NEUROENDOVASCULAR TRIALS

Understanding your Research Role in Stroke and Device Trials

Biography

Christy Anton is a Clinical Research Coordinator at Rush University Medical Center. She received her degree in Biological Sciences from the University of Illinois. Christy spent 5 years at the Northwestern University Lurie Comprehensive Cancer Center as a Research Study Program Coordinator working on ECOG studies prior to focusing on the development of the Brain Tumor Institute Bio-specimen Biorepository. She joined the Rush Neuroendovascular Team in 2012 focusing on device trials. She has since worked on over 20 studies; including the SWIFT PRIME study, recently published in the New England Journal of Medicine

Disclosures:

None

TOPICS FOR DISCUSSION

✓	Clinical Trials: Definitions and The Importance of Clinical Trials
✓	Introduction to the FDA and Medical Device Approval Process
✓	Roles and Responsibilities of the Research Team

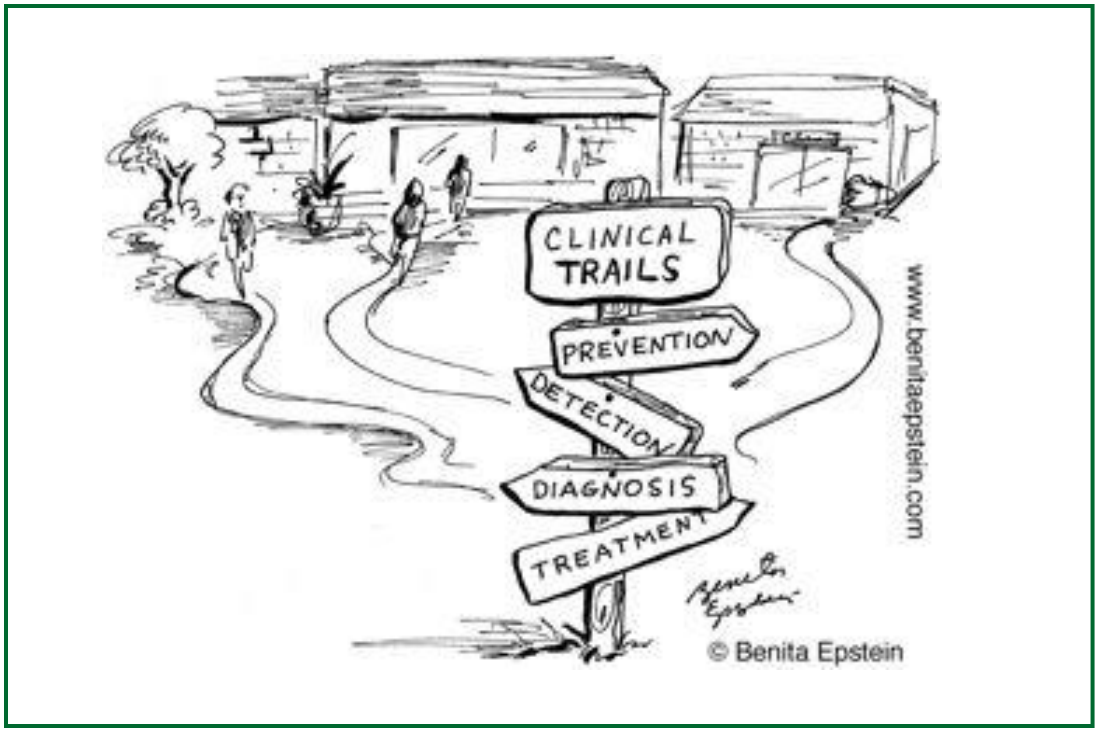
RESEARCH

- The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions

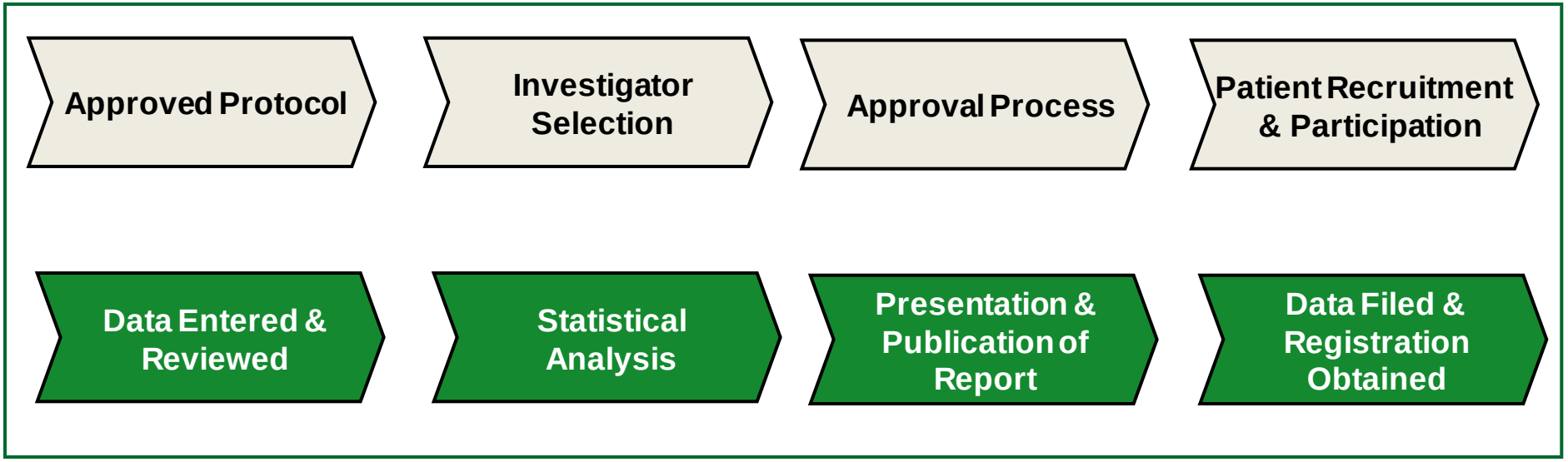
Why offer research trials to our patients?

