Sample Requests for Group 1b Testing

Christopher Ablenas
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My Background

- Sr. Biologist/Evaluator in the Biotherapeutics Quality Division of the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada.

- Supervisor for the Biotherapeutics Quality Division lot release laboratory.

Disclaimers

- The views expressed in this presentation are those of the presenter and do not convey official Health Canada policy.

- The information in the talk relates to pre-market lot release testing of biotherapeutic products.

Presentation objectives

Provide a brief overview of the BRDD lot release program.

Present logistics of pre-market testing for biotherapeutics.

Considerations for sample request timelines.

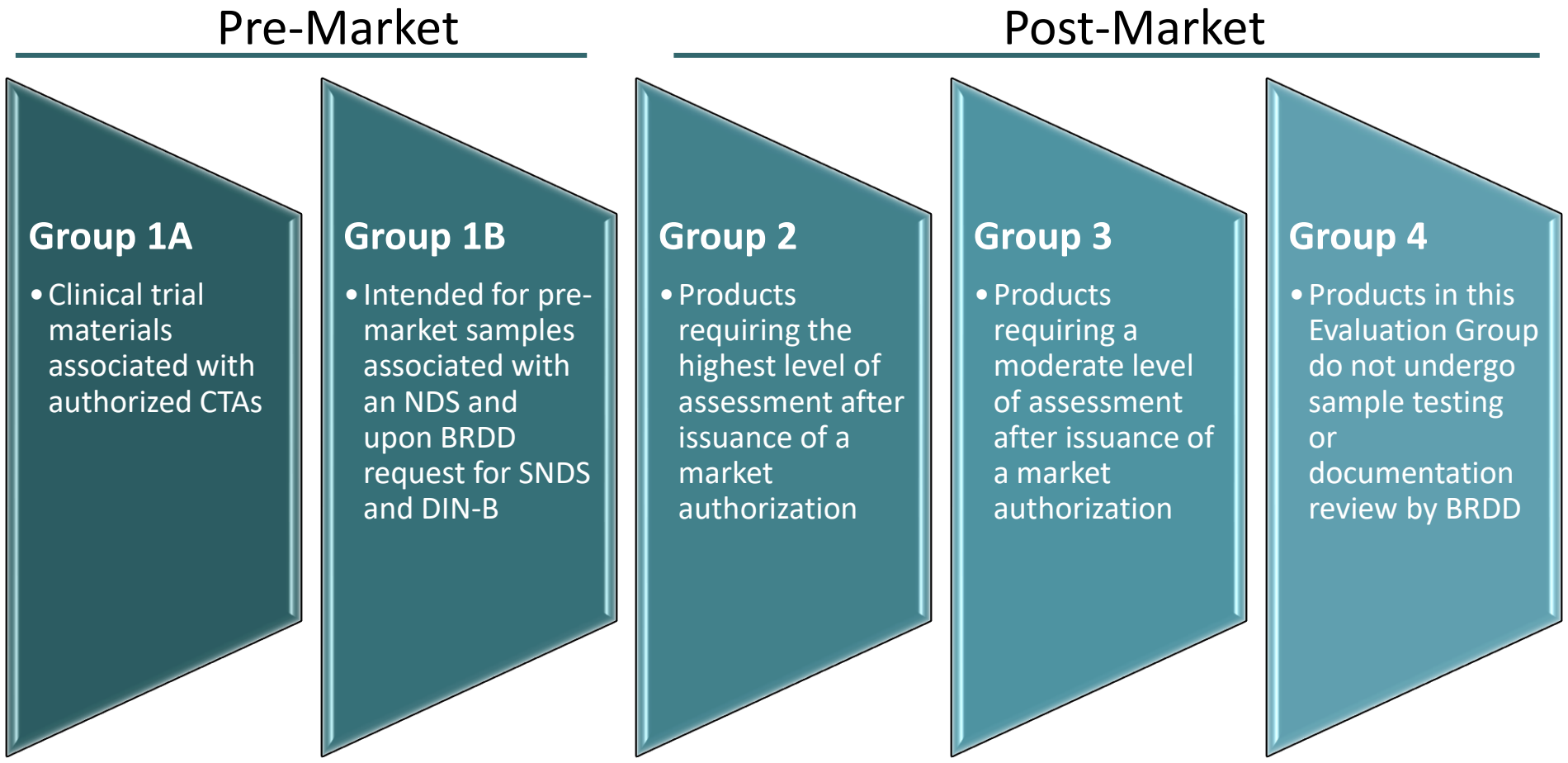
BRDD Lot Release Program

- Each lot of a Schedule D (biologic) drug is subject to the Lot Release Program before sale in Canada.

- The authority comes from the *Food and Drug Regulations:* subsections C.04.015 and C.08.002(3).

