



Emerging Opportunities for Precision Medicine

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Team Introduction



CBE represents a diverse range of backgrounds and interests, and our team is no different. We are pleased to present this deliverable, which represents eight weeks of research on bringing innovations in precision medicines to market.



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PROJECT OVERVIEW

Over the course of four weeks, our team of five students was tasked with researching the science behind recent precision medicine innovations and analyzing how well-equipped the US healthcare system is to handle bringing these technologies to market.

In the following deliverable, we outline actionable strategies – based on in-depth research from Harvard databases and interviews with industry experts – to ease the integration of two innovative case studies in precision medicine to patient care.



Section 1: Industry Overview

Section 2: Precision Immunization

Section 3: Liquid Biopsy

Section 4: Expert Interviews

Section 5: Implementation Strategies

Precision Medicine Industry Trends



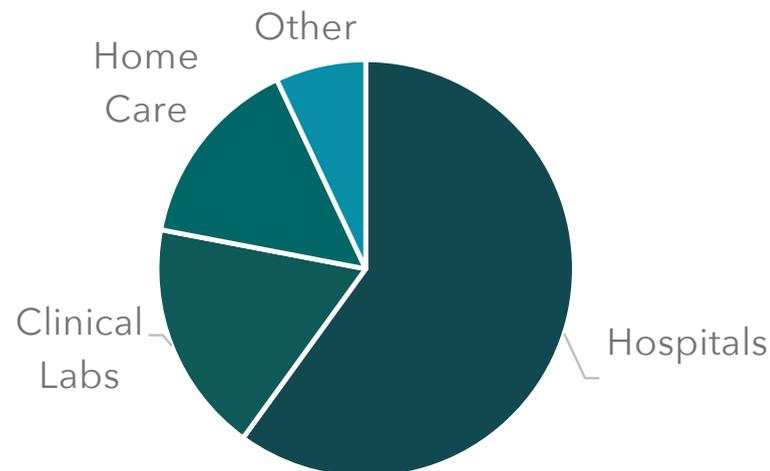
The Precision Medicine Industry is in a period of high growth with new technological developments in Artificial Intelligence, CRISPR-Cas9 gene editing technology, and mRNA vaccines adding to its life saving potential.



PRECISION MEDICINE

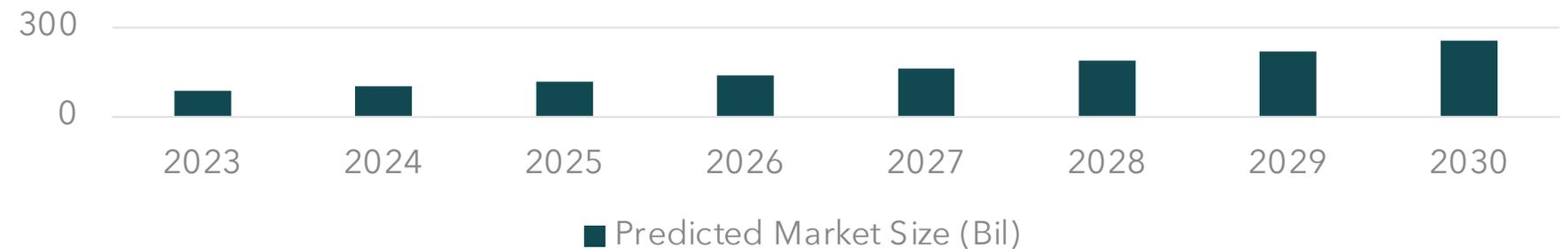
- Also known as **personalized medicine**
- Takes each **individual patient's genes, environment, and lifestyle** into account in order to **optimize treatment and disease prevention**
- Uses **emerging technologies** to tailor treatments to patients who will benefit from them most
- DNA sequencing, classification of biomarkers, phenotyping technologies, and health information technologies are used

MARKET REVENUE SHARES



[BioSpace](#), [FDA](#), [Pharmaceutical Technology](#)

Predicted Market Size (Billion USD)



Trends in New Technology

A.I.	<ul style="list-style-type: none"> • Significantly reduces the amount of time to interpret sequencing data that is crucial to identify unique mutations and suggest personalized treatments 	<ul style="list-style-type: none"> • Expedites drug development by identifying candidates with novel designs and therapeutic value as well as offering improvements to the efficacy of drugs
CRISPR-Cas9	<ul style="list-style-type: none"> • Has potential to transform entire biotech industry due to ability to treat genetic disorders caused by single-gene mutations quickly and precisely 	<ul style="list-style-type: none"> • Roadblocks include ethical issues surrounding gene editing and low enrollment in clinical trials due to risk of adverse effects in patients
mRNA	<ul style="list-style-type: none"> • mRNA vaccines entered the market with the COVID-19 vaccine in 2021 • FDA has turned attention towards mRNA vaccines outside of COVID-19 recently 	<ul style="list-style-type: none"> • mRNA vaccines with precision medicine will lead to improved treatment outcomes by fighting diseases at the root cause and tailoring to individual cases

Public-Private Partnerships in Precision Medicine



Public-private partnerships are crucial to success in precision medicine because they allow drug development to occur much more efficiently when there is cooperation between government agencies, researchers, and industry.

Innovative Medicines Initiative (IMI)

- The IMI is a **joint undertaking** between the **EU and the European Federation of Pharmaceutical Industries and Associations (EFPIA)** that is the “**world’s largest public-private initiative in the life sciences**”
- Accelerating Research and Development for Advanced Therapies (ADAT) is a **consortium of 34 public and private organizations from the US and Europe**, including Pfizer. They are working under the IMI to **develop new, advanced cell and gene therapies for rare diseases**

Lung-MAP

- A unique public-private partnership between the **National Cancer Institute (NCI) and private pharmaceutical companies that provide their drugs for clinical trials.**
- Very successful because it **brought together academia, patient advocacy groups, federal agencies, and industry** with a **shared goal of getting effective treatments to patients as quickly as possible**

NIH Accelerating Medicines Partnership

- The National Institute of Health (NIH) has launched several **Accelerating Medicines Partnerships**, including the Alzheimer’s Disease Program which is a public-private partnership between the **NIH and several private companies and organizations.**
- This project supported single-cell profiling and computational modeling to enable a **precision medicine approach to drug development**

Critical Path Institute

- An independent, non-profit founded in 2005 by the FDA as a **neutral third party to facilitate public-private partnerships** of regulatory agencies, academic institutions, pharmaceutical firms, and patient groups
- Has had **tremendous success developing drugs quickly and efficiently** to treat many diseases including Non-Small Cell Lung Cancer, Tuberculosis, Type-1 Diabetes, Alzheimer’s Disease, and Parkinson’s Disease
- **Precision medicine leader** discovering biomarkers for polycystic kidney disease as a drug development tool

[C-Path](#), [Lung-MAP](#), [NIH](#), [Pfizer](#)



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Precision Immunization Overview



Vaccination is considered the most economical and effective strategy for the control of infectious diseases. However, these vaccinations often target entire populations rather than focus on specific issues defined by a variety of factors.

