



Ten Reasons Why This Study Won't Work...
In No Particular Order
(and that's important!)

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Well, Actually Only Five Reasons...

1. Logistical Issues
2. Ill-defined Inclusion/Exclusion Criteria
3. Personnel Turnover
4. Resourcing
5. Molecule Doesn't Work

Logistical Issues

- Mis-randomization and mis-labeling
 - It happens!
 - Triple check everything
- Lab supplies aren't available at time of initiation
 - Use comprehensive timeline
- Inadvertent unblinding
 - Use blinded and unblinded monitors where appropriate

III-defined Inclusion/Exclusion

- Too few con meds allowed can overly restrict patient pool
- Too few con meds allowed can skew influence efficacy data
 - Thorough feasibility planning
 - Include patients in the process
 - Use amendments where appropriate

Personnel Turnover

- Site, Sponsor and CRO
 - Good luck preventing this
 - It happens!
 - Video and other recording of SIV
 - Frequent meaningful newsletters

Resourcing

- Site, Sponsor, and CRO
 - Major factor is time and focus
 - Make sure all parties can participate as required
 - Retrain as necessary
 - Reward

Molecule Doesn't Work

- Could be
 - Insufficient biological activity
 - Unmanageable toxicity
- It's a *failure* when we unnecessarily subject patients to the clinical trial process

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