



# **CLINICAL RESEARCH**

## **THE GATEWAY TO SAFE AND EFFECTIVE MEDICINES**

# WHAT IS A CLINICAL STUDY?

Test safety & effectiveness...  
of a medicine...  
with volunteers...  
with careful design, control and supervision

# WHY ARE CLINICAL STUDIES CONDUCTED?

- Test safety & effectiveness of
  - New uses for marketed medicines
  - New medicines
- Required for
  - FDA marketing approval
  - Acceptance by physicians
- All medicines, medical devices, diagnostic tests, and equipment

# ARE THERE DIFFERENT TYPES OF CLINICAL STUDIES?

- Phase I
  - Safety
  - 10-100 volunteers
- Phase II
  - Safety & Effectiveness
  - 100-500 volunteers
- Phase III
  - Effectiveness & Safety
  - 500-10,000 volunteers
- Phase IV (post-approval)
  - New application or safety watch
  - 1,000+ volunteers

# WHO CONDUCTS CLINICAL STUDIES?

- Physicians (“Investigators”)
- Study coordinators
- Study nurses
- Study pharmacists

# WHO CAN BE IN A CLINICAL STUDY?

- People with medical conditions
- Healthy people
- Study requirements
  - Age
  - Gender
  - Other medical conditions
  - Other medications

# WHY DO PEOPLE VOLUNTEER FOR CLINICAL STUDIES?

- Treatment for illness
- Drugs, exams, advice and lab tests at no charge
- Learn about medical condition
- Help discover new medicines
- Help their community
  
- Understand the benefits for you!

# WHAT ARE THE RISKS?

- All marketed drugs have risks
  - Minor discomfort
  - Serious injury
  - Death
- Experimental drugs have risks too
- Close monitoring of your health
- Consider the risk of no new drugs
  
- Understand the risks!

## HOW DO I OBTAIN THE INFORMATION I NEED TO MAKE A DECISION?

- Informed consent
- Ask questions
- Primary care physician
- Friends & relatives
- Internet
  
- Do your research!

# WHO LOOKS OUT FOR MY INTERESTS?

- Investigator
- Drug company
- Ethics committee (IRB)
- FDA
- Primary care physician
- You!

# WHERE DO I FIND CLINICAL STUDIES?

- Your doctor
- Newspapers, radio & TV
- Internet
  - [www.centerwatch.com](http://www.centerwatch.com)
  - [www.cancer.org](http://www.cancer.org)
  - [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
  - and many more



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