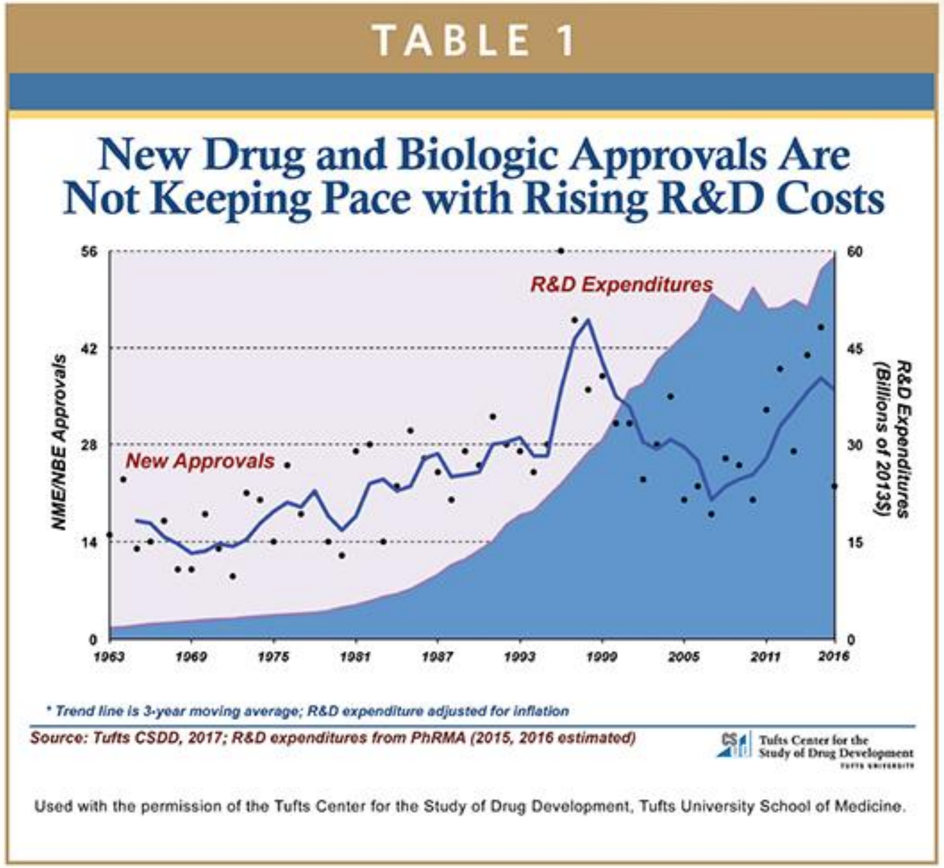
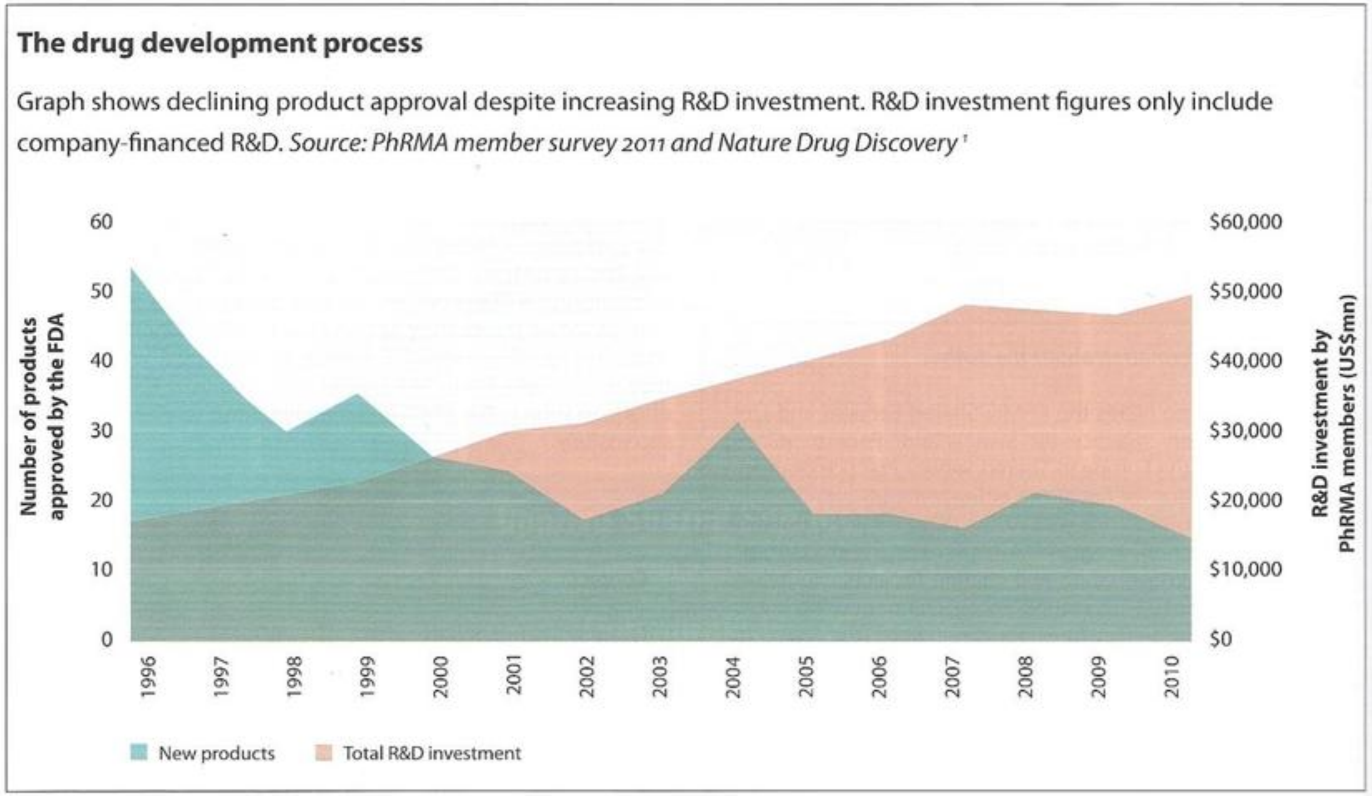
Current Limitations: The R&D Paradox. In the biopharmaceutical industry, there is the "R&D Paradox." Despite technological advancements, the cost of developing new drugs is skyrocketing, while the rate of FDA approvals remains unpredictable.



