CALYX™

CASE STUDY

Managing Stem Cell Shipping Effectively with IRT

SITUATION

Clinical trials involving stem cell therapies present added complexity in regard to treatment logistics: the treatment is collected from a patient or donor, shipped to a manufacturing site, modified, and then shipped to the treatment facility for patient administration.

Effective treatment requires cell preservation, which is often done by cryopreservation. If the cryopreservation is not well-managed or is suboptimal, cell viability and the therapy production process can be negatively impacted. Additionally, the efficacy of the therapy may be compromised due to non-ideal frozen storage conditions.[1]

CHALLENGE

- Double-blind trial
- Surgery date at least 2 weeks post-randomization, to allow sufficient time for stem cell production and shipment
- Stem cell expiration within 48 hours; shipment date within 48 hours of surgery
- Expiry date specific to each kit, which is unusual for an IRT

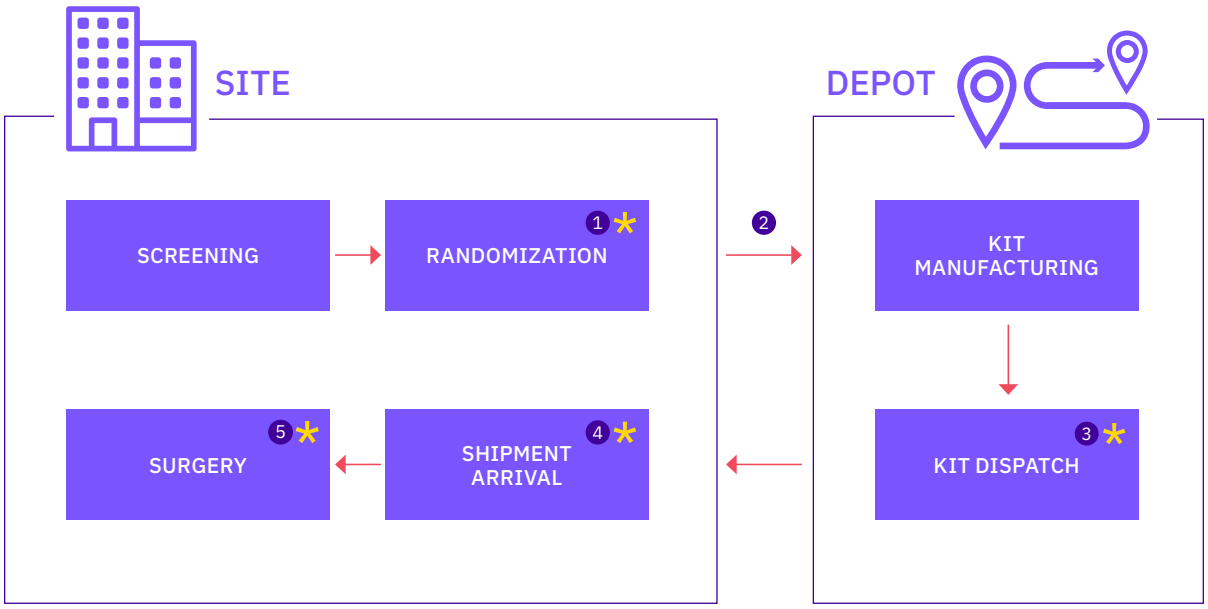
ADDITIONAL CHALLENGE

- Single manufacturing facility located in Spain to cover sites located in:
  - Belgium
  - Israel
  - Canada
  - Italy
  - Czech Republic
  - Poland
  - France
  - Spain
  - Hungary
  - United States

1. Hunt C, J: Technical Considerations in the Freezing, Low-Temperature Storage and Thawing of Stem Cells for Cellular Therapies. Transfus Med Hemother 2019;46:134-150. doi: 10.1159/000497289

SOLUTION

Calyx delivered an effective IRT solution that enabled cell preservation during this challenging trial.



1. Site randomizes the patient and enters the expected surgery date and time
2. IRT sends patient number, surgery date, treatment group and kit number to manufacturing facility
3. Depot confirms kit dispatch in IRT, entering the latest arrival date and time, to account for kit expiry date
4. Upon shipment arrival, site enters actual date and time of arrival
5. Site enters the actual surgery date and time

* IRT controls in place to manage kit expiry

Contact hello@calyx.ai to learn how Calyx IRT can enable your trials' success.

KEY HIGHLIGHTS

- Strict controls set in IRT to allow sufficient time between randomization and surgery
- IRT accounted for potential differences between depot and site local times to ensure expiry controls did not fail
- IRT capped the number of patients enrolled in the same region over time to account for manufacturing limits
- Caps were editable by study team for simplicity and improved reaction time to unforeseen situations
- In-depth training provided to site users to reduce risk of delaying stem cell production and shipment

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Reliably solving the complex.

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