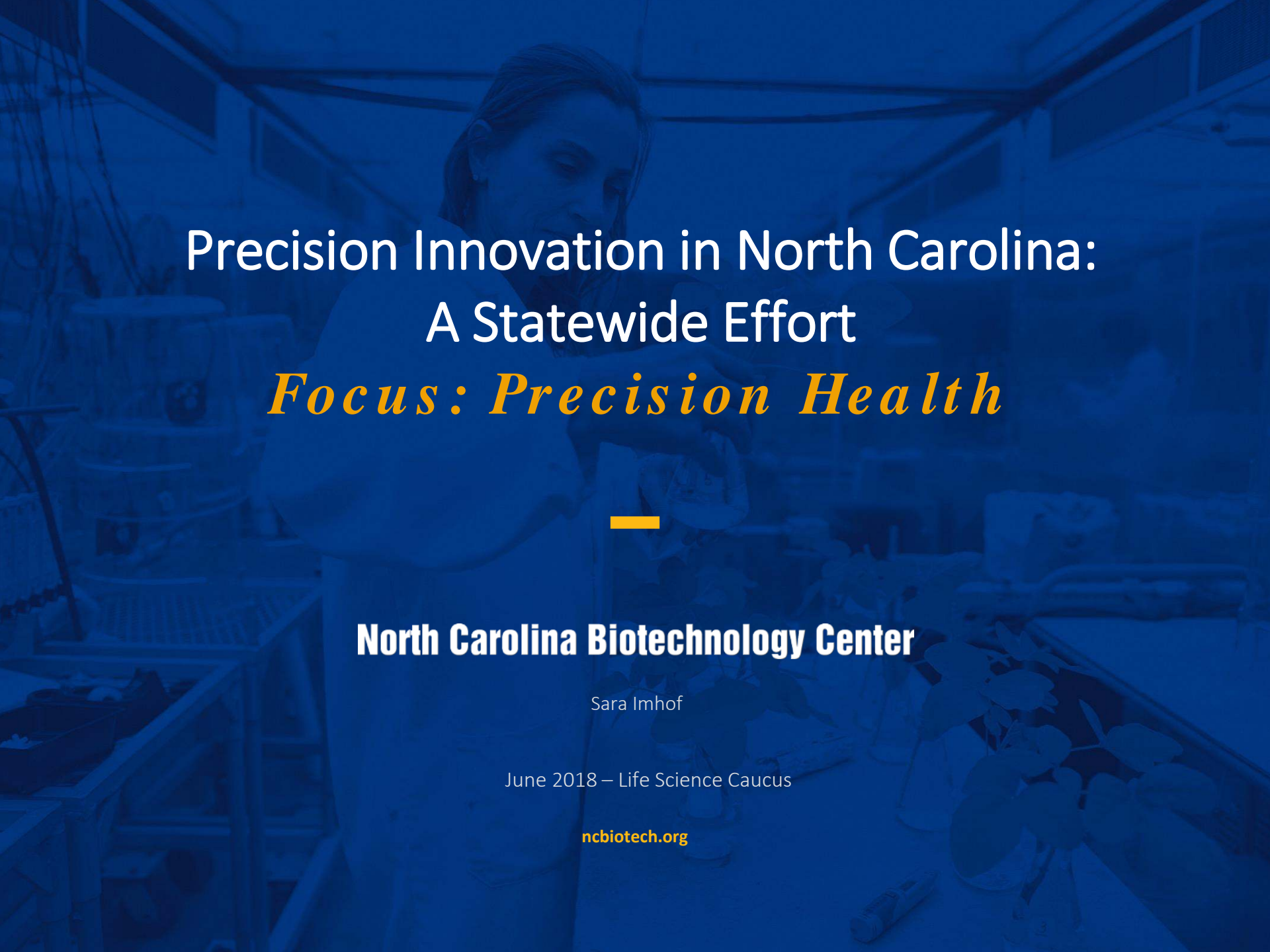


Precision Innovation in North Carolina: A Statewide Effort

Focus: Precision Health

North Carolina Biotechnology Center

Sara Imhof

June 2018 – Life Science Caucus

ncbiotech.org

Precision Innovation

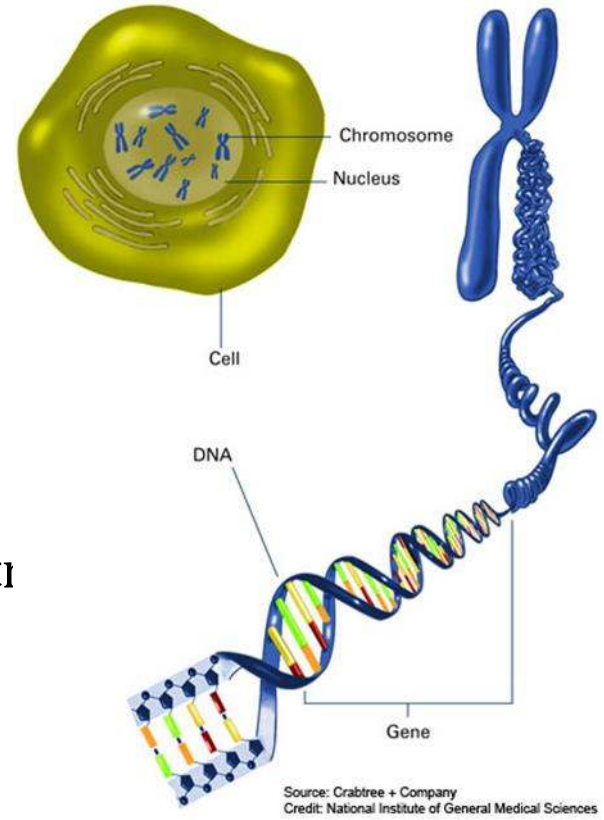
- **Precision Agriculture** is a management system that is information and technology based, is site specific and uses one or more of the following sources of data: soils, crops, nutrients, pests, moisture, or yield, for optimum profitability, sustainability, and protection of the environment.

- **Precision Livestock Farming (PLF)** is the use of process engineering and advanced technologies to optimize the contribution of each animal.

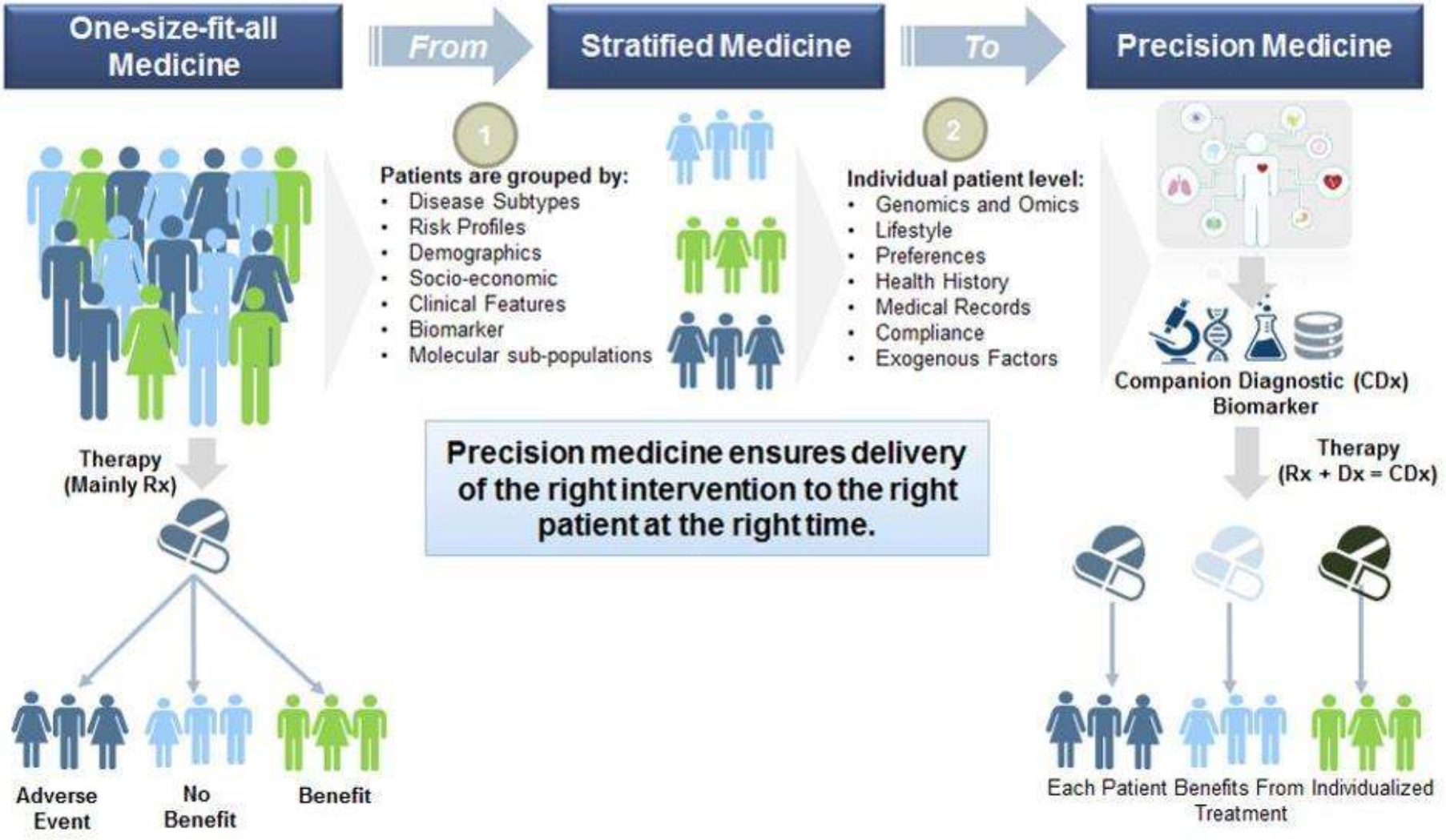
- **Precision Medicine** is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment and lifestyle.

Variation in the Human Genome

- Our genome contains 3 billion base pairs of DNA
- Between 2 people, there are approximately 3 million base pair differences
- Understanding variation has shown promise for improving disease treatı and outcomes



Precision Medicine; Paradigm Shift in Treatment



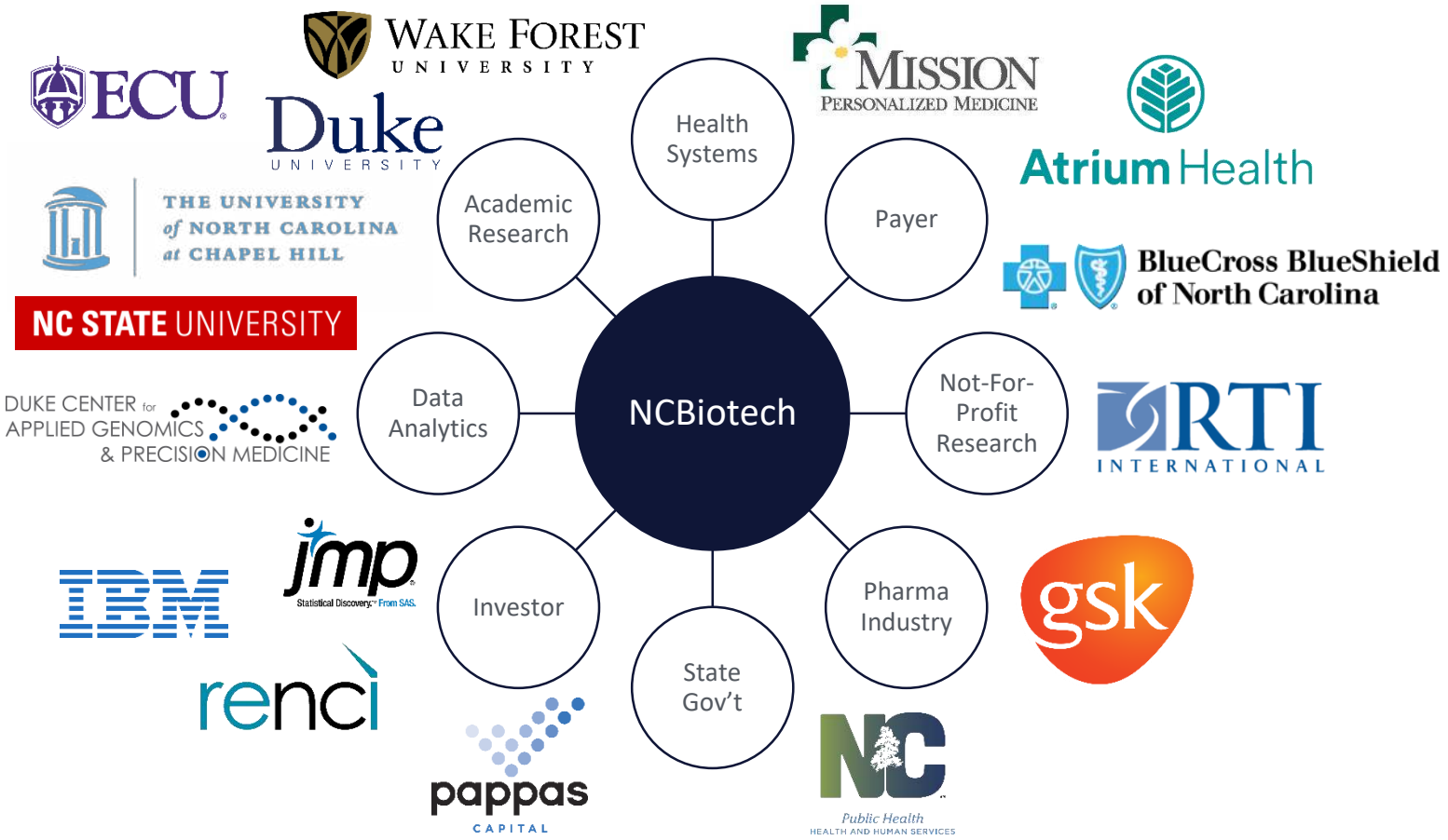
Source: Frost & Sullivan -Figure 1: New Paradigm Shift in Treatment

Precision Health

Precision health extends opportunities provided by the preventive, therapeutic, and diagnostic elements of precision medicine to address disease and population health challenges.

The goal of precision health is to improve overall population health by reducing disease burden through the delivery of optimized screening, prevention, and intervention services to those who will benefit, thereby sparing expense and adverse effects for those who will not.

North Carolina Precision Health Collaborative



Advancing transformative, data-driven precision health through innovation and partnership

Precision Health IMPACT: benefiting ALL of NC

Research * Education * Health Care Delivery System
Data / Infrastructure * Economic Development * Population / Public Health

What is the NIH *All of Us* Research Program?

All of Us RESEARCH PROGRAM | The Future of Health Begins With You

The *All of Us* Research Program is a historic, longitudinal effort to **gather data from one million or more people** living in the United States **to accelerate research and improve health**. By taking into account individual differences in **lifestyle, socioeconomics, environment, and biology**, researchers will uncover paths toward delivering **precision medicine – or individualized prevention, treatment, and care – for all of us**.

"All of Us is among the most ambitious research efforts that our nation has undertaken!"

NIH Director Francis Collins, M.D., Ph.D.

What are the potential activities asked of participants in the current protocol?

Enroll, Consent and Authorize EHR

- *Recruiting 18+ years old initially; plan to include children in 2019*
- *Online, interactive consent*
- *Includes authorization to share Electronic Health Record (EHR) data*

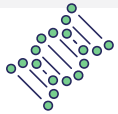
Answering Surveys

- *Three initial surveys: The Basics, Overall Health, & Personal Habits*
- *Additional surveys will be released on an ongoing basis.*

*Physical Measurements**

- *Blood pressure*
- *BMI*
- *Heart rate*
- *Height*
- *Hip circumference*
- *Waist circumference*
- *Weight*

**Based on diverse sampling and capacity*



*Provide Biosamples**

- *Blood (or saliva, if blood draw is unsuccessful)*
- *Urine specimen*
- *Biosamples will be stored at the program's biobank*

**Based on diverse sampling and capacity*

Wearables and Digital Apps

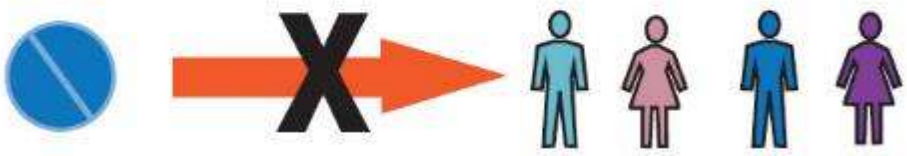
- *Share data from wearable fitness devices, starting with FitBit*
- *Share data about mood & cardio-respiratory fitness through integrated apps*
- *More integrations to come*

Coming soon

Precision Therapy / PGx

Pharmacogenomics – the study of how genes affect drug response

>95% of people have an actionable genotype, >95% of people will be on a drug that has pharmacogenetic information – in their lifetime.



The same dose for everyone is not the correct approach

Potential Results from precision therapy / PGx

Potential impact of PGx, based on return of genetic information with CDS

Extending precision medicine to primary care within EHR, With appropriate testing and clinical decision support there are significant improvements in patient safety and reduction of healthcare costs.

- In a 110 patient randomized controlled trial in 60-days in home health[1]
  - 52% reduction re-admissions (p=.007)
  - 42% reduction in ER visits (p=.045)
  - Estimated savings of over $4000 per patient

- In a 1025 patient trial in 120-days in ambulatory care[2]:
  - 71% reduction in ER visits (p=.0002)
  - 39% reduction in hospitalizations (p=.0273)
  - Estimated savings of over $1000 per patient

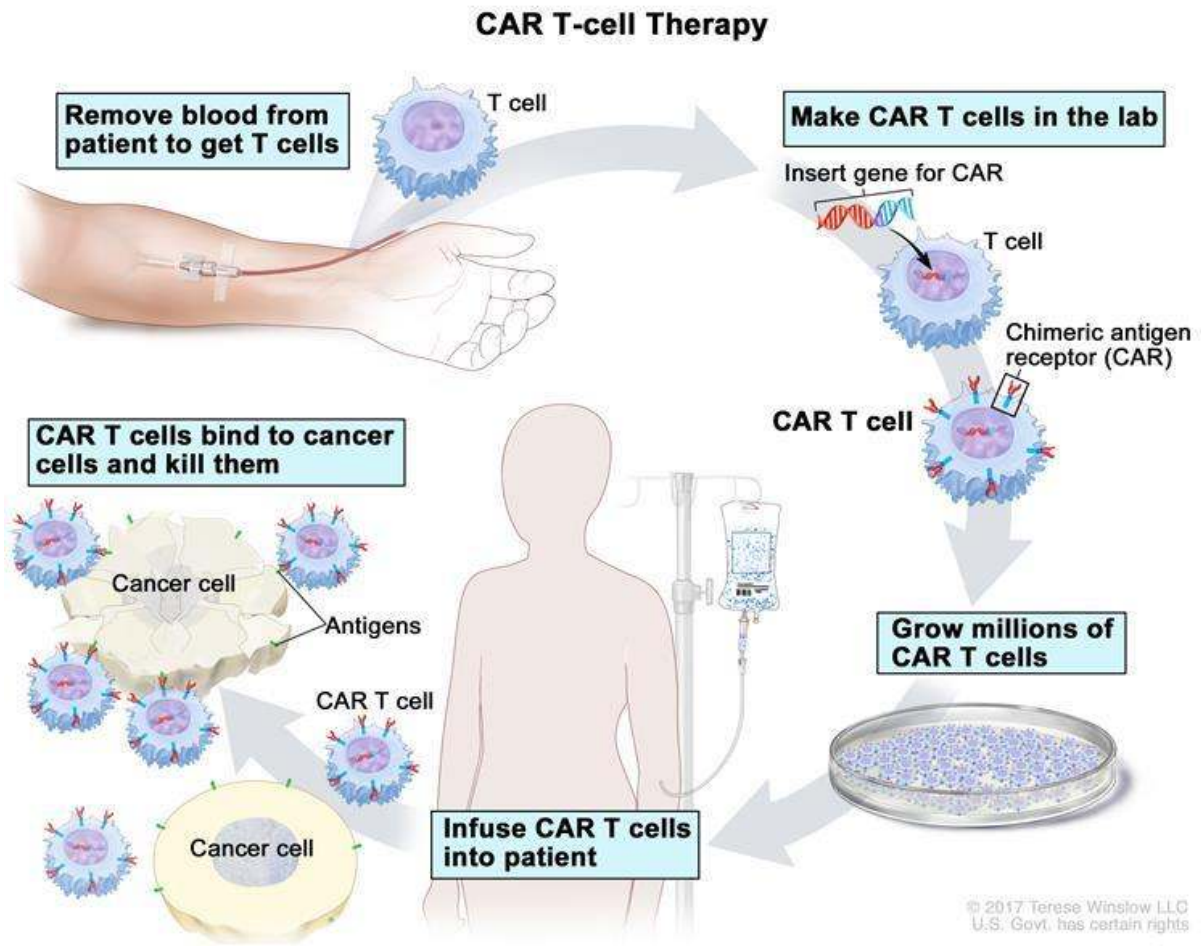
1. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0170905
2. https://www.ncbi.nlm.nih.gov/pubmed/?term=26478982

