

Cell and gene therapy solutions

Challenging cell therapy program with intramyocardial IP administration

Background

Our client conducted a clinical trial investigating cardiovascular autologous cell therapy delivered via intramyocardial injection. Patient identification was challenging due to stringent inclusion criteria, including daily angina episodes and exercise treadmill test criteria. The investigational product (IP) was administered during a preplanned cardiac catheterization procedure. Continuous safety assessment was ensured through prescribed Data Monitoring Committee (DMC) meetings coordinated by our team.

Challenges

- **Regulatory landscape:** Complex and varied between countries/sites
- **Site selection:** Ability to coordinate complex premeds, IP handling, just-in-time protocol requirements
- Complex IP transportation coordination; e.g., dry ice and liquid nitrogen containers
- **Specialized equipment for IP preparation:** Laminar flow hoods, centrifuges and -80°C freezers
- Acquisition of specialized and costly IP delivery equipment (specific catheter and cardiac mapping of ischemic tissue)

Strategy

- Robust onsite PSV supported by **IP flow document and site protocol requirements**
- Strong site relationships supporting in-depth mapping of approval pathway; document checklist
- **Communicate upfront** to sites re: days for shipping and receipt of IP and IP expiry; ensure process developed to coordinate IP transport and follow-up
- **Worked with catheter equipment manufacturer** to coordinate site activations in time for site equipment purchase, installation and equipment training
- **In-house IP dose coordination and management:** Dedicated resource to coordinate all patients' **just-in-time IP shipment:** from premed dosing to central cell manufacturing facility (stem cell isolation and expansion) and back to clinical site for intramyocardial IP injection

Results

The study met target recruitment goals within a challenging patient population. There were no missed doses of the incredibly complex investigational product.

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