

**4th Drug Discovery
& Development
Symposium**
BERLIN 2017

**PHARMA TASK FORCE
BREAK OUT SESSION**

DATE

10 July 2017
12:30-13:30

LOCATION

Salon Humboldt
Hilton Hotel, Berlin



AGENDA

1 // PVRI Pharma Task Force Goals & Objectives

PETER FERNANDES

2 // Discussion on two key initiatives (work in progress)

Initiative 1

Harmonize innovative approaches through clinical trial designs, endpoints, biomarkers

PETER FERNANDES, SYLVIA NIKKHO, LARRY ZISMAN

Overview

The PVRI Pharma Task Force's mission is to create and provide a platform for early and continuous dialogue on innovative clinical and regulatory development strategies where there is free and open discussion between Pharma, Academics and Regulators Worldwide.

One of the goal of the PVRI Pharma Task Force is to investigate possible approaches for Small Population Clinical Trials for developing Orphan Drugs in the field of Pulmonary Hypertension (PH). Such approaches should be directed towards ultimately making safe and effective therapies available to these critically ill patients in a timely manner. In order to maximise the scarce resources available for recruiting subjects for clinical trials in rare diseases, there is a critical need to coordinate and harmonise innovative approaches through clinical trial designs, endpoints, biomarkers, translational research, and enrichment strategies.

In order to further encourage and support this mission, a PVRI Pharma Steering Committee was formed in February 2017. This committee will foster and facilitate the creation of this platform to gather the relevant information and organise workshops with Pharma, Academic and Regulators to discuss and harmonise these possible options and solutions in a non-competitive manner.

We will present to you the preliminary concepts (work in progress) of this initiative for your feedback and discussion. We will solicit volunteers to help take this to the next level.

Initiative 2

Matching industry projects/interests with individual investigator interests and core strengths

ANDREW NELSON, JONATHAN LANGLEY

Overview

A summary document articulating research interests amongst industry partners and academic members will be presented. This document will include top line areas of interest as well as contact information. We will present the concepts of this research interest document to you for feedback and discussion, with the objective of dissemination to the broader PVRI Industry-Academia.

The current goal would be to populate this with industry and academics similar weighted information and then post it on PVRI website. This should be accompanied by a search tool for the page so one could then peruse at leisure matching interests.

We can get more sophisticated as we develop this tool. We look for your support populate this document and to take this to the next level.