4th International Phase-0/Microdosing Stakeholder Meeting

Intra-Target Microdosing (ITM): Revolutionizing Clinical Pharmacology and Drug Development

Monday, April 24, 2023, Wyndham Boston Beacon Hill, Boston, USA and Online

https://phase-0microdosing.org/ • https://www.wyndhambeaconhill.com/

Organizing Committee:

Chair: Tal Burt, MD, Co-chair: Kirsten Anderson; Yuichi Sugiyama, PhD, Kev Dhaliwal, MD, PhD, Joseph A. DiMasi, PhD, Go van Dam, MD, PhD, Markus Weiss, PhD.

Goals:

1. Formulate guidelines for the application of ITM and other Phase-0/Microdosing approaches.
2. Establish recommendations for further research and development.

Objectives:

1. Provide update on validation, methodology, applications, and research.
2. Obtain input from stakeholders (regulatory, academia, industry, CROs, non-profit, patient advocacy) on the value, prospects, and challenges facing these approaches.
3. Establish consensus statements on future directions in research and applications.

Registration and Breakfast (7 – 8 a.m.)

Morning presentations (8 – 12 Noon):		
Tal Burt, MD	Introduction to Intra-Target Microdosing (ITM)	8:00 - 8:25
Oliver Jonas, MD	Lab-in-a-Patient Microdevices for Multiple Drug Screening in Oncology	8:25 – 8:50
Nathan Schauer, PhD	Multiplexed Microdosing of Surface-Accessible Tumors for Comparative Spatial Oncology	8:50 – 9:15
Yuichi Sugiyama, PhD + Yasunori Aoki, PhD	ITM Modeling and Simulations	9:15 – 9:45
Break		9:45 – 10:00
Kev Dhaliwal, MD, PhD	Pulmonary ITM	10:00 – 10:25
Technology Panel	Technology Aspects of ITM and Other Phase-0 Approaches	10:25 – 10:55
Regulatory Panel	Regulatory Aspects of ITM and Other Phase-0 Approaches	10:55 – 11:35
Joseph DiMasi, PhD	The Economics of Implementing Phase 0 Techniques – Methods for Measuring Financial Value	11:35 – 12:00
Lunch		12:00 - 1:00

Breakout Sessions	Moderators	
A. ITM	Kev Dhaliwal, MD, PhD	1:00 – 3:00
B. Technology	Oliver Jonas, PhD	
C. Regulatory	Tal Burt, MD	
D. Strategy and Execution	Nathan Schauer, PhD	
Break		3:00 – 3:15
Consensus Session. Moderators: Tal Burt and Kev Dhaliwal		3:15 – 5:00

Abstract

Concerns about the costs and duration of drug development projects and the risks of exposing animals, in early work, and humans to novel chemical entities, have led to efforts to improve drug development with limited exposure studies using microdosing and other Phase-0 approaches. Common to these approaches is the implied safety of limited exposures to the investigational drug. For example, with microdosing the dose is less than 100 µg or 1/100th of the anticipated therapeutic dose. With Intra-Target Microdosing (ITM) the microdose is administered directly into an area about 1/100th of the body mass, momentarily generating therapeutic-level exposures. Such approaches allow safer and earlier entry into human testing, and human-based selection from preclinical candidates. These approaches are also called Exploratory Investigational New Drug (eIND) applications and exploratory clinical trials and are regulated under the internationally harmonized ICH M3 guidance. The program includes discussion of regulatory topics relevant to the future of the field.

Phase-0 approaches allow study of drug pharmacokinetic (PK) and pharmacodynamic (PD) properties. Specific applications include use in target localization, drug-drug interactions (DDIs), effects in vulnerable populations (e.g., pediatric), and ITM. The sub-therapeutic doses in Phase-0/Microdose studies require the use of sensitive analytic tools such as Accelerator Mass Spectrometer (AMS), Positron Emission Tomography (PET) and Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS). These tools are used to study disposition, effects, and metabolites of the novel drug under study. Technological advancements, especially as they pertain to administration of the test article to ITM targets of interest and obtaining the relevant samples will be discussed.

Recent research has advanced the validity and applicability of microdosing and other Phase-0 approaches. The approaches can accelerate drug development timelines and reduce developmental attrition by increasing the quality of candidates entering clinical development and by reducing the time to 'go-no-go' decisions. The meeting will engage participants in discussion of the recent advances, implementation challenges, and future directions in research and applications of these approaches.

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Registration Information

Register at tburt@phase-0microdosing.org

Please provide the following:
Name and degree:
Experience, expertise, and/or interests relevant to Phase-0/Microdosing:
Organization:
Role:
Contact info:

Registration fees:

Industry: $400

Non-industry: $200

10% 'early-bird' discount (before March 24) (industry/non-industry): $360/180

10% discount for 'online' registrants (industry/non-industry): $360/180

15% 'early bird' and 'online' discount (industry/non-industry): $340/170

Payments can be made at:

https://www.paypal.com/donate?hosted_button_id=4KNV6PZ25JVLU

Early-bird accommodation discounts are available until March 23 at:

Wyndham Boston Beacon Hill Hotel, 5 Blossom Street, Boston, MA, USA 02114
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