



Baseline epidemiological study in preparation for a phase IIb trial of GMZ2 candidate malaria vaccine

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Outline

- Trial site preparation
- Baseline epidemiological study

Key Elements of Clinical Trials

Personnel

- Adequate number of trained key personnel
- Adequate number of support staff

Facilities and Equipment

- Field Site/Clinic
- Laboratory

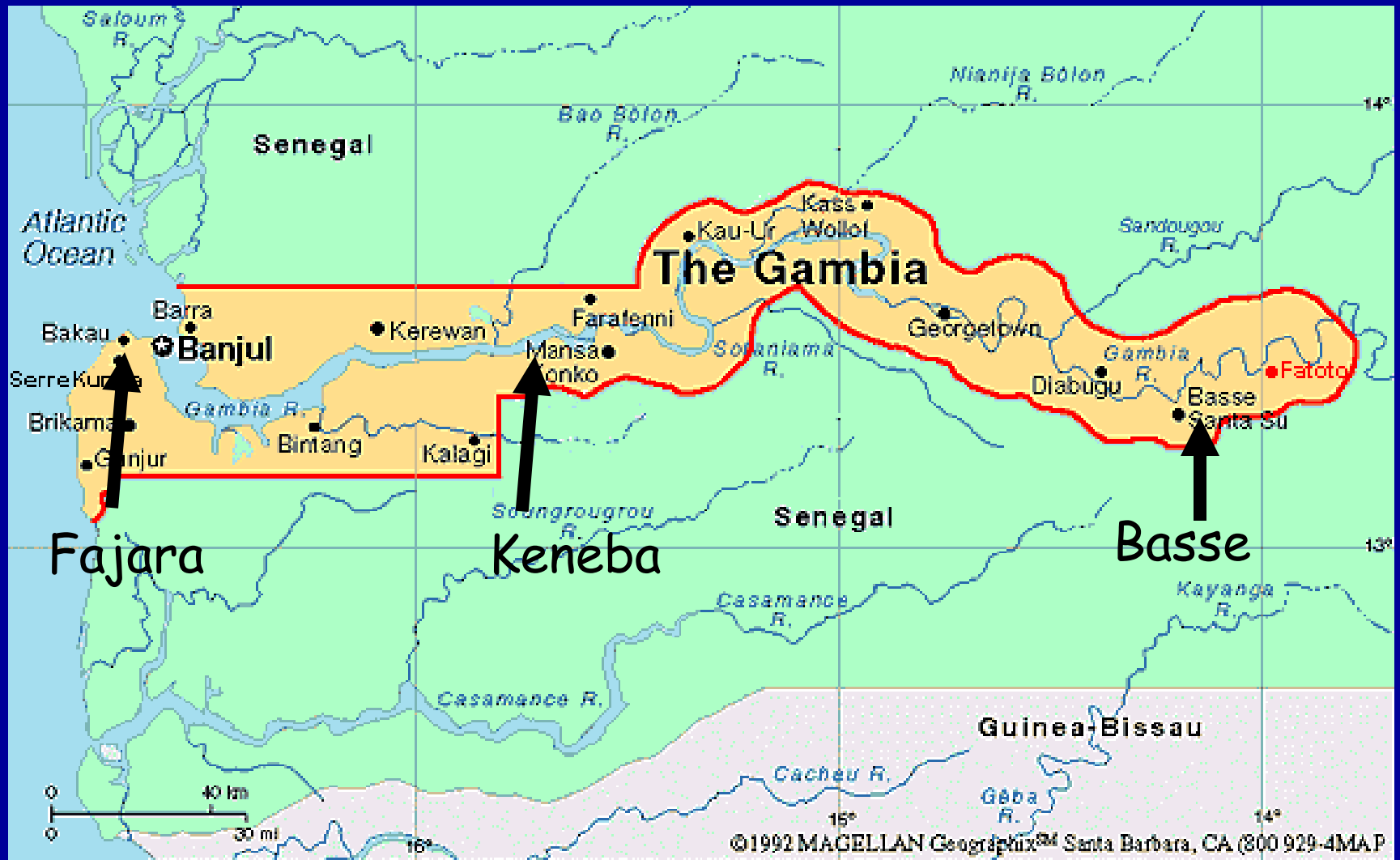
Epidemiology

- Disease
- Population

Ethical conduct of Research

Capacity building

MRC Field Sites



Basse Field Station

- Located 373 KM from the coast
- Several clinical trials
 - Malaria
 - ARI
- Has excellent accommodation
- Good internet connectivity
- Mobile/land phones
- Excellent laboratory facilities
- Rural community
- DSS in the Study area



MRC Ward, Basse Health Centre

Inpatient facility

- 18 pediatric beds
- 24-hour nursing staff



OPD facility

Clinical examination & treatment room

- Major renovations late 2001
- Back-up generator
- Ambulance for referral to Bansang Hospital



Basse Demographic Surveillance System

characterization of study populations

- mapping of the study area
- regular census
- data on migration
- data on occupation
- birth rate
- age specific death rates



Transportation

- Motor cycles
- All-terrain motor vehicles to transport study subjects and investigators
- Other forms of transport may be needed



Diagnostic facilities

- Diagnostic facilities for common medical conditions
- Facilities at local health centre may require upgrading
- collaboration with other institutions to assist in diagnosis in selected cases



Choice of instrumentation

Criteria:

- User-friendly
- Easy to troubleshoot/repair/
service
- Company customer support



Detection & investigation of serious adverse events

- The most appropriate will depend on local circumstances
- In rural areas will need mortality surveillance system
 - village reporter
 - verbal autopsy (disadvantage: difficult to standardize and validate)
 - hospital records
 - autopsy

Internet Connectivity

- Improved Communications
- Access to Information & Research Tools
- Facilitate Training
- Increased Sense of Membership in the Global Scientific Community

