

Triage Cancer Webinar Series

Precision Medicine – The future of personalizing cancer care



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About Triage Cancer

Triage Cancer is a national, nonprofit organization that provides information and resources on cancer survivorship issues



Triage Cancer Speakers Bureau

International Speakers Bureau of experts & survivors experts in the areas of medicine, mental health, nursing, social work, patient navigation, nutrition, oncofertility, law, employment, education, financial management, insurance, relationships, sexuality and intimacy, pain and palliative care, advocacy, and other areas of cancer survivorship

Request a Speaker

Event & Speaker Request Form

Triage Cancer can provide you with a single speaker for your educational event or multiple speakers on a variety of cancer survivorship topics through our Speakers Bureau. Triage Cancer can also provide event coordination and logistical support services for cancer survivorship educational events.

Please complete the form below to provide us with information about your event request.

Are you requesting a speaker for your event?

Are you requesting multiple speakers for your event?



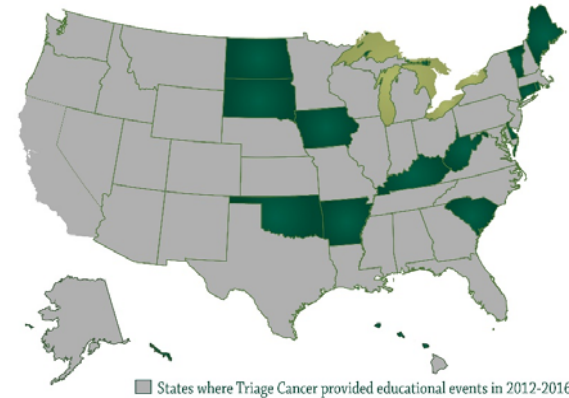
Triage Cancer Educational Events

In-person educational events for:

- Patients & survivors
- Caregivers
- Advocates
- Health care professionals
- & others

<http://TriageCancer.org/Events-Calendar>

States Visited by Triage Cancer



Upcoming Webinars

Recordings of Past Webinars
and

Full 2017 Schedule is Now Available at:

<http://tragecancer.org/webinars>

CEUs for Nurses are pending

Triage Cancer Chart of State Laws

Employment, disability and health insurance, & more

<http://TriageCancer.org/statelaws>

State Laws

Employment Related State Laws

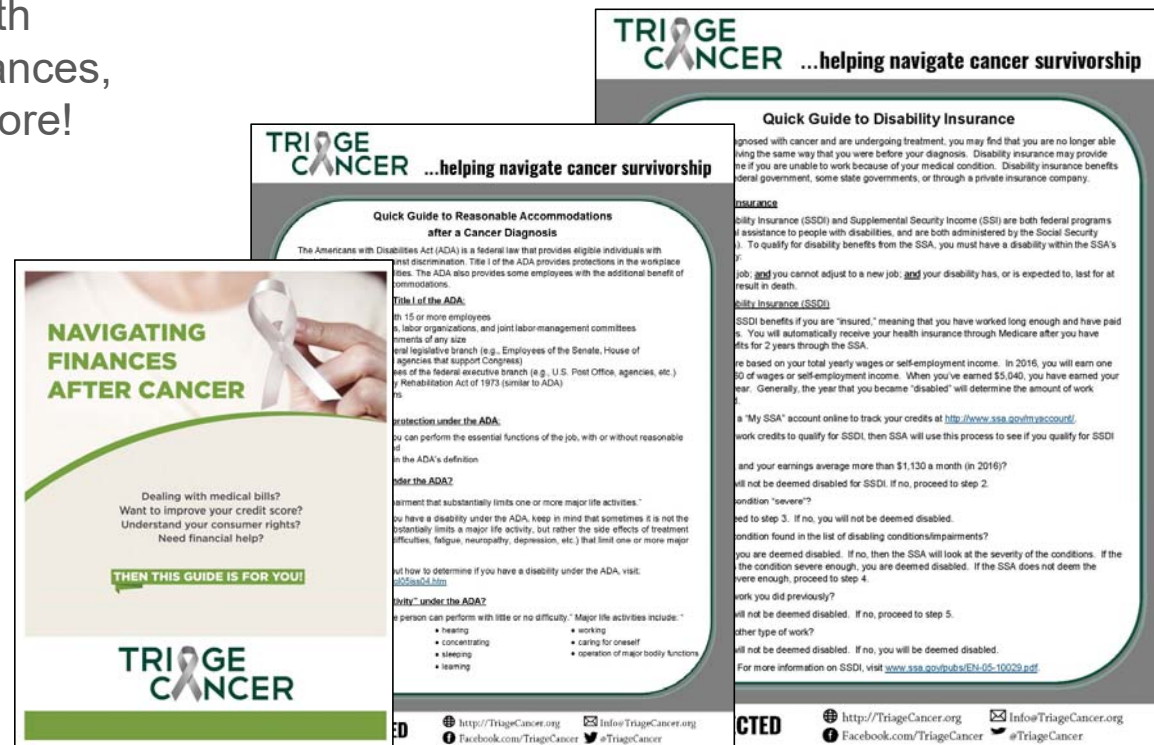
This chart covers the state laws that provide benefits and protections in the areas of: Employment & Disability Insurance. Scroll down for a second chart covering the state laws that provide benefits and protection in the area of health insurance. This information changes frequently.

