World Health Organization

MINISTRY OF HEALTH
THE REPUBLIC OF UGANDA

SOLIDARITY PARTNERS

Platform Adaptive Randomised Trial for NEw and Repurposed Filovirus treatmentS

Setting up an RCT to evaluate candidate therapeutics in the context of an outbreak

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R&DBlueprint
Powering research
to prevent epidemics

Setting up an RCT; Protocol Science and Ethics

- Protocol Development
- Funding
- Study Investigators, Scientific Advisory Committee, DSMB,
- Ethics and research regulatory requirements and approvals
- Clinical Trial Insurance
- Community Advisory Board
- Community Engagement Plan
- Correspondence with research regulators
- Joint review mechanisms
- Approvals

Setting up an RCT; site and population

- Site selection
- Set up
- Inspection; SIV, SAV
- Study population, screening/enrollment and accrual goals
- Informed consent process
- Psychosocial management
- Community engagement plan
- Community preparedness
- Health worker engagement
- Patient recruitment and retention
- Myths
- Translation of documents to local languages

Setting up an RCT; Staff

- Study investigators
- Scientific Advisory Committee
- DSMB,
- Clinical trial implementing team; recruitment & training (Protocol, GCP, HSP), motivation
- Internal and external monitors
- Data managers
- Clinical trial manager
- Study coordinator
- Psychosocial management
- Investigator and staff qualifications,
- Site personnel specific roles and responsibilities and day-to-day operations

Setting up an RCT; facilities and equipment:

- Study product management
- Document storage
- Data management
- Communication
- Administrative issues; patient welfare
- Research laboratory: specimen preparation and storage, protocol specific testing,
- Office space and equipment
- Oversight and communication
- Clinical: triage, waiting area, consenting areas, examination rooms, inpatient rooms,
- Protocol required equipment,
- Emergency equipment
- Clinical laboratory: phlebotomy area
- Monitoring areas
- Any additional study areas; staff
- Nutrition/feeding
- Sanitation

Setting up an RCT; study product

- Procurement
- Availability
- SOP on study product handling & storage
- Pharmacy space, conditions,
- Dosage, preparation and administration
- Accountability procedures
- Concomitant medications
- Storage facilities and security
- Dispensing, transport, and administration
- Disposition of unused study product

Setting up an RCT; Documentation

- Source documentation and case report form procedures
- Data management
- Electronic data capture
- Source documents
- Case report form (paper or electronic).
- Databases
- Adverse event (AE) and serious adverse event (SAE) monitoring and reporting
- Site management: regulatory, communications, supervision, quality management
- IRB/IEC, regulatory requirements, and Good Clinical Practice (GCP)
- Site personnel training (Including: Human Subject Protection training, GCP, protocol-specific training)
- QC/QA
- Training records for all staff listed on the Site Signature List/Delegation of Authority

Setting up an RCT; Laboratory

- SOPs; Specimen Preparation, Handling, and Shipping
- Study Manual of Procedures
- Specimen collection, processing, and storage
- Phlebotomy area
- Protocol required equipment
- Clinical and research laboratory procedures
- Laboratory certifications/reference values
- Central/core laboratory procedures/shipping
- Biohazardous training documentation
- Lab certification

Setting up an RCT; Safety concerns

- Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters
- AE, SAE, grading, assessment and reporting
  - SAE form and electronic case report form (eCRF)
  - reviewed and evaluated by an ISM, and the IRB,
- Appropriate/advanced medical care
- Clinical Trial Insurance

Setting up an RCT; IRB/IEC and Regulatory Requirements

- ICH/GCP Compliance
- Protocol adherence
- Protocol deviation reporting and documentation
- Regulatory documentation/records storage (electronic, paper)
- Records retention
- Informed consent forms and process
- IRB/IEC submissions and approvals screening-enrollment log requirements
- Possibility of regulatory agency inspection

Administrative Items

Activation Memo:

- No screening/prescreening procedures should occur until the Site Activation Memo has been obtained.

Subject Records: confidentiality

- All records should be kept in a locked file or maintained in a locked room at the sites.
- Electronic files should be password protected.

Screen Failures:

- Screening records will be kept to document the reason why an individual was screened but failed entry criteria.
- Screen fail reasons will be recorded in the eCRF.

Questions?

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