

## OBJECTIVE

Clinical research leadership, consulting, and data science

Bridging clinical science and technology to drive innovation and speed; Mixing vision with a hands-on approach; Incorporating machine learning technologies in clinical research processes.

## PROFILE

Accomplished biometrics and clinical research leader with more than 25 years of experience spanning biometrics, data science, data management, data analysis and visualization, and information systems; 15 years of Biometrics experience for phase I to IV studies in various therapeutic areas, and several years of technical experience in software engineering and information systems. Trained as a physician with graduate degrees in biostatistics and clinical informatics.

## RELEVANT EXPERIENCE

- Biometrics Head at InCarda – 4 years
- Vendor management in several Biotech (CytomX, Corcept) – 3 years
- Information Systems, programming and Validation at EORTC (oncology) – 3 years
- Platform Director / CTO at GEREQ/McGill - 6 years
- CEO / Head at EZUS / ClinInfo - 8 years
- Therapeutic Areas:
  - Cardiovascular
  - Medical Devices
  - Infectiology
  - Pain
  - Oncology
  - Metabolic Diseases
  - CNS
  - Pediatrics

## CREATE VALUE THROUGH

- Translating complex data and statistical results into clear, visual stories
- Speeding-up data cleaning and analysis readiness through AI driven tools and processes
- Bringing a strategic vision with hands-on technical skills and delivery
- Unique blend of medical training, statistical expertise, and software engineering incl. AI
- Biometrics programming using modern toolkits (R/Shiny, Python/Pandas/Dash/Plotly, SAS)
- FDA and EMA submissions preparation and review
- Regulatory and inspection readiness

## SELECT PROFESSIONAL SKILLS

- Comprehensive and in-depth knowledge of the clinical research process
- Multilingual programmer with fluency in R (Pharmaverse), Python, SAS, Java, JavaScript
- Full-stack data science expertise
- CIOMS and SuSAR safety reporting
- CDISC standards and regulatory compliance
- CSV validation, GxP compliance
- Clinical data quality processes and norms
- CRO & Vendor Governance
- Leading teams to excellence

## STRENGTHS

Quick understanding of problems and needs  
High quality fast delivery of outputs and solutions  
Excellence driven responses to requests

## MAIN ACCOMPLISHMENTS

- Development of a full featured EDC system used by 300 studies, 6,000 sites, and 20,000 patients
- Founder and manager of Clininfo: biometrics services, 12 staff, positive revenues incr. 25%/year
- Fully automated data and analytic pipeline generating PK and TLFs from EDC for a phase I unit
- Automatic pipeline for EDC daily reports and a clean patient tracker delivered by email
- Meta-analysis of 5 clinical studies consolidated previous findings leading to a device redesign
- Full phase III SDTM, ADaM & TLFs at a fraction of the cost and half the time of the competition
- Data visualizations Report in R for thousands of samples, lab results, and patient characteristics
- Rescue validation of 3 in-house application leading to successful sponsor re-audit
- CAPA investigation, root cause analysis resulting in remediation, new SOPs, re-training, and success
- In charge of Rave URL/instance: user, study, DB
- 30 articles and conferences, cited 393 times