



The French Translational Pharmacology Association "The Club Phase 1" (AFPT) is pleased to send you the 1<sup>st</sup> edition of the newsletter of our association.

This newsletter allows us to keep you informed on the association events and the pharma world happenings.

## A word from the president

Dear colleagues,

A new board of directors made up of 11 members was elected on June 14<sup>th</sup>, 2019. These new administrators (you will find the list here below) have in their turn elected a new office.

Today, this is in quality of President of the AFPT - Le Club phase 1 and with honour, joy and pride that I address you these few words. I thank all my predecessors and all the former members of the Board of directors for their devotion and full support in the success but also the perennality of our association. I also thank the current administrators for their confidence.

The AFPT - Le Club phase 1 gives the opportunity of gathering between professionals and impassioned of the translational pharmacology. It is a place of exchanges, sharings, interactivities and of acquisition of knowledge. However, the AFPT - Le Club phase 1 would be nothing without its members and sympathizers. You are in the center of our reflection for always better being useful to you. To be adherent is very invaluable and we count on your commitment today and tomorrow. More, we will be more visible and especially more effective.

We are happy to announce to you that today, the AFPT – Le Club Phase 1 has a LinkedIn account.

We are also very happy to announce to you that on 14 and 15<sup>th</sup> May 2020 will be held the AFPT Le Club Phase 1 conference in Paris. The program will cover various important topics to the field with speakers expert in Clinical Pharmacology, PBPK and Regulatory. We are expecting you there very many. Other events will follow. We will keep you informed.

See you very soon, Kind regards  
Lionel Hovsepian

## About us

The 'Association Française de Pharmacologie Translationnelle (AFPT)-LE CLUB PHASE 1' is a non-profit French association, founded in 1993, whose members are implied in human translational pharmacology in industry including biotechnology companies, Contract Research Organizations, Academics....

The association aims to support and promote with all the adequate means the clinical research of health products in France.

More particularly, it proposes:

- to develop scientific, methodological, regulatory and ethic exchanges between the actors engaged in the field of human pharmacology and activities of translational medicine within the framework of the life cycle of the health products, including the drugs and devices;
- to promote the clinical research in France and more particularly the early clinical research;
- to develop the activities of teaching related to its purpose.

The AFPT collaborates with other European pharmacology associations and is a founding member of the European Federation for Exploratory Medicines Development (EUFEMED, <https://www.eufemed.eu>).

## AFPT Last News

The composition of the new office is for the next 2 years the following :

- Lionel Hovsepian (MD), President;
- Eric Legangneux (MD), Vice-President;
- Jean-Louis Pinquier (MD), Vice-President;
- Bernard Orlandini (M.Sc), Secretary;
- Henri Caplain (MD), Assistant Secretary and honor president;
- Denis Gossen (PhD), Treasurer;
- Pierre-François Clot (PhD), member of the board;
- Yves Donazzolo (MD), member of the board;
- Delphine Elmerich (M.Sc), member of the board;
- Philippe Grosjean (PhD), member of the board;
- Maxime Le Merdy (PharmD), member of the board.

## Upcoming activities

### **SAVE THE DATE - 18<sup>th</sup> Annual Conference 14 & 15<sup>th</sup> May 2020**

#### **« Evolution of the approaches and tools in translational and clinical pharmacology »**

UIC-P Espaces Congrès, Paris, France

[Register quickly: places are limited!](#)

## Projects

The AFPT-Le Club Phase 1 is associated with EUFEMED members in a 2-year human pharmacology teaching ( 6 modules).

The AFPT-Le Club Phase 1, with the Universities of Paris-Sud-Orsay and/or Grenoble, will initiate, in 2020, courses on drug safety. Because of its quality, Pharmatrain® will be valid in all European countries. Teachers are welcome.

## Breaking World Pharma News (R&D, Regulatory, Ops...)

European expedited approval over reliant on non-validated surrogate endpoints

Source: <https://tinyurl.com/y3kcnokv>

EMA and FDA are highly aligned on marketing application decisions

Source: <https://tinyurl.com/y25rzuul> , <https://tinyurl.com/y2rf5zk2>

FDA finalises guidance on placebos and blinding in cancer trials

Source: <https://tinyurl.com/y4v48ajp>

Reporting of physiologically based PK (PBPK) modelling and simulation'

Source :[https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-reporting-physiologically-based-pharmacokinetic-pbpbk-modelling-simulation\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-reporting-physiologically-based-pharmacokinetic-pbpbk-modelling-simulation_en.pdf)

## Other

To close this first edition of our newsletter,  
we wish you a season of joy and a great success in the year to come.  
We are looking forward continuing collaboration in 2020.



## Contact



Connect with us on  
**LinkedIn**

