DIRECTION OF CLINICAL RESEARCH AND INNOVATION

Investigation Unit

Centre Oscar Lambret

ORGANIZATION & STRUCTURE

Brochure for sponsors and clinical research organizations (CRO)

General Director
Professor Eric LARTIGAU

Director of Clinical Research and Innovation
Professor Nicolas PENEL

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SOMMAIRE

The purpose of this brochure is to present the research teams handling clinical trials at the Oscar Lambret Center (OLC), from set-up to close-out in accordance with current regulations and biomedical research agreements.

I. General Presentation

A. Areas of Clinical Research

Research is one of the three core missions of the Oscar Lambret Center. The primary task of the Investigational Unit of the Direction of Clinical Research and Innovation (DRCI) is to coordinate the OLC's clinical studies with and for the investigators of the different committees.

The Oscar Lambret Center has played a major part in clinical cancer research for many years. **The center treats all solid tumors in adults and children.**

The center conducts all categories of trials, from phase I to phase IV, with **early phase trials given priority.** Our center is certified by the National Cancer Institute as CLIP² (Certified Early Phase Center) since 2015 (renewed in 2019 for 5 years).

To facilitate multidisciplinary patient care, we maintain relationships with Lille University Hospital and other facilities in the region for radiotherapy, CLIP², patient referrals, multidisciplinary consultation meetings (MCM), etc.

RESEARCH AREAS

BREAST - SARCOMAS - EARLY PHASES OF ALL SOLID TUMORS - HEAD AND NECK - ALL PEDIATRIC SOLID TUMORS - Tumors of unknown primary site - Pain - Geriatrics - Lung - Anesthesia - Palliative care - Gastrointestinal - Technological innovations in imaging - nuclear medicine - radiotherapy

Active patient population 2018/2020:

2018	2019	2020
6444	6627	6671

THE CENTER'S ORGANIZATION

B. Activities in 2020

Committees	Number of studies	Number of inclusions Interventional studies
ANESTHESIOLOGY & RECOVERY & ALGOLOGY (Department)	2	0
GASTROINTESTINAL	30	85 (6,81%)
GYNECOLOGY	18	57 (4,56%)
NEURO-ONCOLOGY	0	0
PEDIATRICS (Department)	32	41 (3,28%)
LUNG	6	9 (0,72%)
SARCOMAS/RARE TUMORS	14	118 (9,45%)
BREAST	28	200 (16,02%)
ALL TUMORS/EARLY PHASES	23	244 (19,55%)
UROLOGY	14	66 (5,28%)
UAT (Upper Aero-digestive Tract)	11	34 (2,72%)
TOTAL	178	1248

C. Quality Assurance

2015

CLIP2 certification for adults and pediatrics

2017

Renewed authorization for adult and pediatric early phase studies

2018

ISO 9001:2015 certification => "...to conduct early phase clinical research in a certified center, for sponsors (from concept to promotion) and investigators (from feasibility to close-out, including patient care)"

2019

CLIP² re-certification

2021

ISO 9001:2015 certification renewed incorporating pharmaceutical activities

ISO 9001 certification guarantees the Clinical Research and Innovation Division's stakeholders (patients, doctors, staff and partners) that an excellent Quality Management System (QMS) is in place. Additionally, our QMS manages both clinical studies currently enrolling and projects sponsored by the Oscar Lambret Center.

The DRCI is audited regularly by sponsors. It has also been inspected by various relevant authorities:
- by the FDA in 2014
- by the Regional Health Authorities in 2017
- by the ANSM in 2019
No major risks were identified.

When a study is set up, the site CRA provides the CRA monitor with our internal procedures on source documents used, patient enrolment and patient monitoring by the DRCI.
These documents are shared solely with the personnel involved in the study.

If you wish to obtain a regulatory document (site authorization, pharmacy authorization, radiotherapy authorization, nuclear safety authorization, pharmacy destruction procedure, maintenance or accreditation documents (NTF), etc.), please contact DEVIENNE Nathalie (investigation@o-lambret.fr)

II. Practical Information

A. Contractual Obligation

For a pharmaceutical sponsor, the current version of the French unique hospital contract (UHC) is used. This is signed within 15 working days from receipt of the cost estimate signed by the coordinator or within 45 days of negotiations when the OLC is the coordinator.

