Case Study

Turning Regulatory Pressure into a Strategic Partnership: A Public Release of Clinical Information (PRCI) for a Large Biotech Organization

A large biotech sponsor required support for a high-stakes Public Release of Clinical Information (PRCI) submission to Health Canada under significant regulatory and operational pressure. MMS was engaged to rapidly establish structure, governance, and execution capability, delivering a compliant, end-to-end solution within a heavily compressed timeline.

The Challenge

MMS was engaged to lead a high-stakes Public Release of Clinical Information (PRCI) submission for a new sponsor under extreme operational and regulatory constraints. The engagement was greenfield, with no established frameworks inherited from the sponsor, and required full compliance with Health Canada PRCI standards.

Key constraints included:

- A 67% compressed timeline (4-week mandate versus a 12-week industry standard)
- A zero-failure mandate requiring complete regulatory compliance and data integrity

The Solution

MMS deployed a specialized, highly controlled operating model designed to deliver speed without compromising quality or compliance.

- Elite SME deployment with a targeted redaction strategy to protect intellectual property while meeting Health Canada requirements
- Operational governance using standardized workflows and real-time tracking to eliminate silos and accelerate review cycles
- Systemic resilience supported by 24/7 operational continuity with zero downtime across the critical submission path

The Results

The engagement delivered measurable outcomes that exceeded regulatory and sponsor expectations:

- Delivery completed in 4 weeks, three times faster than the industry standard
- 33,612 pages processed across 115 complex clinical documents
- 100% recall and completeness, with zero sensitive identifiers missed
- 99.8% precision and accuracy, minimizing over-redaction while preserving data utility

MMS evolved from a focused confidential commercial information (CCI) assessment role into full end-to-end PRCI lifecycle ownership, significantly broadening its impact across the sponsor's portfolio.

Through aligned SME teams, contingency planning, backup reviewers, alternate document versions, and parallel workflows, execution risk was proactively managed to ensure uninterrupted delivery.

Leveraging a follow-the-sun global delivery model, MMS produced submission-ready documents around the clock, maintaining continuous momentum across time zones.

By delivering flawless execution under intense regulatory pressure, MMS transformed a high-risk bottleneck into a repeatable, scalable delivery engine, securing trusted advisor status and a long-term partnership.

Key Success Factors

- A focused team of experienced SMEs enabled rapid decision-making, precise redaction strategies, and full alignment with Health Canada PRCI requirements
- Pre-defined workflows, governance checkpoints, and real-time tracking tools eliminated inefficiencies and ensured consistency across all documents
- Parallel workflows, backup reviewers, and contingency planning reduced execution risk and prevented delays across critical submission milestones

Let's Talk!

If you'd like to discuss this case study further or learn more on how our technology enabled services can support your development project, please visit **mmsholdings.com** or get in touch **info@mmsholdings.com**