Association Française de Pharmacologie Translationnelle
Le Club Phase 1

EUFEMED
European Federation for Exploratory Medicines Development

HEALTHI | université PARIS-SACLAY
Interdisciplinary Action *Health and Therapeutic Innovation*

Course: "Pre-Clinical and Clinical Safety in Early Development Human Trials"

09-13 March 2026 – 5 full days in Paris-Saclay University, France

Venue: UNIVERSITÉ PARIS-SACLAY, SITE HENRI MOISSAN
17 avenue des Sciences
91400 Saclay, France

Coordinator: Dr Henri Caplain, **emails:** hencaplain@orange.fr, afpt.cp1@gmail.com

Course exclusively in English and in presential due to its interactive nature.

Minimum number of participants: 10

Introduction

This course addresses postgraduates in life sciences interested in early clinical development of medicinal products. The training of several days provides a concise overview on safety in Human Pharmacology / Translational Medicine spanning from non-clinical pharmacology and toxicology over first-in-man to proof-of-concept clinical trials.

Learning Outcomes

On successful completion, students should be able to demonstrate an understanding / knowledge of the following:

- Minimal nonclinical safety package to support the first dose in human (FIH) (**Remember**).
- Risk assessment from non-clinical safety package (**Apply**).
- How to read and understand an Investigator's Brochure (IB) prior to early clinical trials (**Apply**).
- Contributing safety findings from early phase trial to the IB (**Apply**).
- Specific aspects of how-to set-up and conduct safe early phase clinical trials (**Apply**).
- Selection of appropriate trial population (**Understand**).
- Assessment, evaluation, and reporting of safety data from early clinical trials (**Understand**).
- Defining pharmacokinetic (PK) endpoints / exposure limit for early phase clinical trials (**Apply**).
- Safety biomarkers (**Understand**).
- Development safety update reports (**Apply**).
- Development of risk management plans (**Apply**).
- Most important medical emergencies in early clinical trials (**Remember**).
- Characteristic safety issues involved in the development of biologicals and advanced therapies (**Understand**).

Minimal pre-training documentation to be covered prior to the training:

- **ICH guidance**:
  - ✓ M3(R2) and M3(R2) Q&As (R2): Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization (MA) for Pharmaceuticals (**Mandatory**).
  - ✓ M6: Virus and Gene Therapy Vector Shedding and Transmission (Optional recommended).
  - ✓ M7(R2), M7(R2) Q&As and M7(R3) Maintenance EWG/IWG: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (**Mandatory**).
  - ✓ M12: Drug Interactions Studies (Optional recommended).
  - ✓ S2(R1): Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use (Optional recommended).

- ✓ S3A and S3A Q&As: Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies (**Mandatory**).
- ✓ S3B: Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies (Optional).
- ✓ S4: Duration of Chronic Toxicity Testing in Animals (Rodent and Non Rodent Toxicity Testing) (**Mandatory**).
- ✓ S5(R3) and S5(R4) Revision of S5 Guideline on Detection of Toxicity to Reproduction for Human Pharmaceuticals (**Mandatory**).
- ✓ S6(R1): Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (**Mandatory**).
- ✓ S7A: Safety Pharmacology Studies for Human Pharmaceuticals (**Mandatory**).
- ✓ S7B: The Non-Clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (**Mandatory**).
- ✓ E14/S7B: Clinical and Nonclinical Evaluation of QT/QTc Interval prolongation and Proarrhythmic Potential (Optional recommended).
- ✓ S8: Immunotoxicology Studies for Human Pharmaceuticals (**Mandatory**).
- ✓ S9 and S9 Q&As: Nonclinical Evaluation of Anticancer Pharmaceuticals (Optional).
- ✓ S10: Photosafety Evaluation of Pharmaceuticals (Optional recommended).
- ✓ S11: Nonclinical Safety Testing in Support of Development of Paediatric Medicines (Optional).
- ✓ S12: Nonclinical Biodistribution Considerations for Gene Therapy Products (Optional).
- ✓ S13 EWG: Nonclinical Safety Studies for Oligonucleotide-based Therapeutics (Optional).
- ✓ E2A: Clinical safety Data Management: Definitions and Standards for Expedited Reporting (**Mandatory**).
- ✓ E2F: Development safety update report (**Mandatory**).
- ✓ E6(R3) EWG: Good Clinical Practice (**Mandatory**).
- ✓ E8 (R1): General Consideratoins for Clinical Trials (Optional).
- ✓ E11 (R1): Clinical Investigations of Medicinal Products in the Paediatric Population (Optional).
- ✓ E14 and E14 Q&As(R3): The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (**Mandatory**).
- ✓ E14/S7B IWG and E14/S7B DG: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential (**Mandatory**).
- ✓ E15: Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories (Optional).
- ✓ E20 EWG: Adaptive Designs for Clinical Trials (Optional).