At the OLC, the contract is signed in triplicate, in French (although English translations are accepted for UHC). Our signatories are:

- The General Director (Professor Eric Lartigau)
- The Sponsor
- The Principal Investigator

Contracts can be signed using Docusign. The link giving access to the agreement must be sent to the following 3 addresses:
- investigation@o-lambret.fr to coordinate the signatures (this address is accessed by 4 people)
- conventions-DRCI-DG@o-lambret.fr
- The principal investigator's email address, which is provided when the agreement is reviewed

No contract is signed with the OLC's technical unit or any external doctors.

Documents (feasibility studies, confidentiality and other agreements, cost estimates) are prepared by:
- Fabienne Dumont, Study Coordinator for the following committees: Gynecology, Pediatrics and UAT and the Medical Imaging and Nuclear Medicine departments
- Justine Longue, Study Coordinator for the following committees: Neurology, Lung Radiotherapy, Breast and Urology
- Pauline Smis-Papillon, Study Coordinator for the following committees: Anesthesiology & Algology, Gastrointestinal, Psycho-oncology, Sarcomas and All tumors
- Nathalie Devienne, Administrative Assistant: Tel: 00 333 20 29 59 35 / Fax: 00 333 20 29 59 71

For a quick response concerning new study proposals, please CC to the following address: investigation@o-lambret.fr (which is accessed by all 4 people above).

PLEASE NOTE: partnerships with pharmaceutical companies or CRO are created to improve responsiveness and centralize administrative documents.

B. Staff

1. Doctors

All the doctors practicing at the OLC are involved in clinical research as national coordinators and/or investigators.
In each committee/department, a study contact is appointed, who liaises between the CRID and the committee/department.

Committee/Department	Clinical Research contact
ANESTHESIOLOGY & ALGOLOGY	Dr AHMEIDI Abesse
GASTROINTESTINAL	Dr JAFARI Merdhad / Dr PIGNON Flore
GYNECOLOGY	Dr NARDUCCI Fabrice
IMAGING (DEPARTMENT)	Dr CEUGNART Luc
NEUROLOGY	Dr MOUTTET AUDOUARD Raphaëlle
PEDIATRICS	Dr DEFACHELLES Anne-Sophie
THORACIC	Dr LE TINNIER Florence / Dr GAYE Elisabeth
SARCOMA	Prof PENEL Nicolas
BREAST	Dr MAILLIEZ Audrey
ALL TUMORS	Prof PENEL Nicolas
UROLOGY	Dr CARNOT Aurélien
UAT (Upper Aero-digestive Tract)	Dr ABDEDDAIM Cyril / Dr LIEM Xavier

2. Research Coordinators & Technicians

The Investigational Unit of the DRCI has a team of Study Coordinators (SCs) and clinical research technicians (CRTs). The lead SC and back-up SC are designated during the clinical study set-up.

C. Training

Investigators undergo TransCelerate-certified training in Good Clinical Practice (GCP). These certificates and the investigators' CVs are available on request from Nathalie Devienne at: investigation@o-lambret.fr - Tel: 00 333 20 29 59 35 / Fax: 00 333 20 29 59 71

Study Coordinators undergo the following training:
- Diploma in Clinical Research
- Good Clinical Practice certification (TransCelerate)
- IATA certification for delivering blood and tumor samples
- Use of various types of eCRF (Inform, Rave, OCRDC, etc.)

III. From Trial Feasibility to Implementation

A. General information

When sending a project proposal to the doctor, CC to the generic email address investigation@o-lambret.fr for a quick response to your request.

First contact by email: investigation@o-lambret.fr

B. Feasibility and selection

Feasibility studies are completed by the investigator, the respective technical unit manager concerned with scientific elements, and the Study Coordinator for logistic and administrative aspects.