	Has Fair Employment Law (Covering Employers With Less Than 15 Employees):	Has State Disability Insurance:	Has Paid Sick Leave:	Has Paid Family Leave:	Has Employer Credit Check Law:	Has Medical Marijuana Law:	Has Social Media Privacy Law
ALABAMA	1					✓	
ALASKA						✓ full legalization	
ARIZONA						✓	
ARKANSAS	9 (but 15 for RA's)						✓
CALIFORNIA	5	✓	✓ San Francisco (full pay), Oakland, Emeryville	✓ 6 weeks	✓	✓	

Triage Cancer Quick Guides & Materials

Quick Guides on
employment,
disability, health
insurance, finances,
advocacy & more!

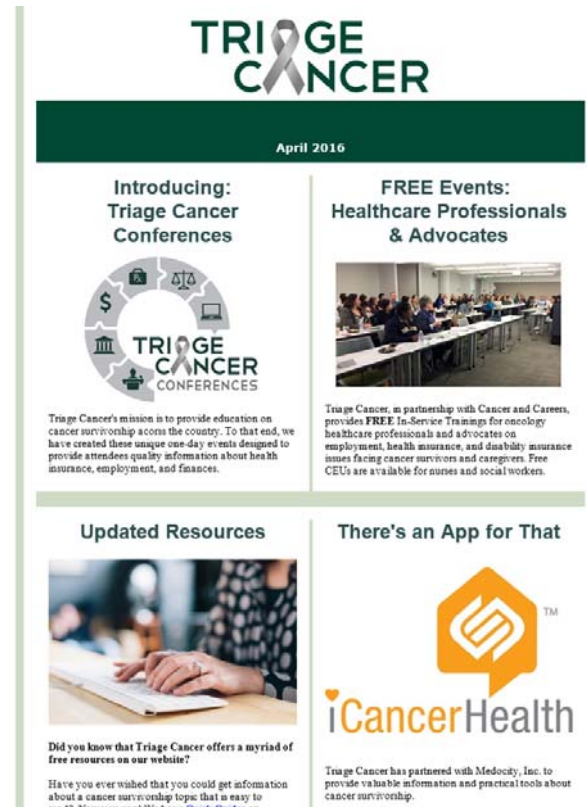
<http://trriagecancer.org/resources/quickguides>



Triage Cancer Educational Blog & E-Newsletter



<http://trriagecancer.org/blog>



Supporter
Triage Cancer Webinar Series



www.science37.com

Today's Speaker: Dr. Sikaria

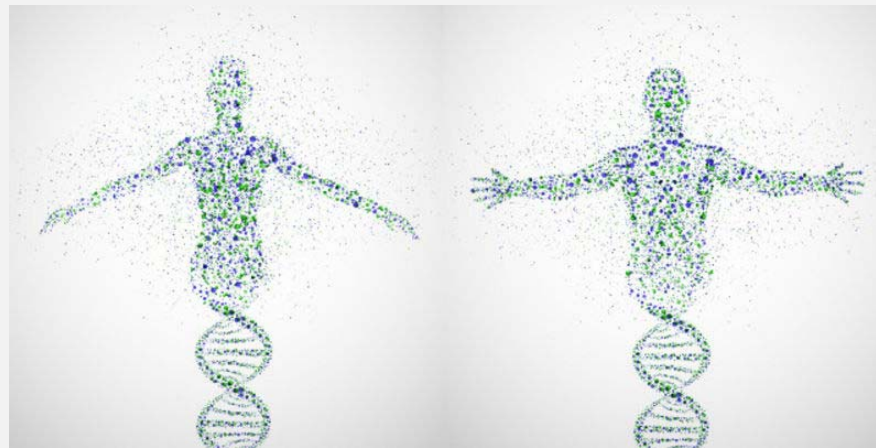


OVERVIEW

- What is precision medicine?
- How do genes and other factors impact precision medicine?
- How is precision medicine affecting cancer treatment?
- How does precision medicine relate to oncology research?
- How will precision medicine affect the future of cancer care and research?

PRECISION MEDICINE

- Takes into account individual variability in genes, environment, and lifestyle for each person
- Focus interventions on those who will benefit, sparing expense and side effects for those who will not



PRECISION MEDICINE: A PARADIGM SHIFT

Traditional “One-Size-Fits All” Approach

All patients with the same diagnosis receive same treatment



Precision Medicine Approach

Treatment strategy based on patient's unique genetic profile



Genetic Profile A
Targeted Therapy



Genetic Profile B
Standard Therapy

- Biologic diversity provides opportunities for exploitation of interpatient tumor heterogeneity by **ungrouping a population into molecularly defined subsets** in which mutations and/or abnormal gene expressions drive cancer cell growth and survival and can serve as drug targets
- Treatment decisions made based on tumor phenotype and genomic profile hold the promise to **maximize efficacy and minimize toxicity**

Image adapted from http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_age_of_pmc_factsheet.pdf

IMPRECISION MEDICINE

For every person they do help (blue), the ten highest-grossing drugs in the United States fail to improve the conditions of between 3 and 24 people (red).

