LIFE SCIENCES

CRITICAL DRIVERS FOR SUCCESSFUL CLINICAL TRIALS

WASHINGTON, D.C.

BIOPHARM DAY SEMINAR

MAY 30, 2019

VENUE
BETHESDA MARRIOTT
5151 POOKS HILL ROAD,
BETHESDA, MD 20814 - USA

SGS

It is with great pleasure that SGS Life Sciences invites you to the US Biopharm Day Seminar which will be held in the Washington D.C. area. This one-day seminar on Clinical Research will address the benchmark practices for defining and measuring relevant clinical end-points along the drug development pathway to optimize the chance of success in patient trials.

Pragmatic topics such as regulatory pathways, study feasibility, adaptive study design, modelling and simulation, human challenges trials, patient sites selection and activation, SMART clinical trial monitoring will be introduced in short presentations by key industry experts, discussed and then challenged in Q&A sessions and at thematic round tables.

There will be a forum for sharing ideas regarding concrete solutions. Two informal, interactive sessions will provide you and your peers the opportunity to exchange thoughts on the latest clinical trials initiatives and industry endeavors to revitalize the global drug pipeline.

SESSION 1 – REDUCING THE ODDS OF FAILURE IN LATE PHASE BY IMPROVING THE PROGNOSTIC VALUE OF EARLY PHASE DATA

SESSION 2 – TURNING 'HIGH VALUE STUDY' FEASIBILITY INTO SUCCESSFUL 'PATIENT TRIAL' EXECUTION

AGENDA

9:30	WELCOME BREAKFAST & OPENING		
10:00 - 11:00	REDUCING THE ODDS OF FAILURE IN LATE PHASE BY IMPROVING THE PROGNOSTIC VALUE OF EARLY PHASE DATA	K. LEMMENS, MD, Medical Director Early Phase, SGS	
15 MIN.	***COFFEE BREAK***		
11:15 - 12:30	**ROUNDTABLE**		
12:30	*LUNCH BREAK / NETWORKING SESSION*		
13:45 - 14:45	TURNING 'HIGH VALUE STUDY' FEASIBILITY INTO SUCCESSFUL 'PATIENT TRIAL' EXECUTION	KEITH PIETROPAOLO, VP of Clinical Operations and Project Management, Atea Pharmaceuticals	JANELLE JOHNSON, Director International Project Management ADRIAN WILDFIRE, Scientific Director
15 MIN.	***COFFEE BREAK***		
15:00 - 16:15	**ROUNDTABLE**		
16:30	*CLOSING RECEPTION*		

TO REGISTER

Free of charge seminar, registration mandatory.

Please contact Tanieka Denton: tanieka.denton@sgs.com
or register directly here

ABSTRACTS, BIOGRAPHIES AND ROUNDTABLES

MORNING SESSION

REDUCING THE ODDS OF FAILURE IN LATE PHASE BY IMPROVING THE PROGNOSTIC VALUE OF EARLY PHASE DATA

K. LEMMENS, MD
Medical Director Early Phase
SGS

ABSTRACT

The development of new pharmacological compounds is lengthy and costly, with many failures still during later phase clinical trials. This R&D challenge has resulted in a new paradigm of early phase development in which the goals and objectives of phase 1 trials move beyond traditional dose/toxicity testing.

To estimate a drug's clinical potential, information on safety, pharmacokinetic and pharmacodynamic outcomes are all paramount. Via translational approaches, critical information on a compounds dose-response effect can be acquired already in the early clinical phase. In this context, new strategies emerge such as implementation of new biomarker technologies, combined protocols with food effect or drug interactions and addition of patient or special population cohorts. As a result, early phase clinical studies often display more complex and combined designs.

Key learning objectives:

- How challenges in clinical development lead to more complex early phase "umbrella" protocols
- The goals and objectives nowadays of early phase clinical trials
- The benefits of adaptive designs in early phase
- How biomarkers can be useful in the early development stage
- What is the importance of preclinical data when optimizing early phase designs

Katrien Lemmens

Katrien, MD, graduated in 2000 at University of Antwerp with a Medical Degree, and obtained a PhD in Medical Science (pharmacology) in 2006. After continuing medical training in Cardiology (London, Antwerp), and Post-Doctoral Research in Physiopharmacology at the University of Antwerp she joined the pharmaceutical industry in 2011, in the position of Medical Director and Principal Investigator at the phase I Clinical Pharmacology Unit of Janssen R&D. In 2013, she became Assistant Professor in Pharmacology at the University of Antwerp. Since 2016, Katrien is Medical Director Early Phase at SGS Life Science, providing medical expertise and leadership to the early phase clinical pharmacology activities.

