

Clinical Research for Cancer Patients

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Quality Cancer Care Alliance (QCCA)

Pierce County Survivorship Conference

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Cancer Death Rates Down

A major study concludes that improvements in treatment have helped cut cancer death rates in half

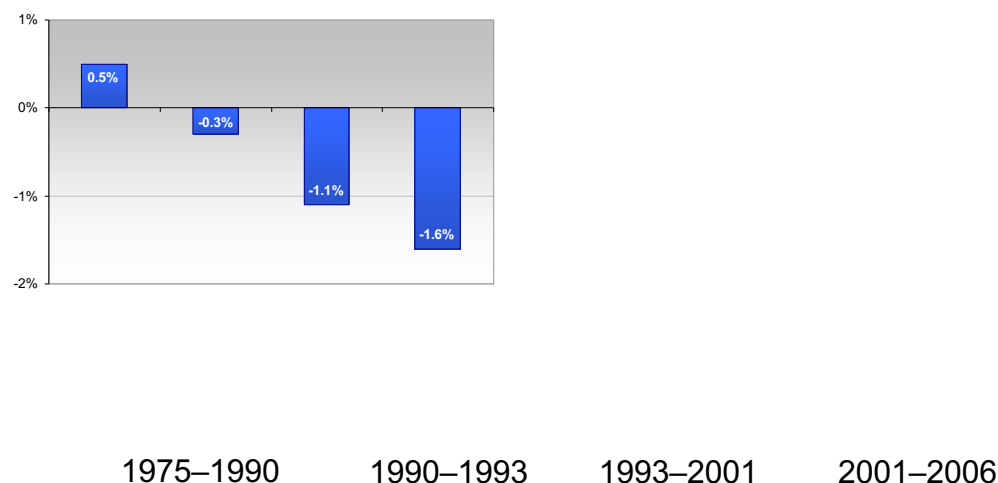
“*From Killer to Chronic Disease: Drugs Redefine Cancer for Many*”

—*Washington Post*

“*I think we really are in the midst of a revolution in the treatment of cancer*”

— *Dr. Len Lichtenfeld,
American Cancer Society*

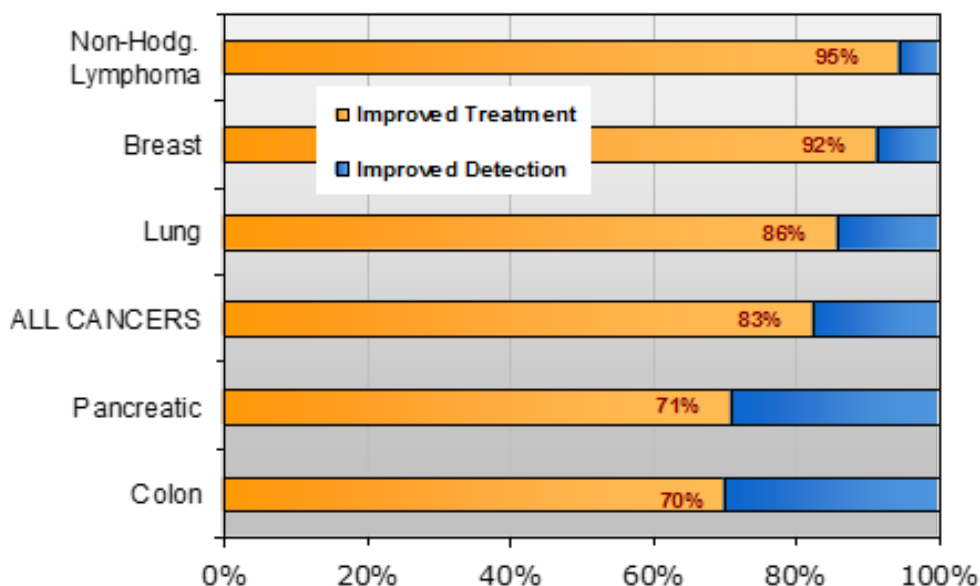
Annual Change in U.S. Death Rate from Cancer¹



Gains in Cancer Treatment Drive Improvement in Survival Rates

Share of Life-Expectancy Gain Attributable to Improved Treatment vs. Improved Detection, 1980-2000*

Cancer Site (Total Life Expectancy Gain)



“Gains in cancer survival have been largely driven by improvements in treatment.”

