

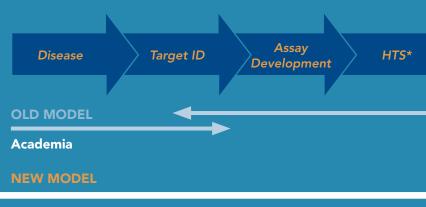
OF YESHIVA UNIVERSITY

Albert Einstein College of Medicine Center for Experimental Therapeutics

# A Bold New Initiative Bringing Hope and Help to Patients



# The Drug Development Process



**Einstein Center for Experimental Therapeutics** 

## Einstein Center for Experimental Therapeutics

In the intersecting worlds of science and medicine, there is no greater reward—or challenge—than discovering new therapies to cure or successfully treat the many devastating diseases that afflict humanity.

For more than five decades, the Albert Einstein College of Medicine has been one of the world's leading biomedical research institutions, making many significant contributions, from Taxol for cancer treatment to drugs currently in clinical trials for gout and leukemia. Einstein's many contributions have led, either directly or indirectly, to improvements in human health.

Recently, a disturbing new trend has evolved within the pharmaceutical industry, which threatens the development of new therapeutics. In response, Einstein is undertaking a bold, new initiative and launching the *Einstein Center for Experimental Therapeutics*.

#### The Decline in New Drug Development

In the "glory days" of the 1970s, '80s and '90s, pharmaceutical companies poured billions of dollars into translational and clinical research. Today, the playing field has changed dramatically.

The pharmaceutical industry is grappling with longterm fiscal concerns as patents on "blockbuster" drugs expire and its "pipelines" of new drug candidates are disappointing. The FDA has seen a sharp decline in the number of new drug applications. Many companies have already dramatically reduced their investment in research and development. The impact on patients desperately awaiting new medications to treat devastating and even life-threatening diseases is enormous.

#### **Einstein Launches New Initiative**

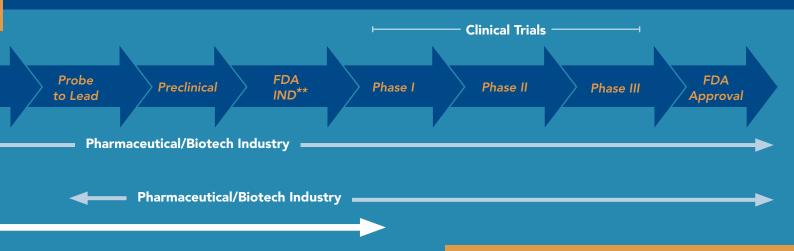
In an effort to reverse this worrisome trend, the *Einstein Center for Experimental Therapeutics* will build on the College of Medicine's strong basic research program. Specifically, the center will provide resources to allow researchers to advance their most promising, experimental therapeutic projects. In doing so, Einstein will be among the vanguard of medical institutions that are taking up the challenge to ensure that biomedical research will continue its vitally important work of discovering potential new drugs.

Our objective is to provide "proof" that our discoveries have been sufficiently developed and validated to merit pharmaceutical investment in their clinical development. No single institution can fill the gap in research and development created by pharmaceutical company retrenchment. Yet by partnering with industry in a new model of drug development (see above diagram), we can begin to reverse the negative trend and provide solutions for improving human health.

The new center will target common major diseases that affect millions of people such as cancer, heart disease, neurodegenerative diseases and autoimmune and infectious diseases. It will also focus on "rare" diseases and disorders. These diseases afflict a small percentage of the population and are generally ignored by the pharmaceutical industry even though they represent a large number of patients globally.

## Funding for the New Center

Biomedical research is expensive. Yet, thanks to Einstein's existing capabilities and strengths, the new center can be created in a cost-effective manner. We already possess a remarkable talent pool of researchers and unique facilities that cannot be found at any other medical school in the country.



High-throughput screening \*\* Investigational New Drug

Nonetheless, Einstein will need approximately \$20 million to launch the center and carry it through its first five years. Four million dollars are earmarked for start-up costs. These funds will be used to prepare and renovate existing space and to acquire:

- Additional robotics technology and chemical "libraries" for high-throughput screening
- Other specialized laboratory supplies and equipment.

The center's annual operating budget during this period is expected to be about \$3 million.

The center will range across a number of laboratories and buildings on the Jack and Pearl Resnick Campus. It also will leverage technology and personnel that already exist, while enabling the targeted hiring of specialized new faculty.

## Leveraging Our Strengths to Enhance Partnerships with Industry and Increase Revenue Streams

Einstein ranks among the top 25 medical schools in the country in total research awards from the National Institutes of Health (NIH), and among the top 10 in NIH support per investigator. In 2011, the NIH created the National Center for Advancing Translational Sciences to accelerate drug development. Establishing the *Einstein Center for Experimental Therapeutics* will position Einstein's investigators to take advantage of this new source of funding.

Using the center's new resources, our researchers will be able to advance further in the drug development process. This will enable new partnerships with industry, which is eager to develop new models for collaboration with academia (see above diagram and sidebar). It will also strengthen Einstein's intellectual property portfolio and facilitate licensing to industry, thereby enhancing royalty revenue.



#### **Disease Targets**

Scientists are constantly advancing research on key diseases. Next, they zero in on **identifying targets** for treatments of these diseases.



**Identifying Therapeutics** With a logical target in mind, researchers **develop assays** and may use **high-throughput screening** (HTS) to identify **lead** compounds for use as chemical **probes** and possible drug development.

**Preclinical Studies** Candidate drugs must be evaluated for toxicity and ability to be absorbed if given orally. Medicinal chemistry becomes critical to move from lead compound to eventual drug.

#### Later-stage Drug Development

Promising drug candidates must receive **Investigational New Drug** (IND) approval before human testing in phase 1 through 3 clinical trials. This can eventually lead to FDA approval.







## Investing in the Future

For more than five decades, Einstein's mission has been to combine the pursuit of scientific excellence with the goal to improve human health. By investing in the **Einstein Center for Experimental Therapeutics**, donors can enable our researchers to discover new therapies

that will cure or successfully treat many of the devastating diseases that affect humanity.

We welcome these donors to structure their gifts and pledges commensurate with naming opportunities related to physical spaces (e.g., labs, rooms), programs, endowed faculty positions and more.

#### On the cover:

Illustration of a carbon nanotube. Their use in drug delivery has the potential to revolutionalize medicine.





Albert Einstein College of Medicine OF YESHIVA UNIVERSITY For more information, please contact: Office of Institutional Advancement 718.430.2371 or institutionaladvancement@einstein.yu.edu