2019 Scientific Track Daily Themes

Preclinical Development | Bioanalytics | Clinical Pharmacology | Manufacturing & Bioprocessing | Formulation & Quality

Preclinical Development

Monday, November 4th

Next Generation Technologies in Preclinical Development

This theme will explore recent advances in new technologies enabling improved or orthogonal drug discovery and preclinical assessments.

Biomolecule sub-track sessions focusing on T-cell engaging molecules and CAR-T therapies may include but are not limited to: target identification and selectivity, application of multi-specifics in solid tumors, protein/cell engineering, avidity driven molecule development, predictions of cytokine release syndrome, achieving balanced T-cell activation, recent case studies detailing challenges, success strategies, and lessons learned.

Chemical sub-track sessions focusing on artificial intelligence in drug discovery may include but are not limited to: machine learning and deep/unsupervised learning, employing big data in computational drug repurposing/repositioning, advanced target scoring/identification, improved QSAR and drug property predictions, and recent applications in personalized medicine and rare disease

Tuesday, November 5th

Emerging Research Tools for High Quality Candidate Selection

This theme will cover new developments in research tools critical for evaluating, de-risking and selecting optimal drug candidates. This encompasses improved understanding and characterizing of biological systems, advances in function assays, and novel delivery strategies incorporating early stage “fit for purpose” models for formulation optimization.

For biomolecules, more specific topics may include but are not limited to: deep sequencing to improve screening accuracy and robustness, enhanced immunogenicity predictions, advanced animal models, and imaging techniques for improving predictions.

For chemical entities, more specific topics may include but are not limited to: applications of organ on a chip models, gut microbiome studies, innovations in ADME and transporter assessments, and regulatory considerations in the preclinical space.

Wednesday, November 6th

PK and PD Modeling in Effective Preclinical to Clinical Translation

This theme with delve into the current "state of the art" regarding applications and implications of PK/PD modeling and simulation including toxicodynamic aspects for therapeutic index assessment, first in human dose projections, biomarker based clinical response predictions, improved drug-drug interaction liability assessments, covariate analysis in translation, advanced systems pharmacology modeling, and model driven go/no-go decisions.

Biomolecular sessions are intended to focus on multi-specifics, CAR-Ts and novel drug modalities including immunological markers within PK/PD models, and specific PK/PD models for combination products.

Chemical sessions are intended to focus on advances in physiological based modeling and simulation regarding preformulation, efficacy and safety predictions, and specific PK/PD models for combination products.

Bioanalytics

Monday, November 4th

Innovative Bioanalytical Solutions and Future of Bioanalysis

The challenges facing bioanalytical scientists require solutions using new ways of thinking and application. Many exciting trends are emerging in bioanalysis. This theme will allow members to share and learn about new developments in sample collections, assay strategies, and technologies. New modalities, such as gene and cell-therapies, and demand for high sensitivity assays will require adaption of new and evolving bioanalytical technologies. Patient centric bioanalysis involves lower sample volume, remote sample collection/analysis.

We invite you to submit case studies related new technologies/new solutions to bioanalytical challenges. Examples may include but not limited to: micro sampling, microfluidics, HRMS, Acoustic Droplet Dispensing Mass spectrometry, qRT-PCR, and Branched DNA etc.

Tuesday, November 5th

Advances in Precision/Personalized Medicine & Biomarkers

To maximize therapeutic benefit for individual patients, precision/personalized medicine aims to target the right drug at the right dose for the right patient. This theme will focus on strategies for biomarker method development and validation from discovery to companion diagnostics. The breadth of bioanalytical approaches include but not limited to conventional LBA and LC-MS methods, imaging, flow cytometry, and omics methodologies. Novel strategies such as digital biomarkers and real-world outcomes introduce challenges to ensure consistency outside a central testing facility.

We invite you to share your insights by proposing topics/case studies related to the above topics.

Wednesday, November 6th

Dialogue on Emerging Regulatory Guidelines and Experiences

Bioanalytical (BA) scientists, including health authorities, share a common goal to ensure that the BA strategies and assays are suitable for efficacy and safety assessment of therapeutics. Regulatory

agencies continue to update guidelines that encompass bioanalytical, metabolite, immunogenicity, and biomarkers; and span topics from assay validation to data interpretation and risk assessment. As bioanalytical learning evolves, alternative scientific approaches may be applied with appropriate justification.

We welcome case studies on scenarios/unique challenges where alternative approaches were applied or no guidance was available. Both proactive strategy discussions with regulators as well as responses to health authority's observations and questions are also welcome.

Clinical Pharmacology

Monday, November 4th

Role of Modeling and Simulation in Dose and Dosing Regimen Selection

The value of model-informed drug discovery and development (MID3) in enabling decision-making and increasing efficiency is well established across drug discovery, development, commercialization, and life-cycle management stages. Clinical pharmacology is the key player in selecting the right (or best) dose and dosing regimen. Quantitative modeling approaches represent an integral component in dose selection at different stages of development including selection of first-in-human dose, dose escalation decisions, recommended phase 2 dose (or doses), fixed dose combination products, supporting the label dosing recommendations, the design of post-marketing dose refinement/finding studies, and personalized dosing.

Approaches of modeling and simulations pertinent to dose selection include PK/PD for target coverage, population pharmacokinetics, exposure-response analyses, and physiologically-based pharmacokinetic modeling. This theme will discuss novel modeling and simulation approaches in guiding dose selection throughout the continuum of drug development. Case studies (both successful and not) where modeling and simulation informed decisions around dose selection as well recent advances, challenges, and future applications of MID3 in dose selection will be discussed.

Tuesday, November 5th

Clinical Pharmacology Paths for Small Populations

Several patient subpopulations are typically excluded from pivotal clinical trials. These subpopulations include, but not limited to, patients with advanced degrees of renal or hepatic impairment, pediatrics, ethnic subpopulations in support of global registrational plans, women of child-bearing age, and pregnant women to name a few. Furthermore, patients with rare genetic makeup could also be either excluded from pivotal trials or enrolled in limited numbers insufficient for adequate characterization of the benefit-risk profile in these subpopulations. Underrepresentation of these subpopulations presents a challenge of extrapolating findings from the general population to these vulnerable patients. Clinical pharmacology plays an important role in bridging this gap through the design of efficient dedicated clinical trials in these subpopulations, use of quantitative modeling approaches, and modernizing eligibility criteria for pivotal clinical trials. Sessions in this theme will explore clinical pharmacology associated challenges and novel approaches to guide efficient drug development in underrepresented subpopulations from the perspective of pharmaceutical industry, regulatory authorities, academic institutions, and health care providers.

Wednesday, November 6th

Lessons Learned from Regulatory Interactions in Clinical Pharmacology for Innovative New Chemical Entities, Complex Generics, and Biosimilars

Expediting novel drug development and approval is vital for making useful therapies available to patients with unmet medical need. Streamlining the development and path to approval of NCEs, complex generics and biosimilars promises cost-savings and increased patient access to innovative and affordable therapies. Interactions between academia, the pharmaceutical industry and health authorities around the globe can be complex, often resulting in enlightening perspectives related to state-of-the-art study design, data analyses, interpretation and compromise. Although some of these interactions may be partially available to the public through review documents or assessment reports, an integrated story of events and lessons learned are usually not available. Sessions in this theme will focus on learnings from these interactions, offering a novel perspective on the current status, challenges, opportunities, and future directions of drug development, with a focus on topics related to clinical pharmacology from development to approval of NCEs, complex generics and biosimilars.