Cancer Type	Life-Expectancy Gain
Non-Hodgkins Lymphoma	3.1-3.6 yrs
Breast	5.9-6.0 yrs
Colon	2.8-3.2 yrs
Pancreatic	0.6 yrs
Lung	0.4-0.5 yrs
ALL CANCERS	2.8-3.2 yrs

Note: Asterisk (*) indicates Life Expectancy gains from 1990-2000 because 1980 data was not available for these conditions.

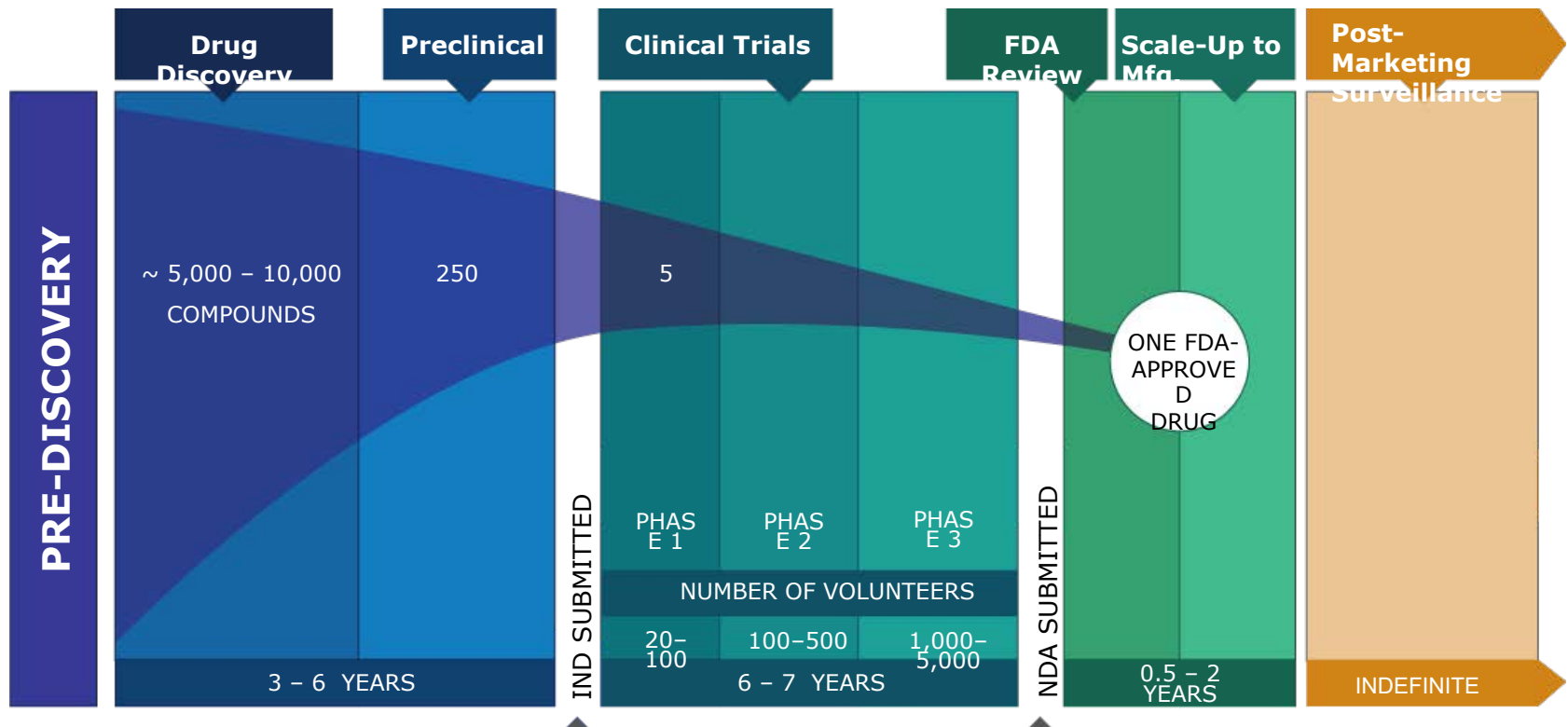
Source: Adapted from E. Sun et al., “The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database,” *Journal of Clinical Oncology*, May 2008.

