Revolutionizing Healthcare with Synthetic Clinical Trial Data

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May 10, 2023

Synthetic Data Applications

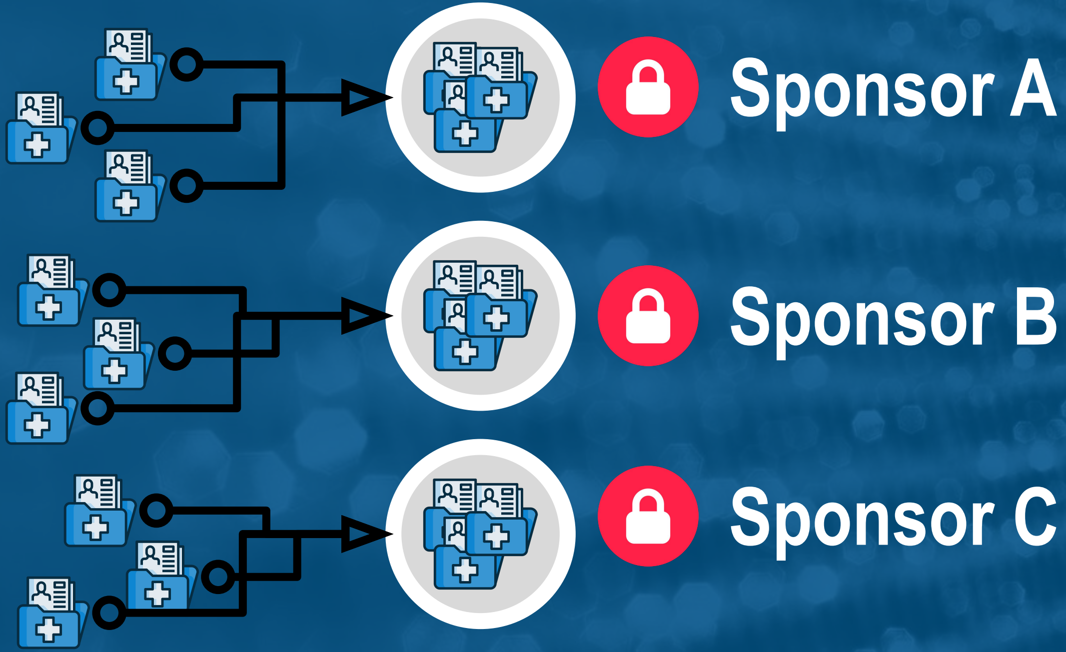
Data sharing

Data augmentation

Icons Source: Flaticon; Full credits in the last slide

Data Sharing

Clinical trial data remains siloed due to patient privacy and sponsor privacy concerns



Icons Source: Flaticon; Full credits in the last slide

Collaboration remains limited due to data access restrictions

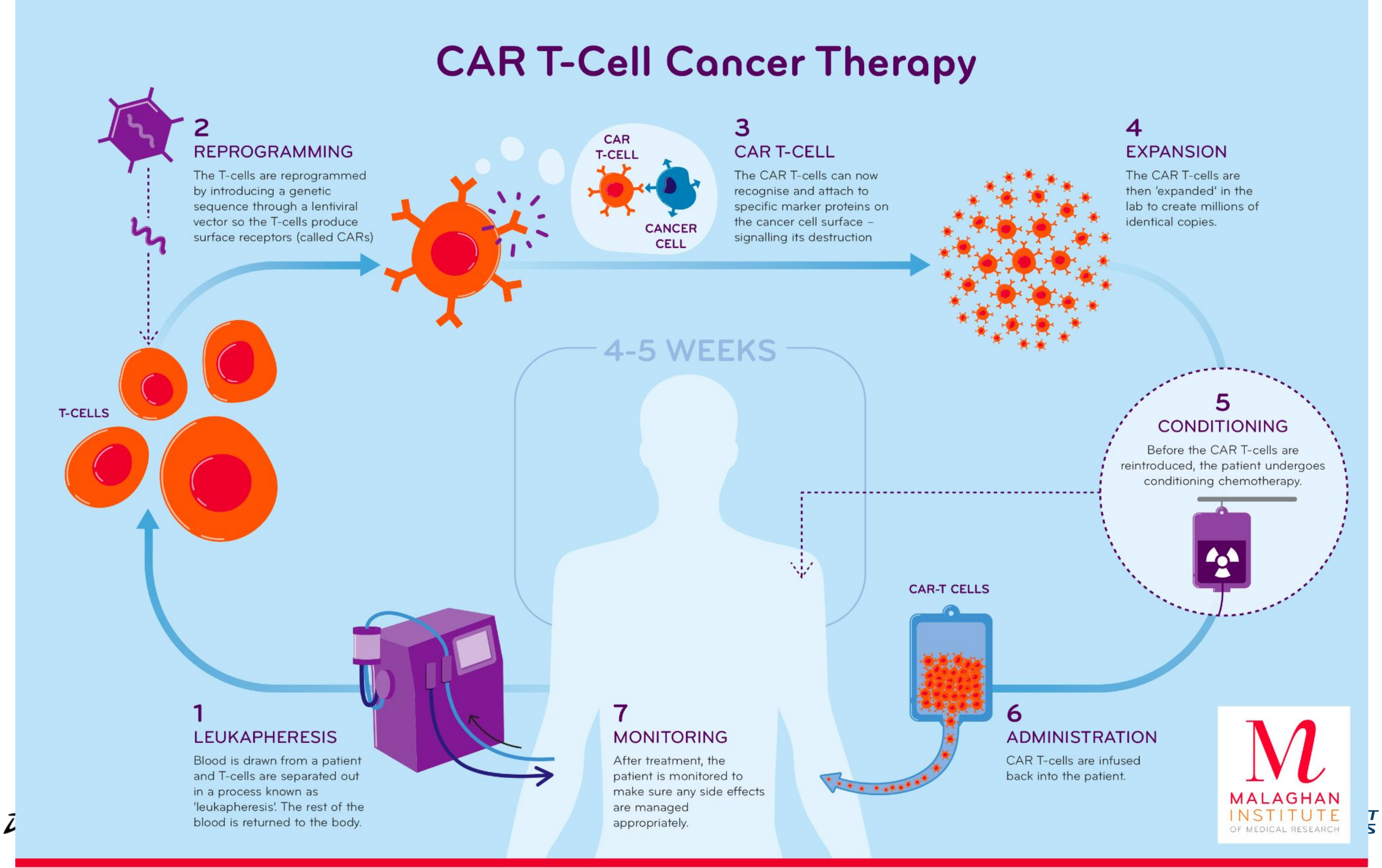
Sponsor A

Sponsor B

Sponsor C

Icons Source: Flaticon; Full credits in the last slide

Why is collaboration necessary?



CAR T-Cell Cancer Therapy
2
REPROGRAMMING
The T-cells are reprogrammed by introducing a genetic sequence through a lentiviral vector so the T-cells produce surface receptors (called CARs)
CAR T-CELL
CANCER CELL
3
CAR T-CELL
The CAR T-cells can now recognise and attach to specific marker proteins on the cancer cell surface – signalling its destruction
4
EXPANSION
The CAR T-cells are then 'expanded' in the lab to create millions of identical copies.
T-CELLS
4-5 WEEKS
5
CONDITIONING
Before the CAR T-cells are reintroduced, the patient undergoes conditioning chemotherapy.
CAR-T CELLS
1
LEUKAPHERESIS
Blood is drawn from a patient and T-cells are separated out in a process known as 'leukapheresis'. The rest of the blood is returned to the body.
7
MONITORING
After treatment, the patient is monitored to make sure any side effects are managed appropriately.
6
ADMINISTRATION
CAR T-cells are infused back into the patient.
MALAGHAN INSTITUTE OF MEDICAL RESEARCH

TIME

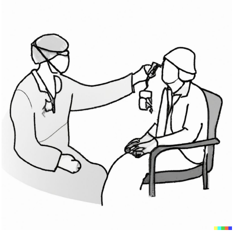
HEALTH • CANCER

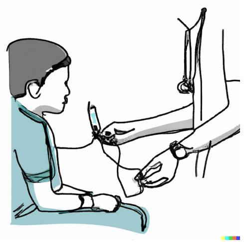
Cancer's Newest Miracle Cure

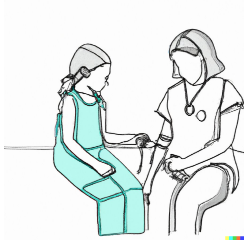
August 21, 2017 issue of TIME.

"Went looking for a miracle…"

Source
CHOP News (May 2022)



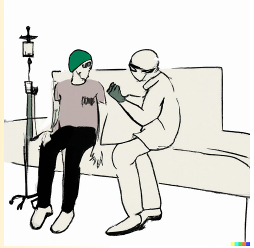


Cell therapy almost always begins its development journey by offering a treatment option to patients with very advanced & difficult to treat cancers.

* visuals created using DALL-E

No one can know exactly how any one patient will respond to these experimental treatments …

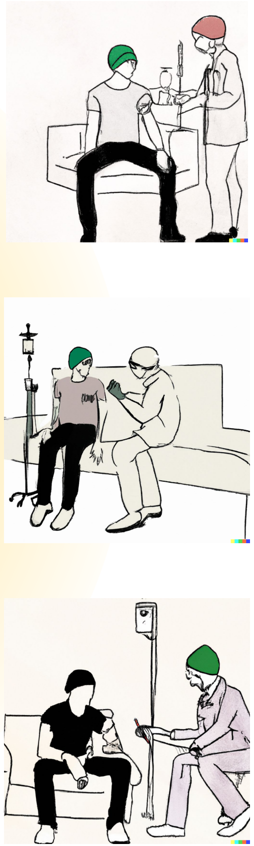
* visuals created using DALL-E



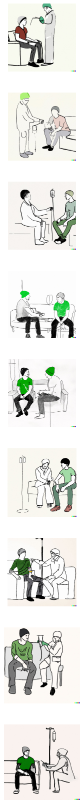
… but we do know that making a personalized medicine for an individual relies on our experience treating similar people with similar diseases

* visuals created using DALL-E

1 patient



1 doctor



1 trial

1 sponsor

Medidata AI

If we could learn from the combined experience of the whole world, rather than just relying on the experience of a single doctor or hospital or sponsor …

How well could we do?

