CURRICULUM VITAE

Adam Daniels



Senior manager: clinical systems, product ownership and AI-assisted development

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I take clinical systems from selection to live use: requirements, configuration, testing, process documentation, training and change management, then running them day to day. I have done this as CTMS business owner at GW Research and through two global migrations at Jazz Pharmaceuticals, on Medidata and Veeva. I directed validation and UAT so each system stayed ready for inspection under GCP and FDA 21 CFR Part 11. I have assessed eTMF, EDC, eCOA, RTSM and eQMS systems and recommended which to adopt. Before that I spent 16 years delivering trials, from site monitoring to managing GW's pivotal epilepsy trials across Europe. That is how I know what trial teams need from their systems. I now also build AI-assisted software to GxP standards, including epiClavis, a validation plug-in for regulated industries.

01 · Experience

Independent

epiCorpus 2025 to present

Built **epiEspañol**, a Spanish translation service with payments built in, which is not yet live. Ran the whole build with Claude as an AI coding assistant: React front end, serverless functions, Postgres database and payments. Designed custom agents and skills that hold the work to the project's standards. Developing epiClavis, a plug-in that applies GxP validation standards to software for regulated industries. Each change is justified, decisions are recorded and the evidence is ready for audit.

Senior manager, GCDO technology

Jazz Pharmaceuticals 2021 to 2025

Business owner for the CTMS on Medidata and Veeva. Led two global migrations from start to finish, covering requirements, configuration, testing, rollout, process documentation, training and change management. Managed the system day to day after each go-live. Evaluated clinical technologies across the company, among them eTMF, eCOA, EDC, Veeva SSU and Site Connect, and recommended which to adopt. Worked with data engineering on Clinical Data Factory pipelines and defined Power BI dashboard requirements for clinical teams. Directed validation and UAT so the systems stayed ready for inspection under GCP and FDA 21 CFR Part 11.

Clinical systems development manager

GW Research 2019 to 2021

Led the CTMS implementation from start to finish as business owner. Chose the vendor, agreed requirements with the people who would use the system and configured it to meet them. Directed testing and validation, wrote the process documents, trained users and managed the change across the company. After go-live, managed the system day to day. Evaluated clinical technologies for GW's clinical operations, including eQMS, eTMF, eCOA, Safety Gateway and RTSM.

Clinical project manager, then EU manager

GW Research 2014 to 2019

Managed GW's pivotal epilepsy trials across Europe, including trial set-up, site management, monitoring, cross-country co-ordination, and regulatory and ethics submissions. Set milestones, built recruitment projections and oversaw staff training.

Senior associate, lead CRA, CRA

Amgen, Genzyme, Harrison Clinical Research, Quintiles 2003 to 2014

Progressed from site monitoring to overseeing CRA work across the EU at Genzyme, then to senior associate at Amgen. Managed site monitoring, regulatory submissions, budgeting, forecasting and continuous improvement across several therapeutic areas.

02 · Skills

CLINICAL SYSTEMS

CTMS business ownership (Medidata, Veeva) · end-to-end implementation: vendor assessment and selection, requirements, configuration, testing, process documentation, training, change management and live support · eTMF · EDC · eCOA · eQMS · RTSM · Veeva SSU and Site Connect · Safety Gateway

QUALITY AND COMPLIANCE

GxP · GCP · GAMP 5 · ALCOA+ · 21 CFR Part 11 · EU Annex 11 · computerised-system validation · UAT direction · inspection readiness · regulatory and ethics submissions · requirements and traceability

DELIVERY

Product ownership · Agile and waterfall · Jira · Miro · backlog and user stories · stand-ups and retrospectives · process and change management · budgeting and forecasting · milestones and recruitment projections · staff training · continuous improvement · executive reporting

DATA AND BUILDING

Power BI · Tableau · dashboard requirements · Clinical Data Factory pipelines · VBA · AI-assisted development · React · Supabase · Vercel

03 · Education

DEGREE	BSc (Hons) Biochemistry (Pharmacology), University of Surrey
CERTIFICATIONS	Agile Certified Product Manager & Product Owner (ACPM), Platinum Edge · Lean Six Sigma Yellow Belt, The Knowledge Academy
LANGUAGES	English (native) · Spanish (basic, improving)
BASED	Sitges, Barcelona · open to remote and hybrid work, and to travel