Drug Discovery



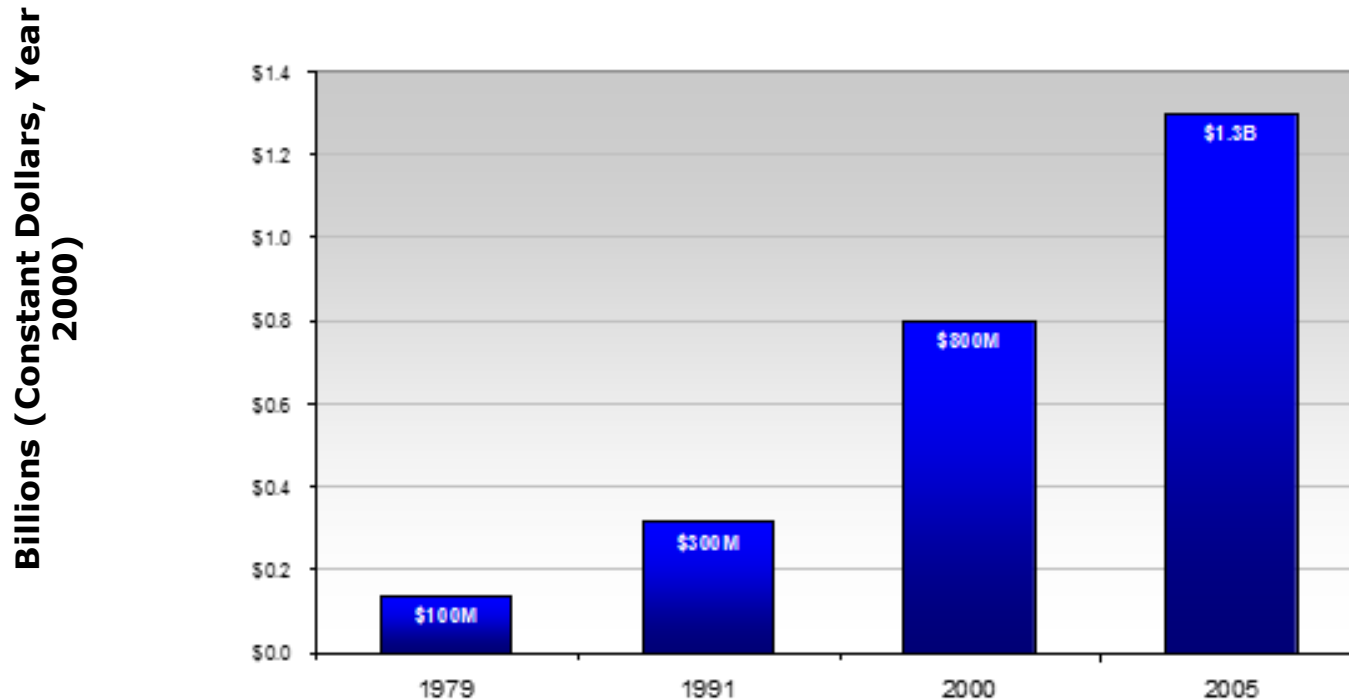
Drug Development Takes Longer Than it Did in the Past

Developing a new medicine takes an average of 10–15 years; the Congressional Budget Office reports that “relatively few drugs survive the clinical trial process”



The Cost of Developing a New Drug Has Greatly Increased

Cost to Develop One New Drug¹



Sources: ¹J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007; J. DiMasi et al., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 2003.

What are Clinical Trials

Clinical trials are research studies that involve people to find new ways to improve treatments and the quality of life for people with disease.

Researchers design cancer clinical trials to test new ways to:

- Treat cancer
- Find and diagnose cancer
- Prevent cancer
- Manage symptoms of cancer and side effects from its treatment

Types of Trials

- Treatment Trials

Drugs or Vaccines

Approaches to surgery or radiation therapy

Combination treatments, including some that work to boost your immune system to help fight the cancer

- Prevention Trials

- Screening trials

- Quality-of-Life/Supportive Care/Palliative Care Trials



“After my mother died from breast cancer, I wanted to do whatever I could to keep from getting cancer.”

Clinical Trial

- Every trial has a person in charge, usually a doctor, who is called the principal investigator.
- The principal investigator prepares a plan for the trial, called a protocol.
- The protocol explains what will be done during the trial. It also contains information that helps the doctor decide if this treatment is right for you.

The Protocol

- The reason for doing the trial
- Who can join the trial (called “eligibility criteria”)
- How many people are needed for the trial
- Any drugs or other treatments that will be given, how they will be given, the dose, and how often
- What medical tests will be done and how often
- What types of information will be collected about the people taking part

Informed Consent

- Informed consent is the process of learning the key facts about a clinical trial before deciding whether to participate.
- If the participant decides to enroll in the trial, the informed consent document will be signed. Informed consent is not a contract. Volunteers are free to withdraw from the study at any time.

Phases of Trials

Phase 1 (15-30 people)

- To find a safe dose
- To decide how the new treatment should be given (by mouth, in a vein, etc.)
- To see how the new treatment affects the human body and fights cancer

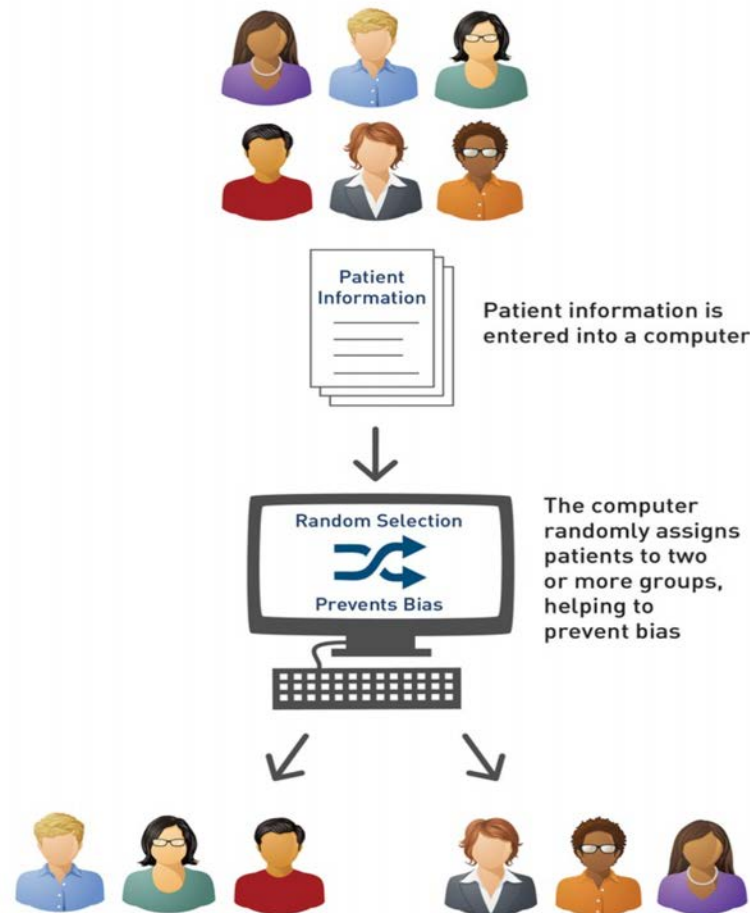
Phase 2 (Less than 100 people)

- To determine if the new treatment has an effect on a certain cancer
- To see how the new treatment affects the body and fights cancer

Phase 3 (From 100 to several thousand)

- To compare the new treatment (or new use of a treatment) with the current standard treatment

Clinical Trials Randomization



Clinical Trials in the US

- Pharmaceutical Trials
- Publicly funded trials-NIH

Why Participate in Trials

- Clinical trials represent the engine for new treatment for cancer
- Only 3-5% of adult patients participate in trials in the US- (compared with > 60% of children)
- It will take a long time to discover benefits of treatment if participation remains low

Myths about Clinical Trials

Myth 1: I don't want to be a guinea pig for an experimental treatment.

THE TRUTH:

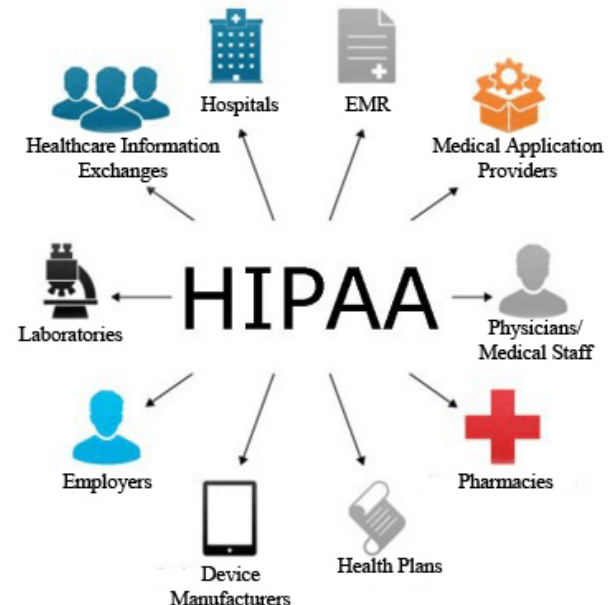
Cancer clinical trials are developed with high medical and ethical standards, and participants are treated with care and with respect for their rights.



Myth 2: People might access private information about me if I participate.