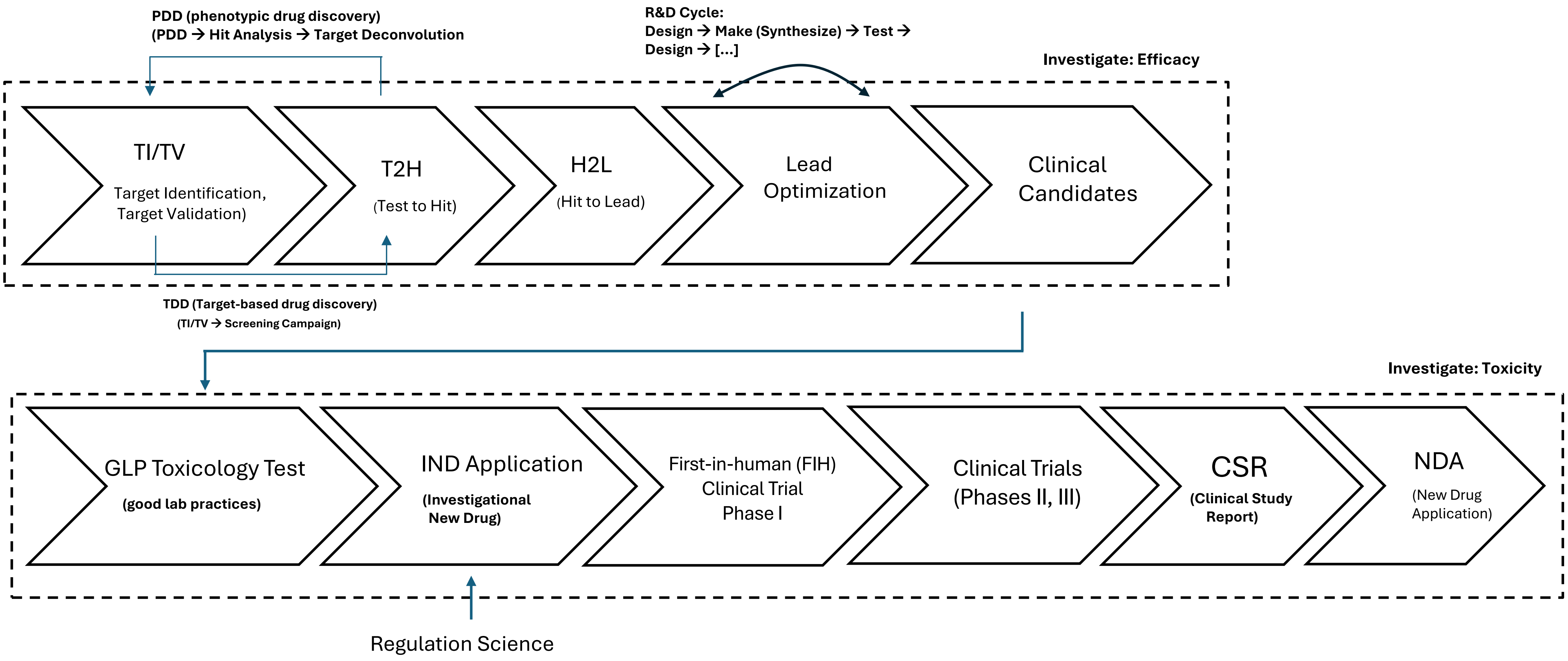


[1] **Mullard**, A, *Nature Reviews Drug Discovery* 10, 82-85 (February 2011)

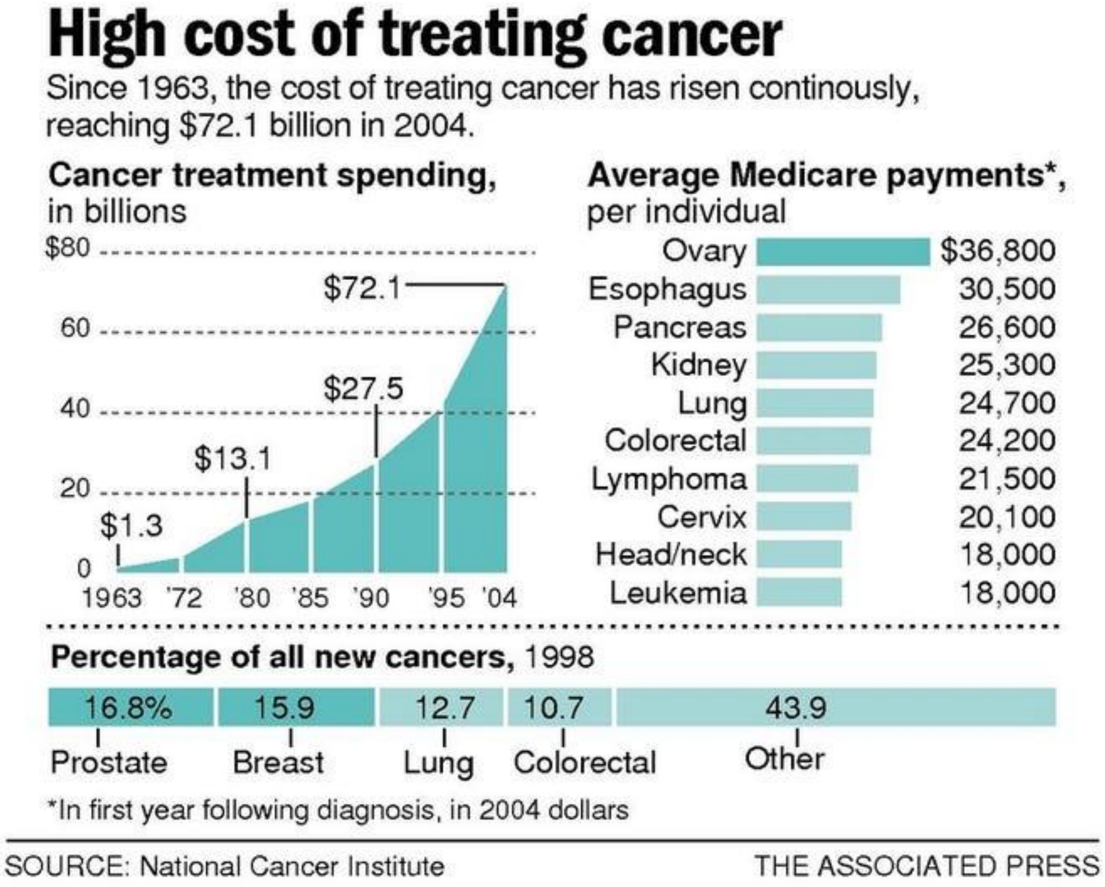
https://drug-dev.com/drug-development-to-de-risk-patient-acceptance-of-biologic-drugs-focus-early-on-delivery/

Tufts. http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014.pdf.

The Efficiency Gap: Typically, it takes approximately 17 years to go from initial drug candidate discovery to Phase 3 clinical trials and to final regulatory approval. Out of 10,000 potential drug candidates, only about three successfully make it to market.



The Financial Burden: Developing a single new drug costs roughly $4~11 billion. These astronomical costs in R&D, production, and distribution are ultimately passed down to patients as high medical expenses.



Article | August 30, 2017

Novartis Sets a Price of $475,000 for CAR T-Cell Therapy

Author(s): Tony Hagen

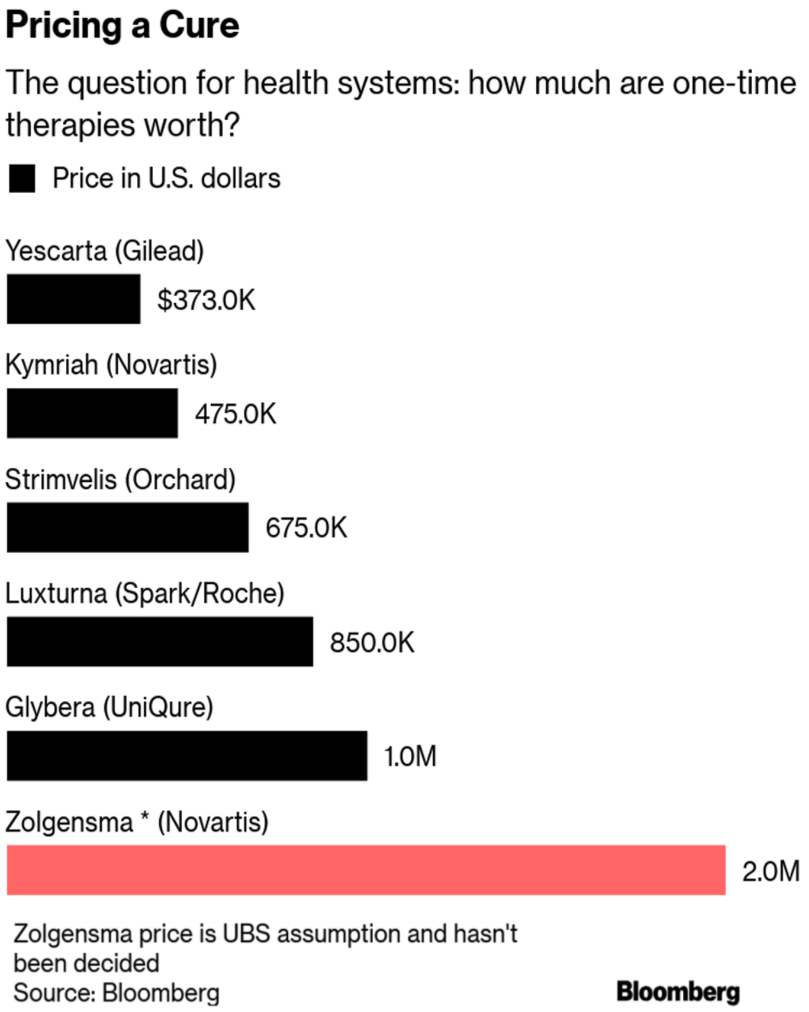
Novartis' just-approved chimeric antigen receptor (CAR) T-cell therapy tisagenlecleucel is going to be introduced on the market at a price of $475,000 for a single infusion, an amount that is within the range anticipated by oncologists.

CAR T-cell therapies have advanced treatment for patients with certain cancers. They offer sustained remission, fewer side effects, and a short treatment duration. However, they come with a hefty price tag. Between the cost of drug acquisition and administration, as well as management of adverse events (AEs), the cost for Carvykti is more than half a million dollars per patient per treatment. In some patients, the treatment might need to be repeated.

https://www.onclive.com/view/novartis-sets-a-price-of-475000-for-car-tcell-therapy

https://www.managedhealthcareexecutive.com/view/fda-approves-carvykti-for-earlier-treatment-in-multiple-myeloma

The Crisis in Rare Diseases: For rare genetic disorders, the situation is even more dire. For instance, gene therapies like those recently approved by the FDA for hemophilia can cost millions of dollars per dose.



