

"Can clinical research be done at home? The Oncopole experience in Toulouse-France"

ESTRABAUT Myriam

Head of CT home care platform

What are we talking about?

Decentralized clinical trials (DCTs) incorporate procedures specific to the needs of clinical research, which are carried out at a distance from the investigating site.

Digitization of clinical trials is defined as the dematerialization of certain clinical trial procedures, i.e. the use of electronic tools to deliver information to patients (e.g. econsent), remote monitoring, etc...

Only part of the clinical trial is decentralized, with the core of the clinical trial remaining in the investigating site

<u>Hybrid</u>



Home nursing benefits





Our experience



oral IMP at home

2020





Context: Patient distribution in 2023



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Our partners

Home care partner

- Pharmaceutical industry status
- Specialized in Clinical Research
- Previous collaboration with OCR
- Collaboration contract signed in September 2024









Our partners

EHR dedicated to hospitalization at home



mhcare

Electronic Health Record Integrated Care Pathways

- Medical record
 - CPOE, ePrescribing, medical historic
 - Diagnostic, Medication.

• Continuity of care record

- nursing care plans, guidelines, protocols
- vital signs monitoring, eforms.
- Multiple Integrated Care pathways
 - Hospital At Home, Complex Chronic conditions
- Dashboard, Notifications.

- Used treat patients at home outside clinical trials (current practice in France)
- Certified :
 - ISO 13485 ;
 - Class 1 CE approved
 - class 2A certification ongoing

- Electronic transfert of the visit report directly into our EMR in real time

Oncopole CLAUDIUS REGAUD



Our partners



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Our site control MHCARE® EHR acces used at home

- 1. Nurse identification
- 2. Site « push » the patient from site EMR to MHCARE[®] EHR
- 3. Site create MHCARE[®] EHR acces (ID + PASSW) and give acces to the specific patient data
- 4. After the visit when all the data are electronic transfered , site remove acces to MHCARE® EHR

The nurse do not have a view on all patient's EMR only what she/he need

- Name, contact, adress etc., Site contact
- Study memo sheet
- Site's note added specificaly for the visit
- Mailsbox available to tchat with the site

The MHCARE[®] EHR is accessible from an application with a computer, IPAD or phone ; can be used offline



Home trial services

Type of home care

- Vital Signs
- PK sample Processing
- IMP Administration
- ECG
- Caregiver/Patient Training
- Quality of life Questionnaire
- Patient's diary review
- Tele-consultation

Oncopole CLAUDIUS REGAUD Type of IMP administration support

- IMP Infusion
- IMP Injection Subcutaneous
- IMP Injection Intramuscular
- Oral
- Topical
- Transdermal
- Observation

Operating diagram





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Our experience









Conclusion

CT home care meets the needs of all stakeholder :

- PATIENT by reducing protocol constraints / fatigue
- SPONSOR by allowing
 - Faster decentralization implementation because it is simply an extension of our center's care offering
 - Faster contractualization via the study contract
- SITE by allowing us to **masters the process** and choosing the personnel intervening at home





Audit of our vendors

- Quality certification of CT home care platform
- Develop our platform to propose decentralization to national territory
- Create our own mobile unit





Thanks for your attention

