

Clinical Research for Cancer Patients

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Northwest Medical Specialties

Quality Cancer Care Alliance (QCCA)

Pierce County Survivorship Conference

2016

Cancer Death Rates Down

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

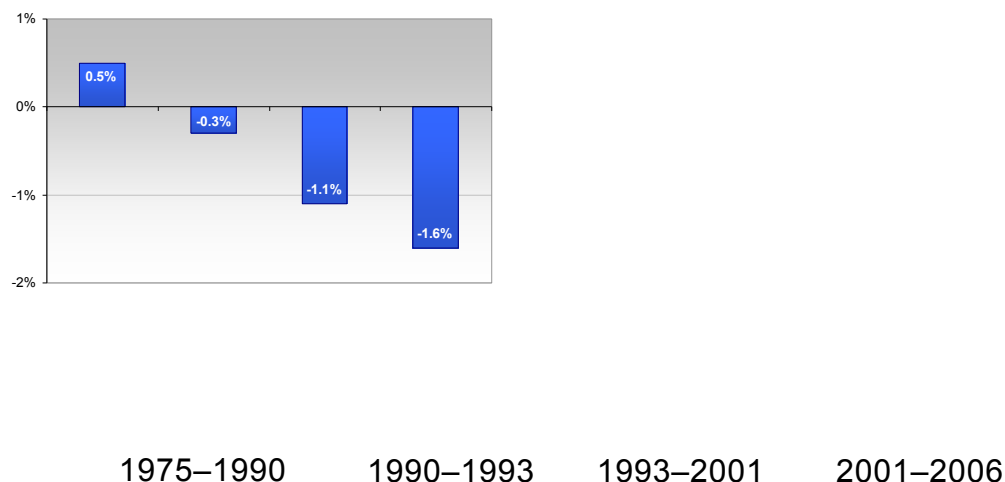
“*From Killer to Chronic Disease: Drugs Redefine Cancer for Many*²”

—*Washington Post*

“*I think we really are in the midst of a revolution in the treatment of cancer*³”

— *Dr. Len Lichtenfeld,
American Cancer Society*

Annual Change in U.S. Death Rate from Cancer¹

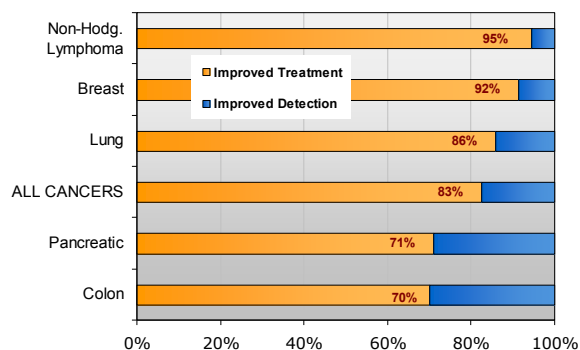


Sources: ¹B.K. Edwards, et al. "Annual Report to the Nation on the Status of Cancer, 1975-2006, Featuring Colorectal Cancer Trends and Impact of Interventions (Risk Factors, Screening and Treatment) to Reduce Future Rates," *Cancer*, 1 February 2009, p. 544-573; ²R. Stein, "From Killer to Chronic Disease: Drugs Redefine Cancer for Many," *The Washington Post*, 2003.; ³J. L. Lichtenfeld, PhRMA "Future of Innovation" Briefing, (Washington D.C.) 2006.

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.

