



# JACQUES HERVÉ

EXPLORA CONSULTING SERVICES



## CORE COMPETENCIES

- Clinical operations
- Study management
- Phase I to Phase III studies
- CRO experience
- Non-Profit Organizations experience
- Biotech experience
- Big Pharma experience
- Line management
- Full study lifecycle
- Study documents preparation
- Cross-functional oversight
- Study reporting
- Regulatory and Ethics submissions
- CRO/vendor bidding
- Study implementation
- Clinical Trial Risk Management



## PROFESSIONAL EXPERIENCE


**Director, Clinical Operations** Medicines for Malaria Venture (MMV) - Geneva, Switzerland  
01/2024 - 03/2026


- Lead end-to-end operations of MMV clinical trials (Phases I-II)
- Align operational strategy with MMV scientific and strategic objectives
- Accountable for clinical risk management, safety and data integrity
- Develop and maintain SOPs, tools and systems to optimize performance
- Oversee trial budgets, timelines, quality metrics and vendor performance
- Drive continuous improvement and process innovation within Clinical Ops
- Represent MMV externally with partners, CROs and sites (incl. bid defenses)
- Explore and implement emerging technologies (e.g., AI for clinical research)

**Associate Director Clinical Operations** Medicines for Malaria Venture (MMV) - Geneva, Switzerland  
01/2019 - 01/2024

- Supported the clinical operations leadership in the planning and execution of MMV-sponsored clinical trials (Phase I-IV), with a focus on early-phase development.
- Provided operational oversight of early-phase trials, including planning, execution, reporting, and issue resolution.
- Identified operational risks and implemented mitigation and corrective actions in collaboration with Quality
- Ensured ICH-GCP and regulatory compliance across trial design and conduct.
- Advised on operational aspects of partner-sponsored trials, contributing MMV's added-value expertise.

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With over 25 years of expertise in clinical operations and study management, I have successfully contributed to a wide range of Phase I to Phase III complex international studies. My career spans diverse roles across Contract Research Organisations (CROs), Non-Profit Organisations, Biotech firms, and major pharmaceutical companies.

- Collaborated with internal functions (Regulatory, Medical, BD, Legal, Finance, CMC, Quality) to optimise trial delivery.
- Recruited and oversaw clinical trial management staff and contributed to CRO and vendor selection processes.
- Reported on key trial metrics relating to quality, timelines, productivity, and budgets

■ **Senior Clinical Trial Lead** Novartis Institutes for Biomedical Research (NIBR) - Basel, Switzerland  
06/2017 - 10/2019

- Led complex Phase 2 Proof-of-Concept studies across multiple therapeutic areas within Translational Medicine (TM). Responsible for operational delivery from concept to reporting, ensuring ICH-GCP and Novartis standards.
- NASH (Metabolic Disease) PoC — US, Europe, Australia/NZ, China - 25 sites 221 patients completed
- Hidradenitis Suppurativa (Dermatology) PoC — US, Europe - 20 sites 90 patients completed

■ **Head of Clinical Operations** Genkyotex Innovation - Geneva, Switzerland  
10/2011 - 04/2016

- Led Phase 1 and Phase 2 programs, managing teams and ensuring timely, budget-aligned delivery of results.
- Completed 4 Phase 1 studies within 2 years (SAD, MAD, DDI, food effect)
- Phase 2 PoC – Diabetic Nephropathy conducted in US, Europe & Australia 26 sites / 112 patients completed — delivered on time and on budget

■ **Senior Clinical Operations Manager** PATH (Program for Appropriate Technology in Health) - Geneva, Switzerland  
07/2009 - 09/2011

- Led clinical operations for a multi-study Phase 3 program in Sub-Saharan Africa
- Contributed to marketing authorization of a new meningitis vaccine
- Vaccine now widely used across the African meningitis belt
- Global health organization partnered with WHO and funded by the Bill & Melinda Gates Foundation.

■ **Clinical Operations Manager** ORION Clinical Services - Melbourne, Australia  
10/2005 - 07/2009

- Set up and led ORION's Australian clinical team; coordinated multinational Phase 3 studies in oncology, pain, and urology.
- Managed 53 sites / 292 patients enrolled



## QUALIFICATIONS

■ **M.Sc. : Drug Development**  
**University of Pharmacy** - Rennes, France, 01/1994

■ **B.Sc. : Human Biology**  
**University of Sciences** - Rennes, France, 01/1993

■ **Advanced Degree : Biomedical Research**  
**Ecole Supérieure de Biologie Appliquée** - Paris, France, 01/1991