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FDA approves $3.5 million treatment for hemophilia, now the most expensive drug in the world

(CNN) — A new gene therapy for the fatal genetic disorder metachromatic leukodystrophy, or MLD, will carry a wholesale price of $4.25 million, its manufacturer announced Wednesday, making it the world's most expensive medicine.

nature

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EDITORIAL | 04 December 2019

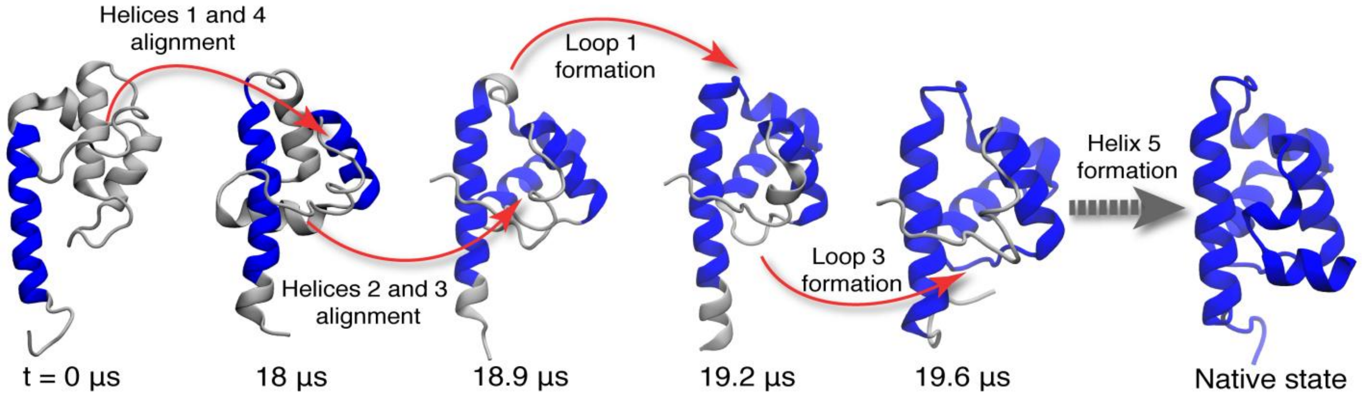
Expensive treatments for genetic disorders are arriving. But who should foot the bill?

The majority of people with sickle-cell disease are live in the world's poorest communities and cannot afford the eye-watering costs of treatments.

https://www.marketwatch.com/story/this-is-the-most-expensive-drug-in-america-2016-04-09

The Bottleneck of Classical Simulation: The computer simulations currently used by pharmaceutical R&D still suffer from significant drawbacks. Even when utilizing the world's most powerful supercomputers, Molecular Dynamics (MD) simulations for protein structures can take months. This is due to the exponential complexity of calculating quantum interactions within large biological systems.

supercomputer



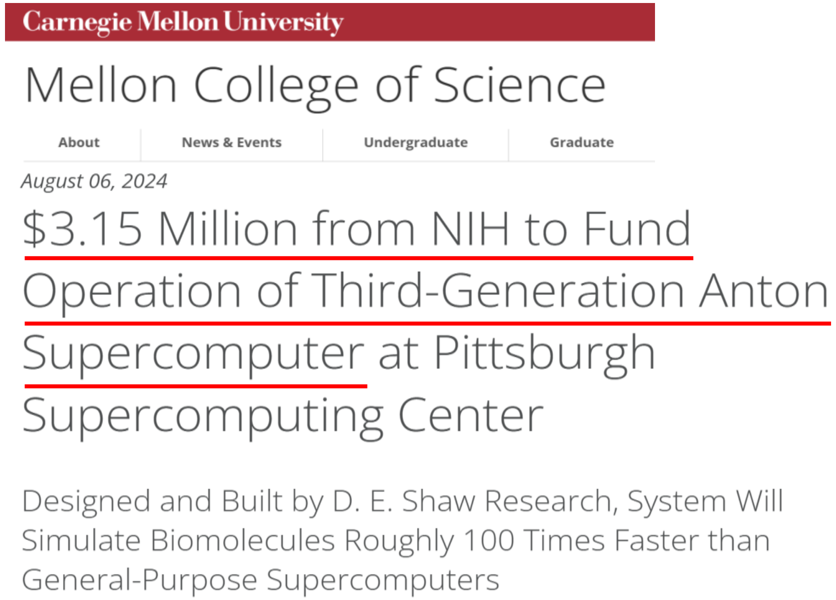
~ microsecond simulation = ~ months (at best) computing time

MD simulations, which track the motions of every atom in a large molecule, are limited in their time scales by computer power and architecture. It can take months for a supercomputing system to simulate only tens of microseconds of a protein's dynamics. But many proteins fold on the millisecond time scale.

Borman, Stu. "Anton Supercomputer Proves Mettle." *Chemical & Engineering News*, vol. 88, no. 42, 18 Oct. 2010, cen.acs.org/articles/88/i42/Anton-Supercomputer-Proves-Mettle.html. Accessed 23 Feb. 2025.

https://cen.acs.org/articles/88/i42/Anton-Supercomputer-Proves-Mettle.html
https://www.ks.uiuc.edu/Research/folding/

Operational and Environmental Costs: Running these massive simulations incurs substantial costs for electricity, cooling, and maintenance. This high energy consumption contributes to environmental pollution and resource depletion, creating an unsustainable industrial cycle.



Carnegie Mellon University

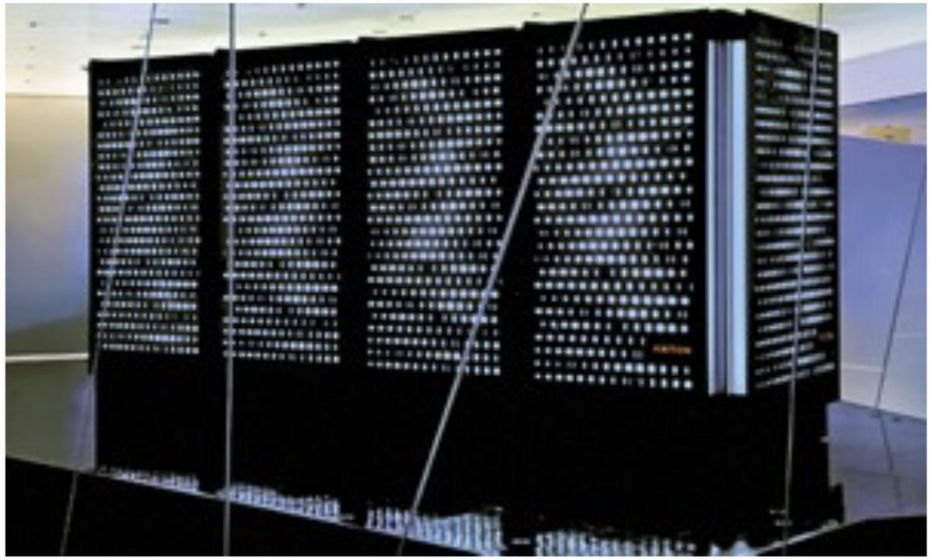
Mellon College of Science

About | News & Events | Undergraduate | Graduate

August 06, 2024

$3.15 Million from NIH to Fund Operation of Third-Generation Anton Supercomputer at Pittsburgh Supercomputing Center

Designed and Built by D. E. Shaw Research, System Will Simulate Biomolecules Roughly 100 Times Faster than General-Purpose Supercomputers



Credit: Courtesy of Matthew Monteith

Shaw Research's supercomputer Anton is designed to simulate the dynamics of biological macromolecules.