* visuals created using DALL-E

Relapse

The journey of a CAR-T trial participant begins with the return of cancer …

* visuals created using DALL-E

Relapse

Enrollment

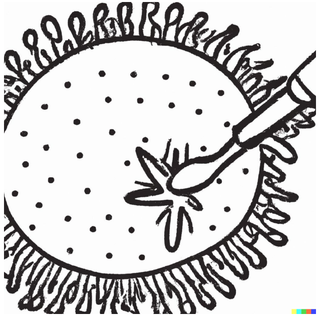
… the failed search for a viable approved treatment, and an introduction to a clinical investigator …

* visuals created using DALL-E

Relapse

Enrollment

Apheresis



Manufacturing

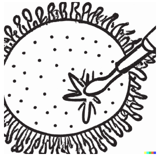
… removal of healthy lymphocytes and manufacture of a targeted dose of CAR-T cells …

* visuals created using DALL-E

Relapse

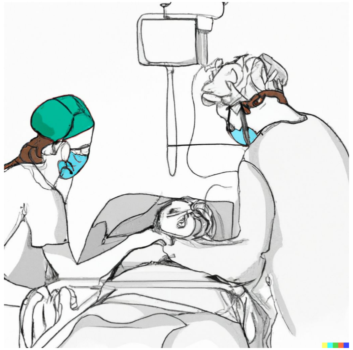
Enrollment

Apheresis



Manufacturing

Treatment



Management

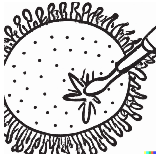
… treatment with investigational CAR-T therapy and careful management of patients through the side effects that follow …

* visuals created using DALL-E

Relapse

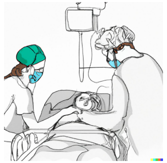
Enrollment

Apheresis

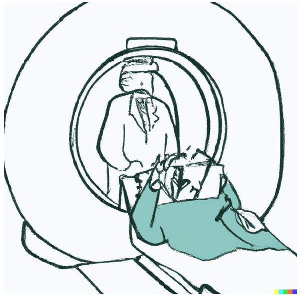


Manufacturing

Treatment



Management



Response

Control

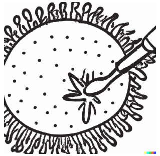
… finally, a new response to treatment, disease control …

* visuals created using DALL-E

Relapse

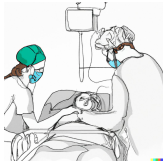
Enrollment

Apheresis

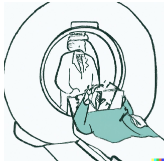


Manufacturing

Treatment



Management



Response

Control

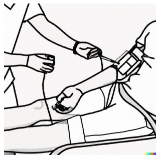
Home.

… and a return Home.

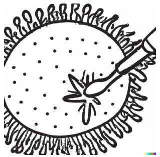
* visuals created using DALL-E

Relapse

Enrollment

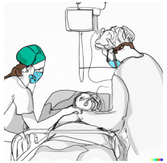


Apheresis

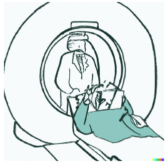


Manufacturing

Treatment



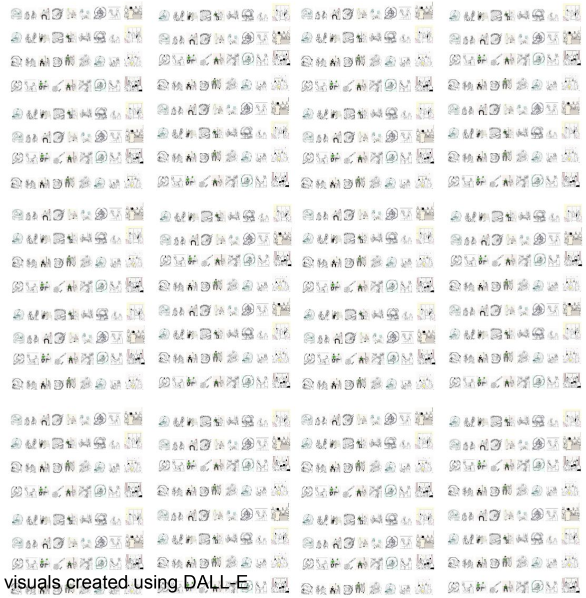
Management



Response

Control

Home.



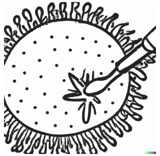
Now, what if we understood this journey for 100 patients?

* visuals created using DALL-E

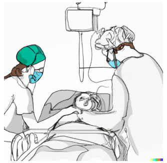

Relapse

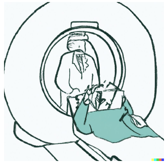

Enrollment


Apheresis


Manufacturing


Treatment


Management


Response

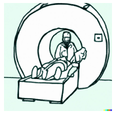

Control


Home.

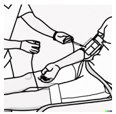
For 3,000?

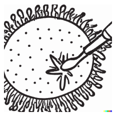
* visuals created using DALL-E

1 patient. 1 journey. 1 experience.

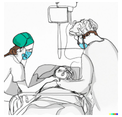

Relapse

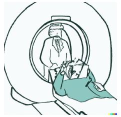

Enrollment


Apheresis


Manufacturing


Treatment

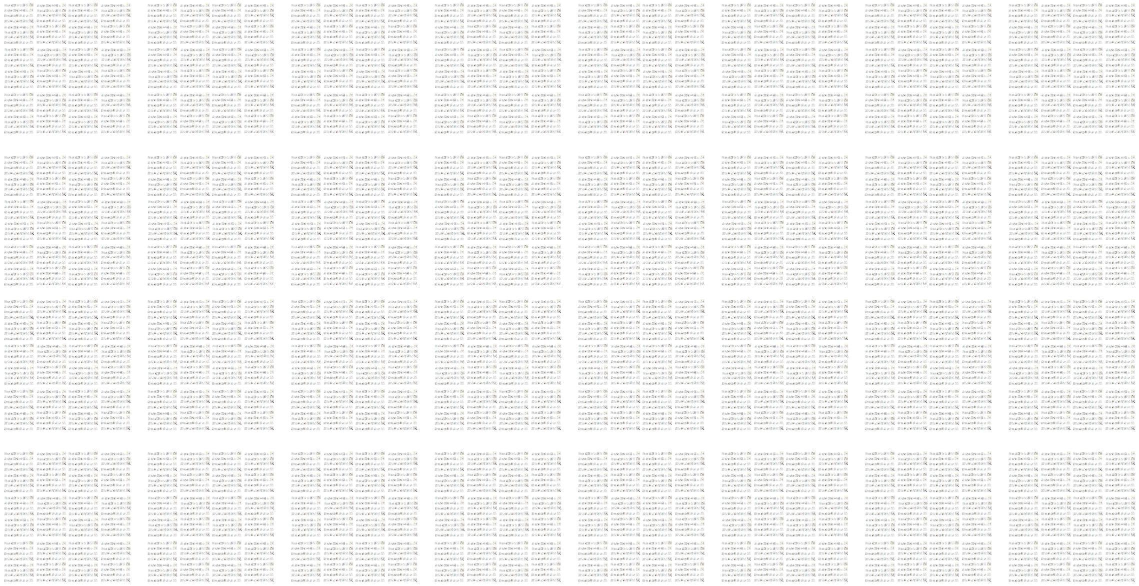

Management


Response


Control


Home.

Medidata AI — 3,000 CAR-T patient journeys today … and growing

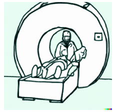


* visuals created using DALL-E

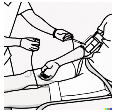
If we could learn from the combined experience of the whole world, rather than just relying on the experience of a single doctor or hospital or sponsor, what?

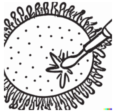
How well could we do?

IF WE™

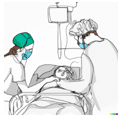

Relapse

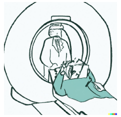

Enrollment


Apheresis


Manufacturing


Treatment


Management


Response


Control

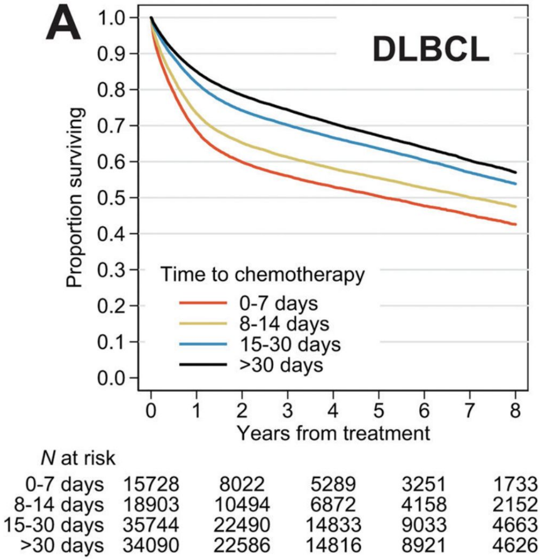

Follow-up

Every step in the patient's journey provides opportunities to design better trials to prove the benefit of new treatments

* visuals created using DALL-E

Relapse

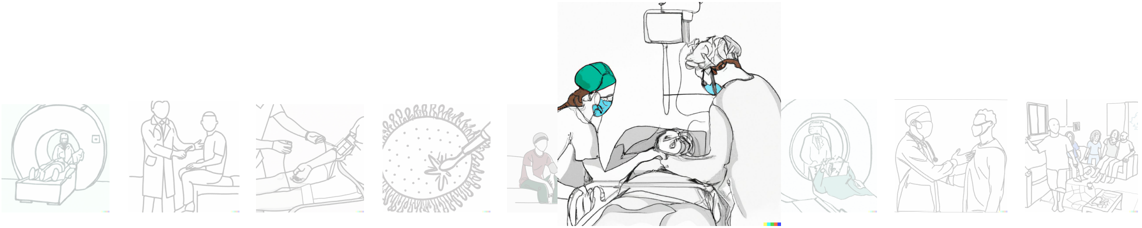
Example



The length of **time between diagnosis and treatment** may be the **single strongest predictor of the prognosis** for trial participants with high risk lymphoma

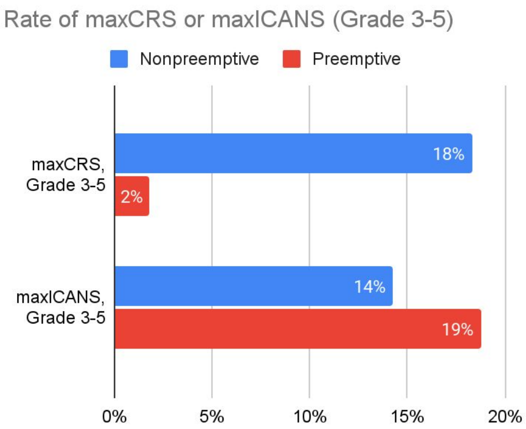
Alshaibani, A. et al (2019). *High risk patients with diffuse large B cell lymphoma are not enrolled on clinical trials.* JCO 37, e19058–e19058.

