

## Location

Maison de la Chimie  
28, rue Saint Dominique  
75007 PARIS  
France  
Tel : (+33)1 40 62 27 00



## Registration

Mandatory registration before 15 November 2017

Please send a mail to the following contact:  
[Leclubphase1@gmail.com](mailto:Leclubphase1@gmail.com)

Limited number of seats

**Fees** (without hosting)

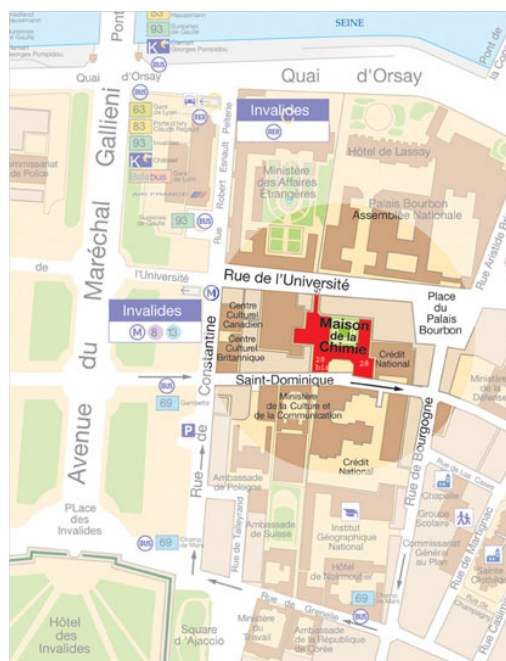
Free for members and invited students  
100 € for non-members

## Access

RER: Line C, station Invalides

Metro: Lines 8, 12 et 13, station Assemblée Nationale, Solférino and Invalides

Bus: Lines 63, 69, 83, 93 et 94



## Hotels close to the event

Hôtel Saint Dominique  
62, rue Saint Dominique

Best Western Tour Eiffel Invalides  
35, boulevard de la Tour Maubourg

Hôtel de Varenne  
44, rue de Bourgogne

Booking directly at the hotel



*Association des professionnels du développement  
précoce du médicament*

## Presents

Workshop on how to implement the  
recently released EMA guideline on  
« First-in-Human » trials?

A practical and interactive conference with broad  
early development stakeholders

**23 November 2017**

**13:30 pm to 16:30 pm**

**Paris**

With:

*Pr. Dominique Deplanque, MD, PhD*

**Professor of Medical Pharmacology**

University Lille 2 - Inserm - CHU of Lille, France  
National coordinator of the French Clinical Investigation Centers (CIC)  
Medical coordinator of CIC1403 - Lille  
INSERM laboratory U1171 (Degenerative and vascular cognitive disorders)

*Dr. Christophe Massard, MD, PhD*

**Medical Oncologist**

Institut Gustave Roussy - University Paris Sud, France  
Head of Gustave Roussy Drug Development Department (DITEP)

*Pr. Marc Pallardy, PharmD, PhD*

**Professor in toxicology**

University Paris Sud, France  
Dean Faculty of Pharmacy  
Team Leader of the INSERM laboratory UMR 996 “Cytokines, chemokines and immunopathology”

*Dr. Yves Donazzolo, MD, MSc*

**Clinical Pharmacologist**

Optimed-Eurofins, Grenoble, France  
CEO  
Early clinical development trials investigator

*Dr. Dominique Masset, PharmD, PhD*

Agence Nationale de Sécurité du Médicament (ANSM), Saint-Denis, France  
Head of Pharmaceutical Quality, Viral Safety Toxicology and Non-Clinical Evaluation

*Dr. Marc Martin, PhD*

Agence Nationale de Sécurité du Médicament (ANSM), Saint-Denis, France  
Deputy-Head Evaluation Division

## Program

### 13h30 - Welcome

*Dr. Henri Caplain*, MD, MSc, President Club Phase 1

### 13h35 - *Pr. Marc Pallardy*

Non-clinical development perspective

### 13h55 - *Pr. Dominique Deplanque*

Clinical Investigation Centers perspective

### 14h15 - *Dr. Yves Donazzolo*

Early phase development trials investigator perspective

### 14h35 - *Dr. Christophe Massard*

Oncology early clinical development perspective

### 14h55 - Pause

### 15h10 - *Dr. Dominique Masset & Dr. Marc Martin - ANSM*

ANSM introduction/philosophy & practical point of view

### 15h40 - Q&A (Questionnaire filled by the attendees before the workshop)

### 16h10 - Roundtable with Stakeholders and Attendees

### 16h30 - End of the workshop