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# Sanie Sesay

Physician Scientist

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<b>Profile Summary</b>	Experienced Clinical Research Leader with over 20 years in drug and vaccine development, infectious diseases, and clinical trials. Proven track record in leading global clinical study teams and driving efficiency in vaccine R&D. Passionate about innovative clinical trial designs and improving global health outcomes.
<b>Education</b>	<p><b>Advanced Vaccinology, Diploma</b>, University of Geneva, Switzerland and Fondation Mérieux, France, 2021</p> <p><b>Ph.D. in Tropical Medicine</b>, Liverpool School of Tropical Medicine (LSTM)/College of Medicine Malawi (CoM), 2014</p> <p><b>Diploma of Tropical Medicine and Hygiene (DTM&amp;H)</b>, Royal College of Physicians UK, 2011.</p> <p><b>MSc. in Epidemiology (Distance Learning)</b>, London School of Hygiene and Tropical Medicine (LSHTM), 2010.</p> <p><b>Advanced Diagnostics, Diploma</b>, University of Geneva, Switzerland and Fondation Mérieux, France, 2010</p> <p><b>Bachelor of Medicine and Bachelor of Surgery (MBBS)</b>, College of Medicine and Allied Health Sciences (COMAHS), University of Sierra Leone, 2000.</p>
<b>Honors and awards</b>	<ul style="list-style-type: none"> <li>• Malaria Capacity Development Consortium Postdoctoral Fellowship, 2014.</li> <li>• ACT Consortium Strategic Funding Access Award ,2013.</li> <li>• Gordon Research Conferences travel award, 2013.</li> <li>• American Society of Tropical Medicine and Hygiene travel award, 2012.</li> <li>• American Society of Tropical Medicine and Hygiene proxime accessit Young Investigator award, 2012.</li> <li>• FEMTO Trust Award, 2010.</li> <li>• Fondation Mérieux and London School of Hygiene and Tropical Medicine Fellowship, 2010.</li> <li>• Malaria Capacity Development Consortium Ph.D. Fellowship, 2009.</li> <li>• Medical Research Council (UK) The Gambia Scholarship, 2006.</li> <li>• Outstanding performance in providing post-conflict medical care to victims of sexual assault, 2004.</li> <li>• Sierra Leone Government Medical Scholarship, 1993.</li> </ul>
<b>Professional experience</b>	<p><b>March 2025-date: Vaccine Expert</b> – European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium.</p> <ul style="list-style-type: none"> <li>• Serve as a subject matter specialist who provides technical expertise on vaccine-related topics, contributes to policy development, and represents industry perspectives in discussions with European regulatory bodies and health authorities.</li> <li>• Collaboration with stakeholders across the pharmaceutical industry, regulatory agencies like EMA, and public health organizations to address vaccine development, access, and policy issues in Europe.</li> </ul> <p><b>December 2021-date : Transformation Leader (Clinical)</b> – Acceleration &amp; Efficiency, Vaccines R&amp;D Sanofi, France.</p> <ul style="list-style-type: none"> <li>• Engage with the Global Project Heads &amp; the Global Project Teams to target the optimal Time-To-Market for the best targets (high medical &amp; economical value) &amp; to avoid future gaps (in terms of launch date) in the pipeline.</li> <li>• Engage with internal (Medical, GRA, Public Affairs, Pharma CSO, etc...) &amp; external stakeholders to identify other acceleration opportunities.</li> <li>• Lead the efficiency effort across R&amp;D at Clinical perimeter.</li> </ul> <p><b>August 2023-date: Review Editor</b>, Editorial Board of Surveillance (specialty section of Frontiers in Malaria)</p> <ul style="list-style-type: none"> <li>• Review 5-10 manuscripts per year.</li> <li>• Assist in the strategic direction of the Journal by nominating emerging themes for potential article collections.</li> </ul>

**October 2021-date: Lecturer Sanofi R&D Faculty**, Sanofi, France.

- Delivery of lectures, live and recorded, on the following topics:
  - Pediatric Vaccine Development, the Challenges and Opportunities
  - Controlled Human Infection Models
  - Vaccines for Emerging Infectious Diseases
  - RSV Vaccines

**September 2014-date: Honorary Lecturer (Public Health)**, Department of Public Health, College of Medicine, University of Malawi.