- **EMA guideline**:
  - ✓ EMEA/CHMP/SWP/28367/07 Rev.1: Guideline on Strategies to Identify and Mitigate Risk for First-in-Human and Early Clinical Trials with Investigational Medicine Products – 20 July 2017 (**Mandatory**).
  - ✓ EMEA/CHMP/GTWP/125459/2006: Guideline on the Nonclinical Studies Required before First Clinical Use of Gene Therapy Medicinal Products – 30 May 2008 (Optional recommended).
  - ✓ EMA/838713/2011 Rev. 2: Guideline on good pharmacovigilance practices (GCP): Module V – Risk Management Systems (Rev. 2) – 28 March 2017 (**Mandatory**).

- ✓ EMA/873138/2011 Rev 2: Guideline on Good Pharmacovigilance Practices (GVP): Module VI – Collection, Management, and Submission Reports of Suspected Adverse Reactions to Medicinal Products (Rev. 2) – 28 July 2017 (Optional).
- ✓ Clinical Trials Facilitation and Coordination Group (CTFG): Recommendations Related to Contraception and Pregnancy Testing in Clinical Trials – version 1.1 21 September 2020 (**Mandatory)**.

- **US-FDA guidance**:
  - ✓ Guidance for industry: Format and Content of a Risk Evaluation and Mitigation Strategies (REMS) Document – 04 January 2023 (Optional).
  - ✓ Guidance for Industry: Safety Testing of Drug Metabolites – Rev.2 – March 2020 (Optional).
  - ✓ Guidance for Industry: Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers – 28 July 2005 (**Mandatory**).

- **Slides received from the speakers** in the 2 weeks preceding the start of the course (**slide desk**).

This AFPT- Le Club Phase 1 course tries to meet the standards for high-quality postgraduate education and training in Medicines Development established by **PharmaTrain** and the recognition application is proceeding.

Day 1: Monday 09-March-2026 – Minimal Non-Clinical Safety Package to Support the First Dose in Human.

08:45 – 09:00 **Introduction of Faculty and Participants – Overview on Training Course.**

Coordinator: Henri Caplain, Senior Clinical Pharmacologist, Advisor in Early Clinical Development, Clinical development strategy, Translational Pharmacology, and Drug Safety Risk Management, Honorary President AFPT-Le Club Phase 1

09:00 – 10:30 **Design, Conduct and Interpretation of General and Reproductive Toxicology Studies.**

Learning objectives: To provide an understanding/knowledge of general and reproductive toxicology evaluation supporting the first dose in human.

Key concepts: Design of general and reproductive toxicology studies; Dose and species selection; Safety ratio/safety margin; No Observed Effect Level/No Observed Adverse Event Level (NOAEL); Lowest Observed Adverse Effect Level (LOAEL); Maximal Tolerated Dose (MTD); Maximum Feasible Dose (MFD); Limit doses/exposures in repeated -dose toxicity studies; Target organs; Relevance of animal models, including target expression, pharmacodynamics, metabolism and PK aspects, and off-target binding activities and receptor/ligand occupancy and kinetics; Micro-dosing and sub-therapeutic dose concepts and limitations; Juvenile animal testing; Duration of studies to support clinical trials and marketing approval; The use of organoids; Refining, Reducing, Replacing the use of animals in non-clinical testing, 3Rs programmes, their sustenance and development.