1. ABILIFY (aripiprazole) Schizophrenia



2. NEXIUM (esomeprazole) Heartburn



3. HUMIRA (adalimumab) Arthritis

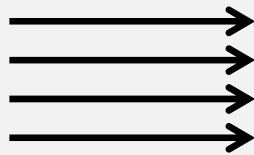


4. CRESTOR (rosuvastatin) High cholesterol

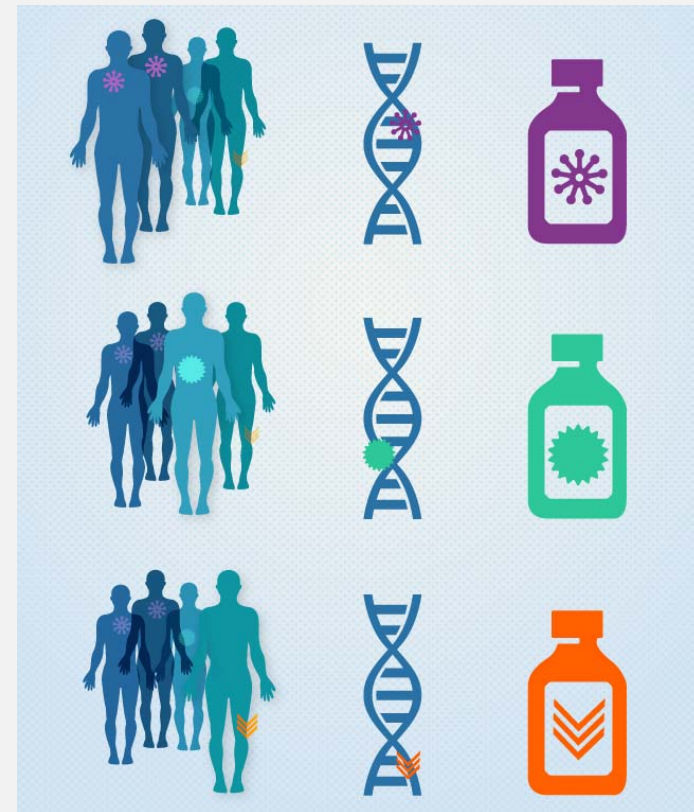


PRECISION MEDICINE IN CANCER

EGFR
BCR-ABL
ALK
HER2

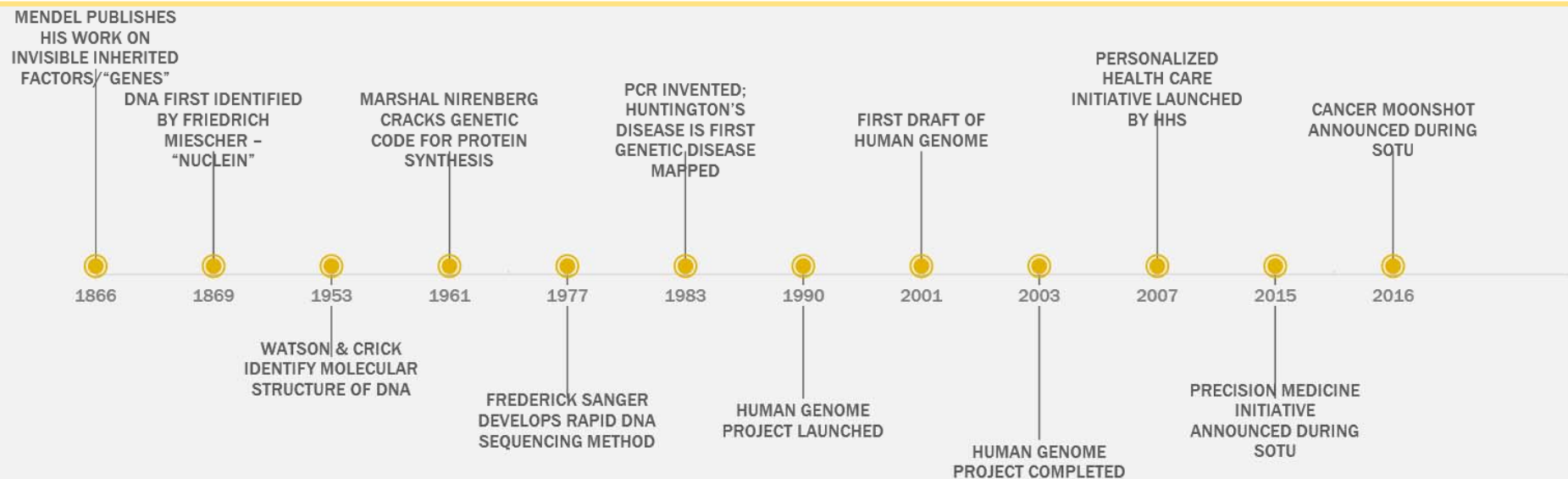


erlotinib
imatinib
crizotinib
trastuzumab



HISTORY OF PRECISION MEDICINE

Historical Milestones



PERSONALIZED VS PRECISION

- Physicians like to think all medicine in “personalized”
- Precision refers to more accurately defining patient subpopulations and appropriate treatment
- Goal is to "lead a new era of medicine, one that delivers the right treatment at the right time”
- “Precision medicine” initiative announced by President Obama in his 2015 State of the Union address

PRECISION MEDICINE IS BASED ON

- Genes and Genomics
- Other “omics”
- Environmental factors
- Behavioral differences

