# CLINICAL TRIAL SUPPLIES

*D2M Santé ensures the complete manufacture (including production and packaging) of investigational medicinal products. D2M Santé prepares clinical trial supplies whatever the dosage forms used (except sterile dosage forms) and the pharmacological profile of the active substance to be tested (except cytotoxic, hormonal, and psychotic medicinal products).*

## OUR "PROCESSING KNOW-HOW"

- Writing of the clinical trial application file for both national and international trials
- Generation of randomisation listings and preparation of sealed decoding envelopes
- Importation of Comparator products
- Immediate and outer packaging of investigational medicinal products
- Pharmaceutical and Regulatory Releases for the investigational medicinal products
- Site distribution logistics in partnership with the CSP-EPL European company
- Destruction of treatment units when returned from investigational sites

## OUR "DEVELOPING KNOW-HOW"

- Manufacture of Placebo including relevant Formulation Development
- Masking of Investigational medicinal products
- Stability study designs (choice of relevant criteria)
- Investigational medicinal products Quality Control Monographs

## Some achievements

| CLINICAL PHASE DEVELOPMENT | DOSAGE FORM | ACHIEVEMENTS |
|---|---|---|
| **PHASE I** | Cutaneous Powder | Clinical trial Authorisation Application file<br>Analytical development<br>Bulk product manufacturing<br>Immediate packaging<br>Outer packaging<br>Pharmaceutical release |
| **PHASE II**<br>(escalating dose clinical trial) | Oral gel | Formulation development<br>Analytical development<br>Bulk product manufacturing<br>Immediate and outer packaging<br>Pharmaceutical release<br>Clinical trial supplies distribution |
| **PHASE III** | Oral tablets<br>(packaged in blisters) | Randomisation list<br>Decoding sealed envelopes<br>Development and manufacture of a relevant Placebo<br>Manufacture of bulk products and quality controls<br>Immediate and outer packaging<br>Pharmaceutical release<br>Clinical trial supplies distribution |
| **PHASE IV** | Oral solution | Quality control of bulk products<br>Immediate and outer packaging<br>Pharmaceutical release<br>Clinical trial supplies distribution |

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