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OBJECTIVE

Providing comprehensive clinical research support in data science, data management, biostatistics, programming, quality assurance, software engineering, and computer system validation.
Bridging clinical science and technology to drive innovation and speed; Blending vision with a hands-on approach; Incorporating machine learning technologies in clinical research processes.

PROFILE

Accomplished biometrics and clinical research leader with more than 20 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

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

STRENGHTS

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

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 including AI
- Biometrics programming using modern toolkits (R/Shiny/Admiral, Pandas/Dash/Plotly, Git, Jira)
- FDA and EMA submissions preparation and review
- Regulatory and inspection readiness

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