PHARMACIST'S ROLE IN ENHANCING PATIENT PARTICIPATION IN CLINICAL TRIAL RESEARCH

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Objective: To help the pharmacist regardless of practice setting to become familiar with clinical research, locate enrolling clinical trials, and gain the ability to discuss with patients, caregivers, and other healthcare providers, the advantages and disadvantages of participating in clinical research.

Sources:
Articles in the English language were retrieved through a Pubmed search (1966-January 2006) using MESH terms, Pharmacist-physician communication; pharmacist-patient communication; clinical research studies; clinical trial; patients; accrual; barriers; patient participation; experimental treatment; treatment; enrollment; predictors. Additional information was obtained from the websites for ClinicalTrials.gov, ICMJE.org, IFPMA.org, and CBI Registry and Results Databases Conference.

Study Selection: All articles were evaluated, and all information deemed relevant was included.

Conclusion: Looking for opportunities to improve patient care through referral to a clinical trial requires an understanding of the drug development process and the resources available to locate appropriate clinical trials for their patient population. It is essential for the pharmacist interested in collaborative efforts with the patients, caregivers, and physicians to incorporate this value-added service to their armamentarium of patient care services.

Keywords**:** Pharmacist-physician communication; pharmacist-patient communication; clinical research studies; clinical trial; barriers; patient participation; enrollment

INTRODUCTION

Growing coverage by the media of the recent withdrawals from the market of high-profile drugs have negatively impacted the public's view of clinical trials. For example, the Paxil case brought to the public's attention by Senator Elliott Spitzer of New York for the failure of the drug company to fully disclose the results of their pediatric Paxil studies[1], and more recently confirming their fears in trial participation, the headline news of clinical trials gone wrong in patients in the UK participating in a Phase 1 trial.[2] Movies, television programs, and novels often portray clinical trial research as clandestine.[3-6] The call by the medical community and the public for the pharmaceutical industry to be more transparent and accountable for clinical trial research[7], the International Committee of Medical Journal Editors (ICMJE) demand for more clinical trial disclosure at the onset of the trial[8], pending legislation related to clinical trials research both at the national and state levels[9,10], and the World Health Organization's position on clinical trial registration[11] have all played a major role in stimulating an increased interest in clinical trial research albeit much of the media coverage is negative. Unfortunately the public and prospective volunteers obtain most of their "education" about clinical trial research through the media outlets.

Pharmacists traditionally have been involved in clinical trial research in a variety of ways, from providing drug and record keeping for drug accountability to taking on the roles from study coordinator to principal investigator.[12] Today, pharmacists are on the forefront of patient care and do make a significant impact on the health status of patients' directly through pharmaceutical care and indirectly by connecting patients to pharmaceutical treatments through the practice of Evidence Based Medicine with existing treatments or with participation in clinical trials. As medication experts, pharmacists are educated to develop the skills to solve medication related problems and improve patient outcomes with their interventions. While not limited to clinical trial research, the basis of evidence based guidelines are derived from clinical expertise and valid clinical research.[13] Evidenced based practice guidelines often recommend enrollment in a clinical trial when other standard therapies fail and a treatment or cure is not possible.[13] An understanding of clinical trials and resources to learn about on-going clinical trial research is essential for the pharmacist interested in collaborative efforts with the patients, caregivers, and physicians to incorporate this value-added service to their armamentarium of patient care services.

The purpose of this paper is to help the pharmacist become familiar with clinical research, locate enrolling clinical trials, and gain the ability to discuss with patients, caregivers, and other healthcare providers, the advantages and disadvantages of participating in clinical research.

BACKGROUND OF CLINICAL TRIAL REGISTRIES

Clinical trial registries are not a recent phenomenon. In 1988, the Health Omnibus Programs Extension (HOPE) Act, Section 2317 was passed by Congress. This Act directed the Department of Health and Human Services (DHHS) to help develop methods to distribute information on HIV research, treatment and prevention.[14]

Approximately ten years later, Congress responded to the advocates for cancer and AIDS patients looking for the best treatment options for their diseases by adding a provision to the FDA Modernization Act (FDAMA 113) that mandated the National Institutes of Health (NIH) establish a publicly accessible database of clinical trials for trials involving the treatment of serious or life-threatening diseases or conditions.[15] This Act specified which trials and what essential information must be available to the public by researchers. (See Table 1). The NIH developed this database known as clinicaltrials.gov through its National Library of Medicine (NLM).[15] This database became publicly accessible in February 2002 and is available at www.clinicaltrials.gov. Today, there are greater than 20,000 hits per day on the clinicaltrials.gov website.[16] In July 2001, the FDA released their Guidance for Industry which further defined the requirements for the pharmaceutical industry's participation in clinical trial registration. (See Table 1).[15] The original intent of the clinicaltrials.gov database was to enable patients expanded access to clinical trials.