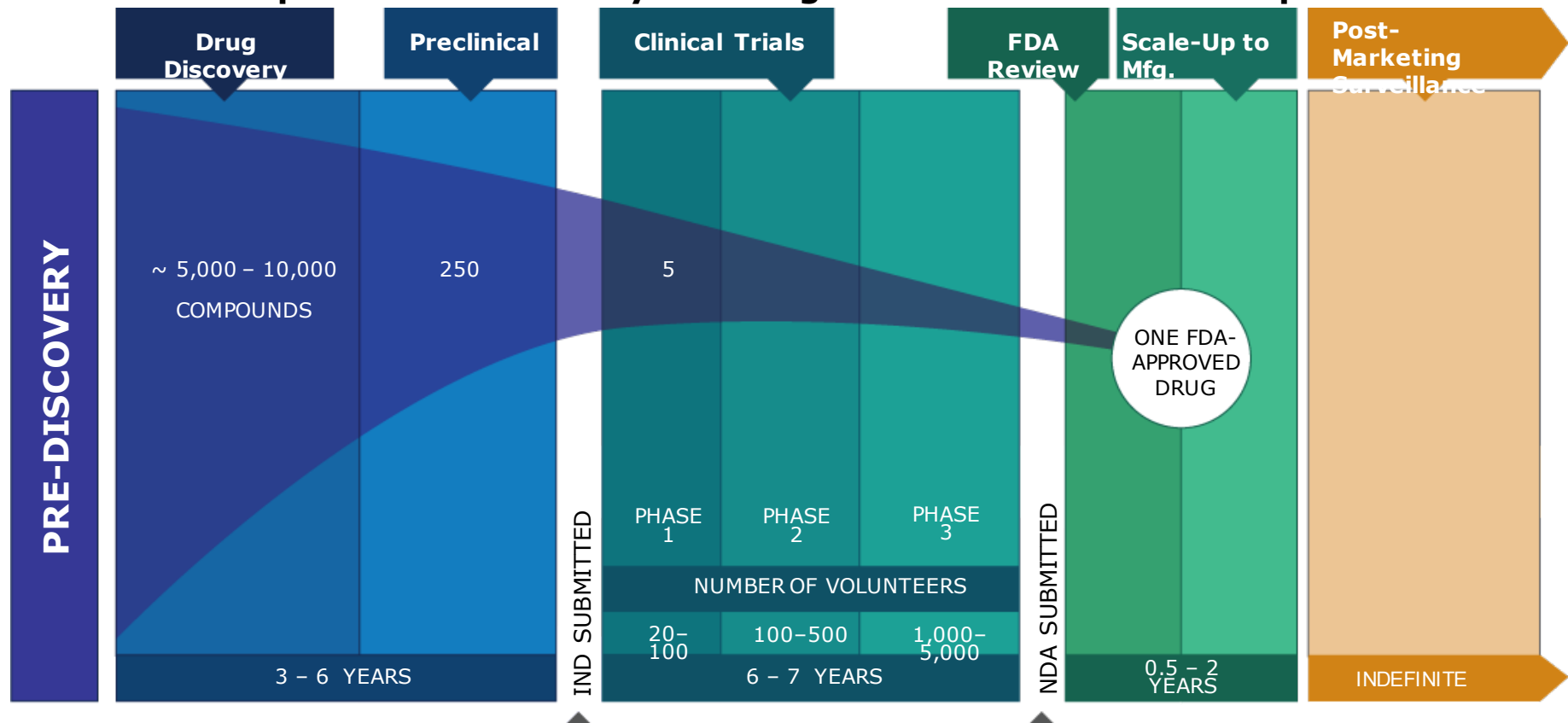
Source: Adapted from E. Sun et al., “The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database,” *Journal of Clinical Oncology*, May 2008.

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”

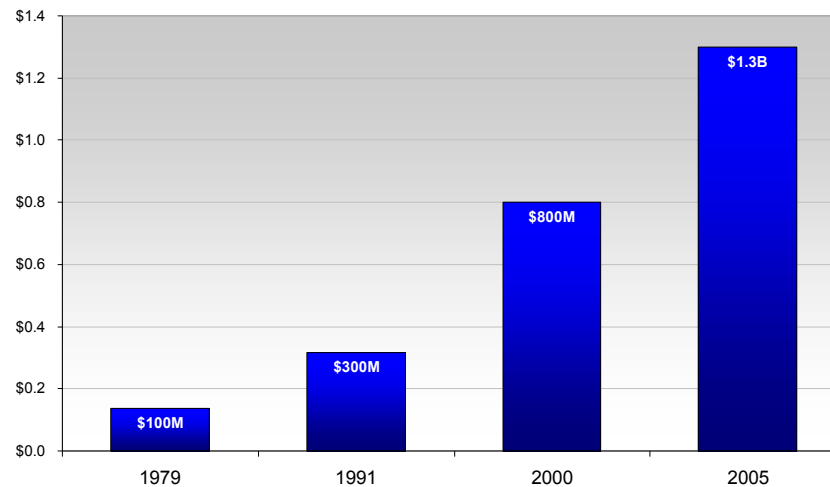


Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org; CBO, *Research and Development in the Pharmaceutical Industry*, 2006.

