

**SAFETY**

**Is the investigational medication/treatment safe?**

- Are there side effects?
- How does it affect or move through the body?
- Is it safe to use at the same time as other medications?

**Who's in it?**

Small group of healthy people—generally less than 100



PHASE 1

**EFFICACY**

**Is the investigational medication/treatment effective in treating the targeted condition?**

- Does it relieve, reverse or stop the progression of the condition?
- How safe is it?
- What is the most effective dosage?

**Who's in it?**

Generally 100-300 people with the exact condition being studied



PHASE 2

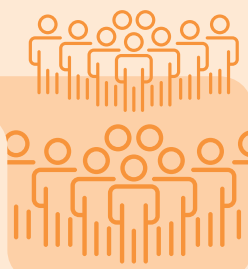
**FOLLOW UP**

**After the investigational medication/treatment is approved, how does it work for other patients with the condition?**

- More safety/efficacy information is gathered
- Are there long-term benefits?
- Are there long-term risks?

**Who's in it?**

Often several thousand people who have been prescribed the investigational medication



PHASE 4

**CONFIRMATION**

**How does the investigational medication/treatment compare to the standard treatment for the condition?**

- More effective, less effective, or the same?
- Longer-term adverse effects?
- How does it affect quality of life, or survival?
- How might it be used along with existing treatments?

**Who's in it?**

Often 300-3,000 people with the exact condition being studied



PHASE 3