Addressing Common Challenges in Bioequivalence Studies Due to COVID-19: OGD's Approach for Timelines, Clarity, and Consistency

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Disclaimer

- This presentation represents the views and perspectives of the speaker and does not necessarily reflect the views of the FDA.

Outline

- Overview of Common Generic Drug Industry Challenges due to COVID-19
- OGD COVID-19 Approach
- How to Submit Questions Related to Interrupted Bioequivalence (BE) Studies During the COVID-19 Pandemic

Challenges to Generic Drug Industry due to COVID-19

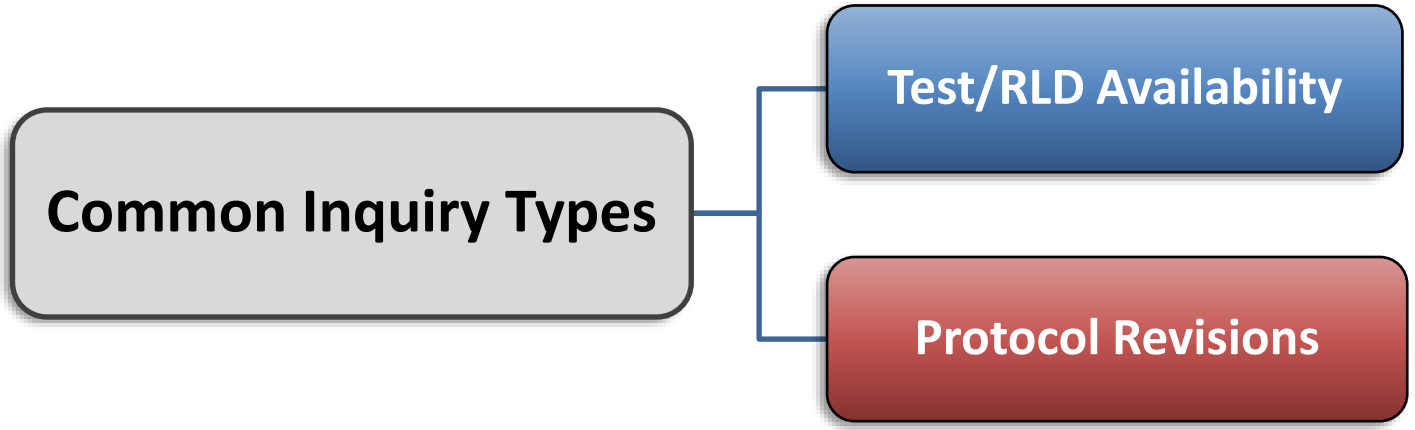
- COVID-19 presents many novel and unique challenges to generic drug industry
  - Early Stage (March-June 2020) – Lockdown
    - Study site closure – Study interruption
    - Study subjects missing sampling points
    - New batch availability due to API (Active Pharmaceutical Ingredient) source supply issue
  - More Recently (July 2020 - now) – Social Distancing
    - Study design modification (e.g., adaptive study design)
    - Protocol deviations/modifications (e.g., longer washout period, or any changes to the protocol to ensure safety of the patients)
    - Simulation/modeling approach (e.g., a large number of drop-outs)
    - "Remote" Study

Sources of Scientific Inquiries Related to COVID-19

External Email Inquiry	Controlled Correspondence	ANDA Assessment	Pre-ANDA Meeting Request
• From Various Email Boxes at OGD or CDER levels	• Division of Filing Review • Office of Bioequivalence • Office of Research and Standards • Office of Pharmaceutical Quality	• General Correspondence • Post-CRL MR* • FDA Internal Consult	• Office of Research and Standards