Showing appreciation for the altruistic motives of individuals who volunteer to participate in clinical trials with the intent to contribute the advancement of medical knowledge, and the need to meet the ethical obligations of research by reporting results honestly as well as lessen publication bias[17], the International Committee of Medical Journal Editors declared they would not consider a manuscript for publication unless the trial had previously been fully registered to a publicly available trial registry prior to the onset of enrollment.[8] These guidelines are more stringent than the guidelines specified in FDAMA 113; furthermore, these guidelines specify what features the database itself must possess. Since the ICMJE requirements became effective July 1, 2005[8], there is much debate in the research community regarding when and how much sensitive information (i.e., full study title, primary and secondary endpoints, targeted number of subjects, and study dates) about a clinical trial should be disclosed while it is ongoing.[11] Therefore, some researchers register more information than others.[8] (Table 2)

There are approximately 17,000 enrolling clinical trials registered to clinicaltrials.gov, approximately 5,000 are NIH and other federal agencies trials, 4,000 industry sponsored trials, and 8,000 university/organization clinical trials.[16] While clinical trial information and other healthcare information is readily available to the computer savvy and health literate potential patient or caregiver, it may be overwhelming for some (e.g. health illiterate) and inaccessible for others (eg. elderly, low socioeconomic, those with no computer access) that are most in need of therapies available in clinical trials. Therefore, increased access to clinical trial information provides important benefits to patients as well as to the medical community in that it can help to make possible medical and clinical decisions about potential drug therapies.

With the proliferation in usage of the internet as a health resource, multitudes of clinical trial databases for both ongoing trials and results of research have evolved leading to some confusion by the healthcare consumer. Some are public databases, some commercial (hospitals, clinical research organizations, pharmaceutical companies), and others are managed by disease-state organizations, and self-help groups. At the present time, the Gold Standard of trial databases is the ClinicalTrials.gov database.[8] It is the only database that meets the requirements of the ICMJE and the World Health

Organization (WHO); however, the International Standard Randomized Controlled Trial Number (ISRCTN) database is currently under development and is purported to meet the ICMJEs guidelines[18] The International Federation of Pharmaceutical Manufacturers (IFPMA) has developed a portal for searching for clinical trial information This allows for a comprehensive search for a clinical trial from other clinical trial databases around the world. The World Health Organization (WHO) has disclosed similar plans for a portal that will search all member registries or primary registries and as well as portals or associated registries and upload the trial information to the Registry Platform. The WHO platform will establish standards and content of clinical trial registration, assign a Unique Clinical Trial Registration Number(UCTRN) in hopes of preventing duplicate trial registrations, and work with stakeholders to balance the protection of sensitive information while restoring the public trust in medical research. A test version of the portal is expected to be operational by the third quarter of 2006.[19]

Altruism is cited by many to be the major motivating factor for participating in clinical research;[20] however, there are many nonaltruistic motives that are also cited. These motives include the feeling of being a "special patient" while in the trial, the pursuit for improved health, access to new therapy before it is widely available or received FDA approval, obtaining state of the art medical care at a leading healthcare facility, and playing an active role in one's own healthcare.[21] Other reasons cited include searching for easier alternatives to current therapies, treatment success, and media campaigns, direct-to-consumer (DTC) advertising, newspaper, radio and television advertisements that have attracted their attention.[22]

Participation in a clinical trial does not guarantee a positive outcome to the participant; however, research suggests that cancer patients involved in clinical trials may experience better outcomes than those cancer patients who do not participate.[23] Typically, the patient and/or the caregiver or a family member of the participant reports a positive opinion of clinical trial participation. Patients feel they have received better care and information about their treatments and condition than they would had they not been in a clinical trial.[24] This is perhaps due to the phenomenon of feeling closer relationship to the treating physician or researcher and the personal need for access to the best treatments/diagnostics.[24,25] Clinical trial participants overwhelming report positive experiences in the quality of care they received. The CenterWatch 2004 Participant Survey reports the 91% would volunteer for another study while 84% would feel safe in recommending participation in a clinical trial to family and friends.[25]