Why Precision Immunization?

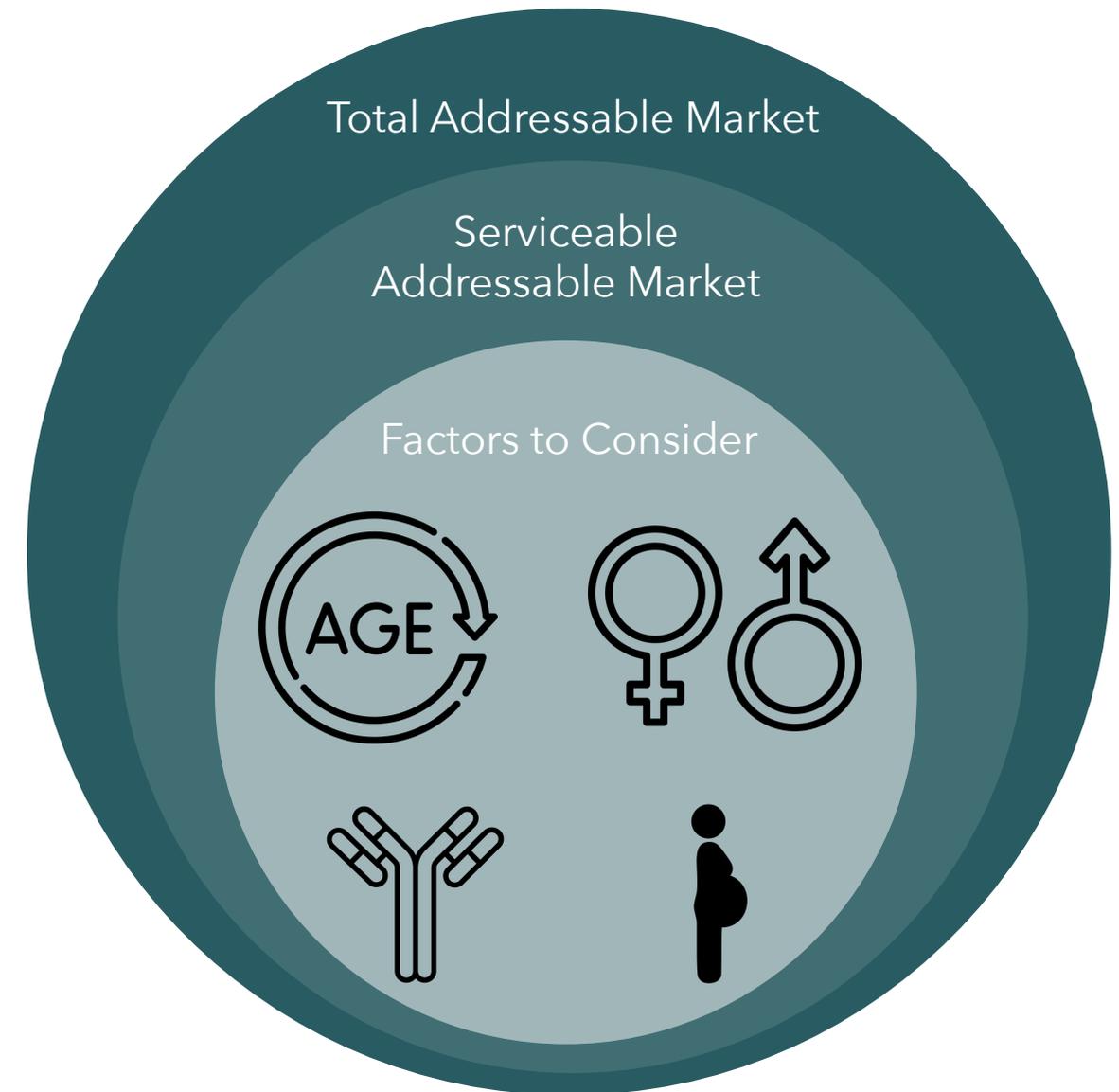
While vaccines have been named one of the **top 10 greatest health achievements**, vaccines are usually made based off of the information from **healthy individuals** within the population. In addition, only standard immunization is approved for the general population. Some vaccines are **unable** to elicit responses from **certain immune systems**, and therefore, precision immunization will be able to ensure that more individuals are protected.

Current Precision Immunization Development

The **current state** of precision immunization is that its still in its **infancy**. Not many organizations around the world have developed personalized routines and vaccinations, although countries like the **United States, the United Kingdom,** and **Australia** have begun vaccine recommendations for specific groups. The first and most important step is to establish a large database encompassing information from various clinical trials which include **immunogenicity** and **safety**.

Factors Considered When Developing Drugs

Different dosage levels, doses of vaccines, intervals between doses, and type of vaccines are required for **different people**. Factors that fall into consideration when developing precision immunizations include **age, sex, pre-existing antibodies**, and whether the individual is classified as a **Special Individual**. These include **pregnant women**, patients living with **HIV**, and **cancer patients**. In sum, an individual's genes, environment, and lifestyle is accounted for.



[Frontier](#), [National Library Of Medicine](#), [Oxford Academics](#)

Factors Influencing Precision Immunization



When determining an individual's specific need for precision immunization, normal and special factors must be taken into consideration to maximize impact and account for all personal circumstances.