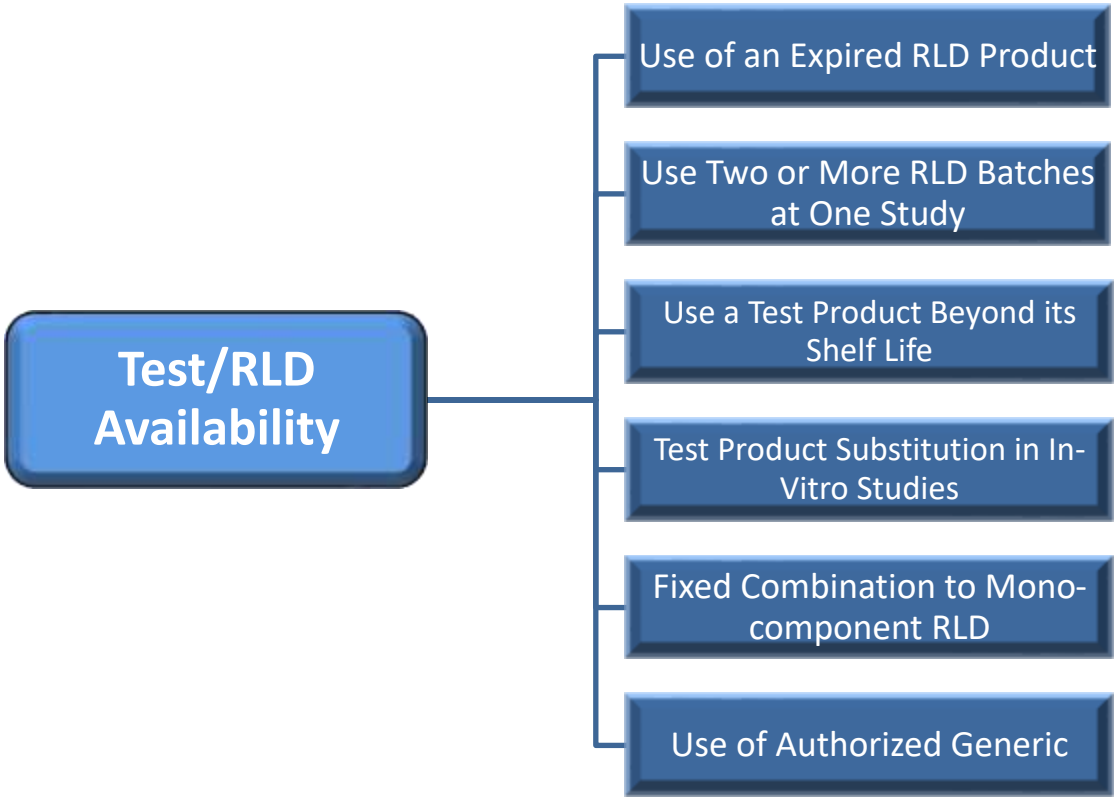
*Post-CRL MR = Post-Complete Response Letter Meeting Request

