Clinical Research
The Bare Essentials

Aly Talen

[Genae Logo]
Disclosure

Speaker name: Aly Talen

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☒ Other(s), founder and shareholder genae

☐ I do not have any potential conflict of interest
Essentials

- design
- publication
- regulatory
Design

Team up with a statistician
Keep focus on your hypothesis
Include budget & funding
Create ‘solid’ documents
Intellectual property

Intellectual Property (IP)?

→ IP protection needed?

→ Or are you possibly breaching IP?
Budget

Budget all aspects:

- Insurance needed?
- Database, corelab, .. ?
- How many sites? Who’s involved?
- What’s payable? What’s on the institution/public healthcare?

Funding:

- Research grant? Industry, public, academic? Prepare a full plan to ensure grants
Documents

Your plan: protocol

Your patient: patient information & consent

Your data: case report form/database

You: insurance
Requirements

Verify the requirements:

- Competent Authority / Ethical Committee
- Clinical research guidelines (ISO14155)
- Data protection
- Other? Check with your hospital / EC
Execution

Stick to your protocol

Get consent from your patient

Collect data
Event reporting

Report the (serious) adverse events* as per the requirements:

- Authorities
- Ethical committees
- Manufacturer(s)

* Serious Adverse Event ≠ Major Adverse Event
** Approval needed!
Results

Report the result to your EC

Research grant used? Report to funding party

Create your manuscript (focus on planned hypothesis)
If you don’t know or not sure

ASK AN EXPERT
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