

Language: English

Symposium fees:

AFPT-Le Club Phase 1 member fees (2020 membership): **TBC**
Non-member fees: **TBC**
Academic student: **TBC**

Registration:

Required before: **April 30, 2020**
Registration form online on:
<https://www.clubphase1.com/>

If you have any questions, please email us at leclubphase1@gmail.com

Location:

UIC-P Espaces Congrès
16, rue Jean Rey
75015 PARIS
France
Phone: +33 (0) 1 44 49 22 31



Access:

RER: Line C, Champs de Mars
Metro: Line 6, Bir Hakeim
Bus: Lines 42, 69, 82 and 87
Taxi: One taxi station next door
Paris Airport Shuttle « Le Bus Direct »
Station « Tour Eiffel » (18-20, rue Jean Rey):
<http://www.lebusdirect.com/>



Suggested accommodations:

Eiffel Seine hotel, 3*
3, bld de Grenelle, 75015 Paris
France Eiffel hotel, 3*
8, rue St Charles, 75015 Paris
Campanile Paris 15, 2*
30, rue St Charles, 75015 Paris
Pullmann Paris Tour Eiffel, 4*
22, rue Jean Rey, 75015 Paris
Hotel Mercure Centre Tour Eiffel, 4*
20, rue Jean Rey, 75015 Paris

18th Annual Conference

PARIS - MAY 14 -15, 2020

Preliminary Program

“Evolution of the approaches and tools in translational and clinical pharmacology”

Organisation Committee:

Association Française de Pharmacologie Translationnelle (AFPT) - Le Club Phase 1 Board

AFPT - Le Club Phase 1 (Association Loi 1901)
Is a founding member of



Preliminary Program Day 1

08.30-09.00

Welcome coffee/tea

Session 1: translational biomarkers and multi-specific antibodies, update and specificities

09.00-09.45

Safety biomarkers in clinical trials: an update

09.45-10.30

Development of translational biomarkers

10.30-11.00

Break

11.00-11.45

Multi-specific antibodies development: preclinical aspects

11.45-12.30

Multi-specific antibodies development: clinical aspects and regulatory impact

12.30-14.00

Lunch

Session 2: PBPK, a new paradigm in drug development

14.00-14.45

Dose guiding in early stage: First-in-Human (FIH) new approaches and case studies

14.45-15.30

Correlation in vivo in vitro (IVIVC)/formulation optimization/virtual Bioequivalence

15.30-16.00

Break

16.00-17.00

Panel discussion with speakers and Health Authorities (FDA and EMA representatives)

17.00-17.30

Physiologically based pharmacokinetic (PBPK) - PD for FIH

17.30

Cocktail □

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Preliminary Program Day 2

08.30-09.00

Welcome coffee/tea

Session 3: quantitative systems pharmacology, an innovative approach

09.00-09.45

Quantitative systems pharmacology (QSP): introduction, case studies and regulatory impact

09.45-10.30

QSP: role in toxicology and how it can be linked with PBPK for early assessment: case studies link with PBPK

10.30-11.00

Break

11.00-11.45

To QSP/System biology and beyond: case studies

11.45-12.30

Panel discussion with speakers:

- Ambitions and perspective of QSP models for drug discovery/development/safety*
- Reality of QSP modeling in an industry with short timelines: short term investments versus long term advantages*

- What are the challenges the industry must overcome in order to match the expectation: model sharing? training?*

12.30-14.00

Lunch

Session 4: Enriched clinical trials

14.00-14.45

Adaptive clinical trials: ICH E20 informal working group on a concept paper and business plan for adaptive clinical trials

14.45-15.30

Adaptive platform trials: definition, conduct and reporting considerations

15.30-16.00

Break

16.00-17.00

Digital endpoints: interest for the conclusion of the trial and potential regulatory concerns

17.00-17.30

Conclusion and end of the meeting

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