Activity Outline
FDA Workshop: Precision Dosing: Defining the Need and Approach to Deliver Individualized Drug Dosing in the Real World Setting
August 12, 2019
FDA White Oak Campus: Great Room

Activity Coordinator
Bernadette Johnson-Williams
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Description

The Food and Drug Administration in collaboration with the University of North Carolina will host a 1-day public workshop, "Precision Dosing: Defining the Need and Approaches to Deliver Individualized Drug Dosing in the Real-World Setting." Some clinical trials in drug development are conducted to optimize the dosing regimen of a new drug for the target patient population. Clinical pharmacology trials serve as the major source of evidence for dose individualization (precision dosing) taking into account patient factors that can modify drug response. Despite these efforts prior to a drug's approval, further dose optimization may be required after drug approval (e.g., accounting for extremes of age, body habitus, organ function and complex multiple characteristics including genotype, drug interactions, and co-morbidities). The opportunities and challenges for further dose optimization/individualization will be discussed from multiple perspectives including drug developers, regulators, physicians, pharmacists and patients. These relevant groups will also discuss in what contexts precision dosing may be needed, and the challenges of generating evidence to support precision dosing and applying individualized dosing regimen in clinical practice. In addition to evidence created during the new drug development process, real-world data/evidence will be discussed to address some challenges that cannot be addressed by pre- and post-approval clinical trials. The process of translating the knowledge to tools that can be utilized by the medical community for patient care will also be discussed.

References

- Precision Dosing: Public Health Need, Proposed Framework and Anticipated Impact. Clinical Translational Science 2017, 00, 1-11, Gonzalez, et al.
- Thomas M Polasek, Sepher Shakib & Amin Rostami Hodjegan (2018) Precision Dosing in Clinical Medicine: present and future, Expert Review of Clinical Pharmacology, 11:8, 743-746, DOI: 10.1080/17512433.2018.1501271

Learning Objectives

- Discuss the need for more precise dosing
- Investigate opportunities in drug development and real-world settings to generate information needed to support precision drug dosing
- Discuss the translation of the dosing information to electronic drug dosing delivery tools to enable precision dosing in clinical practice

Target Audience
This activity is intended for physicians, pharmacists, and nurses.

Agenda
Day 1 August 12, 2019

Time	Topic	Speaker
8:00 - 8:05 AM	Overview and Workshop Objectives	Bernadette Johnson-Williams, M.Ed
8:05 - 8:30 AM	Drug Dosing in the Real World: Challenges and Opportunities	Issam Zineh, PharmD, MPH
8:30 - 11:00 AM	Moderator Session 1- The Need for Precision Dosing and its Challenges	Rajnikanth Madabushi, PhD
8:30 - 8:55 AM	Regulatory Considerations in Determining Optimal Doses for Patients	Robert Temple, M.D.
8:55 - 9:20 AM	Does Drug Development Provide the Information Necessary to Allow Precision Dosing?	Jack Cook, PhD *Not offered for CE*
9:20 - 9:45 AM	What are the Benefits and Challenges of Individualized Dosing Regimens from a Patient Perspective?	Cynthia Bens, BA
9:45 - 10:10 AM	Are We Really Going to Buy Into Individualized Dosing?	Michael Neely, MD, MSc., FCP

10:10 - 10:20 AM	*Break*	
10:20 - 11:00 AM	Panel Discussion	Issam Zineh, PharmD, MPH Rajnikanth Madabushi, PhD Anya Harry, MD, PhD Nestoras Mathioudakis, MD, MHS *Not offered for CE*
11:00 - 1:55 PM	Moderator Session II - Precision Dosing: A Focus on Solutions	Yaning Wang, PhD
11:00 - 11:25 AM	Drug Development to Enable Precision Dosing	Richard Peck, MD *Not offered for CE*
11:25 - 11:50 AM	Pharmacometric Strategy and Tools in the Design of Precision Dosing for the Electronic Patient Care Environment	Daniel Gonzalez, PhD, PharmD
11:50 - 12:15 PM	Using Real World Data to Fill Evidence Gaps for Precision Dosing	Sara Van Driest, MD, PhD
12:15 - 1:15 PM	*Lunch*	
1:15 - 1:55 PM	Panel Discussion	Yaning Wang, PhD Gideon Blumenthal, MD Josh Oyster, Esq
1:55 - 4:00 PM	Session III-Moderator -Translating Real-World Dosing to Patient Drug Dosing Tools	Thomas Polasek, MD, PhD, BSc, BPharm(Hons)
1:55 - 2:20 PM	Individualized, Maximally Precise Drug Therapy: A Physician's Bedside Viewpoint	Roger Jelliffe, MD
2:20 - 2:45 PM	Clinical Implementation of PK/PD Model-Informed Decision Support Tools for Precision Dosing	Sander Vinks, PhD, PharmD
2:45 - 3:10 PM	The Evolution of Clinical Decision Support Tools that Enable Precision Dosing	Srijib Goswami, PhD
3:10 - 3:20 PM	*Break*	
3:20 - 4:00 PM	Panel Discussion	Thomas Polasek, MD, PhD, BSc, BPharm(Hons) Larry Lesko, PhD Susan Abdel-Rahman, PharmD Jonas Santiago, PharmD, MS Linda Ricci
4:00 - 4:20 PM	Meeting Summary and Closing Remarks	Robert Powell, PharmD