Speaker: Franck Chanut, Head of Preclinical safety Projects, France, Sanofi R&D

10:30 – 10:45 **Coffee Break**

10:45 – 12:15 **Nonclinical Pharmacology Studies.**

Learning objectives: To provide an understanding/knowledge of pharmacodynamic and safety pharmacology evaluation supporting the first dose in human.

Key concepts: Primary pharmacodynamic studies (*in vitro* and/or *in vivo*); Design of safety pharmacology studies; Core battery systems; Assessment of effects on cardiovascular, respiratory and central nervous systems (CNS); Supplemental and follow-up safety pharmacology studies; Secondary organ systems of interest; Use of in silico, animal- and cell-based models of disease mechanisms to study the pharmacology of a new drug.

Speaker: Stephanie Plassman, Senior expert in non-clinical drug development, Preclinical Safety (PCS), AGAH Regent, Germany (**online**)

12:15 – 14:00 **Lunch**

14:00 – 16:00 **The Use of Nonclinical Pharmacology and Pharmacokinetic assessments; PK/PD Modelling to Bridge Nonclinical and Clinical Safety Endpoints.**

Learning objectives: To provide an understanding/knowledge of nonclinical pharmacology and pharmacokinetic evaluation supporting the first dose in human and PK/PD modelling to bridge nonclinical and safety endpoints.

Key concepts: Assessment of the mode of action/effects of candidate compound on the target; Absorption/distribution/ metabolism and excretion (ADME) assessment; Toxicokinetic evaluation; In vitro and in vivo study of metabolism and pharmacokinetics, defining therapeutic margins; ; Half-life, C_{max}, systemic exposure (AUC), in vitro metabolic and plasma protein binding for animals and humans, clearance, volume of distribution, intrinsic and extrinsic factors which affect the PK; PK linearity/non-linearity/ Dose-proportionality; Steady-state; Accumulation factors; Metabolites assessment (animals and nonclinical characterization for humans); Pharmacogenetics/polymorphisms/ Pharmacometrics/PK/PD modelling.

Speaker: PhinC

16:00 – 16:15 **Coffee Break**

16:15 – 18:00	**On- and Off- Target Binding Affinities.** Learning objectives: To provide an understanding/knowledge of on- and off-target evaluation before the first in human studies, including in-vivo models and modern in silico enhancements; Identify, characterize and contextualize off-target interactions that can lead to adverse effects, thereby informing risk assessment. Key concepts: On- and off-targets, target panels, target binding and functional target interaction; Receptor/ligand occupancy and kinetics; Secondary pharmacology data integration and margin of safety. Speaker: Friedemann Schmidt, Head of Digital Toxicology, Sanofi R&D and Technical University Darmstadt, Germany
18:00	**Adjourn**

Day 2: Tuesday 10-March-2026 – Minimal Non-Clinical Safety Package to Support the First Dose in Human and Principles of Risk Assessment from Non-Clinical Safety Package.

