ICPM 2018

Workshop 1

Innovations in Clinical Trials

Topics:

- **Adaptive design in clinical trials**
- **Patient involvement in protocol design**
- **Risk based monitoring approach in clinical trials**

Chairs:

- **Iwamoto, Kazuya (Covance, Japan)**
- **Klingmann, Ingrid (PharmaTrain, EU)**

Panelists:

- **Dubois, Dominique (IFAPP Academy)**
- **Hirakawa, Akihiro (The University of Tokyo, Japan)**
- **Saeki, Satoshi (Astellas, Japan)**
- **Vandenbroucke, Pol (Pfizer, US)**

Objectives

Significant advances have been made in the design and execution of clinical trials in order to maximise their chances for success and reduce their costs. Advances such as adaptive design are focused on the needs and opportunities to innovate drug development, bringing increased efficiency and improved decision making, and ultimately increasing the likelihood of bringing beneficial therapies to market. Also involving the end-user of drug development, the patient, into the design of clinical trials turns out to be an essential success factor as it helps clinical trialists to focus on the trial's relevance and acceptance for the patient. During the execution phase, emphasis on risk management such as risk based monitoring helps the study teams to focus their attention and activities on the areas of greatest need:patient safety and data quality.

This session will bring experts to address innovations and challenges in clinical trials form design to execution to discuss where the clinical trial methodology will be heading towards in the near future.

Learning Outcomes

At the end of this session the attendees will be able to:

- **Understand the concept of adaptive designs and how this will increase efficiency of clinical drug development.**
- **Recognize how relevant patient involvement in the protocol design phase is today and will be in future**
- **Learn the key element of risk-based monitoring as proposed by ICH-GCP(r2) and TansCelerate BioPharma Inc. and understand how this is applied in clinical trials.**