Continuing Education Accreditation

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In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 5.50 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 5.50 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-19-064-L04-P for 5.50 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 5.50 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Abdel-Rahman, Susan, PharmD, Professor and Section Chief, Children's Mercy Hospital *I received Honorarium from Becton Dickinson for a role as Consultant.*
- Bens, Cynthia, BA, Senior Vice President, Public Policy, Personalized Medicine Coalition - nothing to disclose
- Blumenthal, Gideon, MD, Acting Deputy Director, FDA - nothing to disclose
- Cook, Jack, PhD, Vice President, Clinical Pharmacology, Global Product Development, Pfizer, Inc *I received Salary from Pfizer products for a role as Employee. I received Stocks from Pfizer products for a role as Employee.*
- Gonzalez, Daniel, PhD, PharmD, Assistant Professor, University of North Carolina at Chapel Hill *I received Research grant paid to employer/institution from Boehringer Ingelheim for a role as Other - To visit the BI campus in Fall 2019 and give a talk. . I received Research grant paid to employer/institution from Cempra Pharmaceuticals, Inc for a role as Consultant. May reference off-label use.*
- Goswami, Srijib, PhD, CEO, InsightRX *I received Salary from InsightRX, Inc. for a role as Employee.*
- Harry, Anya, MD, PhD, Global Lead, Clinical Trial Diversity, GlaxoSmithKline *My spouse and I received Salary from GlaxoSmithKline Infors-HT for a role as Employee.*
- Jelliffe, Roger, MD, Professor of Medicine Emeritus, USC Keck School of Medicine *May reference off-label use.*
- Johnson-Williams, Bernadette, M.Ed, Senior Regulatory Health Project Manager, Office of Clinical Pharmacology/OTS - nothing to disclose
- Lesko, Larry, PhD, Professor Emeritus, University of Florida *I received Other from InsightRx for a role as Board Member.*
- Madabushi, Rajnikanth, PhD, Team Lead, OCP Guidance and Policy Team, OCP/OTS/CDER/OMTP/FDA - nothing to disclose
- Mathioudakis, Nestoras, MD, MHS, Associate Professor, Johns Hopkins University - nothing to disclose
- Neely, Michael, MD, MSc., FCP, Professor of Pediatrics, Children's Hospital Los Angeles, University of Southern California *May reference off-label use.*
- Oyster, Josh, Esq, Attorney, Ropes & Gray LLP *May reference off-label use.*
- Peck, Richard, MD, Global Head Clinical Pharmacology, F Hoffmann la Roche Ltd *My spouse and I received Salary from F Hoffman la Roche for a role as Employee. My spouse and I received Stocks from F Hoffman la Roche for a role as Employee.*
- Polasek, Thomas, MD, PhD, BSc, BPharm(Hons), Medical Director, Certara *I received Salary from Development of model-informed precision dosing software by Certara for a role as Employee. I received Salary from Strategic consultant for pharmacogenomic testing by Sonic Healthcare for a role as Consultant.*
- Powell, Robert, PharmD, Adjunct Professor, University of North Carolina School of Pharmacy - nothing to disclose
- Ricci, Linda, Associate Director, Office of Product Evaluation and Quality, FDA/CDRH - nothing to disclose
- Santiago, Jonas, PharmD, MS, Deputy Director, FDA/CDER/OMP/OMPI/Division of Medical Policy Programs - nothing to disclose

- Temple, Robert, M.D., Deputy Director for Clinical Science, CDER, FDA - nothing to disclose
- Van Driest, Sara, MD, PhD, Assistant Professor, Vanderbilt University Medical Center *May reference off-label use.*
- Vinks, Sander, PhD, PharmD, Professor, Division Director, Cincinnati Children's Hospital Medical Center *I received Other - Fee for service contract work paid to employer/institution from Academic Pharmaceuticals for a role as Consultant. I received Other - Fee for service contract work paid to employer/institution from Airway Therapeutics for a role as Consultant. I received Research grant paid to employer/institution from BTG International, Inc for a role as Consultant. I received Research grant paid to employer/institution from Certara for a role as Consultant. I received Other - Fee for service contract work paid to employer/institution from Concert Pharma for a role as Consultant. I received Other - Fee for service contract work paid to employer/institution from Honz Pharmaceuticals for a role as Consultant. I received Other - Fee for service contract work paid to employer/institution from Horizon Pharma, Inc for a role as Consultant. I received Other - Fee for service contract work paid to employer/institution from IGIA Pharmaceuticals for a role as Consultant. I received Other - Member Drug Safety Board from Pfizer for a role as Consultant. I received Other - Fee for service contract work paid to employer/institution from PPSI for a role as Consultant. I received Research grant paid to employer/institution from Gerber Foundation for a role as Other - Principal investigator.*
- Wang, Yaning, PhD, Director, Division of Pharmacometrics, OCP/OTS/CDER/FDA - nothing to disclose
- Zineh, Issam, PharmD, MPH, Director, US Food and Drug Administration - nothing to disclose

Planning Committee

- Bergman, Kimberly, PharmD, Lead Pharmacologist, Office of Clinical Pharmacology - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Johnson-Williams, Bernadette, M.Ed, Senior Regulatory Health Project Manager, Office of Clinical Pharmacology/OTS - nothing to disclose
- Madabushi, Rajnikanth, PhD, Team Lead, OCP Guidance and Policy Team, OCP/OTS/CDER/OMTP/FDA - nothing to disclose
- Powell, Robert, PharmD, Adjunct Professor, University of North Carolina School of Pharmacy - nothing to disclose
- Strauss, David, MD, PhD, Division Director, US FDA - nothing to disclose
- Wang, Yaning, PhD, Director, Division of Pharmacometrics, OCP/OTS/CDER/FDA - nothing to disclose
- Zhu, Hao, PhD, Deputy Director, CDER/OTS/OCP/DPM - nothing to disclose
- Zineh, Issam, PharmD, MPH, Director, US Food and Drug Administration - nothing to disclose

CE Consultation and Accreditation Team

- Miller, Isaac J., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 100% of the activity.