

Case Study

Improving Oncology Decision-Making Through Advanced Survival Data Analytics

In oncology drug development, sponsors and regulators are often required to make critical decisions before overall survival (OS) data have fully matured. While interim analyses can provide early insight into a treatment's potential benefit, interpreting these results carries significant uncertainty. Friends of Cancer Research (*Friends*) convened a multi-stakeholder research initiative to examine how immature OS data can be interpreted more systematically. MMS partnered with *Friends* to develop a more rigorous, data-driven approach for evaluating immature OS data and understanding the risks associated with early decision-making. MMS applied its deep statistical expertise and simulation capabilities, including the use of KerusCloud®, to support the development of an evidence base and practical frameworks that can help inform clinical development and regulatory strategy.

The Challenge

Overall survival remains one of the most important endpoints in oncology research, but it is also one of the slowest to mature. Sponsors frequently need to make development, investment, and regulatory decisions based on interim analyses when only a limited number of survival events have occurred. At these early stages, apparent treatment effects may change significantly as additional data become available, making it difficult to determine whether early findings accurately reflect long-term outcomes. Additionally, early data looks play a crucial role in detecting potential harm, a consideration outlined in FDA's August 2025 draft guidance, *Approaches to Assessment of Overall Survival in Oncology Clinical Trials*.

Traditional approaches often rely on expert interpretation and historical experience, which can introduce variability and uncertainty into decision-making. Friends of Cancer Research recognized the need for a more systematic methodology that could help quantify risk, evaluate different scenarios, and provide stakeholders with greater confidence when interpreting immature OS results.

The Solution

MMS collaborated with *Friends* and participating stakeholders to develop a framework that uses advanced simulation and modeling techniques to evaluate interim overall survival data. Leveraging KerusCloud and MMS' statistical expertise, the team generated realistic oncology trial scenarios and explored how interim results might evolve as additional patient events accumulated.

By simulating a broad range of clinical outcomes, MMS helped assess the probability that an observed treatment effect or harm signal would persist, strengthen, or diminish over time. These analyses provided a structured way to evaluate uncertainty and quantify the risks associated with acting on immature data.

Rather than relying solely on subjective interpretation, the resulting framework established a transparent, evidence-based approach for examining interim OS findings. Assumptions could be clearly defined, tested, and communicated, enabling sponsors and regulators to make more informed decisions grounded in quantitative evidence.

The Results

The collaboration delivered a practical methodology for interpreting immature overall survival data and understanding the implications of uncertainty during drug development. Through simulation-driven analyses, stakeholders gained a more comprehensive view of the potential risks and opportunities associated with early efficacy or harm signals.

The framework is intended to support more consistent evaluation of interim findings, helping stakeholders consider whether emerging results should increase confidence in a treatment effect, raise concerns, or indicate that additional follow-up is required before action is taken.

Beyond addressing an immediate industry challenge, the project demonstrated the broader application of KerusCloud as a platform for evidence generation, statistical decision support, and regulatory strategy. The work also contributed to ongoing discussions across the oncology community regarding how innovative analytical approaches can improve the interpretation of complex clinical data.

Key Success Factors

- MMS brought extensive experience in oncology biostatistics, simulation methodologies, and regulatory science, enabling the team to translate a complex challenge into a practical analytical framework.
- The use of KerusCloud allowed MMS to model a wide range of clinical scenarios and evaluate outcomes that would be difficult to assess through traditional analytical methods alone.
- Working alongside *Friends* and the project multi-stakeholder participants created an opportunity to address a challenge that extends beyond any single sponsor or study, helping develop solutions with broad relevance to the oncology research community.
- The framework provides a structured way to characterize uncertainty and may offer stakeholders a more transparent and consistent basis for evaluating interim survival results and planning next steps.

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