Patients considering participation in clinical research should fully consider the risks involved with participation and discuss this with their pharmacist or healthcare provider. The possibility of unpleasant, serious or even life-threatening side effects to treatments, ineffective treatments, protocols requiring more time and attention than would a non-protocol treatment, long distant travel to the study site, increased treatments, laboratory tests and x-rays, hospital stays, or complex dosage requirements are all important aspects of clinical research that the patient should consider.[26] Each clinical trial will have its own unique protocol with its own set of risks; therefore, the questions in Table 2 should be used as a guide in the decision to participate in a specific trial.

Research trials can be conducted in many different practice settings such as a hospital (operating room, radiology, and cardiac unit), ambulatory care clinic, physician office, and private research centers. Some are sponsored by the pharmaceutical industry, some National Institutes of Health, private researchers, and universities and medical centers.[26]

Costs related to clinical trials (i.e. tests, procedure, drugs, extra doctor visits) are usually covered by the sponsor of the trial; although, some health plans may consider clinical trials as investigational treatments and will not cover the costs of routine healthcare while the insured is participating in a clinical trial. Because of this many states have or are passing legislation that require insurance companies to provide insurance coverage while participating in clinical trial research.[10,27]

Clinical research in humans is conducted in phases. Phase 1 trials are the first studies to involve human subjects. The researchers are looking to evaluate safe doses, routes of administration, side effects, and pharmacokinetics. These are generally very small studies using healthy volunteers or patients who do not have other good treatment options. Phase 2 trials study the safety and efficacy of a drug or intervention and evaluate how it affects the body in patients with the targeted disease. Phase 2 trials are generally larger than Phase 1 trials but may have less than 100 patients. After the drug or intervention shows promise in earlier trials, Phase 3 trials are conducted. These are very large studies whose patient population may be national or international depending on the trial. Phase 3 trials generally compare the new drug/intervention with the current standard of therapy in patients with the targeted disease. Patients are usually randomized to receive the either the study treatment or the standard of care. In double-blind randomized trials neither the investigator nor the patient knows if they are receiving the drug/intervention or the standard of care. Randomization helps to avoid bias and ensure that humans do not affect the study results. Open-label safety studies are late Phase 3 or Phase 4 studies. In these studies patients will all receive the trial drug/intervention and the both the patient and the investigator are aware of the treatment. These are often referred to as long-term safety studies. Phase 4 studies usually take place after the treatment has been approved for use. These can be large long-term safety studies or small investigator initiated studies to look for a new use for the drug.[26-30] Figure 1. summarizes the various phases of a drug development.

Clinical research is regulated by the FDA, Institutional Review Boards (IRBs), and ethics committees; therefore, human clinical research has built-in safeguards to ensure trials are ethical and human subjects are protected. Trials follow a carefully controlled study plan or protocol which has been approved by the FDA detailing exactly what researchers will do during the study. As the trial progresses the data is analyzed and reported to various government agencies and sponsors without revealing any specific patient identifiers (e.g. name, social security number).[26-30]

Clinical trial misconduct in the past may raise concern for potential participants. Unethical clinical trial practices, most notably the Tuskegee experiments, in the US during the 1940's have prompted the federal government to require informed consent documents to protect the participant from misconduct.[31,32] Informed consent is a process of learning the key facts about a clinical trial before making the decision to participate. The informed consent documents are written in patient terms and include information

about reasonably foreseeable harms, discomforts, inconveniences and risks associated with trial participation, the benefits the patient may expect to encounter, alternatives to participating in the trial, the Health Insurance Portability and Accountability Act (HIPAA) considerations, compensation, a contact person, rights of the participant (e.g., right to withdraw at anytime), and additional IRB, institutional policy and local laws. [31-34]

Potential trial participants often cite the risk or fear of receiving a placebo as a barrier to participation in a randomized clinical trial. Randomization means that neither the physician nor the patient can choose which treatment the patient will receive; therefore, reducing study basis.[35] The pharmacist can reinforce to the potential participant that although this may be the only way that he/she may have a chance of getting the new treatment, the trial is being conducted because the researcher does not know which treatment is the best.