Manufacturing & Bioprocessing

Monday, November 4th

Transition from Clinical to Commercial Manufacturing: Enabling Successful PPQs

Successful validation of manufacturing processes includes the stages of (1) Process Design, (2) Process Performance Qualification (PPQ), and (3) Continued Process Verification. It establishes scientific evidence that a process is capable of consistently producing quality product. Process design enables definition of manufacturing processes based on knowledge gained through development and scale-up. PPQ then tests the process and the proposed control strategy to determine if the process is capable of reproducible commercial manufacturing. Stage 3 (Continued Process Verification) then includes ongoing assurance that the process remains in a state of control.

This theme will cover all three aspects of process validation with case studies, and will provide an insight of how the comprehensive development and scale up experience, spanning clinical manufacturing through commercialization, can be leveraged to assure successful validation of the manufacturing processes.

Tuesday, November 5th

Innovation in Conventional Manufacturing Technologies: Creating Flexibility, Cost-effectiveness, & Intelligent Systems

Information technology, automation advances, and enhanced understanding of unit operations in the last decade have led to significant improvements in the conventional manufacturing processes. These advances also include use of process analytical technologies, modeling and simulation, data rich equipment outputs, and others that increase process flexibility and robustness, dramatically lowering cost and risk. Examples include single use systems, smaller footprint processes, highly automated systems, multi-statistical process control (MSPC) tools, soft or spectroscopic process analytical technology (PAT) sensors, and data management systems. Case studies in both chemical entity and biologics manufacturing will be featured that highlight important advances in this field.

Wednesday, November 6th

Continuous Processing in Synthetic and Biologics Manufacturing

Pharmaceuticals have traditionally been manufactured using conventional “batch manufacturing processes”, which are characterized by discrete, disconnected unit operations, and lengthy manufacturing cycles involving complex, scale-dependent equipment. Recent advances in manufacturing technology as well as business pressures to improve efficiencies have prompted the industry to consider a faster, more scalable, nimble, and efficient process commonly known as “continuous manufacturing”. Regulatory agencies are taking proactive steps to facilitate the pharmaceutical industry’s implementation of continuous manufacturing, to enhance the assurance of product quality and to modernize the pharmaceutical manufacturing sector.

This theme will include case studies in both small molecules as well as biologics manufacturing, and bring together pharmaceutical companies, suppliers, regulators, and academics to look at accelerating adoption of continuous manufacturing, with the goal of accelerating development of medicines for the benefit of the patients.

Formulation & Quality

Monday, November 4th

Formulation Development: New Challenges, Approaches, and Solutions

This theme will cover the latest scientific advances in formulation development, and topic-related regulatory and development strategy considerations.

For chemical entities, topics may include: formulation technology improvements to overcome low bioavailability, poor solubility, stability, alternative routes of administration, and improved manufacturability of chemical entities.

For biomolecules, topics may include: formulation technology improvements for novel API modalities (e.g. non-standard mAb proteins, oligos, cell therapies, gene therapies, etc.), vaccines, high/low dose/concentration, in-use compatibility/DP handling, high-throughput screening, in silico molecular property/stability prediction, personalized medicinal products, primary packaging of vials, etc.

Tuesday, November 5th

Novel Analytical Methods for Characterization and Lifecycle Management

Analytical methods are needed to ensure product quality of drug substance, drug product, at release, during stability, and during root cause investigations. This theme will cover topics including, but not limited to: new challenges for analytics (e.g. novel API modalities and formulations), new analytical methods/instrumentation, particulate characterization/quantification for parenteral products, analytical methods capable of controlling multiple attributes, pCQA/CQA identification, and control strategies. This theme will also cover topic-related regulatory, development strategy, and analytical method lifecycle management considerations.

Wednesday, November 6th

Advances in Drug Delivery and Device Technologies

This theme will cover devices and non-traditional formulations such as: overcoming biological barriers, particulate based delivery systems, microneedle dermal patches, hydrogels, novel vaccines, long-acting delivery, implants, prefilled syringes, auto-injectors, patch pumps, inhalation devices, etc. This theme will also cover topic-related regulatory, development strategy, and technology scouting considerations.