

Additional important elements to consider in an OR protocol

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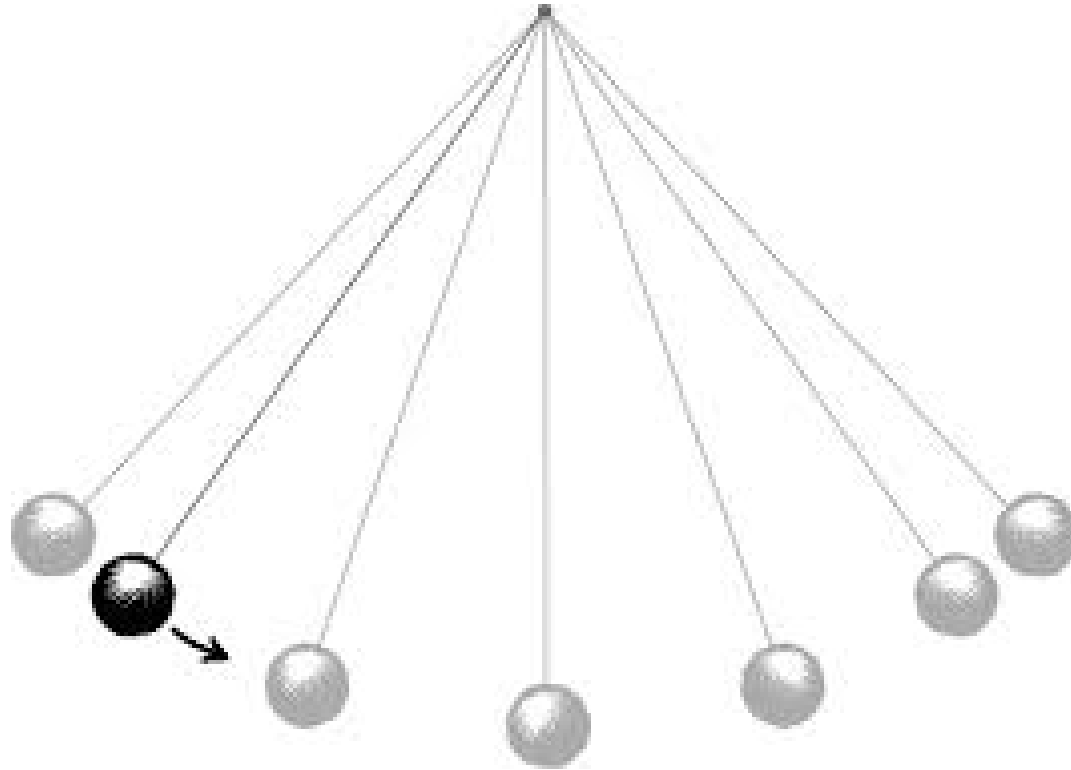
Setting the scene



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It is not all or nothing.....



- Ideal vs real world conditions
- Efficacy vs effectiveness
- Ops research helps to identify and address key challenges



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Eligibility criteria

- What is your **target** population?
- Inclusion and exclusion criteria
 - Age
 - Gender
 - Diagnosis
 - Comorbidities
 - Pregnancy
 - Etc.



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Eligibility criteria – some examples

- Inclusion

- Bacteriologically confirmed with resistance to at least R
- Close contact of patient with lab-confirmed MDR-TB and strong clinical and radiological evidence of TB disease
- Pre-menopausal women who agree to use contraception
- Able to provide informed consent

- Exclusion

- Previously exposed to 2nd line drugs in intended shorter MDR-TB regimen ≥ 1 month
- Abnormal liver or renal function
- Particular resistant patterns
- QTc >500 ms

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Eligibility criteria – wish list

Numbers potentially eligible



Numbers examined for eligibility



Numbers confirmed eligible



Number enrolled



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Identification of eligible patients



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Informed consent

- Share information and opportunity to discuss
- Written (signed vs thumbprint) vs verbal – use data for research
- Consider adding in consent for bio-banking samples if you have the lab infrastructure



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Follow-up during treatment

- Number and timing of visits/telephonic contact
- Investigations – which investigations, how frequent, where?



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Outcome definitions

- Collected prospectively
- Need to be clearly defined
- Evaluation based on smear / culture / clinical response
- Comparability across settings

When to assess recurrence rate?

- Decide on post treatment follow up to assess recurrence rate
 - Example 3 – 6 – 9 – 12 months – declare 12m post Rx outcome
- Sputum sample for culture during post treatment follow up
 - At 6 months
 - At 12 months



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Contact tracing

- Consider including in OR protocol
- Facilitates good practice & formalises the process
- Create a register of exposed individuals linked to an index patient
 - Provide a framework for DR-TB PET operational research