

# Applied Artificial Intelligence for Healthcare

## LECTURES

**Artificial intelligence-assisted patient care. Hope or Hype?**

Irbaz Riaz MD, MBI, PhD, Mayo Clinic

**Artificial intelligence for clinical contextualization of cancer genomic data**

Kenneth Kehl MD, MPH, Harvard Medical School

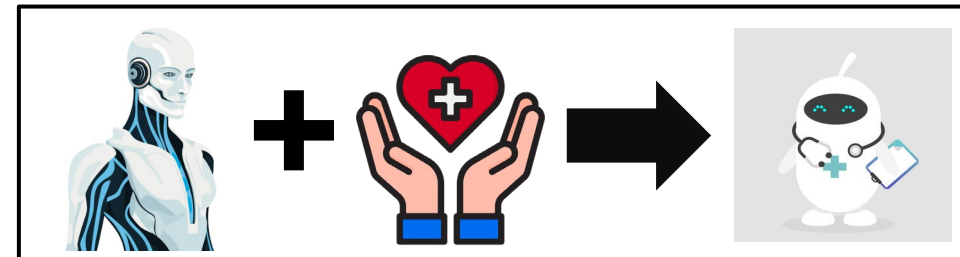
**Probabilistic Models for HealthCare**

YooJung Choi, PhD, Arizona State University

## LAB

**Inference with Large Language Models using Clinical Data**

Syed Arsalan Ahmed Naqvi, M.D.  
Umair Ayub, Ph.D.  
Mihir Parmar, Ph.D. (cand)  
Irbaz Riaz, M.D., M.B.I., Ph.D.





# ARTIFICIAL INTELLIGENCE-ASSISTED PATIENT CARE. HOPE OR HYPE?

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Mayo Clinic Arizona, Mayo Clinic Comprehensive Cancer Center



Mayo Clinic and Illinois Alliance, Computational Genomics Course, 2024

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- X (Twitter): @IrbazRiaz

# BASIC TERMINOLOGY



**Artificial intelligence**

**Machine learning**

**Deep learning**

**Generative AI**

## **Artificial Intelligence (AI)**

- AI refers to computers or algorithms that mimic human intelligence to make data driven decisions.

## **Machine Learning (ML)**

- is a subset of AI that focuses on algorithms that teach itself on how to make decisions without explicit programming

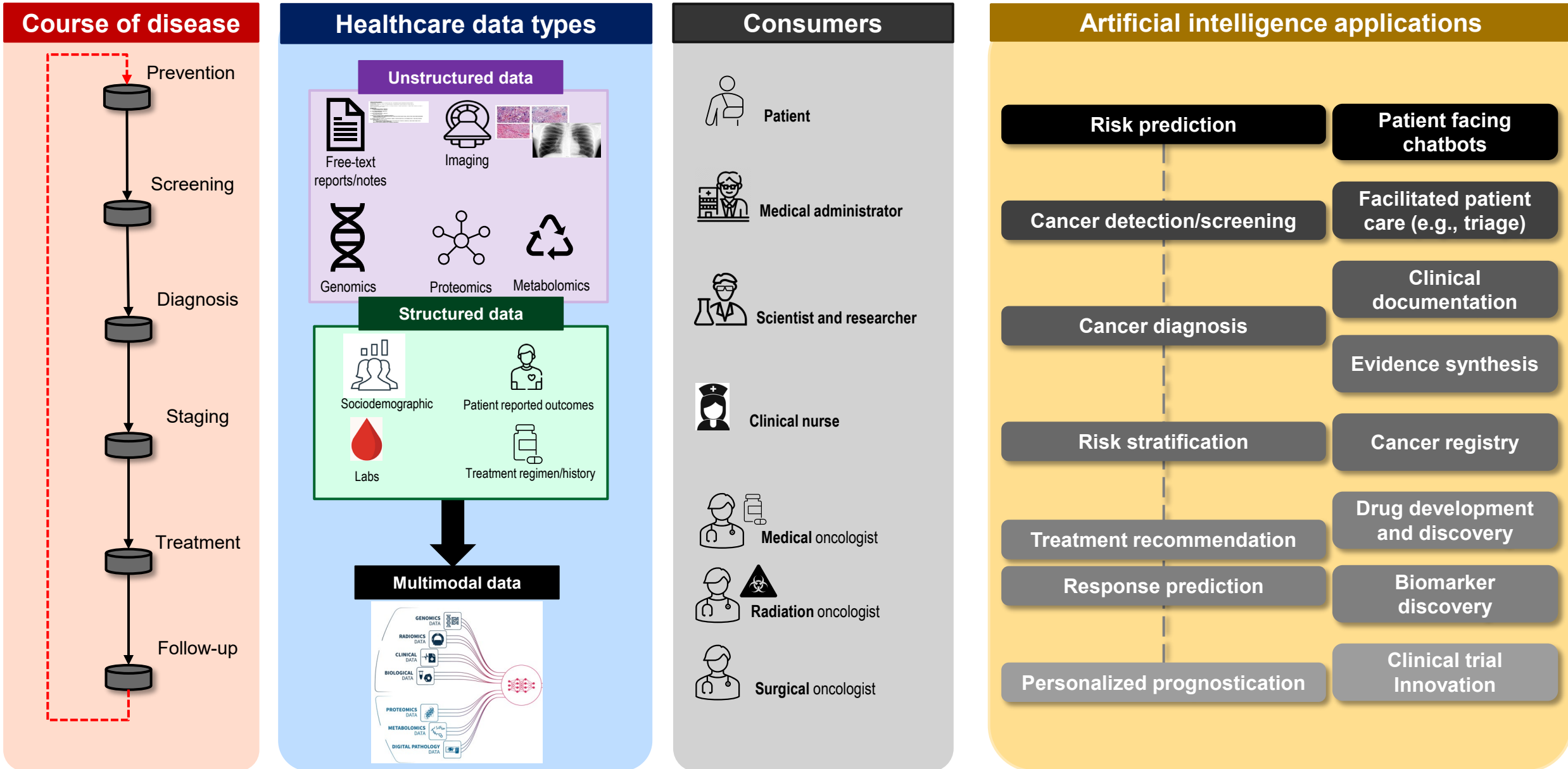
## **Deep Learning (DL)**

- is a subfield of ML that involve neural networks to learn and make intelligent decisions
- DL algorithms attempt to simulate the human brain's architecture
- Try to learn and represent complex patterns from the data.

## **Generative Artificial Intelligence (GenAI)**

- It is a subset of DL that has the ability to generate new content, whether it be images, text, music, or other types of data.
- Produce content that is often indistinguishable from human-created content