The Cost of Developing a New Drug Has Greatly Increased

Cost to Develop One New Drug¹

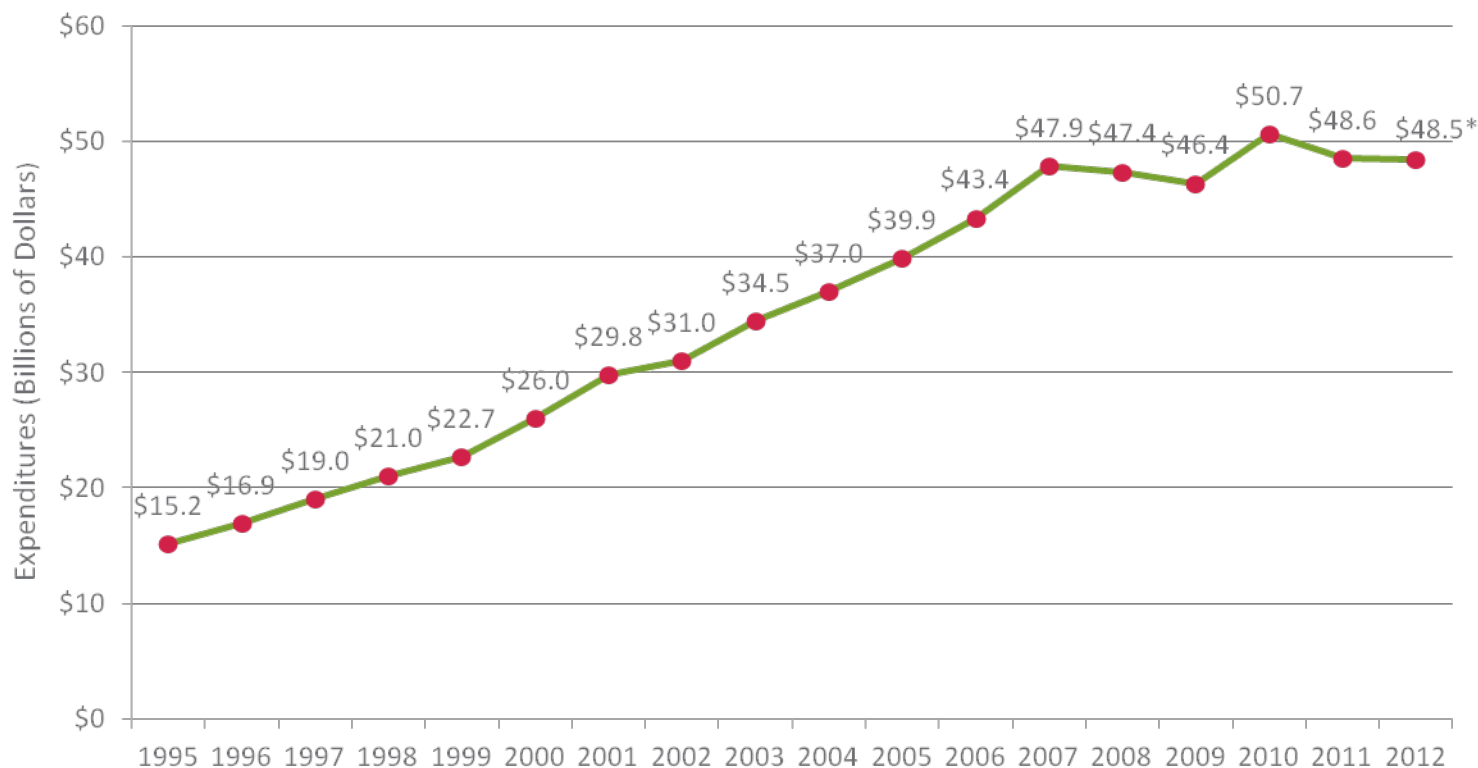
**Billions (Constant Dollars, Year
2000)**



PhRMA Member Company R&D Spending

“The pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm.” — Congressional Budget Office

PhRMA Member Company R&D Expenditures: 1995–2012



Source: PhRMA⁹

*Estimated for CY 2012

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

What is a Clinical trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Reasons to participate in Clinical Trials

- Evaluating interventions (drugs, medical devices, approaches to surgery or radiation) for treating a disease
- Finding ways to prevent the disease or condition. These can include medicines, vaccines, or lifestyle changes, among other approaches.
- Evaluating interventions aimed at identifying or diagnosing a particular disease or condition
- Exploring ways to improve the comfort and quality of life through supportive care for people with a chronic illness

The Protocol

- Who is eligible to participate in the trial
- Details about tests, procedures, medications, and dosages
- The length of the study and what information will be gathered

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.

Myths about Clinical Trials

Myth: 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: 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.

Myths About Clinical trials

Myth: 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: 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.

Myths about Clinical trials

Myth: 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: 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.

Myths about Clinical Trials

- **Myth:** 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:** 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.

Myths about Clinical Trials

- **Myth:** I can only get clinical trials at the academic cancer centers

- **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

Eleven Oncologists, seven mid-levels

Seven 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

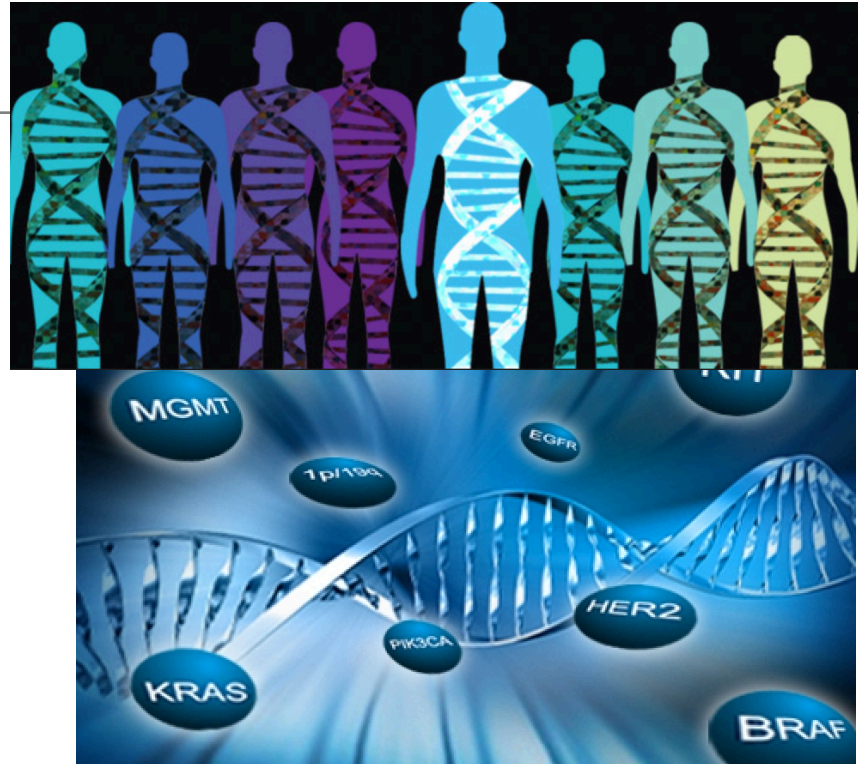
	2002	2012
Research Employees	1	14
Annual Studies	4	~35
Active Patients	31	326