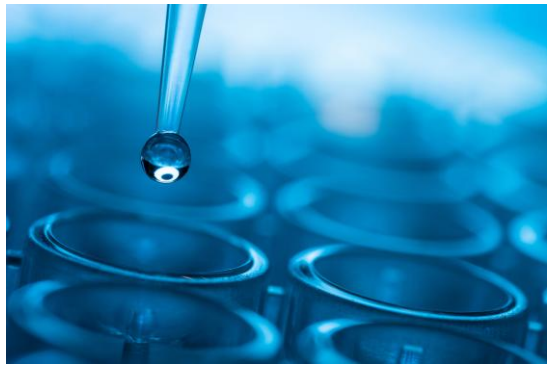
BRDD Lot Release Program

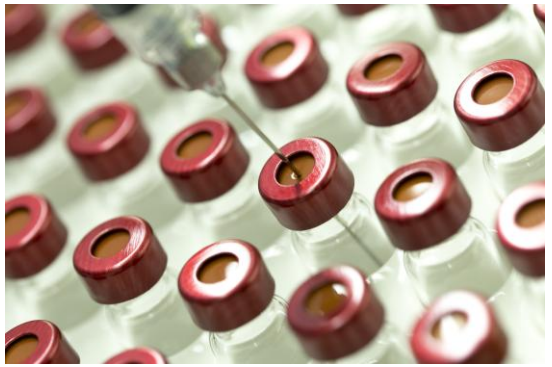
- The lot release program is risk-based.



Group 1B Pre-Market (Consistency) Testing

- BRDD assesses typically 3 lots to:
  - Evaluate the consistency of the manufacturing process.
  - Assess the suitability and robustness of key release methods.

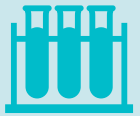




Group 1B Pre-Market (Consistency) Testing (Cont.)

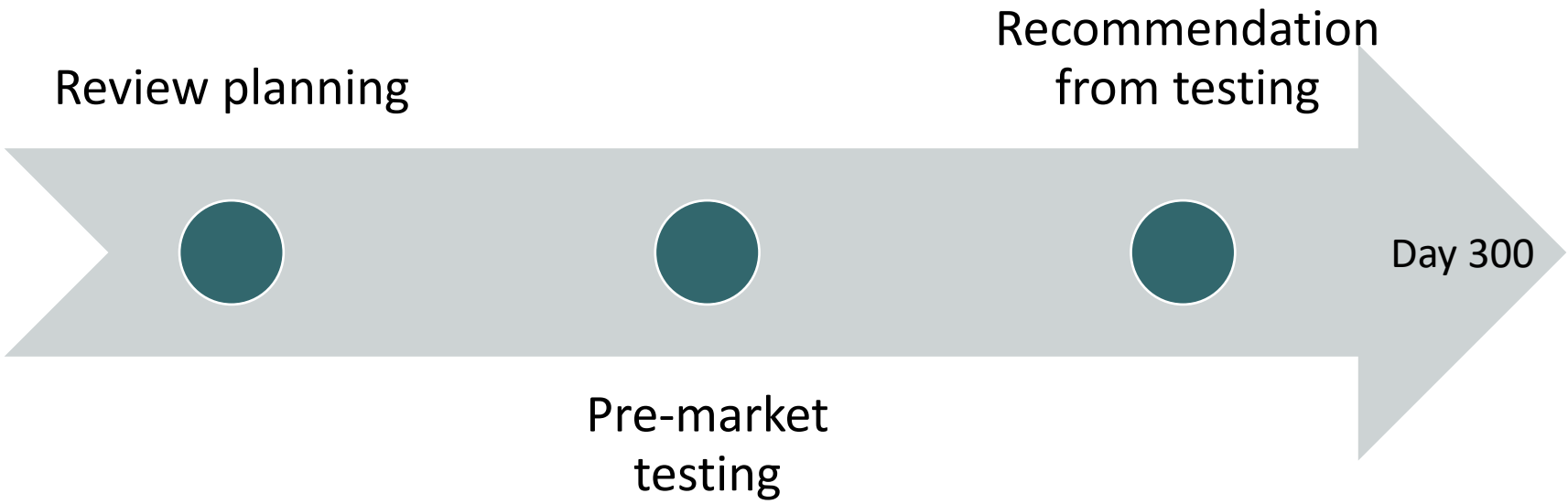
A risk-based approach for determining whether testing is warranted is applied to each submission.

As part of the initial review planning for the submission, the review team will determine if the risks merit performing testing to support review of the analytical procedures/method validation and assessment of the product.