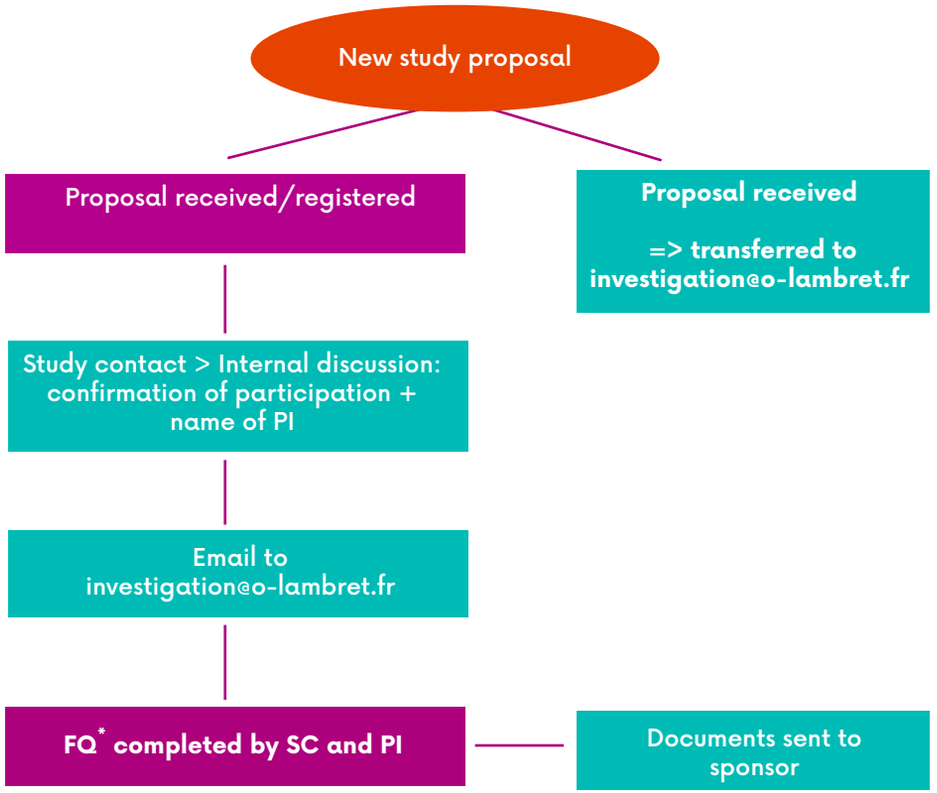
For pharmacological matters, contact the Clinical Trial Pharmacist, Dr. Ilyes Sakji : pharma-ec@o-lambret.fr

Pre-selection visits are conducted by both the Principal Investigator and Study Coordinator, then by the pharmacist.

Contacts: Investigation coordinators, depending on the committee concerned:
- Fabienne DUMONT (investigation@o-lambret.fr)
- Justine LONGUE (investigation@o-lambret.fr)
- Pauline SMIS-PAPILLON (investigation@o-lambret.fr)

Nathalie DEVIENNE n-devienne@o-lambret.fr
should be contacted for:

- Regulatory documents (FDF, FDA 1572, confidentiality agreements, etc.)
- Administrative documents
- Co-investigator declarations
- Requests for CVs
- Laboratory standards & accreditation
- Planning the study set-up



Legend : Yellow/sponsor; pink/DRCI, green/study contact
* Special case for Phase I RIHP: feasibility questionnaire completed by SC + PI + CLIP² coordinator + lead pharmacologist + lead anesthesiologist + methodologist + DRCI Director

C. Clinical Trials Committee

The Clinical Trials Committee (CTC) evaluates the projects to be implemented through the OLC's DRCI. This committee usually meets once a month.
To review the project, the CTC requires the following: ethics committee/ANSM submission letter, validated trial documents (protocol, NICE), laboratory manual, pharmacy manual, cost estimate and agreement.

Special case : if the national coordinator is a doctor at the OLC, the project is submitted to the CTC before regulatory submissions (ethics committee, ANSM).

The Clinical Trials Committee's opinion can be :

- Favorable: the project is accepted
- Suspended: a request for additional information is made in writing by the investigator, who is in charge of exchanging information with the sponsor; a written, point-by-point answer is expected
- Unfavorable: the study is not implemented and the project is archived (this is increasingly rare, especially if all previous steps have been followed)

Whatever opinion is reached, the sponsor will be informed by email.

D. Trial commencement

The trial will commence when we have received :

- The signed agreement
- The CTC's approval

This visit is planned by Nathalie Devienne in conjunction with the investigator and the relevant site Study Coordinator.

Once the date is set, the study materials can be mailed to the following address, adding the name of the Study Coordinator:

Centre Oscar Lambret
DRCI Investigation-Study Coordinator's name
3 rue Frédéric Combemale
59020 Lille
France

To reach the pharmacy, contact the Clinical Trial Pharmacist, Dr. Sakji, at pharma-ec@o-lambret.fr.

IV. Trial Conduct

Clinical trial protocols are conducted in a strict ethical and regulatory environment to ensure patient safety and quality of care.

A procedure is used for reporting serious adverse events immediately (including outside working hours).

A. Selection and inclusion of patients

MCM (Multidisciplinary Consultation Meetings) and committee meetings are organized by disease each week. These meetings identify potential patients for inclusion in clinical trials. The investigators ask the Study Coordinators to check the computer-based patient record (CPR) to pre-screen the selection criteria, in particular logistical criteria.

