

The logo for LING, featuring the letters 'LING' in white, positioned over a stylized graphic of three curved, overlapping brushstrokes in dark blue, red, and yellow.

LING

Clinical Research The Bare Essentials

Aly Talen



Disclosure

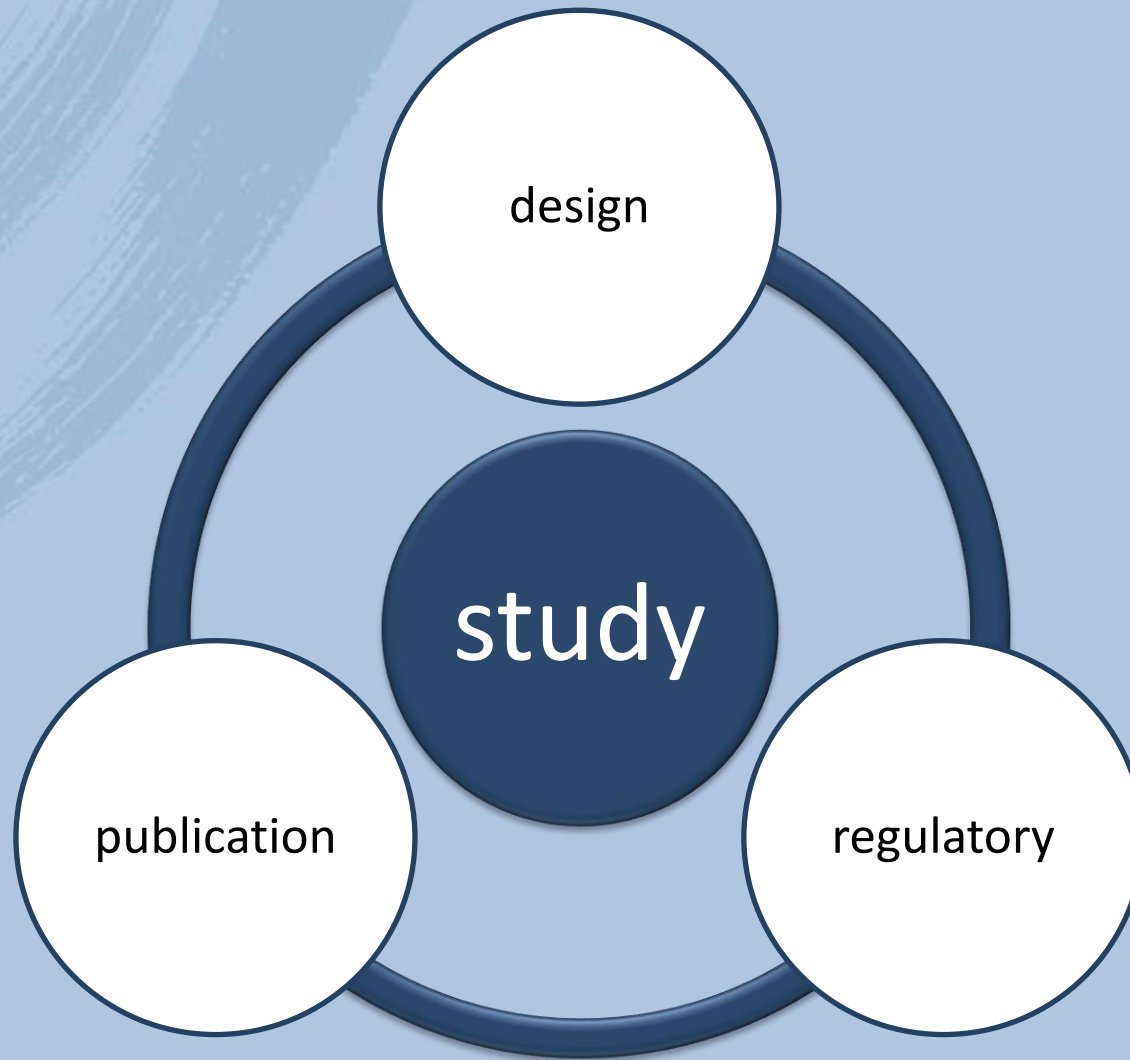
Speaker name:

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

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



Register your study

ClinicalTrials.gov

A service of the U.S. National Institutes of Health



Source: Clinicaltrials.gov: Peripheral Arterial Disease, open studies; January 20, 2016

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)



Change
your plan if
needed**

* *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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