09:00 – 10:30	**Immunotoxicity Assessment.** Learning objectives: To provide an understanding/knowledge of evaluation of potential immunotoxicity. Key concepts: Standard toxicity studies; Study design to assess drug-induced immunotoxicity; Selection of assays; Potential immunotoxicity linked to the pharmacological properties, intended patient population, structural similarity, disposition of the drug. Speaker: Pr. Marc Pallardy, Honorary Dean, Faculty of Pharmacy and Director of Interdisciplinary Action "Health and Therapeutic Innovation" Paris-Saclay University
10:30– 10:45	**Coffee Break**
10:45– 12:15	**Nonclinical Studies Required before First Clinical Use of Gene Therapy Medicinal Product.** Learning objectives: To provide an understanding/knowledge of nonclinical package require before the first use in human of gene therapy medicinal product. Key concepts: Pharmacodynamic "proof of concept" in nonclinical model(s); Biodistribution; Studies to establish dose; Toxicity studies for the whole gene therapy medicinal product (virus or other micro-organism) or vector particle and/or delivery system + expression vector including cassette + transgene; Integration studies; Germline transmission; Target tissue selectivity; Immunogenicity and immunotoxicity; Delivery devices and excipients; Environmental risk/shedding. Speaker: Franck Chanut, Head of Preclinical safety Projects, France, Sanofi R&D

12:15 – 14:00	**Lunch**
14:00 – 15:00	**Genotoxicity Assessment.** Learning objectives: To provide an understanding/knowledge of genotoxicity evaluation supporting the first dose in human and potential genotoxic impurities. Key concepts: Design of genotoxicity assessment; *In vitro* and *in vivo* testing; Genotoxic impurities and threshold of toxicological concern (TTC). Speaker: Guy Bouvier, Toxicology and Product Safety Director, Pierre-Fabre Research Institute (IRPF)
15:00 – 15:45	**Phototoxicity Assessment.** Learning objectives: To provide an understanding/knowledge of photosafety testing before the first use in human. Key concepts: Phototoxicity; Photoallergy; Photogenotoxicity; Photocarcinogenicity; Need for photosafety testing before first in human study; Phototoxicity testing. Speaker: Béatrice Gauthier, Veterinary Pathologist Expert, Sanofi R&D
15:45 – 16:00	**Coffee Break**
16:00 – 16:45	**Nonclinical Local Tolerance Assessment.** Learning objectives: To provide an understanding/knowledge of nonclinical local tolerance evaluation. Key concepts: Design and need of local tolerance studies; Sensitizing potential; Oral, ocular, cutaneous tolerance testing; Transdermal systems; parenteral tolerance testing; Rectal and vaginal tolerance testing. Speaker: Béatrice Gauthier, Veterinary Pathologist Expert, Sanofi R&D

16:45 – 18:00	**Principles of Risk Assessment from Nonclinical Studies, Critical Review of Scientific Literature and Early Clinical Data; Risk Factors.** Learning objectives: To provide the principles behind the principal of risk assessment from nonclinical studies. Key concepts: Importance of toxicokinetic; Risk factors/Safety factor; PK linearity/nonlinearity/dose proportionality/accumulation; Variable bioavailability; Steep dose response curve; Severe toxicities; Non-monitorable toxicities; Reversible/Irreversible toxicities; Toxicities without premonitory signs; Long-lasting binding and effects; Nature of the target and novel therapeutic targets; Differences and similarities between the pharmacology and toxicology of compounds and their metabolites in animals, humans, and cell preparations that provide qualitative and quantitative assessment: genotoxicity, general toxicity, toxicokinetics, pharmacokinetics, drug metabolism, safety pharmacology, immunotoxicity, reproductive toxicity, carcinogenicity; Relevance of nonclinical findings in various organ systems (liver, CNS, endocrine, eye, kidney, reproductive and gastrointestinal tract); Extrapolation of animal findings to human; Differences in nonclinical safety and toxicity packages between small molecules, biological medicines, advanced therapies. Speaker: Nigel Roome, Toxicology and Toxicologic Pathology Senior Consultant
18:00	**Adjourn**

Day 3: Wednesday 11-March-2026 – Safety in Human Pharmacology Trials.

09:00 – 10:30 **First-in-Human Trials (FIH).**

Learning objectives: To provide an understanding/knowledge of how to perform a safe first-in-human study.

