マイクロドーズ臨床試験　第二回国際会議

国際的にマイクロドーズ臨床試験を推進している Phase-0/Microdosing Network と APDD が合同開催するマイクロドーズ臨床試験の現状と将来を討議する国際会議です。

日　時：2020 年 4 月 20 日（月）　9:30～17:30
場　所：東京、日本橋ライフサイエンスビルディング

演　者：Tal Burt M.D.
（President Phase-0/Microdosing Network）
Graeme Young　Ph.D.（GSK）
Wooin Lee Prof.（ソウル大学）
杉山　雄一　Ph.D.（理化学研究所）
山浦　由之　Ph.D.（小野薬品工業）
宮武　大輔　Ph.D.（アステラス製薬）　他

参加費：5,000 円　賛助会員は 1 名無料

一般社団法人　医薬品開発支援機構 APDD
Association for Promoting Drug Development

Second International Phase-O/Microdosing Stakeholder Meeting

State of the Art and Future Directions

A 1-day meeting: Monday, April 20, 2020, Tokyo, Japan

Organized by:
Phase-0/Microdosing Network (Phase-0Microdosing.org) and
Japanese Association for Promoting Drug Development (APDD)

Goals

1. To formulate guidelines for the application of Phase-O/Microdosing approaches
2. To establish recommendations for further research and development

Objectives

1. To provide update on validation, methodology, applications, and research of these approaches
2. To obtain input from major stakeholders (regulatory, academia, industry, CROs) on the value, prospects, and challenges facing these approaches
3. To establish a consensus statement on future directions in research and applications

Meeting format

Overall: 9:30 am - 5:30 pm
9:30 - 12:45 pm: Presentations
12:45 - 1:45 pm: Lunch
1:45 - 3:30 pm: breakout sessions - 4 discussion groups
3:30 - 3:45 pm: Break
3:45 - 5:30 pm: Closeout session - summary of breakout sessions and consensus statements

Abstract

Increasing costs of drug development and ethical concerns about the risks of exposing humans and animals to novel chemical entities favor limited exposure clinical trials such as microdosing and other Phase-O approaches. Phase-O studies, including microdosing, also called Exploratory Investigational New Drug (eIND) or exploratory clinical trials, are a regulatory framework for First-in-Human (FIH) trials. Common to these approaches is the use and implied safety of limited exposure to the test article. With microdosing the dose is less than 100 μg or 1/100th of the anticipated therapeutic dose. Applications include study of drug pharmacokinetic (PK) and pharmacodynamic (PD) properties, target localization, drug-drug interactions (DDIs), effects in vulnerable populations (e.g., pediatric), and Intra-Target Microdosing (ITM). The use of sub-pharmacological doses in Phase-O/Microdose studies requires sensitive analytic tools such as Accelerator Mass Spectrometer (AMS), Positron Emission Tomography (PET) and Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) to determine drug disposition. Utilization of combinations of these analytic techniques increases the versatility of study designs and the power of data obtained. Validation studies over the past decade demonstrated the reliability of extrapolation of sub-pharmacological to therapeutic-level exposures in more than 80% of cases, an improvement over traditional allometric approaches. Nevertheless, utilization of Phase-O/Microdosing by drug developers remains modest though growing in number and scope. The purpose of the meeting is to understand and address this under-utilization and formulate recommendations for future research, development, and applications of these approaches.