

From Listings to Leadership: 18 Years of Statistical Programming Outsourcing

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Evolution of Outsourcing

- 18-year journey from simple listings to protocol leadership
 - Growth from one partner to multiple global partners
 - Rising expectations/aspiration and tech-driven complexity
 - Resource churn affects both partners and sponsors
 - Outsourcing maturity, stable governance, and increased expectations over nearly two decades
 - Retention, WFH/Hybrid issues, Moonlighting challenges
 - Reduced outsourcing value due to continuous cost escalation

Survey



The questions used to collect feedback from partners (2 Global Technology, 3 CROs U.S.- and India-based) contributed to this paper.



How do you assess the overall impact of AI/ML on the addressable market for outsourced statistical programming over the next 3–7 years?



Given the likely automation of routine programming tasks, how is your company repositioning its service offering to capture new, higher-value work?

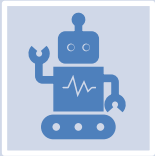


What proportion of your current revenue do you expect to be most at risk from AI/ML automation, and how are you planning to replace or offset that revenue?



Are you pursuing a “build, buy, partner” approach to AI capabilities? Why did you choose that route?

AI/ML Market Impact (Next 3–7 Years)



Market reshapes, not shrinks

Automation reduces routine effort

Demand increases due to trial complexity & regulations

Human judgment becomes more—not less—valuable



Automation of Routine Tasks

Standard TLF generation

QC automation, code translation using GenAI

Still essential: human-in-the-loop for methods, context, and rigor



Revenue at Risk

20–70% revenue at risk depending on service mix

Advanced analytics, governance, and design work expand

Net effect: market reshapes with higher-value mix

Strategic Repositioning



Shift to value-centric consulting

AI governance & oversight services
Interpretation and communication of outcomes



Workforce Transformation

Upskilling in AI/ML and data science

- Hybrid roles and centers of excellence
- Crowdsourcing models for specialized tasks



Business Model Evolution

Shift from volume to value-based pricing

- Tiered pricing for AI-assisted workflows
- Subscriptions for continuous analytics support

Operating Model Evolution



Value-focused scoping

Hybrid/tiered pricing

Contracts requiring AI transparency, privacy, and audit trails

Outcome- and value-based contracting (KPIs, SLAs)

Subscriptions for continuous analytics and insights



Build–Buy–Partner Strategies

Hybrid approach dominates

- Internal platforms + external collaborations
- Need for strict AI governance and auditability



Workforce: Talent shift

Regulatory, ethical, and validation know-how

Centers of Excellence, hybrid roles, and coaching pathways

Task Landscape

Outsourced: complex modeling, regulatory submissions

- Automated: data cleaning, standard analyses
- Hybrid: interim analysis, RWE with expert oversight

Sponsor Actions

- Bring routine analytics in-house
- Contract based on KPIs, outcomes, automation maturity
- Invest in oversight, metric standardization, lineage tools

CRO Actions

- Shift to complex, high-trust services
- Build validation platforms and reusable libraries
- Upskill teams & create AI Centers of Excellence

Conclusion

Routine work will shrink, but the outsourced market expands

- AI enables value-focused services
- Governance and talent investments are critical

Transformation of Outsourcing

Outsourcing in clinical research is evolving from routine tasks to strategic, high-value services.

AI Augmentation

AI enhances human judgment, enabling faster, smarter, and more compliant clinical workflows.

Strategic Success Factors

Success requires evolving models, strong governance, and talent skilled for the AI era.

Call to Action

Embrace innovation, expertise, and partnerships for a technology and human insight-driven future