- Delivering guest lectures or seminars on specialized topics.
- Providing strategic advice on academic programs and initiatives.

**March 2015-December 2021: Clinical Team Leader/Global Clinical Development Strategy Expert (GCDSE)**, RSV and Influenza Franchise, Sanofi, France.

- Provided scientific and clinical leadership in the design and development of clinical studies and programs for Vaccines R&D.
- Had global responsibility and ownership for the Clinical Strategy, the respective Clinical Development Plans (CDP) and study protocols for projects/programs.
- Ensured that CDPs are written in accordance with the Target Product Profile (TPP), Integrated Evidence Generation Plan (IEGP) and according to Franchise and Global Project Team strategy and assures global consistency across regions.
- Provided clinical and R&D expertise, guidance and direction in the context of the region/country, in which they operate.
- Establishes the conditions essential for determining the safety of all subjects involved in Clinical trials for the vaccine development candidates they oversee.
- Leadership of a clinical team with several functional experts.

**September 2018 to September 2021: Guest Lecturer (Clinical Development of Vaccines)**, DAS Management of Clinical Trials MSc course at the Faculty of Medicine, University of Geneva.

- Deliver lecture yearly on the Clinical Development of Vaccines as part of Module 1: Introduction to Clinical Development: Challenges and Prospects.
- Provision of examination questions (MCQs) on lectured topic

**September 2014-February 2015: Postdoctoral Research Assistant**, Department of Clinical Sciences, Liverpool School of Tropical Medicine.

- Fully funded Malaria Capacity Development Consortium Postdoctoral Fellowship to carry out continuation of my PhD research as the GALACTIC study at the Malawi-Liverpool-Wellcome-Trust.

**March 2012-February 2014: Lecturer DTM&H Course**, London School of Hygiene and Tropical Medicine.

- Delivery of annual lecture "On the front lines of Lassa fever"

**November 2011-November 2014: Lecturer East African DTM&H Course**, London School of Hygiene and Tropical Medicine.

- Delivery of lectures on tropical diseases including malaria and viral hemorrhagic fevers including Lassa fever.
- Clinical tutoring on cases admitted at the Kilimanjaro Christian Medical Center.

**February 2007-March 2010: Clinical Monitor**, African Malaria Network Trust, Tanzania.

- Providing consultant medical monitoring services to the Phase 1b MSP3-LSP malaria vaccine trial, Sotuba, Mali.
- Providing consultant medical monitoring services to the Phase 1 AMA-1 malaria vaccine trial, Bandiagara, Mali.

**October 2004-March 2010: Research Clinician**, Malaria Program, Medical Research Council (UK) The Gambia.

- Provision of clinical care to participants enrolled in malaria trials, adequate documentation, and supervise the fieldwork according to study protocol.
- To conduct surveillance for morbidity and mortality among study participants.
- To provide up to date research activities and liaise with the sponsors, local trial and safety monitors.

**June 2006-March 2009: Physician-in-charge: Accident and Emergency Department, and Physician Anti-Retroviral Therapy (ART) Program**, AFPRC. Hospital, Farafenni, The Gambia.

- Providing immediate medical care to patients with acute and life-threatening conditions.
- Management of the treatment of infectious disease complications in HIV patients.

**March 2004-September 2004: United Nations Lassa Fever Consultant**, United Nations Mission to Sierra Leone, Kenema Government Hospital, Kenema, Sierra Leone.

