Intervention thematic group strategic portfolio

Stakeholders meeting
31st January 2013
White Sands Hotel

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Description of the Thematic Group

- Focuses on human populations
  - Individually and community

- Design, test, evaluate and Intervention
  - Diagnostics devices
  - Behavioural
  - Therapeutic (Drugs/Vaccine)

For Care/Cure and/or Prevention of diseases of public health importance
Goal of Thematic Group

Solutions developed (Lab and Field) need to be proven to work in the prevention and treatment of diseases of public health importance.
Research activities, Past Five Years

**Malaria**
- Clinical Surveillance
- Drugs
- Diagnosis
- Vaccine

**Tuberculosis**
- Drugs
- Clinical Surveillance
- Vaccine
- Diagnosis

**HIV**
- Epidemiology
- Intervention/Operations
- Clinical surveillance
Outsuts of the thematic Group, Core Business

**Research**
1. Diagnostic tools testing and validation for use on human populations (example-RDT)
2. Clinical interventions safety, efficacy, acceptability (Vaccines, drugs)
3. Behavioural interventions: Approach, methodology to prevent disease (maternal and newborn’s interventions)
4. Evidence based on clinical surveillance (activities and databases)

**Service**
1. Clinical Services
2. Improvement of QA
3. Consultations
   - Phase I testing
   - Bioequivalence
   - Analysis, EPI & Lab data

**Training**
1. Capacity building and strengthening, thematic
   = Training/ recruitment
   = CRO, GCP, Ethics
2. Support MSc Research in Public Health
Malaria Research
Key Results, Past Five Years

Clinical Surveillance
Bagamoyo and Ifakara

- The surveillance activities allow us to monitor:
  - Trends Malaria
  - Dynamic of diseases burden

- Changes in febrile disease patterns calls for diversification to (Pneumonia, Diarrhoea)
Clinical development of Coartem® & Coartem D®

28-day PCR-corrected cure rate

- Dispersible*: 97.8%
- Crushed: 98.5%

*Dispersion method for tablets
In children 5–17 months of age during 12 months of follow-up

- Vaccine efficacy against clinical disease: 55.8% (97.5% CI: 50.6-60.4)
- Vaccine efficacy against severe disease: 47.3% (95% CI: 22.4-64.2)

In children 6–12 weeks of age during 12 months of follow-up

- Vaccine efficacy against clinical disease: 31.3% (97.5% CI: 23.6-38.3)
- Vaccine efficacy against severe disease: 36.6% (95% CI: 4.6-57.7)
First Challenge study using purified sporozoites in Africa

<table>
<thead>
<tr>
<th>Trial</th>
<th>Group</th>
<th>PfSPZ dose</th>
<th>Route, number and volume of injections</th>
<th>Positive/total</th>
<th>Geometric mean prepatent period days (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RUNMC</td>
<td>2</td>
<td>10,000</td>
<td>ID, 2x 50µl</td>
<td>5/6</td>
<td>12.7 (11.0-14.0)</td>
</tr>
<tr>
<td>IHI</td>
<td>1</td>
<td>10,000</td>
<td>ID, 2x 50µl</td>
<td>11/12</td>
<td>15.6 (13-19)</td>
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<tr>
<td>RUNMC</td>
<td>3</td>
<td>25,000</td>
<td>ID, 2x 50µl</td>
<td>5/6</td>
<td>13.0 (12.3-14.3)</td>
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<tr>
<td>IHI</td>
<td>2</td>
<td>25,000</td>
<td>IID, 4x 10µl</td>
<td>10/11*</td>
<td>13.9 (11-19) **</td>
</tr>
</tbody>
</table>
### Table 4. Comparison of Performance SmaRDT Reader and Human-eye using score method

<table>
<thead>
<tr>
<th>Population</th>
<th>N</th>
<th>Negative % Agreement (95% CI)</th>
<th>Positive % Agreement (95% CI)</th>
<th>Overall % Agreement (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITA subjects with SmaRDT Reader and human-eye results (excludes invalids)</td>
<td>1336</td>
<td>96.9 (93.4, 98.6)</td>
<td>98.7 (97.8, 99.2)</td>
<td>98.4 (97.6, 99)</td>
</tr>
<tr>
<td>ITA subjects with SmaRDT Reader and human-eye results (includes invalids)</td>
<td>1345</td>
<td>95.9 (92.1, 97.9)</td>
<td>98.2 (97.2, 98.8)</td>
<td>97.8 (96.9, 98.5)</td>
</tr>
</tbody>
</table>

