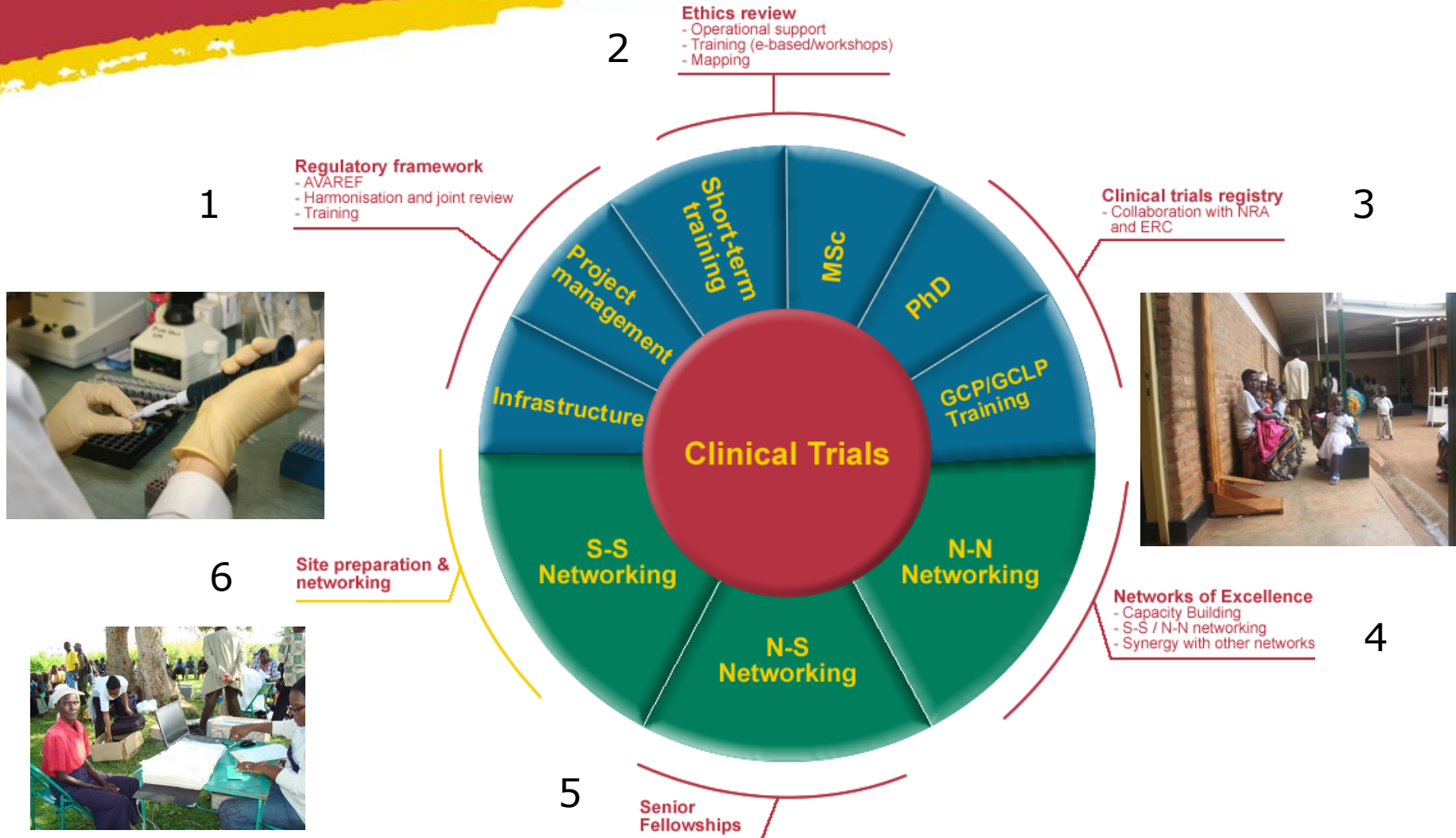


Working in partnerships



- **Coordination of national programmes**
- **Partnerships**
 - Clinical trials
 - Capacity development
 - Networking
- **Fostering synergy with other research and development partners/Stakeholders meetings**

