

Understanding Cell and Gene Therapy and Its Impact on the Workforce

November 12, 2024



Speakers



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Overview of Genomic Testing & Precision Medicine

Jennifer Malinowski, MS, PhD
Director
Access and Policy Research

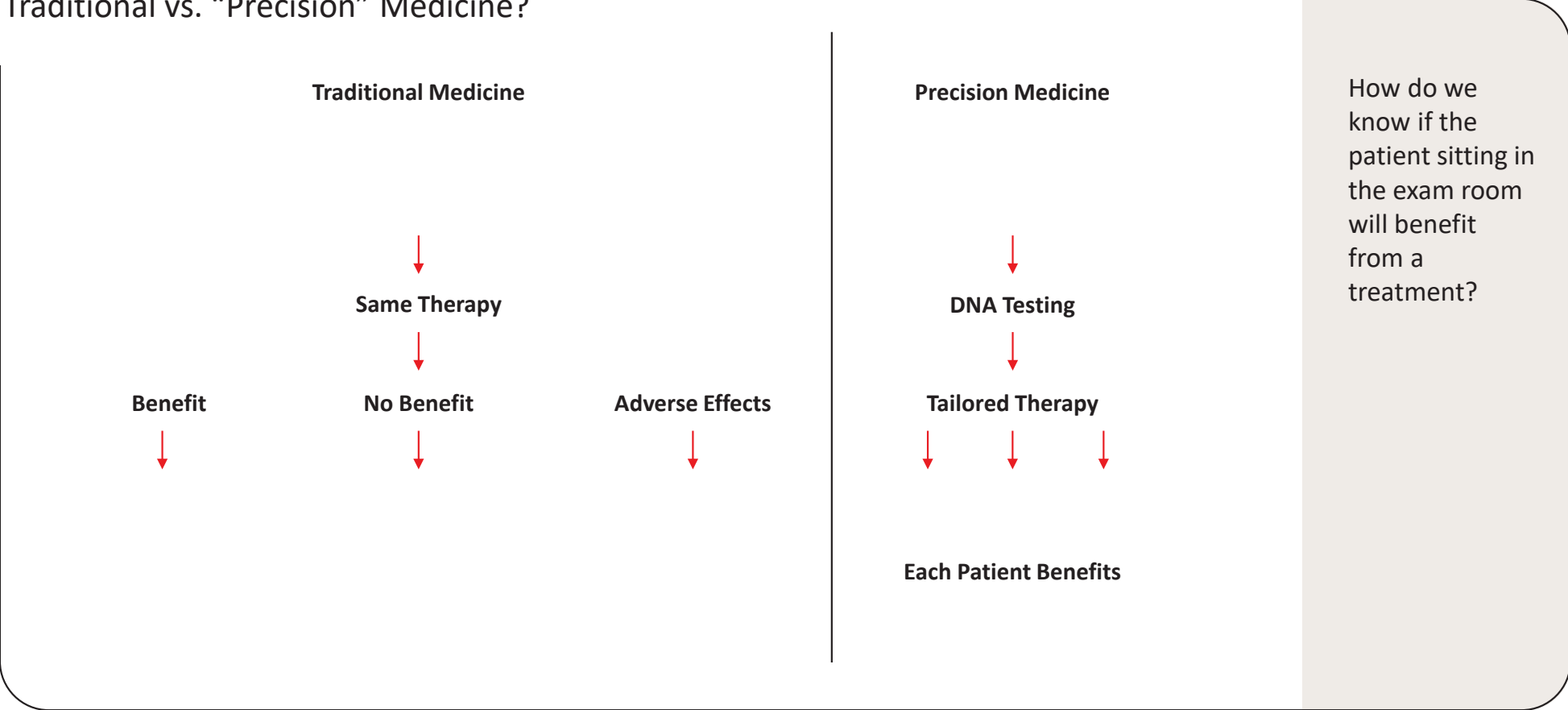
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Key learning objectives