New Era

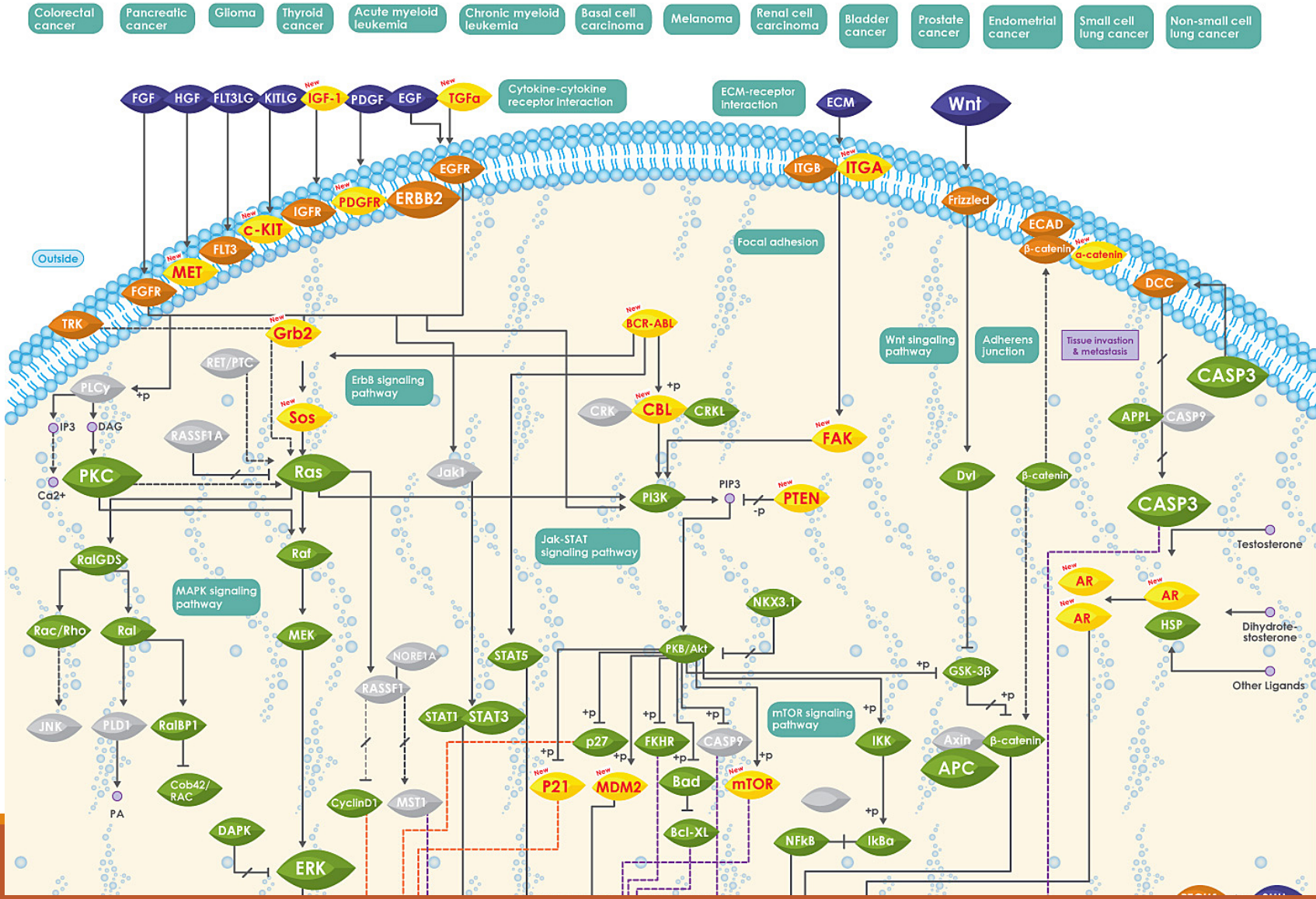
CANCER

IT'S PERSONAL

THE RIGHT PATIENT. THE RIGHT TREATMENT.



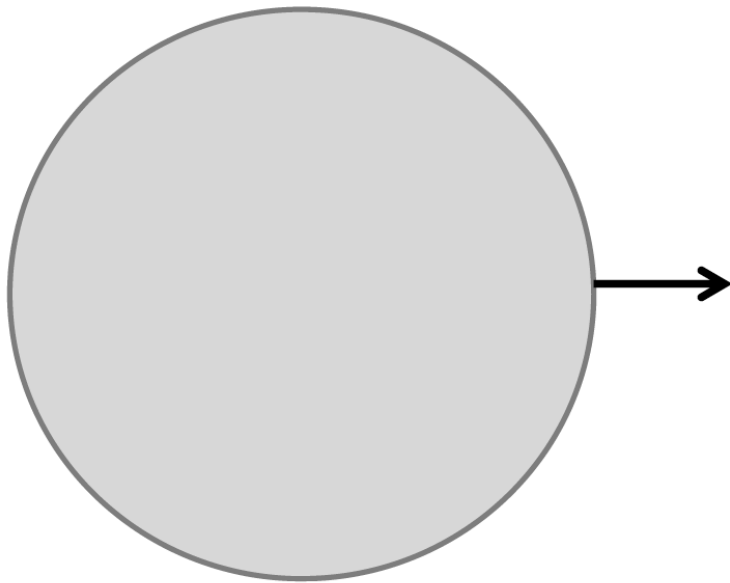
The Immensely Complex Circuitry of a Cancer Cell



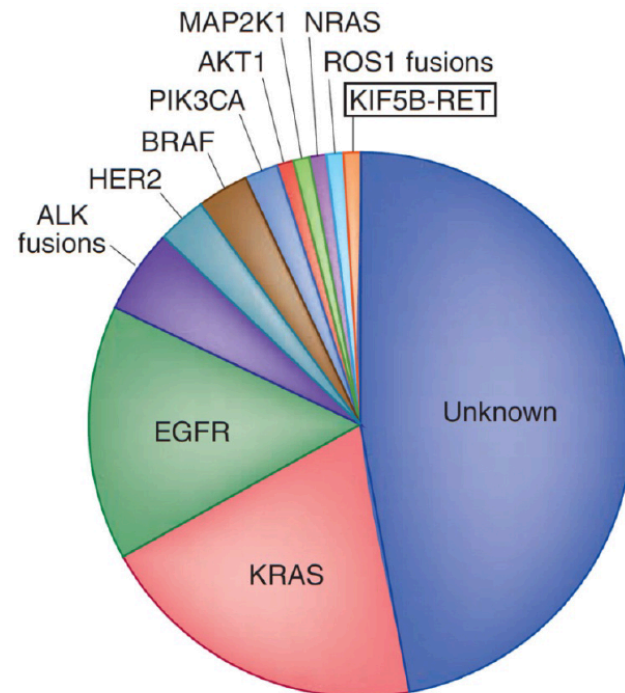
The number of new targets is growing

Lung Adenocarcinoma

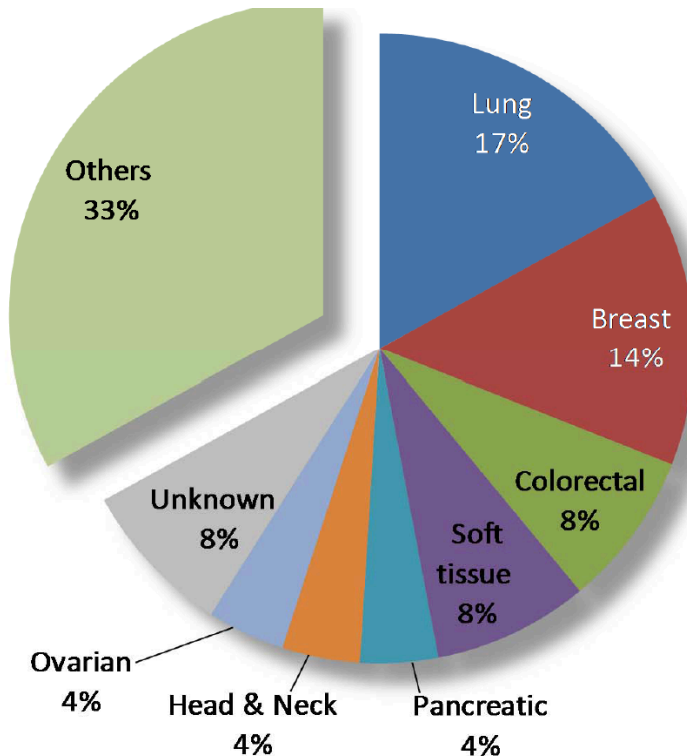
2003



2012



Foundation One™ Experience



Dataset: First 3,936 qualifying clinical specimens in FMI CLIA lab.

