THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Clinical Trials 101

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What is a
clinical trial?

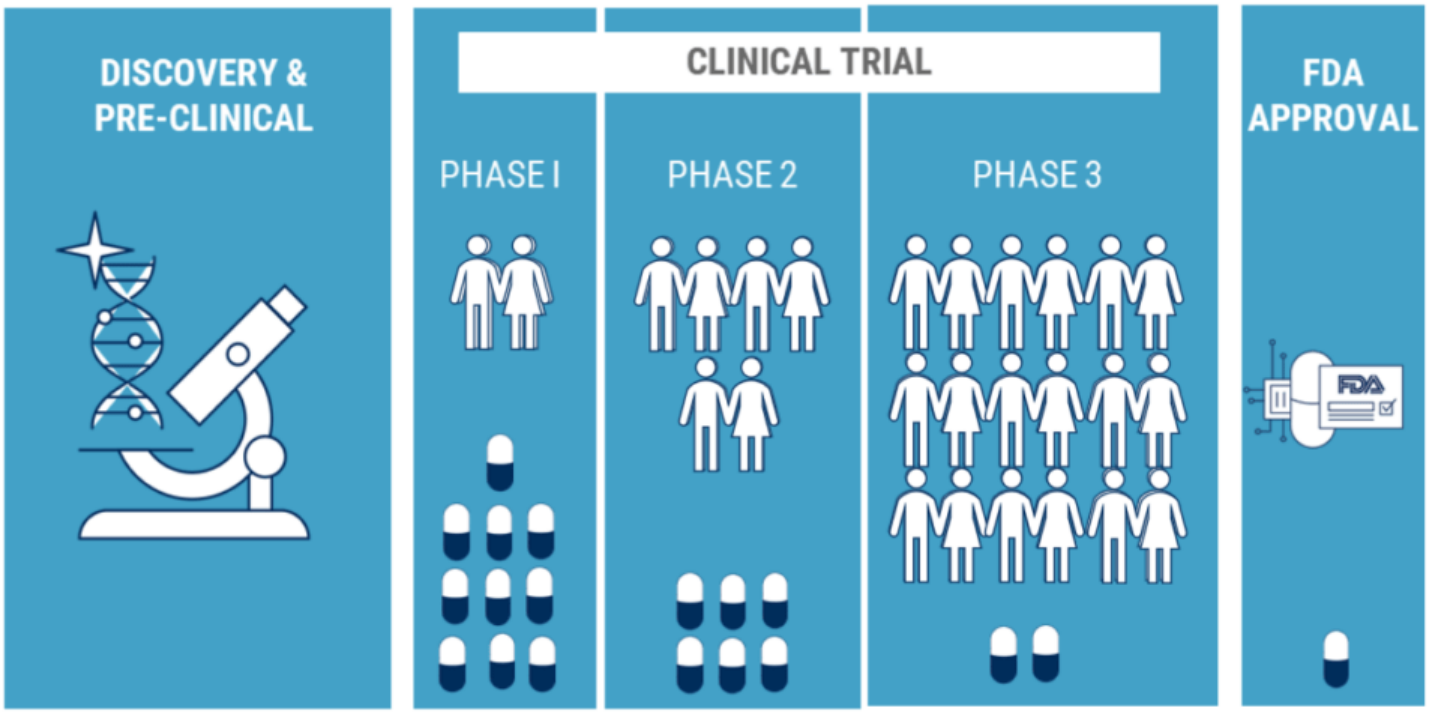
What is a Clinical Trial?

Clinical Trial

- Prospectively planned
- Conducted under well defined conditions:
  - Subject Selection
  - Intervention and evaluation policies
- Specific questions-objectives
- Justify the number of subjects, sample size. Have a statistical plan
- Measurable results rather than plausible reasoning are required to support conclusions

Observational Studies

- Retrospective
- Participants are selected on the basis of presence or absence of an event/condition of interest
- Subjects can be identified from hospital records or other data sources
- Investigators are passive observers


DISCOVERY &
PRE-CLINICAL
CLINICAL TRIAL
PHASE I
PHASE 2
PHASE 3
FDA
APPROVAL
FDA


THE
RESEARCH
LIFECYCLE
POST-AWARD
PRE-AWARD
1
YOUR RESEARCH STRATEGY
2
DEVELOPING YOUR PROPOSAL
3
RESEARCH PROCESS
4
PUBLICATION
5
IMPACT

Research is a***systematic*** investigation, including research development, testing and evaluation, designed ***to develop or contribute to the generalizable knowledge.***

Have a protocol

A well designed protocol provides the clinical research team ***instructions*** and ***directions*** that are strongly ***supported*** by scientific rationale for conducting the study. Adherence to the protocol will provide ***consistent and reliable data, as well as guidance on conducting the protocol in a manner to protect human subjects.***

Have a statistical plan

- Statistical methods to be used to define the analysis:
  - Sample size
  - Treatment assignment
  - Efficacy
  - Safety
  - PK
  - Plans for interim analysis
  - Subject disposition

Collaborate with a biostatistician or methodologist (BERD)

Ask yourself…..

