Risks, Impacts, and Mitigation of Missing ePRO Data on Clinical Trials

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Objectives:
- Although missing and incomplete responses in ePROs can be minimized through risk assessment and mitigation plans, missing data can have varying implications on clinical trials. ePRO can be a reliable solution for preventing various forms of missing data, however, patients can still be non-compliant which is a major cause of missing data. This poster will:
  - Review the regulations of missing data when using ePRO data collection mode
  - Determine missing data plans to prevent missing data in ePRO

Regulatory Views on Missing Data:
- FDA Guidance on PROs states that:
  - Missing data can introduce bias and interfere with the ability to compare effects.
  - Missing data is a major challenge to the success and interpretation of any clinical trial.
- FDA Guidance (2009) also states:
  - "The amount of missing data between groups, clinical trial results may need to be re-analyzed."
  - "If the missing data are unrepresentative of the study population, clinical trial results may need to be re-analyzed."
- Table 1 shows the impact on data's analyzability by the amount missing.
  

Methods:
- Data gathered via PRO-ePRO instruments and patient diaries are commonly used for primary endpoints, secondary endpoints, and exploratory endpoints. These are evaluated for risk of impact of missing data. Mitigation plans are developed for data entry issues and proactive mitigation options are provided.

Results:
- Missing data evaluation of study endpoints are summarized in Table 2:
  - 395 patients provided responses on compliance in their most recent clinical trial.
- As shown in Figure 1, 53.6% (N=210) reported always being compliant with completing daily PRO/when to schedule randomization visit and 46.4% (N=185) reported they were not always compliant. Patients in this survey reported a high level of non-compliance to the project so that an appropriate plan can be developed.

Conclusions:
- The risk of missing data is dependent upon the protocol design.
- Missing data evaluation of study endpoints are summarized in Table 2:
  - 395 patients provided responses on compliance in their most recent clinical trial.
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References: