

QbD and Data Collection

Is it ASAP? As Simple As Possible

CTTI ABDD Workshop

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Two Critical Questions

- **What data do I need to successfully answer the primary study question?**
- **What would prevent errors in collecting that data?**



A Guide to Think about Data Collection

- Is there any component of that data that is more critical than another, i.e., necessary to address the study's primary hypothesis?
- What would prevent me from obtaining that data?
- What can I do to mitigate or eliminate the potential threats to data collection?
- Will exploratory endpoints truly generate valuable information for future study planning or could they be eliminated to simplify data collection and reporting?
- Are all data described in the protocol captured in the CRF (or other data collection tool, e.g. ePRO) and vice versa?
- Are there critical data generated by third parties (e.g. central laboratories and readers, adjudication committees, electronic patient reported outcomes) that must be integrated into the study database? What opportunities for error are there in recording, transferring, and reporting these data?



Data Reporting and Recording

- The manner in which study data are collected and the timeliness of data submission can be important contributors to overall trial quality.
 - Will there be eSource records and how are they to be managed? Will the access to the source data with sufficient controls that any changes remain under the authorization of the clinical investigator and are adequately documented?
- Providing clear instructions on how and when to collect outcomes data can enhance consistency and completeness of data across sites.
- IT systems (e.g. electronic data capture) can also be used to encourage and enforce compliance with the protocol requirements for data capture and reporting.



Example: *Do you need all of these?*

- Date of randomization
- Dosing
- Date of End of Treatment
- Signs and symptoms assessment at baseline and TOC (e.g., cough, sputum production, hypoxia)
- Concomitant antimicrobial therapy
- Temperature



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Summary

- **Prospective assessment of what is critical to success**
- **What can be done to ensure the essential data is captured**

