Veeva RTSM

for Autologous Cell and Gene Therapy Studies

Traditionally, Randomization and Trial Supply management (RTSM) solutions manage the release of Investigational Product at a central warehouse and track this to local depots, sites, then allocation to patients and any subsequent accountability involving the return, verification and destruction of supply.

Clinical trials exploring autologous cell therapies have some unique supply chain and manufacturing needs for RTSM vendors to consider. Autologous designs require patient cells to be tracked from the patient at the apheresis center through to the cell lab and manufacturing facility and back again to the site and patient. This requires the Logistics processes to be more patient-centric than in the traditional model.

In addition to the need for patient-centricity, many of the same fundamental needs and challenges of the traditional model are just as relevant for an autologous chain:

- Time criticality
- Managing temperature deviations and quarantine events
- End to end traceability / chain of custody
- Visibility into status and risks
- Reliable integrated workflows

The autologous chain magnifies these needs and challenges and demands additional levels of flexibility. For example, expiry dates may be extremely short. Events may be time-bound based on hours rather than days and weeks.

Veeva RTSM provides complete randomization and trial supply management capabilities with flexible modular 'building blocks' for all trial complexities. The dedicated Veeva RTSM services team has experience understanding and delivering niche protocol specific designs with speed and accuracy. Through this combination of product and services, Veeva is well positioned to provide this additional flexibility and meet the needs of the growing cell and gene therapy market.

Whilst the 'R' (Randomization) is typically less prevalent in these designs, the 'TSM' (Trial Supply Management) is critical. The native functionality originally designed for supply accountability workflows can be harnessed to track the autologous workflow, including time-bound events, shipment statuses and temperature excursion management. Additional features from Veeva RTSM, such as capping, patient dose management, and seamless connectivity with EDC and logistics providers, including temperature logging and vein to vein chain of custody functionality, bring further efficiencies.

In this era of personalized medicine it is vital that solution providers offer flexibility and adaptability to allow studies to be executed without compromise. The Veeva RTSM team are partnering with sponsors in this area to ensure clinical trial technology is not outpaced by science.

Contact your Veeva account partner or info@veeva.rtsm.com to discuss your specific CGT needs.