GENETICS VS GENOMICS

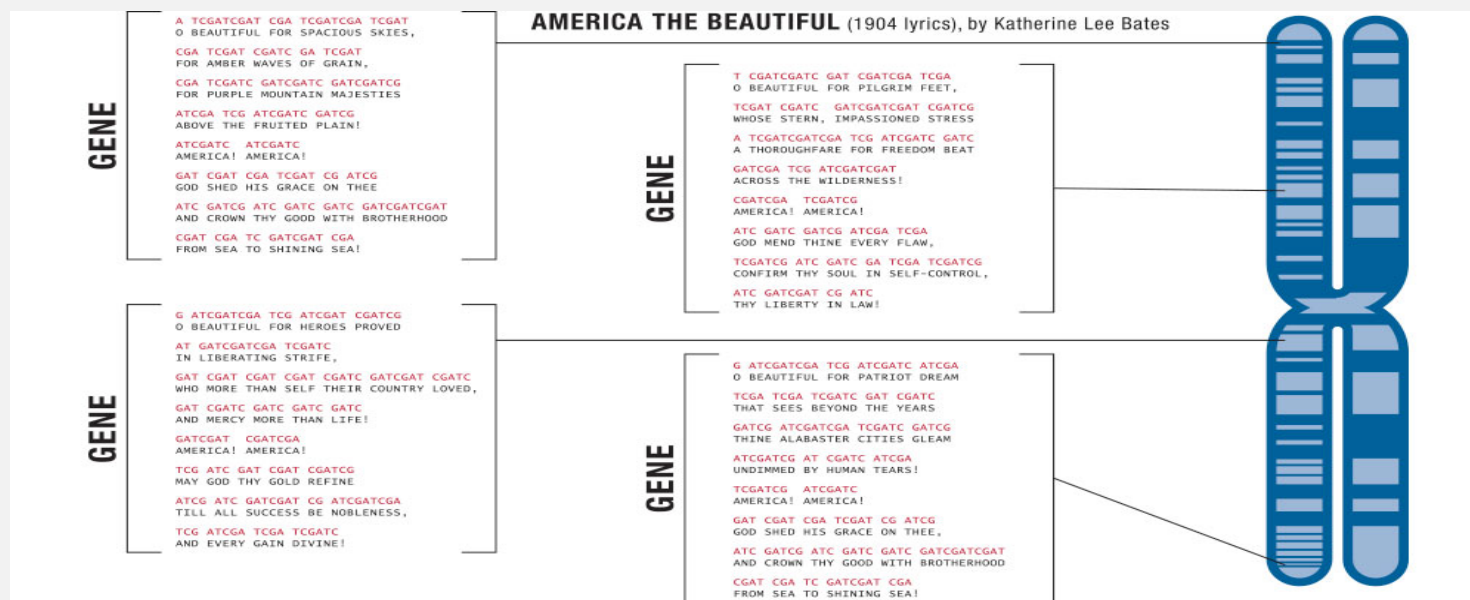
- **Genetics** refers to the study of a particular gene
- **Genomics** refers to the study of the entire genome of an organism

GENETICS VS GENOMICS

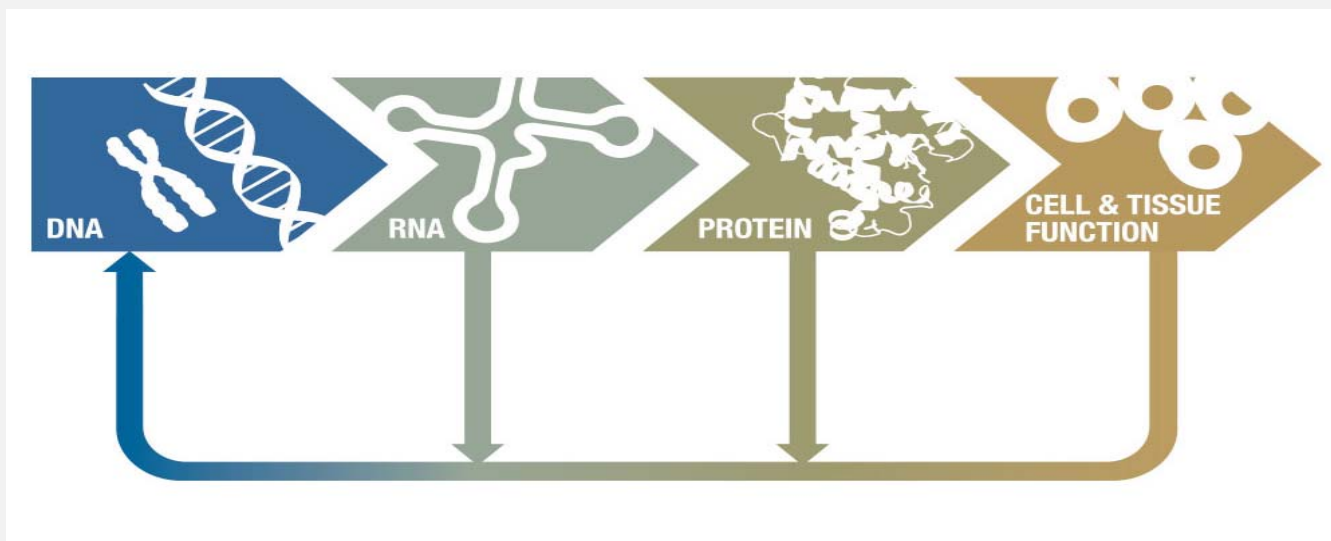
- Human DNA = approximately 3 billion DNA base pairs located on 23 pairs of chromosomes
- Human genome contains 20,000 to 25,000 genes
- In 2003, the Human Genome Project took blood samples from over 100+ to sequence the first complete human genome to provide the basis for ongoing biomedical research → **has led to precision medicine.**