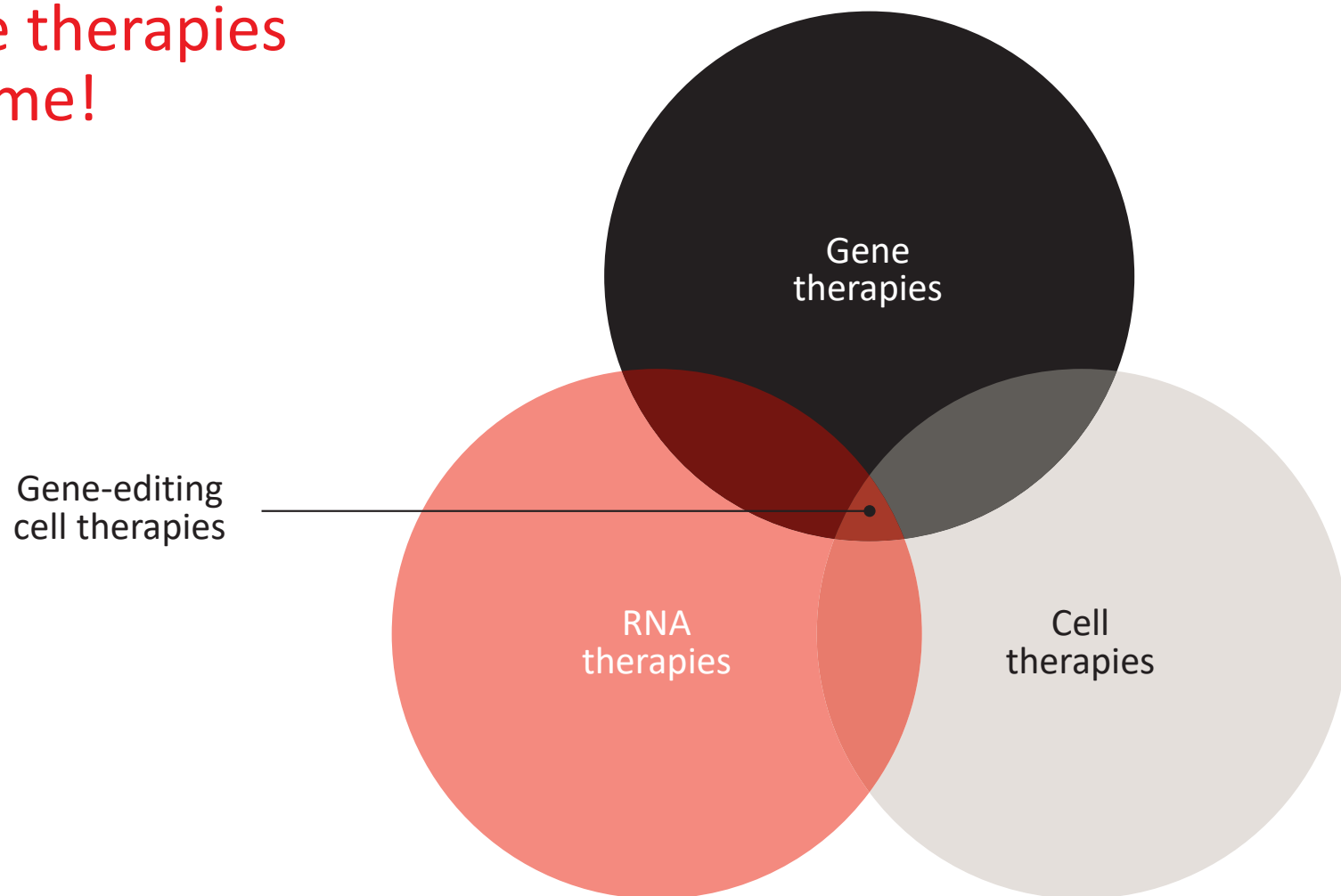
- Precision medicine uses genetic and genomic information to tailor treatment to the individual
- Many treatments rely on genetic/genomic testing for optimal medication dose or patient population selection to avoid adverse events and improve the likelihood of treatment success
- Cell therapies and gene therapies are not the same thing—but share a complexity of manufacturing and patient access
- Cell and gene therapies are the epitome of precision medicine
- Success stories of precision medicine continue to grow, in cancer and non-cancer conditions
- Rare (genetic) disorders are now treatable and potentially curable

Precision medicine confirms patient eligibility

Traditional vs. "Precision" Medicine?

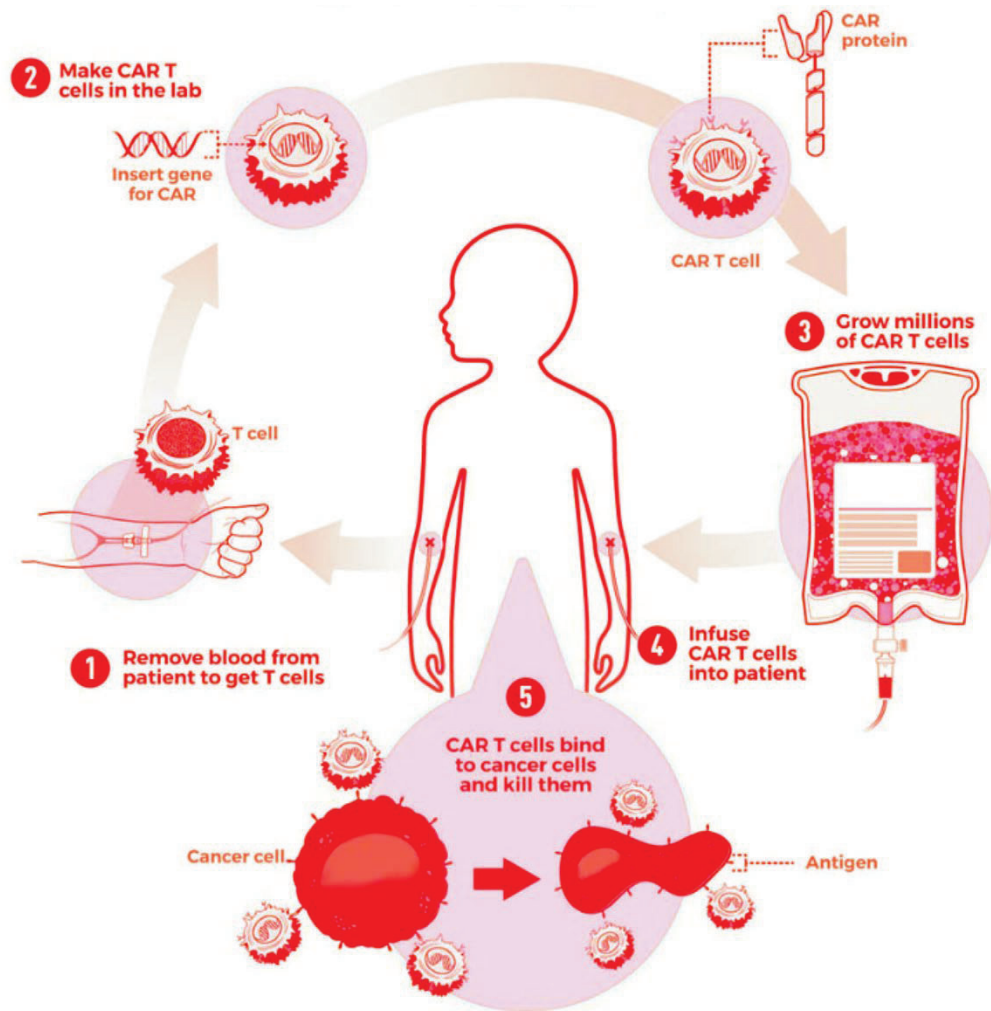


Cell and gene therapies aren't the same!



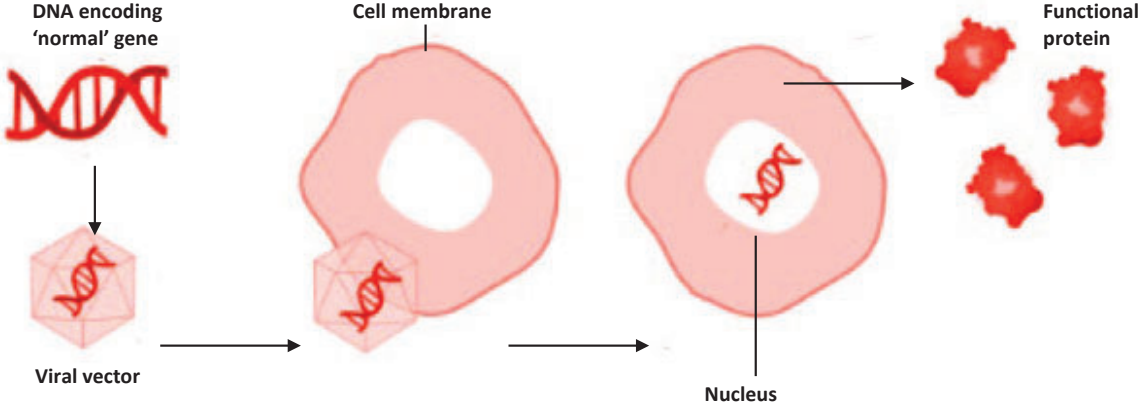
CAR-T therapies are customized to each patient

