

The Path Forward (Panel 3)

- This panel is intended to discuss and build consensus on strategies, clinical trial design considerations, and regulatory paths for slowing the progression of PD.
- Governmental regulators, industry innovators, and academic researchers will offer their perspectives in a setting of collaborative and constructive discussion.
- The ultimate goal is to bring meaningful treatments to patients and those at risk for PD.

The Path Forward (Questions)

1. What research strategies and trial designs (proof-of-concept, phases 2 and 3) are central to the successful development of medical products aimed at slowing the progression of PD?
2. What clinical, genetic and biomarker outcomes would be meaningful to demonstrate slowing of progression in clinically manifest PD?
3. How can clinical development be enriched by genotype and biomarker risks to demonstrate slowing of progression in prodromal PD?
4. Others (from audience)

The Path Forward - Panelists

- **Mark Frasier** PhD, MJFF (Senior VP for PD Research) – neuroscientist
- **Michael Gold** MD, AbbVie (VP, Development Neurosciences) - neurologist
- **Daniel Keene** MD, Health Canada (Senior Medical Officer and Chief, Clinical Trials and Drug Safety Divisions, CERB) – pediatrics and neurology
- **Christopher Leptak** MD PhD, FDA (Biomarker Development and Regulatory Science Team
- **Gerald (Dave) Podskalny** DO, FDA (Cross Disciplinary Team Leader, DNP, CDER) – movement disorders neurologist

Ira Shoulson MD

Professor of Neurology, Pharmacology, and Human Science, Georgetown University and Director of Program for Regulatory Science & Medicine (PRSM)

<http://regulatoryscience.georgetown.edu>

- Prana Biotechnology (Melbourne, Australia) Non-Executive Director and chair of Medical Advisory Committee (since May 2014)
- Grey Matter Technologies (Sarasota, FL) Co-Founder (since Feb 2017)
- Consulting (2017-2018): Auspex Pharmaceuticals, AZTherapies, Banner Health (Genentech, Roche), Dart Neurosciences, Decibel Therapeutics, Jazz Pharmaceuticals, Link Medicine, Lysosomal Therapeutics, MediciNova, Oxford Biomedica, Sarepta Therapeutics, Teva Pharmaceuticals, Vaccinex

The Path Forward (Questions)

1. What research strategies and trial designs (proof-of-concept, phases 2/3) are central to successful development of medical products aimed at slowing the progression of PD?

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The Path Forward (Questions)

4. Others

Early Alzheimer's Disease: Developing Drugs for Treatment Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Billy Dunn at 301-796-2250 or (CBER) Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

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TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	BACKGROUND	2
III.	DIAGNOSTIC CRITERIA FOR EARLY ALZHEIMER'S DISEASE.....	3
IV.	OUTCOME MEASURES	4
A.	Clinical Endpoints for Early AD Trials in Stage 3 Patients.....	4
B.	Clinical Endpoints for Early AD Trials in Stage 2 Patients.....	5
C.	Endpoints for Early AD Trials in Stage 1 Patients	6
D.	Time-to-Event Analysis	6
E.	Assessment of Disease Course.....	6