- Management of all cases of Lassa fever and other viral hemorrhagic fevers in UN personnel stationed in Sierra Leone including at the various Level 1 and 2 Field Hospitals and the Lassa Fever Isolation Unit.
- Management of staff in the Lassa Fever Isolation Unit of the Kenema Government Hospital.

**April 2003-September 2004: Senior Medical Officer in charge of Military personnel and families**, in the Eastern and Southern Province of Sierra Leone.

- Provision of medical care to the personnel and families of six battalions stationed.
- Maintenance of Public Health and Sanitation services in all military deployments.
- Management of staff and resources in a Level 1 Field Hospital.

**April 2003-March 2004: Volunteer Physician**, Lassa Fever Isolation Unit, Kenema Government Hospital.

- Physician volunteer working with the then consultant Dr. Aniru Conteh in the management of patients with Lassa and other viral hemorrhagic fevers.

**December 2003-September 2004: Clinical Supervisor**, International Rescue Committee's Sexual Assault Referral Centre, Kenema Government Hospital, Kenema, Sierra Leone.

- Management of cases of sexual assault presenting at the IRC Rainbow Center in Kenema Government Hospital.

**October 2002-March 2003: Medical Officer-in-charge (post-SLMDA registration)**, Accident and Emergency Unit, 34 Military Hospital, Wilberforce, Sierra Leone.

- Providing immediate medical care to patients with acute and life-threatening conditions.
- Management of all A&E military and non-military A&E staff.

**October 2000-September 2002: House Officer (pre-SLMDA registration)**

- House Officer supervised general rotations in the Medical, Surgical, Ob/Gyn and Pediatric Departments.
- House Officer supervised specialist rotations at the Orthopedic, Neurology, Internal Medicine, Medical Intensive Care, Fertility Clinic, Pediatric Intensive Care and Pediatric Oncology Departments.

**October 2000-March 2003: Clinical Demonstrator and examiner**, Department of Histopathology, College of Medicine and Allied Health Sciences, University of Sierra Leone.

- Demonstrating gross pathology in tissues and organs to aid 3<sup>rd</sup> and 4<sup>th</sup> year medical students identify disease processes.
- Preparation of examination specimens for practical exams and MCQ examination question for final exams