NVIDIA A100 GPU : USD $25,000

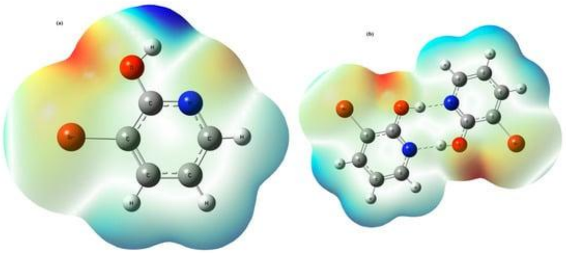
GPU X 1000 = $ 25,000,000

Chiacchia, Kenneth. "$3.15 Million from NIH to Fund Operation of Third-Generation Anton Supercomputer at Pittsburgh Supercomputing Center." *Mellon College of Science, Carnegie Mellon University*, 6 Aug. 2024, www.cmu.edu/mcs/news-events/2024/0806_3-15-million-from-nih-to-fund-operation-of-third-generation-anton-supercomputer.html. Accessed 23 Feb. 2025.

https://www.cmu.edu/mcs/news-events/2024/0806_3-15-million-from-nih-to-fund-operation-of-third-generation-anton-supercomputer.html

The Quantum Solution: A Paradigm Shift. Quantum computers leverage the principles of superposition, entanglement, and interference. Through parallel processing, they can handle multiple variables simultaneously, allowing for far more natural and rapid simulations of complex biological structures like proteins.

Molecular Simulation



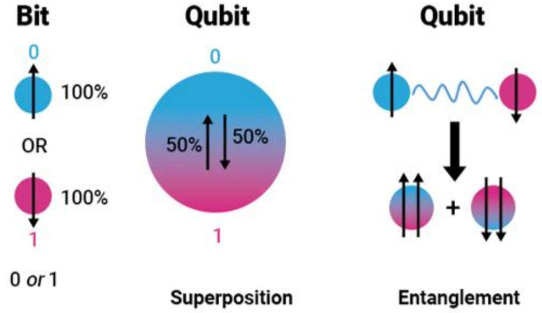
Natural Language

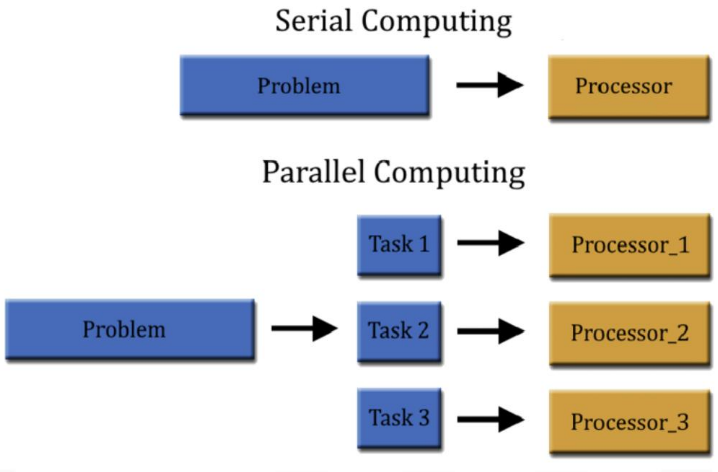
Quantum Mechanics

$$-\frac{\hbar^2}{2m}\nabla^2\psi + V\psi = E\psi$$

Natural Information Processing

Information Unit: Qubit

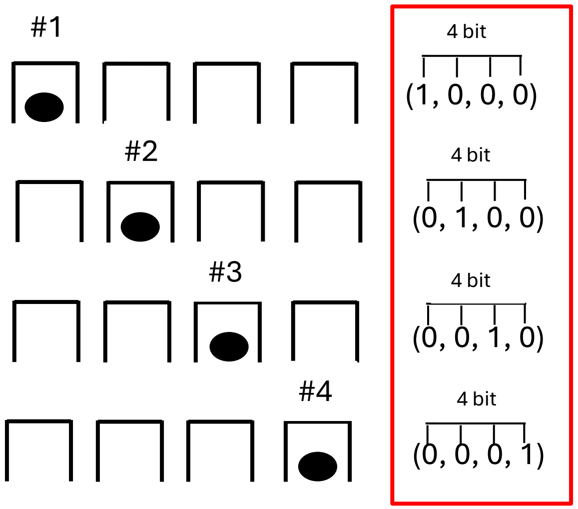




Çavuşoğlu, Ünal, et al. "Performance Evaluation of a Parallel Image Enhancement Technique for Dark Images on Multithreaded CPU and GPU Architectures." ResearchGate, Jan. 2022, doi:10.13140/RG.2.2.20285.67048.

The Speed Advantage: Grover's Algorithm. To understand the speed advantage, let's look at a simple example: finding a coin hidden under one of several boxes.

Classic Approach: Sequential Search



Task: Search Box with Coin → Python Code

```python
def find_coin(boxes):
    for i in range(4): # 4개의 상자를 순서대로 확인
        if boxes[i] == 1:
            return i + 1  # 상자 번호 (1부터 시작)
    return -1  # 동전이 없는 경우 (이 문제에서는 발생하지 않음)
```

```python
boxes = [0, 1, 0, 0]
print(find_coin(boxes))  # 출력: 2 (두 번째 상자)
```

1. Classical Approach (Sequential Search): Total Iterations Needed: Approximately N times. [~ O(N) order]
Example: If there are 4 boxes, you must flip them over one by one. To guarantee finding the coin, you might need up to 4 checks.

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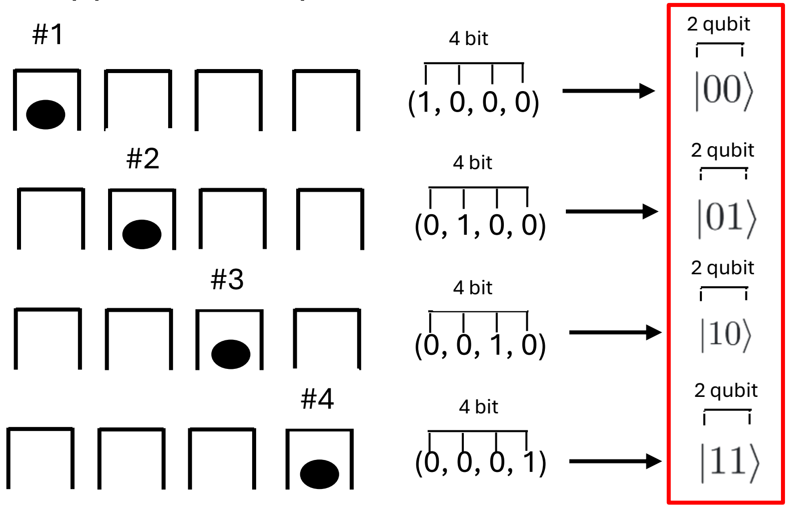

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Quantum Approach: Grover's Algorithm (1996)

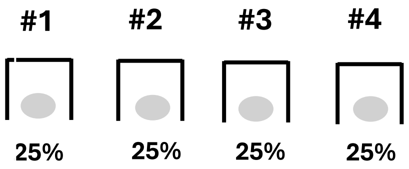
Task: Find the Box with the coin under it. (Answer: 2nd Box)

$|\psi\rangle$: Quantum state expressing the probability of the coin being under it

Start

$$|\psi\rangle = \frac{1}{2}(|00\rangle + |01\rangle + |10\rangle + |11\rangle)$$

Measurement → Quantum Collapse



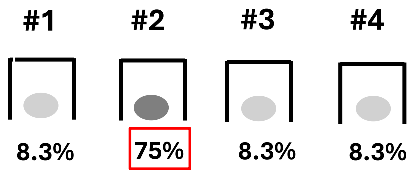
Iteration #1

1. Oracle Operation via CNOT/Z gate, etc
2. Probabilistic Amplification

(e.g.)

$$|\psi\rangle = \frac{1}{\sqrt{12}}(|00\rangle + \boxed{3}|01\rangle + |10\rangle + |11\rangle)$$

Measurement → Quantum Collapse



Iteration #2

1. Oracle Operation via CNOT/Z gate, etc
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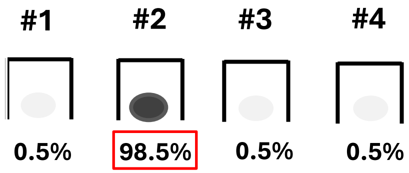
(e.g.)

$$|\psi\rangle = \frac{1}{\sqrt{103}}(|00\rangle + \boxed{10}|01\rangle + |10\rangle + |11\rangle)$$