* visuals created using DALL-E



Management

Example



Pre-emptive treatment of CAR-T recipients with tocilizumab & dexamethasone reduces severe CRS rates but does not decrease rates of ICANS (neurotoxicity)

EHA 2023

Authors:

Esther Nie, MD, PhD[2†]; Penelope Lafeuille, MS[1†]; Sheila Diamond, MS, CGC[1]; Jacob Aptekar, MD, PhD[1]; Vibhu Agarwal, PhD, MBA[1]

Affiliations:

1. *Medidata, a Dassault Systèmes company, New York, NY*
2. *Stanford University, Stanford, CA*

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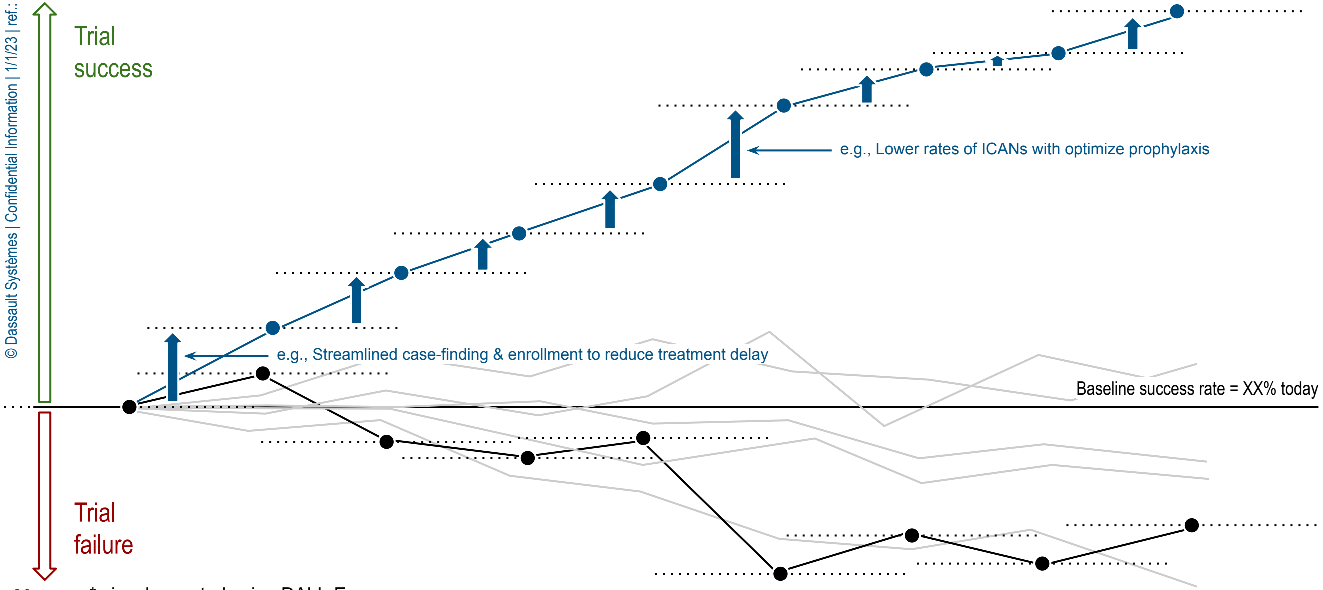
Relapse | Enrollment | Apheresis | Manufacturing | Treatment | Management | Response | Control | Follow-up

Probability of Technical & Regulatory Success

Schematic



* visuals created using DALL-E

If we designed trials so that we made every decision informed by the experience of treating thousands of similar patients

How well could we do?

Select case examples and scientific publications

CASES

Top 20 BioPharma #1

Safer trials, better outcomes

Identified patients at high risk of developing severe CRS based on pre-infusion characteristics. Recommended optimal dosing regimen to minimize CRS by 20-30%

Top 20 BioPharma #2

Broader trial population, greater unmet need

Recommended eligibility criteria for 1L DLBCL trial to expand label and accelerate enrolment. Reduced trial timeline by 6-12 months

EU Biotech

Data-driven trial design, optimization

Developed optimal treatment strategies to minimize CRS and ICANs. 30% fewer cases of grade 3+ AEs. Identified patient likely to respond to therapy based on prior treatments

Top 20 BioPharma #3

Safer treatments in the clinic=bigger market

Predicted which patients are at higher risk of developing CRS based on prior treatment history and patient characteristics. ~20% higher accuracy in identifying high patients

PUBLICATIONS

ASCO®

Predictors of severe CRS in longitudinal CAR T-cell clinical trial data

Poster presentation, 2022

American Society of Hematology

Deriving Predictive Features of Severe CRS from Pre-Infusion Clinical Data in CAR T-Cell Therapies

Poster presentation, 2022

NCCN

Evaluating Early Risk of Cytokine Release Syndrome (CRS) Induced by CAR T-Cell Therapy Using Pooled Clinical Trial Data

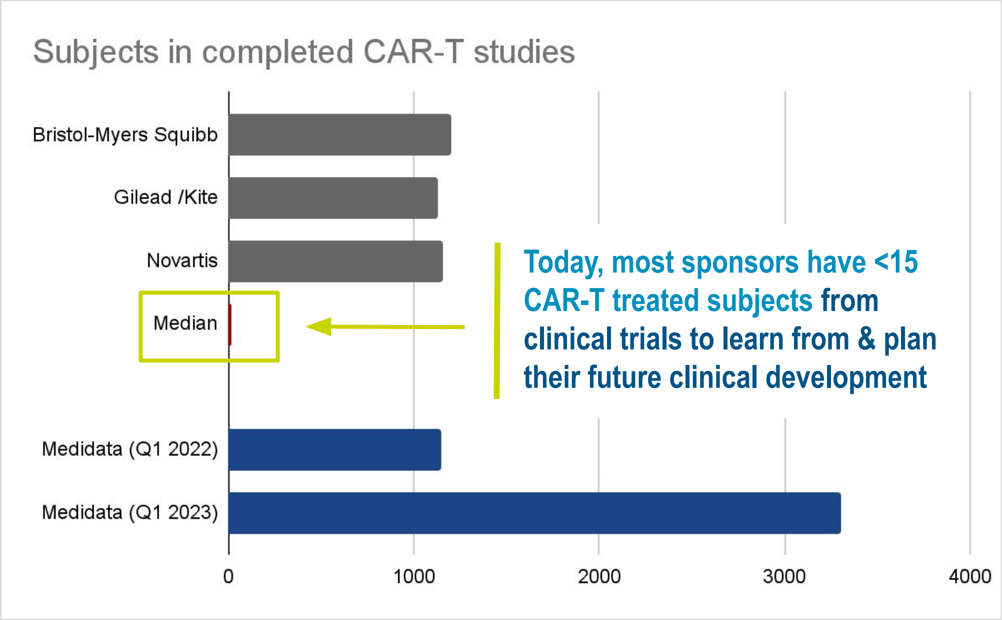
Poster presentation, 2022

EHA

Cooccurrence patterns of CRS and ICANS in patients undergoing autologous CD19-targeted CAR T-cell treatments

In submission, 2023

60% of CAR-T data has been generated by 4 sponsors, and most sponsors working in this space have data on <15 subjects



50+ trials

CAR-T or T-Cell Engager (TCE) clinical trials run on Medidata's platform

>5k+ subjects

available to Medidata AI in unique CAR-T and TCE synthetic dataset

Synthetic data supports a healthy, resilient biopharma ecosystem

Forests rely on **nutrient sharing** by fungi between plants (*mycorrhiza*) to support a healthy, local ecosystem

Mycorrhiza

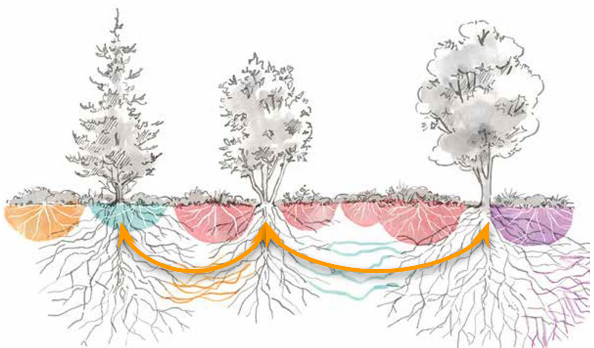
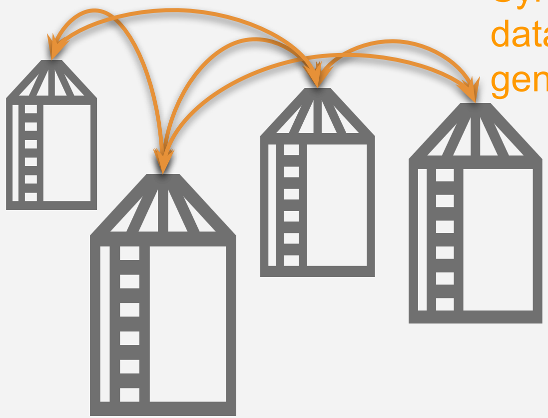


Image from book: https://www.amazon.com/Mycorrhizal-Planet-Symbiotic-Support-Fertility/dp/160358658X?asin=160358658X&revisionId=&format=4&depth=1

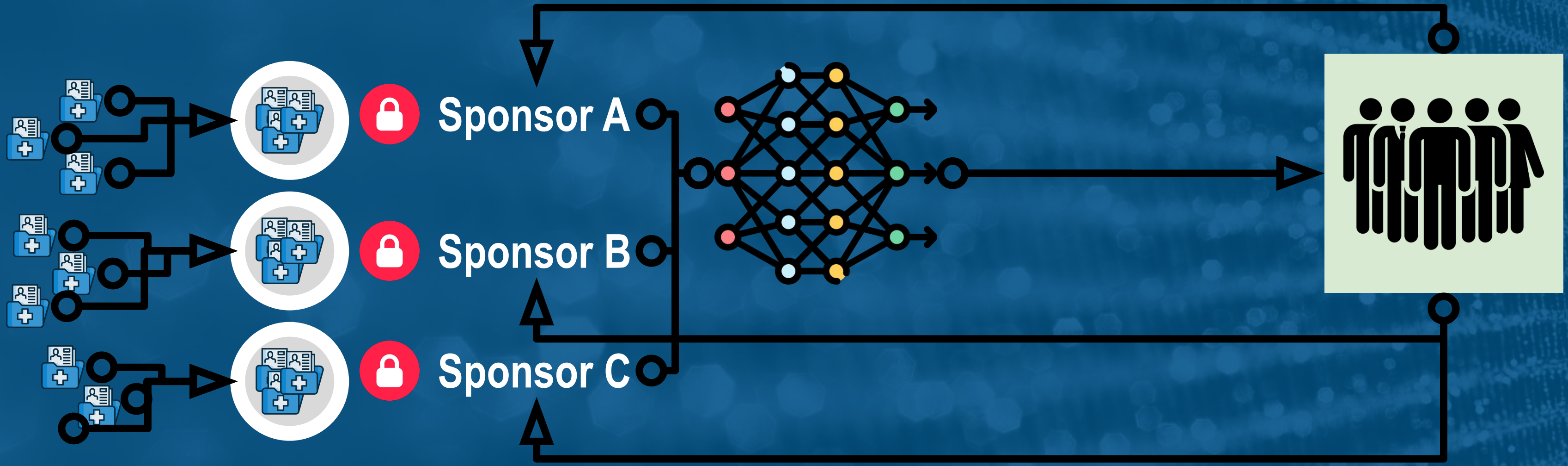
Biopharma relies on **knowledge sharing** to support a healthy, productive ecosystem for innovation

