Governance reflections
Solidarity trial therapeutics

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CORE protocols – a collaborative approach to R&D

Governance is the set of relationships and functions established by a collaborators in a global trial using a CORE protocol to ensure successful implementation of the trial as per international standards.

58 registered platform trials in COVID-19 treatments and prophylaxis (including 10 potential) registered between January 2020 and May 2021. 19 (33%) are trials within a larger master protocol or research initiative:

- Solidarity
- CATCO
- DisCoVeRy
- EU SolidAct
- RECOVERY
- REMAP-CAP
- ACTT (ACTT-1, ACTT-2, ACTT-3, ACTT-4),
- TACTIC (TACTIC-R and TACTIC-E, and
- ACTIV (ACTIV-1 IM, ACTIV-2, ACTIV-3, ACTIV-4, ACTIV-5 BET-A and ACTIV-5 BET-B, and ACTIV-6), and
- TOGETHER (TOGETHER 1, 2, and 3).
# Solidarity trial

636 hospitals in 43 countries in the 6 WHO Regions

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Quality Assurance

Global monitoring

Some issues have been uncovered
SOC
Documentation of ICF
Others
Regular queries

Local Monitoring
Queries
SAEs SUSARs reporting

Global network monitors
From every country + global monitors +
GCP trainers
Weekly independent calls
Collaboration for GCP refresher training

PIs and national coordinators
Encourage to review progress and
maintain dialogue with each site

Safety monitoring team
# Simplicity of procedures

1. **Start enrolment via study website - Global enrolment and randomisation center.**
   - Hospital, the ID of the randomising health staff

2. **Obtain informed consent**

3. **Enter registration information**
   - Patient ID, age, sex
   - Patient characteristics (diabetes, heart disease, chronic pulmonary disease, asthma, tuberculosis, HIV infection, current smoking)
   - COVID severity at entry (shortness of breath, administration of oxygen, provision of ventilation and, if already imaged, any major radiological abnormality).

4. **Proceed with randomisation**

5. **Initiate administration of drug allocated**

6. **At the end of hospitalization, enter information on 3 main patient outcomes (while in hospital)**
   - Provision of ventilation or intensive care
   - Duration of hospital stay
   - Mortality
Study governance

Co- Sponsors: Agreement between the MOH and WHO

Steering Committee (SC): responsible for all aspects of study not assigned to DMC. SC, which will not have access to study data, will be responsible for all adaptations. A sub-group of the national investigators.

National Principal Investigators group – including all the investigators in various countries

Data monitoring committee (DMC): Apply pre-defined and SC-defined efficacy and lack of benefit criteria to vaccines, and address potential safety issues.

Independent expert group for prioritization of treatments to be included
Other experiences

Ebola ça suffit
Solidarity trial vaccines
Meningitis vaccine project
WHO R&D Blueprint therefore would like to encourage and facilitate the creation of a global “Consortium” to evaluate the efficacy and safety of treatments for human monkeypox

- To develop a global **CORE protocol** design to facilitate collaboration, and integration of clinical research with outbreak response
- To ensure that such protocol design includes the possibility for **add-on studies to address additional questions** that are relevant in each setting
- To promote the use of **simple protocols** benefiting from **digital data collection tools** (GCP compliant) accessible to all.
- A governance framework where participating researchers have a role and shape it