The EDCTP approach in supporting clinical trials





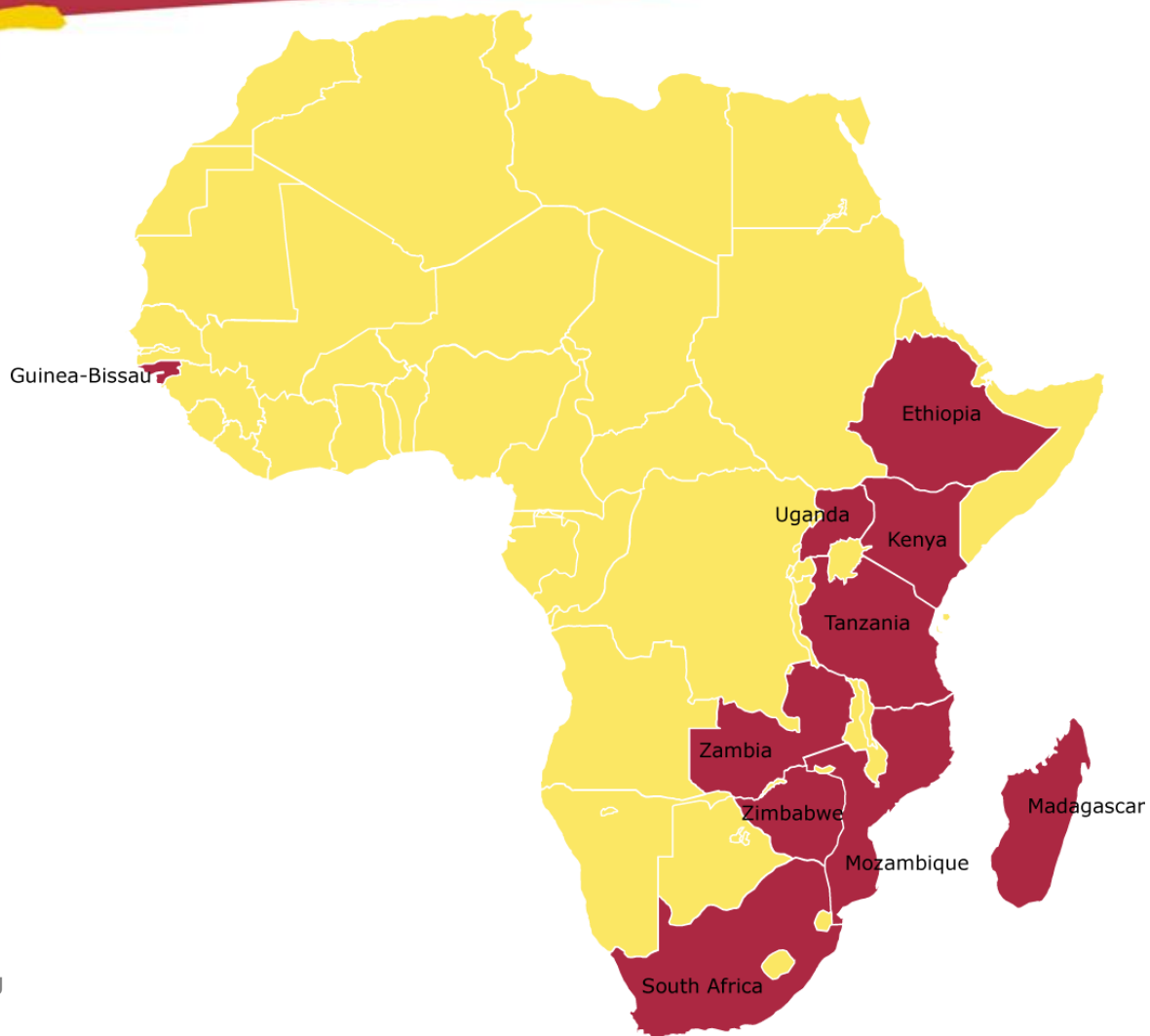
Ethics Review and Regulatory Capacity Building Support