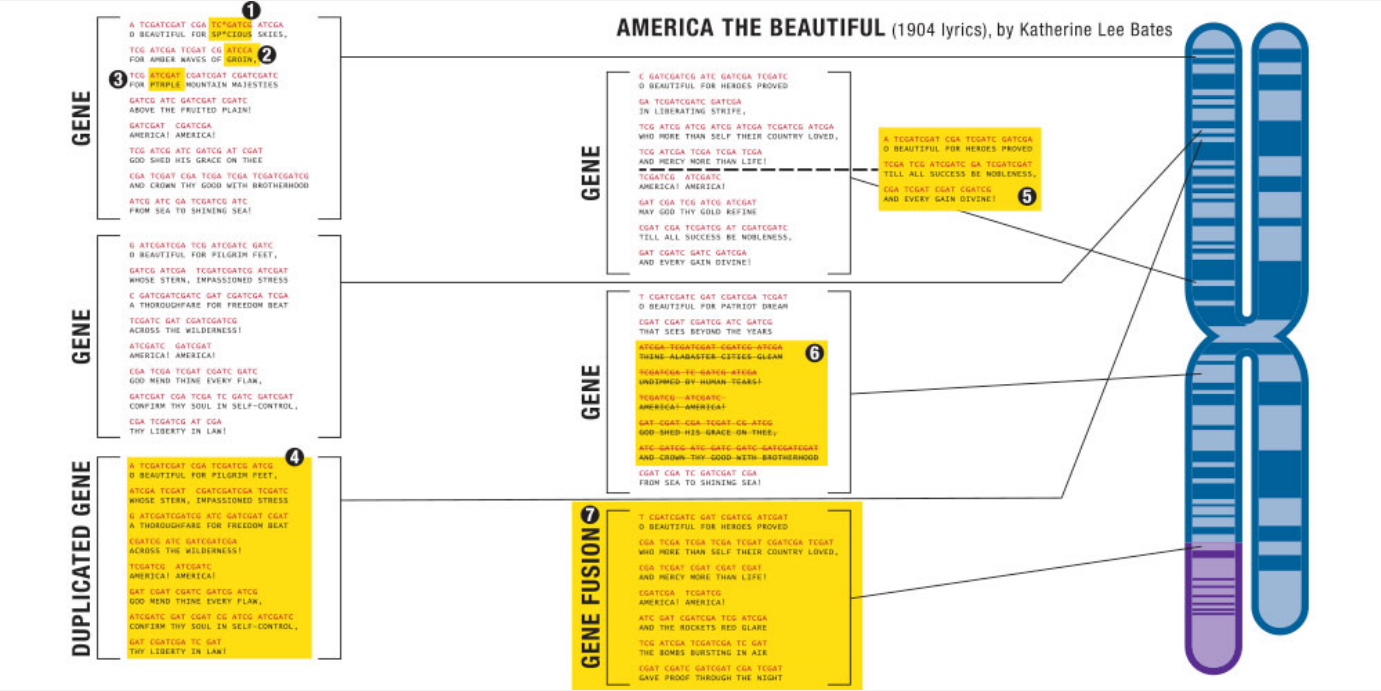
GENOMIC STRUCTURE



DECIPHERING THE GENETIC CODE



THE IMPACT OF GENETIC MUTATIONS



GENETIC VS GENOMIC TESTING

- Specific single gene tests
 - Usually for a focused evaluation of a heritable disease
 - E.g. *BRCA1* and *BRCA2* testing
- Specific gene panels
 - Panels testing for multiple mutations that cause the same phenotype
 - E.g. Comprehensive cancer panel (*APC*, *ATM*, *BRCA*, *CDH1*, *CHEK2*, *MLH1*, *PTEN*, *STK1*, *TP53*, *VHL*, etc.)
- Whole genome or exome sequencing
 - Exome sequencing – sequencing the coding regions of our DNA
 - Genome sequencing – sequencing the coding and regulatory elements of our DNA

TYPES OF GENETIC TESTING AVAILABLE

- Specific genetic carrier traits
 - Direct-to-consumer testing kits
- Genotyping panels of selected susceptibility variants
 - Panels that include SNPs associated with common, complex diseases
- Tumor Genetic Analysis
 - Next Generation Sequencing

Health Risks (122) ?

↑ ELEVATED RISKS

	YOUR RISK	AVERAGE RISK
Coronary Heart Disease	33.1%	24.4%
Psoriasis	15.0%	10.1%
Restless Legs Syndrome	5.2%	4.2%
Exfoliation Glaucoma	2.9%	1.0%
Lupus (Systemic Lupus Erythematosus)	1.1%	0.2%
♀		

See all 122 risk reports...

Traits (62) ?

REPORT	RESULT
Alcohol Flush Reaction	Does Not Flush
Bitter Taste Perception	Can Taste
Blond Hair	28% Chance
Earwax Type	Wet
Eye Color	Likely Blue

See all 62 traits...

Inherited Conditions (53) ?

REPORT	RESULT
Hemochromatosis (HFE-related)	Variant Present
ARSACS	Variant Absent
Agnesis of the Corpus Callosum with Peripheral Neuropathy (ACCPN)	Variant Absent
Alpha-1 Antitrypsin Deficiency	Variant Absent
Autosomal Recessive Polycystic Kidney Disease	Variant Absent

See all 53 carrier status...

Drug Response (25) ?

REPORT	RESULT
Clopidogrel (Plavix®) Efficacy (CYP2C19-related)	Updated Reduced
Abacavir Hypersensitivity	Typical
Acetaldehyde Toxicity	Typical
Fluorouracil Toxicity	Typical
Hepatitis C Treatment Response	Typical

See all 25 drug response...

OTHER SOURCES OF PRECISION VARIATION

- Other “omics”:
 - Epigenomics: how much of your DNA is expressed or suppressed
 - Proteomics: variation of proteomes under different conditions that affect biological diseases
 - Metabolomics: unique chemical fingerprints that specific cellular metabolic processes
 - Lipidomics: pathways and networks of cellular lipids in biological systems
 - Exposomics: totality of human environmental exposures from conception onwards
 - Microbiomics: the collective genomes of the microorganisms that reside on or in the individual human body