Insights move between
companies via
Synthetic data network that digests, mobilizes & delivers **information & insights** to PharmaCos & Biotechs
to develop safe, effective medicines within
a therapeutic area

Synthetic data generator



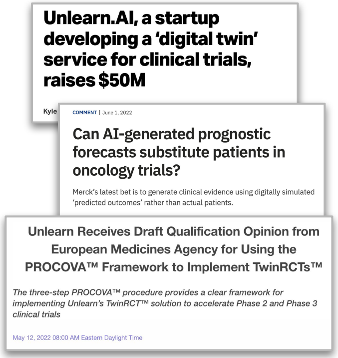
Synthetic data is a solution to encourage collaboration and continue innovation in pharma



Icons Source: Flaticon; Full credits in the last slide

Synthetic Data landscape

Clinical Trials



Unlearn.AI, a startup developing a 'digital twin' service for clinical trials, raises $50M

COMMENT | June 1, 2022

Can AI-generated prognostic forecasts substitute patients in oncology trials?

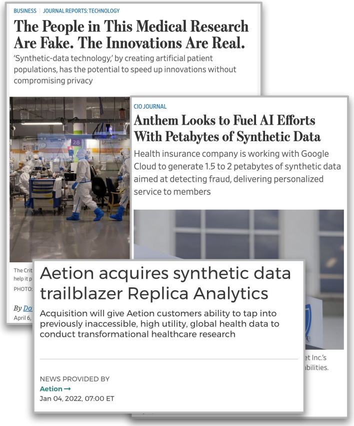
Merck's latest bet is to generate clinical evidence using digitally simulated 'predicted outcomes' rather than actual patients.

Unlearn Receives Draft Qualification Opinion from European Medicines Agency for Using the PROCOVA™ Framework to Implement TwinRCTs™

The three-step PROCOVA™ procedure provides a clear framework for implementing Unlearn's TwinRCT™ solution to accelerate Phase 2 and Phase 3 clinical trials

May 12, 2022 08:00 AM Eastern Daylight Time

Real World Data



BUSINESS | JOURNAL REPORTS: TECHNOLOGY

The People in This Medical Research Are Fake. The Innovations Are Real.

'Synthetic-data technology,' by creating artificial patient populations, has the potential to speed up innovations without compromising privacy

CIO JOURNAL

Anthem Looks to Fuel AI Efforts With Petabytes of Synthetic Data

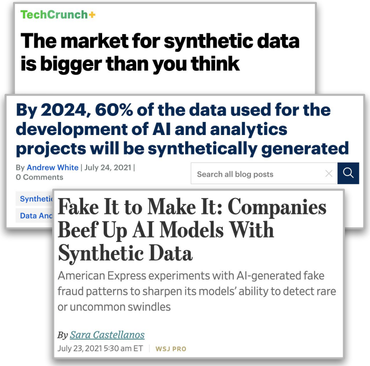
Health insurance company is working with Google Cloud to generate 1.5 to 2 petabytes of synthetic data aimed at detecting fraud, delivering personalized service to members

Aetion acquires synthetic data trailblazer Replica Analytics

Acquisition will give Aetion customers ability to tap into previously inaccessible, high utility, global health data to conduct transformational healthcare research

NEWS PROVIDED BY
Aetion →
Jan 04, 2022, 07:00 ET

Industry at Large



TechCrunch+

The market for synthetic data is bigger than you think

By 2024, 60% of the data used for the development of AI and analytics projects will be synthetically generated

By Andrew White | July 24, 2021 |
0 Comments

Fake It to Make It: Companies Beef Up AI Models With Synthetic Data

American Express experiments with AI-generated fake fraud patterns to sharpen its models' ability to detect rare or uncommon swindles

By Sara Castellanos
July 23, 2021 5:30 am ET | WSJ PRO

3DS MEDIDATA

3DS DASSAULT SYSTEMES

Available open-source solutions

SmartNoise

MEDIDATA
Simulants

synthcity

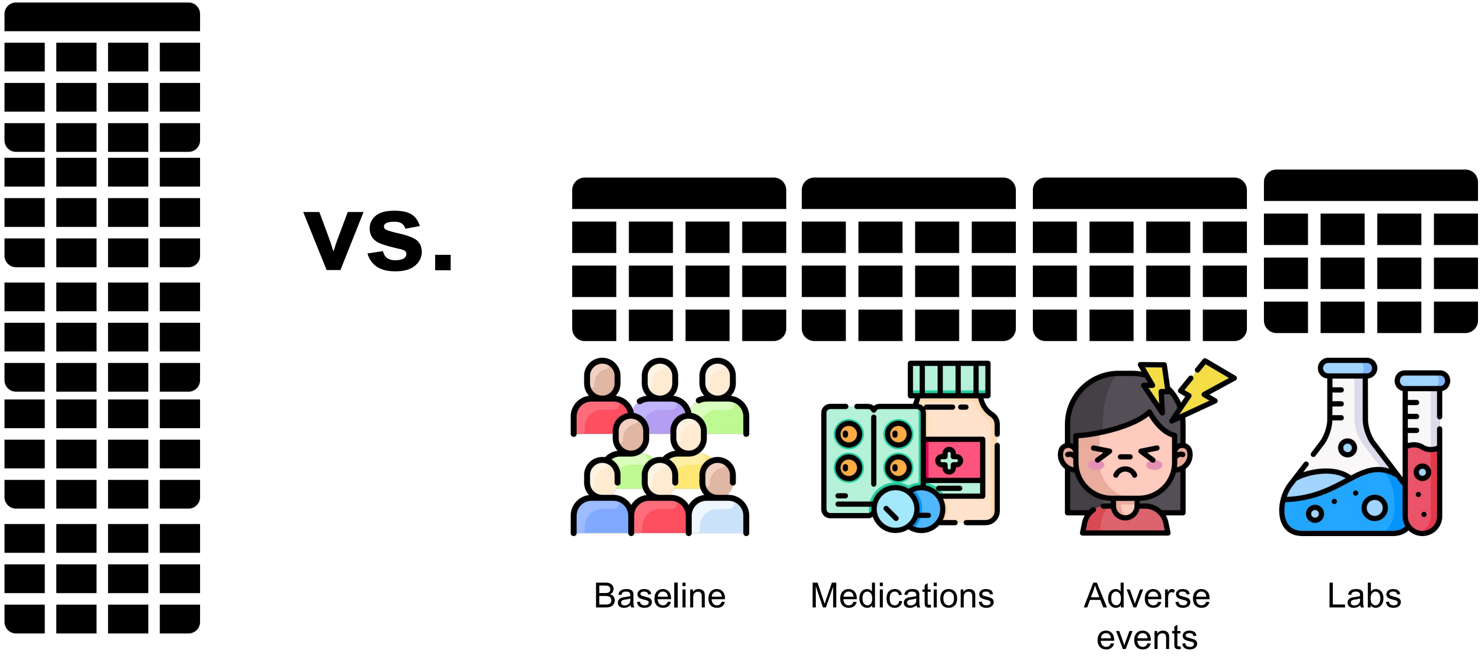
SDV
The Synthetic Data Vault

datacebo

gretel-synthetics by

gretel™

Limitations in current solutions and the uniqueness of clinical trial data



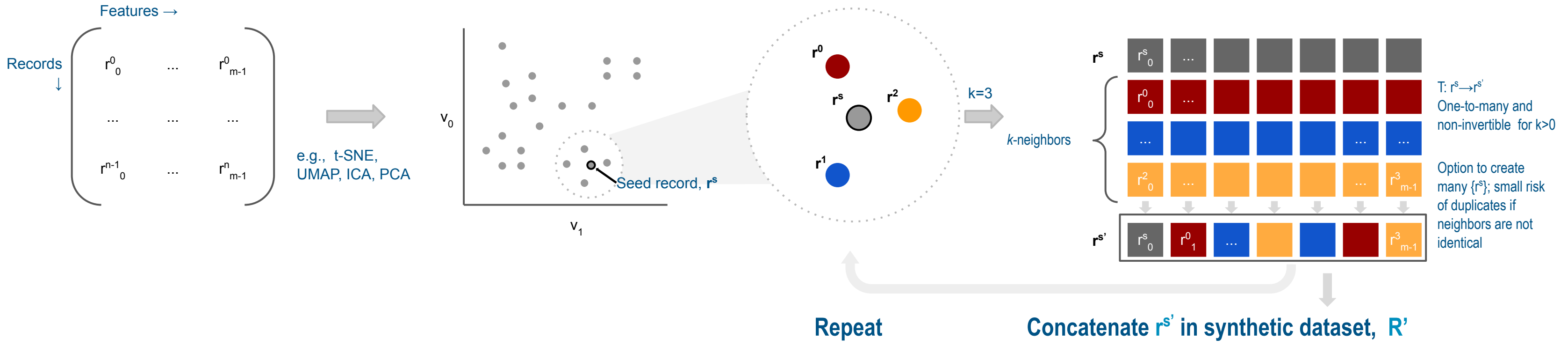
Icons Source: Flaticon; Full credits in the last slide

Simulants: Open-source Methodology

Privacy, fidelity & numerosity can be easily tuned and adjusted through choice of embedding, number of neighbors & feature linking

Simplified Process Diagram

Load source dataset, R → **Embed records, r^i, in metric space** → **Select seed, r^s, and identify nearest neighbors** → **Generate new record(s), $r^{s'}$, by randomly selecting features from *k*-neighbors**



