CSMD 2024

Site Identification and Selection

HOW TO ENSURE LONG TERM COMPLIANCE AND STUDY COMPLETION

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In this session…

- We will explore the critical aspects of site identification and selection for medical device clinical studies.
- We will cover the criteria for site selection, and strategies & tools and technologies that will enhance compliance
- We will look at the importance of site engagement to boost participation and completion rates.

Key Concepts to Ensure Compliance

1. **Criteria for Site Selection**
2. **Training and Education**
3. **Tools and Technologies**
4. **Site Engagement**

1 Criteria for Site Selection

- Infrastructure
- Patient Population
- Regulatory Environment
- Investigator Experience

Infrastructure

Facilities (evaluate clinical spaces, laboratory capabilities, and equipment availability)

Technology (EDC Systems, Data Storage Technology, Secure Communication Platforms)

Specialized medical services (access to radiology, pharmacy, and other medical services)

Evaluation of Facilities (Example for a Heart Study):

1. Clinical Spaces:

- **Cardiology Clinics:**
  - **Private Consultation Rooms:** Ensure there are enough rooms to accommodate patient consultations without causing delays or overcrowding.
  - **Examination Rooms:** These should be equipped with necessary tools like stethoscopes, sphygmomanometers, and facilities for conducting ECGs and other non-invasive tests.
  - **Waiting Areas:** Provide a comfortable environment with adequate seating, especially for elderly patients who may require more support.

2. Laboratory Capabilities:

- **On-Site Laboratories:**
  - **Cardiac Biomarkers:** The lab should be equipped to process tests for troponin, BNP, and other cardiac-specific markers.
  - **Sample Processing:** Ensure the lab can handle the expected volume of samples and has protocols for rapid processing and reporting.
- **Advanced Diagnostic Tools:**
  - **Cardiac MRI and CT Scanners:** These should be accessible for detailed cardiac imaging, and staff should be trained in cardiac-specific imaging techniques.
  - **EHR Integration:** Ensure diagnostic tools are integrated with electronic health records for seamless data sharing and analysis.

3. Equipment Availability:

- **Cardiac Monitoring Devices:**
  - **Holter Monitors:** Ensure availability for long-term ECG monitoring, including software for data analysis.
  - **Event Recorders:** Devices for patients to use when they experience symptoms, capturing transient cardiac events.
- **Emergency Equipment:**
  - **Defibrillators:** Located strategically throughout the facility, especially in high-risk areas.
  - **Crash Carts:** Fully equipped with necessary medications and supplies, regularly checked and maintained.
- **Cardiac Rehabilitation Facilities:**
  - **Exercise Equipment:** Treadmills, stationary bikes, and weight training equipment.
  - **Monitoring Equipment:** Heart rate monitors, blood pressure cuffs, and pulse oximeters.
  - **Qualified Staff:** Nurses, physiotherapists, and exercise physiologists trained in cardiac rehabilitation.

Example Evaluation of Facilities

Patient Population

Demographics

Analyze the patient demographics to ensure they match the study requirements

Disease Prevalence

Consider the prevalence of the condition under study in the site's catchment area.

Recruitment Potential

Assess the site's history of patient recruitment and retention in previous studies.

Regulatory Environment

Local Regulations

Ensure the site complies with local, national, and international regulations

IRB/IEC

Check the efficiency and reliability of the site's Institutional Review Board (IRB) or Independent Ethics Committee (IEC).

Experience

Evaluate the site's experience with regulatory submissions and adherence to guidelines.

Investigator Experience

Expertise in Protocol Implementation

Effective Problem-Solving and Risk Management

Enhanced Patient Recruitment and Retention

2 Training and Education

Training and Education:

Provide comprehensive training for all study personnel on protocols and data collection tools

Offer continuous education and refresher courses to maintain high standards.

Engagement and Communication:

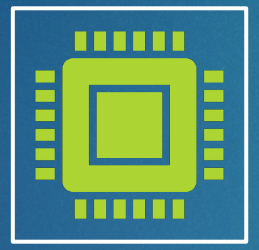
Foster open communication channels between study teams and site personnel.

Engage site staff by involving them in decision-making processes and providing regular feedback.

Problem-Solving Assistance

Provide access to experts and dedicated study monitors to support site staffs for troubleshooting and resolving compliance issues

3 Tools and Technologies



Real-Time Monitoring and Electronic Data Capture (EDC) Systems

Risk-Based Monitoring (RBM)

Communication Platforms

4 Site Engagement

Regular Communication

Recognition and Incentives

Site Visits and Audits

Regular Communication

Status Updates

Provide regular updates on study progress, changes, and expectations

Feedback Process

Establish mechanisms for site feedback to address concerns and improve processes

Monthly Update

Date: June 15, 2024
To: All Investigators and Study Coordinators
Subject: Monthly Update on Transcatheter Heart Valve Study Progress

1. Study Progress
Overall Enrollment:
- **Total Enrolled Participants (US):** 150
- **Total Enrolled Participants (EU):** 140

Site Activation:
- **Total Active Sites (US):** 20
- **Total Active Sites (EU):** 18
- **Newly Activated Sites:**
  - **US:** St. John's Hospital, Seattle; Mercy Health, Chicago
  - **EU:** University Hospital, Munich; Royal Infirmary, Edinburgh

Data Collection:
- **Completed Follow-Ups (US):** 120
- **Completed Follow-Ups (EU):** 110
- **Outstanding Data Queries:** 25

2. Recent Changes
Protocol Amendments:
- **US:** Amendment to include additional imaging follow-up at 18 months.
- **EU:** Amendment to adjust dosage of anticoagulant therapy.