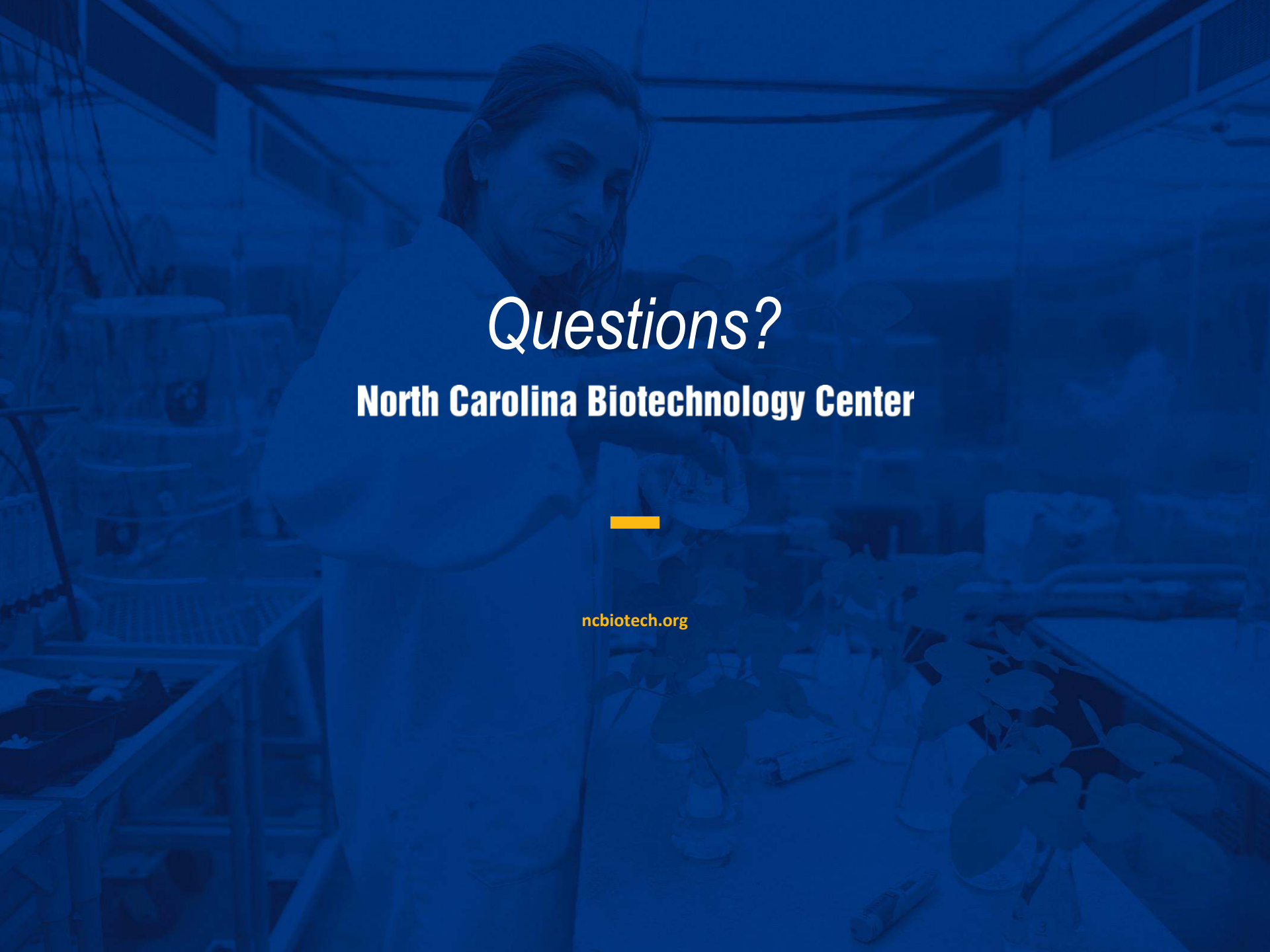
2017 FDA Precision Medicine Milestones

- Record number of personalized medicine approvals (16/46)
- First gene therapies
- First tissue agnostic oncology approval
- First expanded indications based on in vitro data

CREDIT: *PMC 2017 Progress Report*

CAR T-cell Therapy (e.g., Kymriah – Novartis)





Questions?

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