1. M Beigi, A Shafquat, J Mezey, JW Aptekar Synthetic Clinical Trial Data while Preserving Subject-Level Privacy - NeurIPS 2022 Workshop on Synthetic Data for Empowering ML Research
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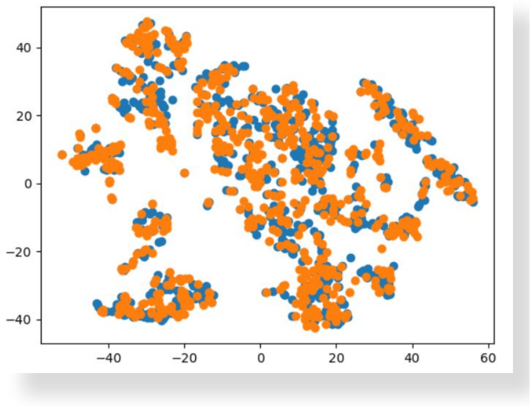
Qualitative: t-SNE Embedding

t-SNE Embedding & Overlap



Alignment between source/template and Simulants generated synthetic dataset indicates synthesis reflects the source population well

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Quantitative: Univariate measures

Comparison of Mean and other statistical similarity metrics

	Template	Simulants
NUM_CYC	7.030086	7.379656
TTE_SD1	56.193410	54.720630
TTE_DEATH	249.376791	254.849570
TTE_BOR	50.110315	49.786533
HEIGHT	161.403023	160.781633
TTE_PFS	179.895415	187.706304
TTE_GLYC_AE	85.014327	85.451289
PRIOR_RADIOTX_TIME	64.816619	68.999284
AGE	65.110315	64.769341
PRIOR_CANC_SURG_TIME	265.462751	230.846705
SLD_BASELINE	61.173352	60.402579
ECOG	0.638968	0.651862
TTE_PR1	62.312321	61.693410
DEPTH_RESP	-24.353725	-24.694126
TTE_SKIN_AE	24.965616	28.411175
PRIOR_CHEMO_TIME	659.383954	659.811605
TTE_CR1	52.563037	53.174785
TTE_PD1	179.385387	179.308023
TTE_2L	179.388252	182.510029

Comparison of mean across numerical features shows the mean of source/template and Simulants generated synthetic data are close.

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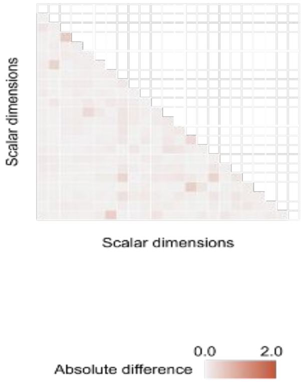
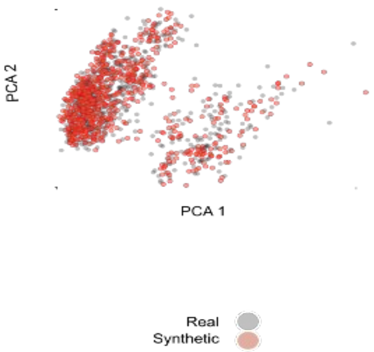
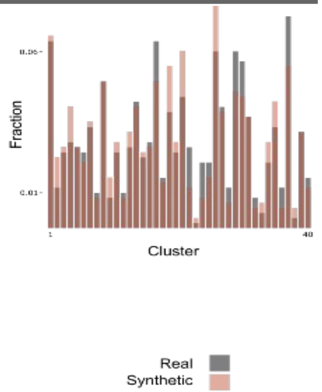
Quantitative metrics

Bivariate metrics

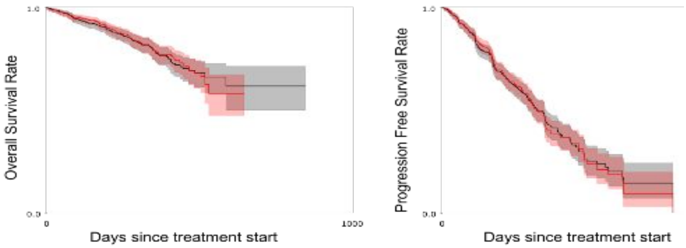


Multivariate metrics





Clinical trial-specific metrics



Bivariate metrics like comparison of pairwise correlations allow assessment of preservation of correlations across features

Clinical trial specific metrics like comparison of survival probability as computed using Kaplan-Meier curves allow assessment of preservation of clinical insights in synthetic data

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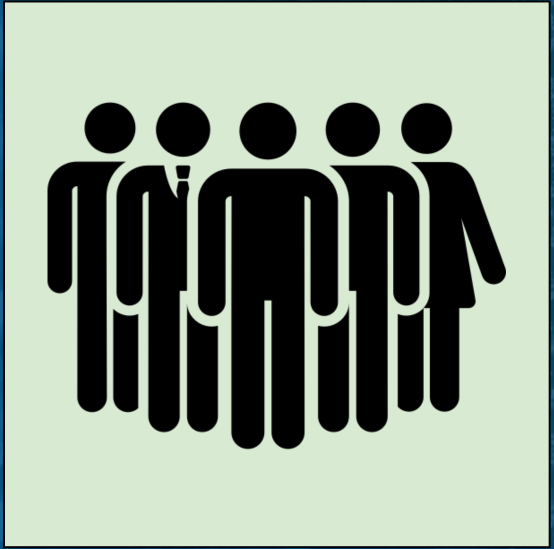
Designing a privacy framework for synthetic clinical trial generation

Synthetic data is a solution to encourage collaboration and continue innovation in pharma

Sponsor A

Sponsor B

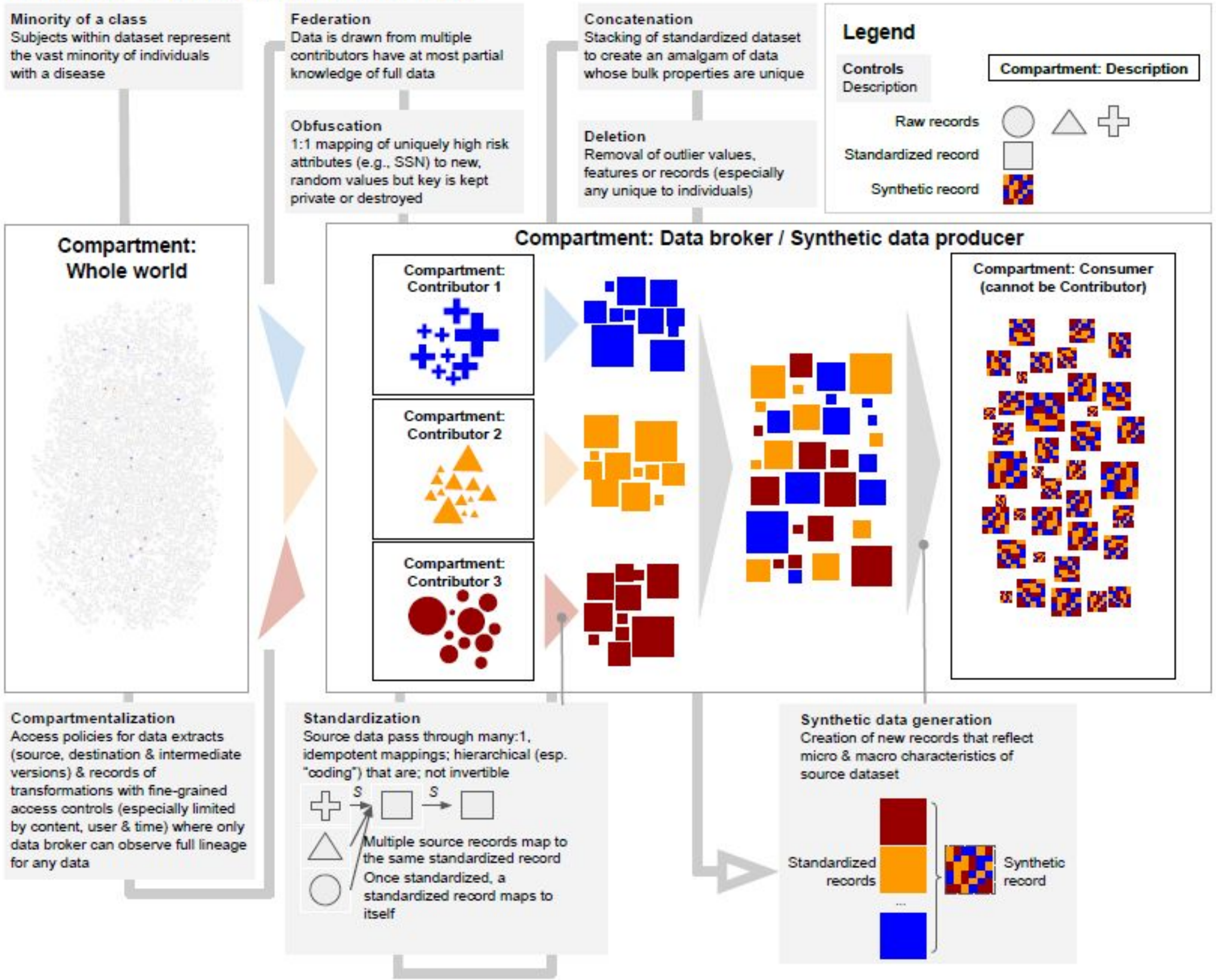
Sponsor C



Icons Source: Flaticon; Full credits in the last slide

Personas	Competing interests			
	Data Contributor privacy	Patient privacy	Privacy of proprietary information	Synthetic data fidelity
Data contributor	✔	✔	✔	
Synthetic Data broker	✔	✔	✔	✔
Data consumer				✔

Overview of privacy system design



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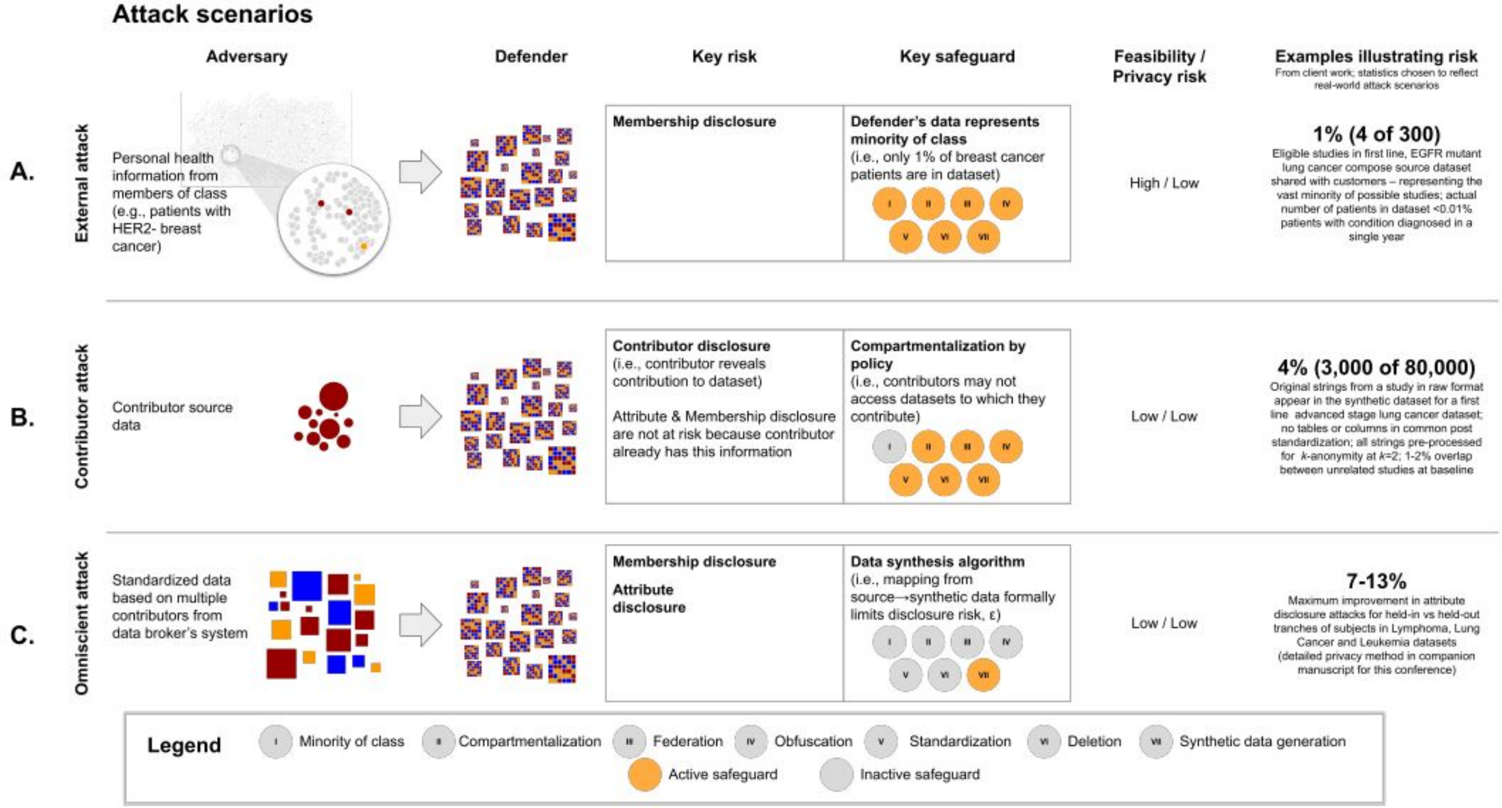
Adversarial Scenarios



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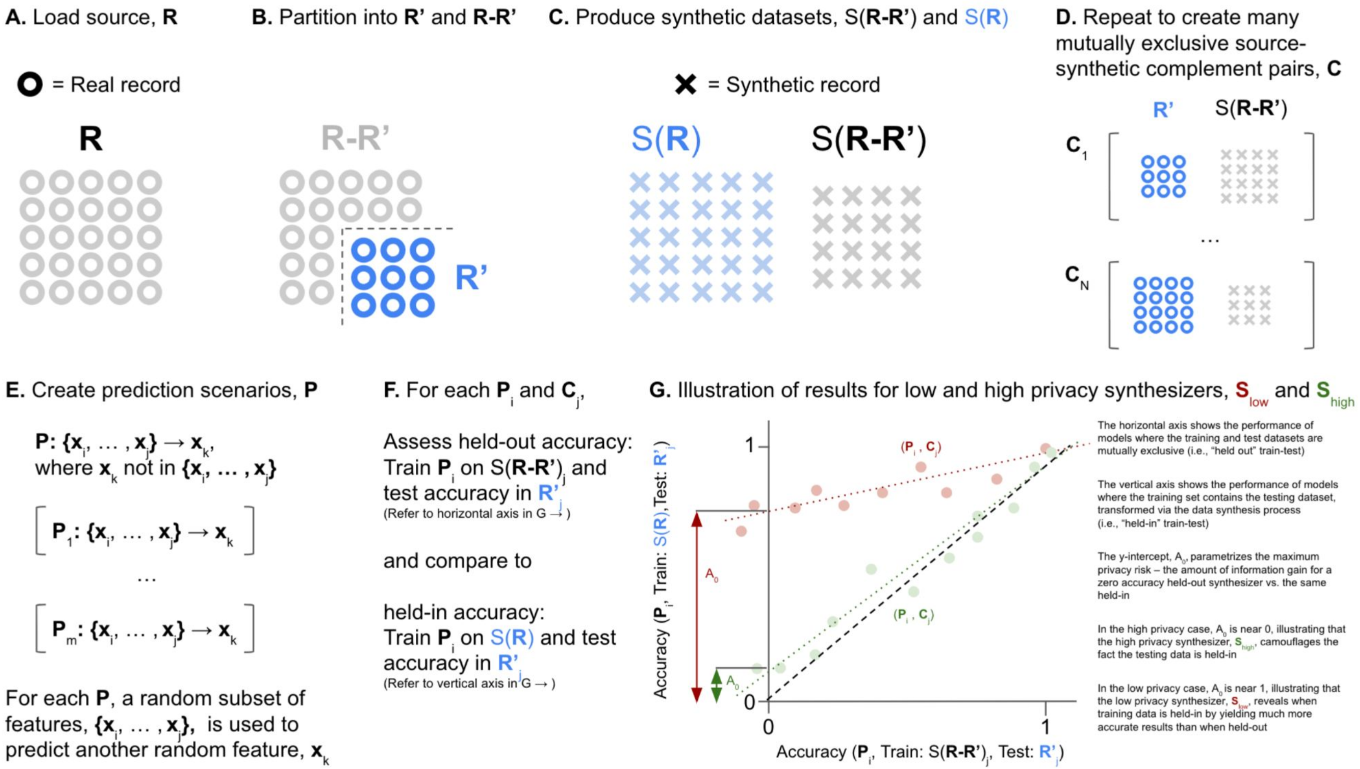
NEURAL INFORMATION PROCESSING SYSTEMS

Overall privacy preservation score



NEURAL INFORMATION PROCESSING SYSTEMS

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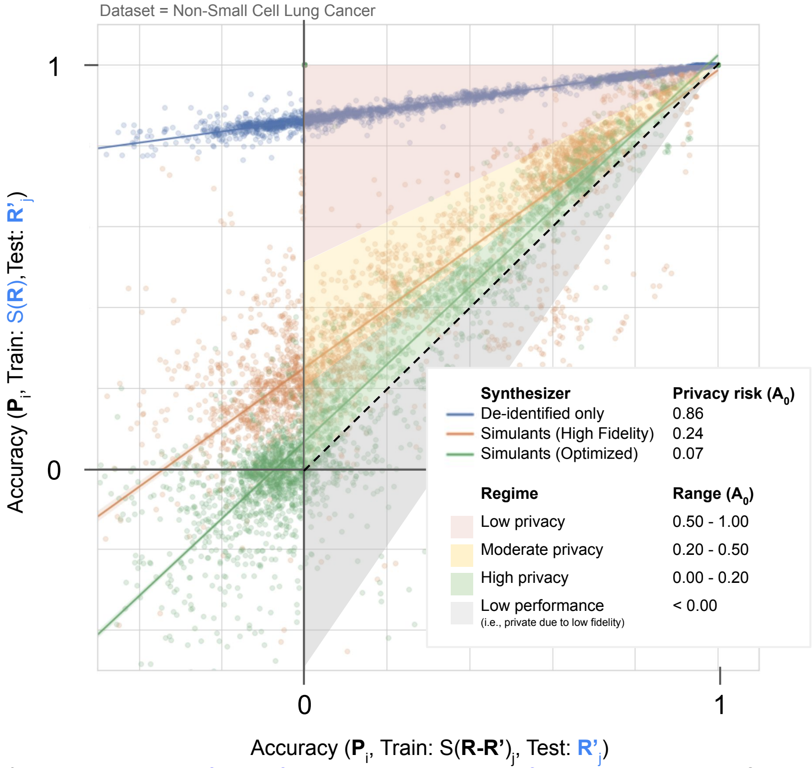
Trial simulation- Standard tests, privacy

Representative privacy plots for high-fidelity & optimized Simulants



NEURAL INFORMATION PROCESSING SYSTEMS

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MEDIDATA

DASSAULT SYSTEMES

Data Augmentation and applications in machine learning

Icons Source: Flaticon; Full credits in the last slide

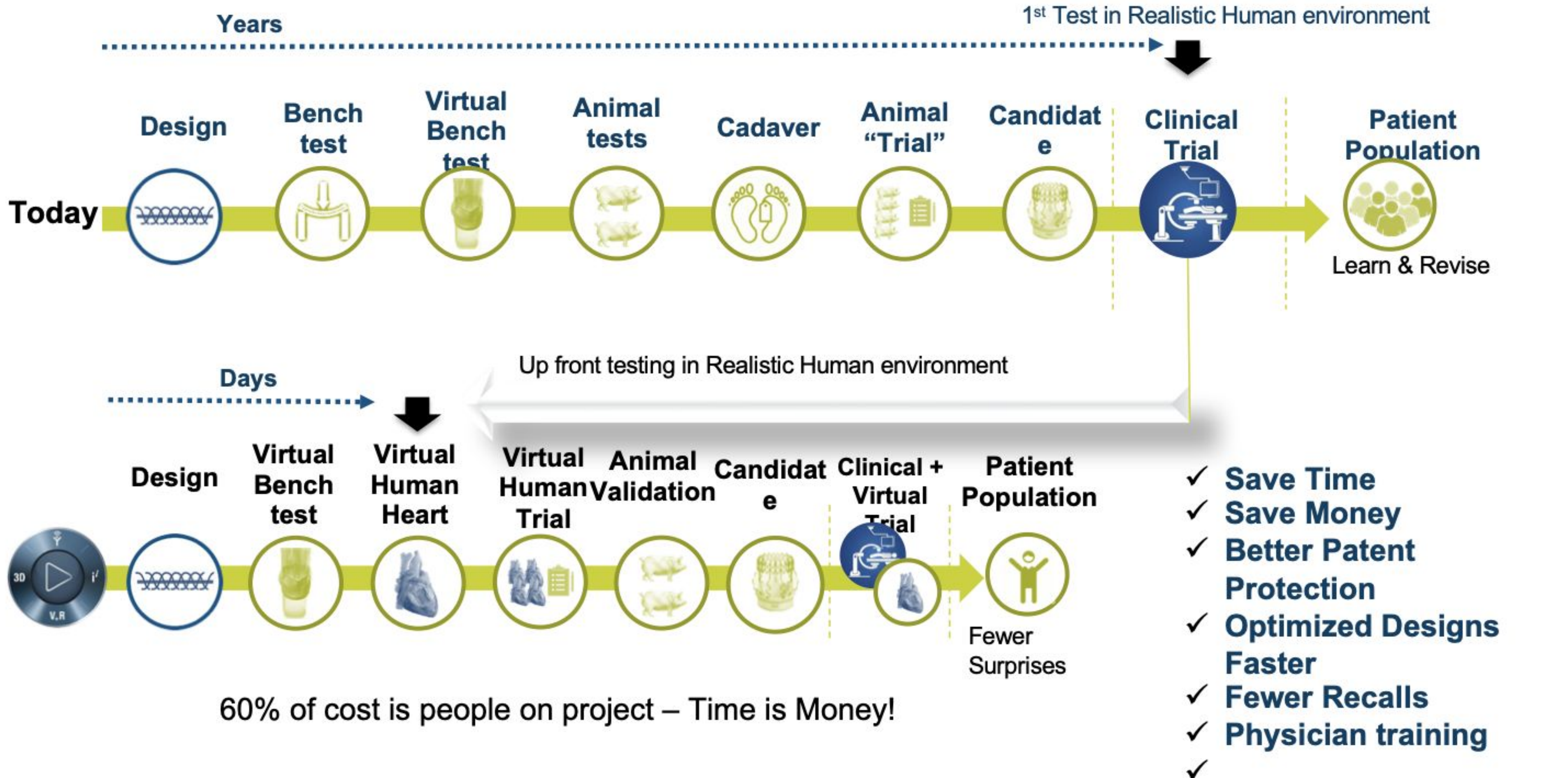
Accelerating *in silico* clinical trials