Patients who meet the protocol criteria will be referred to the DRCI Integrated Care Unit for a consultation with an investigator, who will present the study and obtain consent.

All the studies are listed on the center's website and pre-screening is possible after sending the patient's record to the following address : investigation@o-lambret.fr

The OLC is part of an inter-regional referral network between the Lille CLIP^2 and Caen CLIP^2. This collaborative network aims to give patients in Hauts-de-France and Normandy access to innovation therapeutic.

The doctors in these regions send standardized patient records which are presented every Friday at 1:00pm and each center gives an opinion on the trials available at their facility.
https://archimaid.fr/index.php?terr=59%20-%2062&action=addressing

B. Clinical file and monitoring

A monitoring visit is organized with the lead Study Coordinator of the particular study (preferably by email). During the monitoring visit, the clinical team can make itself available according to the previously established schedule. File storage areas are accessible through restricted access protocols.

The DRCI has a room exclusively for monitoring visits, equipped with computers (internet connection) with limited access to the monitored study via a specific password-protected account. Medical records are in electronic format (DxCare) and the nurses' charts are in paper format.

During monitoring visits, the monitor must sign a confidentiality agreement.
In the event of a health crisis, before coming to the center, their employer's risk management plan must be approved by our General Director and the monitor must sign a statement promising to follow safety measures during the visit.

Our privacy rules are as follows:

- Personnel access codes are issued, upon request, to the sponsors' representatives
- Read-only access is provided for sponsors' representatives
- Access only to records of patients who have given prior consent to participate in the clinical trial
- An audit trail is available upon request by the sponsor or the health authorities

C. Archiving

Study documents are archived at the end of the trial in accordance with regulations, the sponsor's practices and research agreements.

The OLC retains study documents at the facility; first in a pre-archiving room, and later in a final archiving room. Access to these archives is limited.
The rooms have pest controls and temperature and humidity controls. Temperature records are available upon request.
The pharmacy documents are archived in the same rooms.

Sponsors are always contacted before any files are destroyed.

V. Integrated Care

The Investigation Unit has an integrated care team which provides care to adult patients enrolled in trials.
Team: 5 nurses + 1 lead nurse + Sophie Costa, Clinical trial nurse coordinator
s-costa@o-lambret.fr - Tel: 00 333 20 29 58 39 / Fax: 00 333 20 29 55 59

Integrated care infrastructure:

- 10 beds, 4 armchairs and 4 consultation rooms
- 1 sampling room
- 1 technical room
- 1 equipment storage room
- 1 medicine refrigerator*
- Crash cart equipped with a defibrillator, plus intubation and ventilation equipment
- 2 12-lead EKG devices*
- Vital signs monitors (pulse, blood pressure, temperature)* in every treatment room
- Scales*, stadiometers
- Infusion pumps* + syringe pumps*
- 1 refrigerated centrifuge*
- Freezers: 2 freezers at -20°C and 3 at -80°C*, all equipped with sensors to monitor the temperature using Fischer ThermoClient software with email alerts (temperature curves available on request).

* *This equipment is regularly checked.*

All rooms are secured by badge or key access.

Nurses receive annual emergency training.

The OLC Biomedical Department is responsible for the maintenance and calibration of equipment in the Integrated Care Unit and all other poles (anatomical pathology, pharmacy). Maintenance and calibration certificates are only provided after an audit or inspection.

N.B.: Children and young adults participating in clinical trials are managed by the Pediatric Oncology Unit (hospitalization or outpatient), which has all necessary equipment.

EMERGENCIES

An on-call doctor is available 24 hours a day, 7 days a week for patients participating in clinical trials.
An emergency protocol has been created at the OLC to transfer patients to Lille University Hospital.

If hospitalization is required for a patient participating in an early phase clinical trial, a site-authorized room is available.

Each patient included in phase I trials is given an index card with instructions on how to deal with an adverse event.

VI. Other Poles at the Oscar Lambret Center

The DRCI can also count on an efficient technical unit.

A. Pharmacy

Opening hours: 8:45am – 5:00pm

Clinical Trial Pharmacist
Dr Ilyes SAKJI: pharma-ec@o-lambret.fr
Tel: 00 333 20 29 59 06 / Fax: 00 333 20 29 55 13

Product delivery address:
CENTRE OSCAR LAMBRET - Pharmacie-1er étage
3 rue Frédéric Combemale - 59020 Lille Cedex

The pharmacy is authorized to work for clinical trials.

