

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 D<sup>3</sup>i 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

Christophe LE TOURNEAU, MD PhD  
Marie-Paule SABLIN, MD (Head Paris site)  
Patricia TRESCA MD, (Head Saint-Cloud site)  
Emanuela ROMANO, MD PhD (Head immunotherapy)  
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### PHARMACOLOGY UNIT

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Three technicians and a Qualified Person

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### RADIOPHARMACY UNIT

Olivier MADAR, PharmD (Head of Radiopharmacy unit)  
Julien FOUQUE, PharmD (Radiopharmacist)  
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Department  
of Drug  
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and Innovation  
D<sup>3</sup>i

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## CLINICAL TRIAL UNIT

*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-in-human 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.

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 ( $^3\text{H}$  and  $^{14}\text{C}$ )
- 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  $\beta$  particle detection
- $\gamma$  counter

THE RADIOPHARMACY UNIT  
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.

## RADIOPHARMACY UNIT

### HOSPITAL RADIOPHARMACY AND NUCLEAR MEDICINE UNIT

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

### 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-11 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 ( $^{64}\text{Cu}$ ,  $^{68}\text{Ga}$  and  $^{89}\text{Zr}$ ) using a Trasis Mini AllinOne (pending authorities agreements)