

The Neurotech Industry Investing and Partnering Conference

“Navigating Regulatory Pathways in Neurology and Psychiatry”

Focus on FDA and Hurdles for Device Trials

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FDA Focus

Current Mantra: “Science-based decision-making”

- Whistleblower allegations
- Published reports on shortcomings in clinical trials accepted by FDA
- Current regulatory climate: DIFFICULT, particularly for innovative and complex devices/disease states

Reasons

- Brain-drain of experienced reviewers (retirements, departures)
- Personnel and organizational changes
- Risk-averse and unpredictable; changing endpoints and inconsistent requests for information
- Limited experience of reviewers as to what is practical and what has been required in the past
- Limited oversight of reviewers

510(k) Premarket Notifications

- Typically do not require clinical trials
- Clinical data is being increasingly requested
- Little precedence for studies in predicate submissions or in FDA Guidances
- Increased focus on establishing safety and effectiveness rather than substantial equivalence
- New initiative on human factors testing
 - Data and information is being requested in 510(k)s with insufficient guidance as to what is expected

Premarket Approval Applications (PMAs)

- Increased focus on improving quality of clinical data in submissions
- Timeline to approval (from development to market) expanding from 7-9 years to 12-15 years largely due to submission process

Improving Submissions Supported by Clinical Studies

- Early dialogue and interaction with FDA
- Pre-IDE discussion of proposed protocol and investigational plan
- Strategy for meeting
- FDA focus on “clinical utility” – both statistical validity and clinical validity

Enforcement – Drugs and Devices

- Clinical trials are subject to FDA review and inspection
- Increasing activity of BIMO
- Increasing number of FDA warning letters and enforcement actions against sponsors, investigators, and IRBs
- Heightened concern about the IRB system and potential for unethical manipulation– GAO Report (2009)
- Penalties for failure to register “applicable device clinical trial” in ClinicalTrials.gov

Thank you!

Thank you for your time and consideration. If you have questions, please contact:

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