PRECISION ONCOLOGY EXAMPLE: SKIN CANCER



Past → Dacarbazine
↓
5% response rate

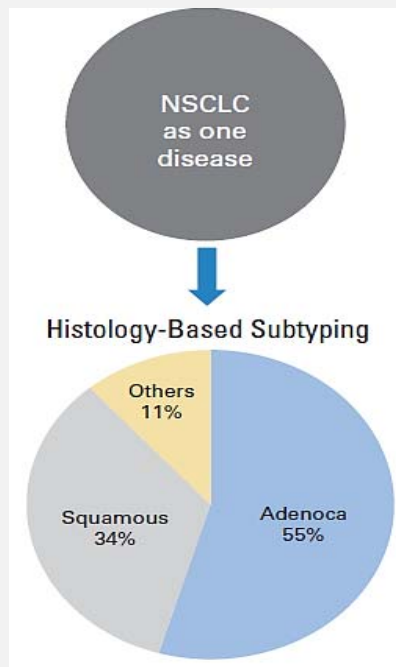


Present → *BRAF*^{V600E}
Vemurafenib

Wagle, Emery, et. al JCO 2011

PRECISION EXAMPLE: LUNG CANCER

Classification



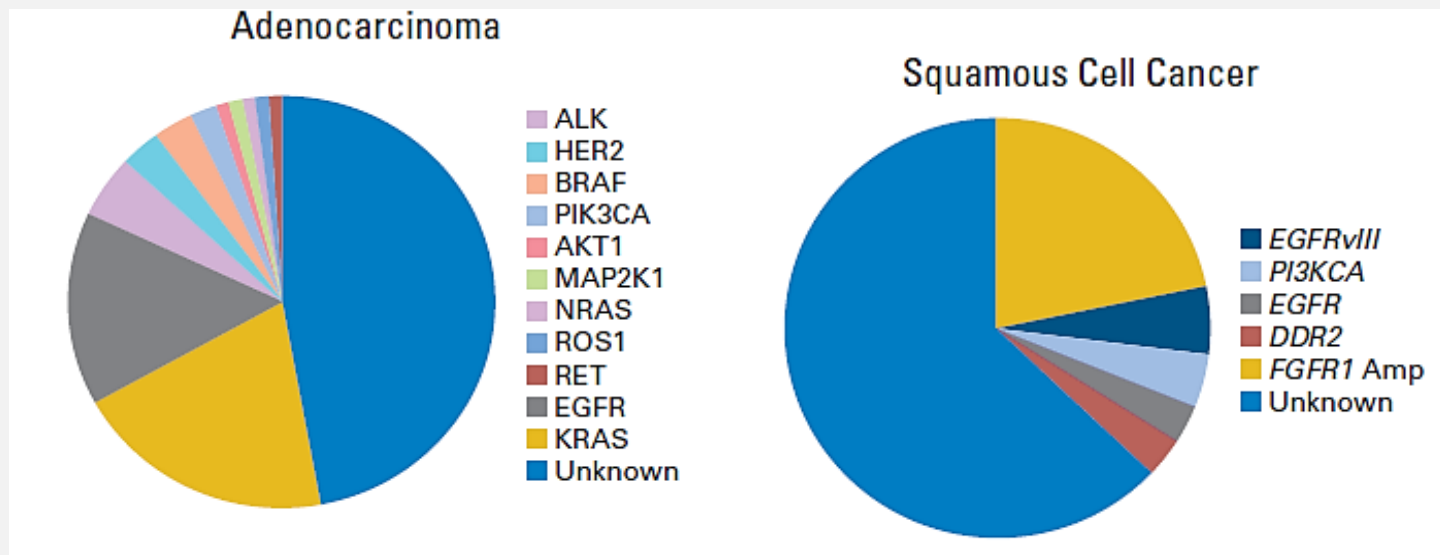
Shotgun or “One-Size-Fits All” Approach



1. Li et al. *J Clin Oncol*. 2013;31(8):1039.

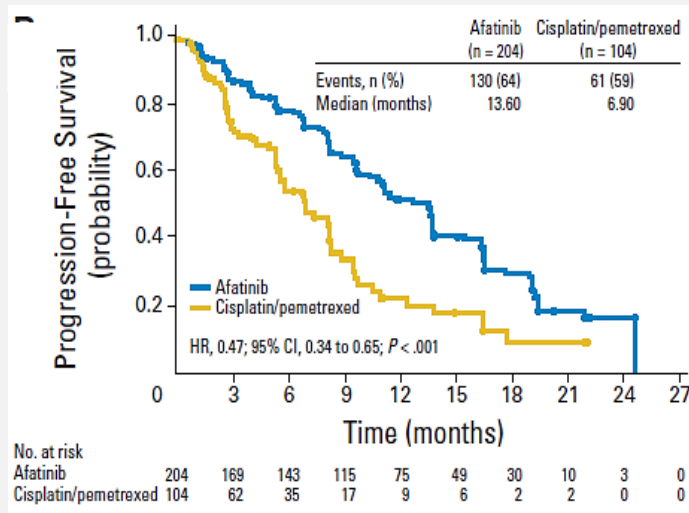
2. NSCLC: ESMO Clinical Recommendations. *Ann Oncol*. 2007;18:(Supp 2):ii30-ii31.