Normal Factors

Age

- Younger infants require **vaccines with multiple doses or adjuvants** to achieve immunization protection. Older adults often suffer from **immunosenescence**, where vaccines have **reduced efficiency**.

Sex

- Females often develop **stronger antibody responses** to vaccines than males. In addition, sex hormones including **estrogen and testosterone control immune responses**, affecting vaccine efficacy.

Pre-existing Antibodies

- These factors result in **antigenic and de novo immune responses**. The former refers to the body's tendency to use **immunological memory** from past infections while the latter refers to when **pre-existing diseases** don't affect **current immune responses**.



Special Individual Factors

Pregnant Woman

- Physiological changes during pregnancy leads to **higher risk of infectious disease**. In addition, immunization of pregnant woman impacts **birth outcomes, with babies having varied birth weight**.

Cancer Patient

- Cancer patients, specifically those **undergoing treatments** not limited to chemotherapy and stem cell transplants have **weakened immune systems**. This reduces vaccine efficacy and timing, requiring **personalized vaccine schedules**.

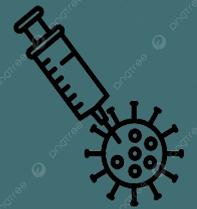
HIV

- Individuals with HIV have **compromised immune systems** that doesn't allow complete immune response. However, the results of **random HIV trials** in France suggests having **unique immunization schedules** can increase immune responses.

Problems With Traditional Vaccinations



Traditional vaccinations encounter many problems as there are multiple factors that affect the efficacy and success of vaccines. There are four main problems that are addressed with precision immunization.

	Issues	Explanation
	Variable Vaccine Response	<ul style="list-style-type: none">Traditional vaccines assume uniform immune systems, but responses vary due to age, genetics, such as how antigens are presented in the immune system, and pre-existing conditions such as how chronic diseases, and immunosuppressive treatments which diminishes vaccine efficacy.Some immunocompromised patients do not develop antibodies even after vaccination.
	Vaccine Failure	<ul style="list-style-type: none">Complex diseases such as HIV have high genetic mutability, and as such it is difficult for traditional vaccines to keep up and successfully do its job.There have been no consistent correlations of protection to vaccine efficacy making it highly difficult to judge vaccine success. Standard platforms have repeatedly failed in drug trials.
	Adverse Reactions	<ul style="list-style-type: none">Some people are more likely to experience overactive immune responses from certain immune conditions. Depending on the individual, the standard dosages could prove to overstimulate or under stimulate the immune system, leading to lower vaccine uptake.Symptoms include pain, swelling, redness at the injection site, fever, fatigue, or headache.
	Health Inequities	<ul style="list-style-type: none">Traditional vaccination tends to ignore cultural, geographic, and socioeconomic populations. Especially during drug trials, the predominant patients are non-minorities. This leads to vaccination being specific to one population and less effective to the others.The gap between rural and low-resource areas is still rising, as strategies are not data informed.

[Columbia](#), [DefinitiveHC](#), [National Institute of Health](#), [ScienceDirect](#)

Precision Immunization As The Solution



Precision immunization presents itself as a solution to many of the problems. With the tailored vaccinations towards unique individuals, many problems are able to be resolved through this innovation in precision medicine.

	Issues	How Precision Immunization Addresses Problems
	Variable Vaccine Response	<ul style="list-style-type: none">• Vaccines are now more tailored towards individual immune profiles including age, sex, genetics, and prior disease exposures.• This helps determine the optimal dosage, timing, and type for demographics like the elderly, infants, individuals with autoimmune conditions, males, and females, increasing vaccine efficacy.
	Vaccine Failure	<ul style="list-style-type: none">• In diseases like HIV and malaria, precision immunization enables Epitope targeting, which is the focus on key parts of the virus that does not usually mutate.• They also have uses of mRNA platforms to rapidly test their customized vaccine, resulting in stronger immune responses even in diseases that typically evade traditional vaccines.
	Adverse Reactions	<ul style="list-style-type: none">• With precision immunization comes predictive models that allocate resources and lead health decisions. There are also real-time data that is used to prioritize high-risk communities.• Examples include the AI dashboard during Covid-19 that helped prioritize vaccine rollouts in underserved communities.
	Health Inequities	<ul style="list-style-type: none">• By identifying under protected communities, precision immunization supports equitable vaccine access and allows underrepresented minorities to be heard and tested.• An example of such is the customized vaccine campaigns in Sub-Saharan Africa designed to procure vaccines based off of local HIV strain diversity and the population needs.

[Columbia](#), [DefinitiveHC](#), [National Institute of Health](#), [ScienceDirect](#)

Benefits and Concerns From Stakeholders



There are a variety of perspectives that go into integrating precision medicine, as many of the stakeholders such as hospitals and policymakers hold different priorities. However, they all have commonalities in their key considerations.

Healthcare and Patient Pros and Cons:

Benefits

- Hospitals mainly see the benefits in how tailored therapies lead to better response rates in diseases like cancer.
- A recent example includes the new drug called **Trastuzumab**, which is a targeted therapy used to treat HER2-positive breast cancer.
- Early diagnosis and optimized therapies also **reduce trial-and-error medication and diagonalization**, leading to more resources available for hospitals and **less economic burden** on patients.
- Hospitals will be able to implement better streamlined **stratification processes**, that focus on high-risk patients sorted based on genetic profiles.
- Precision Medicine also enables the fast transmission of information, where AI-integrated tools synthesize **genetic and clinical data instantly**.
- With the development of more specific diseases, patients with rare mutations might qualify for **clinical trials and orphan drugs**.

Concerns

- In order to make precision medicine feasible, there must be **genome sequencing** in some part to identify the personal aspects of each patient.
- An entire genome sequency typically costs around **\$500 - \$5000**, illustrating the **high upfront costs** needed to accomplish this.
- According to a Medscape survey done in 2021, only **30% of physicians** feel prepared to use genetic testing results.
- In addition, although we have **GINA regulations** that implement health insurance protection, there might be loopholes that insurance companies take leading to **high personal expenses**.
- Lastly, an important **integration issue** arises when implementing these genetic modules as not many vendors support the platform.
- There is also no **universal standard** for genetic data representation or storage, leading to lack of organization and smooth integration.

[National Cancer Institute](#), [eeoc](#), [Healthaffairs](#), [Medscape](#)

Stakeholder and Ethical Challenges



The adoption of precision medicine requires balancing innovation with equity, trust, and responsibility across patients, providers, and stakeholders. There are a myriad of regulatory laws and programs which are involved in shaping this.

Ethical Concerns

- Many challenges with **informed consent** presents itself. Because of the sheer amount of data and multi-purpose uses of the genomes, genomic data may be used to for further research that **hadn't yet been defined**.
- Many IRBs now require **consent**, in which a patient can consent based on how much **information they want to share**.
- With the entire world of genome also presents challenges that involve **unearthing the relevance of different tests**, revealing unrelated but **medically significant risks**. Many genome vendors are debating whether or not these findings should be disclosed.

Regulatory Landscape

- The **Genetic Information Nondiscrimination Act** prevents use of genetic information in health insurance and employment status. However, this does not cover **life, disability, and long-term care insurance**.
- **HIPAA protects health information**, but sometimes genomic data falls into the **grey zone** when stored outside of EHRs and used for other purposes. This leads to many debates on how there should be **one regulatory platform for testing companies**.
- There is **no one set regulation** in how every company is regulated. For example, **23andMe and other testing companies** have different regulations. However, the FDA has a framework for **adoption companion diagnostics**, which are prescription tests.

Stakeholder Involvement

- Many academic institutions have launched their **own programs** that contribute to the implementation of precision medicine.
- Institutions such as Harvard and Stanford have launched their own projects, such as the **Harvard Personal Genome Project** and **Stanford Center for Biomedical Ethics** which focus on long term data use, policies in genetics, and clinical decision-making.
- Non-profits include the **All of Us Research Program** which has a goal of recruiting 1 million individuals for genomic research. They specifically advocate for diversity in genomic datasets to reduce **trial bias and ensure a proper population representation**.

[Allofus](#), [Harvard Personal Genome Project](#), [National Human Genome Research Institute](#), [The New England Journal of Medicine](#), [U.S Equal Employment Opportunity Commission](#)

SWOT Analysis for Precision Immunization Market Entry



Precision immunization holds potential to transform the medical industry, but success depends on overcoming costs, infrastructure, and equity barriers while making use of technological advances.

<h2>S</h2> <h3>Strengths</h3>	<h2>W</h2> <h3>Weaknesses</h3>	<h2>O</h2> <h3>Opportunities</h3>	<h2>T</h2> <h3>Threats</h3>
<ul style="list-style-type: none">• Precision Immunization allows for more tailored treatment plans for patients that improve efficiency and reduce side effects• Diagnostics in rare diseases and oncology has shown high ROI and patient outcomes.• The government has shown commitment in this area through programs like the NIH "All of Us" program and the EU's "1 Million Genomes Initiative"	<ul style="list-style-type: none">• Challenges include high implementation costs with expenses in sequencing, clinical validation, EHR integration, and staff training.• Many physicians lack proper training to interpret genetic analysis properly.• Many genomic tests lack CPT codes which disallow insurance coverage.• Deployment may be impeded due to fragmented data systems and lack of interoperability.	<ul style="list-style-type: none">• Increasing aging populations and chronic diseases drive demand for personalized care.• Models focused on long-term outcomes and cost savings align well with the genomic tools.• There is high potential for scalability in collaboration with pharmacies, private organizations, and academic medical centers.• Artificial intelligence in automation can streamline interpretations and reduce clinical burdens.	<ul style="list-style-type: none">• There is high regulatory uncertainty as approvals from FDA, EMA, and regulators are time-consuming and complex.• Many challenges present itself in data privacy, consent, and genomic discrimination which require thoughtful safeguards.• Equity gaps may show as a result on models trained on population that don't include underrepresented groups.

Case Study: Geisinger Health Systems



Geisinger, a large healthcare system in Pennsylvania, launched MyCode® Community Health Initiative, rising to be one of the most comprehensive precision medicine initiatives in the U.S.



Geisinger

- Geisinger is a healthcare system provider to central, south-central and northeastern **Pennsylvania**.
- The company services over **3 million patients** in 45 counties.
- In 2024, Geisinger reported a **revenue of up to 7.7 B** an 11.7% increase from the same period in 2022.

SIEMENS
Healthineers

BEST
BUY Health

Program Overview

- Geisinger launched MyCode® Community Health Initiative in 2013, rising to be one of the **most comprehensive precision medicine initiatives** in the U.S.
- The goal is to integrate whole-exome sequencing into patient care and return clinically actionable results.

Implementation Model

- Over **325,000 patients** consented to contribute biological samples to the database, which are sequenced and analyzed for mutations in more than **76 genes** associated with serious health conditions, such as **Ovarian Cancer**.
- Actionable findings are returned in an **established clinical workflow**.

Impact and Outcomes

- Identified thousands of individuals with **undiagnosed genetic risks** who can now take proactive steps to become healthy such as surgeries and lifestyle changes.
- Enabled **family members to get tested** as genetic risks are inherited.
- Demonstrated a **scalable model** for systems that combines research and delivery.

Challenges Faced

- Managing sensitive data requires **robust data governance policies** and adherence.
- Primary care physicians need support **understanding test results** as many of them lack training in genomics and reading data.
- **Financial hurdles** still exist in costs associated with follow up diagnostics

Key Takeaway

Effective integration of precision medicine into today's industry depends on aligning technology, clinical workflows, and healthcare infrastructure.

Becker's Hospital Review, Geisinger College of Health Sciences, National Library of Medicine



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Liquid Biopsy: A Breakthrough in Cancer Diagnostics



Liquid biopsy is a new development in cancer diagnostics, involving an analysis of the blood, aiming to improve the accuracy of traditional methods, decrease cost, improve turnaround time, and overall improve patient outcomes.

Introduction



- Liquid Biopsy is a revolutionary technique used for **cancer diagnosis and monitoring**.
 - This technology allows clinicians to detect signs of cancer in patients **non-invasively**, through a simple blood test.
- Several cancers **shed their DNA** into the bloodstream, which is later identified through novel liquid biopsy assays.
- Liquid biopsies **cost far less** than needle-based biopsies, which involve an ultrasound/CT scan, and may require anesthesia.

Benefits



- One of the clear benefits to liquid biopsy as opposed to needle-based biopsy is **patient comfort**.
 - Liquid biopsy is **quicker and safer**, than other detection methods, with results typically taking **5-7 days** rather than 10-14.
- Liquid biopsy is especially **useful for those already diagnosed** with cancer, who may require frequent monitoring to **ensure responsiveness to treatment**.
 - Time is critical, so clinicians need **quick, reliable guidance** to best support patients.

Limitations



- Although liquid biopsy is incredibly promising, it is **not useful for all patients**.
 - Certain cancers do not shed enough DNA to be detected in the blood, leading to **false negatives** that could harm patients.
- The DNA of some individuals can present like ctDNA, leading to **false positives**.
 - Any positive results must be followed by a confirmatory needle-based biopsy, creating additional **discomfort and fear for patients**.

Liquid Biopsy: Current Status



Currently, liquid biopsy is best used for those with a cancer diagnosis to monitor how far the disease has progressed and inform treatment decisions. Current work is focused on improving accuracy for first-time diagnoses.



Reliability

- Given the current risk of false results, liquid biopsy is best used as a follow-up tool to **evaluate how responsive the cancer is to treatment**. For current diagnostics, liquid biopsy is used as a **complementary tool** rather than its own test.
 - Using liquid biopsy for follow-up evaluation **ensures results are reliable**, allowing laboratory technicians to confirm that the DNA detected in the bloodstream matches the DNA found in the tumor.
-



Research

- Current research is focused establishing the efficacy of this technology in pediatric patients, and **improving assay sensitivity**, allowing for improved early-stage detection.
 - Liquid biopsy is also being examined for its use in **personalizing treatment**, which would allow for targeted immunotherapy and identification of other treatment methods.
 - New studies are also interested in developing a **saliva-based molecular test** to further aid the detection and treatment of oral and throat cancers.
-



Future

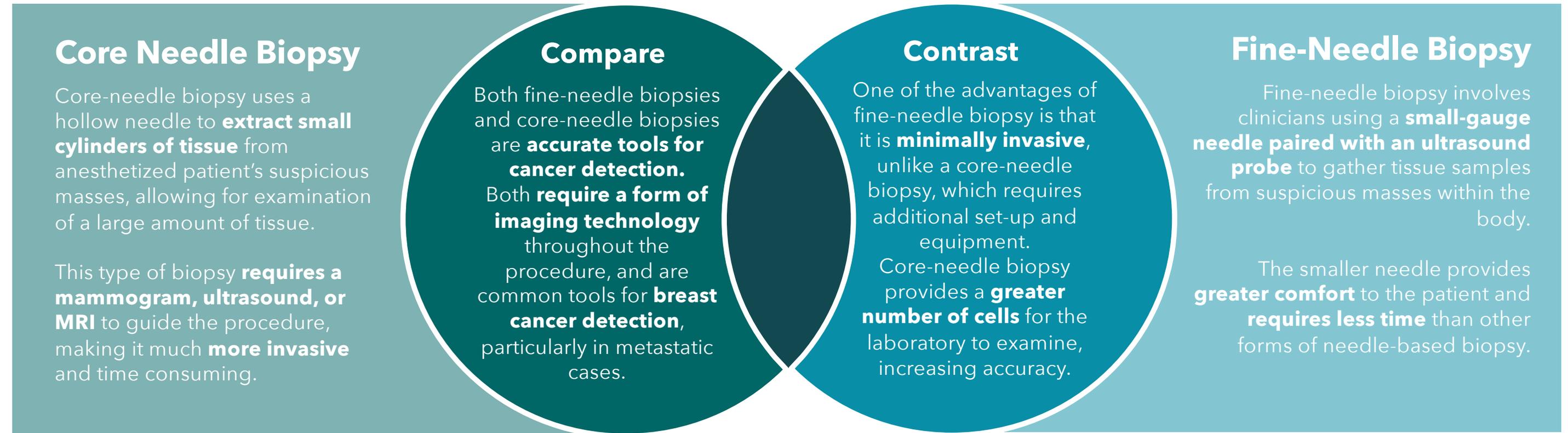
- The largest improvement liquid biopsy researchers are working toward is **accuracy**. Minimizing false results is imperative to patient safety, comfort, and expanding treatment options.
 - Cancer detection using liquid biopsy has shown great potential to **enhance and individualize treatment**, aiming to make once-harsh, broad cancer treatments significantly less toxic to patient's healthy cells.
-

[UChicago Medicine](#), [Stanford Engineering](#)

Traditional Diagnostics: Needle-Based Biopsy Comparison



Core-needle biopsy and fine-needle biopsy are two of the most common needle-based methods of detecting cancer, particularly breast cancer. Both are incredibly accurate but have areas that liquid biopsy can improve upon.