Full presentation available here:
https://events.3ds.com/living-heart-and-virtual-twin-for-humans-symposium

MEDIDATA

DASSAULT SYSTEMES

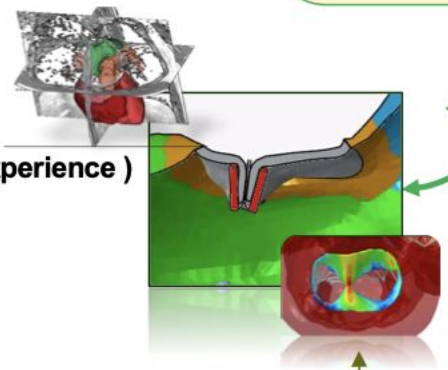
Value Proposition for *In Silico* Clinical Trial – “Years to Days”



iSCT Key Challenge – Defining & Proving the Hypothesis

Identify strong correlation between acute model outputs (surrogate endpoints) & clinical endpoints

Clinical Outcomes = F (Clip Performance X Complexity of Anatomy X Experience)

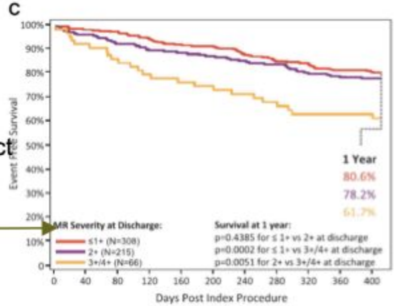


X Physiological Adaptation X Clinical Factors* X Operator

???

Primary device function

Secondary health impact



"acute model outputs" ←→ "observed clinical outcome"

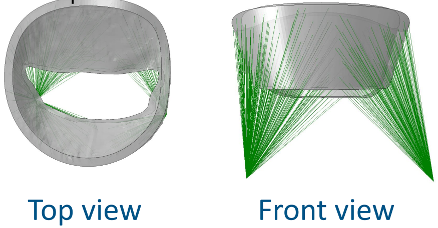
Correlation?

***Circulation.* 2019;139:37–47. DOI: 10.1161/CIRCULATIONAHA.117.031733

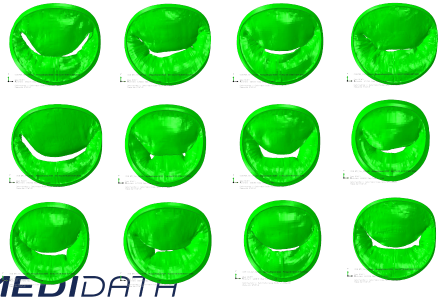
Virtual Patient Engine Schematic

Input:
Initial VPC - A collection of (physics-based) patient model definitions & pre-operative simulation results

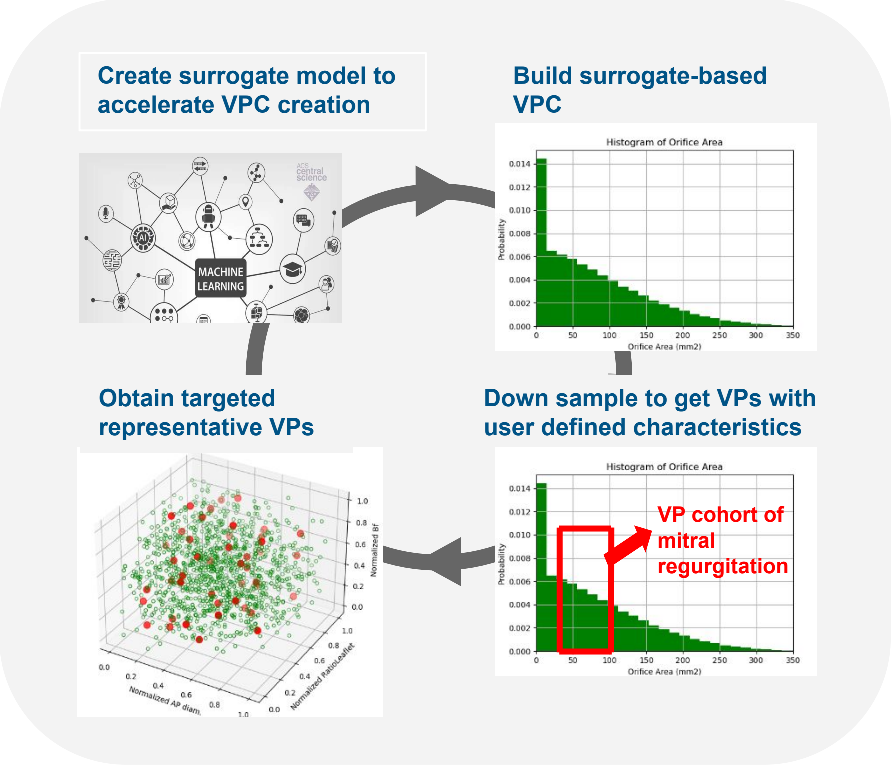
Slide copied from the SIG 35 readout



Output:
iSCT VPC - A physics-based VPC with targeted pre-operative characteristics to be treated in an iSCT



Machine Learning Powered VPE



MEDIDATA
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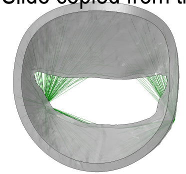
Virtual Patient Engine Schematic

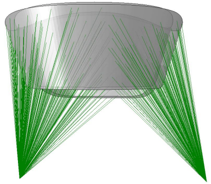
Input:

Initial VPC - A collection of (physics-based) patient model definitions & pre-operative simulation results

Slide copied from the SIG 35 readout



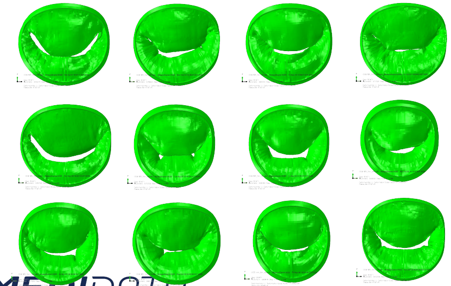
Top view



Front view

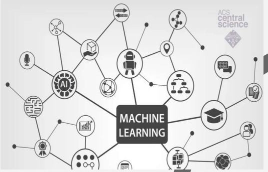
Output:

iSCT VPC - A physics-based VPC with targeted pre-operative characteristics to be treated in an iSCT

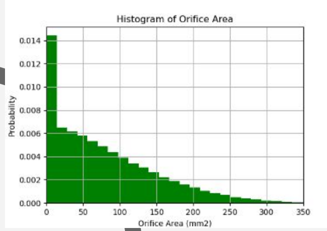


Machine Learning Powered VPE

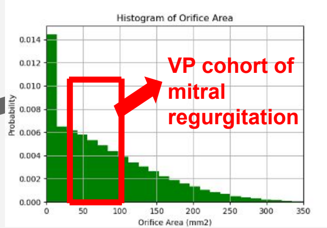
Create surrogate model to accelerate VPC creation



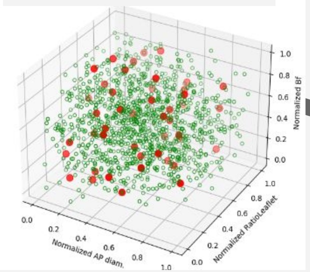
Build surrogate-based VPC



Down sample to get VPs with user defined characteristics



Obtain targeted representative VPs



3DS MEDIDATA

3DS DASSAULT SYSTEMES

Virtual Patient Engine Schematic

Trained on **virtual patients**

Create surrogate model to accelerate VPC creation

Scale up **virtual patients dataset**

Build surrogate-based VPC

Reduces dataset to patient population of interest

Down sample to get VPs with user defined characteristics

Select from remaining **~100 virtual patients**

Obtain targeted representative VPs

Computationally expensive and impractical to scale

Generates redundant samples that don't pass the quality control criteria

14x reduction in total sample size for selection

Virtual Patient Engine Schematic

Virtual patients generated from the physics-based model

Simulants scales the input and output parameters within disease parameters

Select from the scaled virtual **patient population**

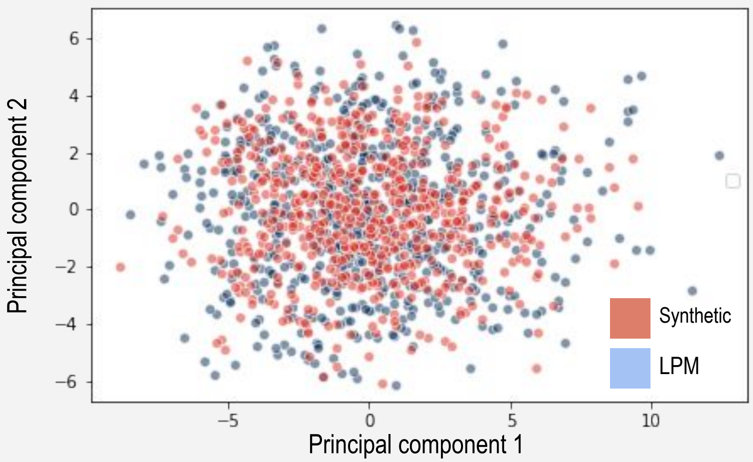
Training dataset generated using the initial physics-based population

