


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

Del Río Gutiérrez JM¹, Serramontmany Morante E¹, Giménez Giner S¹, Rovira Torres P¹, Varón Galcera C¹, García Ortega P¹, Cidoncha Muñoz I¹, Gorgas Torner MQ¹
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?


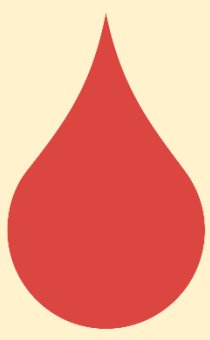




One of the most important challenges we currently face is **the increase of clinical trials (CTs) including CBMPs**.

- 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 -80°C and -200°C 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	
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.**