Chimeric Antigen Receptor (CAR) T cell therapy¹

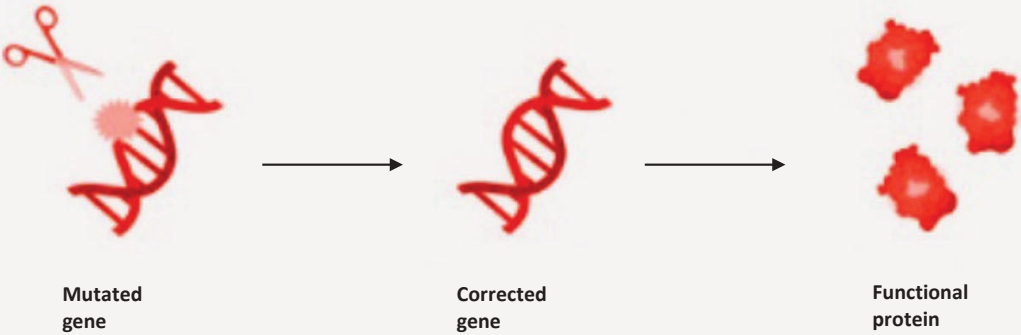


Gene therapies adapt cells & tissues to treat disease

Traditional Gene Therapy



CRISPR Gene-Editing



Manufacturing contributes to cell & gene therapy complexity

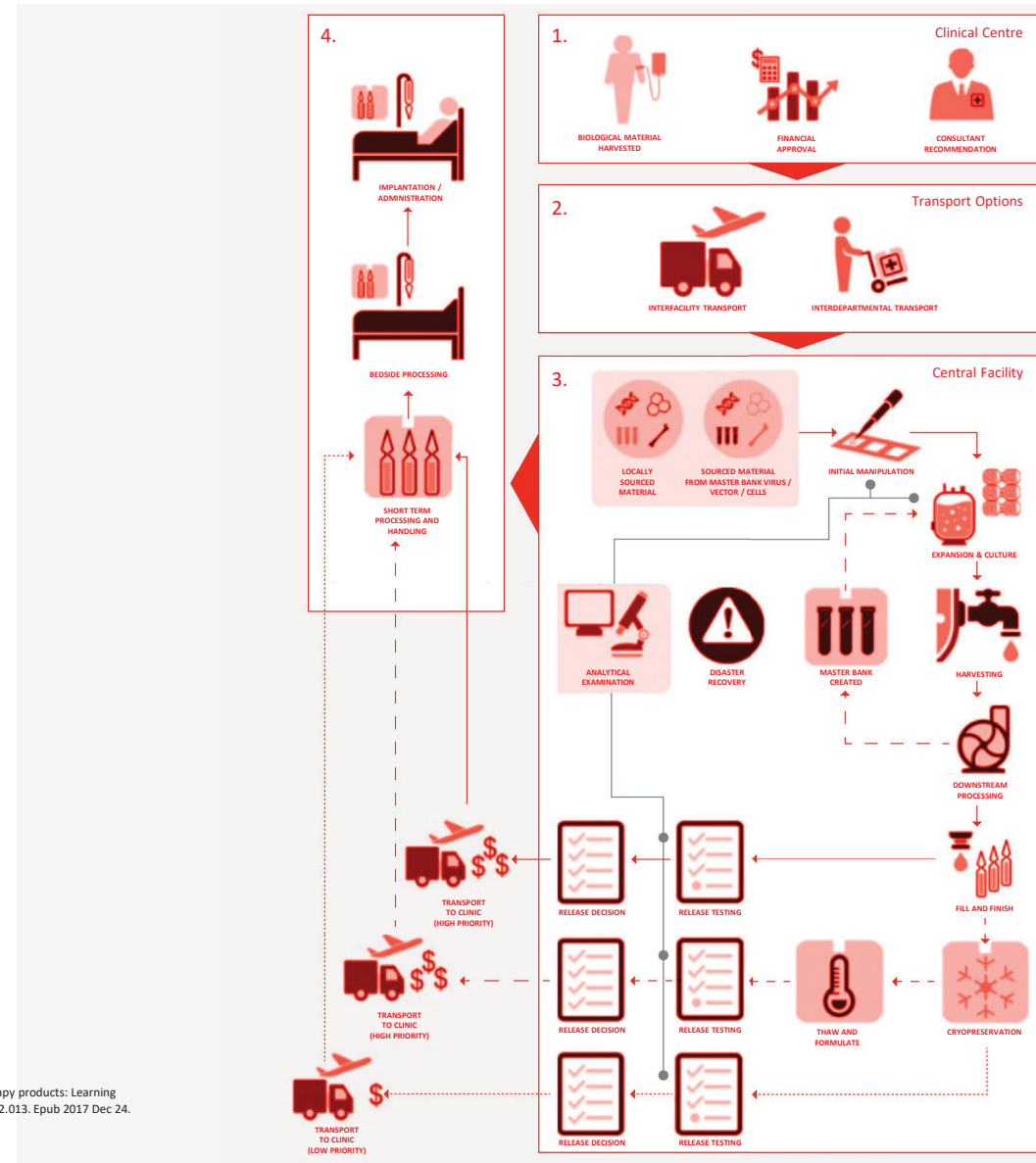


Image reference: Harrison RP, Ruck S, Rafiq QA, Medcalf N. Decentralised manufacturing of cell and gene therapy products: Learning from other healthcare sectors. *Biotechnol Adv.* 2018 Mar-Apr;36(2):345-357. doi: 10.1016/j.biotechadv.2017.12.013. Epub 2017 Dec 24. PMID: 29278756.

Diagnosis by genetic testing reduces risk of heart attack

For patients with familial hypercholesterolemia

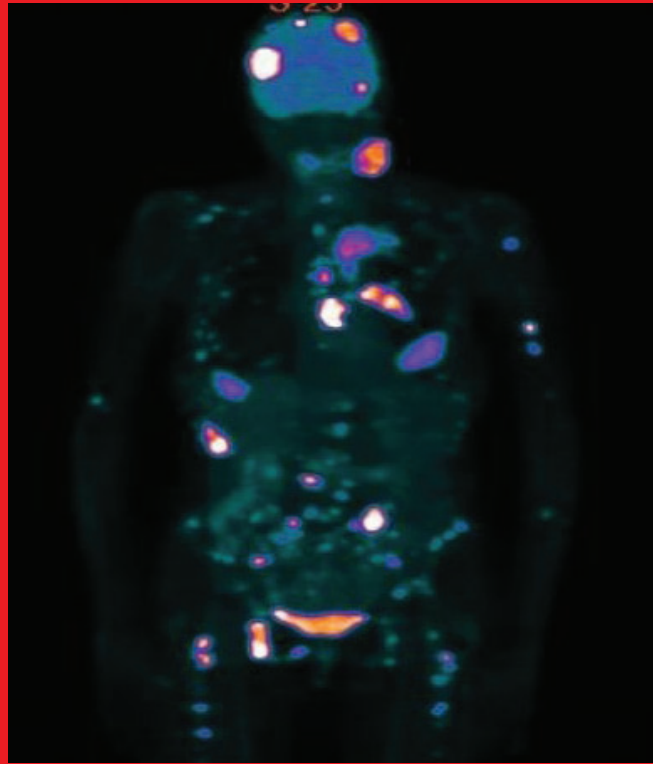
What is FH?