<b>Publications</b>	<ol style="list-style-type: none"> <li>1. <b>Safety and Immunogenicity of Live-Attenuated Intranasal RSV Vaccine in 6-18-Month-Old Toddlers.</b> In press.</li> <li>2. <b>Neonatal Seizures: Case Definition &amp; Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data.</b> Vaccine. 2019 37 (52): 7596-7609.</li> <li>3. <b>Failure to thrive: Case definition &amp; guidelines for data collection, analysis, and presentation of maternal immunization safety data.</b> Vaccine. 2017 35(48 Pt A):6483-6491.</li> <li>4. <b>Safety, immunogenicity, and lot-to-lot consistency of a split-virion quadrivalent influenza vaccine in younger and older adults: A phase III randomized, double-blind clinical trial.</b> Hum Vaccin Immunother. 2017 2:1-13.</li> <li>5. <b>Surveillance in easy-to-access population subgroups as a tool for evaluating malaria control progress: A systematic review.</b> PLoS One.2017 12(8):e0183330.</li> <li>6. Phase 1 randomized controlled trial to evaluate the safety and immunogenicity of recombinant Pichia pastoris-expressed Plasmodium falciparum apical membrane antigen 1 (PfAMA1-FVO [25-545]) in healthy Malian adults in Bandiagara. Malar J. 2016 15(1):442.</li> <li>7. Combining data from multiple spatially referenced prevalence surveys using generalized linear geostatistical models. J R Stat Soc. 2015, 178(2):445-464.</li> <li>8. <b>Lack of decline in childhood malaria, Malawi, 2001–2010.</b> Emerg Infect Dis [serial on the Internet]. 2012 Feb</li> <li>9. <b>Randomized trial of safety and effectiveness of chlorproguanil-dapsone and lumefantrine-artemether for uncomplicated malaria in children in The Gambia.</b> PLoS One. 2011; 6(6):e17371.</li> <li>10. <b>A trial of intermittent preventive treatment and home-based management of malaria in a rural area of The Gambia.</b> Malaria Journal 2011, 10:2.</li> <li>11. <b>Efficacy and safety of a new fixed-dose oral combination of pyronaridine/artesunate versus artemether/lumefantrine in children and adults with uncomplicated Plasmodium falciparum malaria.</b> Lancet, April 2010, 375: 1457 – 1467.</li> <li>12. <b>Changes in malaria indices between 1999 and 2007 in The Gambia: a retrospective analysis.</b> Lancet, November 2008, 372: 1519 – 1606.</li> <li>13. On the Frontlines of Lassa fever. Emerging Infectious Diseases: Vol 10, No. 10, Oct 2004.</li> <li>14. <b>Treatment protocols in the supportive management of Lassa fever</b> (a manual). Published jointly by Medical Emergency Relief International Sierra Leone Office (Merlin/SL) and MoH/SL, June 2004.</li> <li>15. <b>Lassa fever – Practical Guidelines</b> (a manual). Published jointly by the United Nations Mission to Sierra Leone (UNAMSIL) and the Ministry of Health in Sierra Leone (MoH/SL), April 2004.</li> </ol>
<b>Professional registrations</b>	<ol style="list-style-type: none"> <li>1. Registered General Physician: Sierra Leone Medical and Dental Council 2002-2004.</li> <li>2. Registered General Physician: Gambian Medical and Dental Council 2004-2010.</li> <li>3. Registered General Physician: Medical Council of Malawi 2010-2015.</li> </ol>
<b>Patents</b>	November 2024-date: WO2024233873A1 Respiratory syncytial virus vaccine and methods of use.

<b>Professional certificates</b>	<ol style="list-style-type: none"> <li>1. LEAD – Transforming organizations with collaborative methods.</li> <li>2. Scrum Team Member</li> <li>3. Lean Six Sigma Green Belt</li> <li>4. Biomedical Innovation and Entrepreneurship</li> <li>5. Monitoring and Evaluation of Malaria Programs</li> <li>6. Project Management in Clinical and Epidemiological Research</li> <li>7. Scientific Aspects of Clinical Trials in Infectious Disease Protocol Development</li> <li>8. Data and Safety Monitoring Board Member</li> <li>9. Advanced Research Ethics</li> <li>10. Good Clinical Practice</li> <li>11. Clinical Trial Monitoring</li> <li>12. HIV/AIDS/Cancer Palliative Care</li> </ol>
<b>Professional organizations</b>	<ul style="list-style-type: none"> <li>• Sigma Xi Scientific Research Honor Society</li> <li>• Institute for Biomedical Entrepreneurship (IBE) Alumni</li> <li>• Liverpool School of Tropical Medicine Alumni</li> <li>• London School of Hygiene and Tropical Medicine Alumni</li> <li>• HIC-VAC Consortium</li> <li>• Brighton Collaboration</li> <li>• American Association for the Advancement of Sciences</li> <li>• International Society for Infectious Diseases</li> <li>• International Epidemiological Association</li> <li>• American Society of Tropical Medicine and Hygiene</li> </ul>
<b>Specific skills and expertise</b>	<ul style="list-style-type: none"> <li>• Novel Vaccine Development</li> <li>• Clinical Trial Design and Conduct</li> <li>• Clinical Development</li> <li>• Controlled Human Infection Studies</li> <li>• Protocol Development</li> <li>• Post-Licensure Vaccine Safety Surveillance</li> <li>• Clinical Trial Monitoring</li> <li>• Research Ethics</li> <li>• Mucosal Vaccines</li> <li>• Regulatory Submissions</li> <li>• Clinical Trial Management System</li> <li>• Electronic Data Capture</li> <li>• Informed Consent Process</li> <li>• Monitoring and Evaluation</li> <li>• Epidemiological Surveillance</li> <li>• Infectious Diseases</li> <li>• Stakeholder Management</li> <li>• Project Management</li> </ul>