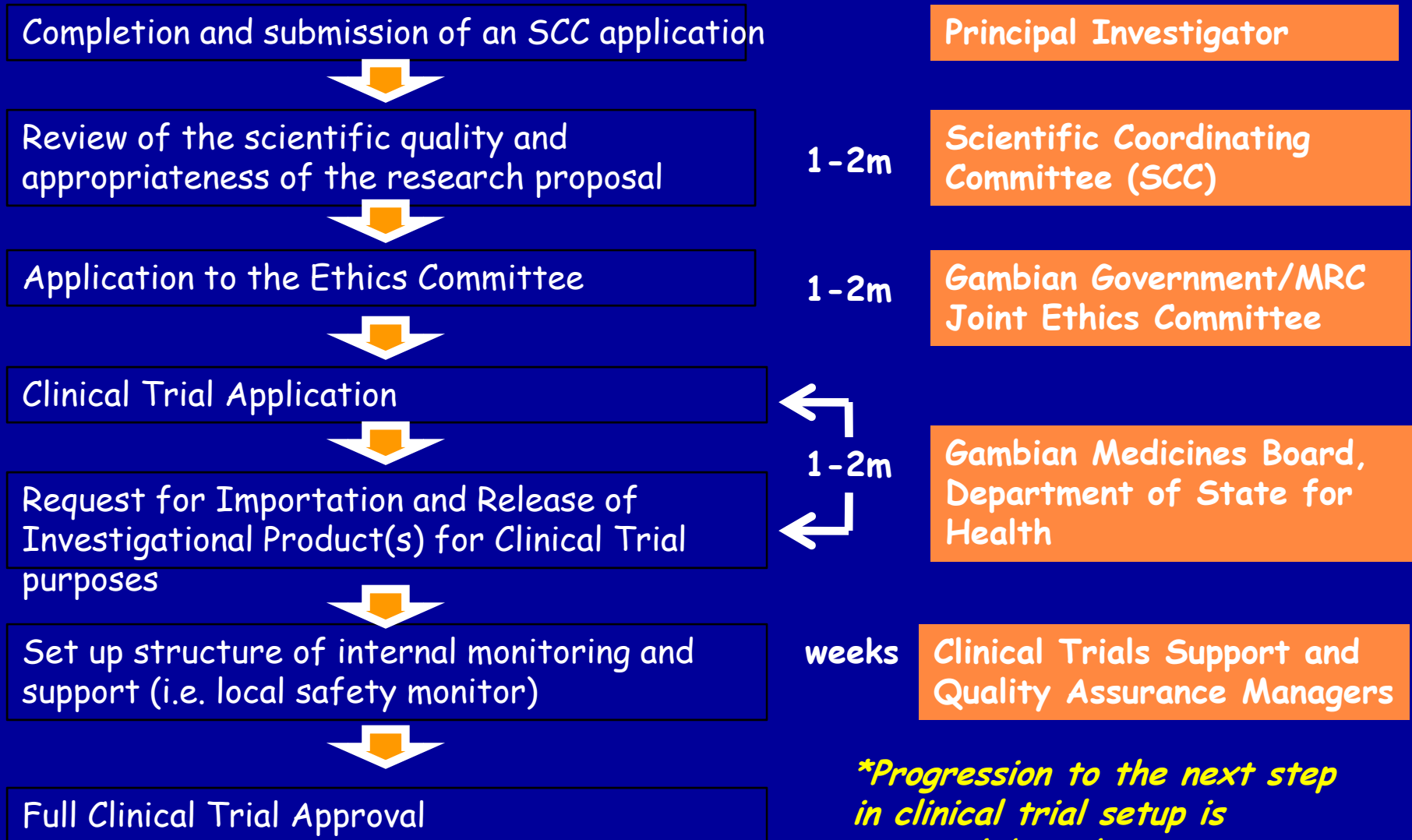
Ethical conduct of research

- Informed Consent
- Institutional review board
- Oversight by (DSMB, Local safety Monitors etc)
- Mechanism for adverse event reporting

Information about the trial

- Distribution of flyers
- Community meetings
- Drama performance
- Radio/TV

Regulatory Environment and Clinical Trial Setup Procedure*



**Progression to the next step in clinical trial setup is approval-based.*

Capacity Building

Assessment of existing trial sites:

- GCP
- GLP
- clinical facilities
- follow-up capacity
- data management
- sample storage
- statistical support

Capacity Building

Training

- Short-term courses & workshops-
 - GCP Training Workshops -
 - Project Management Training -
 - IRB Training
 - Bioethics Workshops
- Training awards linked to ongoing research programs

Epidemiological studies

Geographical and seasonal distribution of the disease of interest

- Prevalence
- Expected incidence by age
- Effect on morbidity and mortality
- Clinical manifestations
- Interaction with other diseases

Baseline epidemiological study

Study objectives

Primary objective:

- To determine site-specific incidence rate of clinical malaria in children aged 1-5 years during the surveillance period.

Secondary objectives:

- To pilot the surveillance system that will be used in the main efficacy trial.
- To measure the prevalence of malarionometric indicators: plasmodic index, splenomegaly, anaemia and parasite densities in children aged 1-5 years.

Study design

- Prospective cohort study .
- Two cohorts based at different sites (ACD and PCD).
- 350 children enrolled in each cohort.
- Passive case detection (PCD) undertaken at health facilities in the study area.
- Children enrolled in the active case detection (ACD) cohort followed-up twice a week .
- Cross-sectional surveys at the beginning and at the end of the surveillance period.

End-points

Primary end-point

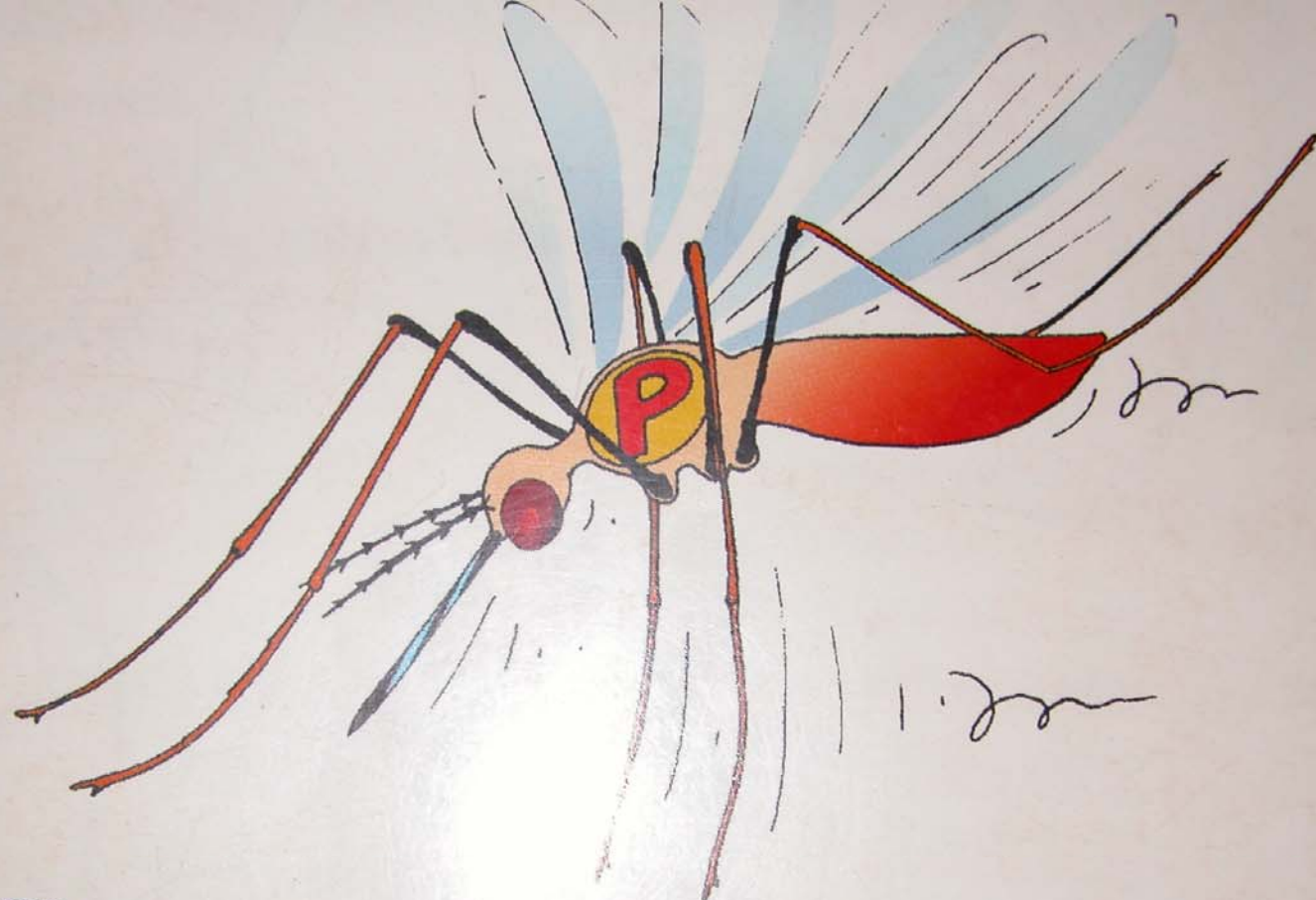
- Site specific incidence rate of clinical episodes of *P. falciparum* malaria.

Secondary end-points:

- Proportion of children with anaemia (Hb < 9.0 g/dL) at the end of the surveillance period.
- Proportion of children with splenomegaly at the end of the surveillance period.
- Geometric mean parasite densities of clinical cases of *P. falciparum* malaria at the end of the surveillance period.

Ancillary studies

- Comparison of tympanic and axillary thermometry in detecting fever in children.
- An evaluation of an electronic data capture system using Netbooks in a baseline epidemiological survey.
- Comparison of three methods for determining malaria parasite density in incident cases of malaria in a baseline survey.



Thank you for listening!


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