# WHAT ARE THE APPLICATIONS OF AI IN HEALTHCARE?



# Patient journey

Risk prediction

Screening

Diagnosis

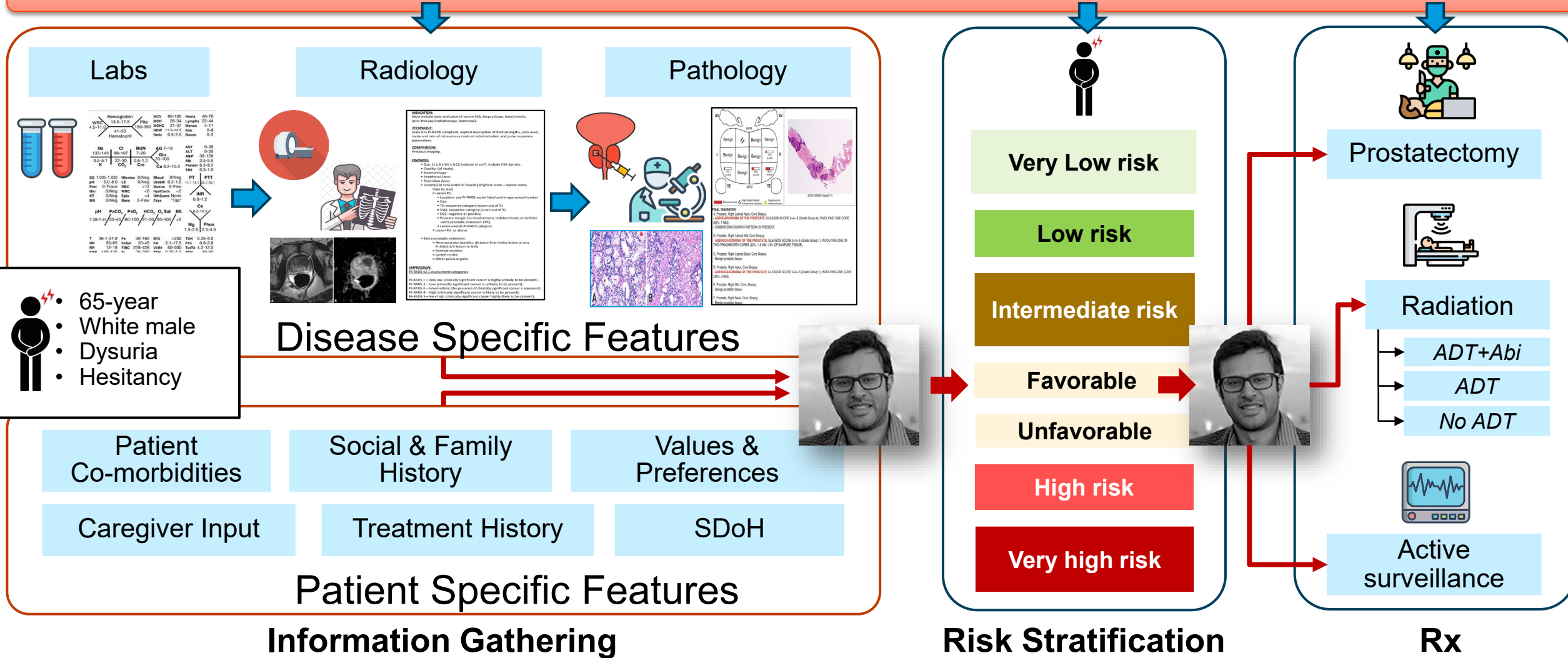
Prognostication and prediction

Treatment Optimization

End of life care

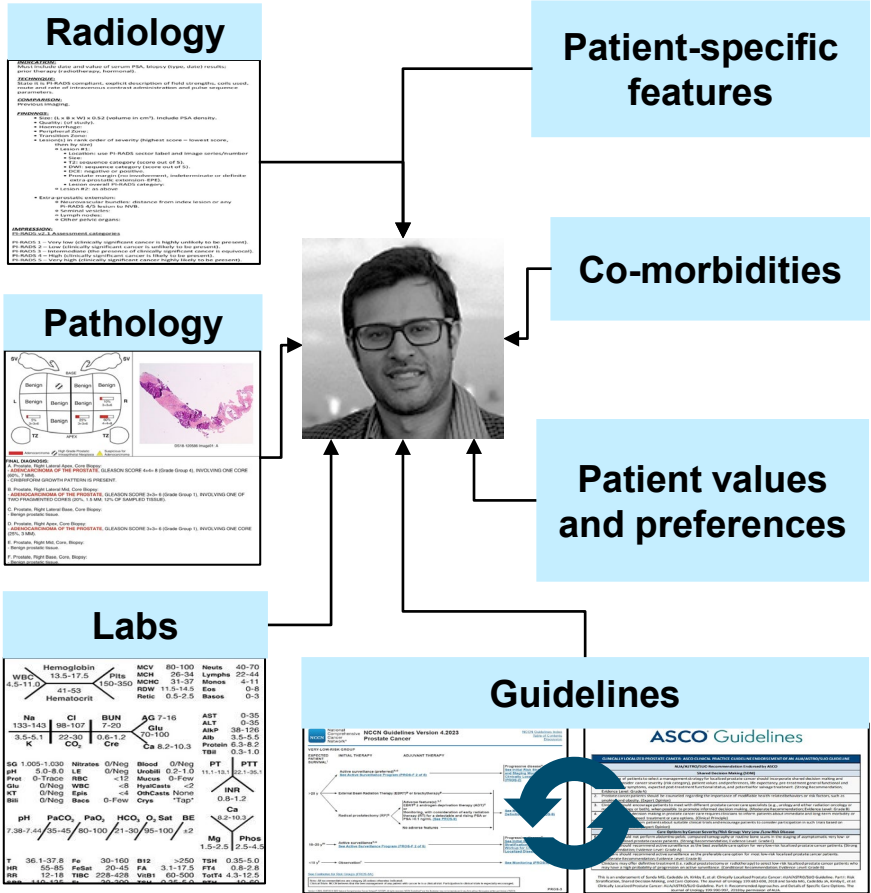
# PROCESS OF TREATMENT SELECTION: LOCALIZED PROSTATE CANCER

## Prostate Cancer Guidelines



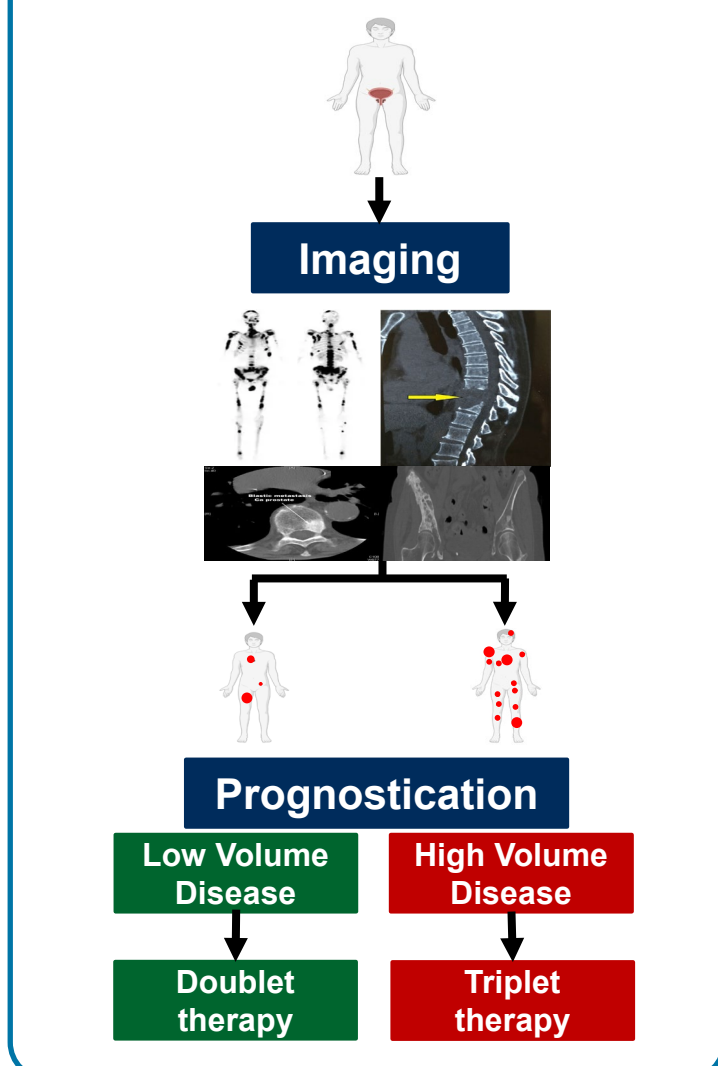
# CHALLENGES IN SYSTEMIC TREATMENT SELECTION

## 1. Too much to do !!

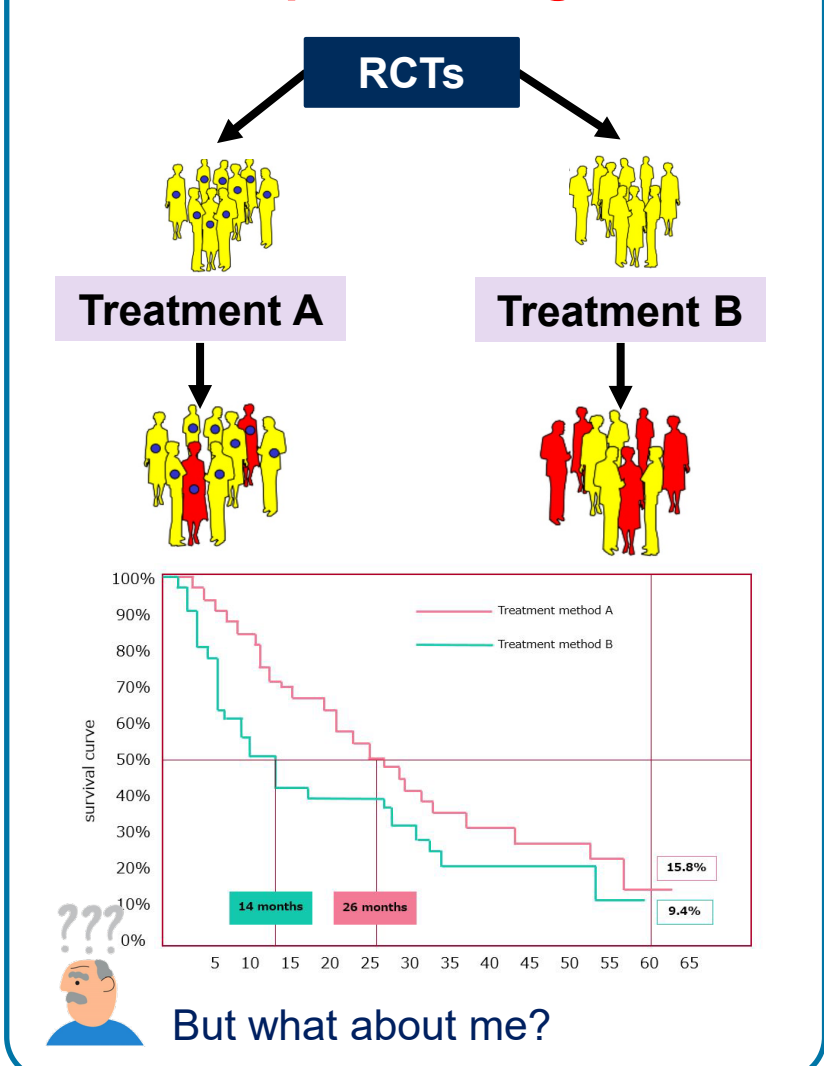


## 2. Rapidly changing evidence

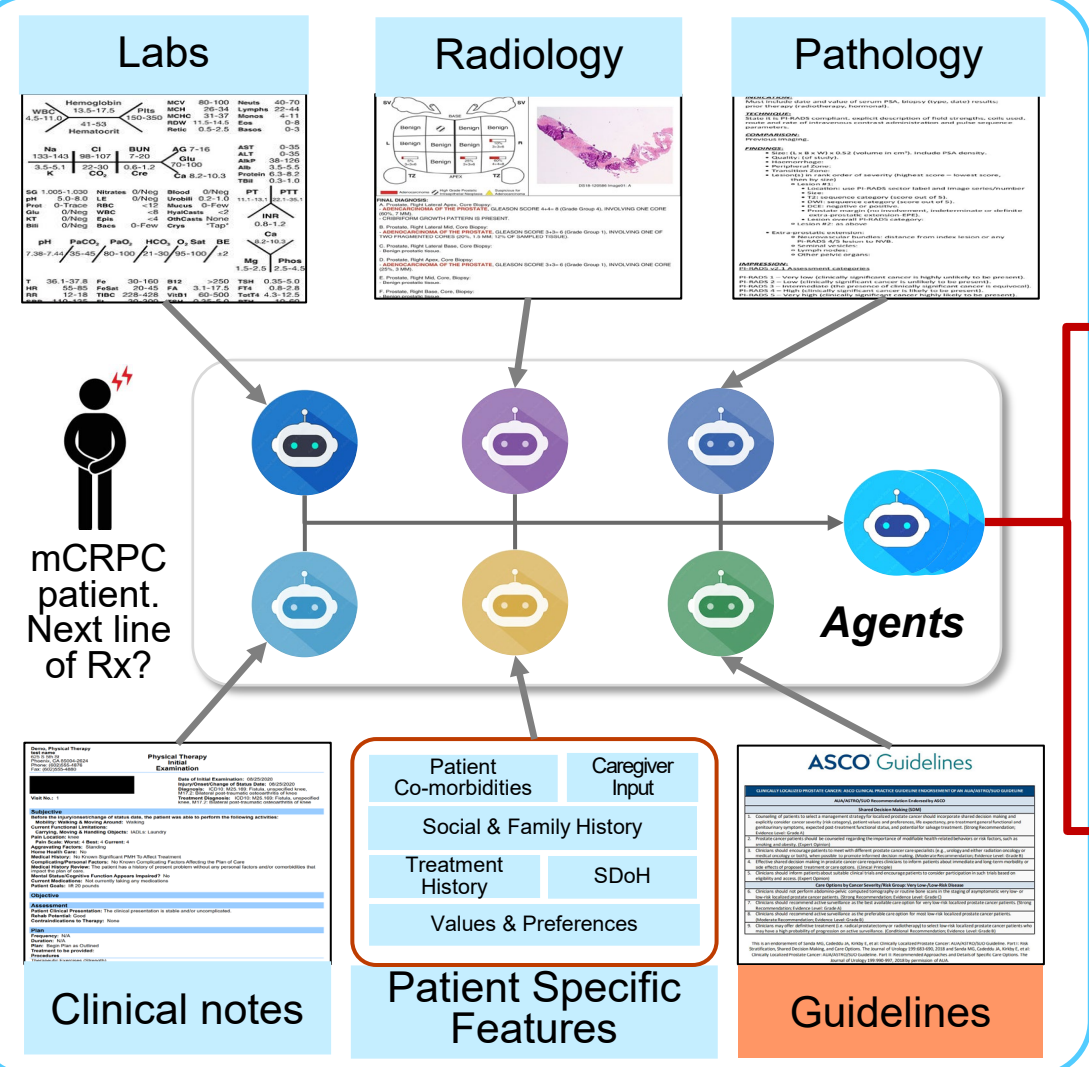
## 3. No real biomarkers



## 4. RCTs report average results



# #1 AI AGENTS AS ASSISTANTS TO HEALTHCARE PROVIDERS



## Summary

**Disease status** mCRPC

**Previous treatment**

1. Abiraterone, disease progression
2. Docetaxel, disease progression

**Performance status**

ECOG 1, peripheral neuropathy from docetaxel

**Genomics** No HRR mutation

**Imaging** Bone mets  
PSMA PET scan: SUVmax 15

**Labs** Hgb: 10, creatinine 1.5

## Recommendations

**Plan**

1. Lutetium-177 for six cycles, no dose adjustment required.
2. Monitor Hb and Cr closely (likely to worsen with lutetium)
3. F/u up in 6 weeks with PSA, CBC, and CMP.

**Counsel for common side effects**

Dry mouth, decreased appetite, abdominal pain, constipation, anemia, fatigue

## Orders

**Reject** **Accept**

**Orders placed in EHR**

## Information Gathering

## Planning

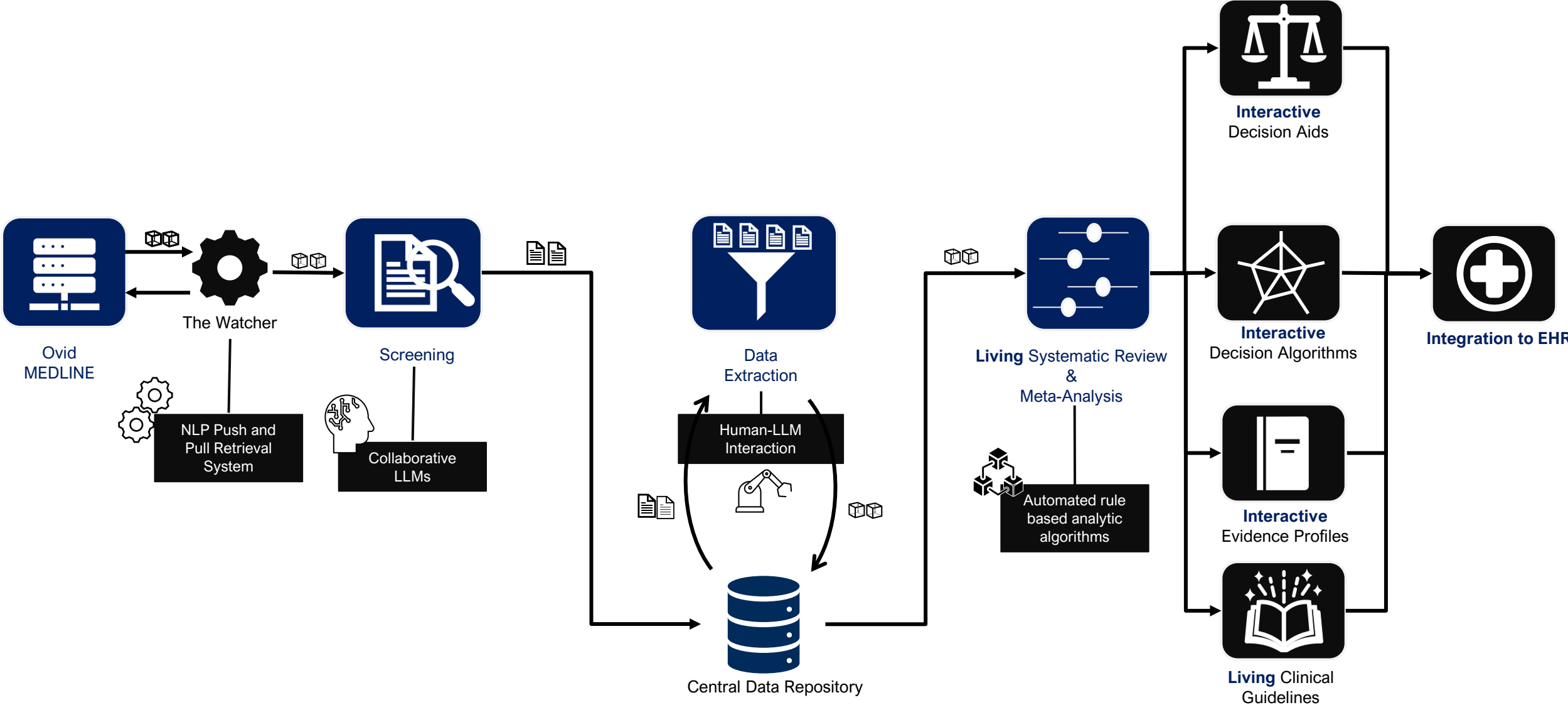
## Action



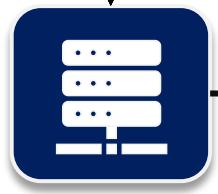
## #2 AI-ENABLED LIVING CLINICAL PRACTICE GUIDELINES

