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Incorporating Clinical Trials Into Your Daily Practice

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I. Introduction/Purpose

A. Jason Chin O.D., F.A.A.O.

1. Credentials 2. Disclosures 3. Experience 4. Goal of talk – To present to you a brief overview on how to incorporate clinical trials into your practice. Contact lens trials will be referenced for example purposes but this guideline can be use for any type of clinical trial.

II. Before you start

A. Evaluation/Considerations: What questions should you ask yourself before attempting to conduct a clinical trial.

1. What kind of trial(s) do you want to do? / What do you want to test?

a) Comparative Trial
b) Marketing Trial
c) New Product Trial

2. Size of study? – How many patients will you need to enroll and complete to demonstrate clinically significant results

3. Do you currently have a sufficient patient database to accomplish your goal or will you need to recruit patients from outside of your practice?

a) Modality of a lens type. i.e. Daily disposable lens wearers, extended lens wearers
b) Specific condition for a lens type. i.e Keratoconus
c) Prescription range. i.e Presbyopes, astigmats
d) Non contact lens wearers. i.e. For comparison of new wearers

3. Do you have the proper space and staffing?

a) Does your practice have enough lanes to allow an efficient flow for the trial?
b) Does your practice have enough waiting area space for an increased volume of patients?
c) Does your schedule have room to incorporate the extra patients you will need to see?
d) Do you have sufficient staffing/techs to handle the increased volume of patients?

4. Do you have the proper time to commit? Will the extra effort be worth it?

a) If not incorporated into your daily routine, do you have other time available? i.e. Weekends
b) Will you be compensated enough to "give up" this extra time?

5. Do you have the proper technology/equipment needed?

Most trials can be conducted with standard equipment. Are you trying to prove something that might require equipment not typically used in standard care.

a) Corneal topographer
b) Anterior Segment OCT
c) Integratable EMR system to capture data
d) Wavefront Aberrometer

Notes:

6. Will you have the proper funding to conduct the trial?
a) Additional expense for staff
b) Additional expense for overhead
c) Additional cost for materials or new equipment if needed
d) Compensation to subjects
e) Compensation for your time

7. Will you be the only Primary Investigator or will you have Sub-Investigators
a) Do you have other OD associates to divide the investigative work load with

8. Any outside hurdles?
a) Location – Does your practice location make it difficult to recruit new patients outside your community?
b) Cultural Diversity of patient population – Are there any cultural barriers in your community that would discourage the conducting of clinical trials?
Are there any cultural barriers in your community that would make recruiting subjects difficult
c) Population/Socio-diversity
More affluent communities may make recruiting more difficult as population
may not be as dependent on additional income.
Lower income communities may have a population more likely to be in favor of participating for additional income.
d) Environmental
- Dryer climates
- Area more prone to allergies
- Both situations may add variables that may "skew" data

B. Find a sponsor/support

1. Corporate Sponsor - i.e. Major contact lens company
2. Self Sponsor/Self funded
3. Contract Research Organization

"A contract research organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis."

a) ORA, Inc.

4. Site Management Organization "A Site Management Organization (SMO) is an organization that provides clinical trial related services to a contract research organization (CRO), a pharmaceutical company, a biotechnology company, a medical device company or a clinical site."

C. Develop/design your protocol

1. Goal/Purpose/Hypothesis of study
2. Which Phase of the Clinical Trial

a) Phase I – "testing a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects."
b) Phase II – "drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety."
c) Phase III – " drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to

Notes:

commonly used treatments, and collect information that will allow the drug or treatment to be used safely."
d) Phase IV – "conducted after the 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."

3. Masked Vs. Unmasked Trial

4. Crossover Vs. Non-Crossover Trial
5. Randomized Vs. Non-randomized
6. Gather References

D. Submit for regulatory approval

- All protocols need to be approved to ensure the trial meets appropriate conduct and guidelines.
- All potentially publishable trials need to be IRB approved.

1. Institutional Review Board (IRB)

"A committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be done"

- May also be known as:

a) Independent Ethics Committee (IEC),
b) Ethical Review Board (ERB)
c) Research Ethics Board (REB)

- May be independent or directly associated to a university or hospital

2. Local approval – May be required in some communities
3. Sponsor approval – Internal IRB and other departments (i.e. legal)

E. Recruitment

1. Practice Database
2. Advertising
3. Referrals
4. Other practices

F. Office and Staff Preparation

1. Obtain necessary equipment and supplies
2. Determine proper patient flow for efficiency
3. Train staff on upcoming trial. Make sure they know their roles.

III. During the trial

A. Scheduling Patients

1. Rolling Enrollment
2. Block Enrollment
3. Advantages and Disadvantages

B. Conducting the study

1. Procedures – In general, not different than daily clinical procedures
2. Delegation of Tasks

Notes:

3. Documentation

a) Patient file

b) Separate source document

c) Case Report Form (Electronic or transcribed)

C. Ensure proper staffing for smooth and efficient conduction of study

Ensure proper patient flow for smooth and efficient conduction of study

1. Stressed subjects = unhappy subjects
2. Unhappy subjects may not want to be subject again in future

D. Potential Problems

1. Patient does not complete all required visits
2. Adverse Events/Serious Adverse Events
3. Time restrictions

IV. After the trial

A. Submit collected data to sponsor (if required)

B. Analyze Data

1. Internally
2. Professional statistician or similar outside entity

C. Present Data

1. Poster presentation at large meeting
2. Paper presentation at large meeting
3. Article in peer reviewed journal
4. Marketing campaign for sponsoring company

D. Continue to build your database for future trials by continuing to actively recruit

E. Continue to brainstorm other possible trials.

Notes: