March 2018: The PINTAD group agreed on the following feedback to the FDA:

General Comments to the statement from FDA Commissioner Scott Gottlieb, M.D. on advancing the development of novel treatments for neurological conditions; part of broader efforts on modernizing the FDA's new drug review programs, with the pilot draft guidance on

- "Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment"
- "Draft Guidance for Industry – Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment."
- "Draft Guidance for Industry: Early Alzheimer's Disease: Developing Drugs for Treatment."
- "Guidance for Industry – Migraine: Developing Drugs for Acute Treatment"
- "Draft Guidance for Industry – Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Effectiveness from Adult to Pediatric Patients 4 Years of Age and Older."

Members of the Pharma Imaging Network for Therapeutics and Diagnostics (PINTAD) carefully reviewed the statement and draft guidances and want to express their appreciation of the opportunity to provide feedback and the signaled facilitation of a streamlined process. Across the documents the concise style and patient centricity was noted and welcomed. The encouragement for further research to drive potentially novel endpoints especially in the Alzheimer's document and to contact the FDA to discuss plans early in development are greatly valued. The group noticed that in the discussion of biomarkers and endpoints imaging was not mentioned (with the exception for serial noninvasive imaging studies for safety in the Duchenne's document), despite its value and prominence. As the FDA is well aware imaging biomarkers can be an important objective, quantitative and reproducible tools in patient selection, the determination of safety, target engagement, and disease modification. We would like to encourage the FDA to reach out to organizations and groups such as the PINTAD in the drafting process of guidance documents.