According to the protocol and the sponsor's requirements, the pharmacy can handle:

- Provision (via the sponsor, or directly from the pharmacy)
- Receipt
- Storage:
  - Room temperature storage and a narcotic safe (15 to 25°C)* in a temperature-controlled room
  - 3 refrigerators (+2°C to +8°C)*
  - 2 freezers at -20°C*
  - 2 freezers at -80°C*
- Inventory management
- Drug preparation (if applicable)
- Dispensing
- Disposal (either destroyed by our service provider or returned to the sponsor)
- Digital document archiving

**This equipment is regularly checked*

The pharmacy is responsible for the feasibility, implementation, delivery and organization of monitoring visits. Contact Dr. Ilyes Sakji at pharma-ec@o-lambret.fr to make an appointment; CC to prepecpharma@o-lambret.fr.

Appointments are afternoons only.

The pharmacy provides a room for monitoring visits and the close-out visit. Two slots are available per day: 2:00pm – 3:30pm and 3:30pm – 5:00pm. It is possible to reserve both slots.

Only the administrative closing letter documents the official end of the clinical trial.

B. Anatomical pathology lab

Primary activity: oncopathology
Volume of activity 6,000 to 7,000 test requests/year

2 principal functions:

- Diagnosis of tumor lesions, providing information to help treat and monitor patients
- Contributes to the Alliance Cancer (OLC-University Hospital) tumor bank through the cryopreservation of tissue samples for translational research

POLE HEAD: Dr Yves-Marie ROBIN
Via Nathalie DEVIENNE: n-devienne@o-lambret.fr - Tel: 00 333 20 29 59 35

C. Laboratory

All biological analyses are conducted at Lille University Hospital's Anatomical Pathology Center.

The laboratory's accreditations are available on its website http://biologiepathologie.chru-lille.fr/politiquequalite/ . The standards and the laboratory Director's CV are available on request from Nathalie Devienne at investigation@o-lambret.fr.
Lab tests between rounds of treatment are carried out at a private laboratory close to the patient's home. Their accreditations are available on the COFRAC website. https://tools.cofrac.fr/fr/easysearch/index.php

D. Radiotherapy

Equipment

- Accélérateurs:

Machine	Brand of treatment	Mechanism of treatment
Clinac1	Accuray	Cyberknife M6
Clinac2	Varian	Clinac 23EX
Cyberknife	Accuray	Cyberknife G4
Tomo 1	Tomotherapy	HI ART
Tomo 2	Tomotherapy	HI ART
Tomo 3	Tomotherapy	TomoHD
Darpac*	Nucletron	Darpac2000

** Darpac is for contact radiation therapy*

- Scanners:

Dedicated simulation scanner (brand)	Model	Year of scanner manufacture
Toshiba	AQUILION 16 LB	2009

POLE HEAD: Dr Xavier MIRABEL
Via Nathalie DEVIENNE: n-devienne@o-lambret.fr - Tel: 00 333 20 29 59 35

E. Medical imaging

Equipment

- MRI (Siemens Magnetom VIDA 3 tesla); GE MRT 750 3T

Power injector: Medrad Spectris Solaris

- CT scanner: SIEMENS Sensation 16 – Somaton

Power injector: Coidien Optivantage

Tumors are evaluated according to the following standards: Recist 1.1, irRECIST, RANO (brain tumors), ITMIG (thymic tumors) and CHOI (hepatocellular carcinoma)

Weekly availability for clinical research:

- Scanner: 3 slots/Mondays, 3 slots/Wednesdays, 1 slot/Fridays
- MRI: 1 slot/Fridays

POLE HEAD: Dr Luc CEUGNART
Via Nathalie DEVIENNE: n-devienne@o-lambret.fr - Tel: 00 333 20 29 59 35

F. Nuclear medicine

Equipment:

- PET scan: SIEMENS BIOGRAPH VISION 450
- Bone scintigraphy: Gamma camera: GEMS Discovery NM CT 670
- Cardiac scintigraphy (MUGA): Gamma Camera GEMS Infinia and Discovery NM CT 670
- Sentinel nodes: Gamma Camera GEMS Infinia

POLE HEAD: Dr Luc CEUGNART
Via Nathalie DEVIENNE: n-devienne@o-lambret.fr - Tel: 00 333 20 29 59 35

VII. Conclusion

The DRCI is available to answer any questions or provide any further information:
investigation@o-lambret.fr

DRCI VALUES

https://www.centreoscarlambret.fr/recherche-cancerologique/direction-de-la-recherche-clinique-et-de-l-innovation

Visit the new DRCI: https://www.youtube.com/watch?v=FjLJjdWJzcs

Contact us
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