“Optimization of the standard guideline process, such that it allows updating of individual recommendations as soon as new relevant evidence becomes available”

# LIVING EVIDENCE SYNTHESIS WORKFLOW



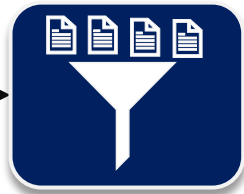
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NCT00104715
- CHAARTED  
NCT00309985
- STAMPEDE  
NCT00268476
- LATITUDE  
NCT01715285



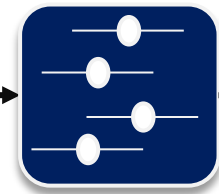
Ovid  
MEDLINE



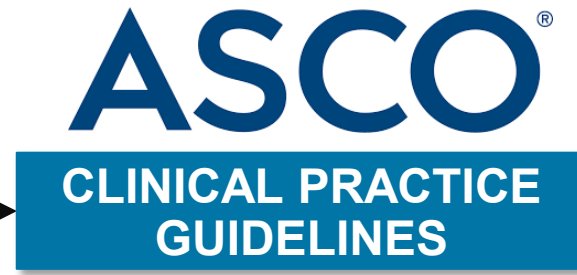
Screening







Data  
Extraction

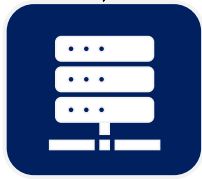


Systematic Review  
&  
Meta-Analysis



-  **GETUG**  
NCT00104715
-  **CHAARTED**  
NCT00309985
-  **STAMPEDE**  
NCT00268476
-  **LATITUDE**  
NCT01715285

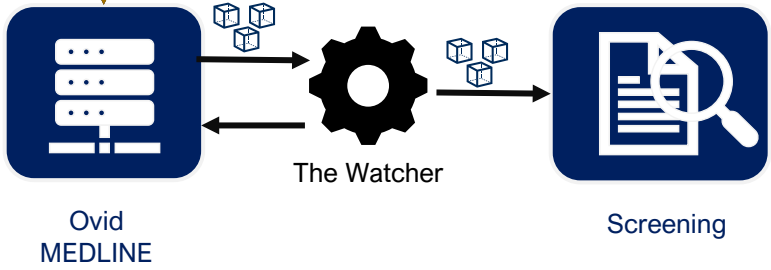
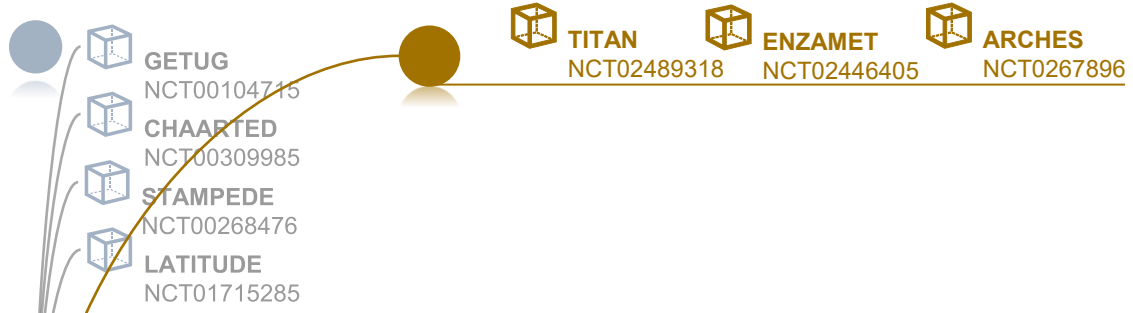
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NCT02489318
-  **ENZAMET**  
NCT02446405
-  **ARCHES**  
NCT0267896

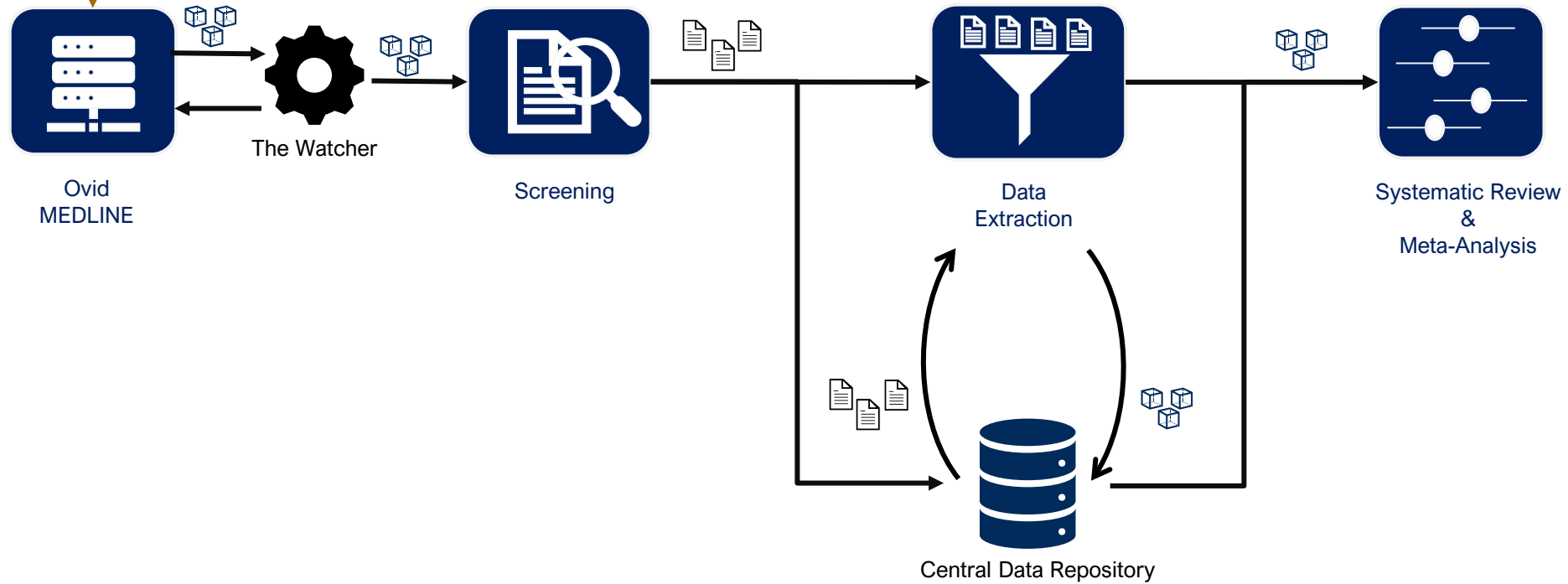
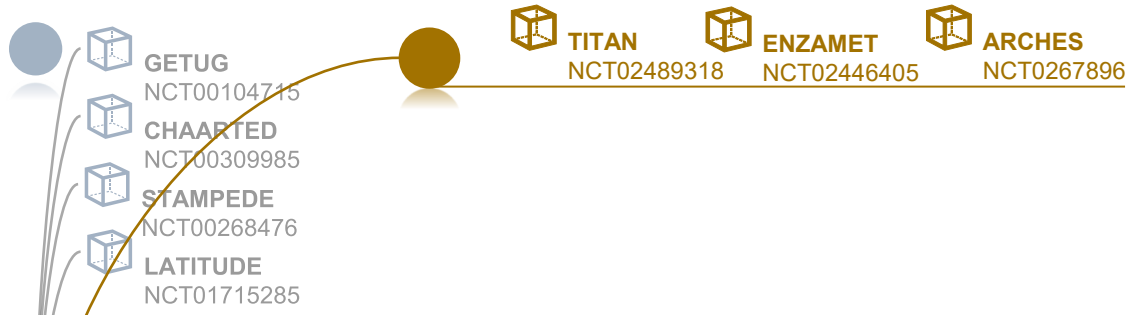


