

CURRICULUM VITAE

PERSONAL INFORMATION

Name: Minja, Rose G.
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Nationality: Tanzanian

WORK EXPERIENCE

2011- To date: Contracted by Swiss Tropical and Public Health as Regional Monitor in Tanzania.

Main Activities: Site assessment, Site initiation, Interim monitoring visits, and close out visits for clinical trials phase I-IV.

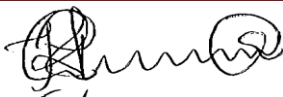
2006 – To date: Employed by Ifakara Health Institute Bagamoyo site

Occupation: Site internal Monitor and Quality assurance

Main Activities: 1. monitoring of investigator driven clinical trials
2. Quality management in clinical trials.
3. Clinical trial coordination.

Clinical Trial Monitoring Experience

1. A phase Ib age-de-escalation dose-escalation randomized double blind, controlled study of the safety and immunogenicity of heterologous prime- boost with the candidate malaria vaccines chAd63RH5 and MVA RH5 administered intramuscularly according to a 0, 2- month vaccination schedule in healthy adults, young children and infants in Tanzania. (**Trial Monitor**) Study on going.
2. Phase I clinical trial to evaluate the safety and Immunogenicity in Age De Escalation of Direct inoculation of a Plasmodium Falciparum Sporozoite Vaccine in Tanzanian adults, children and infants, 99 subject's duration 24 months. (**Trial Quality assurance**) Study is ongoing.
3. Phase III Intravenous ferric carboxymaltose compared with oral iron in the treatment of iron deficiency anemia at delivery in Tanzania 230 pregnant women duration 18 Months. (**Trial Monitor**) Study is ongoing.
4. The effects of tuberculosis on dietary iron absorption and systemic iron utilization: a double stable isotope study in Bagamoyo, Tanzania (**Trial Monitor**) Study ongoing.



5. Phase 1, dose escalation, randomized controlled trial to evaluate the safety, immunogenicity and efficacy of intravenously administered attenuated *Plasmodium falciparum* sporozoite vaccine (PfSPZ Vaccine) in Tanzanian 73 subjects duration 24months. (**Trial Monitor**) Study closed.
6. Phase IV open label of fixed Artemisinin/Naphthoquine (ARCO) Therapy to determine safety, tolerability, Pharmacokinetics and efficacy in adults and children with uncomplicated P. Falciparum Malaria in Tanzania 60subjects duration 24months. (**Trial Monitor**) Study closed.
7. Phase I Controlled human malaria infection by intradermal injection plasmodium Falciparum sporozoites (PfSPZ Challenge) in Tanzania 30 subject's duration 12months. (**Trial Monitor**) study closed
8. Safety and Immunogenicity of Novel candidate Blood stage Malaria, Vaccine P27Awith Alhydrogel Or GLA-SE As Adjuvant in health Malaria Non-Exposed European and Exposed African Adult Aged 18-45years:A randomized, Multi-center Phase Ia/Ib Trial 40 subjects duration 16months (**Trial Monitor**) Study closed
9. Protocol title: A phase III, double blind (observer-blind), randomized, controlled multi-center study to evaluate, in infants and children, the efficacy of the RTS,S/AS01E candidate vaccine against malaria disease caused by P. falciparum infection, across diverse malaria transmission settings in Africa, 1705 subjects duration 5years. (**Site study coordinator**) Study closed.
10. Phase II Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Immunogenicity of H1/IC31[®], an adjuvanted TB Subunit Vaccine, in HIV-Infected Adults with CD4+ Lymphocyte Counts Greater than 350 cells/mm³ 24 subjects duration 8months. (**Trial Monitor**)Study closed.

ACADERMIC QUALIFICATION

- 2008- 2011:** Open University of Tanzania awarded
Bachelor of Arts in Sociology Lower class Honors.
- 1996-1998:** Kibaha Clinical Officers Training Centre (Tanzania)
Awarded Diploma in clinical Medicine.
- 1992-1994:** Jangwani Girls High School awarded
Advance Certificate of Secondary Education.
- 1988-1991:** Uomboni Secondary School awarded Certificate for Secondary Education

PERSONAL SKILLS AND COMPETENCIES

- 2016:** Good Laboratory Practice Audit and Inspection (GLP) by Research Quality Association (LSTM UK)
- 2015:** Project Management course: By Royal Tropical Institute (The Netherlands TZ)
- 2014:** Quality Management system in Clinical trials: By the Royal Tropical Institute (The Netherlands TZ)
- 2014:** GCP TOT course: By The Royal Tropical Institute (The Netherlands TZ)
- 2011** BASIC CRA COURSE by ACRO (Pty) Ltd Johannesburg South Africa



Awarded: Certificate for Basic CRA course Part I and Part II.

2011: Advanced Clinical Monitoring Training Applied GCP and SOP by Swiss TPH (Basel Switzerland)
awarded: Certificate for Advance Monitoring.

2010: Clinical Trial Monitors Training Applied GCP (Bagamoyo Tanzania)
Awarded: Certificate for clinical trial Monitoring.

2009: ADVANCE HEALTH RESEARCH ETHICS FOR INVESTIGATORS
Attended a one week training on health research ethics on biomedical research
By AMANET

2008: RTS,S MALARIA CANDIDATE VACCINE CLINICAL DEVELOPMENT PLAN
Certified and accredited for the assessment of severe malaria in clinical trials by Gsk and malaria vaccine
initiatives MVI (Sep2008).

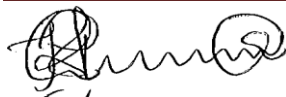
2007: Basics of Health Research Ethics Course (AMANET)

2007 Quality Assurance systems in clinical and laboratory departments
In house Training by GSK BIO.

2006 Good Clinical Practice
Trained on research ethics, subject rights, informed consent and clinical trial monitoring and auditing
procedures by PPD.

PUBLICATIONS:

- 1. Evaluation of the Safety and Immunogenicity of the RTS,S/AS01_E Malaria Candidate Vaccine When Integrated in the Expanded Program of Immunization. (The Journal of Infectious Diseases /0210/2010).
Selidji T. Agnandji^{1,2}, Kwaku Poku Asante³ John Lyimo⁵, Johan Vekemans⁶, Solange S. Soulanoudjingar^{1,2}, Ruth Owusu³, Mwanajaa Shomari⁵, Amanda Leach⁶, Jose Fernandes^{1,2}, David Dosoo³, Maria Chikawe⁵, Saadou Issifou^{1,2}, Kingsley Osei-Kwakye³, Marc Lievens⁶, Maria Paricek^{1,2}, Stephen Apanga³, Grace Mwangoka⁵, Blaise Okissi^{1,2}, Evans Kwara³, **Rose Minja**⁵, Jorn Lange^{1,2}, Owusu Boahen³, Kingsley Kayan³, George Adjei³, Daniel Chandramohan^{3,4}, Erik Jongert⁶, Marie-Ange Demoitié⁶, Marie-Claude Dubois⁶, Terrel Carter⁷, Preeti Vansadia⁷, Tonya Villafana⁷, Marla Sillman⁷, Barbara Savarese⁷, Didier Lapiere⁶, William Ripley Ballou⁶, Brian Greenwood^{3,4}, Marcel Tanner^{5,8}, Joe Cohen⁶, Peter G. Kremsner^{1,2}, Seth Owusu-Agyei^{3,4} and Salim Abdulla⁵.*
- 2. Safety and efficacy of the RTS,S/AS01_E candidate malaria vaccine given with expanded-programme-on-immunisation vaccines: 19 month follow-up of a randomised, open-label, phase 2 trial. (The Lancet Infectious Diseases21/ 07/2011).*
*Dr Kwaku Poku Asante, MD^a, Salim Abdulla, MD^c, Selidji Agnandji, MD^{d, e}, John Lyimo, MD^c, Johan Vekemans, MD^f, Solange Soulanoudjingar, MD^{d, e}, Ruth Owusu, MD^a, Mwanajaa Shomari, BSc^c, Amanda Leach, MRCPC^h, Erik Jongert, PhD^f, Nahya Salim, MD^c, Jose F Fernandes, MD^{d, e}, David Dosoo, BSc^a, Maria Chikawe, MD^c, Saadou Issifou, MD^{d, e}, Kingsley Osei-Kwakye, MD^a, Marc Lievens, MSc^f, Maria Paricek, MD^{d, e}, Tina Möller, MD candidate^{d, e}, Stephen Apanga, MD^a, Grace Mwangoka, MSc^c, Marie-Claude Dubois, MSc^f, Tigani Madi, MD^{d, e}, Evans Kwara, MD^a, **Rose Minja, CO^c**, Owusu Boahen, MPH^a, Kingsley Kayan, Dip Med Lab Tech^a, George Adjei, MSc^a, Daniel Chandramohan, MD^b, Terrell Carter, MHS^a, Preeti Vansadia, MHS^a, Marla Sillman, MHS^a, Barbara Savarese, RN^a, Christian Loucq, MD^a, Didier Lapiere, MD^f, Brian*



Greenwood^b, Joe Cohen, PhD^f, Peter Kremsner, FRCP^{d, e}, Seth Owusu-Agyei, PhD^{a, b}, Marcel Tanner, PhD^{c, h},
Bertrand Lell, MD^{d, e}

3. First results of phase 3 trial of RTS,S/AS01 malaria vaccine in African children. (The RTS,S N Engl J Med 2011; 365:1863-1875 November 17, 2011).

Salim Abdulla, M.D., Ph.D., Nahya Salim, M.D., Omar Juma, M.D., Mwanajaa Shomari, B.Sc., Kafuruki Shubis, M.Sc., Francisca Machera, A.M.O., Ali Said Hamad, M.D., **Rose Minja**, C.O., Maxmillian Mpina, M.Sc., Ali Mtoro, M.D., Alma Sykes, M.D., Saumu Ahmed, M.D., Alwisa Martin Urassa, M.P.H., Ali Mohammed Ali, M.Sc., Grace Mwangoka, M.V.M., Marcel Tanner, Ph.D.;

4. First results of phase 3 trial of RTS,S/AS01 malaria vaccine in African children (The RTS,S Clinical Trials N Engl J Med 13 Dec 2012).

Abdulla S, Salim N, Juma O, Shomari M, Shubis K, Machera F, Hamad AS, **Minja R**, Mtoro A, Sykes A, Ahmed S, Urassa AM, Ali AM, Mwangoka G, Tanner M,

5. A phase 3 trial of RTS,S/AS01 malaria vaccine in African infants. (The RTS,S Clinical Trials N Engl J Med 13 Dec 2012).

Abdulla S, Salim N, **Minja R**, Mpina M, Ahmed S, Ali AM, Mtoro AT, Hamad AS, Mutani P, Tanner M,

6. Efficacy and safety of RTS,S/AS01 malaria vaccine with or without a booster dose in infants and children in Africa: final results of a phase 3, individually randomized, controlled trial (Published Online 24 April 2015.

S Abdulla, N Salim, A Mtoro, S Ahmed, A Hamad, S Kafuruki, **R Minja**, M Tanner, M Maganga, A Mdemu, C Gwandu, A Mohammed.

REFEREE

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