- 82% of cases have “actionable” findings
- On average (mean), 3-4 reportable alterations; 1.6 actionable alterations per sample

Definition of Actionability:

1. FDA approved targeted therapy in tumor type
2. FDA approved targeted therapy in another tumor type
3. Open clinical trial for which alteration confers trial eligibility

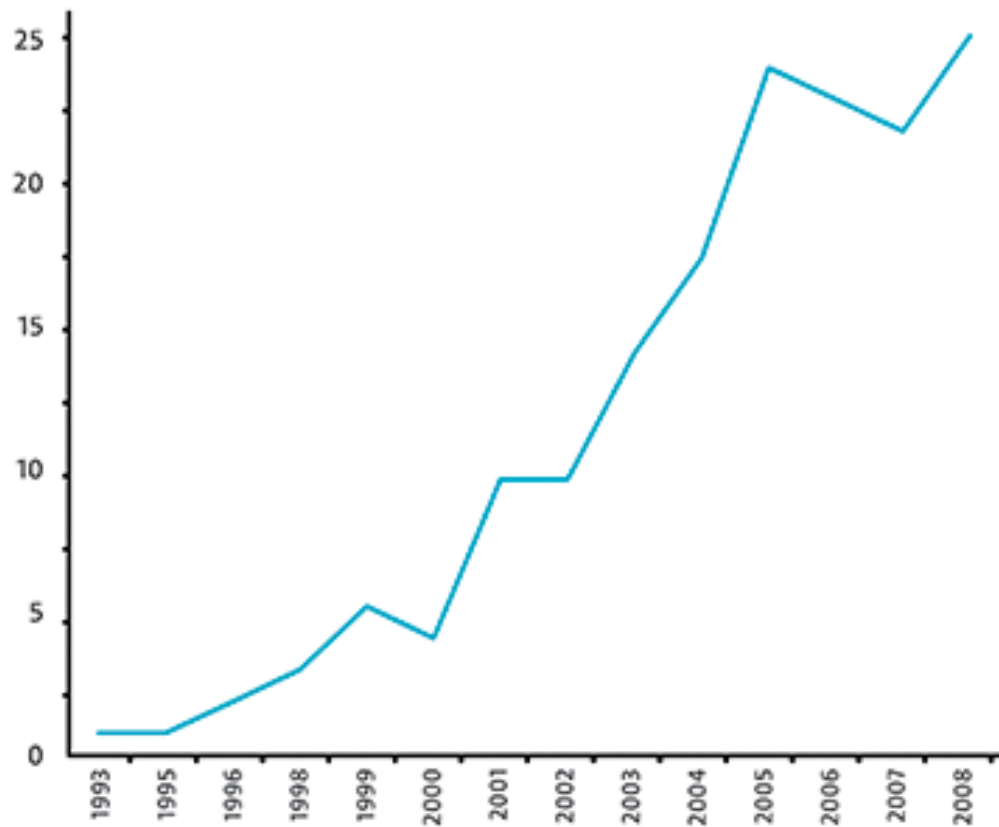
Cancer Diagnostic Market is Rapidly Evolving

Molecular profiling is driving many new targeted cancer therapeutics



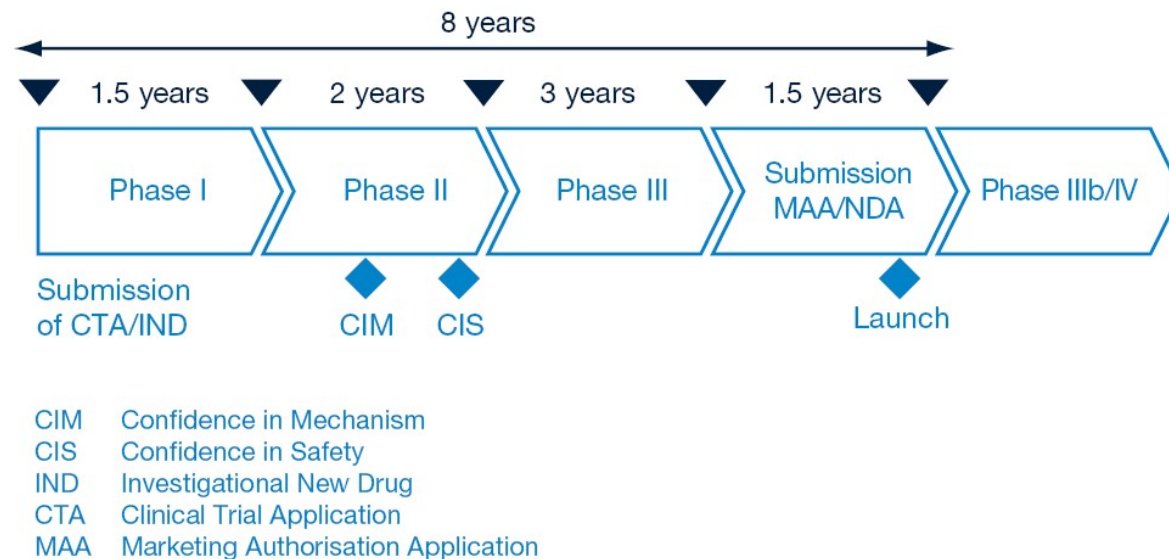
Subset of analyzed targets listed; data from BioCentury Online Intelligence Database