Blinding both the physician and the patient to the treatment may be another area of concern for the patient.[36] The patient should be assured that if medically necessary (e.g. allergic reaction) it is possible to be removed from the study and the physician can learn which treatment the patient had received.[29] There are many additional barriers that potential participants site as reasons for fear of participation in clinical trials. (Table 3)

Pharmacist's Interventions

Clinical trials are generally well designed controlled research studies in which patients may volunteer to participate and have the opportunity to contribute to science while receiving state-of – the art care from the experts in their fields. Understanding the jargon of clinical research is essential when communicating effectively with patients, caregivers, and physicians at their level of understanding. There are several different types of clinical trials (e.g. prevention, screening, diagnostic treatment, supportive care, and genetic), and each type is conducted in Phases. Informed consent, eligibility criteria, study design, randomization, and placebo/ active controlled trials are other terms to become familiar with for effective communication.

Very few patients are aware that they are eligible to participate in a clinical trial; in fact, of all the participants in clinical trials, 70% report they learned about the clinical trials from a media sources or from the internet while the only 30% first learned about clinical trials from their healthcare provider.[25] As the medication expert on the healthcare team, this opens the opportunity for interventions for the pharmacist to assist potential participants in understanding and finding an appropriate clinical trial for their patient's condition or treating a patient in his/her care that is participating in a clinical trial.

As with the multitudes of career pathways for pharmacists, there are numerous ways that the pharmacist may be called upon to provide information about clinical trials. Discussing clinical trial participation with a patient or caregiver, searching for a specific clinical trial when a patient desires to participate in a trial, following evidence-based guidelines that recommend participation in a clinical trial when no current therapies for the particular medical condition exist, or talking with other healthcare team members about the best treatment for a patient are a few examples of how pharmacists may be called on to provide clinical trial information.[13] The community pharmacy offers an

ideal setting for identifying potential research patients. Patients may be frustrated because their standard therapy is not working, they desire to have a simplified treatment regimen for their condition, they are concerned about their physician's suggestion to participate in a clinical trial, or they may just want to participate in a trial for various reasons but are unsure how to go about getting in to a trial; consequently, the patient may ask the pharmacist about clinical trial participation. The community or retail pharmacist may be limited in his/her discussions with the patient to the basics of trial participation due to limited resource allocations in this setting; however, it is important for pharmacists to possess the knowledge and understanding of the jargon of clinical trials (e.g. trial phase, randomization, consent forms, standard treatment), the ability to dispel any myths of clinical research (i.e. the guinea pig feeling) that the patient may feel, and answer general questions about clinical trials and help patients locate relevant clinical trials. In conversation with Associate Dean for Clinical Research and Public Policy, Virginia Commonwealth University, Gary R. Matzke, PharmD, (April 24, 2006), he suggests in the retail setting offering a "health internet cafe" for the customer; teaching the patient how to find legitimate health information including clinical trials while in the pharmacy.

In addition to the above involvement, the clinical pharmacy specialist in the clinic or institutional practice settings may have more resources available (i.e., internet access to clinicaltrials.gov) and know what trials are available to the patients in his/her specialty area. In this effort the pharmacist has the opportunity to become an expert the trial availability for specific conditions in their practice location. Some institutions have databases that house information about trials colleagues are participating as researchers in and some must rely on a public database to obtain this information.

Comprehensive educational programs intended to introduce the public, prospective volunteers, health professionals, the media, and policy makers to the large amount of clinical research activity being supported and conducted with in the community each year have shown promise in dramatically increasing the rate of prospective volunteer inquires and physician referrals to clinical trials. These initiatives included educational materials to assist prospective volunteers in constructing the questions to ask the research community in order to protect their safety and rights, to inform their ability to understand and evaluate clinical research information, and to assist them in making the important decision to participate in a clinical trial. Pharmacists can take on the role of an educator and become engaged in clinical trial recruitment as mentioned above. Other opportunities may be call center screening, study coordinators and researchers.