**Work on mRDT** contributed to the current international panel of samples in use by WHO to validated performance of new RDT produced.
TB Research on going Work

(NC-002)
- To evaluate the safety and efficacy of Pa-M-Z drug in patients with drug-sensitive and drug-resistant pulmonary TB after 8 weeks of treatment

(HIGHRIF)
- Rapid evaluation of high dose rifampicin drug and other rifamycins in tuberculosis = Shorten TB Rx

(TB CHILD)
- Evidence based clinical evaluation of new and emerging diagnostics to improve TB Dx for children, also to find sensitive, safety, affordable tool

(H1/IC31® Vaccine)
- To evaluate the safety, Effect on CD4 and viral load in HIV-infected
Key TB output since 2010

1. Establishment of TB clinical trial sites in Bagamoyo and Mwananyamala
2. Extensive GCP-compliant training of scientists and co-workers
3. Partnership in the relevant consortia for TB drug and vaccine development (IHI will host the PanACEA meeting in 2013)

Publications:
1. 2010–2012, 4 publications since studies
2. 2013, 15 TB related publications planned
   TB CHILD, TB COHORT, HIGHRIF, H1 Vaccine)
HIV/AIDS Researches
HIV portfolio

- **Clinical surveillance** (KIULARCO):
  - Determinants and consequences of non-adherence to HAART
  - SPD: Effectiveness of current models for HIV status disclosure and partner testing

- **Effectiveness** of long term CTX under HAART (KIULARCO)
  - Interventions for improving early HIV detection (MZIMA)
  - Pharmacovigilance of ART
Selected HIV output in the past 5 yrs

Clinical HIV cohort
- Patient outcome evaluation

Determinants of adherence (adults & pediatric)

Infant feeding in HIV context
- SDH (food insecurity and SES) effect on appropriate infant feeding
- Best methods for eliciting information about infant feeding and mortality
areas of Work, Next five years......

**Available Assets, Thematic Group**

1. Phase I clinical trial facilities
2. Reference laboratories (BSL 2+, 3, Clinical)
3. Clinical surveillance facilities
4. Strong working relationship with communities
5. Collaboration with key facilities, e.g. the Ocean Road
6. Committed professional scientists and clinical team

**expand into new research areas/service**

1: Non-communicable diseases (Cancer, Diabetes, and CVD)  
   = Epidemiology, Improve clinical care, behavioral intervention
2: Combinations of disease creating co-morbidity
3: Clinical aspect of correlates of protection for vaccines
4: Emerging and Re-emerging neglected diseases
5: Establish CRO
Malaria Research Activities, Next 5 years (2013-2018)……..

1. Evaluate different Malaria vaccine Candidates
   - Sporozoite
   - Blood stage (P27)

2. Malaria transmission programme of work
   - Gametocytocidal drugs
   - Membrane feeding assays

3. Challenge studies (Products)
   - Safety, tolerability, immunogenicity = CDV

4. Trials on Drugs and Diagnostic devices
   - Improve care
   - Cheaper and fast (POC - tests)
TB Research Activities, Next Five Years (2013-2018)

**Long term goal**

To become a centre of excellence for TB clinical treatment and vaccine trials in Sub Saharan Africa.

1. Consolidation and extension of TB clinical trial capacities for the clinical development of new TB treatment regimens and new TB vaccines
   - Phase I, II and III trials
   - Early Bactericidal Activity (EBA) treatment trials
   - MDR TB

2. Focus on interrelation between TB and DM
   - Epidemiology, pharmakokinetic of TB and DM drugs
   - Immunology, genetic strain diversity in DM population
   - Management guidelines etc. (..)
1. Improve Clinical care of HIV patients
   - Evaluation of new POC Device for CD4+ cells count
   - Test impact of newly developed interventions