Conducting Clinical Trials in the Ophthalmic Setting

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Financial Disclosures

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Introduction

To present an overview on:

1) How to incorporate clinical trials into an ophthalmic practice
2) The benefits of clinical trials in an ophthalmic practice
3) Logistics in conducting clinical trial in an ophthalmic practice
Why Would I Want To Do Clinical Trials In My Practice?
Clinical trials are occurring all over the world*

- 42% U.S.
- 28% Europe
- 10% East Asia

*Pre COVID-19 distribution
How Might This Benefit Me and My Practice???
Benefits

- New Source of income and a controlled source of income
  - Income from an outside corporate sponsor or CRO
  - More control of patient reimbursement – potentially higher monetary return per patient
  - More control of profit margin
  - More control of chair time utilization
Benefits

- Practice builder
- Gives your practice an extra competitive edge
- Might bring new technology into your practice
- Another way to contribute to our field
- Can take you out of the “rut” of your normal everyday routine
So How Do I Get Started?
What kind of trial do you want to perform?
* Comparative trial
* Marketing trial
* New product/technique/treatment trial
Your To-Do List

- How big of a study do you want to conduct?
  * How many patients will you need to enroll and complete to demonstrate clinically significant results?
  * Does your practice have the patient base to accomplish your goal?
  * Do you currently have an easy database to recruit subjects from?
Your To-Do List

- Do you have proper:
  - Space – waiting area, private areas, exam lanes
  - Staffing – reception, technicians, scribes
  - Time
  - Equipment
  - Funding
Will you be the investigator? Will there be any co/sub investigator?

* Principal Investigator (PI) – Individual responsible for overall preparation, administration and conduct of trial. The holder of the grant if applicable. Has ultimate responsibility of conduct on the trial.

* Co/Sub – Investigator (Co-I or Sub-I) – Key personnel who have responsibilities similar to that of the PI but whose actions are still accountable by the PI.
Your To-Do List

- Any obstacles?
  - Location
  - Cultural diversity of population
  - Sociodiversity
  - Environmental
  - Governmental Limitations
So Who Is Paying For This?
Support/Sponsor

- Company/Corporate Sponsor
- Self Sponsor/Self Funded
- Grant (Private or Government funded)
- Contract Research Organization (CRO)
  - Organization the provides support to pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. I.e ORA Inc.
- Site Management Organization (SMO)
  - Organization that provides clinical trial related services to a CRO, pharmaceutical company, a biotechnology company, a medical device company, or a clinical site.
So What Else Do I Need To Do to Get Started?

You Need a Protocol to Follow!
Design the study

- What are your goals, purposes and hypothesis for this trial?
  - What references are available to show relevance for the trial

- Develop a protocol that will prove or disprove your theory
  - What phase of the clinical trial
  - Masked or Unmask trial
  - Crossover or Non-Crossover trial
  - Randomized or Non-Randomized trial
Clinical Trial Phases

- Phase I – testing a new drug or treatment in a small group of subjects for the first time to evaluate its safety, determine a safe dosage range and identify side effects.
- Phase II – drug or treatment is given to large group of subjects to see if it is effective and to further evaluate its safety.
Clinical Trial Phases

- **Phase III** – drug or treatment is given to large groups of subjects to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

- **Phase IV** – conducted after a drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.
Clinical Trial Designs

- Masked Vs. Unmasked
- Crossover Vs. Non-Crossover
- Randomized Vs. Non-randomized
Before a trial can be conducted, it must be approved by an ethics board or committee:

- Institutional Review Board (IRB)
- Independent Ethics Committee (IEC)
- Research Ethics Board (REB)
Ethics for Conducting Trials

- Responsibilities of ethics board is to protect the right, safety and well being of human subjects involved in a clinical trial.

- They review the protocols and procedures to assess the ethics of the research and it’s methods to ensure no significant safety risks to the patient, often conducting some form of risk-benefit analysis.

- Also reviews that the informed consents and consenting process promote fully informed and voluntary participation without unnecessary coercion.
Regulatory Bodies

- U.S.A. – Food and Drug Administration
- U.K. – Medicine and Healthcare Products Regulatory Agency
- China – China Food and Drug Administration
- Brazil – National Health Surveillance Agency
- European Union – European Medicine Agency
  * Global authority for EU countries
    - Each individual country has a regulatory agency that reports to them.

Who makes the decision whether a treatment/therapy can be utilized in your country
Approval

Once all administrative details are completed and the trials is approved by all parties involved, you can finally start working with subjects!
Can I See The Patients Now?

ALMOST THERE!
Recruitment

- From patient database
- From other local practices and practitioners
- Patient referrals
- Media advertising
Conducting Your Trial

- How will you schedule the patients: Rolling or Block Enrollment
- Do you or trial team members need to learn any new procedures?
  * Testing
  * Drug dispensing and/or collection
  * Specimen collection and preservation
- What type of documentation is required?
- Consider what potential problems you might run into and develop a strategy around it?
- Who will be delegated what tasks?
Office and Staff Preparation

- The key to conducting a successful trial is to have an efficient clinical trial team with a smooth trial flow
  - Possess all necessary equipment and supplies
  - Determine proper patient flow for maximum efficiency
  - Make sure all staff members who will be involved are properly trained in necessary testing and knowledgeable about the protocol
Roles of Principal Investigator

- The investigator is the one who is actually conducting the trial. He/She is the leader of the entire trial "team".

- Reports directly to:
  - Sponsor
  - Subjects
  - Regulatory and ethics boards
  - Research facility
Role of Principal Investigator

- Ensuring the trial is conducted ethically and follows Good Clinical Practice (US, EU, and Japan unified standards)
- Ensuring the trial is properly conducted according to the standards set forth by the protocol, sponsor, regulatory boards, etc.
- Protecting the rights, safety, and welfare of the subjects under the investigator's care
- Control of any drugs or devices under investigation
- Ensuring proper informed consent is obtained from each subject
Role of Principal Investigator

- Ensure that ethical committee review, approval, and reporting requirements are met
- Ensure proper and accurate record keeping as well as proper record retention
- Assess and report all adverse and serious adverse events to sponsor, ethics committee and regulatory board
- Follow up on issues that may need monitoring after completion
Conducting Your Trial

Now You Can Finally Start!!!!
Conducting Your Trials

How to be successful?

FOLLOW THE PROTOCOL!!!!!!

Properly screen/recruit your potential study subjects

Treat this like your normal practice.

  Stressed patients = unhappy patients

Unhappy patients may not want to return to complete the study or participate in future studies.
Potential Issues

- Patient does not complete all required study visits
- Adverse Events and Serious Adverse Events
- Time Restrictions
- Unforeseen Issues
I Finally Gathered All The Results, Now What?
You have all this data, what do you do with it?

* Submit collected data to sponsor
* Analyze the data
* Present data
  - Poster presentation
  - Paper presentation
  - Article in Journal
  - Marketing campaign for sponsoring company
After The Trial

- Continue building your database for future trials
- Continue to develop or “bid” for other trials for the future
Clinical trials may not be suitable for every practitioner or every practice setting, but for those that are:

* Increased revenue to practice
* Practice builder
* Gives you an edge over your competition
* Potential for you to try and offer new technology, advancements, techniques or devices before your competition
* Way to contribute to your industry and field
* Can take you out of the "rut" of your normal everyday routine
In my opinion, the most difficult part of the whole process is the initial step of setting up the trials – cost and time investment at the beginning may be a little more involved, but it will pay dividends several times over in the long run if you continue to stick with it.

*The More You Do The Easier It Gets Each Time*

Generally the steps you will be performing in the protocol during the study are the same procedures you do in everyday patient care, so you may not need to “learn” something new.

Bringing clinical trials to your practice not only benefits you, it also benefits your patients, your colleagues and our industry.
Thank You

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