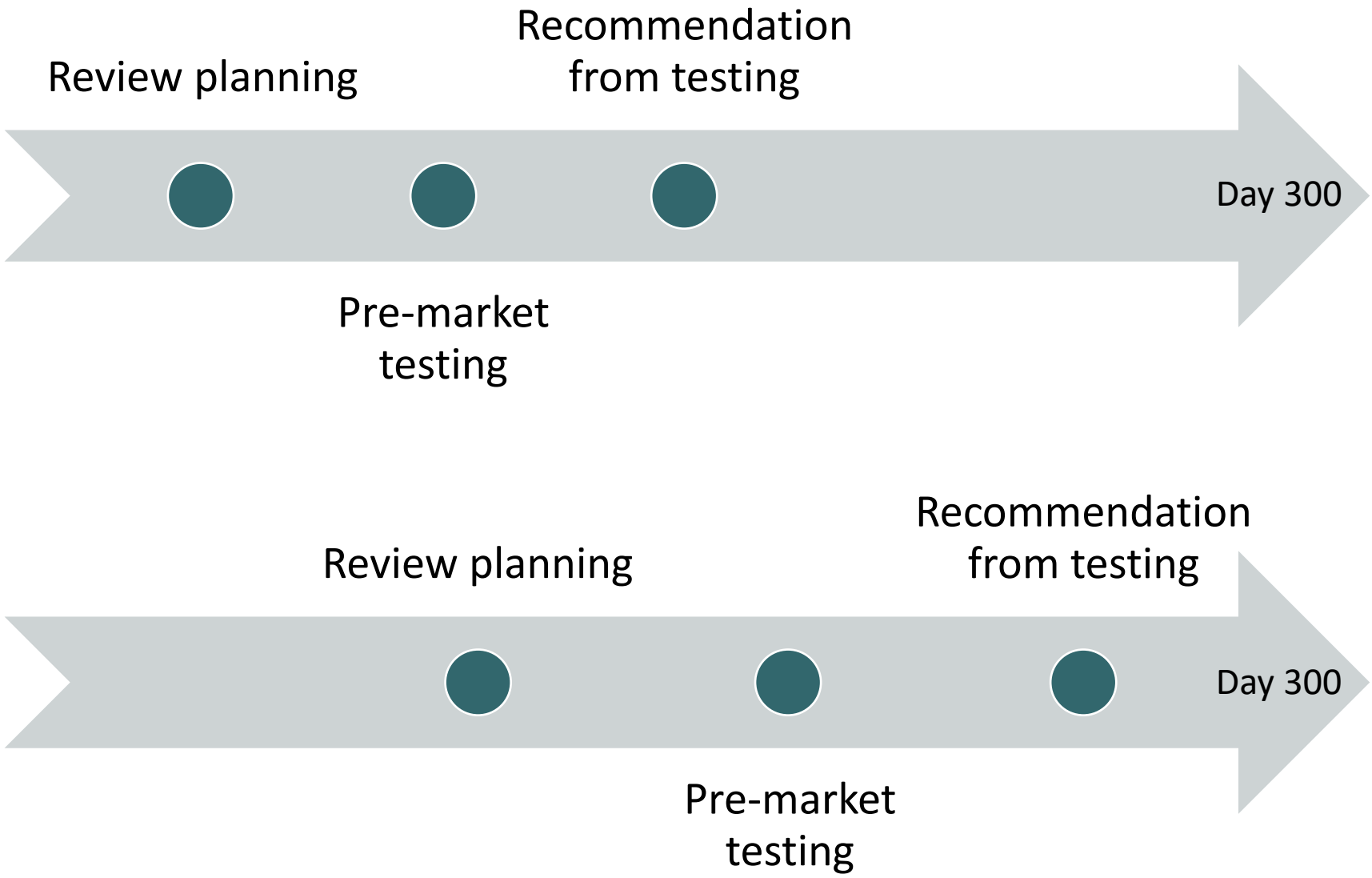


If testing is recommended, the review team will determine which methods they would like to assess in more detail.

