

Programmed Cell Death Receptor-1 (PD-1) Inhibitor Monoclonal Antibody (mAb) in Adult Subjects with Advanced Refractory Solid Tumor Malignancies

Pharm-Olam was contracted to manage and recruit four sites for Phase I, first-in-human research of a PD-1 drug treatment for solid tumor malignancies. The study consisted of 18 patients. These participants were monitored for drug safety, PK, and efficacy. Six cohorts were tested on six different doses or treatment frequencies.

Pharm-Olam reached target enrollment 78 days ahead of schedule. The study needed to be escalated to reflect a high recruitment rate. The cohort management and monitoring strategy evolved to support the quick enrollment and the source data verification that stemmed from it.

Program Overview

Phase I, First-in-man

Indication

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Sites & Locations

4 sites in the United States

Pharm-Olam Services

- Feasibility & Site Solutions
- Project Management
- Clinical Operations & Trial Management
- Data Management
- Medical Affairs & Pharmacovigilance
- Patient Engagement Services
- Biostatistics
- Medical Writing
- Quality Assurance



For more information about Pharm-Olam, please visit www.pharm-olam.com

About Pharm-Olam

Pharm-Olam is helping biopharmaceutical companies create a healthier world as a global, mid-sized CRO that offers agile, innovative and customized clinical solutions in support of Phase I-IV oncology clinical research. They specialize in early phase oncology research and are focused on expediting sponsor's programs to proof of concept. As a global CRO, Pharm-Olam understands the unique challenges presented in this area. They realize that clinical research is a journey and go the distance.