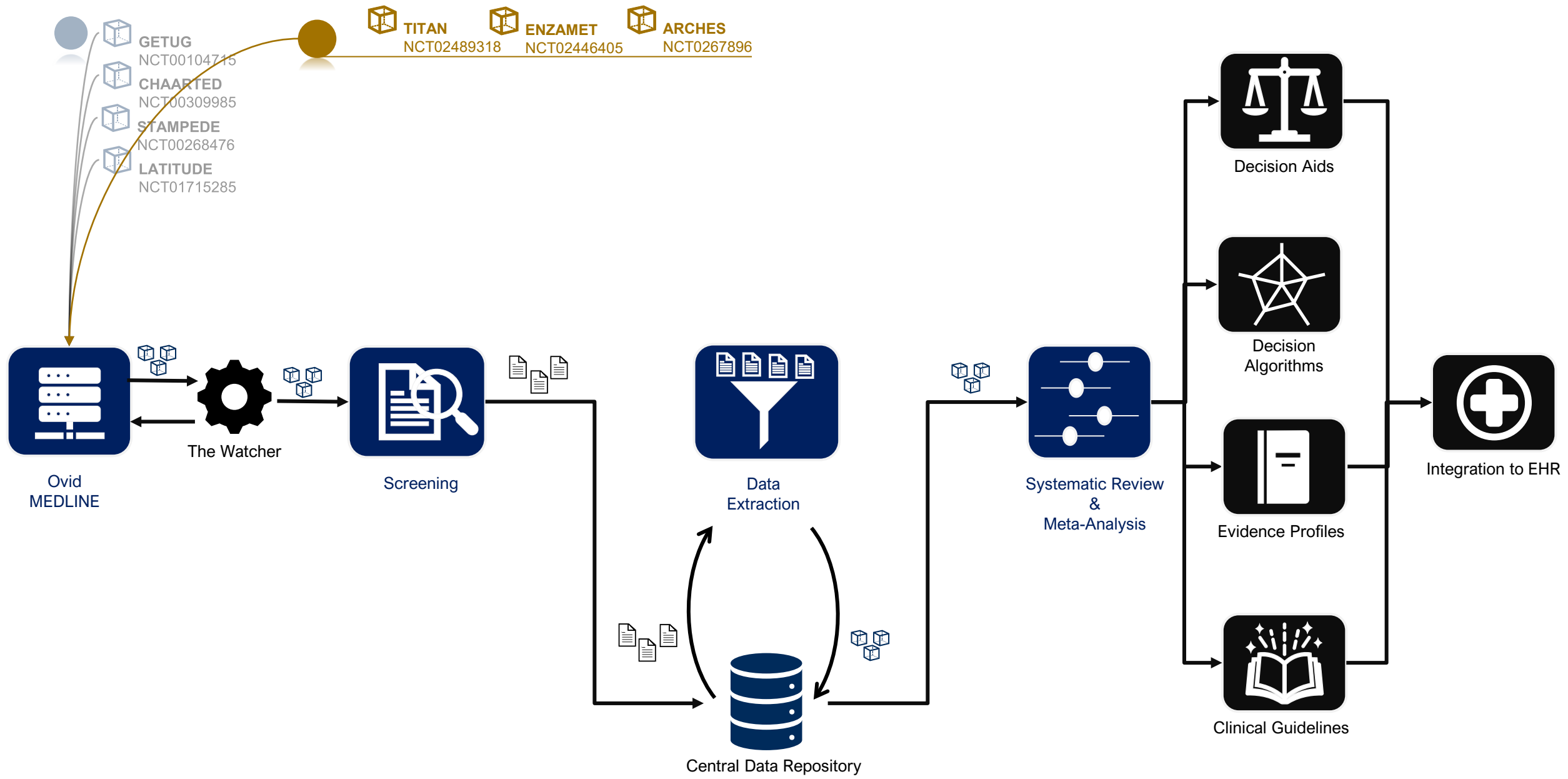
Ovid  
MEDLINE

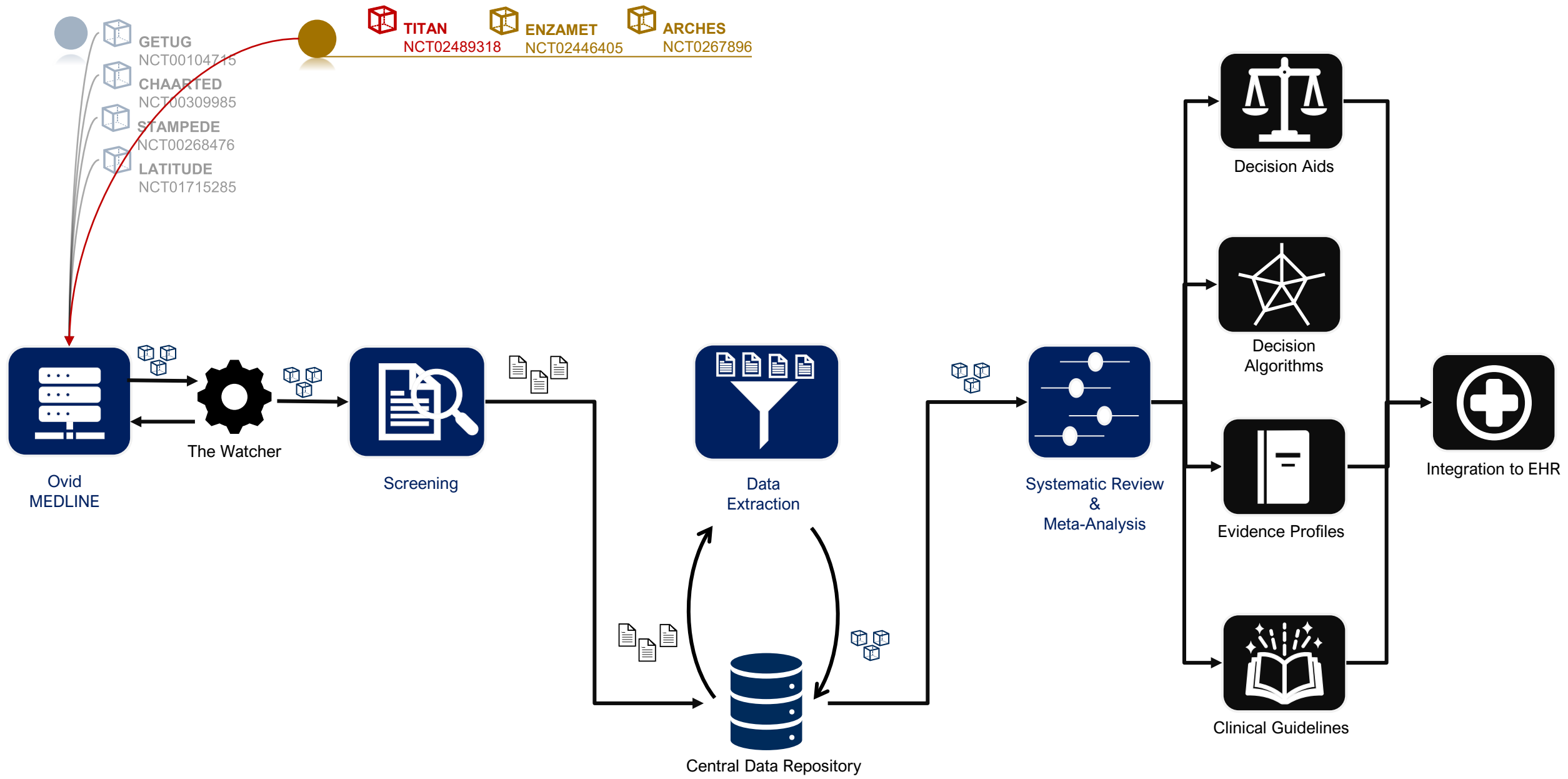


Screening

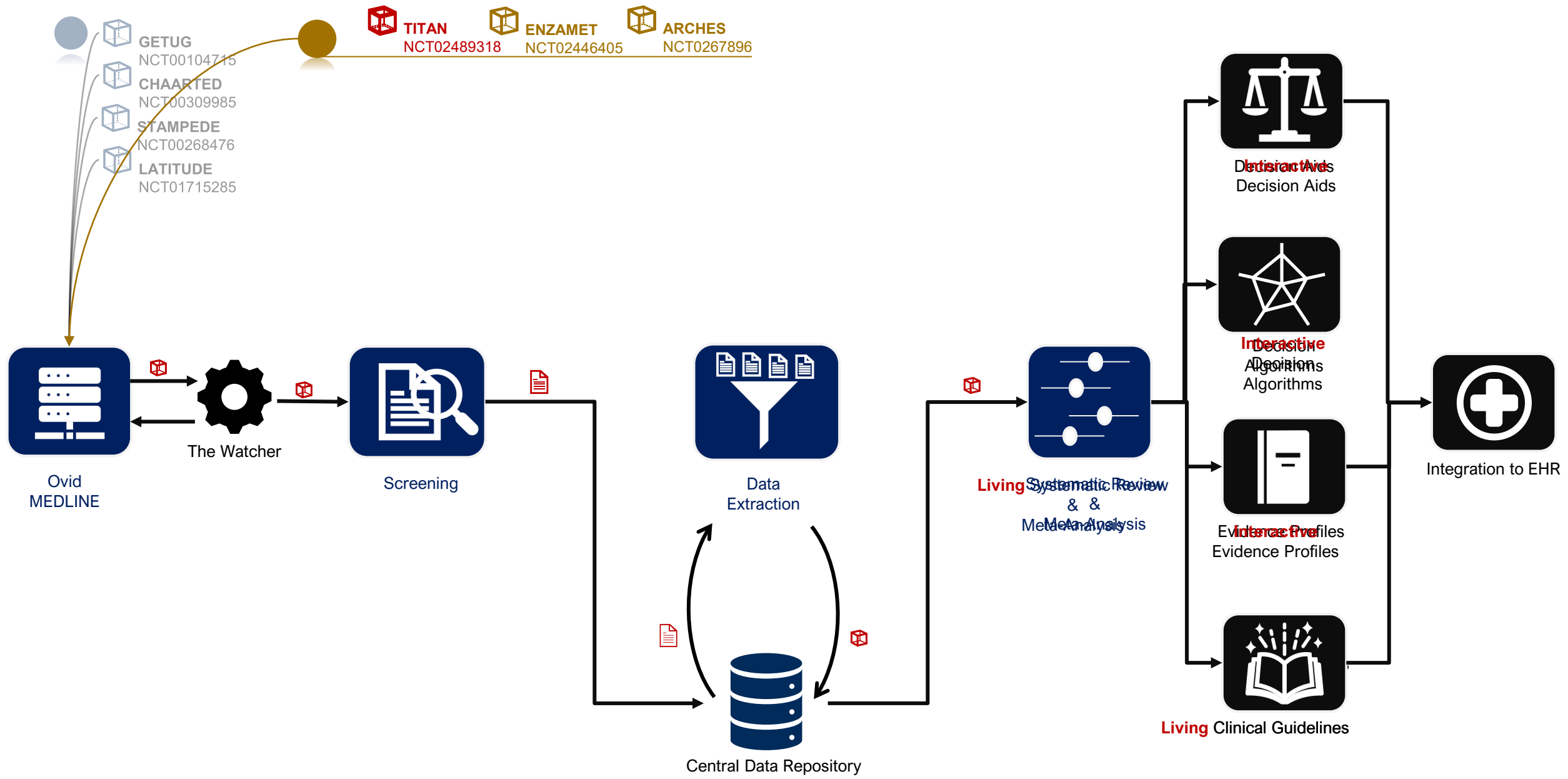


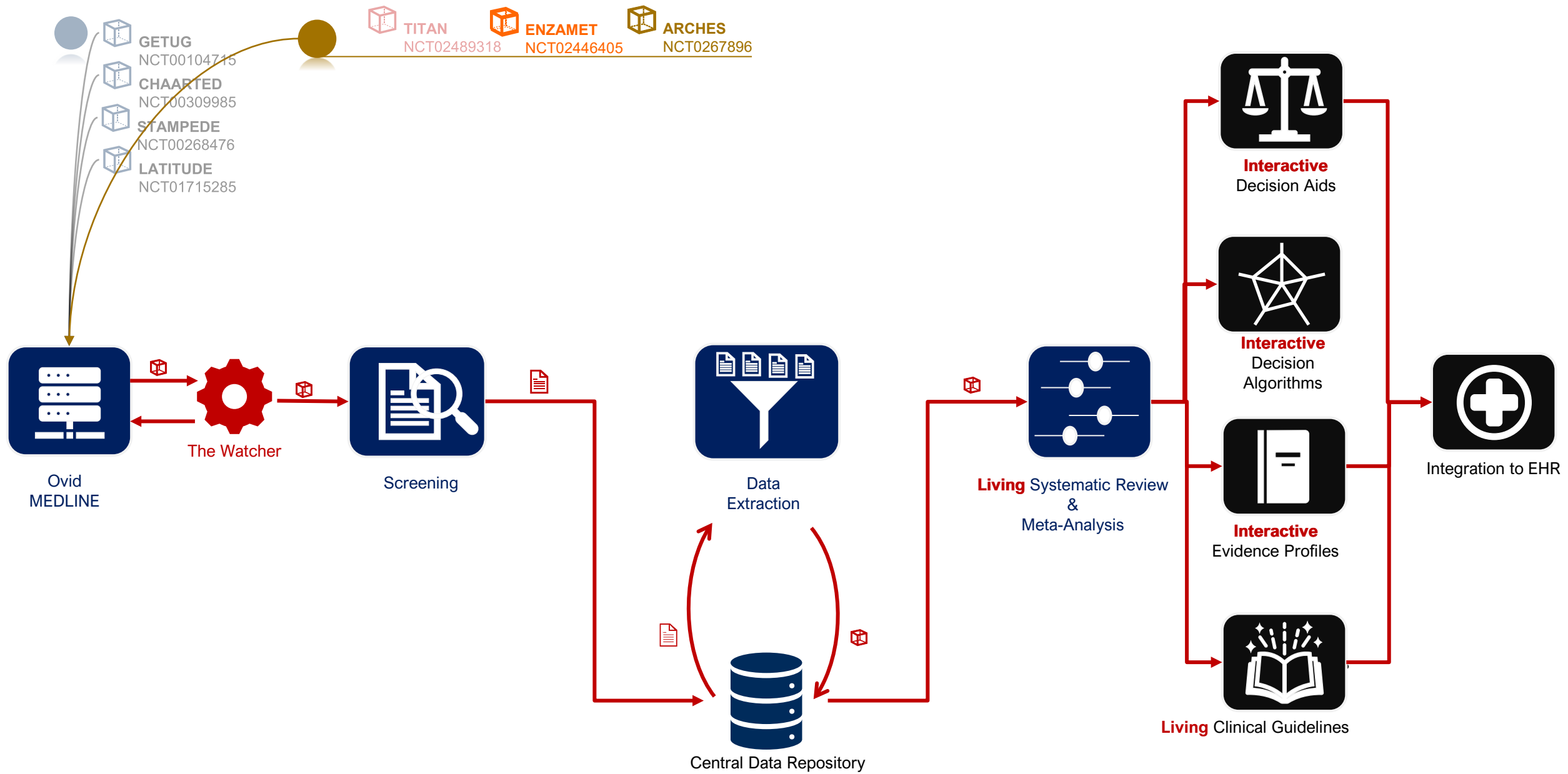




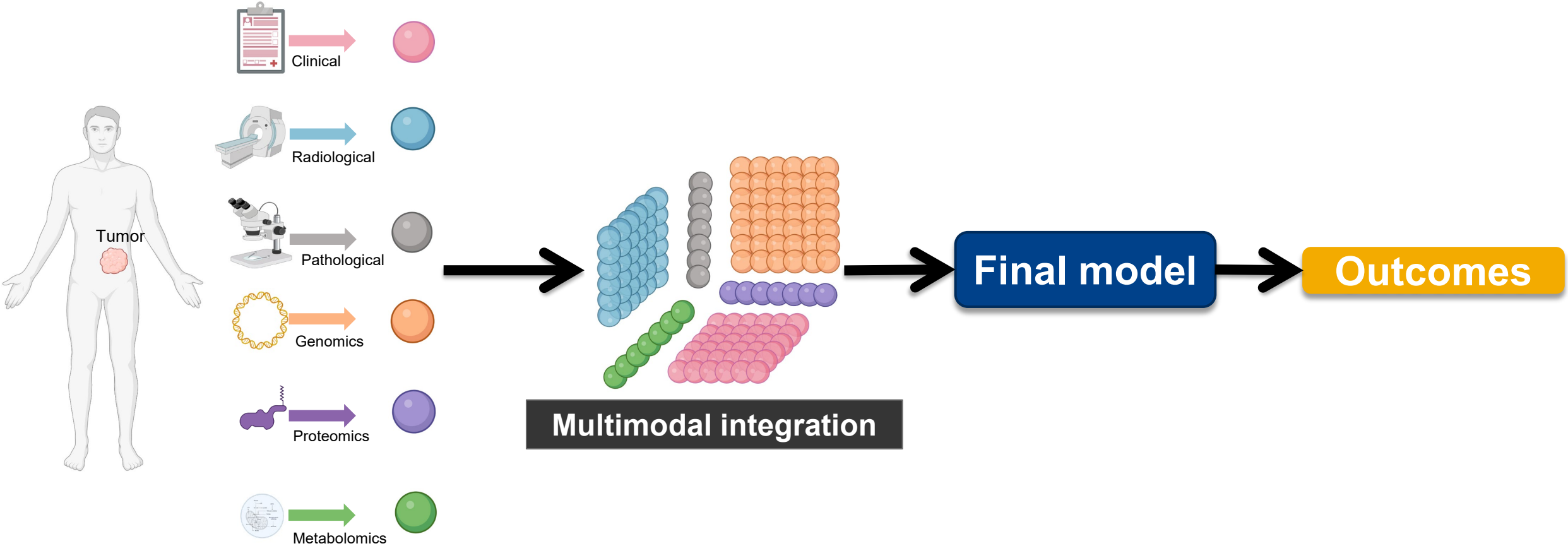








# #3 DIGITAL BIOMARKERS: MULTI-MODAL INTEGRATION CONCEPTUAL FRAMEWORK

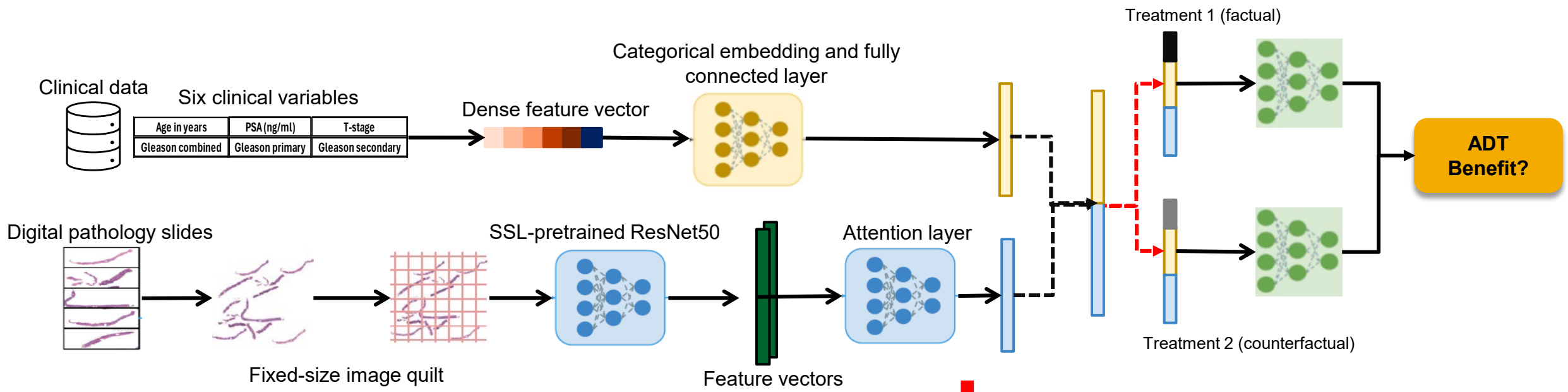


# MULTI-MODAL INTEGRATION

## PREDICTION OF TREATMENT RESPONSE IN LOCALIZED PC

ORIGINAL ARTICLE  
**Artificial Intelligence Predictive Model for Hormone Therapy Use in Prostate Cancer**  
 Daniel E. Spratt, M.D.,<sup>1</sup> Siyi Tang, Ph.D.,<sup>2,3</sup> Yikun Sun, Ph.D.,<sup>2,4</sup> Hwei-Chung Huang, M.A.,<sup>3</sup> Emmalyn Chen, Ph.D.,<sup>2</sup> Osama Mohamad, M.D., Ph.D.,<sup>5</sup> Andrew J. Armstrong, M.D.,<sup>6</sup> Jonathan D. Tward, M.D., Ph.D.,<sup>7</sup> Paul L. Nguyen, M.D.,<sup>8</sup> Joshua M. Lang, M.D., M.Sc.,<sup>9</sup> Jingbin Zhang, M.Sc.,<sup>9</sup> Akisori Mitani, M.D., Ph.D.,<sup>9</sup> Jeffrey P. Simko, M.D., Ph.D.,<sup>9</sup> Sandy DeVries, M.A.,<sup>10</sup> Douwe van der Wal, M.Sc.,<sup>9</sup> Hans Pinckaers, M.D., M.Sc.,<sup>9</sup> Jedidiah M. Monson, M.D.,<sup>11</sup> Holly A. Campbell, M.D.,<sup>12</sup> James Wallace, M.D.,<sup>13</sup> Michelle J. Ferguson, M.D.,<sup>14</sup> Jean-Paul Bahary, M.D.,<sup>15</sup> Edward M. Schaeffer, M.D., Ph.D.,<sup>16</sup> Howard M. Sandler, M.D.,<sup>17</sup> Phuoc T. Tran, M.D., Ph.D.,<sup>18</sup> Joseph P. Rodgers, M.S.,<sup>19,20</sup> Andre Esteve, Ph.D.,<sup>2</sup> Rikiya Yamashita, M.D., Ph.D.,<sup>2</sup> and Felix Y. Feng, M.D.,<sup>2</sup> on behalf of NRG Prostate Cancer AI Consortium\*

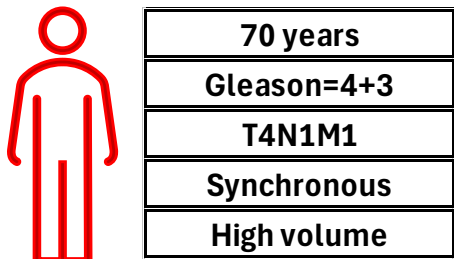
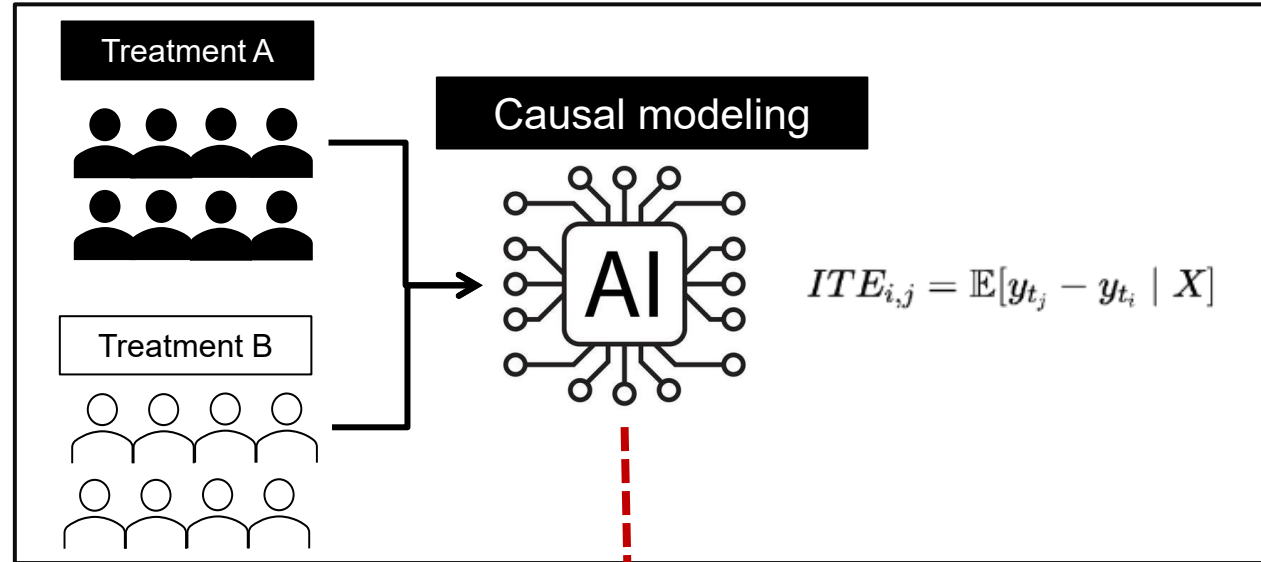