FH is a genetic condition that causes high cholesterol. Left untreated, heart attacks happen in

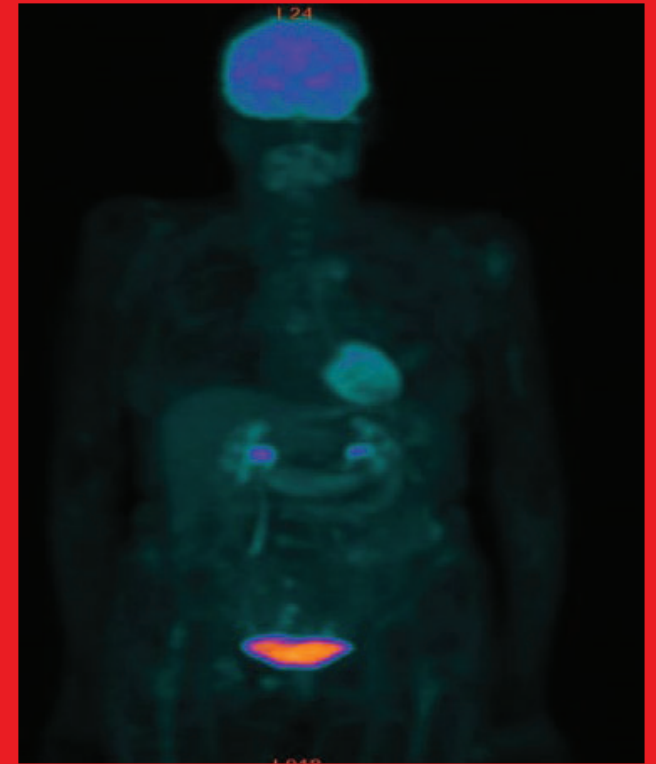


Finding and treating FH early **REDUCES** coronary artery disease risk by about **80%**

CAR-Ts
are fighting
previously
unbeatable
cancers



Pre CAR-T Therapy

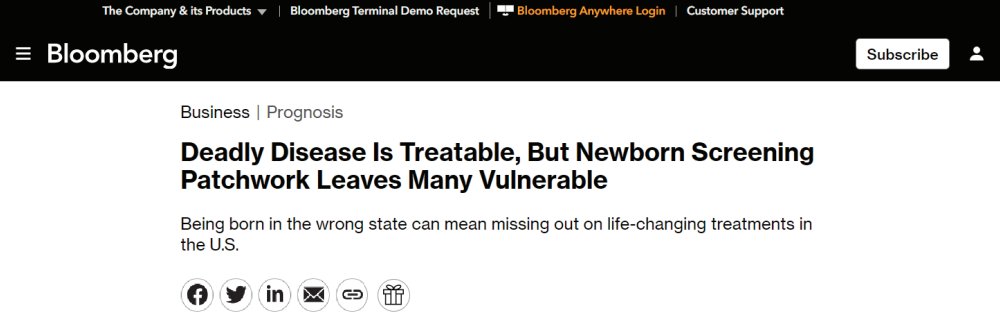


Post CAR-T Therapy

Gene therapies bring hope to patients and families

- Spinal Muscular Atrophy (SMA)¹
- Duchenne Muscular Dystrophy
- Sickle Cell Disease
- Retinal Dystrophy
- Hemophilia
- ... And more

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Deadly Disease Is Treatable, But Newborn Screening Patchwork Leaves Many Vulnerable

Being born in the wrong state can mean missing out on life-changing treatments in the U.S.

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A Dozen Years Since Diagnosis: The Evolution of SMA

by Novartis | November 13, 2023



1. <https://www.bloomberg.com/news/articles/2019-07-17/newborn-screening-for-rare-disease-can-be-a-life-or-death-lottery?embedded-checkout=true>; <https://smanewstoday.com/sponsored-content/a-dozen-years-since-diagnosis-the-evolution-of-sma/#:~:text=Amelia%2C%20the%20youngest%20Medina%2C%20was,treated%20at%20eleven%20days%20old>; <https://www.tmj4.com/news/local-news/fond-du-lac-family-perseveres-despite-all-three-kids-having-same-rare-genetic-disease>

