GLOBAL
REGULATORY WRITING & CONSULTING

CASE STUDY

Managing Complexity: Abbreviated CSR Delivery for a Rare Disease Program

Therapeutic Area: Rare Renal Disease

Product Type: Monoclonal Antibody (mAb)

Document: Abbreviated Clinical Study Report (aCSR)

We support Medtech and Biopharma innovators with strong, collaborative partnerships, tailored regulatory consulting and writing services, and deep strategic expertise.

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GLOBAL'S MEDICAL WRITING CAPABILITIES

- Experienced writers with regulatory and therapeutic knowledge
- Flexible project management approach with customized solutions
- High quality deliverables with consistent client satisfaction
- Focus on efficient practices and streamlined workflows
- Integrative partnership versus provider-client relationship

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ABOUT THE CLIENT

The sponsor, a mid-sized biopharmaceutical company focused on rare, immune-mediated conditions, was supported by a broad cross-functional team spanning clinical operations, medical, and biostatistics. While experienced in clinical development, the team faced evolving timelines and coordination challenges typical of complex, mid-stage programs.

ABOUT THE PROJECT

This **Phase 2, multicenter study** focused on a rare renal condition with high unmet medical need and formed part of a broader clinical program. The aCSR was required as part of a larger set of regulatory documents supporting development progression.

Project scope included multiple writers over several weeks, with structured review cycles and coordination across global time zones.

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ABOUT THE PROJECT CONTINUED

Key challenges:

- Timeline variability due to shifting priorities and input bottlenecks
- Evolving statistical outputs requiring adaptive writing
- Inconsistent source materials across contributing functions
- Cross-functional stakeholder alignment, with input required from several functions simultaneously

GLOBAL's writing team led both document authorship and project governance, coordinating review cycles, comment resolution, and stakeholder communications.

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GLOBAL SOLUTIONS

The GLOBAL team brought several key capabilities to the engagement:

- Experienced, consistent writer support across the aCSR and related program documents
- Structured internal processes, including version control, staged reviews, and peer QC systems
- Proactive engagement with evolving client needs, including flexibility around shifting timelines, statistical updates, and content uncertainties

By maintaining continuity and responsiveness, the GLOBAL team helped reduce risk, clarify ownership, and keep the project aligned with evolving program priorities.

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OUTCOME

The aCSR was delivered within the revised timeline and met all quality expectations. It was integrated into a broader regulatory package supporting subsequent development milestones.

The engagement further strengthened the client's trust in GLOBAL's ability to provide strategic writing leadership and execution across program-level workstreams.

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CONCLUSIONS

This case illustrates GLOBAL's ability to navigate ambiguity, coordinate across stakeholders, and deliver high-quality regulatory documents under dynamic conditions.

It highlights the value of continuity in writer support, structured internal processes, and responsive client engagement, particularly for rare disease biologics where timelines, inputs, and cross-functional coordination can shift quickly.

This project remains a strong reference point for aCSRs in complex development programs, and a replicable model for future client engagements.

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