- Is this feasible?
- Why you want to participate?
- Science?
- Indication?
- PI Collaboration?
- Patient Population?
- Feasible?
- Patient Population?


SAFETY
#1 Patient safety

How do we protect human subjects?

- Design of the study
- Review by the local IRB
- Protocol defined safety measures
- Trained research staff

Know the Rules and Regulations

- International Conference on Harmonization/Good Clinical Practices (ICH/GCP)
- IRB (Institutional Review Board)
- Your Office SOPs (Standard Operating Procedures)
- The Belmont Report
- Declaration of Helsinki
- Institutional requirements
- *Industry Requirements
- *Government agencies (DHHS/OHRP; FDA; NIH)

(* when applicable)

Regulations! Complicated, boring regulations!

We can't go over them

We can't go under them

We can't go around them

We've got to go through them!


Good Clinical Practice (GCP)
GCP is an international ethical and scientific qua
standard for designing, conducting, recording, a
that involve the participation of human subjects
this standard provides public assurance that th
well being of trial subjects are protected, consi
principles that have their origin in the Declarat
that the clinical data are credible. Good Clinic
likely to follow the International Conference o
(ICH) of GCP guidelines in many aspects. G
(GCP) will enforce tighter guidelines on ethic
study. Higher standards will be required in te
documentation for the clinical protocol, record keeping, trainin
facilities including computers. Quality assurance and
that these standards are achieved.
that the studies are
TEAR
FLIP UP

13 Principles of ICH-GCP

1. Ethical principles of the Declaration of Helsinki.
2. Benefit of the individual (benefits justify risk).
3. **Protection of individuals prevail.**
4. Adequate drug data to support clinical trial.
5. Clinical trials should be scientifically sound.
6. **IRB/IEC approvable / favourable opinion.**
7. Subject care is under a qualified physician.
8. Staff is qualified, educated, experienced and trained.
9. **Obtain freely given informed consent.**
10. **Data accuracy.**
11. Confidentiality of records.
12. Good manufacturing practice.
13. Quality systems implemented.

The rights, safety, and well-being of the trial subjects are the most important considerations

A trial should be conducted in compliance with the protocol that has been received prior IRB approval

Freely given informed consent should be obtained from every subjects prior to clinical trial participation

All Clinical trial information should be recorded, stored and handled in the way it allows its accurate reporting, interpretation and verification