LUNG CANCER IS VARIABLE

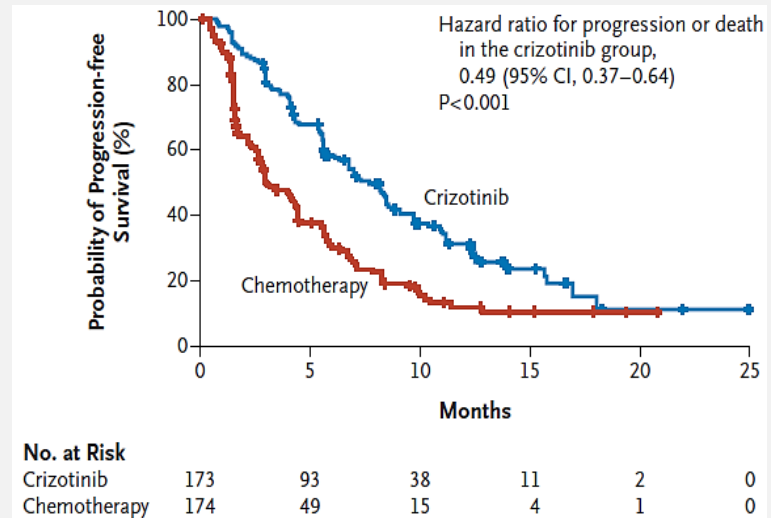


PRECISION MEDICINE TREATMENT OF LUNG CANCER

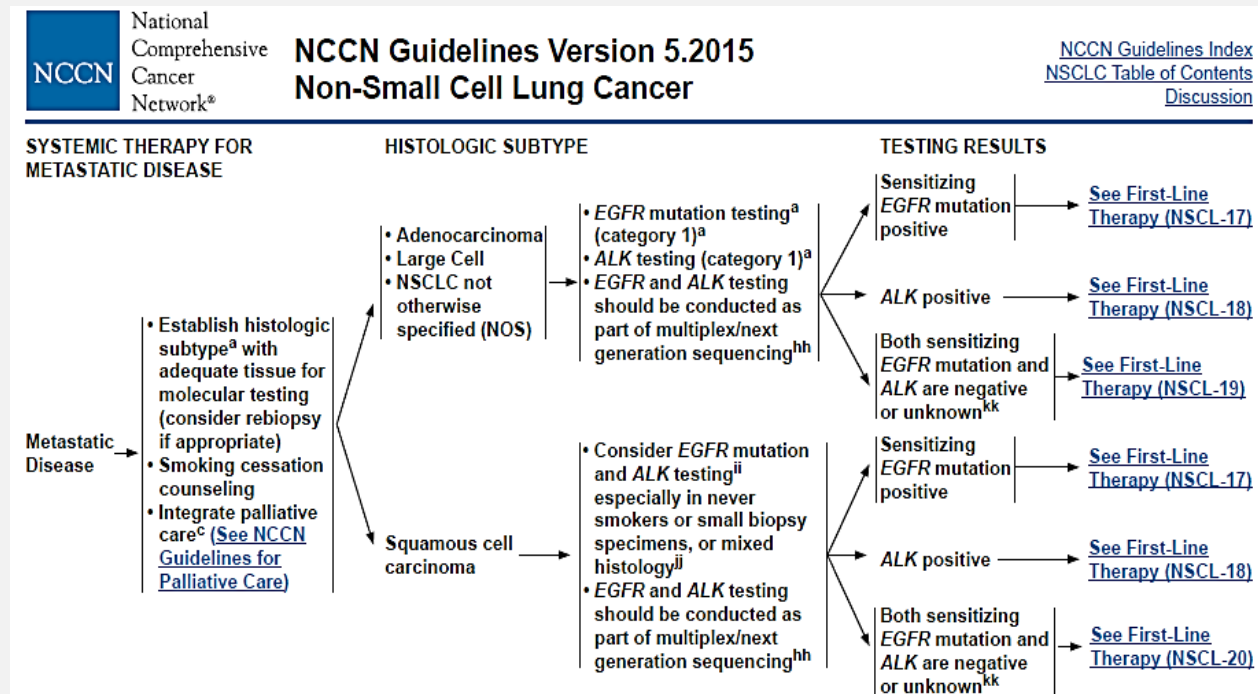
EGFR mutation



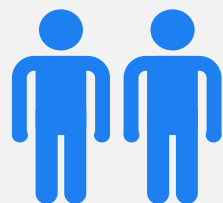
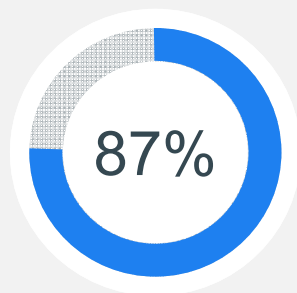
ALK mutation



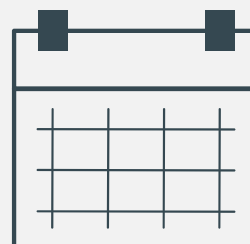
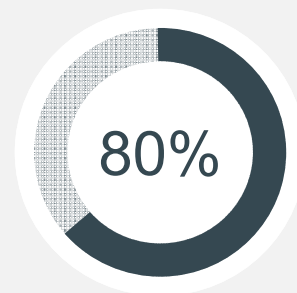
NSCLC TREATMENT GUIDELINES



CLINICAL TRIALS



Patients Somewhat
Willing or Willing to
Participate

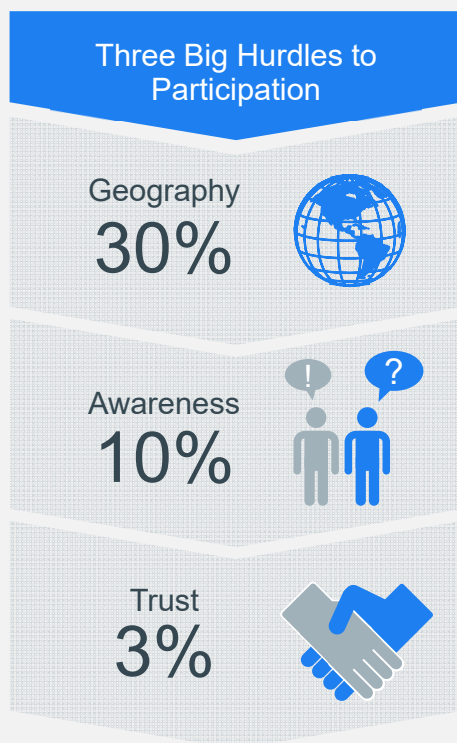


Clinical Trials Delayed
Due to Enrollment

Tufts CISCIP 2013 International Survey on Public and
Patient Attitudes About, and Experiences with, Clinical
Research Studies

Lamberti "State of Clinical Trials Industry"

CLINICAL TRIALS



70% live more than 2 hours travel time away

2/3 of those are unaware



<3% participate

PRECISION MEDICINE INITIATIVE

“Tonight, I’m launching a new Precision Medicine Initiative to bring us closer to curing diseases like cancer and diabetes – and to give all of us access to the personalized information we need to keep ourselves and our families healthier.”

