Life Sciences Case Study

PROJECT OVERVIEW

CLARKSTON CONSULTING

COMMERCIALIZING CELL THERAPY WITH ARGOS THERAPEUTICS

Argos Therapeutics is a biopharmaceutical company focused on the development and commercialization of fully personalized immunotherapies for the treatment of cancer and infectious diseases. Based on the initiation of a Phase 3 clinical trial of their leading candidate product, Argos was starting to look ahead towards commercial launch planning. Autologous immunotherapy has unique challenges, including a supply chain process which ensures the chain of identify of patient materials throughout manufacturing through to treatment.

Argos engaged Clarkston to help them define and prepare their business processes and systems to support commercial operations and reduce risks novel to their technology platform.

Personalized cell therapy models are extremely complex to commercialize because of the complications related to:

- Chain of Identity Management
- Coordination with the Clinics and Apheresis Centers
- Complex Billing and Evolving Reimbursement Processes
- Revenue Recognition Timing and Cash Management Implications
- Patient Enrollment Process
- Logistics and Materials Transportation (inbound/outbound kits, labeling)
- Manufacturing Capacity Allocation and “Reservations”

At the time of this project, Argos was starting their Phase 3 trial for their leading candidate based on their Arcelis platform, a precision immunotherapy technology that captures both mutated and variant antigens that are specific to each patient's individual disease. While supporting clinical manufacturing and awaiting trial data results, the company was preparing for commercial operations. The purpose of this project was to help Argos define, plan, and implement their commercial systems and processes.

KEY TERMS

AUTOLOGOUS THERAPY

Autologous therapy refers to the therapeutic process by which an individual’s cells, tissue, and/or genetic material is extracted and then engineered outside the individual’s body before being reintroduced into the individual. The current primary oncology autologous immunotherapies focus on blood cancers (*vein-to-vein*) and solid tumors (*vein/tumor-to-vein*). Virology is another therapeutic area where autologous therapies are being investigated.

VEIN-TO-VEIN

Vein-to-vein refers to the process by which leukocytes, i.e., white cells, and plasma are collected by an apheresis site from the patient and shipped to a processing center where they are engineered before being delivered and administered to the patient.

VEIN/TUMOR-TO-VEIN

Vein/tumor-to-vein is the process used by Argos. Similar to *vein-to-vein*, *vein/tumor-to-vein* involves the same extraction of leukocytes and plasma for processing and administration to the same patient. A key diference is the added step of a biopsy of the patient’s cancerous tumor, which is then included in the development of the treatment. This creates additional complexities with an increase in patient/clinic coordination activities (e.g., accommodating recovery time for the patient post-biopsy prior to leukapheresis) and additional chain-of-identity concerns to ensure patient materials received at different times are appropriately controlled and matched.

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CLARKSTON CONSULTING

COMPANY:

Argos THERAPEUTICS

INDUSTRY:

Biotechnology

PRODUCTS & SERVICES:

Focuses on the development and commercialization of individualized immunotherapies for the treatment of cancer and infectious diseases in North America

REGULATORY

Facilitated and developed a chain of identity risk assessment as part of an FDA response.

OPERATIONS

Helped define and document business requirements and process flows impacting a wide range of functions, including site/patient enrollment, prescription processing, materials handling, manufacturing, quality control, quality assurance, distribution, and billing.

TECHNOLOGY

Created a landscape model of computer systems and system integrations requirements across the entire organization, as well as a roadmap for deployment. Identified gaps stemming from Argos' unique precision immunotherapy processes, including a need for a provider/patient collaboration platform.

SUPPLY CHAIN

Mapped out manufacturing and 3PL options to meet commercialization requirements. Conducted analysis for in-house and contract manufacturing scenarios as part of a commercialization risk and cost analysis.

PRIMARY OBJECTIVES:

Clarkston was working with this pre-commercial biotechnology company to help them build their commercial readiness. Preparing for commercial launch for a precision immunotherapy product introduces new challenges to a highly complicated product launch process. Some key areas where Clarkston helped the client included:

- Conducting a formal risk assessment for the FDA on chain of identity throughout the product lifecycle, including risk mitigation through defined process and system controls
- Identifying systems and process requirements for product launch, including a gap analysis between traditional biopharma best practices and requirements for personalized medicine manufacturing
- Modeling the locations and best business partners to support capacity planning related to the complexities of the supply chain model

RESOLUTION:

With Clarkton's help, Argos was able to create a unique vision for their commercial needs. As part of their strategic planning activities, the team:

- Developed a recommended systems roadmap for commercialization, including a custom physician / patient collaboration platform, with defined phases for efficient development across a multi-year plan
- Facilitated a chain of identity risk assessment, which articulated the planned use of processes and systems. This risk assessment was part of a response to the FDA
- Identified critical processes and system integrations which would be required to support the unique business processes of an autologous therapy

KEY BENEFITS:

This project provided Argos with a first-of-its-kind analysis for an emerging autologous therapy biotechnology company, including a robust risk assessment on chain of identity for the FDA. The roadmap developed by Clarkston Consulting defined a sustainable, long-term, and scalable commercialization of existing and future cell therapies, tailored for the unique complexities of autologous immunotherapy treatment. This roadmap was further bolstered by a comprehensive computer system landscape definition to ensure a technological environment that could support and evolve with the commercialization of the cell therapy.

BUSINESS VALUE

CHAIN OF IDENTITY RISK ASSESSMENT

From a technical, operational, and strategic perspective, Argos has a thorough understanding of the chain of identify risks associated with this treatment: from initial patient enrollment and material collection/receipt; to manufacturing, inventory and distribution; to dosage administration. In addition, Argos has a fully documented comprehensive and holistic view of the processes and systems needed to mitigate the risks and to ensure the patient gets their uncontaminated dosage. This risk assessment was used as part of an FDA response to demonstrate a secure chain of identity for patients.

INDUSTRY-SPECIFIC COMMERCIALIZATION ROADMAP

Clarkston worked with Argos to define the end to end processes, and then developed an application/system mapping to these defined processes, including identified system integrations, and a multi-year deployment plan. In doing so, the proposed system:

- evolves the existing traditional bio-pharmaceutical manufacturing model to define, initiate, and monitor the differentiated processes around cell therapy,
- meets the industry's regulatory requirements and standards,
- accomodates unique billing needs for reimbursement and outcomes-based contracts,
- supports rapid quality release of batches, and
- provides patient-centric capabilities by allowing open and transparent communication across stakeholders.

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