

VANCE WARREN

Clinical Science Ops Consulting (Phase 1 - Phase 1b)

Purpose-built early phase execution, Clinical Science • Monitoring (CRA) • Operations • USA + Asia

PURPOSE-BUILT FOR URGENT AND RESCUE SCENARIOS

Outcome: safety-first conduct, inspection-ready documentation across the lifecycle, and high-quality PK/PD data.

Safety-first • Data integrity

Sponsor-side + CRO fluency

USA + APAC-ready delivery

30+ YEARS EXPERIENCE ACROSS AstraZeneca, Novartis, Daiichi-Sankyo and BMS

S Clinical Science

- Drug Development Strategy team contributor when required
- Study design support for FIH/SAD/MAD/Phase 1b; PK/PD and dose escalation
- Pre-clinical and non-clinical insight and close collaboration
- Protocol, ICF, and CSR clinical sections: authoring, review, and comment resolution
- Clinical conduct oversight - protocol related
- Clinical data review, trend identification, and decision support for teams
- Scientific liaison with pre-clinical/non-clinical functions, CROs, sites, and cross-functional stakeholders

Phase 1 study focus

- Healthy volunteer and patient studies (Phase 1 - Phase 1b)
- FIH, SAD, MAD; dose escalation decision support
- DDI, food effect, rBA/BE, TQTc, human ADME
- Special populations (renal/hepatic), ethnic bridging

M Clinical Monitoring (CRA)

- Risk-based monitoring aligned with ICH-GCP and early phase best practices
- SQV/SIV/IMV/COV support; site and vendor training for Phase 1 workflows
- Issue escalation, documentation quality, and CAPA follow-through
- Inspection readiness mindset: critical process and data oversight

Engagement model

- Extension of your early phase drug development team or an outsourced Phase 1 function
- Flexible support: strategic outsourcing plan or strategic partner model
- Single-study support for Phase 1 and Phase 1b programs
- Geographic coverage: USA, and APEC member countries

O Clinical Operations

- End-to-end Phase 1 study management: startup through DBL and CSR support
- CRO/CPU selection, RFP and bid defense support; timeline and budget control
- Sample logistics: acquisition, processing, shipment, and BA/PD reconciliation
- Vendor oversight across labs and specialty providers; KPI and risk management

Contact

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