- A multimodal AI model was developed to select patients **likely to benefit from ADT** in patients undergoing radiation therapy for localized prostate cancer (dataset; 5 clinical trials, 5654 patients, 16,204 histopathology slides)



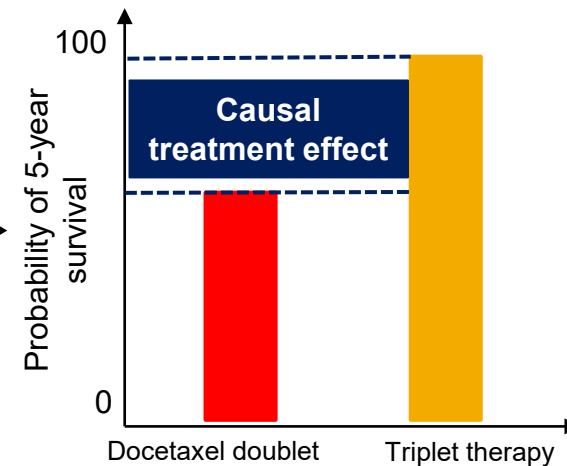
End Point	NCCN Risk	Predictive Model Group	RT+ST-ADT Incidence/N	RT Incidence/N	15-yr Absolute Benefit of ADT (%; CI 95%)	15-yr RMST Benefit of ADT (Years; CI 95%)	sHazard Ratio (95% CI)		Interaction P Value
							95% CI	P Value	
DM	All	Positive	14/273	39/270	10.5 (5.4, 15.5)	0.8 (0.3, 1.3)	0.34 (0.19, 0.63)	<0.001*	0.01*
		Negative	37/515	41/536	0.5 (-2.8, 3.7)	0.1 (-0.1, 0.4)	0.92 (0.59, 1.43)	0.71	
PCSM	All	Positive	10/273	34/270	10.2 (5.5, 14.9)	0.7 (0.3, 1.1)	0.28 (0.14, 0.57)		
		Negative	27/515	37/536	1.2 (-1.9, 4.2)	0.2 (-0.1, 0.4)	0.74 (0.45, 1.22)		

# #4 INDIVIDUALIZED TREATMENT EFFECTS

## CAUSAL INFERENCE ARTIFICIAL INTELLIGENCE



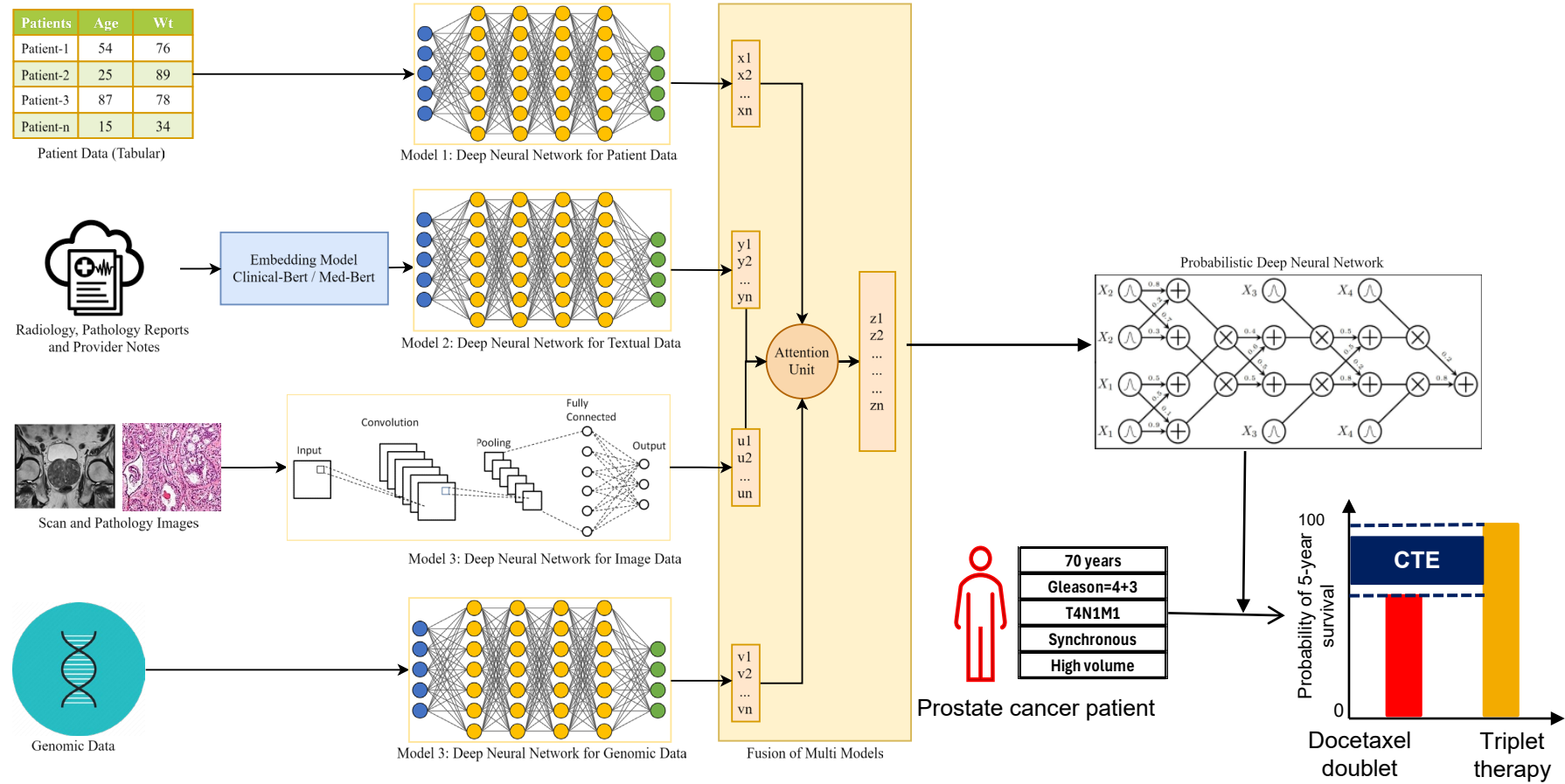
Prostate cancer patient



# MULTIMODAL INDIVIDUALIZED TREATMENT EFFECTS

## PROBABILISTIC MODELING

- To develop a **multi-modal** artificial intelligence model that integrates longitudinal data:
  - Clinical
  - Pathological
  - Imaging
  - Genomic data
- Provides **patient-specific treatment** effects using a probabilistic deep-learning causal inference framework for prostate cancer patients



# KEY TAKEAWAYS

- **Artificial intelligence can synthesize information for optimal systemic treatment decisions**
  - AI agents are well-poised to act as assistants to providers.
  - AI-enabled living clinical practice guidelines are feasible.
- **Artificial intelligence can provide novel insights from multi-modal patient data.**
  - Digital biomarkers utilizing multi-modal data are rapidly evolving.
  - Patient-specific (individualized) treatment effects is an important research topic.

