HOW MEDICINE GETS FROM THE LABORATORY TO THE PHARMACY

TRIAL PLAN DEVELOPED AND REVIEWED
After discovery of a potential treatment, preclinical studies are conducted to answer basic questions about its safety.

CLINICAL TRIALS BEGIN
For a treatment to be approved, it must pass a three-phase clinical trial process.

PHASE I
Researchers test a new treatment with a small group of people (20 – 80) to evaluate its safety, determine safe dosage range and identify side effects.

PHASE II
The study treatment is tested with a larger group of people (100 – 300) to further evaluate safety and assess effectiveness.

PHASE III
The study is tested with an even larger group of people (1,000 – 3,000) to confirm effectiveness, monitor side effects, compare it to commonly used treatments and collect information about safe use.

RESULTS EVALUATED
Results of clinical trials are evaluated and submitted for review.

APPROVAL
After a thorough review, a regulatory agency may approve the new treatment for medical use.

PHASE IV: POST-APPROVAL
Marketing studies are conducted to gain additional insights about the treatment's risks, benefits and optimal use.