- Potential treatment options not available at all hospitals
  - Late or Wake-Up Stroke Treatments in DAWN

CLINICAL TRIALS

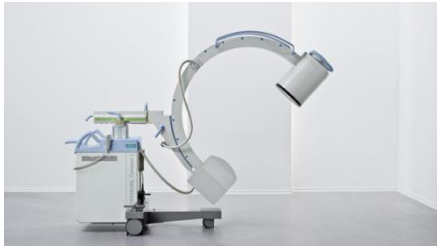


- A company or research institution will select from one of the many available paths for securing FDA approval for their medical device



MEDICAL DEVICES

- The FDA defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized.
  - Simple Devices: Thermometer, Tongue Depressor
  - Complex Devices: Imaging devices, Intracranial Stents

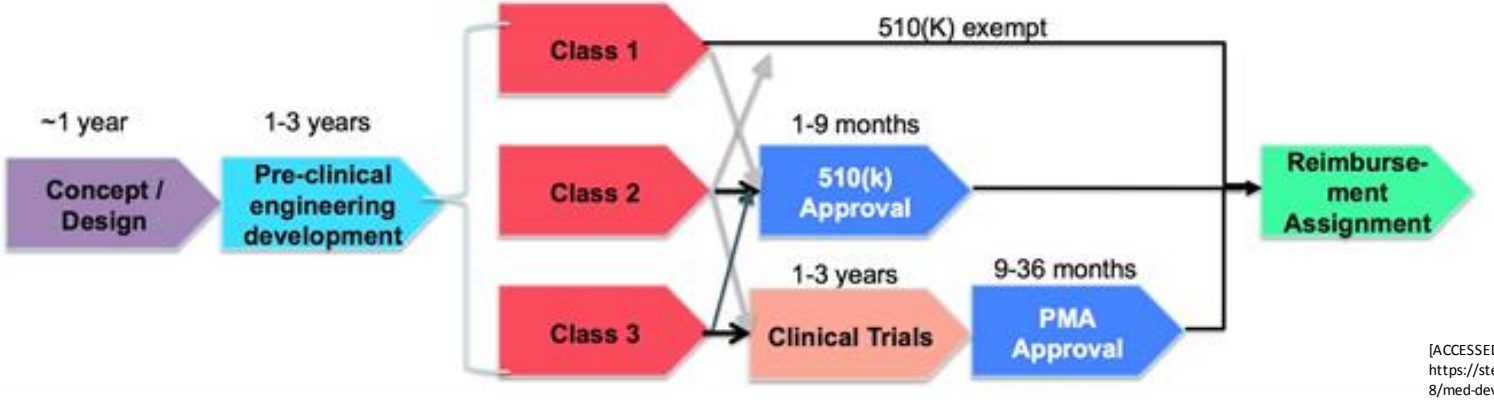

Scanner


FRED


Web DL

PROCESS FOR US FDA DEVICE APPROVAL

- Neuroendovascular devices tend to follow the 510(K) or PMA approval pathway



[ACCESSED 7 JUNE 2015]
https://steveblank.files.wordpress.com/2013/08/med-device-pipeline.jpg

PROCESS FOR US FDA DEVICE APPROVAL

Three major factors dictate time to approval for Medical Devices by the FDA

Number of Sites

- How many sites are participating the trial?
- Is it a global or domestic trial?

Patient Recruitment

- How difficult is it to enroll in this study?
- What is the incidence and prevalence of device use?

Study Design

- How long will it take to determine a Primary Outcome?
- Do you show efficacy or safety concerns sooner than expected?