THE TRUTH:

In nearly all cancer clinical trials, patients are identified by codes so that their privacy is protected throughout and after the study.



Myth 3: Cancer clinical trials are only for people with **no other** treatment options.

THE TRUTH:

Trials can study everything from prevention to early- and late-stage treatment, and they may be an option at any point after your diagnosis.



Myth 4: I'm afraid I might receive a sugar pill or no treatment at all.

THE TRUTH:

Cancer clinical trials rarely use placebo alone if an effective treatment is available; doing so is unethical.



Myth 5: I'm afraid that my health insurance will not help with **the costs** of a cancer clinical trial.

THE TRUTH:

Many costs are covered by insurance companies and the study sponsor, and financial support is often available to help with other expenses; talk to your doctor to understand what costs you could be responsible for.



Myth 6: I'm afraid that once I join a cancer clinical trial, there's **no way out**.

THE TRUTH:

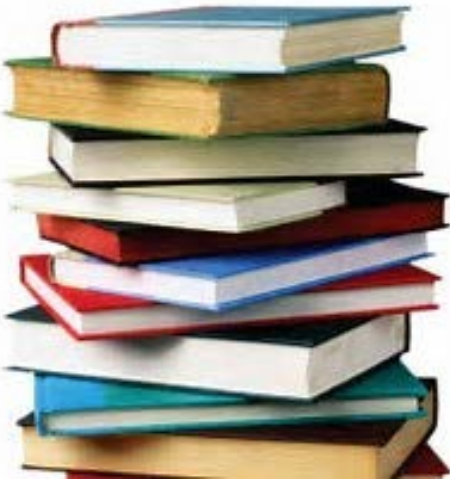
You have the right to refuse treatment in a cancer clinical trial or to stop treatment at any time without penalty.



Myth 7: I can only get clinical trials at the academic cancer centers.

THE TRUTH:

The community oncology centers provide cutting edge, advanced research to their patients



Shift to Community Physicians

- **Pharmaceutical industry has turned to private practice since late 1990s**
 - **No longer academic centers are the primary site for cutting edge research**
 - **Driving force: cost of development of new drugs**
- **In 1981, 80% of clinical trials went into academia. In 1998, this figure dropped by half to 40%**
- **Thousands of private physicians became principal or physician investigators allowing their patients to clinical trials close to home**

A Community Oncology Practice: Northwest Medical Specialties-NWMS

Ten Oncologists, eleven mid-levels

Six clinics

~3,500 new patients annually

Diverse tumor types

- **Solid**
- **Hematology**

Long history of cancer research



Why Community Oncology

- **Speed**
- **Cost**
- **Quality**

NWMS Research Initiative

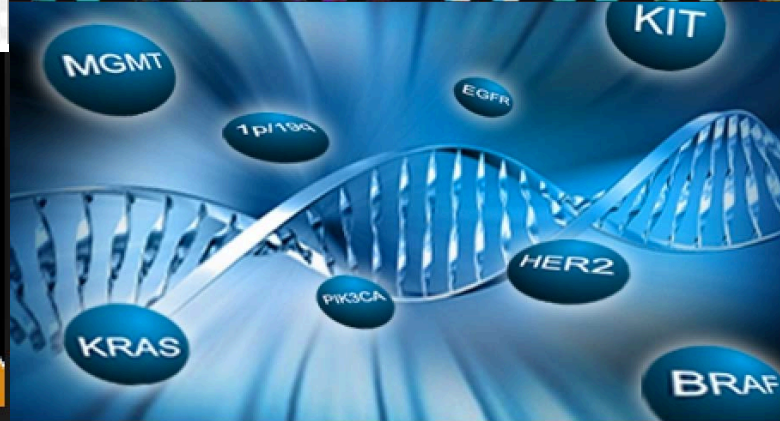
- Major infrastructure investment in 2002

	2002	2012
Research Employees	1	14
Annual Studies	4	~35
Active Patients	31	326

New Era

CANCER
IT'S PERSONAL

THE RIGHT PATIENT. THE RIGHT TREATMENT.