# Clinical trials

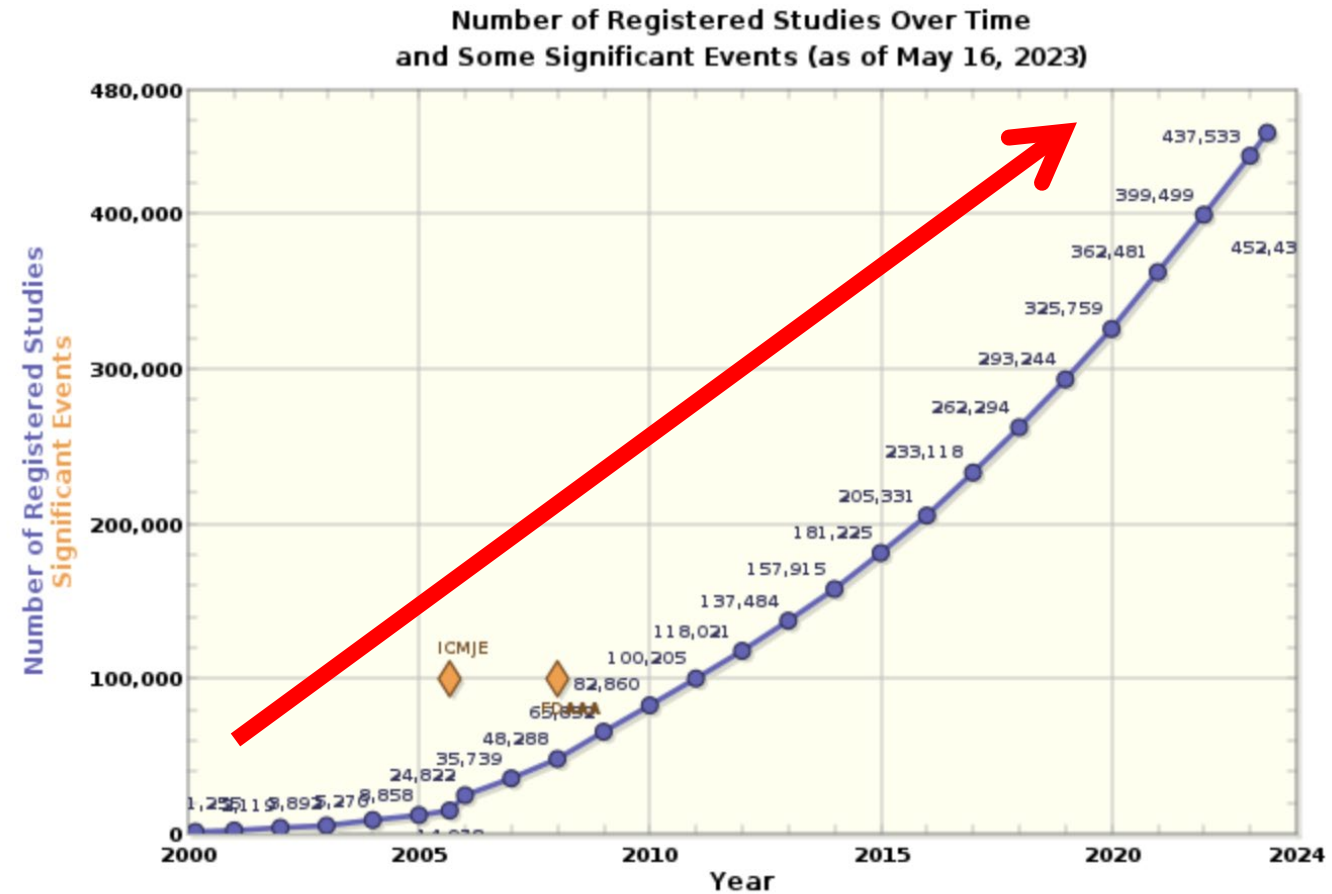
Clinical trials are **systematic experimental research studies** designed to evaluate the safety, efficacy, and optimal use of medical or surgical interventions, including drugs, devices, and treatments





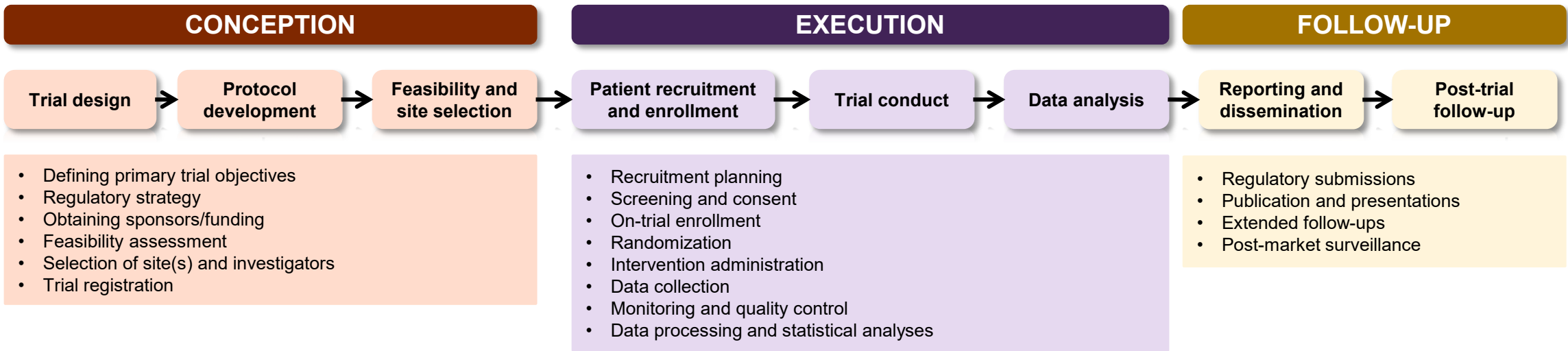
# Clinical trials growth in oncology over the years

- The cumulative annual growth rate of oncology clinical trials has increased in the last two decades since 2000.
- Clinical Trials are an expensive process with many inefficiencies and failure possibilities.
- Performance: Clinical trial enrollment rates have remained below 5%(not good!)