Deciding whether a clinical trial is the course of treatment that is right for the individual patient should be carefully considered. (Table 4) While at the center of every patient encounter is the patient's aspirations for the best possible health outcome, the patient should be counseled on their personal feelings and attitudes about participation in clinical trials. If a clinical trial is a good option for a patient and he or she is reluctant to consider a clinical trial, studies have looked at patient attitudes regarding clinical trials and found the participant attitudes to be very positive.[25]

After determining that the clinical trial option might be a good option for the patient, the pharmacist should be able to discuss with both the patient and the physician, the purpose of the trial, results of previous research with this treatment, types of tests that are

involved, how standard treatments compare to the research treatments, what phase the trial is in, how the trial could affect the patients daily life, side effects , length of the study, costs, confidentiality, outpatient/hospitalized, doctor/patient relationship, and the ability to withdraw from study if necessary.[45] Once the patient has decided that he/she would like to participate in a particular clinical trial, the patient will need to go through a screening process to ensure he/she meets the rigorous inclusion and exclusion criteria for the study.[26] The pharmacist can consult with the patient to construct patient-specific questions to ask the research team (Table 5) Depending on the study the patient may or may not need a referral from his/her physician.

Both the patient and the physician should understand that the established patient/physician relationship does not change when a patient chooses to participate in a clinical trial. This can be likened to a physician referring the patient to a specialist. The patient will remain in his/her physician's practice and will receive some form of treatment, evaluation and follow-up from the clinical trial. The physician should expect to receive regular communications regarding the patient's health status as they would from a specialist.[26-28]

Physicians may be reluctant to refer a patient to a clinical trial as he may feel that it reflects on his inability to effectively manage the patient's disease. A survey conducted by CenterWatch, found additional reasons that physicians do not refer patients into clinical trials are due to lack of information on the treatment or the existence of the trial, not enough time to learn about clinical trials, unsure where to refer their patients, and fear of losing their patient to the physician investigator.[25] As a drug expert, the pharmacist should reinforce to the physician that these are experimental treatments that are designed to address the clinical problems that have not been solved with existing therapies and these clinical trials represent promising new treatment options for the particular disease state or condition.

Knowledgeable patients are accessing healthcare information on the Internet at an ever-increasing rate; it is likely they will encounter information about clinical trials. Knowing where to look for relevant clinical trials for a patient, explaining how to find relevant trials, and the ability to discuss these points with both the patient and physician are imperative for the pharmacist that wants to add this service to their practice.

Clinicaltrials.gov is an easily accessible database of on-going clinical trials found on the worldwide web. The database provides information for patients, family members, healthcare professionals on clinical trials for a wide range of diseases and conditions from both the NIH, other Federal Agencies (e.g., Dept of Veteran Affairs), Industry, Universities, and Organizations. Clinicaltrials.gov is likely to be the most comprehensive registry for on-going clinical trials since it is currently the only database that conforms to the ICMJE Guidelines for clinical trial registries. (Table 2) The amount of information about on-going clinical trials may vary from trial to trial and sponsor to sponsor based on the difference in clinicaltrial.gov and ICMJE guidelines for registration, and the level of disclosure of sensitive trial information by the sponsor. Patients are accessing healthcare information on the Internet at an ever-increasing rate; it is likely they will encounter information about clinical trials.

Commercial sites such as Centerwatch.com and clinicaltrials.com also provide information similar to clinicaltrial.gov and some pharmaceutical companies offer their own searchable registries for clinical trials. Often times, the same information is registered to both clinicaltrials.gov and these commercial databases.

Other good resources are the plethora of health organizations for specific disease states (serious and/or rare). These organizations often provide a registry or information of clinical trials for the particular disease stated (e.g. breastcancer.org, diabetes.org, alpha1.org). Hospitals, medical centers, and universities, often offer a registry for internal use of on-going clinical trials in which there are clinical investigators in the hospital.[31,45] The Association of Clinical Research Professionals (ACRP) offers certification, education/training, and networking opportunities for professionals interested in clinical research.