Measurement → Quantum Collapse



Upon measuring Ψ, the quantum algorithm predicts box 2 with **98.5%** probability after the collapse of quantum state Ψ

https://hgmin1159.github.io/quantum/quantum_algorithm/

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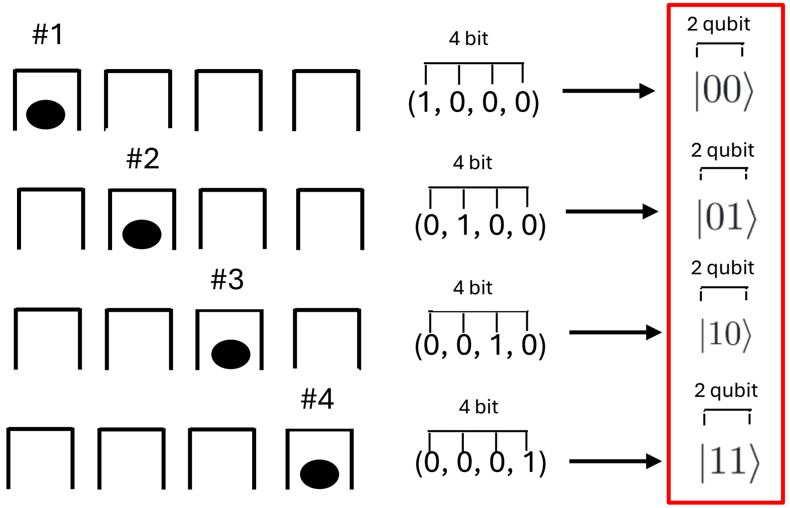
Classic Approach: Sequential Search



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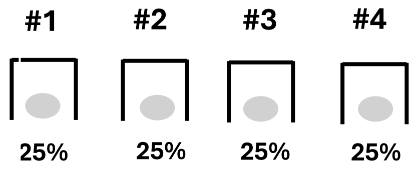

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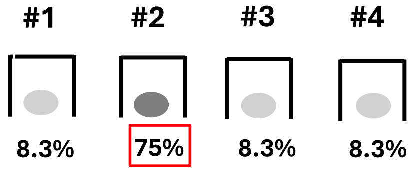

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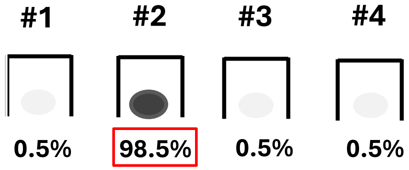


Total Iterations Needed: Approximately Root(n) times. [Complexity: ~ O(√n) order]

1. The "Oracle" Operation: If there are 4 boxes, you flip all boxes simultaneously using a quantum state representing the probability of the coin's location. You only need sqrt{4} = 2 operations.
→ Quadratic Speedup: This significant advantage over classical computation is known as Quadratic Speedup.

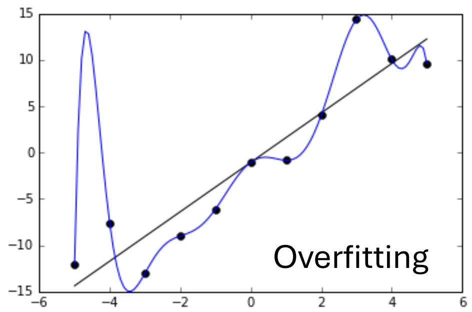
Overcoming Complex Medical Data Challenges: Medical data is notoriously difficult to process due to its multimodal structure, collinearity, unknown variables, and high-dimensionality. Classical statistical algorithms often hit a wall when trying to extract meaningful insights from such noise.

Problem 1: High-Dimensional Data

Definition: Situations where the number of variables greatly exceeds the number of observations (p >> n).

Issues:
- Overfitting: The model learns noise rather than patterns.
- Curse of Dimensionality: Data points become sparse, making distance-based calculations unreliable.
- Non-deterministic models: Results become inconsistent.

Example: Trying to fit 11 data points on a 2D plane using an n-degree polynomial where n >> 11.

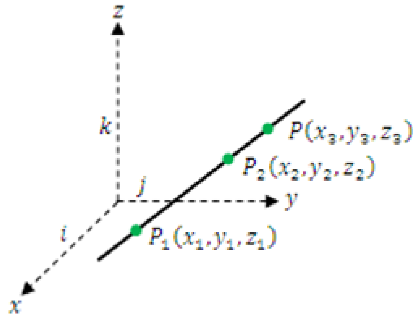


Problem 2: Collinearity

Definition: When multiple independent variables increase or decrease together in the same direction.

Issues:
- Model Instability: The variance of parameter estimates increases, making the model unreliable.
- Loss of Significance: It becomes difficult to reject the null hypothesis, rendering statistical validation meaningless.

Example: Visualizing x, y, z coordinates all increasing in the exact same direction in a 3D space, collapsing the distinct information of each axis.



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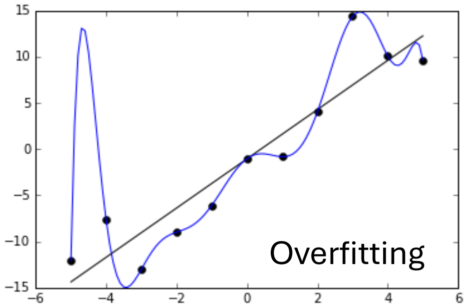

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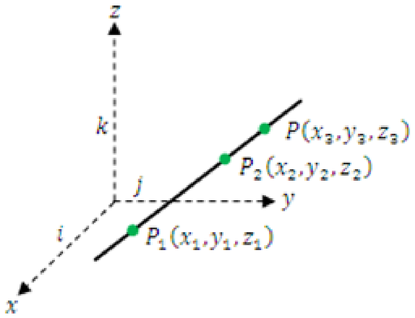

Problem 3: Multimodality

Definition: The presence of heterogeneous data types within a single dataset.

Examples: Electronic Medical Records (EMR), genomic sequences, and medical imaging (MRI/CT).

The Challenge: Capturing the complex cross-modality relationships and hidden patterns remains an unsolved "Grand Challenge" for classical systems.

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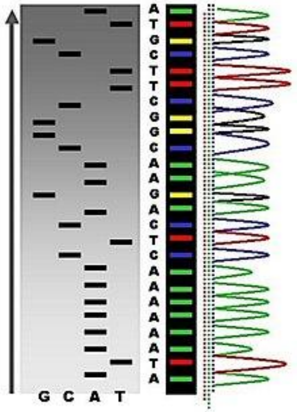

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mp4

When **collinearity** exists, the estimation of regression coefficients becomes unstable, standard errors increase, and t-values decrease. This makes it nearly impossible to determine the statistical significance of individual variables in drug efficacy trials.

$$\text{Cancer Risk} = \beta_0 + \beta_1(\boxed{\text{Smoking}}) + \beta_2(\boxed{\text{Alcohol Consumption}}) + \epsilon$$

High correlation

➔ Find $\hat{\beta} = (\hat{\beta}_0, \hat{\beta}_1, \hat{\beta}_2)$ with least squares method

Linear 2-variable Regression: $Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \epsilon$

1. Data

Y	X_1	X_2
2	1	1
4	2	0
6	3	1
8	4	0
10	5	1

2. Design matrix (X)

$$\mathbf{X} = \begin{bmatrix} 1 & 1 & 1 \\ 1 & 2 & 0 \\ 1 & 3 & 1 \\ 1 & 4 & 0 \\ 1 & 5 & 1 \end{bmatrix}$$

3. Compute: $\mathbf{X}^T\mathbf{X}$, $\mathbf{X}^T\mathbf{Y}$, $(\mathbf{X}^T\mathbf{X})^{-1}$

Compute: $\hat{\beta} = (\mathbf{X}^T\mathbf{X})^{-1}\mathbf{X}^T\mathbf{Y}$

$$\hat{\beta} = \begin{bmatrix} \hat{\beta}_0 \\ \hat{\beta}_1 \\ \hat{\beta}_2 \end{bmatrix}$$

4. Compute: $\mathrm{Var}(\hat{\boldsymbol{\beta}})$, $\mathrm{Var}(\hat{\beta}_1)$, $\mathrm{Var}(\hat{\beta}_2)$

$$\boxed{\mathrm{Var}(\hat{\boldsymbol{\beta}})} = \sigma^2(\mathbf{X}^T\mathbf{X})^{-1} \rightarrow \epsilon \sim N(0, \boxed{\sigma^2})$$

$$= \begin{bmatrix} \mathrm{Var}(\hat{\beta}_1) & \mathrm{Cov}(\hat{\beta}_1, \hat{\beta}_2) \\ \mathrm{Cov}(\hat{\beta}_1, \hat{\beta}_2) & \mathrm{Var}(\hat{\beta}_2) \end{bmatrix}$$

High Var.

