

FDA Draft Controls Guidance: A Roundtable Discussion

 **CRDSA**
Clinical Research Data Sharing Alliance

FDA Draft External Controls Guidance: A Roundtable Discussion

Please join us on Wednesday, July 19, 2023

10:00 am–12:00 pm EDT

7:00–9:00 am PDT

4:00–6:00 pm CEST

- [ASCO CancerLinQ](#)
- Duke Clinical Research Institute
- Muscular Dystrophy Association
- Cystic Fibrosis Foundation
- ACRO
- Critical Path Institute
- Project Data Sphere
- Novartis
- COTA Healthcare
- Duke-Margolis
- TransCelerate
- GSK
- UCB

Please join C-Path and the Clinical Research Data Sharing Alliance (CRDSA) on Wednesday, July 19, at from 10:00 a.m. to noon EDT for a roundtable discussion about the recent FDA draft external controls guidance. The webinar will convene panelists that includes C-Path's Shu Chin Ma and Jagdeep Podichetty, as well as others from industry, academic institutions, and patient advocacy groups to examine critical questions such as:

- Why is regulatory acceptance of alternative control design essential to patients and society?
- What key issues must be addressed to create a viable regulatory pathway?
- How can the community support the FDA in developing guidance that supports the expanded use of alternative control trial designs?

We will also welcome audience participation in a Q&A session. Join the conversation and take part in this important step in FDA guidance development.

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