Personalized Medicine Clinical Trials by Year



Oncology Product Development

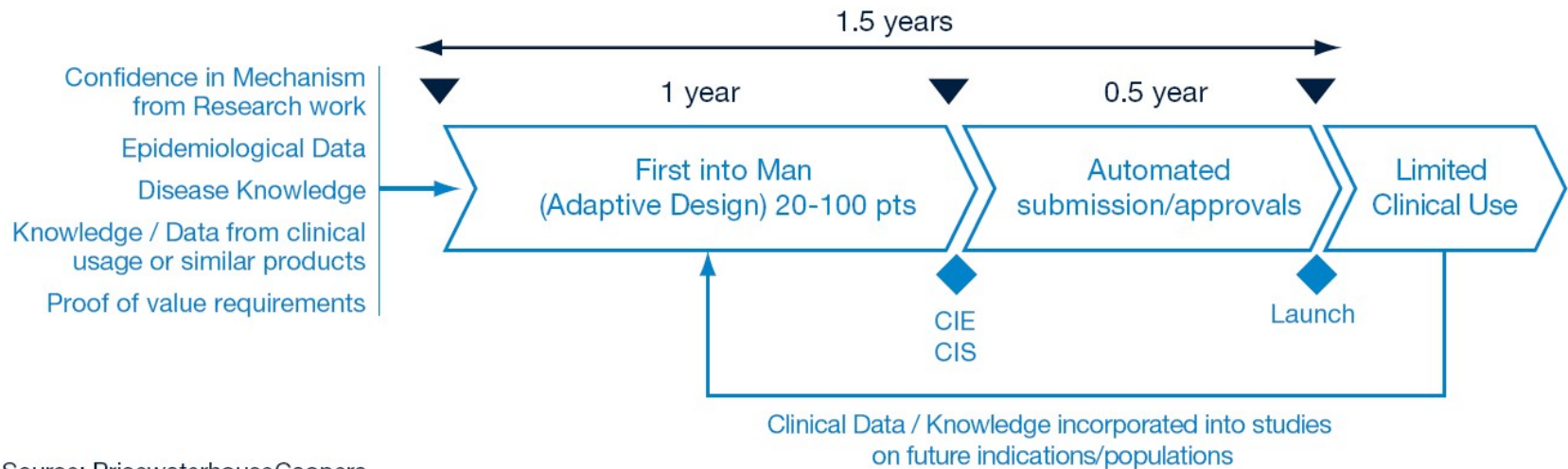
HOWITWORKSTODAY



Source: PricewaterhouseCoopers

An Expedited Approach

A MODEL FOR CANCER MOONSHOT 2020



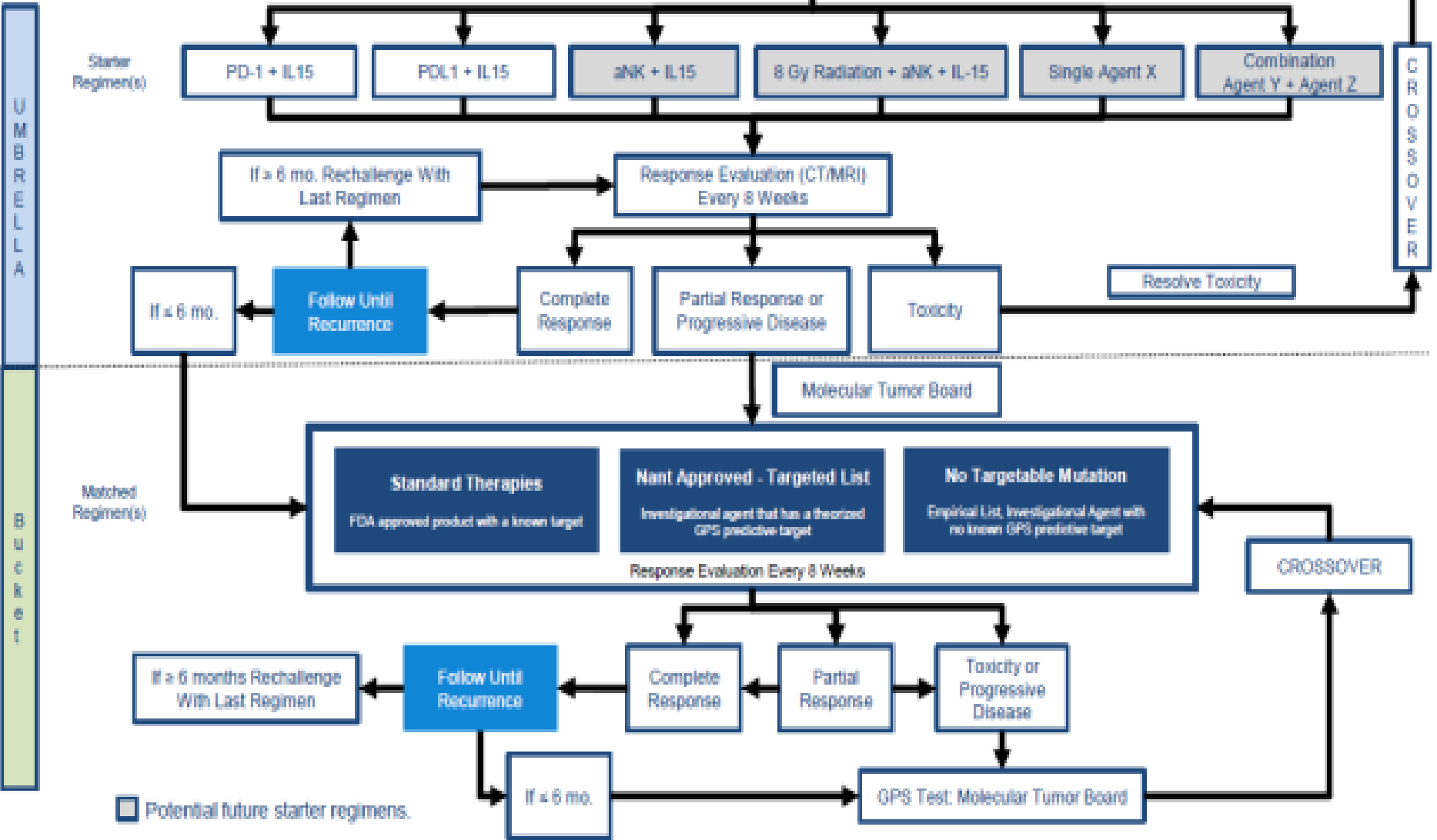
Source: PricewaterhouseCoopers

What is Cancer MoonShot 2020?

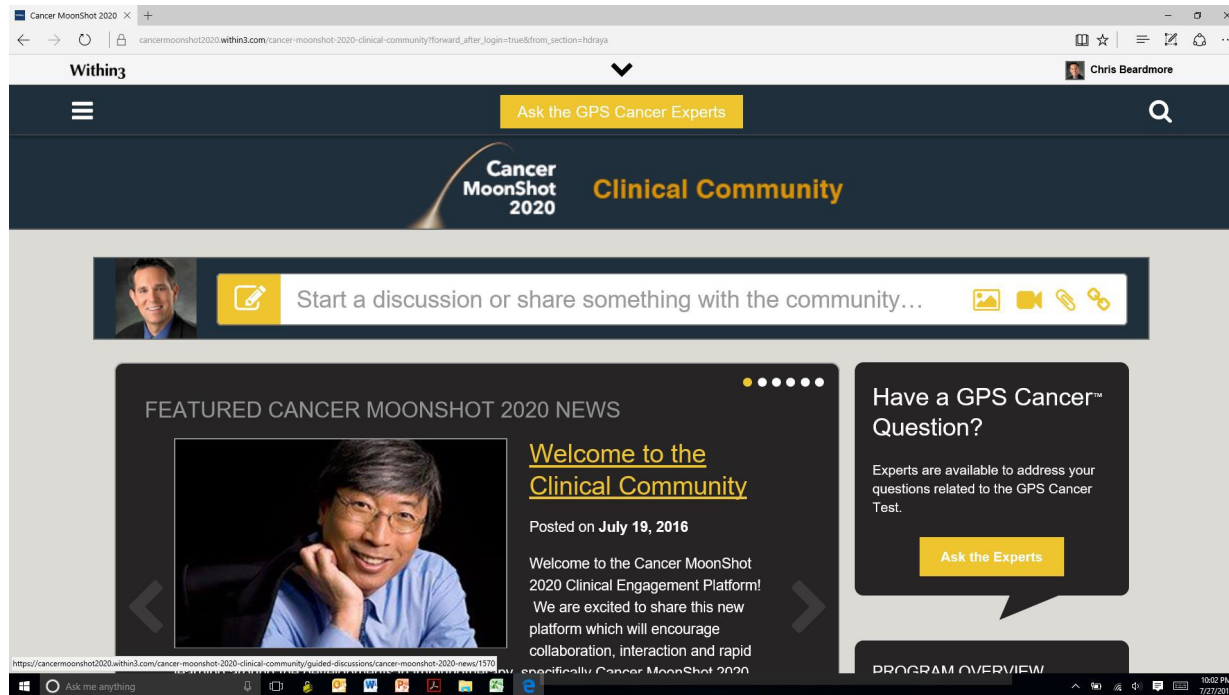
The Cancer MoonShot 2020 Program is one of the most comprehensive cancer collaborative initiatives launched to date, seeking to accelerate the potential of combination immunotherapy as the next generation standard of care in cancer patients.

This initiative aims to explore a new paradigm in cancer care by initiating randomized Phase II trials in patients at all stages of disease in 20 tumor types in 20,000 patients within the next 36 months. These findings will inform Phase III trials and the aspirational moonshot to develop an effective vaccine-based immunotherapy to combat cancer by 2020.

Cancer MoonShot 2020
QUILT – QUAntitative Integrative Lifelong Trial
Study Entry Pathways



Clinical Engagement Platform & Tumor Board



<https://cancermoonshot2020.within3.com/cancer-moonshot-2020-clinical-community>

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

Thank you

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