THE JOURNEY OF A NEW CANCER MEDICINE

The development of a new cancer medicine is a long, complex process that follows well-established paths to make sure they are safe and effective when they reach the public. What goes into bringing a new, novel medicine to market?

DISCOVERY, RESEARCH, AND DEVELOPMENT

- Scientists examine thousands of molecules to find compounds that combat cancer.
- Researchers discover new drugs through new insights into a disease, targeting areas of unmet medical need.
- Once researchers identify a promising compound for development, they conduct experiments to gather information on potential benefits, dosage levels, administration, and side effects.

PRECLINICAL RESEARCH

Researchers evaluate each potential new medicine for use and efficacy in the lab. They can then determine whether the drug should be tested on humans.

CLINICAL RESEARCH

gives answers for how the drug will interact with the human body. Drugs that make it to this stage undergo three phases of a clinical trial:

1. Studies done in small groups of people to test if a new treatment is safe and determine the best way to administer.
2. The drug is tested in a larger group of people to see if one type of cancer responds to the new therapy.
3. Tests whether a new treatment is equal to or better than a standard treatment, confirm effectiveness, and monitor side effects.

FDA REVIEW

The FDA examines all submitted data on the drug and decides whether or not to approve it for patient use.

BETWEEN AUGUST 1, 2015 AND JULY 31, 2016, THE FDA APPROVED

13 new anticancer therapeutics

11 new uses for previously approved anticancer therapeutics

DELIVERED TO PATIENTS

Once the FDA approves a new cancer treatment, the medicine is available to patients.

It typically takes 10-12 years to develop a new medicine.

COMMERCIALIZATION, MARKETING, AND POST-MARKET SAFETY MONITORING

While clinical trials provide important information on a new medicine's efficacy and safety, it is impossible to have complete information about a drug at the time of approval.

The true picture of a product's safety evolves over the months and even years that make up a product's life-time in the marketplace.

PROJECT INNOVATION

Sources

http://www.fda.gov/ForPatients/Approvals/Drugs/default.htm

http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf

https://www.marsdd.com/mars-library/product-development-lifecycle-new-drug-development

http://cancerprogressreport.org/2016/Documents/CPR2016.pdf