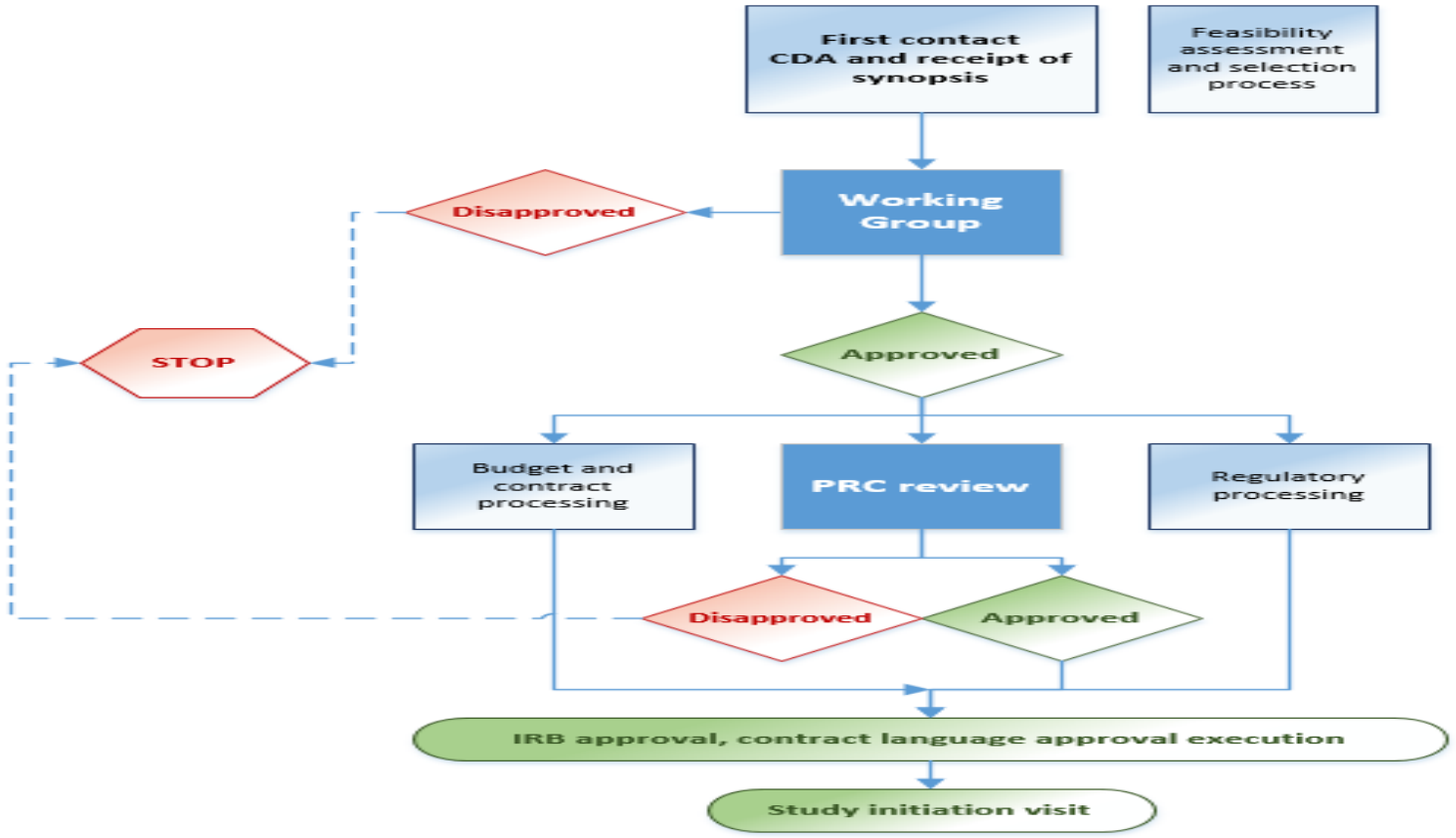
The Importance of Principal Investigators

- Only 15% of doctors participate in research as Principal Investigators
- 90% of the doctors that do participate in their first clinical study never participate in a second one
- This is unfortunate because PIs play a key role in raising awareness to the general public
- Patients are more likely to enroll in a clinical study if their physician is also a PI

Roles and Responsibilities

- Although the PI is ultimately responsible for the overall conduct of the study, it does not mean that he/she has to do all of the work
- Most of the work that goes into running a study will be delegated to the study coordinator and other research staff
- The PI oversees the studies to ensure that GCP guidelines are met and that the protocol is being followed as accurately as possible

Know the workflow



Be involved

- Once the contract is signed, schedule SIV
- Be sure to attend and meet people at SIV (very important)
- Get information about accrual/amendments/toxicities
  - May consider pre-huddle prior to SIV
- Meet with your staff, especially, CRC, data manager
- Go over indication/logistics/planning
- Recruitment Plan
- Remember: Protocol is most important (Written ≠ Intepreted)

Be involved

- Know your patients….
- Eligibility: Dual verification of eligibility. Checklist are helpful, verify backup source
- Follow up, visits, message, calls (all are very important)
- Measurement of primary endpoint, crucial scheduling – CT's, lab results, QOL assessments, Physical exams, etc.
- Documentation – Proof of PI oversight
- Investigator calls, safety calls, monitor visits

Provide oversight

- Enroll, enroll, enroll....
- In a way YOU are the SPONSOR, YOU are the Medical Moniter, YOU are responsible
- AND.....
- THE buck stops at you

If you don’t know……ASK…


asking for
help sucks.
(do it anyways)

Resources

- Your School, Department, Division
- CCTS
  - https://www.uab.edu/ccts/research-commons
- IRB
  - https://www.uab.edu/research/home/investigators
- OSP
  - https://www.uab.edu/research/home/osp-researchers-toolkit

CCTS Resources

- Statistical/Methodological
  - BERD
- Coordinator, Regulatory, Data
  - CRSP
- Training, Budgets, ClinicalTrials.gov
  - CRSP
- CRU,Bionutrition, Biospecimens
  - CCTS
- Recruitment
  - i2b2
- Constructive grant reviews
  - Panels

Mentorship is critical

Mentorship, Mentorship, Mentorship...

Mentors are kinda like shoes...when you find good quality ones you can never have too many


The Benefits of
Being A
Principal
Investigator


PRINCIPAL INVESTIGATOR
IT'S NOT FOR THE WEAK


Best
Principal
Investigator
Ever
and a mug to prove it


Fill in the blanks:
I need _____ so I can
_____


FEED
BACK