Key Takeaway

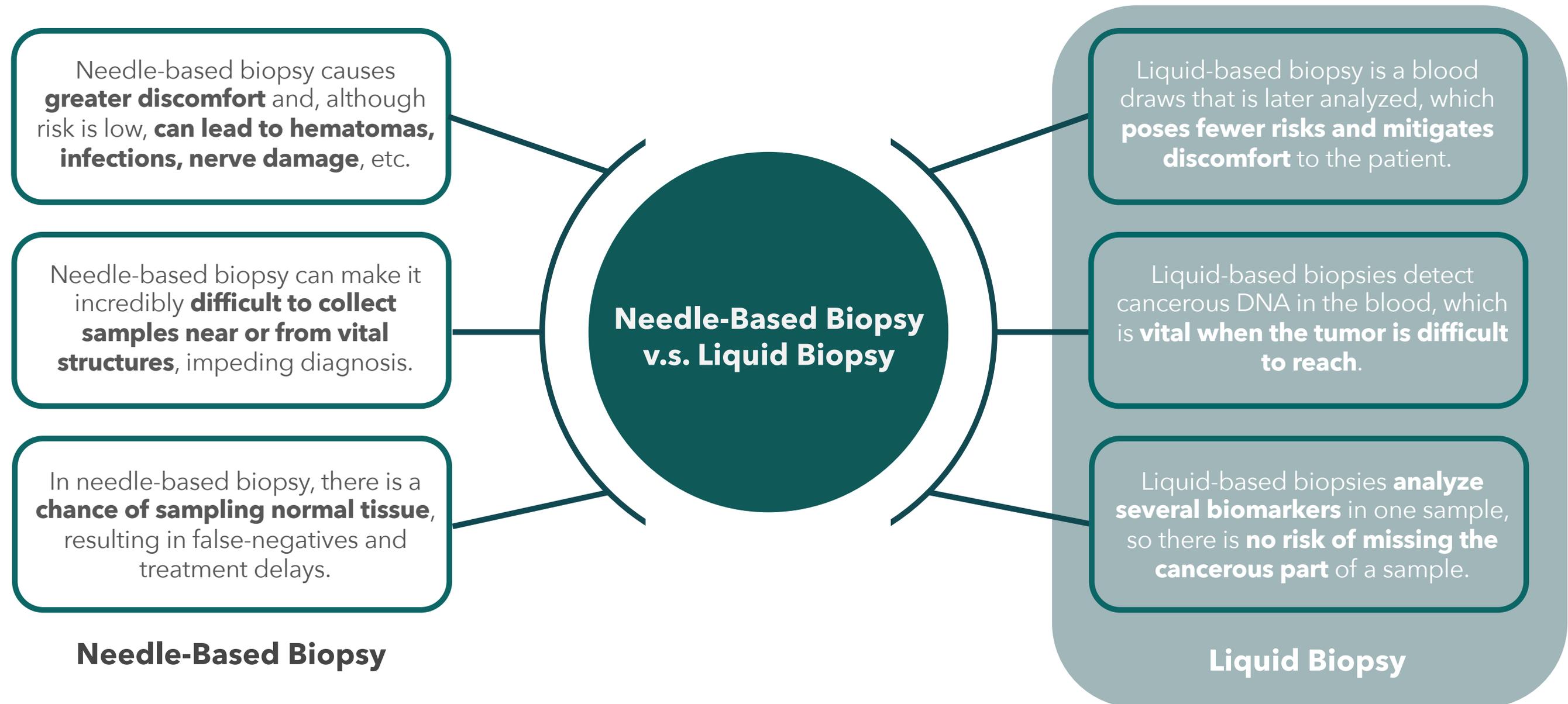
Core-needle biopsy and fine-needle biopsy are both **phenomenal tools for cancer diagnostics**, but these traditional methods require **imaging technology, anesthesia**, and are **invasive**.

[Cleaveland Clinic \(I\)](#), [Cleaveland Clinic \(II\)](#)

Liquid-Based Biopsy: Enhanced Diagnostics



Needle-based biopsy has many issues, such as discomfort, critical detection difficulty, and missing cancerous tissue. Liquid-based biopsy, although still emerging, has been able to mitigate these issues and improve patient outcomes.



[NIH \(I\)](#), [NIH \(II\)](#), [NIH \(III\)](#)

Liquid Biopsy: Sector Analysis



The public and private sectors within liquid biopsy research vary, with the public sector hoping to revolutionize medicine and the private sector focusing on innovation to make the technology marketable and increase profit.

Public and Private Sectors

Public Sector

- The public sector of liquid biopsy initiatives is **funded through federal and state taxes**, research grants, and other public means.
 - Particularly, **public initiatives push for advancements that will revolutionize medicine** rather than creating a product.
 - These advancements can be used to improve cancer detection for a wide range of individuals; however, the lack of profit **can create difficulties for finding funding**.
- Public researchers typically work for organizations such as the **NIH Liquid Biopsy Consortium and the National Cancer Institute**.
 - These agencies tend to focus on **establishing regulatory guidelines** to promote safety and quality.

Private Sector

- The private sector of liquid biopsy typically involves **biotechnology and pharmaceutical companies** conducting research using **investor funds** and research grants.
 - Companies in the private sector are typically **developing liquid biopsy technology for profit**, with funds going toward **FDA approval**, as well as sponsoring the set-up and staff necessary for **clinical trials**.
- Several companies are spearheading the liquid biopsy market such as **Bio-Rad, NeoGenomics Laboratories, Guardant Health**, and many more.
 - These organizations are working toward **making their assays more marketable** and widespread.

Liquid Biopsy: Stakeholder Perspectives



There are numerous benefits and concerns regarding liquid biopsy to researchers, clinicians, and patients. There is debate about how to improve the benefits of liquid biopsy to outweigh its current issues which impede widespread use.

Benefits



Clinicians and researchers are hopeful that liquid biopsy will **allow for earlier detection** of life-threatening cancers.



Clinicians and patients find liquid biopsy incredibly **useful for monitoring disease progression** and cancer prognosis.



Patients and advocacy groups also find that liquid biopsy is **more cost-effective**, which can make treatment more efficient.



Patients and advocacy groups supporting liquid biopsy emphasize its minimally-invasive nature, leading to **improved patient comfort**.



The biotechnology and pharmaceutical industry **view liquid biopsy as a market opportunity**, promoting further research.

Concerns



Clinicians and researchers have **concerns about the sensitivity and validity** of liquid biopsy technology given its novelty.



Clinicians and patients are concerned about the current **risk of false results**, impeding diagnosis and impacting patient outcomes.



Despite the reduced cost of liquid, patients and advocacy groups share concerns that **cost may still be too high** for true equity.



The less-invasive nature of liquid biopsy leads to false positives, potentially **causing undue anxiety** for healthy patients.



Commercializing liquid biopsy is a costly and difficult endeavor, posing an issue for biotechnology and pharmaceutical companies.

[NIH, ScienceDirect \(I\)](#), [ScienceDirect \(II\)](#)

Liquid Biopsy: Regulations, Law, and Ethics



As with every emerging technology, liquid biopsy is surrounded by significant regulatory debate. With hospital regulations affecting sample stability and federal regulations impeding expansion, several stakeholders are concerned.

Hospital Regulations



Individual clinic regulations could cause issues for liquid biopsy technology. **Varying collection, transport, and storage procedures** cause concern for the stability of the samples. If an error is made, **the chance for false results dramatically increases**, unlike in traditional methods with solid tumor samples.