- **African Vaccines Regulators' Forum (AVAREF)**
 - Joint review and inspection, training
 - Harmonisation of National Regulatory Authorities
- **Ethics review**
 - Operations
 - Training – workshops, e-based courses: www.elearningtree.org and www.amanet-trust.org
 - Strengthening of National Ethics Committee
 - Mapping African Ethics Research Capacity (MARC) www.researchethicsweb.org
- **GCP and GCLP training**
- **Clinical trials registration**
 - Pan-African Clinical Trials Registry PACTR www.pactr.org



EDCTP TB clinical trials related project (2004)

- Ethiopia
- Guinea-Bissau
- Kenya
- Madagascar
- Mozambique
- South Africa
- Tanzania
- Uganda
- Zambia
- Zimbabwe



- Clinical Trials - all PRD's
- Clinical Trials - HIV
- Clinical Trials - Malaria
- Clinical Trials - TB
- Training Awards
- Ethics Capacity Strengthening
- Regulatory Capacity Strengthening
- Networks of Excellence



Cohort studies and capacity strengthening in preparation for TB vaccines clinical trials in Kenya

Prospective epidemiological studies of TB in neonates and adolescents in Karemo Division, Siaya District, Western Kenya in preparation for future vaccine trials – KEMRI/CDC, Kisumu, Kenya

KEMRI/CDC , University of Cape Town, SATVI, KNCV Tuberculosis Foundation, VSCR, Fondazione Centro San Raffaele del Monte Tabor (Italy), AREAS, EDCTP



Cohort studies and capacity strengthening in preparation for TB vaccines clinical trials in Uganda

Toward conducting phase III trials of novel TB vaccines in infants and adolescents – Infectious Diseases Institute (IDI), Makerere University, Uganda

IDI, SATVI-University of Cape Town, Swedish Institute for Infectious Disease Control, ITP (Antwerp), Institute of Medical Immunology (Belgium), Uganda TB National Control programme, Karolinska Institute, KNKV Foundation, AERAS, EDCTP



EDCTP Stakeholders' meeting on TB Vaccines, April 2007, The Hague

Partners Present:

AERAS Global TB Vaccine Foundation (AERAS)

Bill & Melinda Gates Foundation (BMGF)

GlaxoSmithKline Biologicals (GSK)

KNCV Tuberculosis Foundation (KNCV)

TBVAC

Vakzine Projekt Management GmbH

World Health Organisation

South African Tuberculosis vaccines Initiative (SATVI)

Medical Research Council, The Gambia

Recommendations:

- Open call for phase II clinical trials of products already in the pipeline
- Repeat call a year later for small proof-of-principle clinical trials
- Support for capacity building and networking



EDCTP funded TB vaccines clinical trials

- **Ag85B-ESAT-6 (H1) + IC31 subunit vaccine (SSI)**
 - Phase I safety and immunogenicity in healthy adults (completed)
 - Phase II safety and immunogenicity in TST positive healthy adolescents (ongoing)
 - Phase II safety and immunogenicity in HIV-infected, BCG vaccinated adults with CD4+ >350/mm³ (under review)
- **AERAS-402/Crucell Ad35 TB vaccine (AERAS)**
 - Phase II safety and immunogenicity in BCG vaccinated, HIV uninfected infants
 - Phase II randomised controlled trial of vaccine prime followed by selective BCG boost among HIV exposed and unexposed infants
- **MVA85A/AERAS-485 booster vaccine (Oxford University)**
 - P-o-C phase IIb clinical trial to evaluate protective efficacy of booster MVA85A/AERAS-485 in healthy, HIV-infected adults



