START-UP & ACADEMICS – THEORY & PRACTICE IN DRUG DEVELOPMENT

EARLY PHASE DRUG DEVELOPMENT COURSE

SEPTEMBER 26 | VILLEJUIF - FRANCE

FUTURE MEANS CREATIVITY

VENUE:
66 RUE GUY MÔQUET
94800 VILLEJUIF
SALLE: 105

SUP biotech PARIS

IN COLLABORATION WITH:

SGS

This course aims to provide participants with a strong insight in how drugs are developed, and how you can successfully make the transition from lab to clinic. This meeting encompasses a theoretical plenary morning session with expert lectures and discussions, and in the afternoon, practical workshops where the participants can apply the lessons learned on actual case studies.

This meeting will address:

- The common hurdles and challenges in early phase drug development
- How early data analysis through pharmacokinetic and modeling & simulation can optimize decision making
- Which regulatory aspects you need to take into account when moving through the different phases of drug development

AGENDA

MORNING: THEORETICAL SESSION OF THE WORKSHOP		
9:15 - 09:30	REGISTRATION AND WELCOME COFFEE	
9:30 - 09:35	OPENING & INTRODUCTION	VANESSA PROUX Directrice Générale Sup'Biotech
09:35 - 10:15	CONTROL OF BIOLOGICS, WHY, WHEN AND HOW	DR. LUC – ALAIN SAVOY, PhD Global Head of Biologics SGS
10:15 - 10:20	Q & A SESSION	
10:20 - 11:20	OPTIMIZING EARLY CLINICAL DRUG DEVELOPMENT IN THE 21ST CENTURY	NARINÉ BARIRIAN PK and Clinical Pharmacology Expert SGS
11:20 - 11:25	Q & A SESSION	
11:25 - 11:35	COFFEE BREAK	
11:35 - 12:15	PHARMACOMETRICS: MODELING & SIMULATION TOOLS TO IMPROVE DECISION MAKING IN CLINICAL DRUG DEVELOPMENT.	ELODIE VALADE Modelling and Simulation Consultant SGS Exprimo
12:15 - 12:20	Q & A SESSION	
12:20 - 12:40	FROM LAB TO MARKET: WHAT DO REGULATORS EXPECT?	BRUNO SPEDER Head Clinical Regulatory Affairs & Consultancy SGS
12:40 - 12:45	Q & A SESSION	
12:45 - 13:30	LUNCH	
AFTERNOON: PRACTICAL SESSION OF THE WORKSHOP		
13:30 - 14:30	START WORKSHOP IN PRACTICE IN SMALL GROUPS	
14:30 - 14:50	COFFEE BREAK	
14:50 - 15:50	WORKSHOP (CONTINUATION)	
15:50 - 16:20	WRAP-UP/ TAKE HOME MESSAGES	
16:20 - 16:30	CLOSING BY VANESSA PROUX & BRUNO SPEDER	

Coffee breaks will be offered by Sup'Biotech. Lunch buffet will be provided by SGS for the workshop afternoon session attendees.
The course is free of charge, however registration is mandatory before **September 20, 2019.**
The afternoon session is limited to a maximum of 30 attendees.
Participation in the workshop, open only to professionals, also qualifies for the morning plenary session.

REGISTER HERE

SPEAKER ABSTRACTS & BIOGRAPHIES

CONTROL OF BIOLOGICS, WHY, WHEN AND HOW

DR. LUC – ALAIN SAVOY, PhD
Global Head of Biologics
SGS

ABSTRACT

Biologics drugs are made of highly complex and heterogenous molecules which require in depth characterisation to guarantee a comprehensive understanding of their physico-chemical structure and biological properties. This characterization will subsequently lead to the selection of analytical methods addressing the monitoring of critical Quality attributes of the Biologic to guarantee its safety and efficacy. Why, when and which charaterisation should be performed during the development of a Biologic will be discussed during this presentation.

BIOGRAPHY

Luc-Alain Savoy obtained his PhD at the University of Geneva which involved the qualitative and quantitative application of mass spectrometry to the analysis of proteins.

Luc-Alain is currently Global Head of Biologics for SGS Life Sciences. Prior to this role, he co-founded, in 1991, M-Scan SA, a contract research organisation specialising in high level bioproducts characterization that was sold to SGS in 2010. Since 2017 he is also chairman of BioXpress Therapeutics a company developing biosimilars.

OPTIMISING EARLY CLINICAL DRUG DEVELOPMENT IN THE 21ST CENTURY

NARINÉ BARIRIAN
SGS PK and Clinical Pharmacology Expert
SGS

ABSTRACT

Over the past three decades costs of drug development have risen sharply, while the likelihood for a new compound to make it to the market declined. This discrepancy reveals the need to rethink the traditional clinical development model.

Modernizing and optimizing early phase clinical studies is paramount for late phase success. Therefore, early phase clinical trials, such as the first-in-human trials, need to be designed in a smart way to gain crucial information on the new compound as early as possible.

Implementing innovative tools, such as biomarkers and better understanding of diseases at the molecular level aid to improve safety/efficacy testing methods and provides the possibility to improve success rates and shorten timelines.

Considering factors linked to the compound pharmacological (PK and PD) characteristics are crucial to find the best clinical trial design which will be acceptable by appropriate Health Authorities and will bring valuable results. Animal and other forms of laboratory research provide the pharmacological foundation for human studies. Before proceeding to early human testing, investigators and reviewers must determine whether the preclinical scientific/pharmacological foundation is adequate. This is a complex and value-laden task.