Key concepts: How to read and understand the safety concerns in the first IBs and its maintenance; General principles of FIH studies, including overall design; Estimating the first safe dose in a FIH trial, including the concepts of Human Equivalent Dose (HED), Maximum Recommended Starting Dose (MRSD), NOAEL-based approach, Minimal Anticipated Biological Effect (MABEL), Minimum Effective Dose (MED), Pharmacological Active Dose (PAD); Allometric scaling; Sequence and interval between dosing of subjects within the same cohort, concept of sentinel subjects; Safe dose escalation scheme and last dose, including the Anticipated Therapeutic Dose Range (ATD); Minimal clinical evaluations and evaluations depending on the nonclinical findings, including the intensity and duration of monitoring; Safety biomarkers; Stopping rules; Appropriate ECG assessment for potential TQT waiver; How to proceed from single ascending dose (SAD) to multiple ascending dose (MAD) – assessment evaluation of SAD/MAD safety and PK data, integrated protocols versus consecutive trials (pros, cons and operations); Maximum duration of treatment; Decision making group or safety review committee; Identification of protocol violations and deviations; Safety data: tables and graphs for the evaluation of adverse events, laboratory data and other data related to safety; PD data: tables and graphs for the evaluation of pharmacodynamic data; Healthy participants versus patients; Inclusion of special population including women, children, elderly, ethnicity, genotype(s), cultural differences, possible interaction with subject's lifestyle, e.g. smoking, use of alcohol or drugs; Use of other medications with the possibility for adverse reactions and/or difficulties in the interpretation of results; Safety criteria of inclusion and exclusion; How to exclude participants with drug abuse and drug dependence; Protection of research participants; Sponsor and investigator role and responsibilities in context of trial participants, in particular, to avoid conflicts of interest.

Speaker: Yves Donazzolo, Clinical Pharmacologist, Associated Professor in Clinical Pharmacology, Grenoble University, Honorary President AFPT-Le Club Phase 1, Past-President EUFEMED

10:30 – 10:45 **Coffee Break**

10:45 – 11:45 **First-in-Human Trials (FIH) (Continued).**

Speaker: Pr. Yves Donazzolo, Clinical Pharmacologist, Associated Professor in Clinical Pharmacology, Honorary President AFPT-Le Club Phase 1, Past-President EUFEMED

11:45 – 12:30 **Management of Medical Emergencies.**

Learning objectives: To provide the principles of the management of medical emergencies in human pharmacology trials.

Key concepts: Pre-trial interviews and screening procedures; Up-to-date resuscitation procedures and guidelines; Diagnosis and management of anaphylaxis and other severe allergic phenomena, cardiac arrhythmias, respiratory emergencies, syncope, convulsions and other neurotoxicity.

Speaker: Pr. Yves Donazzolo, Practitioner Emergency Department, Grenoble University Hospital, Honorary President AFPT-Le Club Phase 1, Past-President EUFEMED

12:30 – 14:15 **Lunch**

14:15 – 16h15 **FIH Oncology Trials.**

Learning objectives: To provide an understanding/knowledge of first-in-human oncology trials.

Key concepts: Trials design, including traditional 3+3 design, Continual Reassessment Method (CRM), Dose Escalation with Overdose Control (EWOC) and other Bayesian approaches; Phase I trials of Agent Combinations; First dose; Dose escalation; Stopping rules; Grading of adverse events including the 'Common Terminology Criteria for Adverse Events' (CTCAE) descriptive terminology; Maximal Tolerated Dose (MTD; Dose limiting toxicities (DLTs); Data safety monitoring board (DSMB).

Speaker: Pr. Christophe Massard, Medical Oncologist, Head of The DITEP (Département d'Innovation Thérapeutique et Essais Précoces) - Gustave Roussy Institute (IGR)

16:15 – 16:30 **Coffee Break**

16:30 – 18:00	**Immunogenicity.** Learning objectives: To provide an understanding/knowledge of immunogenicity in early clinical development. Key concepts: Immunogenicity definitions; Why biotherapeutics are immunogenic?; Impact of immunogenicity on PK/efficacy/safety, examples including ATMPs; Immunogenicity risk assessment, including immunogenicity risk factors, risk-based sampling, and testing strategies; Including when to characterize Anti-Drug Antibodies (ADA)?, neutralizing assays. Speaker: Daniel Kramer, Global Scientific Advisor and coordinator immunogenicity, Sanofi R&D
18:00	**Adjourn**

Day 4: Thursday 12-March-2026 – Early Clinical development of Gene Therapies, Other Clinical Trials, and Pharmacovigilance in Human Pharmacology Trials.