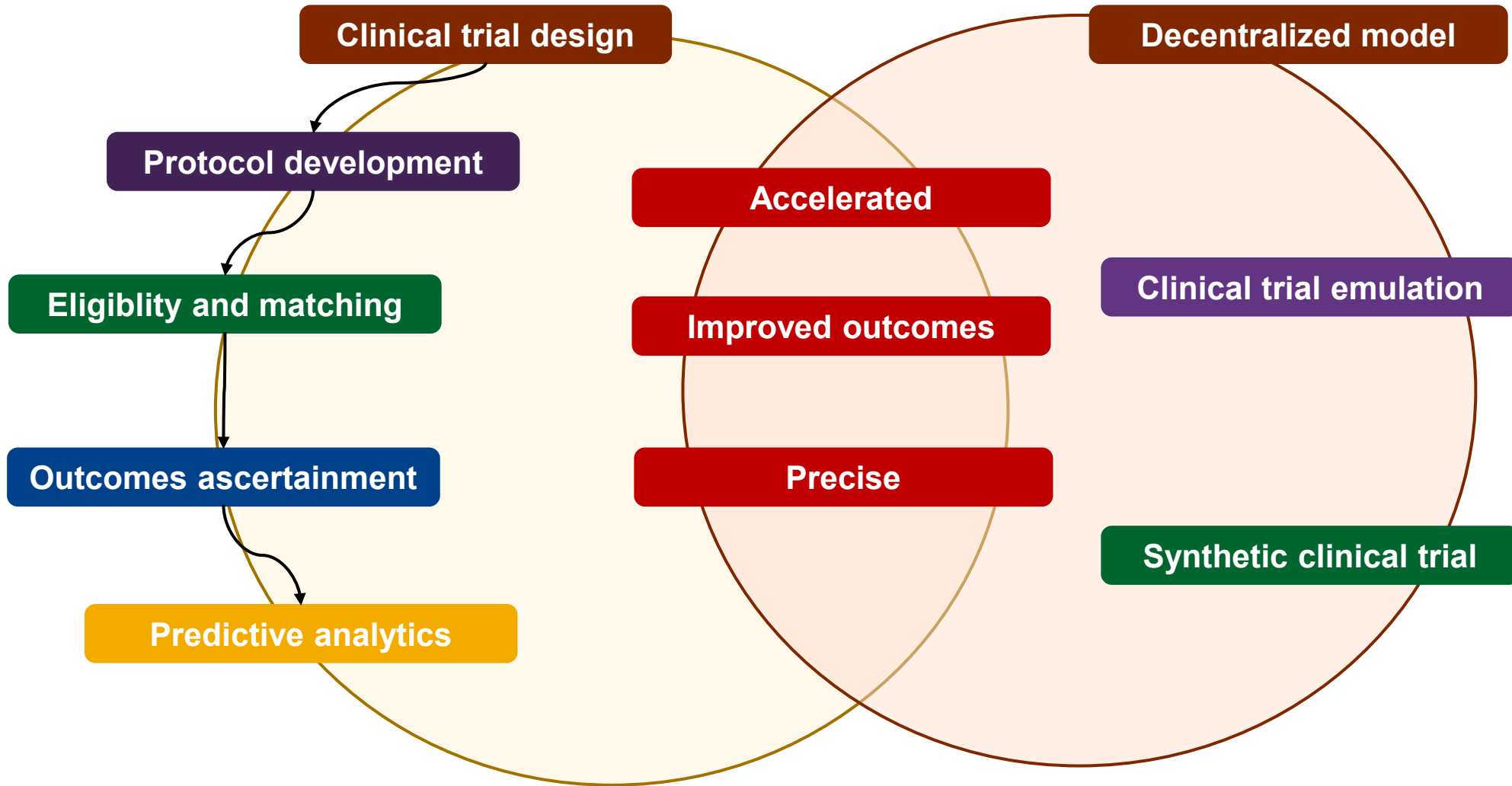


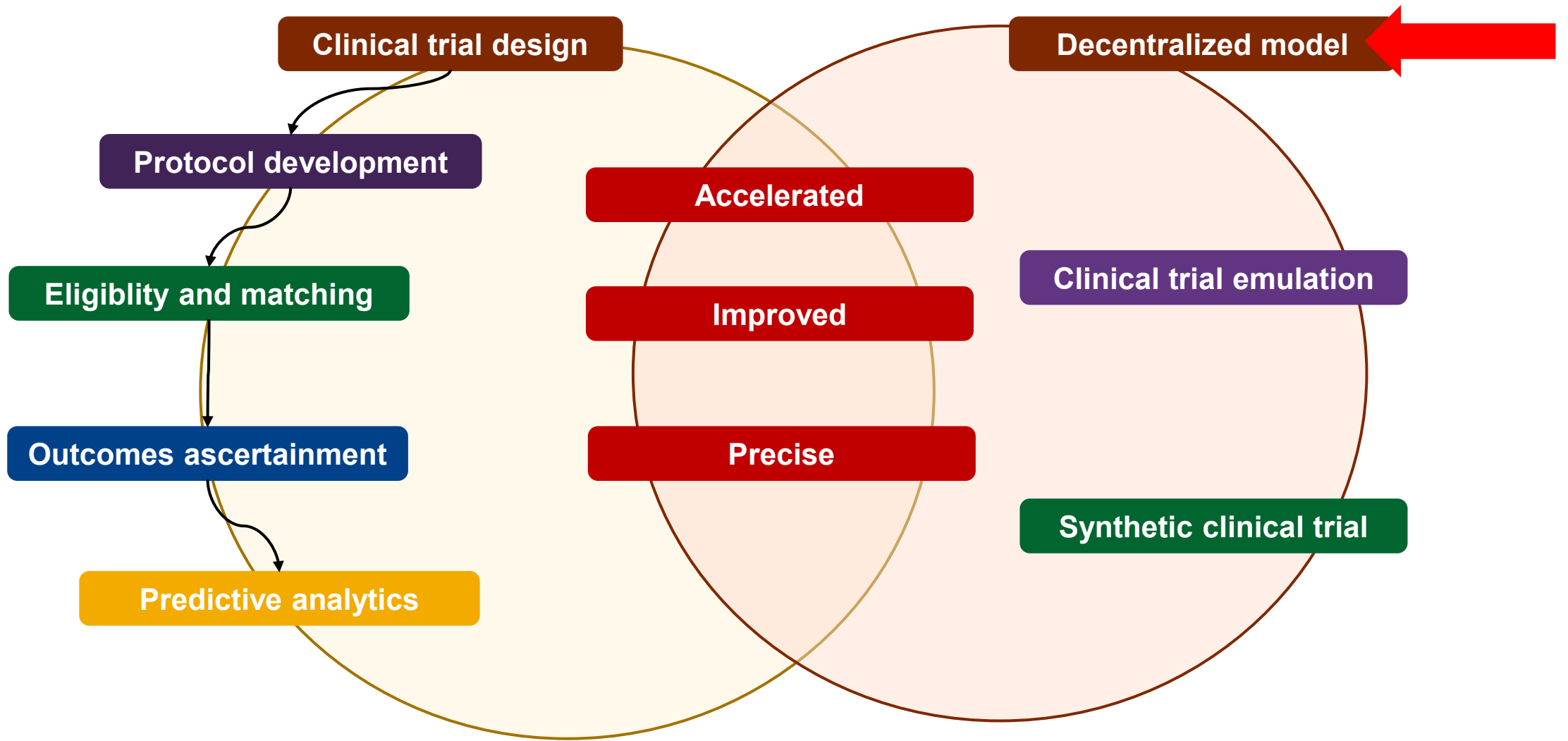
Source: <https://ClinicalTrials.gov>

# Clinical trial journey



# Innovations in clinical trials





# Innovating clinical trials by design

- *Improving clinical trials conduct model*



## Centralized clinical trials

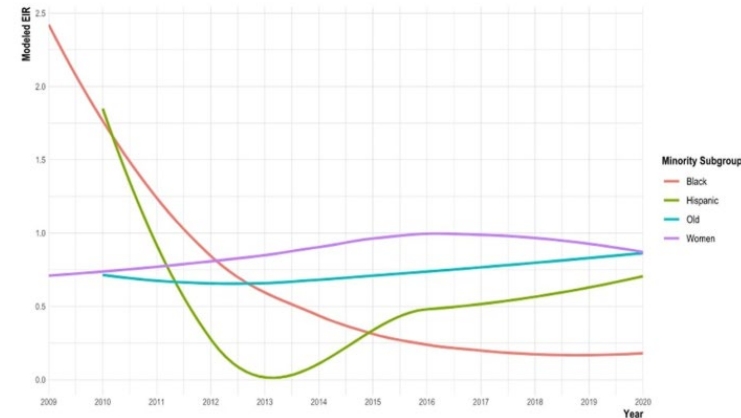
- All trial activity conducted at the **clinical research site**.
- Patient data is captured at set moments during in-person patient visits in a clinical environment

Less than 5% of patients with cancer enroll in a clinical trial, partly due to **financial and logistic burdens**, especially among underserved populations

### Disparities in Representation of Women, Older Adults, and Racial/Ethnic Minorities in Immune Checkpoint Inhibitor Trials



Irbaz B. Riaz, MD, MS,<sup>a,c,h</sup> Mahnoor Islam, MD,<sup>d</sup> Ahsan Masood Khan, MD,<sup>e</sup> Syed Arsalan Ahmed Naqvi, MBBS,<sup>a</sup>



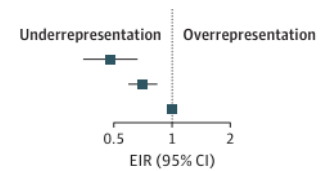
JAMA Oncology | Original Investigation

### Disparities in the Inclusion of Racial and Ethnic Minority Groups and Older Adults in Prostate Cancer Clinical Trials: A Meta-analysis

Irbaz Bin Riaz, MBBS, MS; Mahnoor Islam, MBBS; Waleed Ikram, MBBS; Syed Arsalan Ahmed Naqvi, MBBS;

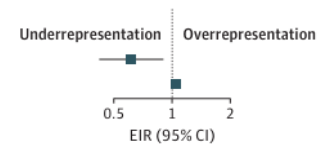
#### A Race

Subgroup	No. of studies	Between-study variance	EIR (95% CI)
Asian or Pacific Islander	19	0.17	0.48 (0.34; 0.66)
Black	38	0.20	0.70 (0.59-0.83)
White	45	0.02	1.00 (0.96; 1.04)



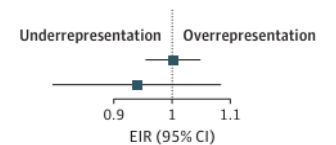
#### B Ethnicity

Subgroup	No. of studies	Between-study variance	EIR (95% CI)
Hispanic	16	0.40	0.62 (0.42-0.90)
Non-Hispanic	17	0.001	1.04 (1.03-1.06)



#### C Age

Subgroup	No. of studies	Between-study variance	EIR (95% CI)
Older adults	48	0.02	1.00 (0.95-1.05)
Younger adults	49	0.25	0.94 (0.81-1.09)



# Innovating clinical trials by design

- *Improving clinical trials conduct model*

Less than 5% of patients with cancer enroll in a clinical trial, partly due to **financial and logistic burdens**, especially among underserved populations



## Centralized clinical trials

- All trial activity conducted at the **clinical research site**.
- Patient data is captured at set moments during in-person patient visits in a clinical environment



## Decentralized clinical trials

- All trial activity conducted **virtually at home**.
- Medicine and supplies delivered directly to the participants
- Patient data is remotely collected “as it happens,” allowing patients to be studied in an unobtrusive manner in real-life situations



## Hybrid clinical trials

- A combination of trial activity conducted at clinical research site and at home virtually.



Original Investigation | Health Policy

## Remote Monitoring and Data Collection for Decentralized Clinical Trials

Bobby Daly, MD, MBA; Otis W. Brawley, MD; Mary K. Gospodarowicz, MD; Olufunmilayo I. Olopade, MD; Lola Fashoyin-Aje, MD, MPH; Victoria Wolodzko Smart, BA; I-Fen Chang, PharmD; Craig L. Tandler, MD; Geoffrey Kim, MD; Charles S. Fuchs, MD, MPH; Muhammad Shaalan Beg, MD, MBA; Lianshan Zhang, PhD; Jeffrey J. Legos, MD, MBA; Cristina Ortega Duran, CIMA; Chitkala Kalidas, PhD; Jing Qian, LLM; Justin Finnegan, MBA; Piotr Pilarski, MD; Harriet Keane, PhD; Johanna Shen, MS; Amy Silverstein, PhD; Yi-Long Wu, MD; Richard Pazdur, MD; Bob T. Li, MD, PhD, MPH

*To assess the current global state of adoption of decentralized trial technologies, understand factors that may be driving or preventing adoption, and highlight aspirations and direction for industry to enable more patient-centric trials*

# Innovating clinical trials by design



- Decentralized clinical trials**

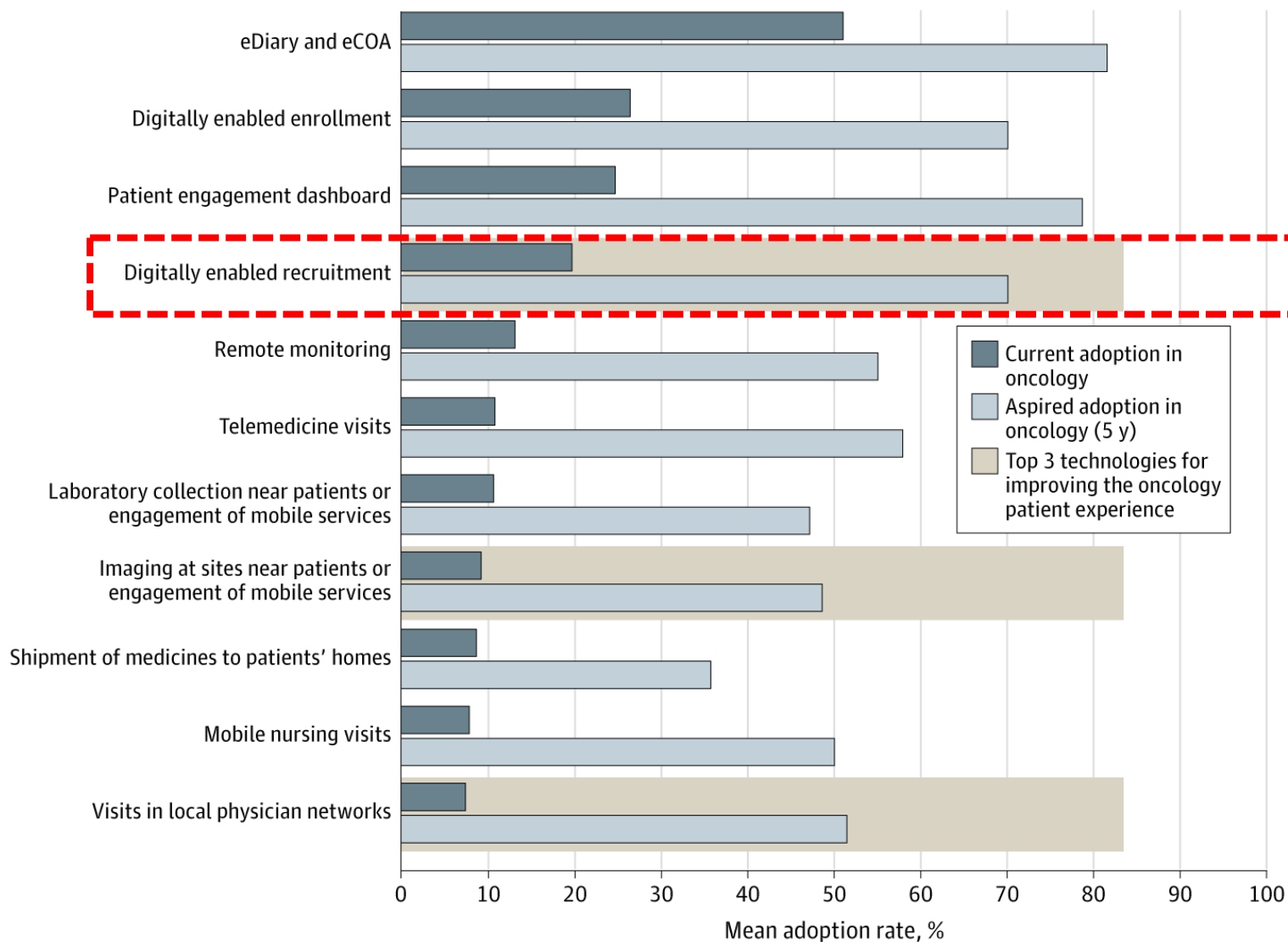
Table. Remote Monitoring and Data Collection Technologies

Technology	Definition
eDiary and eCOA	Electronic methods of capturing notes on patient experience (including adverse events) and efficacy of therapeutics
Patient engagement dashboard	Digital platform with tools and features to facilitate day-to-day trial participation and adherence (eg, patient scheduling, patient reimbursement tracking, symptom assessment, dose reporting)
Digitally enabled enrollment	Methods that support patient enrollment, including prescreening, initial site visit, informed consent, and screening, such as eConsent
Digitally enabled recruitment	Methods that support identification of patients, sourcing, and education of patients for participation in clinical trials, such as digital patient identification and use of social media to identify patients
Remote monitoring	Connected tools and devices to support monitoring of patient health and vitals remotely or outside of a traditional clinical trial site (eg, electrocardiography, pulse oximetry)
Telemedicine visits	Virtual clinical trial visits through use of teleconferencing
Visits in local physician networks	Visits with local oncologists outside the academic trial site (hub-and-spoke network)
Mobile nursing visits	Mobile clinical trial sites that bring health care professionals directly to patients in their homes or places of work
Imaging at sites near patients	Imaging at stand-alone or regional imaging centers
Laboratory data collection near patients	Collection of biospecimens at a retail laboratory or patient's home
Shipment of medicines to patients' homes	Delivery using courier services

