

Teletrials

The primary site perspective

# TrialHub in action

*Allowing patients to participate in clinical trials closer to home*

OFFICIAL

AlfredHealth

The CDA



Satellite



Primary

The feasibility



100



Site Selection

Indemnity



100

75



Contract

Supervisor Plan



60

Budget



Drug Distribution

Delegation Logs



Training



60



Communication



Activation



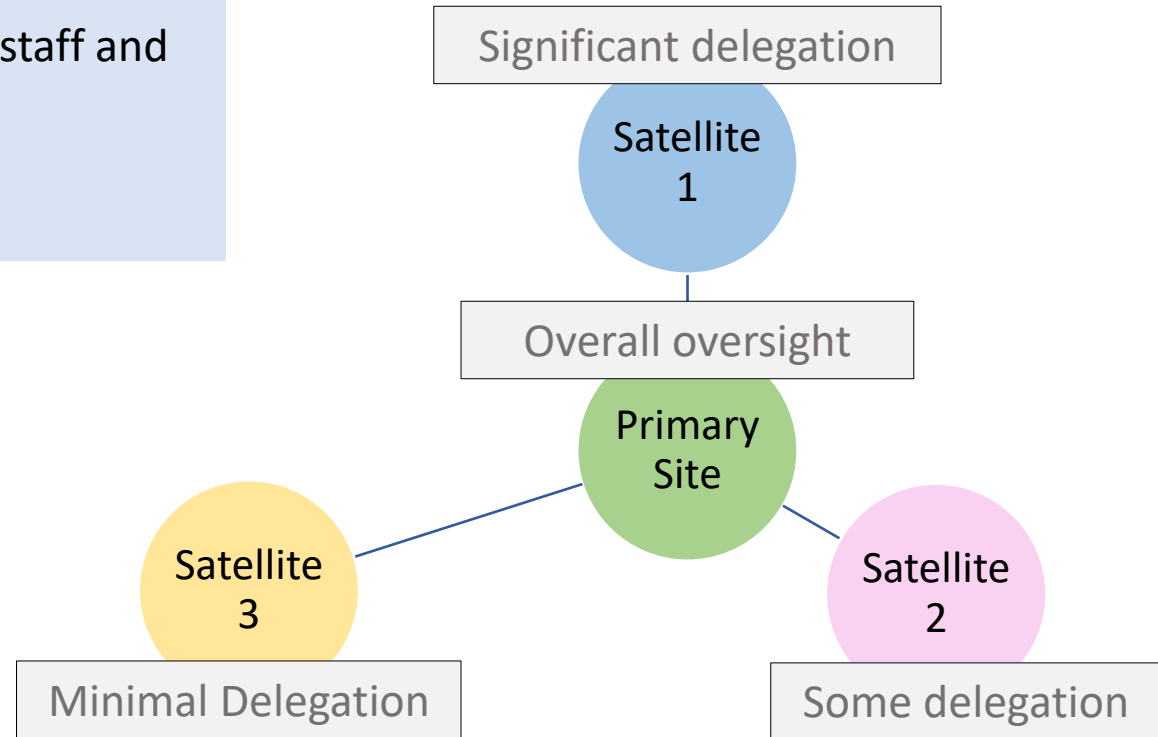
# Delegation of Responsibilities

Primary Site PI - Overall responsibility for the conduct of the trial

Satellite site AI - As delegated\* for the satellite site only

Primary site Research team - mentoring of satellite site staff and compliance

SS research team – as delegated\*

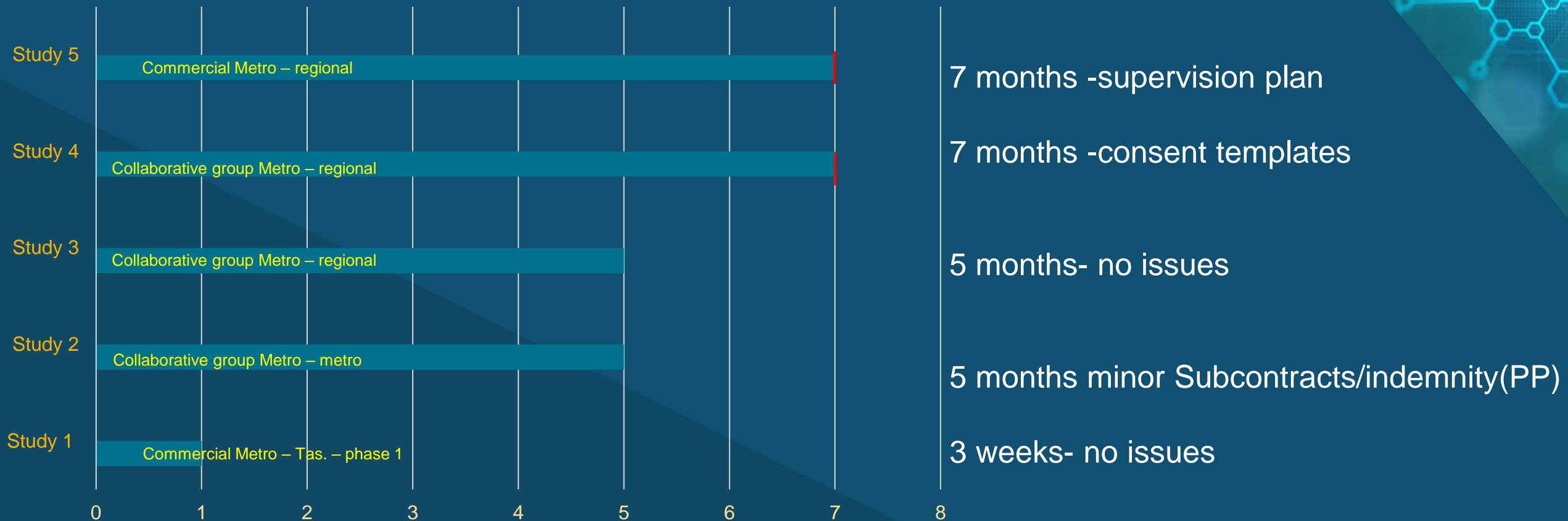


# Positive Progress

- National compendium of Standard Operating Procedures
- Standard templates for CTRAs, indemnities
- Acknowledgement templates - sponsor, PI and satellite sites
- Awareness of the program: Sponsors, PIs and study teams
- Master Supervision plan (WG )
- Improved systems –IP distribution, data, IVRS
- Using a shared Document sharing system
- Scheduled Start up meetings and agendas
- Trial progress meetings
- Fees and charges guidelines

# Case study

5 sponsors, 5 HRECs, 1 Primary site, 4 satellite sites:



**TrialHub** in action – allowing patients to participate in clinical trials closer to home

**OFFICIAL**

# Work still to be done

- Jurisdictional interpretation of submission requirements
- Variation in templates (PICF)
- Clarification of sponsor roles and responsibilities
- Formal education and training of all teams
- Position descriptions
- Workload for the primary site
- Metrics reporting and access to ATP funding schemes