$$\boxed{\mathrm{Var}(\hat{\beta}_1)} = \frac{\sigma^2}{(1-\rho^2)S_{11}}$$

$$\boxed{\mathrm{Var}(\hat{\beta}_2)} = \frac{\sigma^2}{(1-\rho^2)S_{22}}$$

$$S_{11} = \sum(X_1 - \bar{X}_1)^2, \quad S_{22} = \sum(X_2 - \bar{X}_2)^2, \quad S_{12} = \sum(X_1 - \bar{X}_1)(X_2 - \bar{X}_2)$$

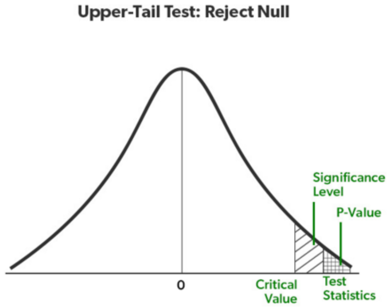
$\boxed{\text{상관계수 } \rho} = \dfrac{S_{12}}{\sqrt{S_{11}S_{22}}}$ | $\rho \rightarrow 1$, $1 - \rho^2 \rightarrow 0$, 일수록 $\boxed{\mathrm{Var}(\hat{\beta}_1) \gg 1, \ \mathrm{Var}(\hat{\beta}_2) \gg 1}$

5. Conduct t-test

$$H_0 : \beta_1 = 0 \qquad H_A : \beta_1 > 0 \qquad t_1 = \frac{\hat{\beta}_1}{SE(\hat{\beta}_1)} = \frac{\hat{\beta}_1}{\sqrt{\mathrm{Var}(\hat{\beta}_1)}}$$

$$H_0 : \beta_2 = 0 \qquad H_A : \beta_2 > 0 \qquad t_2 = \frac{\hat{\beta}_2}{SE(\hat{\beta}_2)} = \frac{\hat{\beta}_2}{\sqrt{\mathrm{Var}(\hat{\beta}_2)}}$$

$$\text{p-value}_1 = P(T > t_1 \mid H_0)$$
$$\text{p-value}_2 = P(T > t_2 \mid H_0)$$



$p \geq \alpha \quad (0.05)$ Cannot reject H0

$p < \alpha \quad (0.05)$ Reject H0, Exists correlation between smoking, alcohol with cancer

6. If Colinearity is High:

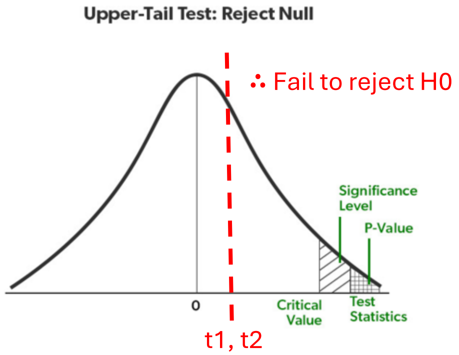
$$\rho = \frac{S_{12}}{\sqrt{S_{11}S_{22}}} \rightarrow 1$$

$\mathrm{Var}(\hat{\beta}_1) \gg 1$

$\mathrm{Var}(\hat{\beta}_2) \gg 1$

$$t_1 = \frac{\hat{\beta}_1}{SE(\hat{\beta}_1)} = \frac{\hat{\beta}_1}{\sqrt{\mathrm{Var}(\hat{\beta}_1)}} \ll 1$$

$$t_2 = \frac{\hat{\beta}_2}{SE(\hat{\beta}_2)} = \frac{\hat{\beta}_2}{\sqrt{\mathrm{Var}(\hat{\beta}_2)}} \ll 1$$



A statistical test might fail to establish a clear correlation between smoking, alcohol consumption, and cancer rates because the variables are too closely intertwined for classical models to isolate.

Practical Applications in Genomics and Epidemiology: By utilizing Quantum Search and Clustering algorithms, we can analyze vast amounts of cancer genomic data to identify and classify pathogenic gene variants or cancer-related mutations much more rapidly than ever before.

1. Cancer Diagnosis

2. Multi-omics data

Genomic Data
Transcriptomic Data
Proteomic Data
Metabolomic Data

Data Preprocessing

3. Quantum Algorithms

(e.g.) Search

Genome/DNA sequence
- Find Pathogenic gene variation compared to normal physical gene variation

Transcriptomic (scRNA-seq) Sequence
- Dysregulated/Aberrant pathways

(e.g.) Clustering/Classification

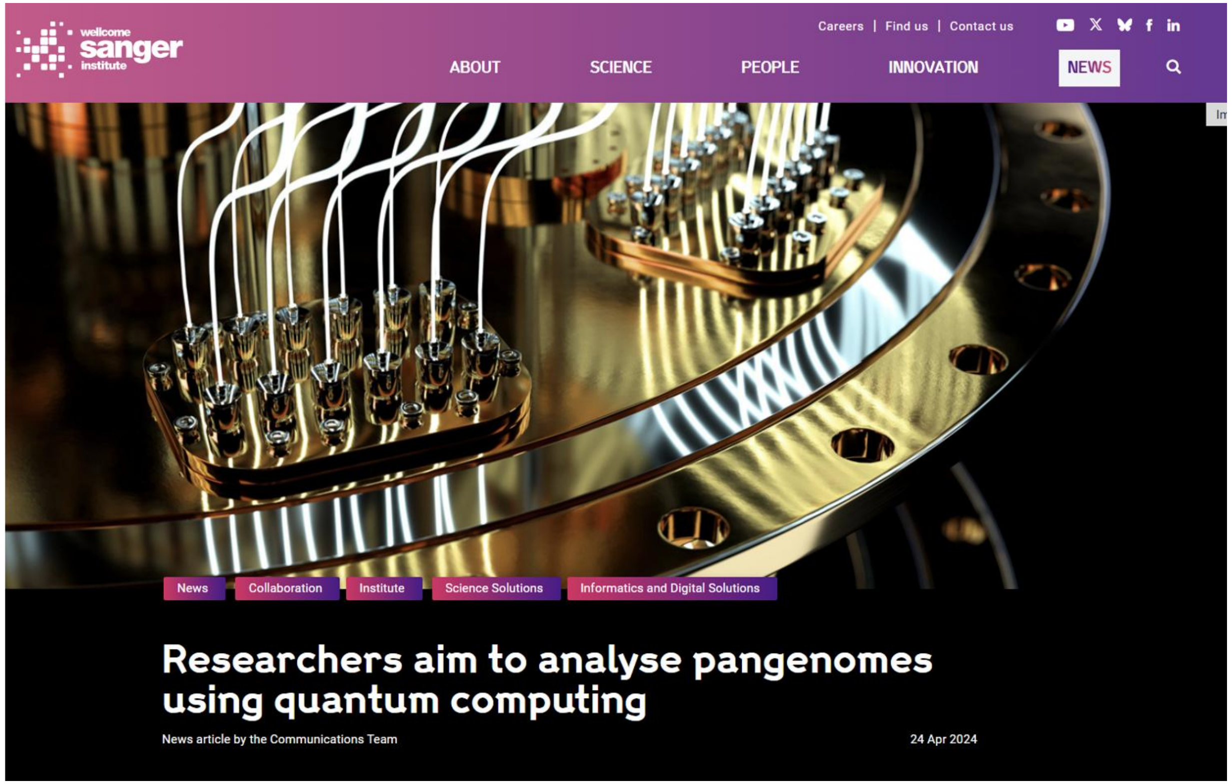
- Cluster tumors into subtypes based on different molecular signatures

- Find correlations (btw genes/pathways) acros s different omics layers → holistic tumor modeling

4. Personalized medicine

(e.g.) Tumor metabolic profile
→ metabolic dependency-targeting therapy
(e.g.) Tumor immune profile
→ tumor-specific immunotherapy

Case Study (Population Genomics): A prime example is the 2024 research initiative by the University of Cambridge. The project secured up to $3.5 million in funding to build, supplement, and analyze Pangenome data using quantum computers, aiming to capture the full diversity of human genetics.