During the workshop, a practical exercise will be provided to reflect on possible tools and designs that can be used to optimize a first-in-human trial, using the theoretical knowledge shared at morning presentation session.

BIOGRAPHY

After obtaining a University degree in Pharmaceutical Sciences, Nariné has started the Research Master in UCL (Belgium) in Cellular and Molecular Pharmacology orientation. The research experience was continued by a PhD in Pharmaceutical Sciences at UCL and St Luc Hospital (Bruxelles) in Clinical Pharmacology and Pharmacokinetics orientation. By doing PhD, Nariné performed her own research clinical trials in the Unité de Pharmacologie Clinique at St Luc Hospital and therefore obtained the first knowledge and experience in Clinical Pharmacology applied to Clinical Trials, which was further continued at SGS. 10 years ago Nariné joined SGS as Pharmacokineticist, then she worked as a PK team Coordinator and now as PK and Clinical Pharmacology Expert. In her function, Nariné is a part of SGS consultancy/experts team supporting/advising the clients in the study designs and Clinical Development plans of their new compounds.

PHARMACOMETRICS: MODELLING AND SIMULATION TOOLS TO IMPROVE DECISION MAKING IN CLINICAL DRUG DEVELOPMENT

ELODIE VALADE
Modelling and Simulation Consultant
SGS Exprimo

ABSTRACT

Drug development continues to be time consuming and expensive whereas pharmacotherapy is often practiced at a suboptimal level of performance. While the data informing the decision are complex and diverse, successful drug development and commercialization requires getting critical decisions right—what is the exposure-response relationship for the drug, what is the optimal dosing strategy, and which patients would derive greatest benefit from it.

Pharmacometrics is the science of interpreting and describing pharmacology in a quantitative fashion. It is defined as the science that quantifies drug, disease and trial information to aid efficient drug development and/or regulatory decisions. Drug models describe the relationship between exposure (or pharmacokinetics), response (or pharmacodynamics) for both desired and undesired effects, and individual patient characteristics. Understanding the dose–concentration–effect relationship is a fundamental component of clinical pharmacology.

This presentation focuses on the application of population pharmacokinetic (PK), advanced pharmacokinetic-pharmacodynamic (PK/PD) and drug-disease modelling & simulation (M&S) to help decision making in clinical drug development. Through several examples, the role of pharmacometrics to support optimisation of dosing regimens, extrapolation and bridging to different study populations (e.g. from healthy volunteers to paediatrics, kidney failure or critically ill patients) and optimisation of clinical study designs (number of samples, estimation of therapeutic window, impact on study outcome, probability of success to meet target or vs. competitors) will be presented.

During the workshop, a practical session will allow you to simulate several trial design scenarios. Together, we will decide the next step for your compound, allowing you the best chances of market approval.

BIOGRAPHY

Elodie Valade joined SGS Exprimo as a Modelling and Simulation Consultant. Elodie obtained a Pharmacy degree (Pharm.D) and a M.S. degree in Pharmacokinetics from the Paris Descartes University, France in 2012. Thereafter, in 2015, she defended her Ph.D entitled "Treatment and Prevention of Transmission of HIV Infection: Pharmacokinetic analysis of emtricitabine by a population approach". In 2016, Elodie joined the Global Clinical Pharmacology department of Johnson & Johnson in Belgium, where she worked more than 2 years as a Postdoc Researcher. She was responsible for population pharmacokinetic and pharmacodynamic modelling and simulation activities supporting drug development, mainly in infectious diseases and oncology therapeutic areas. She was also particularly involved in the evaluation of cardiovascular safety (QT modelling) for several compounds.

FROM LAB TO MARKET: WHAT DO REGULATORS EXPECT?

BRUNO SPEDER,
Head Clinical Regulatory Affairs & Consultancy
SGS

ABSTRACT

Bringing a compound from the lab to the market is a long and winding road with a great number of potential pitfalls. During drug development it is very important to have a clear view on the expectations of Regulatory Authorities at each stage of drug development. During this talk we will highlight the most common regulatory issues that may arise through a number of illustrated case studies and how you can make sure you keep your development on track.

BIOGRAPHY

Bruno is Head Clinical Regulatory affairs & Consultancy at SGS Clinical Research. Bruno is pharmaceutical engineer and has almost 10 years experience in drug development. He supports pharmaceutical and biotech companies in designing their regulatory strategies and supports them in the interactions with regulators like EMA and FDA. He is member of the advisory board of several biotech companies and guest lectures on clinical research in the honours Program of the Ghent University.

ABOUT SGS LIFE SCIENCES

SGS is a leading life science CRO providing clinical research, biologics characterization, biosafety, and quality control testing. Delivering solutions in Europe and in the US, SGS provides clinical trial management (Phase I to IV) services encompassing clinical project management and monitoring, data management, biostatistics, medical writing, pharmacovigilance, PK/PD Modeling & simulations and regulatory consultancy. SGS has its own clinical unit with a total of 88 hospitalization beds in Belgium and has a wealth of expertise in FIH studies, human viral challenge testing, biosimilar and complex PK/PD trials, as well as other regulatory and exploratory trials. SGS has a large database of investigators and key opinion leaders with therapeutic focuses in Infectious Disease, Vaccines, and Respiratory.

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