



Association des professionnels  
du développement précoce du  
médicament

## JOURNEE DU CLUB PHASE 1

22 MARCH 2016

Paris



### Location

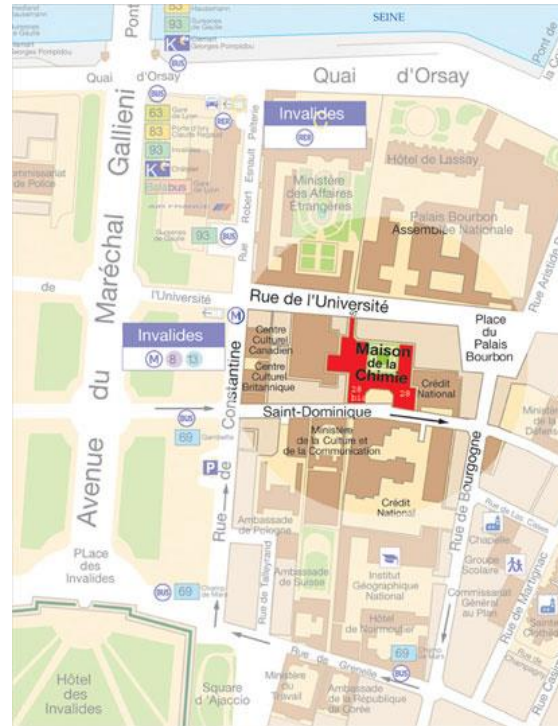
Maison de la Chimie  
28 Rue Saint Dominique  
75007 PARIS  
FRANCE  
Tel : (+33)1 40 62 27 00

### Access

RER : line C, station Invalides

Metros : lines 8, 12 et 13, station Assemblée Nationale, Solférino et Invalides

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



### REGISTRATION

Before 8 March 2016

### FEES (without hosting)

230 € for members

280 € for non members

Limited number of places  
Registration is mandatory

Hotels close to the event  
(Paris 7ème)

- Hotel Saint-Dominique  
62 Rue Saint-Dominique
- Best Western Tour Eiffel  
Invalides:  
35 Boulevard de la Tour-Maubourg
- Hotel De Varenne  
44 Rue de Bourgogne

Booking directly with the hotel.

### Contact

isabelle.paty@ipsen.com

Registration form online soon on  
[www.clubphase1.com](http://www.clubphase1.com)

Organization Committee

Club Phase 1 Board

Club Phase I (Association Loi 1901)

## Morning Sessions

**09.00-09.15**

Welcome & Introduction - Jean-Louis Pinquier

**09.15-09.55**

Immunogenicity ... How to deal with it?

Nathalie Mace -Sanofi

**09.55-10.35**

Prediction of patient placebo response: from myth to reality.

Impact on Proof of Concept clinical trials. Alvaro Pereira -

Tools4Patients

**10.35-11.05**

Break

**11.05 -11.20**

Regulatory update on ICHE14-TQT studies

Pascal Voiriot- Cardiabase Banook Group

**11.20-12.00**

Modeling and simulations as supportive tools for clinical

development Eric Evene - Phinc

**12.00-12.40**

Definition of "adversity" in toxicologic pathology - Results of the

ESTP expert workshop - Practical considerations for NOAEL

definition and first into human studies Xavier Palazzi- Sanofi

**12.40-14.00**

Lunch

## Afternoon Sessions

**14.00-14.40**

Drug Drug Interactions & drug transporters: what's new?

Professor Jean Michel Scherrmann- Université Paris Descartes

**14.40-15.20**

Translational medicine from animal to human : oncology models

Patricia Vrignaud -Institut Gustave Roussy

**15.20-15.50**

Break

**15.50-17.15**

Roundtable about risk mitigation in first in human trials,

Chaired by Jean-Louis PINQUIER, Club Phase 1

Philippe DANJOU, Senior Director R&D, Biotrial

Jean-Claude BUCK, Retired Long-haul Pilot, Air & Space Academy

Virginie BOULIFARD, PhD, Toxicologist, Ipsen Innovation

Isabelle PATY, PhD, Clinical Pharmacologist, Ipsen Innovation & Club

Phase 1

Pr Christian Funck-Brentano, Clinical Pharmacologist, APHP & INSERM

**17.15-17.30**

Conclusions