09:00 – 11h00

Early Clinical Development of Gene Therapies.

Learning objectives: To provide an understanding/knowledge of early clinical development for gene therapies.

Key concepts: Introduction on Advanced Therapy Medicinal Products (ATMP), with definitions; Types of gene therapies, in vivo, ex vivo, gene editing; Clinical Trial Application (CTA)/MA dossier; Nonclinical development and Chemistry, Manufacturing and Controls (CMC); Global clinical development plan, including accelerated development; Tested Populations; Randomized control trials/ nonrandomized trials, control arms.

Speakers: Lionel Hovsepian, Clinical Pharmacologist, Early development expert, Head of Medical, and Valérie Salentey, Head of Regulatory Affairs and Quality Assurance, Sensorion-Pharma

11:00 – 11:15

Coffee Break

11:15 – 12:45

Adverse events (AEs)/Adverse drug reactions (ADRs) Evaluation and Reporting.

Learning objectives: To provide an understanding/knowledge of AEs/ADRs evaluation and reporting.

Key concepts: Role and responsibilities of the pharmaceutical professional in drug safety and pharmacovigilance; Methodology for collection in clinical trials, including reporting; Mechanisms of AEs/ADRs/safety risks; Assessment and classification of AEs, ADRs, serious AEs (SAEs), suspected unexpected serious adverse reactions (SUSARs), and AEs of special interests (AESIs); MedDRA coding and classification; Medical aspects of AEs/ADRs, including principles of event attribution, evidence for association and causality at case level and at aggregated case assessment, expectedness and seriousness assessments; the extent of variation in normality; Safety implications of breaches of good clinical practice (GCP).

Speaker: Henri Caplain, Clinical Pharmacologist, Senior Adviser in Early Clinical Development, Translational Pharmacology, and Drug Safety Risk Management, Past President AFPT-Le Club Phase 1

12:45 – 14:00	**Lunch**
14:00 – 15:15	**Other Human Pharmacology Trials: Food effect, Bioavailability, Drug-drug interactions, Patients with Renal or Hepatic Impairment, TQT Studies, Clinical Development Plan.** Learning objectives: To provide an understanding about the timing and safety implications of other human pharmacology trials, how to assess safety findings and individual exposure and an understanding/knowledge of the integrated cardiac safety, clinical development plan. Key concepts: Safe food effect trial; Bioequivalence study; Drug-drug interactions to be performed in Phase I of clinical development; Patients with renal or hepatic impairment; Design and timing of TQT study; Integrated cardiac safety concept; Proof-of-Concept (POC) and Proof -of-Mechanism clinical trials; Integrated cardiac safety, including appropriate ECG assessment in FIH for potential TQT study waiver, and clinical development plan (integrated nonclinical/clinical). Speaker: Denis Gossen, Senior Clinical Pharmacologist, AFPT-Le Club Phase 1
15:15 – 16:00	**Severity of Adverse Events (AEs), Adverse Drug Reactions (ADRs).** Learning objectives: To illustrate the potential safety impact of AEs/ADRs. Key concepts: General tolerability; Tolerance; Liver/renal toxicity, including drug-induced liver injury (DILI); CNS toxicity; Cardiac toxicity, including pro-arrhythmogenic risk; Immune toxicity, including cytokine release syndrome (CRS); Other system or local toxicities of concern; Monitoring of vital signs; What happens in case of pregnancy during a trial; Predisposing factors and the impact of pre-existing disease on the susceptibility for and severity of adverse events. Speaker: Henri Caplain, Clinical Pharmacologist, Senior Adviser in Early Clinical Development, Translational Pharmacology, and Drug Safety Risk Management, Past President AFPT-Le Club Phase 1
16:00 – 16:15	**Coffee Break**

