



U.S. Food and Drug Administration
Protecting and Promoting Public Health

FDA Perspective International Clinical T



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Outline

1. Background
2. International Clinical Investigators & Clinical Trials
3. Drivers to Conduct Clinical Trials Out the USA
4. Law Governing International Clinical Trials
5. Challenges
6. Addressing the Challenges



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Foreign Clinical Trials (FCTs) BACKGROUND



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Foreign Clinical Trials (FCTs)

- Prior to the 1962 Kefauver-Harrison Amendments, it was uncommon for a Sponsor to submit FCTs data
- In 1975 provisions that permit submission of FCTs data not conducted under an IND were codified in 21CFR312.120
- Since then medical product discovery and development have become increasingly

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