Federal Regulations



The FDA has been **working toward establishing regulatory guidelines** on liquid biopsy in the years since it was first introduced. Although the FDA has approved the use of liquid biopsy products for complementary use, it has **rejected its use for cancer prediction and stand-alone diagnosis**.

Ethical Challenges



One major ethical concern regarding liquid biopsy is **ensuring it is widely available regardless of location, insurance, or income**. Underserved populations often face worse health outcomes due to a lack of access to novel technology, so **widespread liquid biopsy implementation is crucial**.

[ASCO](#), [NIH \(I\)](#), [NIH \(II\)](#)

Liquid Biopsy: Barriers to Implementation



Despite exponential interest, liquid biopsy has not yet been widely adopted in clinics and hospitals. Several barriers to entry exist, including financial, regulatory, and efficacy concerns, impeding the advancement of cancer diagnostics.

Barriers to Implementation	Explanation
 Financial	<ul style="list-style-type: none">Individual liquid biopsy tests can reach thousands of dollars due to how new this technology is. These high costs limit its availability to underserved communities, harming implementation.The claims about the cost-effectiveness of liquid biopsy are being debated, making stakeholders wary of investing in a potentially overpriced tool.
 Regulatory	<ul style="list-style-type: none">As of 2024, only 5 liquid biopsy assays have been approved for clinical use. This is a major barrier, as it indicates a need for more research to sway regulatory bodies.Particularly, far more studies must be conducted to prove the validity of liquid biopsy tests before they can be widely approved and implemented.
 Efficacy	<ul style="list-style-type: none">There is a clear struggle between how accurate cancer diagnostics can get and how fast these diagnoses can be made. Liquid biopsy currently has issues with the sensitivity of assays.Liquid biopsy allows for much earlier detection, however, there is less accuracy as a result. Most clinics will not implement this technology until it can be trusted as a diagnostic tool.
 Systemic	<ul style="list-style-type: none">Due to how young liquid biopsy technology is, and its continuous evolution over the years, there is a lack of knowledge about liquid biopsy among physicians.Training and regulations are not yet well established, and there is also a much lower capacity for these tests among local hospitals compared to large research labs.

[BMC](#), [NIH](#)

Lung-MAP: A Case Study



Lung-MAP is an emerging precision medicine trial aiming to identify the specific drug or drug combination necessary to treat cancer in individual patients, allowing for quicker treatment, recovery, and overall improved health outcomes.

Overview

Description

- Lung-MAP is a widespread clinical trial available to those with treatment-resistant **non-small cell lung cancer**.
- Lung-MAP is an **umbrella trial**, meaning it allows numerous drugs that **target specific genetic changes** in patients to be tested on those most likely to benefit.

Goals

- The goal of Lung-MAP is to learn if these drugs can be used to **slow or stop the progression of non-small cell lung cancer** in patients with more aggressive cancers.
- Improving the speed of cancer treatment is a major goal of Lung-MAP, attempting to bring down the time between diagnosis and treatment to **less than two weeks**.

[National Cancer Institute, NIH](#)

Implementation

Availability

- Lung-MAP is now available at **over 700 testing sites** across the U.S., allowing for a larger pool of potential participants.
- Keeping the test widely available is key for patient and scientific benefit.

Efficiency

- Each year, clinicians screen roughly **500 to 1,000 patients** for changes in the genes implicated in non-small cell lung cancer.
- These are used to match patients to drugs in an expedited manner.

Options

- For those who do not end up matching, and for whom immunotherapy did not previously work, clinicians offer a **combined immunotherapy treatment** to better observe the best options for patients.

Partnership

- **Strong public-private partnership** was key to the success of Lung-MAP implementation, with partners including the National Cancer Institute, Friends of Cancer Research, Amgen, Pfizer, and AstraZeneca.



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Interview: Foundation Medicine



Foundation Medicine is a leading biotechnology company based in Massachusetts, dedicated to developing and manufacturing novel genomic tests to improve cancer diagnostics and recovery outcomes of patients with cancer.



The technology that can analyze ctDNA continues to **evolve rapidly**, bringing levels of sensitivity in detecting tumor fragments in blood that were **previously unachievable**.

Advantages

Not all patients are able to get a tissue biopsy that would allow the clinician information on their genomics. In situations such as the tumor being surgically inaccessible tumor or the patient being too sick for surgery, liquid biopsies help **inform provider's treatment decisions**.

Limitations

The biggest limitation with liquid biopsy is that it is **only successful when the tumor is shedding enough DNA**, which may not be the case in early stages. When liquid biopsy is unsuccessful, providers will often **default to a tissue-based test**, which still provide valuable information on specific genomic alterations.

Affordability

Foundation Medicine believes that **affordability is a crucial part of their services**. The vast majority of patients with advanced cancer, up to 90%, **do not pay for precision medicine tests**. Those with out-of-pocket expenses will pay a maximum of \$100, to ensure each patient receives the best possible care.

Interview: Liquid Biopsies for Maintenance, not Diagnosis



Interview with a breast cancer surgeon who regularly biopsies breast tissue in order to diagnose tumors illuminates some of the potential drawbacks as well as areas of use for liquid biopsy technology,



Needle biopsies will likely still need to be the core mode of biopsy in order to diagnose the cancer precisely and help with pre-surgical planning, however **liquid biopsy could potentially be implemented for basic screening and to monitor existing tumors**. Needle biopsies are crucial for treatment as they allow surgeons to see the architecture of the tumor and see its specific pathology through a core of tissue, which **cannot be replicated with liquid biopsy technology**.

Potential Benefits

- Liquid biopsies **are much less invasive** than needle biopsies, are **not constrained by location** like needle biopsies, and are **less painful**, especially compared to those guided by mammograms.
- Easier and less invasive way to **monitor growth/metastasis of existing tumors**.

Challenges

- Liquid biopsy technology is currently **less accurate than needle biopsies** that obtain tissue directly from the site which could **cause false positives/negatives**.
- Likely **could not identify the vascularity and architecture of the tumor for surgeons**.

Other Technologies

- **Immunotherapy treatments** in breast cancer are precision medicine technologies that have come a long way, especially in **treating aggressive triple-negative breast cancer and metastasis**, with treatments such as Keytruda **increasing the overall prognosis of metastatic breast cancer and improving quality of life for patients**.



