

Research Today For Better Care Tomorrow

# ForeWard

Fall 2007™

# ForeWard

Research Today For Better Care Tomorrow

### STUDY PARTICIPATION OPPORTUNITY

could bring a breath of fresh air to diabetes research

inhaled insulin

Help us study

When you have Type 1 or Type 2 diabetes, you use insulin to maintain your blood glucose levels. Typically, insulin is taken by injection and we know that not everyone feels comfortable with this. That's why we're conducting a research study of an investigational inhaled insulin.

We need special groups of people who have diabetes and chronic obstructive pulmonary disease (COPD), or diabetes and asthma. If you're over 18 years of age and have diabetes and asthma or over 30 and have diabetes and COPD, we'd like to hear from you.

Join our inhaled insulin trial

785-354-0735

**ZEPHYR 2**  
Brightening the future of diabetes research

Version 1 US December 2005

Look inside for **your** chance to create a healthier tomorrow by participating in a clinical research study today!

## LIFECYCLE OF A DRUG: A LONG AND WINDING ROAD

### 3 TO 6 YEARS

Step One: Discovery  
Step Two: Early Testing

### 6 TO 7 YEARS

Step Three: Studies in Humans Begin  
Step Four: Studies in Humans Expand

### ONE-HALF TO TWO YEARS

Step Five: Approval for Wider Use

It takes 10 to 15 years from the time scientists discover the idea for a new medicine until it is proven to be safe and effective for people. Here's an overview:

**Discovery** – Scientists test compounds and their effectiveness to fight against a certain disease or medical condition. They start with as many as 10,000 compounds, and search for the most promising. Some efforts hit a dead end, but others lead to more testing.

**Early Testing** – The number of compounds is ultimately narrowed down from many to between one and five good "candidate drugs." Testing for safety is done on living cells, in animals, and via computer modeling. This "preclinical" testing leads to the next critical stage, clinical research studies involving humans. Before these begin, researchers report their preclinical testing results to the U.S. Food and Drug Administration (FDA) with details about how they expect the drug to work in humans. They then determine how to make enough of the drug for human testing and develop a plan for clinical research studies.

**Studies in Humans Begin** – After the FDA approves the study plan, and before it grants final approval of the drug for use by the general population, three phases of testing are carried out with an increasing number of human volunteers.

Phase I involves 10 to 100 healthy volunteers. This crucial step helps researchers learn the right dosage, check for safety profiles in humans, and observe how the drug behaves in people.

**Studies in Humans Expand** – Phase II studies test the drug in 100 to 500 volunteers who have the condition or medical problem being studied. Researchers monitor the volunteers carefully to evaluate the drug's safety.

Phase III studies are much larger, with 1,000 to 5,000 volunteers. In this phase today, many Phase III studies are conducted worldwide. Here, the final decision is made about the drug's safety and effectiveness.

**Approval for Wider Use** – Successful testing in carefully controlled clinical research studies means the drug is finally ready for review – and hopefully approval – by the FDA. The FDA has a rigorous review process, which includes examination of clinical research study data by both internal and external experts.

All in all, the process by which a new drug reaches patients is carefully and expertly conducted, with a singular goal: new and better treatments. Safety is the overriding concern during the entire clinical research process.

*Some information for this article was adapted from "Drug Discovery and Development," published by Pharmaceutical Research and Manufacturers of America, 2007.*



### STUDY PARTICIPATION OPPORTUNITY

**HELP ADVANCE ASTHMA RESEARCH IN THE AFRICAN AMERICAN POPULATION**

Medical centers in your area are studying the safety and effectiveness of a study medication for the treatment of asthma in the African American population. You or someone you know may be eligible to participate in this clinical research study.

**YOU MUST BE:**

- African American
- At least 12 years old, and
- Take asthma medication daily

Participants will receive study related medical care and medication at no cost. Compensation for time and travel may be offered. Health insurance is not needed.

**CALL 800-280-7155 or visit WWW.ASTHMACLINICALTRIALS**

### STUDY PARTICIPATION OPPORTUNITY

**DIFFICULTY BREATHING?**

QUALIFIED PARTICIPANTS WILL RECEIVE AT NO CHARGE

- \* Study related office evaluations
- \* Physical Exam and Lung Function tests
- \* Study Medication
- \* Compensation for time and travel

**YOU MAY QUALIFY FOR A CLINICAL RESEARCH STUDY**

ARE YOU 40 YEAR'S OLD OR OLDER?

DO YOU SUFFER FROM COPD (CHRONIC OBSTRUCTIVE PULMONARY DISEASE)?

DO YOU SUFFER FROM CHRONIC BRONCHITIS?

DO YOU SUFFER FROM EMPHYSEMA?

To learn more about clinical research studies, contact

**VERITAS CLINICAL SPECIALTIES**  
**785-354-0735**

**FOREsite**  
PUBLISHING, INC.  
www.fspi.info • 866-913-7098

515 SW Horne St., Suite 200, Topeka, KS 66606  
**785-354-0735** [www.verispecial.com](http://www.verispecial.com)

# VOLUNTEER'S VOICE

## “TO HELP FIND A BETTER WAY”

When it comes to volunteering for clinical research studies, Dianne and Ernie Bishop are veterans. Ernie participated in his first study nearly ten years ago, and has been involved in a couple more since then. Dianne's volunteered in two studies over the past few years.

The Bishops, in their late 60s, helped with studies that focused on medicines for controlling high blood pressure and high cholesterol, conditions they both live with and share with millions of others. The way they see it, they are benefiting themselves and others at the same time.

“Maybe I can help find a better way to treat the problem and also help myself,” Dianne says. “It's a win-win situation.”

Ernie's first study, in 1998, involved a new cholesterol medicine.

“I didn't know anything about clinical research,” he

explains. “My doctor recommended it. I was checked out to see if I qualified and there were lots of checkups during the study. They are very thorough about that.”

Dianne also found the care and oversight during the studies to be comforting.

“They watch you so closely. they see you so often, you feel absolutely safe,” she says. “You can ask questions anytime.”

Dianne and Ernie understand that new medicines wouldn't become available without the exhaustive testing that is done through clinical research. They have encouraged friends and family to consider volunteering, too.

“I tell others it's a wonderful thing to do,” says Dianne.

Adds Ernie, “I don't know if you'd call it noble, but it's important to bring new medicines along.”



DIANNE AND ERNIE BISHOP

## RESEARCHERS BRING HOPE WITH NEW TREATMENT OPTIONS

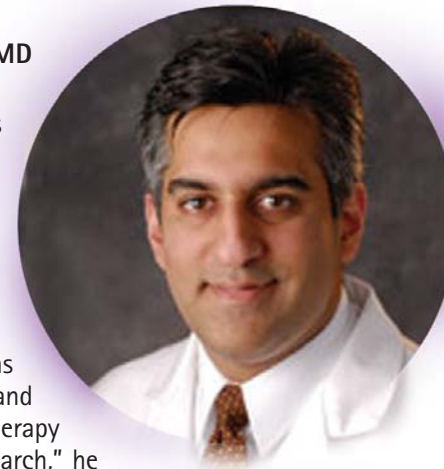
The goal of clinical research is to find new and better treatment ideas, and that desire – ultimately to make people's lives better – is precisely what doctors strive for, too.

“All physicians are inherently looking for ways to help treat patients,” says Osman Malik, MD. “Being involved in clinical research for the past five years has given me the opportunity to try cutting-edge therapies in a safe and scientific way for the benefit of my patients.”

Dr. Malik specializes in studies that concentrate on lung disease and disorders, including asthma and chronic obstructive pulmonary disease (COPD). Clinical research in these areas is focused on new medications, new systems to deliver medications, and new bronchoscopic procedures to improve lung function.

Clinical research often provides the opportunity for those with severe illness – such as lung and breathing problems – to try new options. Dr.

OSMAN MALIK, MD



Malik encourages patients to consider volunteering for studies for that very reason.

“Often people with severe illnesses need more help and options for their healthcare and turn to alternative therapy options through research,” he explains. “We give very careful screening before enrollment and frequent monitoring during the study. We also provide 24-hour access to our research team to handle any issues or concerns.”

More information about clinical research studies at Veritas Clinical Specialties is available online at [www.verispecial.com](http://www.verispecial.com) or from any member of the research team.

**STUDY PARTICIPATION OPPORTUNITY**

**extra**

Are you still letting allergic asthma symptoms and attacks disrupt your life?

Volunteers needed for a research study.

If you are interested in learning more about the EXTRA Study, call toll free **1-888-662-6728**.

Study medication will be provided. You may receive compensation for your time and travel.

**STUDY PARTICIPATION OPPORTUNITY**

**CAN'T BREATHE?**

CLINICAL RESEARCH STUDY FOR PATIENTS WITH **CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)**

Medical researchers across the U.S. are currently conducting a clinical research study for patients with severe breathing difficulties.

**Study participants must:**

- Have chronic bronchitis or emphysema
- Have a history of heavy smoking

**Participation will include, at no charge:**

- Supervised medical care as it relates to the clinical study
- Study medication

Compensation for travel may be provided.

**CALL TODAY! 1 866 565 0251**  
or visit [COPOStudies.com](http://COPOStudies.com)

**STUDY PARTICIPATION OPPORTUNITY**

**A potential new treatment for emphysema**

*“I used to take breathing for granted. Now, after years of smoking, I've developed emphysema and every breath is hard work” –An emphysema patient*

**The EASE™ Trial**

**CLINICAL RESEARCH STUDY RECRUITING PATIENTS**

Research teams across the US are currently recruiting patients for a clinical trial evaluating the safety and efficacy of a new treatment, called the Airway Bypass procedure to improve pulmonary function and breathlessness in patients with advanced widespread emphysema.

Participation covers medical care at no charge to you, including:

- Supervised pulmonary rehabilitation therapy
- Enrollment in the EASE Trial investigational study
- All follow-up visits related to the trial

You may qualify for the EASE research trial if you:

- Are age 35 years or older
- Have been diagnosed with advanced widespread emphysema
- Have stopped smoking for at least 2 months before you enter the trial

**For more information call: 1-785-354-0735 or visit [www.easetrialus.com](http://www.easetrialus.com)**

**RESEARCH RESOURCE:**  
[www.innovation.org](http://www.innovation.org)

A project of the Pharmaceutical Research and Manufacturers of America, this website is a one-stop resource on innovations in medicine. You'll find information and fact sheets about:

- New medicines in development
- Patient assistance programs (for those needing help to pay for prescriptions)
- Drug discovery and research
- Treatment 'progress reports' for Alzheimer's disease, breast cancer, and leukemia
- Stories of patients and researchers.