COLLABORATION & EFFECTIVE RESEARCH TEAMS

The ideal Research Structure is comprised of **7 Active, Engaged** Stakeholders

- ✓ US FDA
- ✓ Trial Sponsor
- ✓ Principal Investigator (PI)
- ✓ Institutional Review Board (IRB)
- ✓ Study Coordinator
- ✓ Data Manager
- ✓ Study Monitor

KEY EXTERNAL STAKEHOLDERS

US FDA

- Domestic Food and Drug Administration
- Oversight and protection for consumers (e.g. emphasis on safety)
- IDE and PMA or 510(devices)
- Post Approval Engagement (Inspections, Recalls, FINS)

TRIAL SPONSOR

- Academic Institutions
- Pharmaceutical and Medical Device Companies (Manufacturers and Commercialization Experts)
- Investigator Initiated Trials
- Government Entities & Institutions (NCI/NIH/CDC)

KEY INTERNAL STAKEHOLDERS

PRINCIPAL INVESTIGATOR (PI)

- Maintains a complete understanding of the Investigator Brochure and protocol
- Conducts study in compliance with protocol
- Responsible for safety of the study subjects
- Delegate work to qualified staff
- Manage the informed consent process
- Report any serious adverse events
- Maintain accurate records for inspection

STUDY COORDINATOR

- Conduct the study from screening to close-out
- Execute and sustain the informed consent process
- Screening and eligibility determination
- Schedule and conduct subject visits
- Responsible For:
  - Study documents, data collection, reporting
  - Education of treating team
  - Report Adverse Events and/or SAE's

COLLABORATION & EFFECTIVE RESEARCH TEAMS

Teamwork is the key to effectively conducting research across a platform

The Principle Investigator (PI) is ultimately responsible for the study conduct

- Education of all participating team members
- Clearly defining roles & responsibilities of team. Providing training where/when needed
- Maintain adaptability
- Removal of institutional and external hurdles to success

COLLABORATION & EFFECTIVE RESEARCH TEAMS

- The Coach (PI) & Quarterback (Study Coordinator) work with the team for a win
  - Education and Training
    - All personnel that will be part of the patient surgery (pre-op, procedure, PACU) understand the treatment the patient is undergoing and why it is investigational
      - ✓ Have team attend Site Initiation Visits (SIV's), review new studies at monthly team meetings
    - Conduct in-services for staff unable to attend initial training

ROLES & RESPONSIBILITIES

PROCEDURE NURSE

- Help capture study required data points prior to and during procedure
  - Non-Standard of Care labs
  - Pregnancy Test
  - New time points for standard labs
    - ACT values, PRU/ARU's
- Communicate patient report to coordinator for subject screening during tele-stroke patients
- Input data into the patient EMR and verify congruency to study data

RADIOLOGY TECHNICIAN

- Obtain study required imaging & accessory devices prior to procedure
  - Know if calibration devices are required
- Review Investigational Devices
  - Become familiar with:
    - Device Storage Location
    - New device sizing
    - New materials
    - Changes to imaging protocols
      - Image submission to sponsor for core lab review

TIPS & TRICKS

PRIOR TO/DURING PROCEDURE

- Email unit directors to alert the team of a study subject and/or send weekly case schedule with anticipated research cases
- Have quick study reference binders in easy access locations
- Create screening flowcharts
  - Quick screening tools for clinic visits or while screening potential subjects during diagnostics angiograms
- Pre-procedure "Time-out"
- Review data collection worksheets with Study Coordinator
  - Ask for your own cheat sheets to record data during procedure

POST PROCEDURE

- Save all device packaging
- Complete Imaging requirements
- Verify the data:
  - Have a post-procedure huddle:
    - What did the team do well?
    - Where are the areas for improvement?
    - When is the subject due back for a follow-up?
    - Review all required data points
      - Treatment lesion size consistency

ACHIEVING DATA INTEGRITY:

✓	Clinical trial results must be verifiable and replicable

Quote: "One of the most common inspection findings […] lack of reliable, accurate and adequate source documentation"

✓	Post-procedure team huddles are valuable tactics towards ensuring the correct data points and values are obtained

Example: You want the aneurysm size measurements written on the coordinator worksheet to match the data that goes into the EMR

ACHIEVING DATA INTEGRITY: ALCOA

ATTRIBUTABLE	It should be clear who has documented the data.
LEGIBLE	Readable and signatures identifiable.
CONTEMPORANEOUS	The info should be documented in the correct timeframe along with the event flow. If not documented immediately, a chronology should be.
ORIGINAL	Original, if not – should be an exact copy. The first record made by the appropriate person. The investigator should have the original source doc.
ACCURATE	Accurate, consistent and real representation of facts

HIGH-QUALITY COLLABORATION

EFFECTIVE TEAM

Everyone in the procedure room **has a role** during a research case and everyone's data and actions will be examined by the FDA

COMMUNICATION

Effective communication is the key to the research team success

Determine which obstacles need to be overcome and the process for doing so: Driven by experience, collaboration and timeline feedback

QUESTION & ANSWER

THANK YOU