Take-away points

- Precision medicine uses genetic and genomic information to tailor treatment to the individual
- Many treatments rely on genetic/genomic testing for optimal medication dose or selection of patient population to avoid adverse events and improve the likelihood of treatment success
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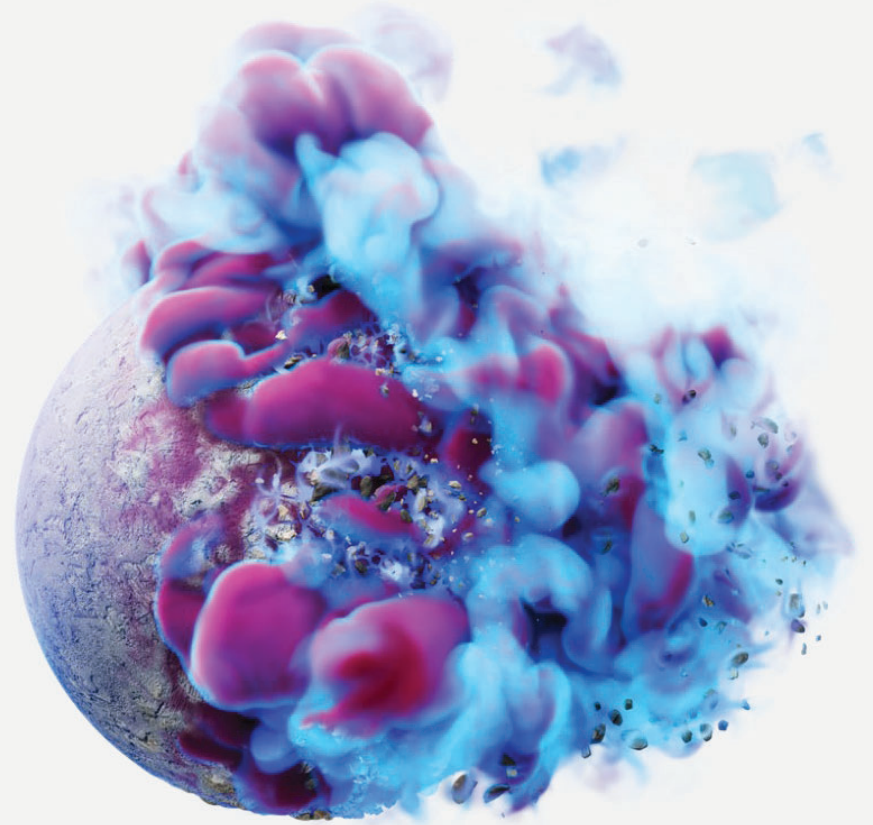


Randy Wyse
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Trust

Transformative Therapies Require Innovative Payment Models

November 2024

Deloitte.

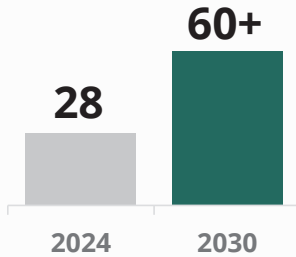


While many employers have not had CGT claims, the number of patients on CGTs is expected to grow significantly – increasing the likelihood of expensive ‘lightning strike’ claims and increased cost of care

More CGTs in the Market

Anticipated 30+ new launches by 2030 across Oncology, Blood & other diseases^{1,2}

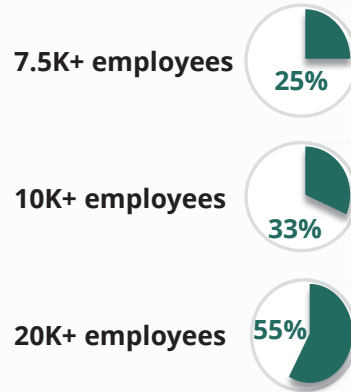
Covering 100k-300k+ US Patients by 2030



More Anticipated Claims

Higher % probability to receive at least 1 gene therapy claim by 2029 for employers³

% likelihood for employers with...



Costlier Coverage & Claims

We anticipate an increase in stop-loss premiums to maintain the existing limit range of \$800K-\$2M for recurring therapy claims

“
Soon stop-loss providers will **have to carve out gene therapy coverage or raise premiums** very high. -- VP & Chief Analytics Officer at a Transportation Manufacturer”

1) FDA. [Approved Cell & Gene Therapies](#). Accessed August 28, 2024. 2) CVS Health. [Gene Therapy Report Q1 2024-Q4 2026](#). 2024. 3) Brown & Brown. [2023 Employee Benefits Market Trends](#). 2023. 4) [Science Translational Medicine](#). 2024 5) Gallagher Research & Insights. 2024 Cell & Gene Therapy Employer Research.

As more CGTs come to market, available solutions in the market will fall short in enabling adequate CGT access and affordability – exposing >100M employees to risk

The market was **not built for one-time, high-cost curative therapies.**

The price tag for a CGT treatment is significantly higher than traditional, typically chronic treatments that “amortize” the cost of care over months or years.

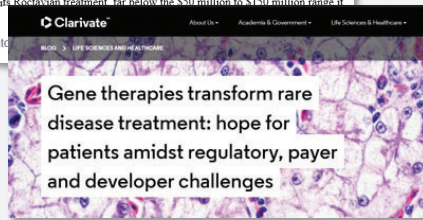
Recent Examples:

New sickle cell gene therapies are a breakthrough, but solving how to pay their high prices is a struggle

BioMarin preaches patience amid slow sales for hemophilia gene therapy

The company earned only \$3.5 million last year from its Roctavian treatment, far below the \$50 million to \$150 million range it had forecast eight months ago.