TB Vaccines clinical trial sites and networks: Ag85B-ESAT-6 (H1) + IC31

Phase I (THYB-03)

Clinical trial site: AHRI/ALERT (Ethiopia)

Armauer Hansen Research Institute (Ethiopia), Staten Serum Institut (Denmark), Leiden University (Netherlands), Institut Pasteur (Madagascar), Kilimanjaro Medical Centre (Tanzania)

Phase II (THYB-04)

Clinical trial sites: AHRI/ALERT Campus, Butajira, Nazaret, Debre Zeit (Ethiopia)

Armauer Hansen Research Institute (Ethiopia), SSI (Denmark, Leiden University Medical Centre (Netherlands), Aarhus University Hospital (Denmark), Bandim Health Project (Guinea Bissau)



Ag85B-ESAT-6 (H1)+IC31: phase II CT to evaluate safety and immunogenicity in HIV-infected adults (Under review)

Phase II double-blind, randomised, placebo-controlled study to evaluate safety and immunogenicity of Ag85B-ESAT-6 (H1) + IC31 in HIV-infected, BCG vaccinated adults with CD4+ counts >350 cells/mm³ with no evidence of TB disease

Trial sites: Bagamoyo (Tanzania), Johannesburg (S. Africa)

Aurum Institute (S. Africa), SSI, (Denmark), STI (Switzerland), Ifakara Health Institute (Tanzania), AERAS TB Foundation, KNCV (Netherlands), AMC (Netherlands)



AERAS-402/Crucell Ad35 boost TB vaccine

Randomised, double-blind controlled phase II clinical trial in BCG vaccinated, HIV uninfected infants to evaluate safety and immunogenicity

Trial sites: Kisumu, Kampala, Maniça, Worcester

University of Cape Town, SATVI (S. Africa) KEMRI/CDC (Kenya), Infectious Disease Institute of Makerere University, Makerere School of Public Health (Uganda) Manhiça Health Research Centre (Mozambique), Hospital Clinic Barcelona, Institute of Tropical Medicine (Belgium), Swedish Institute of Infectious Disease Control, Karolinska Institute (Sweden)



AERAS-402/Crucell Ad35 prime TB vaccine (Under review)

Phase II randomised controlled trial of a new viral-vectored tuberculosis vaccine prime followed by selective BCG boost among HIV exposed and HIV unexposed infants

Trial sites: Worcester, Kayeletisha (S. Africa), Kisumu (Kenya)

SATVI-IIDMM-University of Cape Town (S-Africa), KEMRI/CDC (Kenya), NIMR-MMRP (Tanzania), KI (Sweden), CHUV (Sweden), Stellenbosch University (S. Africa)



MVA85A/AERAS-485

P-of-C Phase IIb CT to evaluate protective efficacy of a recombinant modified vaccinia virus Ankara expressing immunodominant antigen 85 (MVA85) from *M. tuberculosis* in HIV-infected adults using a heterologous prime-boost strategy with BCG as a primer

Clinical trials sites: S. Africa, Senegal

Medical Research Council Gambia, University of Oxford, University of Cape Town, Universitaire Aristide Le Dantec Dakar, Pasteur Institute Belgium



Summary of EDCTP-funded TB vaccines clinical trials

Vaccine	Study population	Status
Ag85B-ESAT-6 (H1) Phase I	Healthy adults	Completed
Ag85B-ESAT-6 (H1) Phase II	Healthy TST positive adolescents	Ongoing
Ag85B-ESAT-6 (H1) Phase II	HIV-infected BCG-immunised adults	Planned
AERAS-402/Crucell Ad35 Phase II (boost)	HIV uninfected infants	Ongoing
AERAS-402/Crucell Ad35 Phase II (prime)	HIV exposed and unexposed infants	Planned
MVA85A/AERAS-485 Phase II	HIV infected adults	Ongoing



Thank you



<http://www.edctp.org>