The IFPMA is a searchable portal that contains information on on-going clinical trials from multiple registries from around the world. This was recently opened to the public in September 2005; currently, it is a bulky and slow system (www.ifpma.org/clinicaltrials.htm); however, upgrades in the near future promise to make it more user friendly.[19]

Conclusion

Evaluating patient participation in clinical trial research is best accomplished in close partnership with the patient and their physician. Acting as an advocate for the patient, the pharmacist should make it a priority to learn about the availability of clinical trials pertinent to their patient population in order to assist their patients and physicians to make informed decisions about participation in clinical trials. A thorough understanding and ability to discuss the different types of trials (prevention, treatment, open-label, and randomization), provide information to their patients about clinical trials, and be able to provide a well-balanced discussion of the advantages and disadvantages of trial participation with both the physician and the patient is imperative to pharmacist's success in this endeavor.

Table 1. FDAMA 113 and FDA Guidance for Industry Registration Requirements[16]

Disease State	Serious or life threatening disease or conditions
Study Design	Studies designed to test effectiveness
Time Frame	Within 21 days after trial is open for enrollment
Information to be disclosed	Study title and purpose in lay terms, recruiting status, eligibility criteria, study locations, and contacts
Foreign trials	Conducted under US IND, required. Not under US IND, not required.
Responsibility for posting	Trial sponsor is responsible to submit this information to the database

Table 2. Comparison Chart FDA/ICMJE Requirements [8,16]

ClinicalTrials.gov Data Element	Requirements		
	ClinicalTrials.gov		WHO/ ICMJE*
	FDMA 113 Trials (IND)	All Other Trials (Non-IND)	
Descriptive Information			
Brief Title (lay language)	Required	Required	Required
Official Title			Required
Brief Summary (lay language)	Required	Required	
Detail Description			Required
Study Phase	Required	Required	
Study Type (Interventional/Observational)	Required	Required	Required
Study Design	At least 1 Required	Allocation, Masking, Assignment Required	Required
Primary Outcome Measure(s)			Required
Secondary Outcome Measure(s)			Required
Condition(s)	Required	Required	Required
Intervention: Type/Name	Required	Required	Required
MEDLINE PMID: Citation/Results Reference			
Link: URL/Description			
Recruitment Information			
Overall Recruitment Status	Required	Required	Required
Start Date			Required
Completion Date			
Other Dates			
Eligibility Criteria	Required	Required	Required
Gender	Required	Required	
Age: Minimum/Maximum	Required	Required	

Accepts Healthy Volunteers?			
Target Number of Subjects			Required
Location and Contact Information			
Facility Location	Required	Required	
Facility Recruitment Status	Required	Required	
Contact Information (Central or per Facility)	Required	Required	Required[#]
Facility Investigators			
Overall Study Official(s)		Required	Required[#]
Administrative Data			
Unique Identifier (NCT number) – assigned by system	Automatic	Automatic	Required
Organization's Protocol ID Number	Required	Required	Required
Secondary Protocol ID Number(s)			Required
FDA IND/IDE Protocol? (yes/no)	Required	Required	
Detailed IND/IDE Information	Required	Required only if "Yes"	
Human Subjects Review Approval? (yes/no)	Required	Required	Required
Additional human subjects review information		Required	
Study Sponsor(s)	Required	Required	Required
Collaborators			Required
Record Verification Date	Required	Required	
First Received Data – assigned by system	Automatic	Automatic	Required

Italicized data elements are not displayed at the public site * Registry required for publication eligibility

Table 3. Barriers to Participation in Clinical Trials[23-25, 35-44]

Distrust in physicians
Aversion to randomization
Distrust in medical therapies
Perceived ethical misconduct in clinical studies
Insufficient knowledge of availability of on-going trials (eg. lack of access to internet)
Physician support for clinical trials absent
Low expectations in the benefits from new therapy
Uncertainty of personal benefit
Poor comprehension about the trial
Guinea pig feeling
Education level (higher than high school positively influence participation)
Race or ethnic background
Randomization
Blinding
Seriousness of disease state
Safety

Table 4. Questions to Ask About Clinical Trials (adapted from cancer.org)[27]

