exploristics
INNOVATIVE ANALYTICS SOLUTIONS

Case Study

Early Phase Oncology Trial

Biostatistics Support for an Early Phase Oncology Clinical Trial.

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The Challenge

A small privately owned immuno-oncology company had multiple development programmes in advanced melanoma and advanced pancreatic cancer. These involved the development of an investigational immunotherapy intended to complement other cancer therapies, including immune checkpoint inhibitors (CPIs) and chemotherapy.

Following completion of a successful first-in-human phase 1 study with this agent in adult patients with confirmed diagnosis of stage III or IV melanoma, the company wished to explore the long-term safety and tolerability of its continued administration. There was particular interest in observing the long-term survival of the individuals who had participated in the phase 1 study. In addition, the company wished to conduct an integrated safety summary (ISS) covering all completed studies for inclusion in the Investigators' Brochure. Oncology studies can be challenging for many statistical providers due to the complex data that are collected. Therefore, the company needed to work with an efficient, flexible statistics consultancy who could deliver high-quality results in a timely manner.

Exploristics' Biostatistics Services provided comprehensive support throughout the long-term follow-up study and during the production of the ISS, overseeing all data management and statistical analysis activities.

The Approach

Data Management and Study Set Up

Exploristics developed study documentation in accordance with the Clinical Study Protocol, to outline all data management and validation activities, ensuring transparency and integrity of the database throughout the study duration. The study database was designed to electronically capture all data recorded upon the paper case report form (CRF). Data validation programmes were run to efficiently identify any discrepancies in the data which needed to be queried. The database was reviewed by both the Medical monitor and by Exploristics on an ongoing basis and underwent thorough quality control (QC) checks and reconciliation processes prior to database lock. CDISC standards were applied to the data to ensure alignment with the best practice in the industry.

Statistical Analysis

Exploristics provided end-to-end statistics and programming support from the development of a detailed Statistical Analysis Plan (SAP), the generation of analysis-ready (AR) data to the production of tables, figures and listings (TFLs). An additional SAP, AR datasets and TFLs was produced for the integrated safety summary (ISS).

In addition to reporting common data, such as demographics, Exploristics developed the code to automatically define more complex outcomes relating to treatment emergent adverse events and survival. We also supported additional exploratory analysis to evaluate the impact of dosing and dosing schedules.

All the statistical outputs were delivered on time, on budget and to a high quality. This provided the company with the key evidence needed to invest in further development of the investigational immunotherapy.

The Impact

- The study demonstrated the long-term safety of the investigational immunotherapy and that both its dose can be reduced, and the dosing frequency can be extended over time. This has led to a further melanoma study trialing the investigational product (IP) in combination with a range of checkpoint inhibitors (CPIs).
- The results were submitted for publication in Pigment Cell & Melanoma Research and presented at the European Society for Medical Oncology (ESMO) Symposium on Immuno-oncology (2015) and the Society for Melanoma Research Congress (2019).
- The study received widespread media coverage, with one subject documenting their recovery for a national newspaper while participating in the study.

Testimonials

"These results are hugely encouraging. They suggest that [the IP] could be an effective first line treatment option for different types of metastatic cancers, which is a considerable step forward.

Professor Angus Dalgleish
Principal Investigator

"We have been able to record nine surviving patients at five years and eight surviving patients at eight years. This is encouraging data which forms a solid basis for and reinforces the hypothesis behind our ongoing phase 2 study of [the IP] in combination with checkpoint inhibitor therapy in advanced melanoma.

Dr Alberto Fusi
Principal Investigator

"Although the checkpoint inhibitors have improved the outlook for patients with various malignancies, including metastatic melanoma, there remains a need for cancer treatments which contribute to extended survival without additional toxicity. Results from this small study of patients with advanced melanoma, together with those from the previously reported randomised phase II study in advanced pancreatic cancer, suggest [the IP] may offer that potential.

Dr Kevin Bilyard
Sponsor CEO

Why Exploristics?

Expertise In Early Development

The development of investigational drugs is a complex and expensive process with many risks. For over ten years our teams have been supporting and de-risking clinical development with their in-depth statistics and modelling expertise. Our study planning, statistical analysis and programming services add value to early stage development programmes by ensuring they deliver the robust evidence needed for incisive, informed decision-making.

With many of our development solutions built around our unique **KerusCloud** platform, we can provide exceptional, bespoke, end-to-end biometrics support from strategic decision-making and protocol development to analysis, reporting and stakeholder engagement.

Robust Evidence Packages

The unique offering of our comprehensive biostatistics services in combination with **KerusCloud** ensures that Exploristics can help to generate strong evidence packages to support regulatory engagement or investment, accelerating development timelines and increasing the value of pipelines.

Exploristics, Your Essential Biostatistics Services Partner

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