



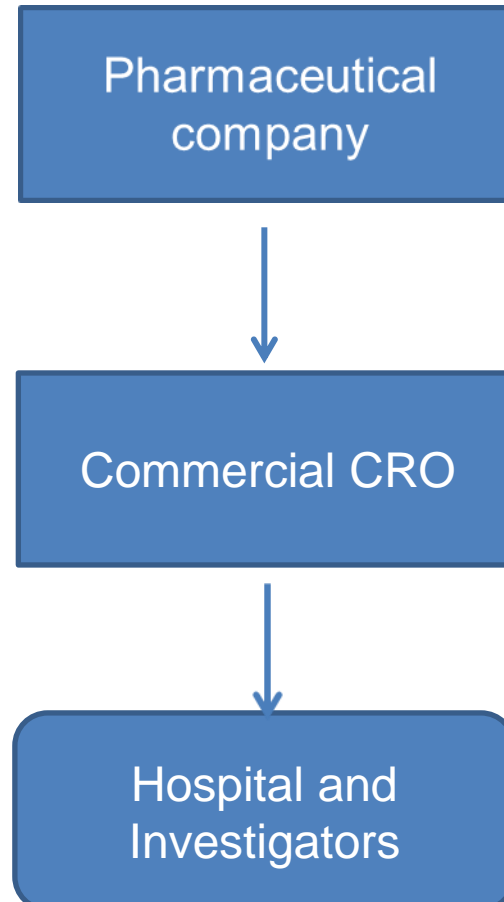
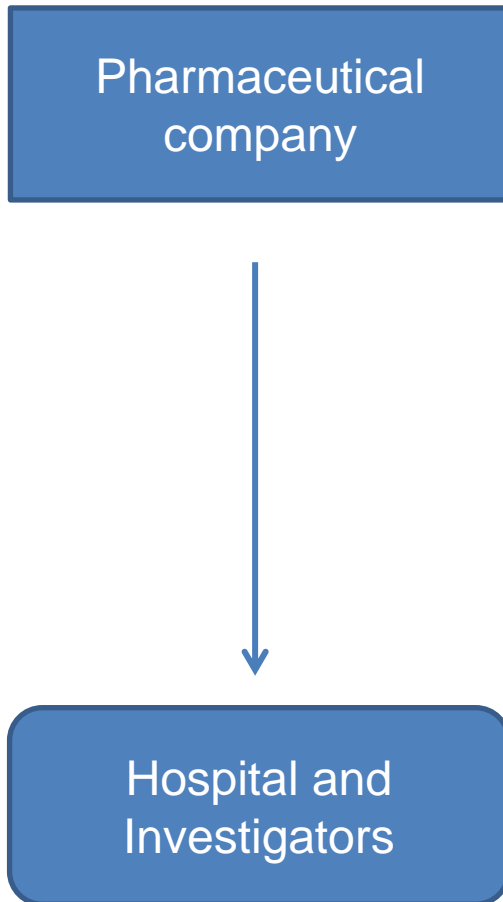
## Academic Clinical Research Organization partnership in Clinical Research

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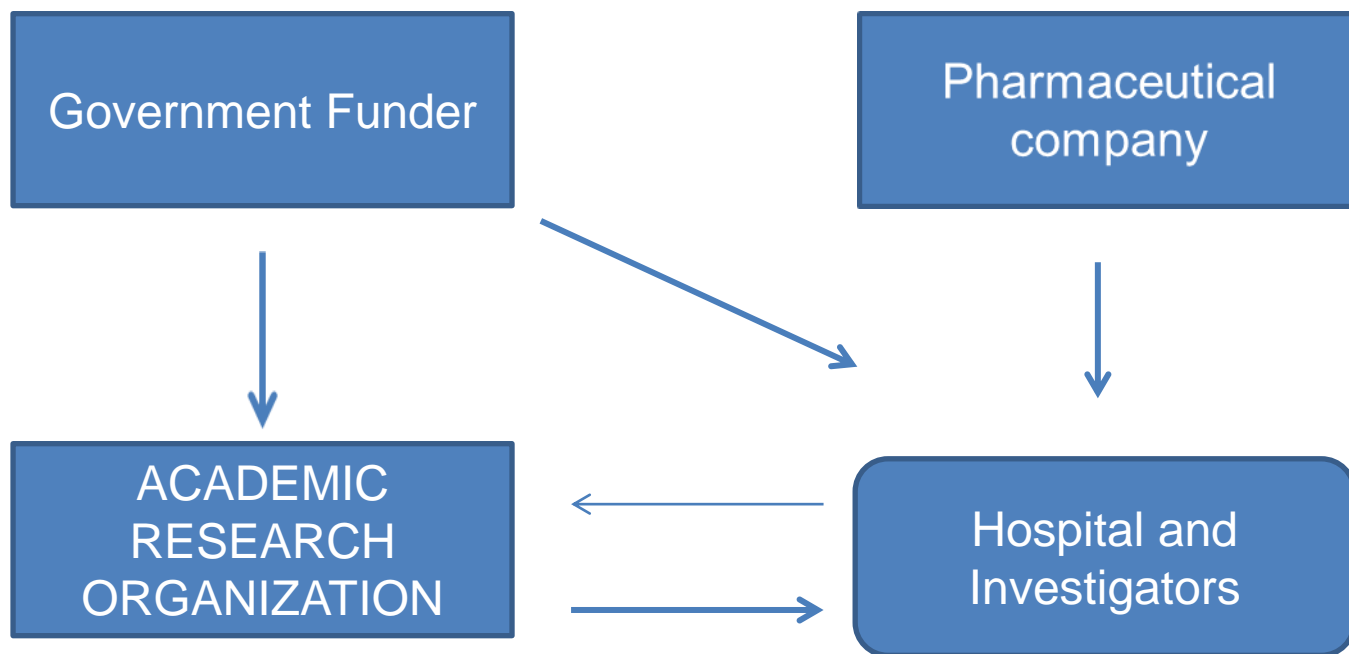
# SCRI is an Academic Research Organization, subsidiary of Ministry of Health Holdings



