

## Risks to clinical trials

### Inadequate funding

- > Funding will run out during the trial

### Recruitment target not met

- > Inaccurate estimate of participant availability
- > Slower recruitment than expected

### Outcomes not collected

- > Outcome measures not feasible
- > Participant drop out

### Protocol violation

- > Protocol compliance difficult for participants
- > Protocol compliance difficult for trial team

### Data and samples

- > Data collection errors
- > Data entry errors
- > Loss of data through theft, malware etc
- > Loss or degradation of samples or biospecimens

### Staff and skills

- > Lack of experience in trial central management
- > Lack of trial statistics skills
- > Site coordinator or research assistant under skilled

### Team cohesion

- > Overall team cohesion fails during the trial

### Contracts and indemnity

- > Contracts not in place
- > Indemnity not in place

### Impact on standard of care

- > Question is irrelevant to practice
- > Question becomes irrelevant due to other advances in understanding of problem or another similar trial is published

### Harm to participant

- > Intervention is unsafe
- > Protocol is unsafe
- > Error in following protocol