UNIVERSITY OF CAMBRIDGE

wellcome sanger institute

https://www.sanger.ac.uk/news_item/researchers-aim-to-analyse-pangenomes-using-quantum-computing/

- Useful as reference genome in:
  - Disease Treatment
  - Population Genetics / Evolution Studies
  - Anthropology

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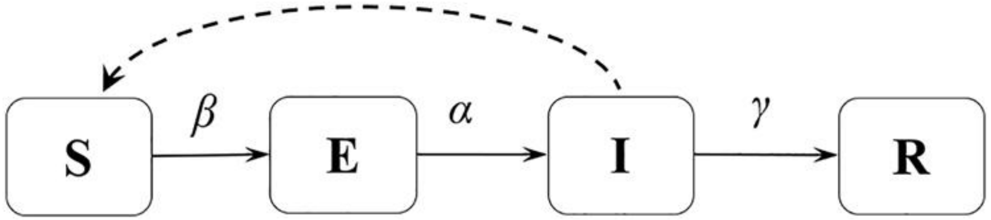
Researchers aim to use quantum computing to assemble and analyse pangenomes

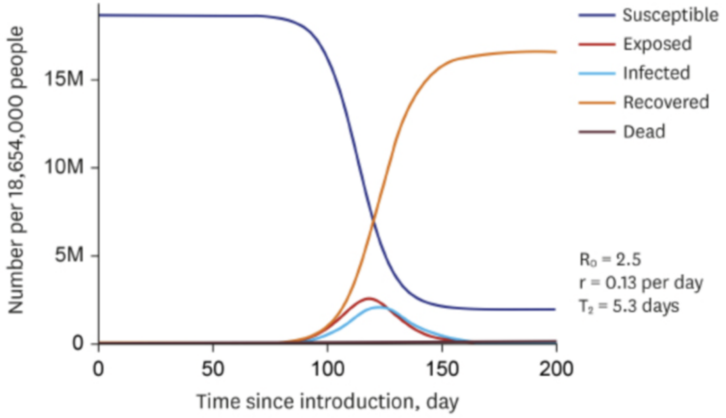
Experts in quantum computing and genomics to develop new methods and algorithms to process biological data

IBM Q System One Quantum Computer at the Consumer Electronic Show in 2020. Credit: AA+W Adobe Stock

Pandemic Response and Disease Modeling. Quantum Optimization algorithms can also be applied to disease spread models, such as those for COVID-19. By predicting epidemiological model parameters with higher accuracy, they enable the development of more effective quarantine and prevention strategies.



$$\frac{dS}{dt} = -\beta IS/N$$
$$\frac{dE}{dt} = \beta IS/N - \sigma E$$
$$\frac{dI}{dt} = \sigma E - \gamma I$$
$$\frac{dR}{dt} = \gamma I$$



S: Susceptible individuals
E: Exposed individuals (infected but not yet infectious)
I: Infectious individuals
R: Recovered or removed individuals

β (beta): The transmission rate
γ (gamma): The recovery rate
σ (sigma): 1/latent period

Input:

- Cost function $C(\beta, \sigma, \gamma)$ to be minimized.

Quantum Optimization → Parameter Estimation

$$\boldsymbol{\theta}^{(t+1)} = \boldsymbol{\theta}^{(t)} - \alpha \nabla C(\boldsymbol{\theta}^{(t)})$$
$$\theta = (\beta, \sigma, \gamma)$$

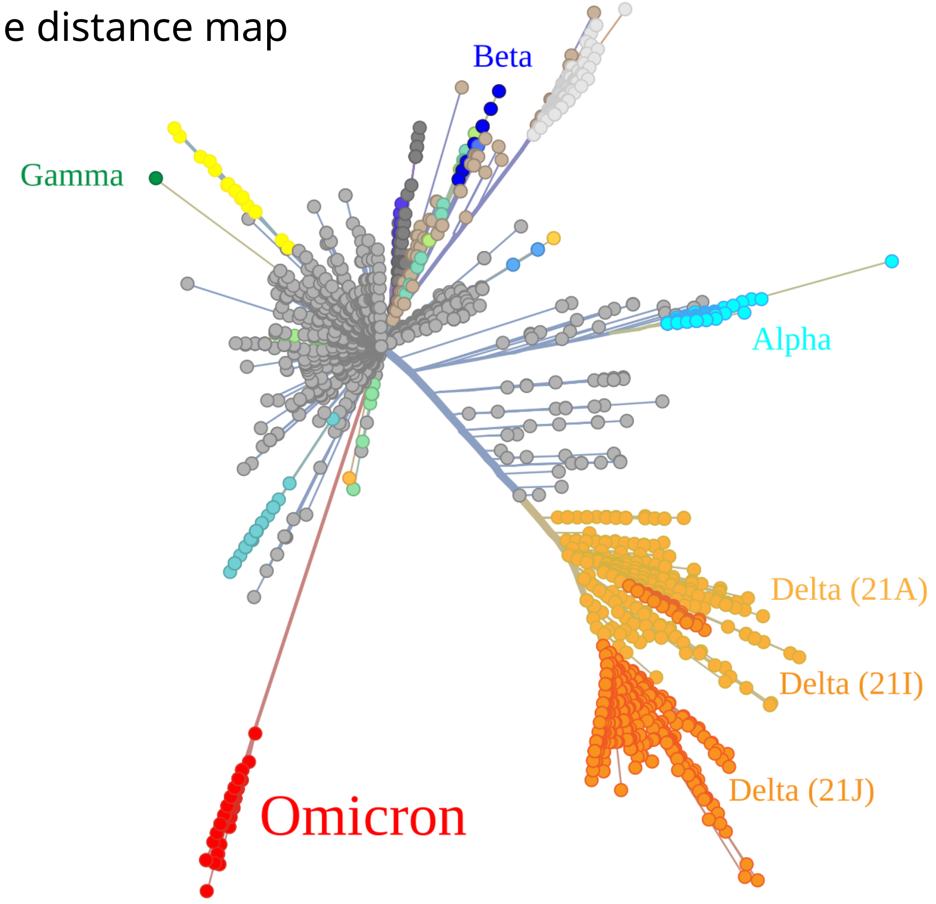
Output:

- Optimal parameter set $(\beta^*, \sigma^*, \gamma^*)$.

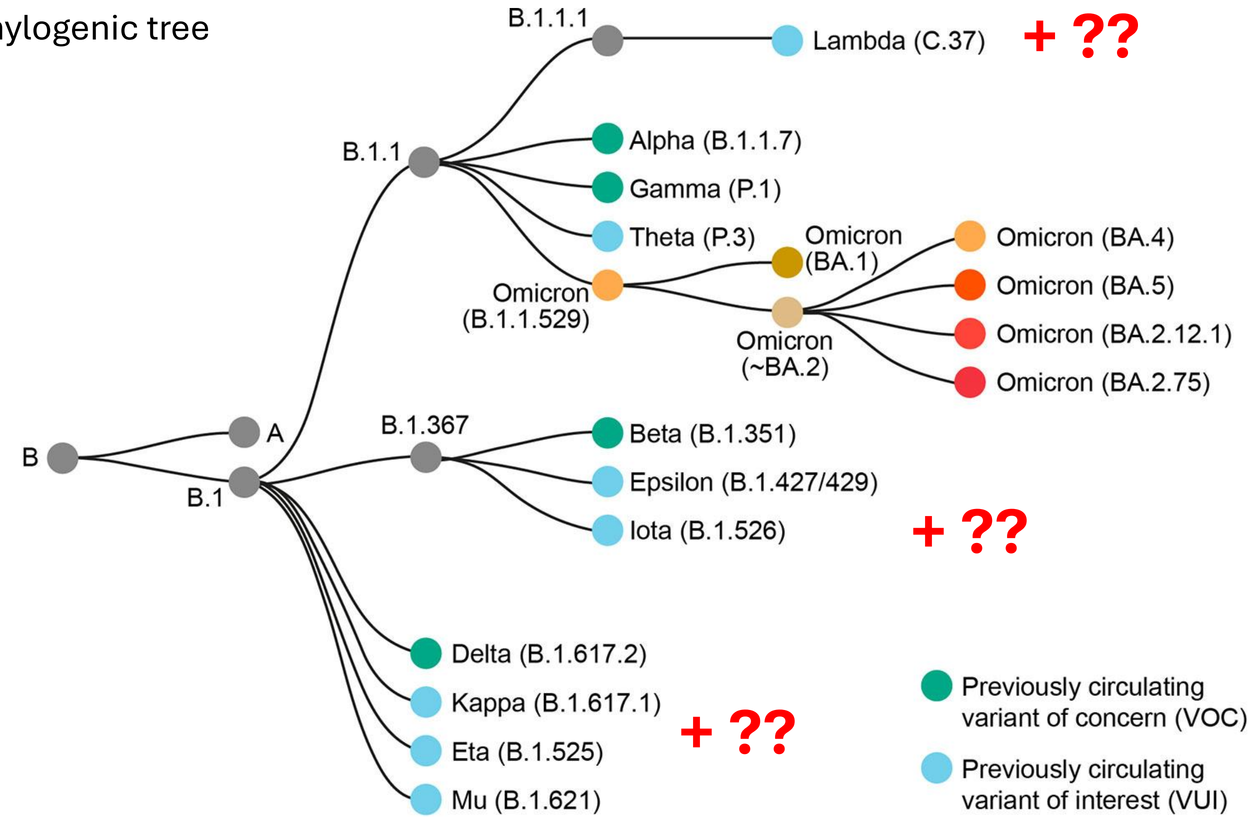
Khokhar, Ali Shahryar. "A Review of Quantum Gradient Descent." *LUMS SSE PHY 612 Quantum Information Science - Spring 2023*, Lahore University of Management Sciences, 2023, https://physlab.org/wp-content/uploads/2023/04/QuantumGD_24100266.pdf.