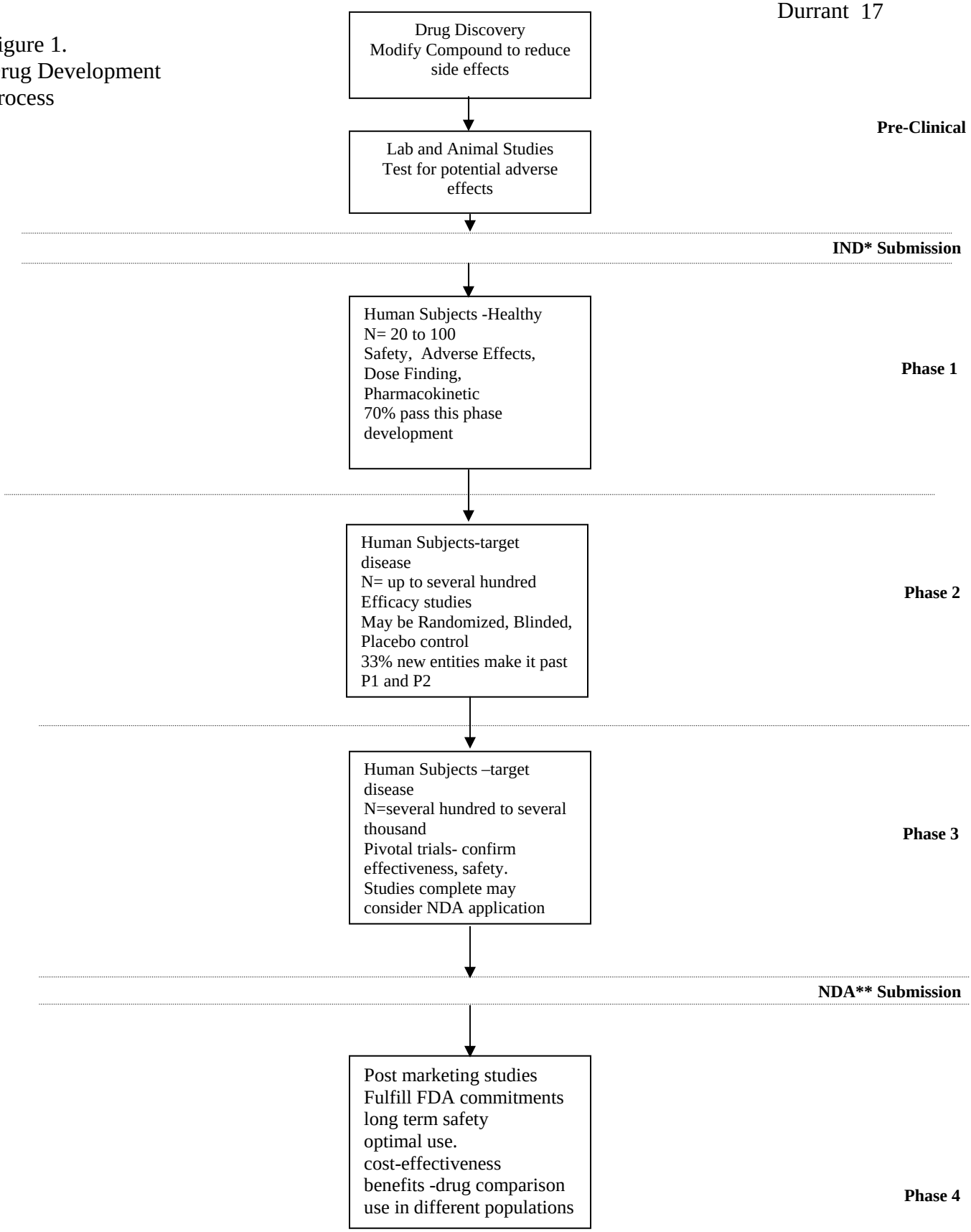
Why is the study being done?
What happens if I change my mind after I enroll in the study?
What treatment options do I have for my condition?
What are the advantages of participating in this trial?
What are the disadvantages of trial participation?
What are the results of earlier studies on this treatment?
What kinds and how often will tests be performed?
Who will pay for these tests and treatments
Who will my doctor be?
Will there be travel involved?
Who pays for travel expenses?
Will participation affect my daily life?
What side effects might I expect?
Will this require hospitalization?
How long will the study last?
What type of long-term follow-up will there be?
Can treatment continue past the end of the study?
Any other participants that I can speak to?
If harmed by the research, what treatment am I entitled to?

Table 5. Patient Work Sheet

1. Sign consent form- study start date
2. Research coordinator- tests, activities, appointments contact information
3. Contact information- signs and symptoms to be aware of.

Adapted from www.cancer.org

Figure 1.
Drug Development Process



IND* = Investigative New Drug Application
NDA**= New Drug Application

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