Regulatory Updates:
- **US:** New FDA guidance on remote monitoring implemented.
- **EU:** Updated MHRA requirements for reporting adverse events.

Operational Changes:
- New EDC system implemented for streamlined data entry and management.

3. Expectations and Upcoming Milestones
Patient Recruitment Goals:
- **US:** 180 participants
- **EU:** 170 participants
- **Deadline:** September 30, 2024

Upcoming Site Visits:
- **US:** July 10-15, 2024, at Mayo Clinic, Rochester; Cleveland Clinic, Cleveland
- **EU:** July 20-25, 2024, at Charité, Berlin; Hôpital Européen Georges-Pompidou, Paris

Data Submission Deadlines:
- **Next Data Lock:** August 15, 2024
- **Upcoming Interim Analysis:** September 1, 2024

Key Deliverables:
- Finalize patient recruitment strategy by June 30, 2024.
- Submit site monitoring reports by July 15, 2024.

4. Investigator and Site Coordinator Feedback
Recent Challenges:
- Delays in data entry at several sites due to staff shortages.

Solutions and Support:
- Additional training sessions provided for data entry personnel.
- Temporary staffing support arranged for high-need sites.

5. Contact Information
For any questions or concerns, please contact:
- **Study Coordinator (US):** Dr. Jane Smith, jsmith@example.com, (555) 123-4567
- **Study Coordinator (EU):** Dr. John Doe, jdoe@example.com, +44 20 7946 0958

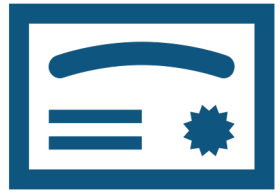
Thank you for your continued dedication and hard work on this important study.

Example Status Update

Recognition and Incentives

Acknowledgment

Recognize and reward high-performing sites to boost morale and engagement



Incentive Programs

Implement incentive programs to encourage compliance and high-quality data collection.

Recognition vs. Incentives

Recognition

- **Certificates of Excellence:**
  - Awarded to sites that demonstrate consistent high performance and adherence to study protocols.
  - Example: A site that maintains 100% data accuracy for six consecutive months receives a certificate during the annual investigator meeting.
- **Public Recognition:**
  - Highlighting high-performing sites in study newsletters or during meetings.
  - Example: A site with the highest patient recruitment rate is publicly acknowledged and praised in the monthly newsletter.
- **Plaques:**
  - Physical awards presented to sites as a token of appreciation.
  - Example: A plaque awarded to a site for exceptional compliance and data quality throughout the study.

Incentive Programs

- **Performance Bonuses:**
  - Financial rewards for meeting specific performance criteria.
  - Example: A site that achieves 100% data entry accuracy and timely submissions for three consecutive months receives a $1,000 bonus.
- **Milestone Payments:**
  - Financial incentives for reaching specific milestones in the study.
  - Example: Sites receive $500 for every 20 patients successfully recruited and retained in the study.
- **Professional Development Opportunities:**
  - Sponsorship for conferences, workshops, or advanced training courses.
  - Example: Sites with consistent high performance are provided with sponsorships to attend international medical conferences, enhancing their professional growth and network.

Site Visits and Audits

Frequent Visits

- Conduct regular site visits to monitor compliance and provide support

Audits

- Perform audits to ensure adherence to protocols and regulatory requirements.

Site Visits vs. Audits

ASPECT	SITE VISITS	AUDITS
Purpose	Ongoing support, protocol adherence, patient safety, communication	Compliance verification, data integrity, participant protection
Frequency	Regular intervals (monthly, quarterly)	Less frequent, scheduled or unscheduled
Scope	Review study documents, verify informed consent, monitor recruitment, provide training	Comprehensive review of all study activities and documentation
Nature	Collaborative, supportive	Formal, rigorous, compliance-focused
Conducted by	Study monitors, CRAs	Internal audit teams, external regulatory bodies
Outcome	Enhanced site performance, issue resolution	Formal audit reports with findings and corrective actions

Roadmap to high-quality data and successful study outcomes

Maria Nyåkern, Ph.D.

- Maria Nyåkern, Ph.D., is an accomplished leader and entrepreneur with two decades of expertise in the healthcare and MedTech industries. She has successfully established and expanded several consulting firms focused on medical device innovation and clinical research. As the founder of AKRN Scientific Consulting, a leading Madrid-based medical device CRO, Maria spearheaded significant business growth, culminating in the strategic acquisition of AKRN by the North American CRO, NAMSA, in 2022. This acquisition significantly enhanced clinical development and commercial capabilities in the medical devices sector.
- Maria is celebrated for her extensive expertise in the clinical evaluation and investigation of medical devices, particularly those integrated with AI, adhering to stringent EU MDR 2017/745 and ISO 14155:2020 standards. Her dedication to advancing medical technology and fostering emerging scientific talent has been recognized on a European level, underscoring her contributions to scientific progress, technology transfer, and societal improvement across Europe.

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