<b>Addendum</b>	<p>This section is intended to provide further information on key roles in my professional experience on request. This information is confidential and should not be shared with other parties without my knowledge or consent.</p>
<b>Professional experience</b>	<p><b>December 2021-date : Transformation Leader (Clinical)</b> – Acceleration &amp; Efficiency, Vaccines R&amp;D Sanofi, France.</p> <ul style="list-style-type: none"> <li>• In this role, I engaged with NV Global Project Teams, Global Clinical Development functions and Clinical Teams to identify &amp; design solutions focusing on Clinical Development activities to optimize NV projects' critical paths.</li> <li>• Together with a co-business lead from the Operational Leadership, I successfully transformed the Clinical Trial Preparation of the whole Vaccines R&amp;D defining a new standard for the preparation of the conduct of clinical trials, surmised into a new Quality Document.</li> <li>• We conducted trainings in all Global Clinical Development functions, Clinical Teams and Business Units as part of a structured Change Management Program.</li> <li>• This success resulted in my selection for the prestigious internal Leadership Excellence Training program in 2025</li> </ul> <p><b>March 2015-December 2021: Clinical Team Leader/Global Clinical Development Strategy Expert (GCDSE)</b>, RSV and Influenza Franchise, Sanofi, France.</p> <ul style="list-style-type: none"> <li>• I served seven years as a Global Clinical Development Strategic Expert (GCDSE) in the Influenza and RSV Franchises, including three years as the GCDSE managing the clinical development for all RSV programs.</li> <li>• I managed the late-stage development of a subunit Influenza vaccine (Vaxigrip Tetra®) up to licensure in the first three years of my role.</li> <li>• From then on, I managed all RSV vaccines including one jointly managed asset with AstraZeneca (licensed as Beyfortus®), and two internal assets: a live attenuated RSV vaccines for toddlers and an RSV vaccine for older adults.</li> <li>• During my tenure as a GCDSE, I was intimately involved in Global RSV policy groups as the Sanofi Vaccine Expert, including the World Health Organization (WHO) Guidelines on the quality, safety and efficacy of respiratory syncytial virus vaccines (Annex 2, TRS No 1024) and the Innovative Medicines Initiative (IMI) Respiratory syncytial virus consortium in Europe (RESCEU).</li> <li>• I was also led the clinical development of a variety of other discovery and preclinical projects, and the internal clinical feasibility assessment for some assets to determine their probability of success and fit for inclusion in the New Vaccines Portfolio.</li> <li>• Depending on the phase of development of the project and prio in the New Vaccines pipeline, I led a team of approximately 10 to 30 individuals in the Extended Clinical team in a matrix environment.</li> </ul> <p><b>October 2004-March 2010: Research Clinician</b>, Malaria Program, Medical Research Council (UK) The Gambia.</p> <ul style="list-style-type: none"> <li>• In this role, I was involved in the design and implementation of clinical trials of antimalarial drugs, as well as malaria epidemiology studies.</li> <li>• In the first two years, I was the Lead Investigator of the GSK-sponsored LapDap® Phase III trial in the Gambia.</li> <li>• I was the Principal Investigator of the MRC-sponsored trial evaluating the potential benefits of combining IPT in children with home management of malaria.</li> <li>• I was the Principal Investigator of the EDCTP-sponsored PYRAMAX Phase II and III trials conducted in the Gambia.</li> <li>• I was a Lead Investigator in the landmark epidemiological study that was the first to conclusively demonstrate the impact of malaria interventions on malaria transmission (Ceesay et al).</li> <li>• Depending on the phase of the clinical trial, I led a team of approximately 20 to 40 clinical trial site direct reports.</li> </ul>

