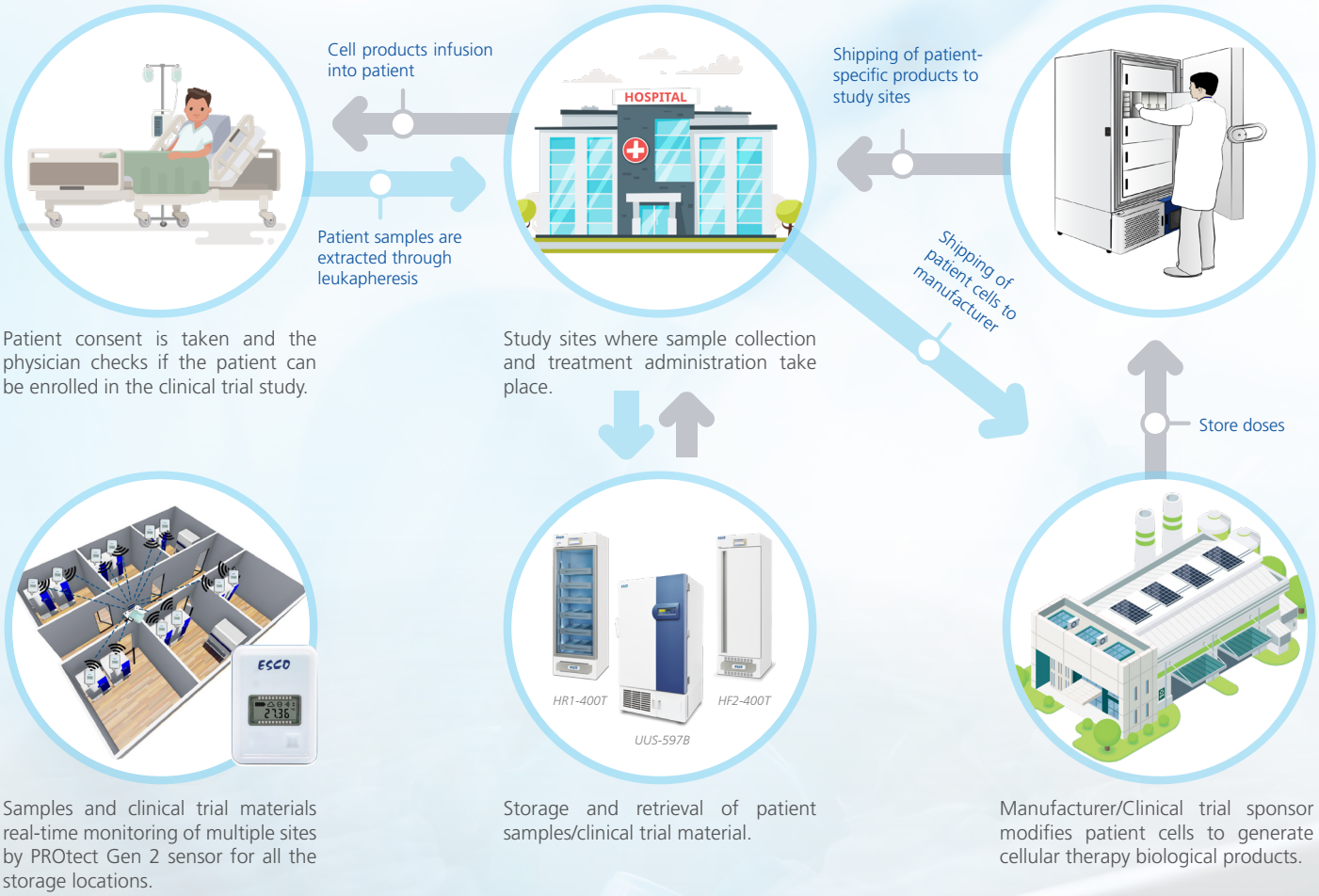
IN THE LOOP

Trial Trail: Ensuring Good Cold Chain for Complex Clinical Trials

The recent advancements in precision medicine mainly involve biologics that are developed to be stable within the temperature range of 2°C to 8°C. Biopharmaceuticals in development have been in the pipelines of top biotech companies and are expected to continuously grow each year. To ensure the validity of clinical trial results of these products, the investigational products should be handled under proper storage, handling, and distribution until it reaches the clinical trial sites.

COMPLEX CLINICAL TRIAL STORAGE AND MONITORING

Clinical trials involving cellular therapies are on the rise with the advancements in gene editing technologies. Technologies such as chimeric antigen receptor (CAR) T-cell therapy allows the modification of the patient cells for a targeted, personalized, and theoretically lesser side-effect type of medication against cancer.



Patient consent is taken and the physician checks if the patient can be enrolled in the clinical trial study.

Study sites where sample collection and treatment administration take place.

Samples and clinical trial materials real-time monitoring of multiple sites by PROtect Gen 2 sensor for all the storage locations.

Storage and retrieval of patient samples/clinical trial material.

Manufacturer/Clinical trial sponsor modifies patient cells to generate cellular therapy biological products.

Figure 1. Sample cold chain trail in autologous CAR-T therapy workflow

The complexity of the cold chain in clinical trials involving cellular therapies is further magnified with multiple study sites on a global scale. Storage and distribution should be monitored to ensure the proper storage of the products and guarantee reliable results. Failure of storage processes should be properly documented and thus, monitoring devices and data-retrievable refrigerators and freezers are necessary.

Esco Scientific offers a suite of cold chain solutions— HP series models cater to a wide range of temperature storage starting from +2°C to +15°C for the lab refrigerators (HR1) up to -10°C to -40°C for the lab freezers (HF2 and HF3). Lexicon® II series offers long-term sample storage and preservation at ultra-low temperatures of -50°C to -86°C. From cold storage products to reliable monitoring devices, Esco also offers PROtect Gen 2— ***ensuring sample security and precise monitoring***.

Reference:
[1] Ruiz, L. August 2014. Good Cold Chain in Clinical Trials. https://journalforclinicalstudies.com/wp-content/uploads/2014/08/Good....pdf

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