CCR Clinical Research Forum

Rare Diseases at FDA Center for Drug Evaluation and Research- Challenges and Progress in Drug Development

Dr. Scott Winiecki, M.D.
Lead Medical Officer, Rare Disease Team
Office of New Drugs, CDER, FDA

DATE: Monday, April 15th, 2024

TIME: 3:00 PM – 4:00 PM

LOCATION: WebEx

Join us to learn more about:

- General introduction of rare diseases & Brief review of Historical Orphan Drug Act
- Rare disease and orphan product approval trends
- Challenges and considerations in rare disease drug development
- FDA guidance document on rare disease development

Webex information:

https://cbiit.webex.com/cbiit/j.php?MTID=m55a7402234da4e8c5f9afe5cd83c31a0

- ✓ Enter your full (first and last) name and email address.
- ✓ You will be muted upon entry- type any questions you have.
- ✓ The session will be recorded for future access.

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