-President Barak Obama

THE PRECISION MEDICINE INITIATIVE



PMI OBJECTIVES

- Develop ways to measure risk for a range of diseases based on the interaction between environmental exposures and genetic factors.
- Identify the causes of individual differences in response to commonly used drugs (pharmacogenomics).
- Discover biological markers that signal increased or decreased risk of developing common diseases.
- Use mobile health technologies to correlate activity, physiological measures, and environmental exposures with health outcomes.
- Develop new disease classifications and relationships.
- Empower study participants with data and information to improve their own health.
- Create a platform to enable clinical trials of targeted therapies.

PMI FUNDING:

The President called for \$215 million in fiscal year 2016 to support the PMI

- \$130 million allocated to NIH to build a national, large-scale research participant group (cohort)
- \$70 million allocated to National Cancer Institute to lead efforts in cancer genomics
- \$10 million to FDA to acquire additional expertise and advance the development of high quality, curated databases
- \$5 million to Office of the National Coordinator for Health Information Technology (ONC) to support the development of interoperability standards and requirements that address privacy and enable secure exchange of data across systems

PRECISION MEDICINE INITIATIVE ONCOLOGY RESEARCH GOAL

- Apply precision medicine to cancer treatment.
- To reach this goal, PMI-Oncology will support:
 - Identification of new cancer subtypes, therapeutic targets
 - Efficiently test combination therapies
 - Partner with private sector to accelerate precision medicine
 - Understand and combat drug resistance
 - NCI clinical trials as model research study:
 - NCI-MATCH: solid tumors, lymphomas (multi-drug, multi-arm)
 - Lung-MAP: squamous cell lung cancer (multi-drug, multi-arm, randomized)

ALL OF US RESEARCH PROGRAM



ALL OF US RESEARCH PROGRAM

WHAT IS IT?

Precision medicine is a groundbreaking approach to disease prevention and treatment based on people's individual differences in environment, genes and lifestyle.

The *All of Us* Research Program will lay the foundation for using this approach in **clinical practice**.

WHAT ARE THE GOALS?

Engage a group of **1 million or more U.S. research participants** who will share biological samples, genetic data and diet/lifestyle information, all linked to their electronic health records. This data will allow researchers to develop more precise treatments for **many diseases and conditions**.

Pioneer a new model of research that emphasizes **engaged research participants, responsible data sharing and privacy protection**.



Research based on the cohort data will:

- Lay **scientific foundation** for precision medicine
- Help identify new ways to **treat and prevent disease**
- Test whether **mobile devices**, such as phones and tablets, can encourage healthy behaviors
- Help develop the **right drug** for the **right person** at the **right dose**

WHY NOW?

The **time is right** because:

We have a greater understanding of human genes



People are more engaged in healthcare and research



We have the tools to track health information and use large databases



Research technologies have improved



Follow the Program's progress and be one of the first to join this landmark effort.

www.nih.gov/AllOfUs-Research-Program

ALL OF US RESEARCH PROGRAM

- Formerly known as the PMI Cohort Program
- Participant-engaged, data-driven enterprise supporting research including lifestyle, environment, and genetics to produce new knowledge with the goal to develop more effective ways to prolong health and treat disease
- Will enroll participants from diverse social, racial/ethnic, ancestral, geographic, and economic backgrounds, from all age groups and health statuses.
- Broad, powerful resource for researchers working on a variety of important health questions
- Importantly, the program will focus not just on disease, but also on ways to increase an individual's chances of remaining healthy throughout life

PRECISION MEDICINE ONCOLOGY CHALLENGES

- What are the driver mutations?
- Can drugs be developed for each mutation?
- Is drug resistance inevitable?
- How will platforms be validated?
- How will clinical trials be designed?
- What about tumor heterogeneity?
- Will approved and investigational drugs be available?

WHAT CAN YOU DO?

- Discuss with your physician if precision medicine should be part of your care.
 - Would you benefit from genomic sequencing?
- Consider participating in population based or tumor registry clinical trials.
 - Non-invasive research for oncologists to learn more about all cancers.
- Discuss with your physician if clinical trials might be right for you.
 - Registry of clinical trials can be found at clinicaltrials.gov.
 - New technology and patient focused trial models are making it easier for the patient to participate in a variety of trials.
 - One such company is Science 37 (which sponsored this talk) which is attempting to accelerate clinical research by using technology to remove geographic barriers so any patient can participate in a clinical trial.

CONCLUSION

- Precision medicine is an evidence based medicine approach utilizing specific information about a patient to tailor treatment to that patient.
- The Precision Medicine Initiative is a government supported push to increase medical knowledge and patient access to cutting edge care.
- Clinical trials support and participation is critical for precision medicine to become ubiquitous part of the care process.

THANK YOU

- Questions?

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Facebook

[www.Facebook.com/TriageCancer](https://www.facebook.com/TriageCancer)

Blog

www.TriageCancer.org/blog