

IMP management through eCRF

SolidAct

Theradis Pharma:

- 1. Management of the IMP stock**
- 2. Labelling**
- 3. Shipment of IMP to the sites (along with a delivery confirmation receipt)**

Inserm:

- 1. Imports IMP files in the eCRF (= available IMP at Theradis Pharma's)**
- 2. Creates orders in the eCRF for IMP to be sent to a site (blocks of 10). An alert email will be received by Theradis Pharma.**
- 3. Records the information from the delivery confirmation receipts in the eCRF. Only IMP with the "Available at Investigator's" status can be allocated to a patient.**
- 4. Order re-supplies of IMP for sites (alert emails from eCRF when site's stock is getting low)**

What is needed by Inserm:

- List of sites + sites' number + name of PI + expected inclusion per site**
- Confirmation from the sponsor that a site has been opened and can receive IMP**