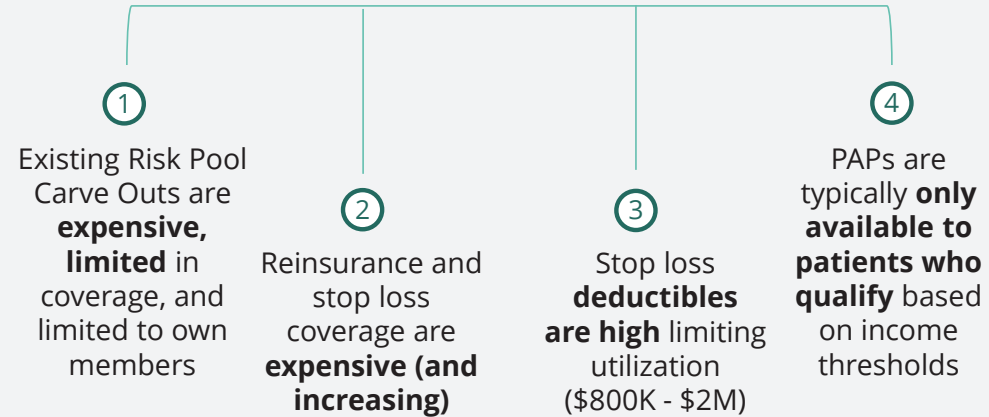
Published Feb. 23, 2024 / Ben Fidler Senior Editor



While multiple programs / services have been developed, they are **unlikely to be sustainable**



Common models - these leave critical financing gaps...



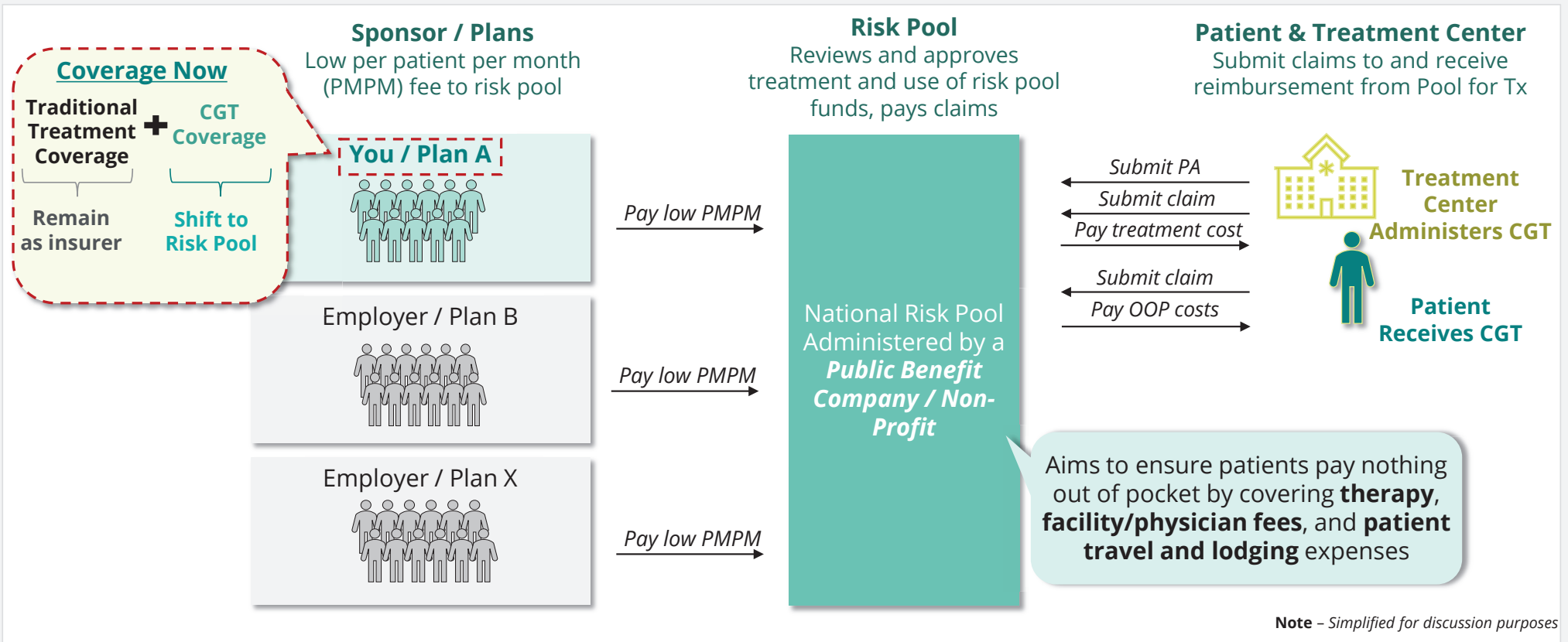
1) Deloitte. [Innovative CGT Financing Models](#). 2024.

We explored three innovative models – supplementing existing offerings and creating new offerings – that we believe could fundamentally change the way CGTs are financed

	1	2	3
Model	Supplemental Risk Pool	New Insurance Product	Therapeutic Health Credit
Description	Sponsors contribute funds to a nationally available risk pool which is used to cover the cost of CGT treatments for patients	Generate new financing opportunities through new insurance policies or offering riders on existing insurance plans	Develop financial instruments for CGTs which can be traded in the market
Value prop	Create a larger risk pool to distribute risk (and costs)	New insurance offering to protect against high costs	Introduce new players to share in risk and repayment

1) Deloitte. [Innovative CGT Financing Models](#). 2024.