16:15 – 17:00	**Development Safety Update Report in Phase I Clinical Development.** Learning objectives: To provide an understanding/knowledge of how read and fill a development safety update report after the first Phase I clinical trials. Key concepts: Rational for writing DSURs; ICH E2F and CIOMS V; Assessment process; DSUR outcomes; Compliance; Benefit/risk balance assessment concept. Case study(ies) Speaker: Henri Caplain, Clinical Pharmacologist, Senior Adviser in Early Clinical Development, Translational Pharmacology, and Drug Safety Risk Management, Past President AFPT-Le Club Phase 1
17:00 – 18:00	**Risk Management Plan in Early Drug Development.** Learning objectives: To provide the principles of the risk management plan in early drug development. Key concepts: Risk concept; Crisis management; Impact of AE on drug development and further trials; Risk management plan and planning; Risk evaluation and mitigation strategy; Safety specifications; Important identified and potential risks, missing information; Risk assessment; Risk minimization activities; Risk communication; Effectiveness of risk minimization; DRMP/DSUR progression during drug development; How to fill a risk management plan prior to the CTA/IND. Case study(ies) Speaker: Henri Caplain, Clinical Pharmacology, Senior Adviser in Early Clinical Development, Translational Pharmacology, and Drug Safety Risk Management, Past President AFPT-Le Club Phase 1
18:00	**Adjourn**

Day 5: Friday 13-March-2026 – Case Studies on Risk Management in Human Pharmacology Trials and Exam.

09:00 – 10:30	**Case Studies.** Work by sub-group on a case study Facilitator: Henri Caplain, Senior Clinical Pharmacologist, Advisor in Early Clinical Development, Clinical development strategy, Translational Pharmacology, and Drug Safety Risk Management, Honorary President AFPT-Le Club Phase 1
10:30 – 10:45	**Coffee Break**
10:45 – 11:45	**Case Studies.** End and reporting Facilitator: Henri Caplain, Senior Clinical Pharmacologist, Advisor in Early Clinical Development, Clinical development strategy, Translational Pharmacology, and Drug Safety Risk Management, Honorary President AFPT-Le Club Phase 1
11-45 -- 12:15	**Training Debriefs and Summary.** Facilitator: Henri Caplain, Senior Clinical Pharmacologist, Advisor in Early Clinical Development, Clinical development strategy, Translational Pharmacology, and Drug Safety Risk Management, Honorary President AFPT-Le Club Phase 1
12-15 -- 14:00	**Lunch**
14:00 -- 16:00	**Exam.** 1) Selection of multiple-choice questions (1 hour): 60% of questions must be correctly answered to pass test and receive a certificate. 2) Short questions (4 of 15 minutes each): 10/20 must be obtained to pass test and receive a certificate.
16:00	**End of the training**

Attendance Fees

1.600 € + VAT (21%)	Members of the AFPT-Le Club Phase 1, and other EUFEMED members (AGAH, Germany - AHPPI, UK - POLFEMED, Poland - ACRON, The Netherlands – HEALIXIA, Belgium)
2.100 € + VAT (21%)	Non-Members

Payments of a registration fee covers the cost to attend all courses, educational material, coffee breaks, and all lunches during the course. Notice that this registration fee does not cover transportation fee and accommodation fee.

Special fees and free invitation (limited numbers) for students are available on request.

Venue

UNIVERSITÉ PARIS-SACLAY, SITE HENRI MOISSAN, PÔLE BIOLOGIE-PHARMACIE CHIMIE
17 avenue des Sciences
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Contact and further information

Organiser and responsible for the programme

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CLICK HERE FOR REGISTRATION

Registration deadline: 27 February 2026