The Immensely Complex Circuitry of a Cancer Cell

Colorectal cancer

Pancreatic cancer

Glioma

Thyroid cancer

Acute myeloid leukemia

Chronic myeloid leukemia

Basal cell carcinoma

Melanoma

Renal cell carcinoma

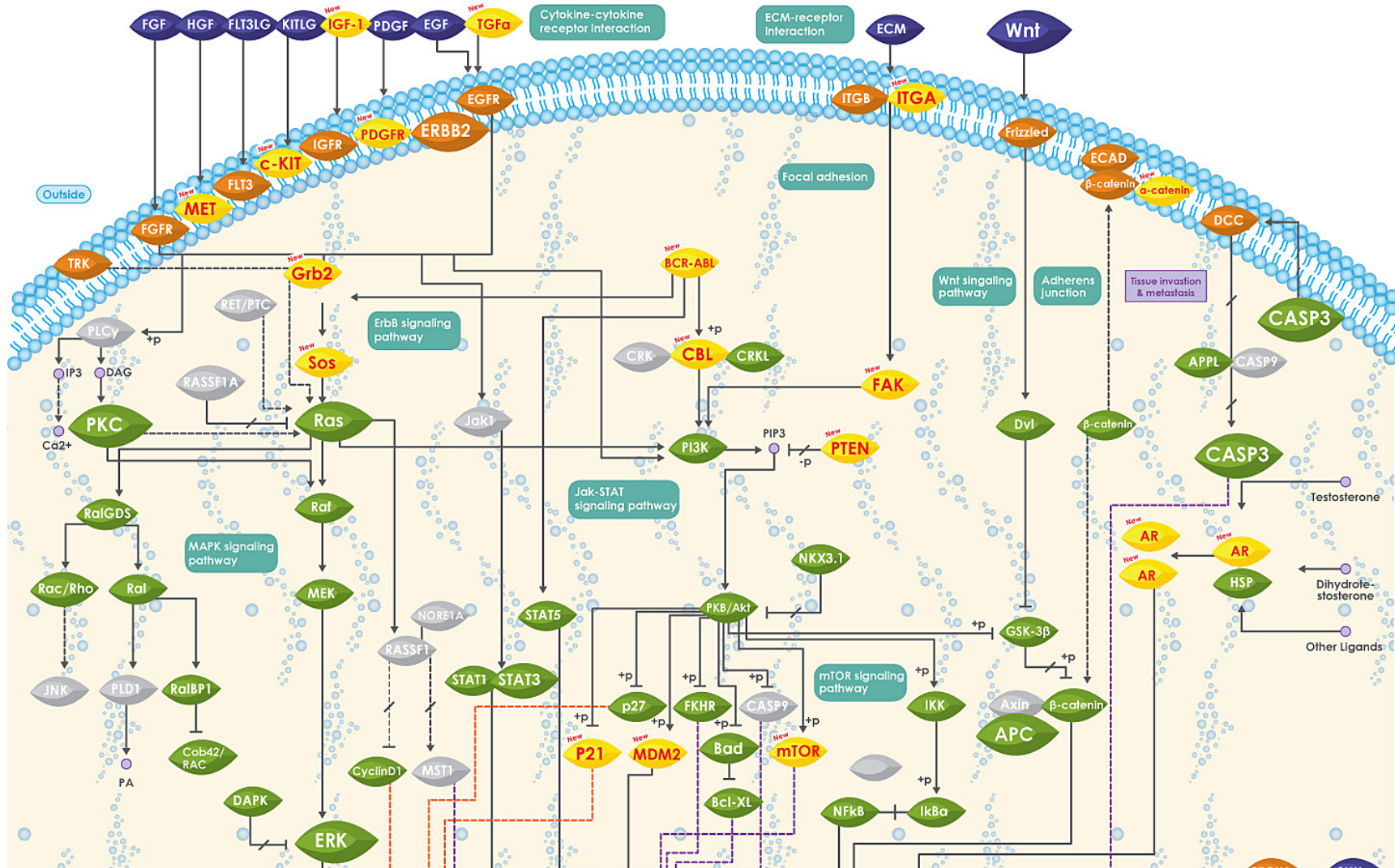
Bladder cancer

Prostate cancer

Endometrial cancer

Small cell lung cancer

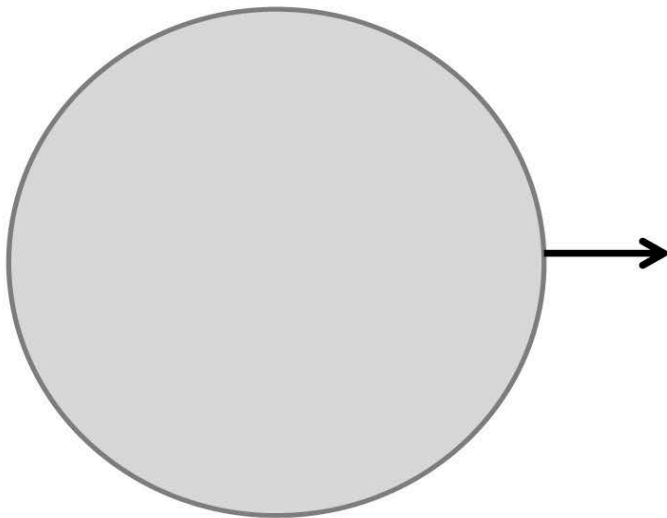
Non-small cell lung cancer



