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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:

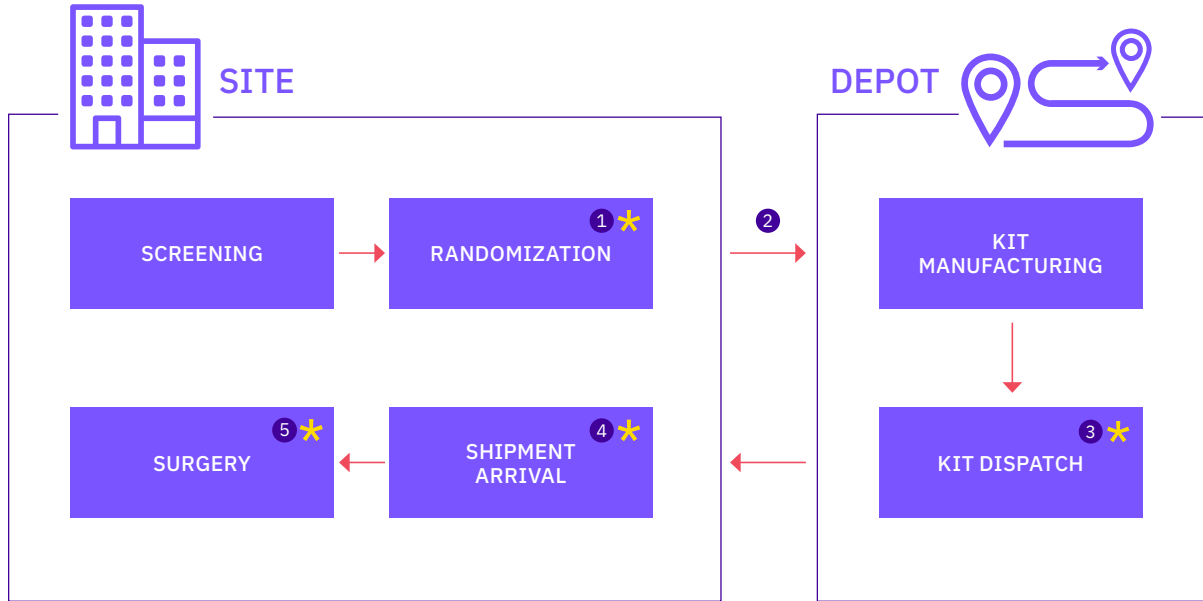
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| – Belgium | – Poland |
| – Israel | – France |
| – Canada | – Spain |
| – Italy | – Hungary |
| – Czech Republic | – United States |



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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