A novel supplemental risk pool spreads risk across multiple employers – insulating against sizable cost increases and lightning strike claims

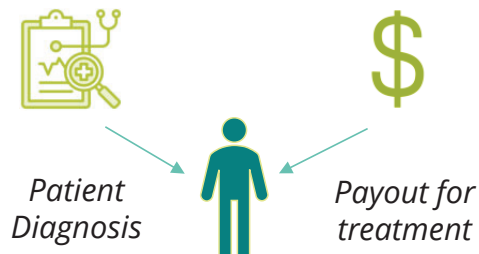


Note – Simplified for discussion purposes

Who benefits? The sponsor

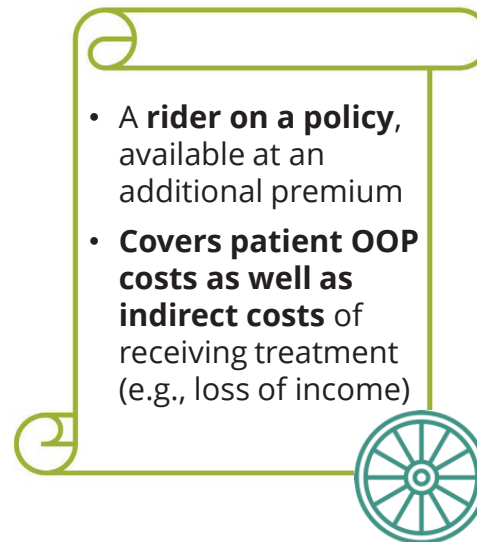
New insurance product models could include: accelerated benefits products, supplemental insurance products, and an extended/optional warranty model

Accelerated Benefit Product



Patient receives a **premature payout from their insurer upon CGT diagnosis** to cover the cost of treatment

Supplemental Insurance Product



Extended/Optional Warranty



Purchased at the time of care (point of differentiation from today's warranty models)



Ensures repayment or a cash outlay to the patient **in the event the therapy does not work** as intended

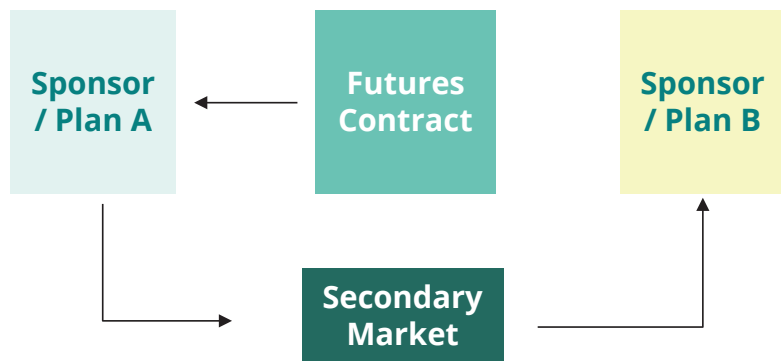
*While likely not enough to cover the full cost of treatment, this would **provide an added benefit to patients** as they undergo therapy and need additional financing support*

+ *Who benefits?* The patient / member

Therapeutic health credit drives access to therapies using financial instruments that exist today – allowing for the diversification of the risk associated with “lightning strike” nature of CGT claims

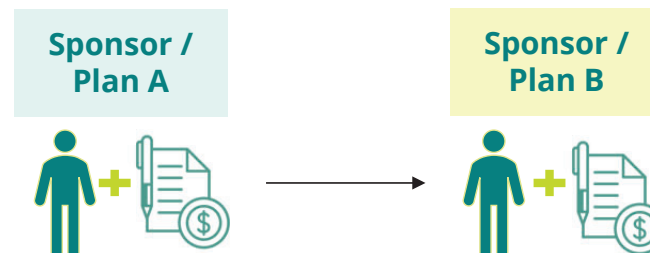
Futures Contracts Approach

1. Health plan sponsor acquires **futures contract** to cover the cost of an unexpected claim



2. If the claim does not materialize, a **secondary market would allow the sponsor to sell the contract to another sponsor** who has an immediate need for a treatment

Loan Contracts Approach



A low-interest loan could make a CGT more like the traditional chronic care model familiar to health plan sponsors.

These loans with repayment terms could become “pre-existing conditions”, allowing the **asset to transfer with employees if they leave the company.**

+ *Who benefits?* The sponsor (likely larger companies)

What should you do TODAY to prepare for potential CGT claims?

1 Develop your strategy

2 Check your policies

3 Talk about emerging models



Questions? Let's connect.

Drew Wilkins

Managing Director, Deloitte Consulting

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Coverage and Policy Considerations

Coverage Options

1. Stop Loss Coverage
2. Innovative Payment Options
 - Outcome-based contracts
 - Installment payments
 - Volume discounts
3. Centers of Excellence
4. Utilization management
5. Multi-employer risk pool

Policy Considerations

- Medicaid CGT Access Model
 - Direct negotiation b/w states and manufacturers.
 - Drug makers agree to outcomes measures and deeper discounts, states agree to access standards
- MVP Act (H.R. 2666)
 - Enables value-based purchasing of cell and gene therapies by clarifying impact on “Medicaid best price” policies

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