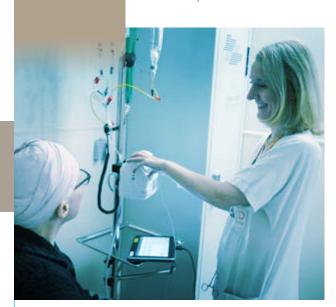
Department of Drug Development and Innovation Christophe LE TOURNEAU, MD PhD **Head of Department**



The CTU runs industrial and academic clinical trials. The CTU also sponsors early phase clinical trials. In this latter case, the Institut Curie is responsible for the full development of the trial, including establishing the budget, raising the funds needed to complete it, and conducting the trial on site and with partner centers according to best clinical practices. Data analysis, communication and publication of the results are handled by the Institut Curie.

Several clinical trials are currently being coordinated by principal investigators of the Institut Curie, involving high throughput sequencing, targeted therapies, immunotherapy, and innovative approaches such as nanoparticles activated by radiotherapy.

The CTU of the D3i works closely with the RADIOPHARMACOLOGY DEPARTMENT. the RADIOPHARMACY UNIT for radio-labelling with short life isotopes and the PHARMACOLOGY UNIT for the PK/PD studies.

CONTACTS

CLINICAL TRIAL UNIT

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institut**Curie**



Department

CLINICAL TRIAL

The CLINICAL TRIAL UNIT is located in 2 sites of the Institut Curie hospital group (Paris and Saint-Cloud).

- In Paris site, the Clinical Trial Unit (CTU), completely renovated, has 14 places (6 beds and 8 seats) and is under the responsibility of Marie-Paule SABLIN, MD. The team has 6 MDs. 6 nurses, 2 caregivers, and 3 assistants. Patients are treated in phases I and II clinical trials including first-inhuman phase I trials.
- In Saint-Cloud, the CTU has 6 places (2 beds and 4 seats) and is under the direction of Patricia TRESCA, MD. The team has 4 MDs. 4 nurses, and 2 assistants. Patients are treated in radioactive phase 0 clinical trials including first-in-human trials.
- Maud KAMAL, PhD leads a scientific coordination unit focusing on ancillary studies of early phase clinical trials and precision medicine. She works with 2 other people funded on projects.
- The Immunotherapy axis is under the responsibility of Emanuela ROMANO, MD PhD, in close collaboration with the Cancer Immunotherapy Center led by Sebastian AMIGORENA, PhD.
- An Epigenetic Axis is under construction, and will open soon.

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THE PHARMACOLOGY UNIT is located in the Saint-Cloud site of the Institut Curie hospital group.

The unit is internationally wellknown because specialized in PK/PD and radiopharmacology studies.

Radio-Pharmacology Department Olivier MADAR, PharmD Head of Department

PHARMACOLOGY UNIT

PK/PD STUDIES

- Drug and metabolites quantification in biological samples (in vitro and in vivo studies) according to GLP rules
- PK/PD modeling (Monolix, NonMem and Micropharm)
- Limited sampling strategy
- Onsite PK sampling
- PK data simulation from animals to humans by allometric rules
- Clinical PK study design

RADIOPHARMACOLOGY STUDIES

- Mass balance study (³H and ¹⁴C)
- New drug metabolite identification
- Biodistribution of radiolabeled molecules

GUIDANCE ON FDA/EMA REGULATION AND IND SUBMISSION

• Collaboration with the Clinical Investigation Unit of Institut Curie hospital group



MATERIALS

- 4 UPLC®-MS/MS
- 2 UPLC® with UV or fluorescence detection
- Atomic absorption spectrometry
- UPLC® with UV and radioactive detection
- Liquid scintillation counter for β particle detection
- Y counter

is located in both sites of the Institut Curie hospital group. The team is involved in the radiolabeling of drugs with various short life isotopes

for molecular imaging.

THE RADIOPHARMACY UNIT



HOSPITAL RADIOPHARMACY AND NUCLEAR MEDICINE UNIT

- 2 sites in Institut Curie: Paris and Saint-Cloud
- Preparation of radiopharmaceuticals for PET ([¹8F]FDG, [¹8F]FCH, [¹8F]FDOPA and [¹8F]NaF) and SPECT imaging and therapy (Zevalin® and Alpharadin®; Lutathera® in the near future)
- Clinical studies (ongoing clinical study with [18F] FAZA produced onsite; [18F]FES)

CYCLOTRON (IN COLLABORATION WITH ADVANCED ACCELERATOR APPLICATIONS, AGREEMENT RECEIVED IN NOVEMBER 2013)

- GMP production and quality control facilities
- Development of new methods of radiolabeling with carbon-11, fluorine-18, copper-64, gallium-68 and zirconium-89
- Labeling of biomarkers for PET cancer preclinical and clinical studies
- Labeling of drugs and biomolecules (peptide and antibody) for early preclinical and clinical PK development

GUIDANCE ON FDA/EMA REGULATION AND IND SUBMISSION

• Collaboration with the Clinical Investigation Unit of Institut Curie hospital group



MATERIALS

- Cyclotron GE Healthcare PETtrace 18 MeV for production of fluorine-18 and carbon-11
- Onsite delivery of copper-64. In the near future: zirconium-89 and gallium-68 generator.
- Production facilities equipped with 3 synthesis modules:
- Trasis AllinOne (mainly used with fluorine-18)
- Trasis Mini AllinOne (for copper-64, gallium-68 and zirconium-89)
- GE Healthcare FX C pro (for carbon-1 only)
- QC laboratory:
- UPLC® with UV and radioactive detection
- Dose calibrator
- GC with Headspace sampler
- Radio-TLC scanner
- Non GMP laboratory dedicated to the early development of radiolabeling with radiometals (⁶⁴Cu, ⁶⁸Ga and ⁸⁹Zr) using a Trasis Mini AllinOne (pending authorities agreements)