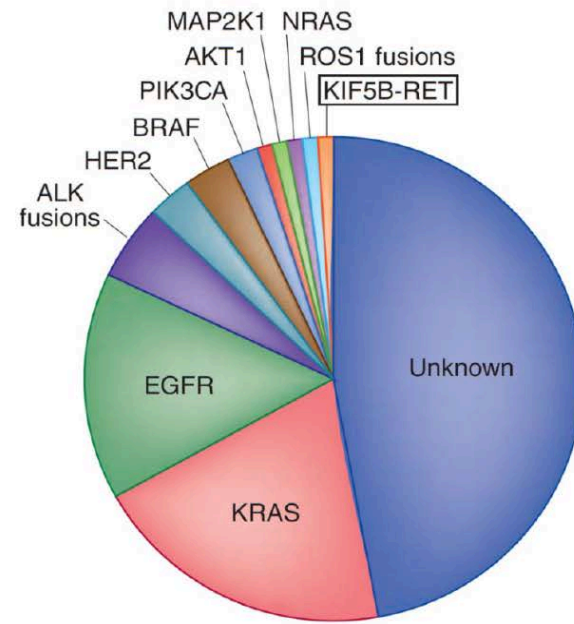
The Number of New Targets is Growing

Lung Adenocarcinoma

2003

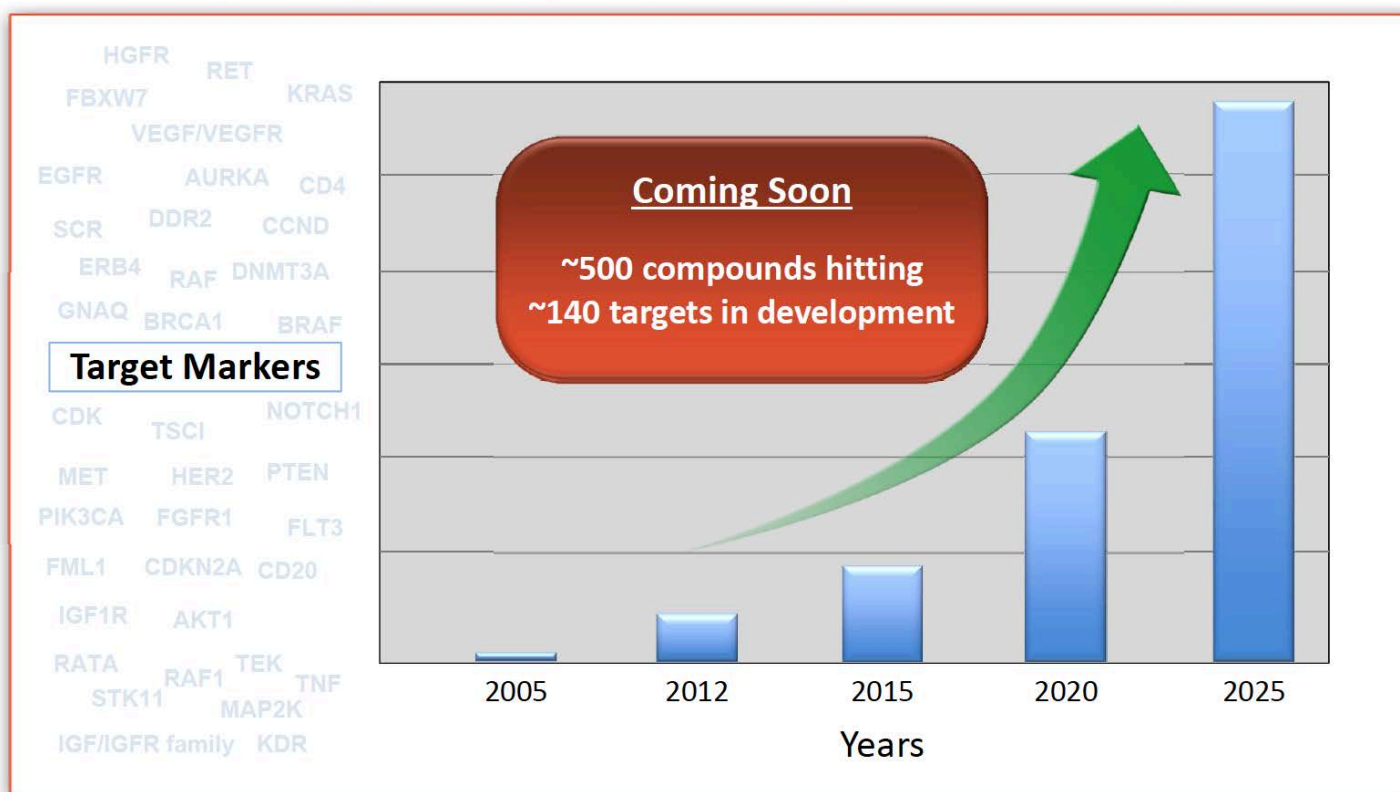


2012



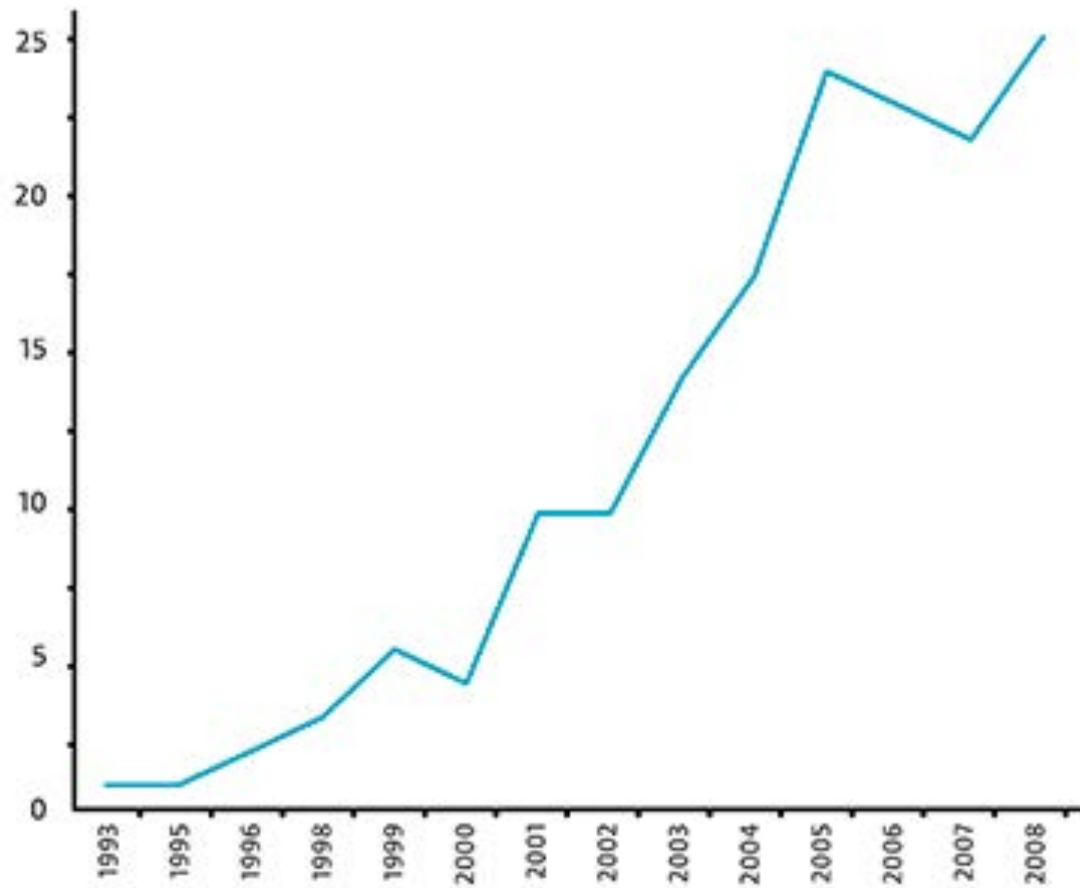
Cancer Diagnostic Market is Rapidly Evolving

Molecular profiling is driving many new targeted cancer therapeutics



Subset of analyzed targets listed; data from BioCentury Online Intelligence Database

Personalized Medicine Clinical Trials by Year



Towards curing cancer



Summary

- **Exciting time for oncology with exciting new drugs, immunotherapy and testing abilities**
- **More adult patients need to participate**
 - **To help drug discovery**
 - **To develop biomarkers**
 - **To advance molecular diagnostics**
- **Data needs to be captured, analyzed and shared in all cases**