# TRADITIONAL PHARMA SPONSORED STUDIES FUNDING MODEL



# EXAMPLE OF A PARTNERSHIP CO-FUNDING FOR INVESTIGATOR-INITIATED STUDY IN SINGAPORE INVOLVING PARTNERHIP WITH ARO



# Overview of Investigator Initiated Clinical Trials Activities

## Main study activities

- Project management
- Monitoring
- Data management
- Biostatistics
- Use of database (Oracle or REDCap)

PI has an idea

Grant approved

Study starts

Study ends

Data cleaned

End of publication

## Pre-grant activities

- Protocol design
- Budgeting
- Site feasibility
- Consultations on trial operations
- Project management (e.g. with external funder)

## Supportive Study activities

- QA & compliance
- Project management
- Software licenses (Oracle, SAS)

## Post-study activities

- Manuscripts writing
- Secondary analysis
- Re-check data

# Partnership between ACRO (SCRI) and Hospital in conducting a clinical trial

## ACRO responsibilities

Sponsor  
Protocol design  
Sample size calculation  
Overall project management  
Preparation of research database  
Monitoring of data entry  
Management of data  
Investigations  
Monitoring of safety event  
Analysis of data  
Publication

## Staff involved:

*Epidemiologists,  
Biostatisticians  
Project Manager  
Clinical Research Associates  
Research Informatics  
Data Management*



## Site responsibilities

Site feasibility  
Protocol submission to IRB/HSA  
Screening of suitable patient  
Recruitment of patient  
Consent taking  
Examination of patients  
Conduct Lab/imaging tests  
Investigational drug administration  
Follow-up of patient  
Data entry  
Safety reporting to IRB and HSA  
Site study closure

## Staff involved:

*Investigators (doctors)  
Clinical Research Coordinators  
Research assistants*

# Eg of Tripartite Partnership by ACRO



## **SCRI – Study Sponsor (Singapore) (funded by NMRC core and project grant)**

Sponsor Oversight  
Investigational Vaccine Importation  
Quality Assurance and Audit  
Safety Management  
Medical Monitor

## **MicroVAX – Study Funder (U.S)**

Study Protocol Design  
Supply Investigational Vaccine,  
Funds CRO (Project Management, Data  
Management and Monitoring)  
Safety Reporting to FDA, US



## **NCC – Study Site (funded by NMRC for MUC-1 trial)**

Study Protocol Design  
Subject Recruitment and Conduct of MUC-1 trial  
Investigational Vaccine Management  
Safety Reporting to IRB, SCRI, and MicroVAX  
Biostatistics



## Treatment that aids body's fight against cancer on trial – Straits Times 24 Jan 2015





# Examples of other Clinical Research supported by SCRI

- ASCOLT – study of Aspirin in colon cancer
- ADEPT – study of platelet transfusion in dengue
- ATOM – study of atropine eye drops in children myopia
- PAROS- study of pre-hospital and emergency care

All of them have major public health impact to the population, none of them have commercial benefits to pharmaceutical companies

# ARO: CHALLENGES AND OPPORTUNITIES IN INVESTIGATOR-INITIATED STUDIES

## ■ Challenges

- Less resources/funding compared to traditional pharmaceutical sponsors studies
- Institution or ACRO has to act as “sponsor” of the study and bear the risk of the trial
- Need to collaborate with many parties

## ■ Opportunities

- Principal Investigator drives the study/protocol and not the pharmaceutical companies
- Collaboration with many non traditional parties and countries (eg Myanmar, Mongolia, Cuba)
- Good learning experience for site team (coordinators, research assistants)

# Why partnership with Academic Research Organization is important?

- Partnership contribution in expertise : epidemiologist, biostatistician, project management and monitoring, data management etc.
- Focus on high public health impact projects which has low financial returns for commercial funders
- Partnership with Academic Medicine Centre in developing healthcare excellence to the community



# Thank You