Simulants pipeline generates synthetic data comprising of parameters of interest

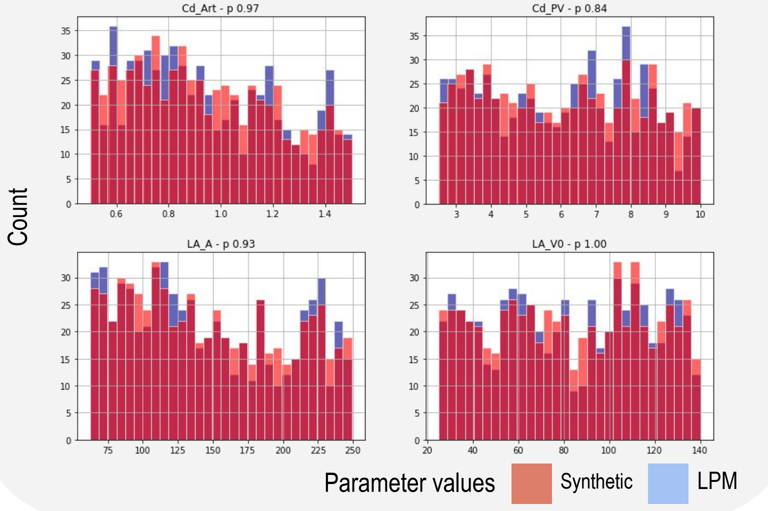
Obtain targeted representative VPs

Synthetic data aligns with physics-based model simulated patients

Synthetic vs. physics-based simulated data



100% alignment across input parameters between datasets

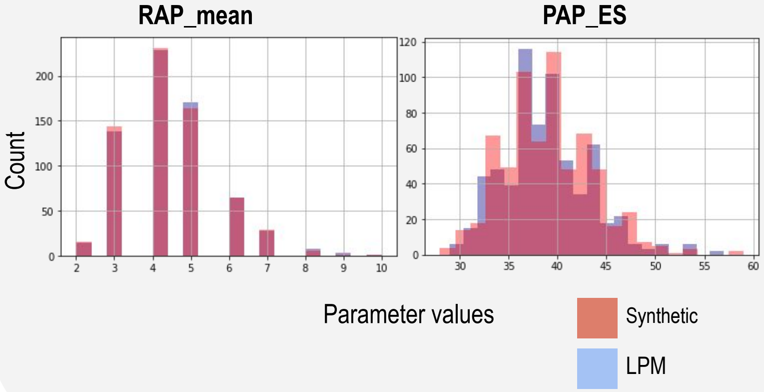


Alignment between source/template and Simulants generated synthetic dataset indicates synthesis reflects the source population well

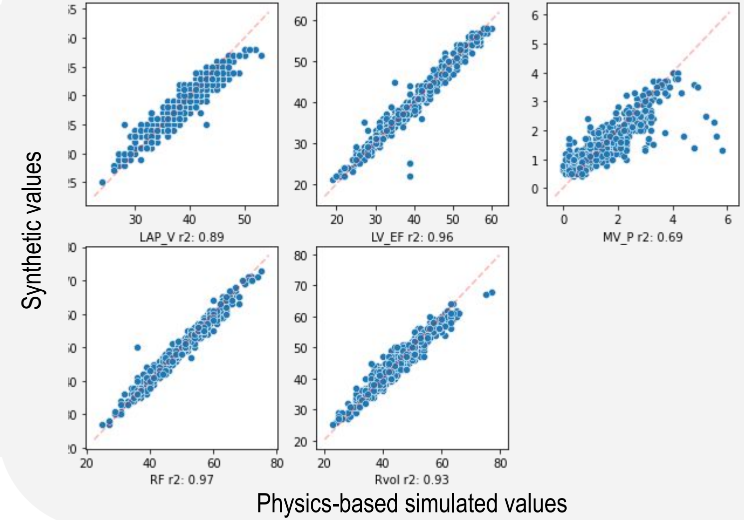
Alignment between input parameters is evaluated by performing the K-S test for input parameters produced by Simulants and the physics-based model. All 14 input parameters had non-statistically significant differences using the K-S test.

Synthetic data aligns with physics-based model simulated patients

97% alignment across output parameters between datasets



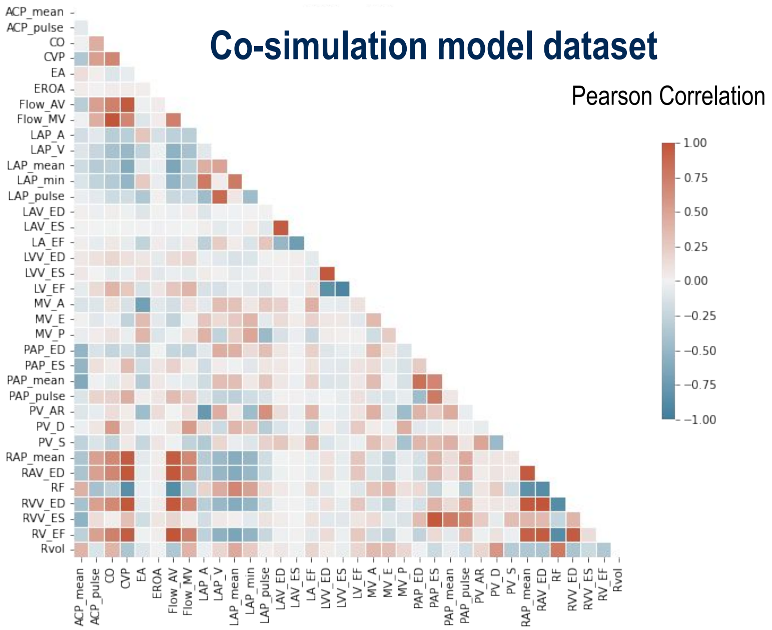
Synthetic vs. LPM simulated data

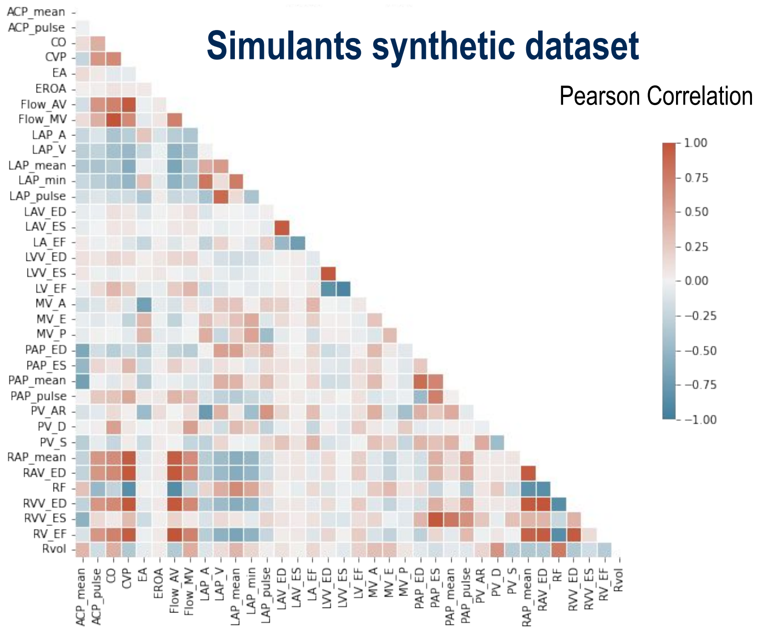


Alignment between output parameters is evaluated by performing the K-S test for output parameters produced by Simulants and the physics-based model. 34 parameters out of 35 parameters (i.e. MV_P) had non-statistically significant differences.

The diagonal in each plot indicates model performance on par with expectation. The x-axis shows the parameter values from the physics-based model and y-axis shows the Simulants-generated parameter values. High r^2 values (close to 1) indicate Simulants performance and agreement between the two models

Preservation of bidirectional relationships in synthetic data





Heatmaps indicate correlation across features in the source/physics-based simulated dataset and Simulants synthetic dataset. The similarity between the heatmaps indicates the bidirectional relationships and correlations observed in the dataset generated using the physics-based patient model are preserved in the Simulants-generated synthetic dataset.

Acceleration via synthetic data

97% Agreement between simulated and synthetic output parameter distributions

100% Agreement between simulated and synthetic input parameter distribution

100% Preservation of sample size

Simulants is successfully able to mimic the the physics-based co-simulation model

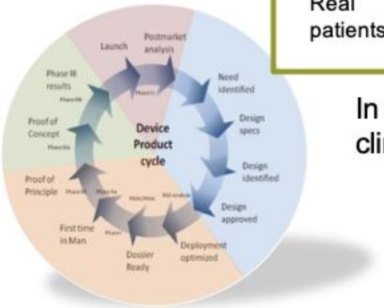
Summary of advantage of Simulants

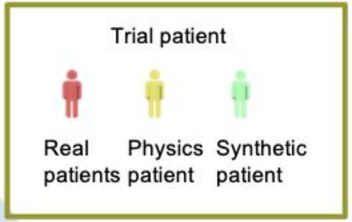
Though the current VPE framework offers a competitive advantage over the Finite Element Analysis to simulate the living heart, a Simulants powered pipeline offers:

- **Fast and robust** way to generate synthetic parameter sets that reflect the physics-based parameter simulation
- **Reduce the computational cost** of running the Finite Element Analysis where the current process is slow and intensely computationally expensive
- **Doesn't depend on domain knowledge** of parameter boundary values
- **Preservation and scaling of sample size** of the physics-based dataset
- **Removal of redundancy** in the pipeline by only producing parameter sets that are aligned with the parameter distribution
- Potential to **target synthetic generation** of the distribution of interest (e.g. mitral valve regurgitation)

Future directions

Conduction 'in Silico clinical trials' using patient-specific models, physics based population models and synthetic patients to form virtual cohorts for testing the safety and/or efficacy of new drugs and of new medical devices.





In silico clinical trial

Real patient (Patient specific models, acute and long end points, clinical outcome)

Physics patient (population models, detailed physics and physiology correlations, defining hypothesis)

Synthetic patient (Enrichment with VP augmentation, identifying correlation between acute and clinical outcome, proving hypothesis)

Key takeaways

Data sharing is critical for continued innovation in the biotech and pharma industry

Synthetic data provides a fast, secure and reliable way to share private data

Synthetic data allows an innovative way to synthesize and augmented training datasets to improve AI/ML model performance

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Presentation credit:

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Strategy Director, Simulants

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