LOVELYN CHARLES

Medical & Regulatory Writing — Vaccines, Emerging Infectious Diseases and Post-Approval

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PROFILE

I write the clinical and regulatory documents that move programmes forward: protocols, Investigator's Brochures, Clinical Study Reports, DSURs, post-marketing commitments and funding submissions. A decade of vaccine and infectious disease work sits behind the words. I was clinical science lead for the post-approval programme of a licensed monoclonal antibody for Ebola, where I owned the FDA post-marketing requirements. I have also led clinical science on a Phase 1 vaccine study for a disease with no approved vaccine, and managed investigational product on Phase 2 trials for GSK and Johnson & Johnson in West Africa. I know why these documents are written the way they are, because I have also had to execute against them across the full lifecycle, from first-in-human to post-approval.

DOCUMENTS I WRITE

Clinical study protocols and amendments · Investigator's Brochures · Clinical Study Reports (ICH E3) · Informed Consent Forms and plain-language summaries · FDA Type C meeting briefing packages · Development Safety Update Reports (DSURs) and aggregate safety narratives · Peer-reviewed manuscripts, abstracts and posters · ClinicalTrials.gov registrations and results postings · Clinical summaries for regulatory submission · Study procedures manuals and site-specific addenda · Clinical sections of grant and funding applications

FUNDING & GRANT SUBMISSIONS

Authored an executive summary report to support governance review, stage-gate assessment and strategic decision-making for a clinical development programme, and the clinical sections of funding submissions supporting a neglected tropical disease vaccine programme, including the adaptive trial design synopses underpinning Phase 2 and Phase 3 planning. Completed Policy Development and Advocacy for Global Health at the University of Washington. I take on grant and funding work for epidemic-preparedness and neglected-disease funders such as CEPI, BARDA, the Gates Foundation and Wellcome. It is writing that requires understanding both the science and how funders read, which few writers can cover credibly.

THERAPEUTIC FOCUS

Vaccines and therapeutics — viral haemorrhagic fever, Ebola, Lassa, meningococcal, COVID-19 · Emerging infectious disease and biodefense · Adult, adolescent, paediatric and infant populations · First-in-human through Phase 3 and post-approval · Post-marketing requirements (PMR / PMC) · Multi-country and LMIC trials

SELECTED EVIDENCE

— **Clinical science lead, post-approval programme for a licensed monoclonal antibody for Ebola** — owned the FDA post-marketing requirements and commitments, from study design through delivery.

— **Clinical science lead, Phase 1 Lassa fever vaccine trial** — executed the full Phase 1 study, and authored the CSR and adaptive trial design synopses for Phase 2 and Phase 3.

— **Co-author of two books** — *Clinical Trials: Design, Execution and Analysis*, and *Post-Marketing Surveillance: Identifying Outcomes in the Community*, Apteryx Media Inc. 2026.

— **Unblinded pharmacist on two Phase 2 vaccine trials** — the first Ebola vaccine trial conducted in Nigeria (GSK) and a prime-boost regimen for Johnson & Johnson whose product is now authorised in the EU.

— **Site and study manager, UBC Vaccine Evaluation Center, Vancouver** — managed a Phase 3 meningococcal vaccine trial, coordinated the MOSAIC Canada study during the COVID-19 pandemic, and was unblinded pharmacist on an infant Phase 2/3 study.

— **ClinicalTrials.gov PRS Administrator, Emergent BioSolutions** — trial registration and results disclosure across the portfolio, the statutory transparency obligation under FDAAA 801.

— **Published co-author on Lassa vaccine safety** — a Brighton Collaboration BRAVATO benefit/risk template for a VSV-vectored Lassa fever vaccine (*Vaccine*, 2025), and a CEPI SPEAC report on sensorineural hearing loss in Lassa virus disease.

— **Enrolment target exceeded** — 531 participants against a target of 500, ahead of schedule, with no delays attributable to investigational product supply or cold chain.

— **Five multi-country trials delivered across four therapeutic areas** as CRO project manager, on time and on budget.

CREDENTIALS

MSc Pharmaceutical Sciences, University of British Columbia · MSc Pharmaceutics & Drug Delivery and B.Pharm, University of Nigeria · ACRP-CP® · PEBC International Pharmacy Credential Assessment · ICH-GCP · Health Canada Division 5 · TCPS 2 · Writing in the Sciences, Stanford University · Member, American Medical Writers Association

ENGAGEMENT

Remote, Pacific Time, with overlapping European and North American hours. Fixed fee per document, or day rate where a programme needs ongoing support. Comfortable working inside sponsor or CRO systems and templates. Rates on request. Available from August 2026.