123

Survival of the Fittest: Digitising Survival Data for Enhanced Decision-Making in Clinical Trials

James Sykes[1,2], Nelson Kinnersley[3,2]
[1]Blue Earth Diagnostics, Oxford, United Kingdom. [2]Blue Earth Therapeutics, Oxford, United Kingdom. [3]Octa Consulting, London, United Kingdom

James Sykes
Please provide a brief biography for the Presenting author(s)
James Sykes is a seasoned Statistician with over a decade of experience in the pharmaceutical industry. Over the course of nine years, he honed his expertise working for various Contract Research Organizations (CROs), predominantly in Oncology, contributing to numerous clinical development programs. In 2023, James joined Blue Earth Diagnostics as the Director of Biometrics, where he oversees the design, analysis, and interpretation of clinical data to support innovative diagnostic solutions. James also heads the Biometrics function at Blue Earth Diagnostics sister company, Blue Earth Therapeutics, which focuses on the development of innovative radiopharmaceuticals for the treatment of cancer. His career reflects a commitment to advancing healthcare through robust statistical methodologies and collaborative leadership.

Nelson Kinnersley
Please provide a brief biography for the Presenting author(s)
- Nelson Kinnersley is a Biostatistician with over 30 years of drug development experience in a variety of roles in Big Pharma and while consulting with numerous Biotechs. Nelson relishes working in cross-functional teams developing novel therapies for rare diseases &/or areas of high unmet medical need.
- Having worked on or managed teams through multiple Filings in USA, Europe and beyond, Nelson is also passionate about how Biostatistics can contribute to the design and analysis of Early Development studies.

Single topic, multi-speaker session, Workshop or Single presentation submission

A single presentation/poster

Single presentation or poster submission

Individual patient data (IPD) is widely regarded as gold standard for ensuring reliability and robustness of clinical data analysis. Digitizing survival data is one example of how we can reconstruct IPD from published figures.

In absence of IPD, decision-making often relies on models to approximate and represent data. For instance, exponential distributions could be used to fit survival curves based on specified median progression-free survival, enabling predictions of events at specific timepoints. This helps address key questions, like evaluating how effectively a new trial benchmarks against competitors at defined timepoints.

Challenges arise when chosen models fail to accurately reflect data it seeks to represent, potentially compromising the validity of analysis and/or the assumptions used to design a future trial. Moreover, even when models perform adequately, there is always an opportunity to explore approaches that may outperform traditional model-based methods.

To address these challenges, we leverage the **IPDfromKM** Shiny app to reconstruct IPD from published Kaplan-Meier survival curves. Through practical examples (oncology and

non-oncology), we compare traditional modelling methods with IPD-driven approaches, including:

1. **Piecewise exponential:** Using hazard rates from digitized IPD, we evaluate whether these models better capture sharp declines in survival or scenarios with non-proportional hazards.
2. **Bootstrapping:** Generating Kaplan-Meier curves from reconstructed IPD, we will explore their potential to quantify uncertainty in studies with smaller sample sizes.

We aim to demonstrate the versatility and potential advantages of IPD-based methods over traditional approaches, offering valuable insights into scenarios where conventional models fall short or additional refinement is needed.