Section 1: Industry Overview

Section 2: Precision Immunization

Section 3: Liquid Biopsy

Section 4: Expert Interviews

Section 5: Implementation Strategies

Integrating Precision Immunization into Patient Care



Precision immunization has the potential to improve vaccine effectiveness and reduce public health disparities, but successful adoption depends on aligning data systems, funding mechanisms, and public trust.



BMC Medical Education, CDC, National Academy of Medicine, National Human Genome Research Institute

Precision Immunization: Final Insights



Although precision immunization has a long way to go, further partnerships to encourage future research, physician training, and development can pave the way to market integration for this novel technology with high potential.



Precision Immunization Overview

Precision immunization is a novel technology revolutionizing **personalized vaccination**. Specifically, it is the use of **genomic, immunologic, and clinical data** to tailor vaccine types, timing, dosages, and delivery to a unique individual's body. The goal is to **maximize effectiveness, reduce side effects, and improve overall population health** through targeted interventions.

Research

Emerging studies have shown how individuals respond differently to vaccines based on age, sex, genetics, and microbiome composition. They have also demonstrated how **immune profiling can enhance vaccine response**, particularly in immunocompromised and elderly populations.

Availability

While precision immunization is **still in its early stages**, many components like pharmacogenomic screening, targeted COVID-19 vaccines, and cancer vaccine trials are already in use. However, precision immunization is **not widely available** due to a lack of EHR integration and low awareness.

Efficiency

Tailoring vaccines can **prevent over-vaccination, ineffective responses, and side effects** that cause further consequences. Targeted vaccine delivery can **reduce costs** associated with trial-and-error, hospitalizations due to vaccine-preventable illnesses, and systemic side effects.

Implementation Barriers

Data Integration and Infrastructure: There is a lack of interoperability between genetic testing platforms and electronic health records making it difficult to embed recommendations into clinical workflow.

Clinical Readiness: A large portion of physicians lack **immunogenetics training** and may be unwilling to adopt **unfamiliar data-driven protocols** without clear guidance and support.

Equity: Precision immunization might exacerbate **health disparities** by being **inaccessible to underrepresented and rural populations** without enough public funding and outreach.



Implementation Strategy

It is essential that **EHR records are integrated with immunogenomic** alerts to adopt precision immunization into clinical settings. **Training programs** will also be needed to educate patient and physician while building trust. Through partnering with **community clinics, Medicaid, and public health agencies**, it will ensure there is equal access to precision immunization. Finally, securing **NIH and public-private funding** will be integral in reducing costs.

[CDC](#), [National Center of Biotechnology Information](#), [National Human Genome Research Institute](#), [National Institute of Health](#), [Nature](#)

Liquid Biopsy: Implementation Strategies



Widely integrating new precision medicine techniques is challenging, however, focusing on key goals such as developing a master protocol for testing, establishing strong sector partnership, and keeping the test accessible is key.

Integration Considerations

Master Protocol

- Lung-MAP specifically created a **master protocol** to allow for **feasible, and adaptable rules** surrounding the study.
- Developing such protocols is key for **efficient screening** and drug assignment, proper **clinician training**, and overall patient safety.

Public-Private Partnership

- An important aspect of implementing liquid biopsy is teaming public and private sectors, **keeping cost less of a barrier**.
- Lung-MAP's **private sector provided funding and therapeutics**, while the **public sector acted as an advisory board**.

Eligibility & Spread

- One of the key features of Lung-MAP is its **low barrier-to-entry**, with only a **few disqualifying criteria** necessary for patient safety.
- Liquid biopsy clinicians should aim for it to be as widely available as Lung-MAP, to allow for **increased testing** and quicker care.

Impact

Lung-MAP aims to provide results in

2 Weeks

through improved molecular testing.



Liquid Biopsy could provide results in as little as

5 Days

with developing improvements

Liquid Biopsy: Final Insights



Liquid biopsy is revolutionary, and despite current barriers, the widespread implementation of this technology is possible through close partnership between biotechnology companies and public research/regulatory bodies.



Liquid Biopsy Overview

Liquid biopsy is a novel technology revolutionizing the field of cancer diagnostics. It involves **collecting a blood sample and analyzing the sample for cancer cell DNA**. Liquid biopsy is especially useful as a non-invasive method of **monitoring disease progression**, especially in patients with advanced cancers, and better **informing clinician's vital treatment decisions**.

Research

Current liquid biopsy research is aimed at establishing its use in pediatric oncology and **increasing the sensitivity of assays** to enhance early-stage detection. Studies are also exploring the use of liquid biopsy as a means for personalizing treatment to **allow for targeted immunotherapy**.

Availability

It is imperative that liquid biopsy technology is **widely spread** and made available to underserved communities. Several biotechnology organizations are **working toward further developing this technology** and increasing access, including Bio-Rad, NeoGenomics, and Guardant Health.

Efficiency

This technology is particularly useful when **time is of the essence**. Unlike many needle-based methods, liquid biopsy may be able to provide results in as little as **5 days or less**. In oncology, the sooner a clinician can diagnose cancer, the better prognosis patients have.

Implementation Barriers

Financial: Individual tests can reach thousands of dollars due to the novelty of this technology. The **cost-effectiveness** of liquid biopsy is being debated, making investors wary.

Regulatory: Only 5 liquid biopsy assays have been approved for use by the FDA, indicating a need for **continued research** to establish the efficacy, accuracy, and safety of this technology.

Clinical: There is a lack of knowledge about liquid biopsy among clinicians, and **training has not been well established**. Additionally, local hospitals lack the capacity to implement new technologies.



Implementation Strategy

Developing a **master protocol with feasible, adaptable guidelines** for liquid biopsy is essential for establishing its use in clinical settings. Ensuring **few disqualifying criteria and low cost** is also crucial, as this technology could be required as a critical part treatment. Finally, the most important aspect in implementing liquid biopsy is **strong public-private partnership**, which will allow lower cost and expedited decision making.

[BMC](#), [Emergen Research](#), [NIH \(I\)](#), [NIH \(II\)](#), [UChicago Medicine](#)