



Setting up trial units



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SMO –site owned

- A sub-division of Wits Health Consortium
- WHC –a research company
- Owned by Wits University
- 2 dedicated large trial sites



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Dedicated Clinical Trial Centres?

- Regulatory demands -**huge**
 - Clinical trial complexity 
 - Recruitment demands 
 - Paper work  
 - Demand from industry –to curb costs -fewer, bigger centres
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- **It's getting harder to do trials part-time**
 - **Ideal time –more work to SA-not enough sites**

Trial Centre Models

- Full-time stand alone model –large or small
- Part-time -linked to a practice - GP or Specialist
- Part-time -linked to an SMO
- **Choice is based on the key objectives –no right/wrong**
 - Academia support?*
 - Part-time interest vs full-time career?*
 - Patient support?*
 - Financial top up?*
 - Appetite for risk*
 - Therapeutic interest areas*
- **Who you plan to partner with?**
- **It must work financially**

Trial Centre Models

- Full-time stand alone model –large
 - expensive to set up -large **infrastructure**
 - high **staff** costs
 - need lot's of **studies** to make ends meet –much higher risks
 - needs rigorous support **systems and processes**
 - but... very versatile –can do GP and Specialist studies
 - ideal for academia –supports research within a faculty
 - can develop an international reputation and compete with the best in the world for recruitment and quality

Key issues

- Critical challenges for trial sites
 - *quantity and quality of studies securedand to ensure steady flow of work*
 - *capacity to recruit patients –a full-time process*
 - *average fee per visit -is it increasing in line with inflation?*
 - *what should facility fee be??*

Key issues

- Critical challenges for trial sites
 - *staff training and when to hire regulatory issues*
 - *how to maintain quality whilst growing → quantity and type of data queries generated*
 - *development and implementation of rigorous support systems and processes*
 - *How to integrate monitors into study team*

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