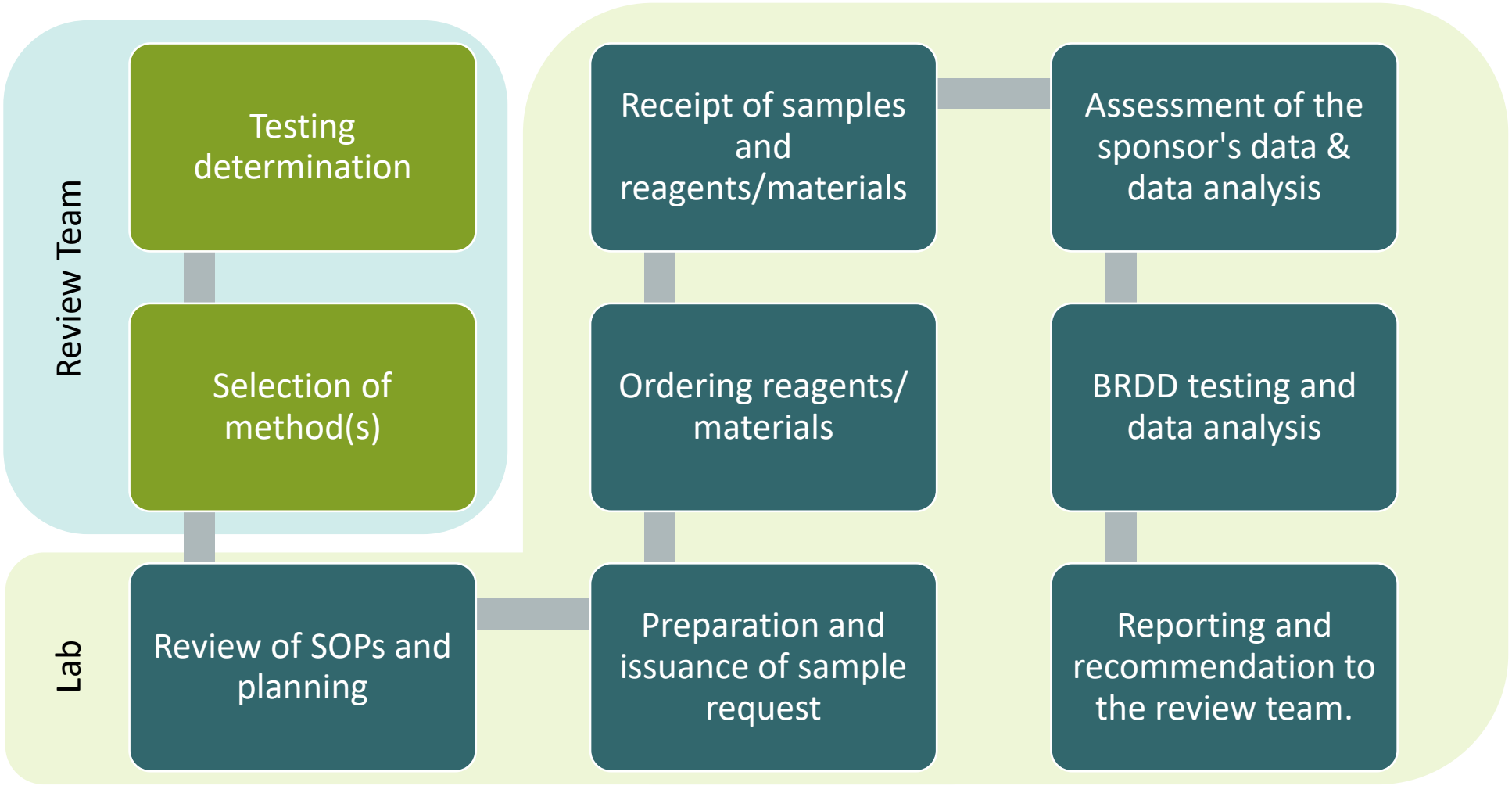
Review Timeline



Quality Review Timelines Can Vary



Group 1B Testing Workflow



Request Samples from Sponsor

- As applicable, request samples of drug product, reference standard, assay controls, critical/qualified reagents, cell lines, formulation buffer, and any reagents or materials not available/feasible for BRDD to obtain.
  - Do any items have limited shelf lives?
  - The sponsor is responsible for importation of the requested materials and is responsible for any import documentation as well as customs brokerage arrangements and costs.

Planning for Testing

- Order reagents/materials
  - Do any items have limited shelf lives?
  - Are any items not available in Canada? (no Canadian supplier)
  - Are any items on backorder?

Scheduling of Testing

- Availability of staff and other workload in the lab
- Will there be a delay in receiving samples from the sponsor or any unexpected delays in receiving the reagents/materials ordered?
- How much time is required to perform testing
  - Cell-based assays that require several cell passages prior to testing of samples are more time consuming.
- Any special safety considerations for handling (e.g. cytotoxic ADC)

Responding to the Sample Request

- Considerations:
  - BRDD acknowledges that it can be challenging for sponsors to ship samples and have them received by BRDD within the 15 day target timeline.
  - Receipt of samples is one of several critical components to scheduling of testing in a timely and resource efficient manner.
  - Sponsors may request pause the clock if more time is needed to respond to the sample request.

Responding to the Sample Request

- Dos and Don’ts
  - Do reach out to BRDD as soon as possible if the sponsor foresees having issues responding to the sample request within the target timeline.
  - Don’t wait until the deadline to indicate samples have not been shipped and an extension is required.
  - Do provide as much of the requested information and documentation as possible if there will be a significant delay in shipping samples (e.g. courtesy copy via e-mail).

Conclusion

- Group 1b pre-market testing is performed within the review timelines for the submission to inform the review of the dossier.
- The BRDD lot release labs strive to be as efficient as possible and unforeseen delays can cause havoc for scheduling of testing and management of materials.

Thank you!