CHECKLIST

Optimizing your oncology endpoint data collection

Checklist to guide discussions with your CRO or data collection vendor

The following checklists aim to support the capture of accurate, high-quality data in your upcoming oncology trial(s). To optimize your data collection strategy across data sources, use these considerations to guide your conversations with CROs or data collection specialist vendors to evaluate their suitability for your trial(s).

Overall vendor selection strategy

The following considerations are important for your overall vendor selection strategy and how your data will be collected.

- Amount and length of experience in oncology trials, including your trial's specific indication
- Availability of scientific expertise in oncology to provide guidance on best practices and endpoint data collection
- Proven level of regulatory expertise and experience to support all phases of development and submission
- Familiarity with the latest oncology regulatory guidelines, including specific regulations within the countries in which your trial will run
- Whether support is required for protocol development
- Guidance on minimizing participant burden (e.g., DCTs/at-home trials to reduce site visits, training, single helpdesk)
- Strategies to reduce the number of change orders during the trial duration
- Access to the vendor's scientific teams and senior management for expertise, feedback and issue resolution
- Availability of 24/7 (remote and site) support
- Support for time zones globally
- Consideration of planned countries for logistical planning

Does your vendor have the option of clinical adjudication for your study? For successful adjudication, ensure your partner:

- Provides a proven, experienced, dedicated project team and global clinical experts
- Uses technology that ensures privacy, regulatory compliance and data integrity
- Utilizes the latest in AI technology and machine learning to ensure PHI/PII redaction
- Provides 24/7/365 support

Imaging

- Amount and length of experience in oncology trials, including the following:
  - Specific indication
  - Imaging endpoints
  - Criteria selection
  - Imaging modality requirements for the trial
- Organization of the central read, especially the use of in-house or external readers, level of reader experience and reader training
- Process of finding readers for rare populations or indications
- Ease of uploading images to the core lab by sites
- Method of site training
- Reporting and information available to study teams

Cardiac safety

- Vendor's experience with implementing an oncology-specific strategy to satisfy the ICH E14 QT requirements, including the recent revisions to the "6.1" pathway incorporating non-clinical data
- Proficiency in best practice for blood pressure assessment in clinical trials consistent with the FDA Pressor Effect Guidance
- Capability for at-home collection of cardiac safety data to reduce participant burden
- Expertise in analysis methodologies most suitable for ECGs collected from patients with advanced disease and comorbidities
- Awareness of the pitfalls with site-based ECG assessments and the risk for adverse impact on patient recruitment and retention due to false-positive and/or false-negative readings

eCOA and connected devices

- Recommendation for paper versus electronic data collection
- Level of experience using PROs in oncology trials
- Recommendation for an at-site or at-home model, or hybrid with BYOD
- Advice on an indication-specific endpoint strategy to differentiate your product, incorporating quality of life data, for example, or precision movement data
- Consideration of connected devices for the protocol to reduce participant burden and capture additional QoL data
- Availability of any home-grown assessments
- Familiarity with the commonly used oncology assessments
- Plan for monitoring chemo-induced peripheral neuropathy
- Requirement to license any planned assessments