# DEVELOPMENT OF A PROTOCOL TO STANDARDISE CELL-BASED MEDICINAL PRODUCTS HANDLING IN AN ONCO-HAEMATOLOGY CLINICAL TRIALS UNIT

Del Río Gutiérrez JM[1], Serramontmany Morante E[1], Giménez Giner S[1], Rovira Torres P[1], Varón Galcera C[1], García Ortega P[1], Cidoncha Muñoz I[1], Gorgas Torner MQ[1]

[1] Pharmacy Department.

## WHAT WAS DONE?

Management of **Cell-Based Medicinal Products (CBMPs)** was protocolised in an onco-haematology clinical trials unit.

## WHY WAS IT DONE?

One of the most important challenges we currently face is **the increase of clinical trials (CTs ) including CBMPs.**

- These drugs require special storage, preparation, delivery and administration**.**
- Developing standard operating procedures (SOPs) and ensuring proper coordination between all professionals involved, including pharmacists, **is essential**.

## HOW WAS IT DONE?

**Pharmacists, doctors and nurses** participate in a multidisciplinary team to standardise CBMPs handling. Following protocol was agreed:

1. The entire multidisciplinary team is notified when a CBMP prescription is planned **to ensure proper coordination.**

2. The CBMP is manufactured by the **CT sponsor**. Then, it is transferred to the blood bank for cryopreservation. CBMPs usually require a temperature between -80ºC and -200ºC and expire in some weeks.

3. Before CBMP administration , patients **undergo lymphodepletion**. The lymphodepletion regimen is performed according to the CT protocol or arranged between medical and pharmacy teams. Chemotherapy, serum therapy and antiemetic regimen are discussed and specified.

4. Once the treatment is prescribed, **it is verified by a pharmacist who ensures its suitability.**

5. On the infusion day, the blood bank delivers the CBMP. Then, a pharmacist **checks** if it arrives in proper condition and it is defrosted. The pharmacy department reconditions the CBMP in another infusion bag or syringe if required. **This is the most critical point because CBMP expires after some minutes of defrosting, requiring extensive coordination**.

6. CBMP is administered according to the CT protocol.

## WHAT HAS BEEN ACHIEVED?

72 patients were recruited

**1 assay** requires CBMP syringe reconditioning in the pharmacy department.

| Total: 15 CT | |
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| **8 CBMP Chimeric Antigen Receptor T-Cells** (CAR-T-CELLS) | **7** haematological neoplasms |
| 4 **Specific Peptide-Enhanced Affinity Receptor T-Cells** (SPEAR-T-CELLS) | |
| 2 **Tumour-Infiltrating Lymphocytes** (TILs) | **8** solid malignant neoplasms |
| 1 **cytokine-stimulated Natural-Killer-Cells** (CS-NK-CELLS) | |

The described process optimises CBMPs handling, avoids delays in administration and reduces the risk of misuse.

## WHAT IS NEXT?

**CBMPs** represent a novel therapy, and pharmacists have an essential role in developing new procedures to incorporate them into clinical practice. **This protocol may be helpful for other centres to implement guidelines to work with CBMPs.**

Contact us:
josemanuel.delrio@vallhebron.cat