Common Types of Inquiries Due to COVID-19

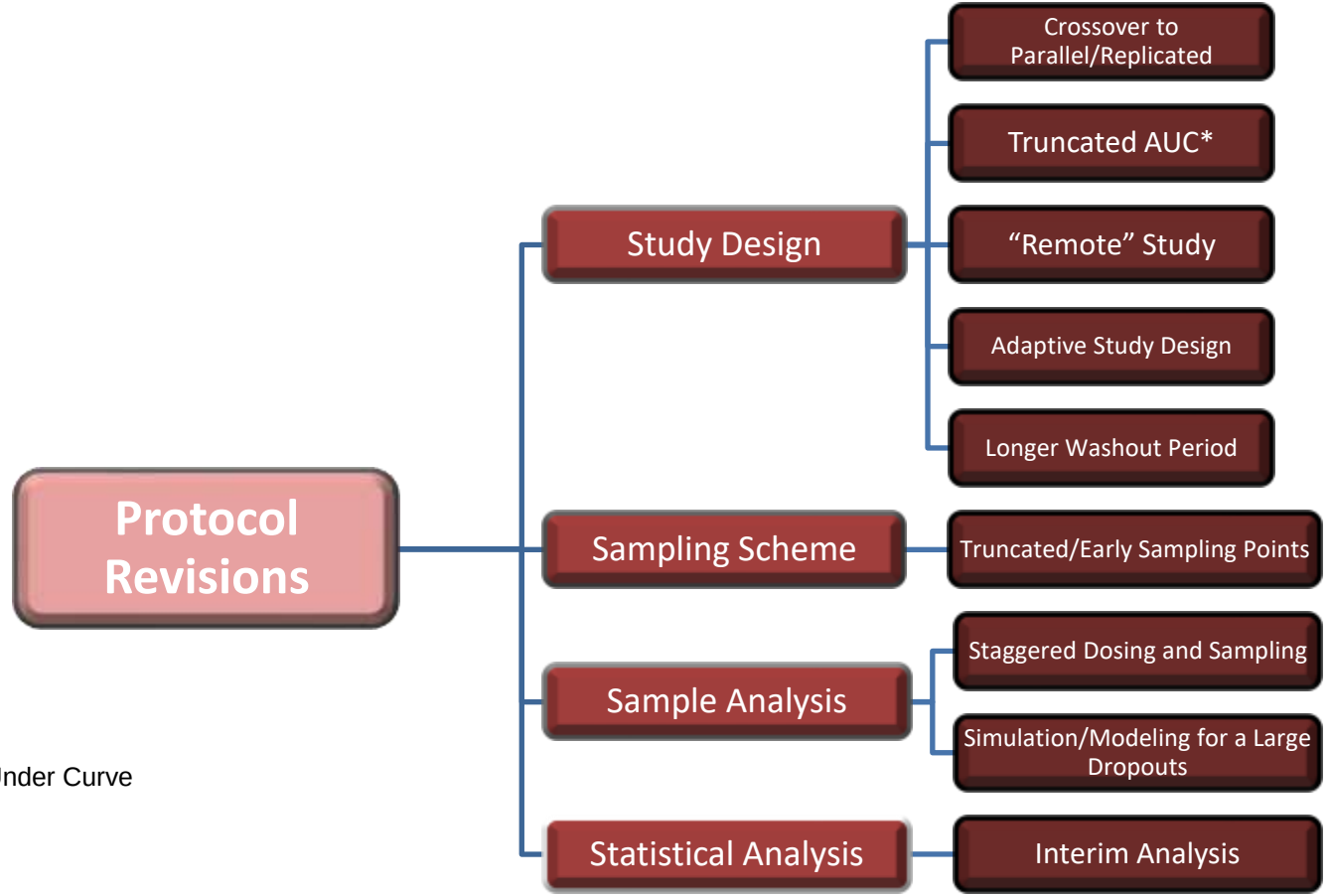


RLD = Reference Listed Drug

“Test/RLD Availability” Inquiries

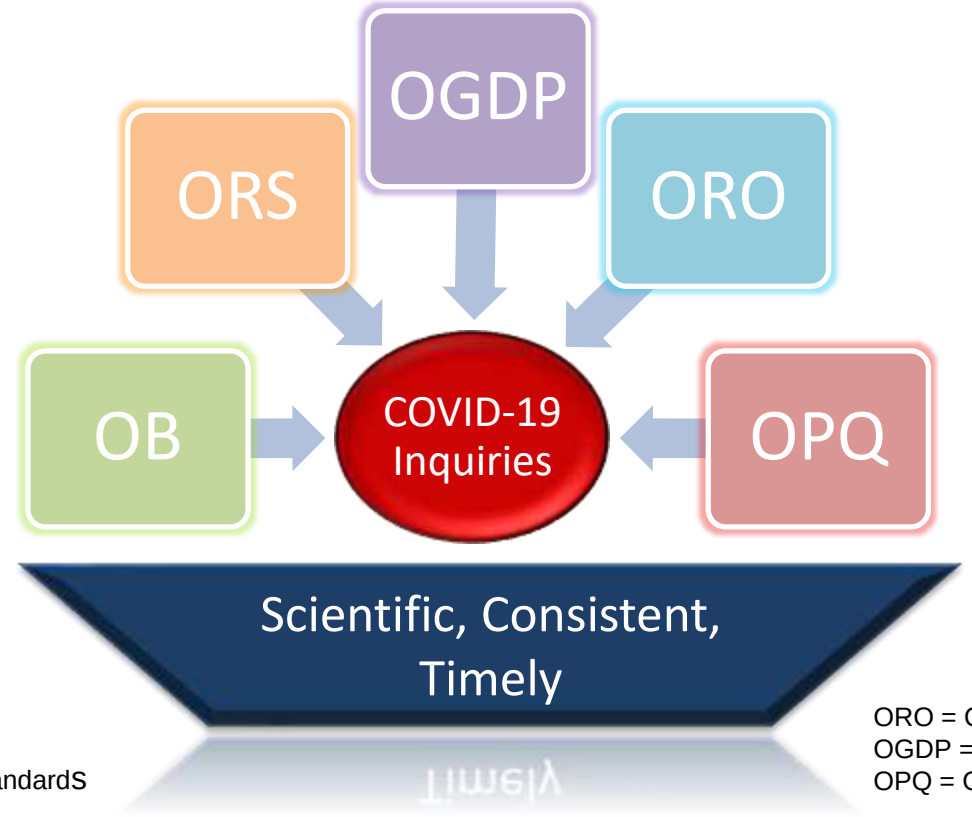


“Protocol Revisions” Inquiries



*AUC = Area Under Curve

OGD COVID-19 Approach
"Bringing Everyone to the Table"



OB = Office of Bioequivalence
ORS = Office of Research and StandardS

ORO = Office of Regulatory Operations
OGDP = Office of Generic Drug Policy
OPQ = Office of Pharmaceutical Quality

OGD's Approach

- OGD wants to support industry in the continued development of generic drugs
  - OGD recognizes the importance of the timely assessment of generic drugs that are used to treat COVID-19 or its symptoms
  - OGD aims to promptly respond to COVID-19-related inquiries
  - OGD welcomes proposals for alternative BE approaches to demonstrate BE between test and reference products
  - OGD evaluates the scientific issues and provide scientifically-based advice to inform decision making

Submitting Questions on Interrupted Studies During the COVID-19 Pandemic

- For ANDAs that have already been submitted to FDA, ANDA applicants should direct questions to the Regulatory Project Manager for their ANDA.
- Prospective applicants may use OGD's genericdrugs@fda.hhs.gov mailbox to submit general questions related to the impact of COVID-19 on BE studies or to notify FDA of BE studies that have been interrupted.
- For ANDAs that have not yet been submitted to FDA, prospective applicants should submit specific questions related to their impacted BE studies via the controlled correspondence process, or if applicable, the pre-ANDA meeting request pathway.

Summary

- COVID-19 presents multiple novel and unique challenges to generic drug industry
- OGD follows a multi-disciplinary approach to address COVID-19 inquiries in a consistent and timely fashion
- Submit your question on interrupted BE studies through an appropriate regulatory pathway

Challenge Question #1

- **Which source(s) do OGD receive COVID-19 scientific inquiries from?**

A. External Email Inquiry
B. Controlled Correspondence
C. ANDA General Correspondence
D. Pre-ANDA Meeting Request
E. All of the Above

Challenge Question #2

- **Which route(s) from below may you submit your questions on interrupted bioequivalence studies during the COVID-19 pandemic:**

A. Submit your questions to the Regulatory Project Manager for your ANDA
B. Submit your questions to genericdrugs@fda.hhs.gov mailbox
C. Send your questions via controlled correspondence
D. Send your questions via pre-ANDA meeting request
E. All of the above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