ROUNDTABLE

How designing an early phase study to ensure reportable scientific data while maintaining operational feasibility

FIH trials are aimed at obtaining reliable information on safety, tolerability, PK and PD and tend to become increasingly complex. Despite of its exploratory nature, the information collected must be scientifically valid, taking into consideration the operational aspects. This workshop will discuss how Science can go hand-in-hand with the execution of the trial in the phase I unit.

AFTERNOON SESSION

TURNING 'HIGH VALUE STUDY' FEASIBILITY INTO SUCCESSFUL 'PATIENT TRIAL' EXECUTION

KEITH PIETROPAOLO
VP of Clinical Operations and Project Management,
Atea Pharmaceuticals

JANELLE JOHNSON
Director International Project Management
SGS

ADRIAN WILDFIRE
Scientific Director
SGS

ABSTRACT

Robust feasibility is a foundational brick in gearing up for a successful trial. Performing an in-depth feasibility goes significantly beyond simply finding pockets of patients and high enrolling sites. SGS' approach to feasibility is unique and includes several key stakeholders to ensure we are going to execute the most productive study possible; keeping a focus on the protection of primary and second endpoints. This translates into delivery of very well executed programs and solid data for analysis.

In this session, you'll hear from three categories of stakeholders and their view on the value in this approach: Project Management (Janelle Johnson); Medical and Scientific (Adrian Wildfire) and Sponsor (Keith Pietropaolo).

BIOGRAPHIES

Keith Pietropaolo

Keith Pietropaolo has nearly 20 years of global drug development experience across multiple therapeutic areas. He is currently the VP of Clinical Operations and Project Management at Atea Pharmaceuticals, Inc. in Boston. Prior to joining Atea, Keith has held numerous scientific and operational clinical positions at Alnylam, Sideris, Idenix and Averion, where he has led clinical development programs and project teams for both early and late phase drug candidates. He spent over 10 years at Idenix Pharmaceuticals, where he managed a portfolio of global phase I-III clinical trials across multiple antiviral programs.

Janelle Johnson

Janelle Johnson is Director International Project Management for SGS Life Sciences North America. Prior to joining the team in 2016, she has held positions of increasing responsibility in both Clinical Operations and Project Management in pharmaceutical, biotechnology, clinical research organizations. Her career spans more than 15 years, across all phases and in variable therapeutic areas, inclusive of a strong focus in oncology. Janelle holds an MBA, Graduate Certificate in Epidemiology, PMP, and is a member of Delta Epsilon Tau Honor Society (MBA).

Adrian Wildfire

Adrian has 30 years' experience in communicable diseases. He obtained his Fellowship in Medical Microbiology in 1990 and a Masters in Parasitology in 1998. The author / co-author of numerous papers with many of the UK's leading infectious disease experts and KoLs in tuberculosis, HIV, and influenza, his early training at the Wolfson Institute and London School of Hygiene and Tropical Medicine prepared him to lead ID teams within various research institutions and organizations.

ROUNDTABLE

Key drivers to implement a S.M.A.R.T. Monitoring

This workshop will review the foundations for a Specific, Measurable, Achievable, Relevant and Time-bound clinical trial monitoring.

Bridging FDA & EMA requirements for successful clinical development

Bridging the requirements between European and US regulations and streamlining your development program is not always an easy task. Careful assessment and planning of regulatory guidance will allow for a smooth development of your compound. This roundtable will discuss how a successful international development program can be implemented from a regulatory point of view and how the development of your compound can be optimized.

ACCOMMODATION & REGISTRATION

The seminar is offered free of charge. However, only pre-registered attendees will be admitted.
Register here or contact Tanieka Denton: tanieka.denton@sgs.com

VENUE

Bethesda Marriott
5151 Pooks Hill Road, Bethesda, MD 20814 - USA
Phone: (301) 897-9400
https://www.marriott.com/hotels/travel/wasbt-bethesda-marriott/

ABOUT SGS LIFE SCIENCES

SGS provides clinical research and bioanalytical testing with a specific focus on early stage development and biometrics. Delivering solutions in Europe and in the Americas, SGS offers clinical trial (phase I to IV) services encompassing drug development consultancy, clinical project management and monitoring, biometrics, PK/PD modeling and simulation, and regulatory and medical affairs services. SGS has its own Clinical Pharmacology Unit in Belgium, including a human challenge testing facility and two phase I patient units based in Belgium and Hungary. SGS has a wealth of expertise in First-In-Human studies, viral challenge testing, biosimilars and complex PK/PD studies, with a therapeutic focus on infectious diseases, vaccines, and respiratory.

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