Phylogenetic Analysis: During a global pandemic, quantum algorithms can calculate the genetic distance between viral variants and analyze phylogenetic trees. This allows us to identify mutations that may lead to increased transmissibility or immune evasion, effectively predicting potentially dangerous variants before they spread..

SARS-CoV-2 mutation gene distance map

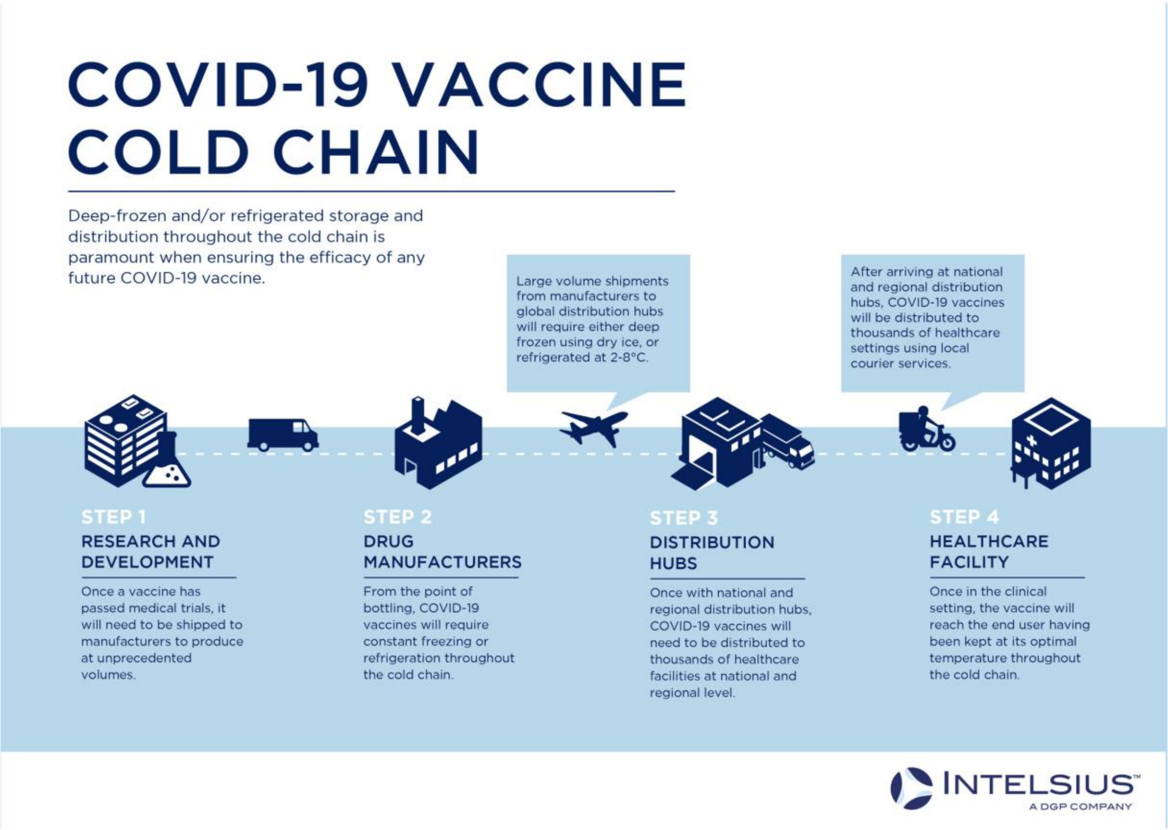


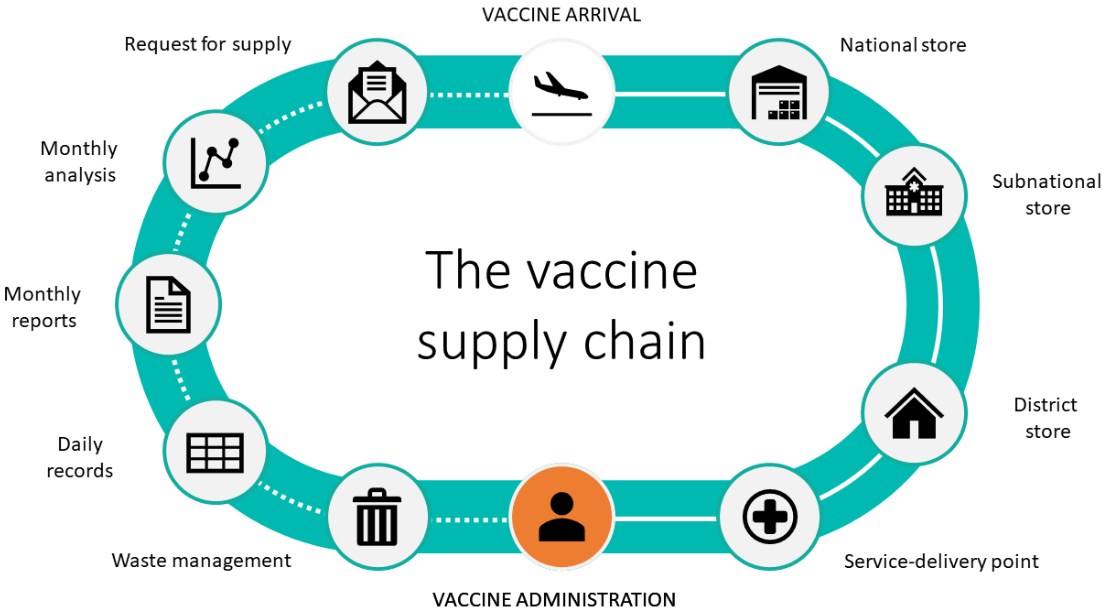
SARS-CoV-2 variants Phylogenic tree



"Corrigendum: SARS-CoV-2 Omicron variants: burden of disease, impact on vaccine effectiveness and need for variant-adapted vaccines." ***Frontiers in Immunology*****, vol. 14, 2023, https://doi.org/10.3389/fimmu.2023.1130539/full.**

Supply Chain Optimization: Furthermore, quantum algorithms can optimize complex supply chain operations during global health crises. This ensures that vaccines, medications, and medical resources are allocated with maximum efficiency, even under extreme logistical constraints.





https://intelsius.com/news/covid-19-vaccine-role-dry-ice/

https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/supply-chain

3. Conclusion: For a Healthier and More Equitable Future. In conclusion, quantum computing is the key to solving the most persistent challenges in global health. Our goal should be to leverage this technology to tackle these “grand challenges" and ensure that the benefits of medical innovation reach everyone. We must strive to build a future where no one is marginalized and all of humanity can prosper together through the power of quantum-enhanced medicine.

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EDITORIAL · Volume 12, Issue 3, E341, March 2024 · *Open Access* Download Full Issue

The landscape for rare diseases in 2024

The Lancet Global Health

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By definition, rare diseases affect a small number of individuals (fewer than 1 in 2000 people in any WHO region); yet, with more than 7000 types of rare disease in existence, the burden worldwide is not insignificant. To date, approximately 300 million people live with rare diseases. Such individuals are often a neglected and marginalised group, especially those in low-income and middle-income countries. Around 80% of rare diseases

Saha, Sujata, et al. "Trends in Maternal Mortality, 2000–2020: Estimates by WHO, UNICEF, UNFPA, World Bank Group, and UNDESA/Population Division." The Lancet Global Health, 22 Feb. 2024, www.thelancet.com/journals/langlo/article/PIIS2214-109X(24)00056-1/fulltext. Accessed 23 Feb. 2025.

https://www.mcri.edu.au/impact/a-z-child-adolescent-health/o-r/rare-genetic-disorders