Original Investigation | Health Policy

## Remote Monitoring and Data Collection for Decentralized Clinical Trials

Bobby Daly, MD, MBA; Otis W. Brawley, MD; Mary K. Gospodarowicz, MD; Olufunmilayo I. Olopade, MD; Lola Fashoyin-Aje, MD, MPH; Victoria Wolodzko Smart, BA; I-Fen Chang, PharmD; Craig L. Tondler, MD; Geoffrey Kim, MD; Charles S. Fuchs, MD, MPH; Muhammad Shaalan Beg, MD, MBA; Lianshan Zhang, PhD; Jeffrey J. Legos, MD, MBA; Cristina Ortega Duran, CIMA; Chitkala Kalidas, PhD; Jing Qian, LLM; Justin Finnegan, MBA; Piotr Pilarski, MD; Harriet Keane, PhD; Johanna Shen, MS; Amy Silverstein, PhD; Yi-Long Wu, MD; Richard Pazdur, MD; Bob T. Li, MD, PhD, MPH







## Decentralized clinical trials

### Improved patient access

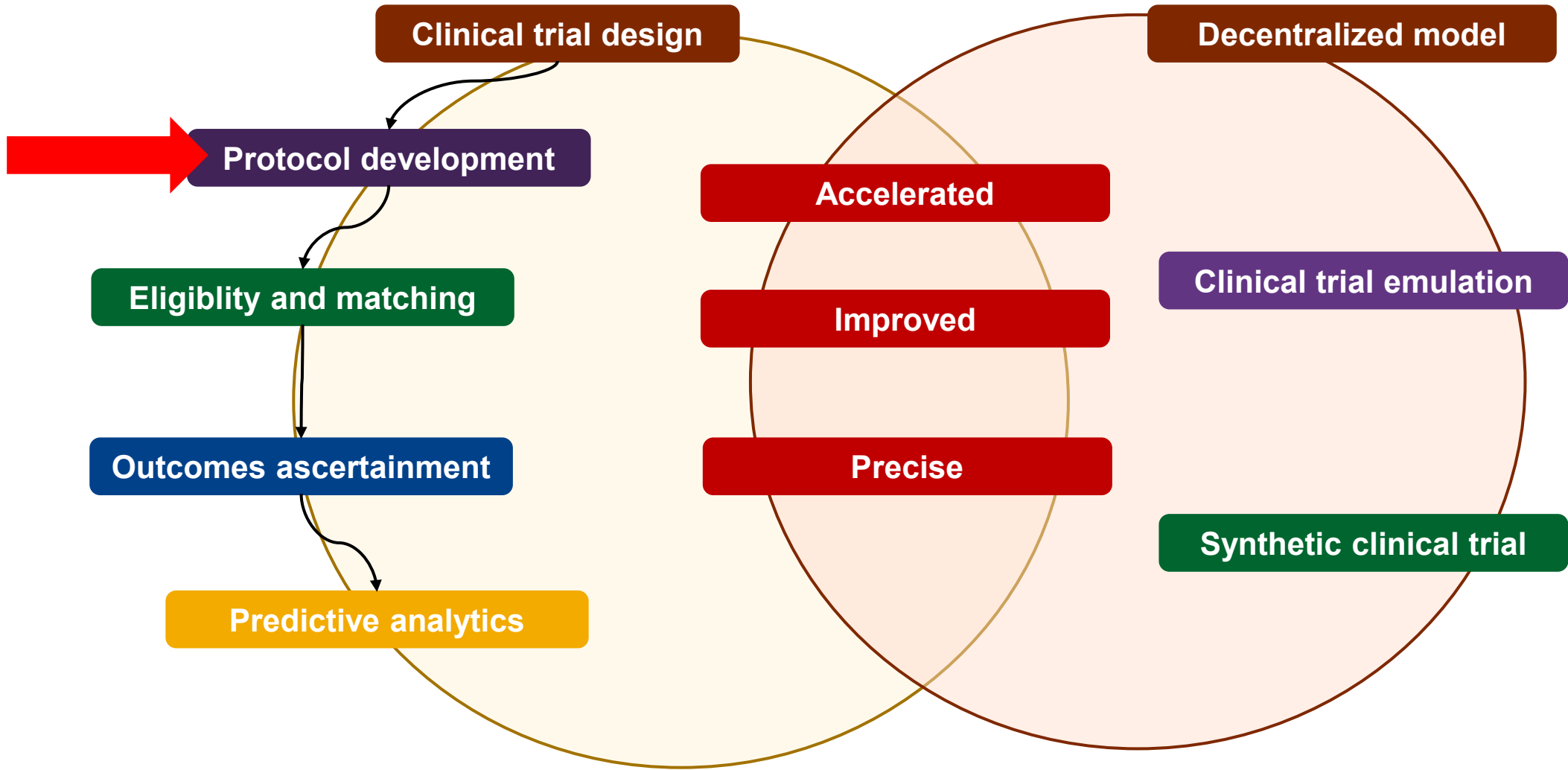
- Allow patients to **participate from their homes**
- **Eliminate the need** for travel to medical centers
- Increases access to clinical trials for patients who may face geographical or mobility challenges, thereby **improving enrollment**

### Increased patient retention

- Patients are more **likely to remain engaged** in trials when they can participate from home
- This ensures adequate follow up, thereby **reducing attrition**

### Real world data generation

- Allow for the collection of real-world data in patients' natural environments
- Providing insights into how treatments perform **outside of controlled clinical settings**



**Clinical trial design**

**Decentralized model**

**Protocol development**

**Accelerated**

**Clinical trial emulation**

**Eligibility and matching**

**Improved**

**Outcomes ascertainment**

**Precise**

**Synthetic clinical trial**

**Predictive analytics**

# Protocol development

You are a clinical study designer, and you need to generate the introduction section of a clinical trial protocol based on information about the study and drug metadata. Follow the same format and writing style as the example below:

Example 1 Input:

...

Generated:

...

Example 2 Input:

..

Generated:

..

Metadata for prediction: ..

Now Begin!

Generate the introduction section:



Generated Text for 'gpt-3.5-turbo-16k-0613' model with two examples provided:

## 2. Introduction

### 2.1 Study Rationale

Type 2 diabetes (T2D) is a metabolic disorder that is commonly associated with comorbidities such as obesity, hypertension, and dyslipidemia. These comorbidities increase the risk of chronic diabetic complications and make it challenging to achieve adequate glycemic control (Garber 2012; Neeland et al. 2019; Dwivedi et al. 2020). Therefore, there is a need for therapeutic interventions that can simultaneously target T2D and obesity to address this unmet medical need (Lau and Teoh 2015; Aroda 2018; Pereira and Eriksson 2019; Chun and Butts 2020). LY3209590 is a long-acting insulin, specifically a basal insulin Fc-conjugated (basal insulin-FC), that is being developed to improve glycemic control in patients with T2D, including those with comorbid obesity and insulin-requiring patients (Eli Lilly). It is designed to provide a prolonged and consistent release of insulin to maintain stable blood glucose levels throughout the day.

### 2.2 Background

T2D is characterized by impaired glycemic control due to insulin resistance in peripheral tissues and inadequate insulin secretion by beta cells (Zheng et al. 2018). The use of insulin therapy is often necessary in the management of T2D, especially in patients who cannot achieve glycemic control with oral antidiabetic medications alone (Eli Lilly). The primary objective of this phase 2, randomized, open-label trial is to evaluate the safety and efficacy of LY3209590 in participants with T2D, including those with comorbid obesity and insulin-requiring patients.

The study will assess the impact of LY3209590 on body mass index, hemoglobin A1c percentage and hypoglycemia incidence. Participants will receive LY3209590 in combination with other antidiabetic medications, including metformin, to evaluate its effectiveness in real-world clinical practice.

### 2.3 Benefit/Risk Assessment

The safety and efficacy of LY3209590 have been assessed in preclinical and early clinical trials. The known and expected benefits and risks of LY3209590, including adverse events related to insulin therapy, will be evaluated in this trial. The benefits of LY3209590 include improved glycemic control and potential weight management benefits due to its Fc-conjugated formulation. The risks associated with LY3209590 are primarily related to hypoglycemia and adverse events commonly observed with insulin therapy. Based on the available data, including data from early clinical trials and the known safety profile of insulin therapy, the potential benefits of LY3209590 outweigh the anticipated risks. The trial protocol includes measures to minimize the risk to participants, such as regular monitoring of blood glucose levels and appropriate adjustment of insulin dosage based on individual needs.

Overall, this phase 2 trial aims to further evaluate the safety and efficacy of LY3209590 in a larger population of patients with T2D. The results of this trial will provide valuable information to support the continued development of LY3209590 in phase 3 clinical trials.

## 3. Study Design

### 3.1 Overall Design

This trial is a phase 2, randomized, open-label trial to evaluate the safety and efficacy of LY3209590 in participants with T2D. The trial will include participants with comorbid obesity and insulin-requiring patients who have inadequate glycemic control despite treatment with other antidiabetic medications. Participants will be randomly assigned to receive either LY3209590 or standard-of-care therapy. The primary endpoints of the trial include changes in body mass index, hemoglobin A1c percentage, and hypoglycemia incidence. Secondary endpoints include changes in fasting plasma glucose levels, postprandial glucose excursions and patient-reported outcomes.

Participants will receive LY3209590 in combination with other antidiabetic medications including metformin. The study duration is anticipated to be several months to allow for adequate evaluation of the short-term and long-term efficacy and safety of LY3209590. The trial design incorporates measures to minimize bias, including randomization, blinding of outcome assessors, and appropriate statistical analysis. Safety evaluations will be conducted throughout the trial period to monitor for adverse events and ensure participant well-being.

Overall, this study design aims to provide robust evidence on the safety and efficacy of LY3209590 in a real-world clinical setting, further informing its future clinical development.




(Note: The additional sections of the protocol, such as the study procedures, statistical analysis plan, and ethical considerations, have not been provided. These sections would typically be included in the introduction of a clinical trial protocol.

Table 2: Evaluation Metrics for GPT Models

Model	#	Time	In. Tok.	Out. Tok.	Error	Cos. Sim.	bleu1	bleu2	bleu3	bleu4	Precision	Recall	F1
gpt-3.5-turbo	0	88.55	375	344	-	0.6	0.22	0.11	0.06	0.04	0.33	0.19	0.24
gpt-3.5-turbo	1	146.87	1,188	477	-	0.82	0.53	0.4	0.33	0.27	0.62	0.5	0.55
gpt-3.5-turbo	2	-	-	-	Max Tok.	-	-	-	-	-	-	-	-
gpt-3.5-turbo	3	-	-	-	Max Tok.	-	-	-	-	-	-	-	-
gpt-3.5-turbo-1106	0	7.44	375	255	-	0.6	0.11	0.05	0.03	0.02	0.32	0.15	0.2
gpt-3.5-turbo-1106	1	9.69	1,970	299	-	0.55	0.19	0.1	0.06	0.04	0.43	0.23	0.3
gpt-3.5-turbo-1106	2	13.84	3,554	442	-	0.62	0.32	0.16	0.09	0.06	0.34	0.25	0.29
gpt-3.5-turbo-1106	3	13.37	4,356	373	-	0.78	0.35	0.25	0.19	0.14	0.62	0.37	0.47
gpt-3.5-turbo-16k-0613	0	70.47	375	361	-	0.61	0.23	0.11	0.06	0.03	0.32	0.19	0.24
gpt-3.5-turbo-16k-0613	1	153.33	1,970	693	-	0.63	0.39	0.2	0.1	0.06	0.27	0.26	0.26
gpt-3.5-turbo-16k-0613	2	719.03	1,990	398	-	0.81	0.43	0.32	0.26	0.21	0.71	0.47	0.57
gpt-3.5-turbo-16k-0613	3	70.06	4,356	296	-	0.63	0.18	0.11	0.08	0.06	0.41	0.22	0.29
gpt-4	0	20.39	375	303	-	0.58	0.17	0.07	0.03	0.01	0.27	0.16	0.2
gpt-4	1	34.16	1,970	467	-	0.58	0.32	0.15	0.08	0.04	0.29	0.24	0.26
gpt-4	2	22.54	2,772	297	-	0.74	0.22	0.15	0.11	0.08	0.53	0.32	0.4
gpt-4	3	9.29	4,356	94	-	0.52	0	0	0	0	0.57	0.13	0.22
gpt-4-1106-preview	0	36.93	375	518	-	0.65	0.37	0.16	0.05	0.02	0.24	0.23	0.24
gpt-4-1106-preview	1	37.32	1,970	611	-	0.64	0.41	0.18	0.08	0.03	0.26	0.29	0.27
gpt-4-1106-preview	2	37.19	2,772	637	-	0.7	0.44	0.21	0.11	0.06	0.27	0.31	0.29
gpt-4-1106-preview	3	24.24	3,574	409	-	0.67	0.31	0.15	0.08	0.05	0.3	0.25	0.27

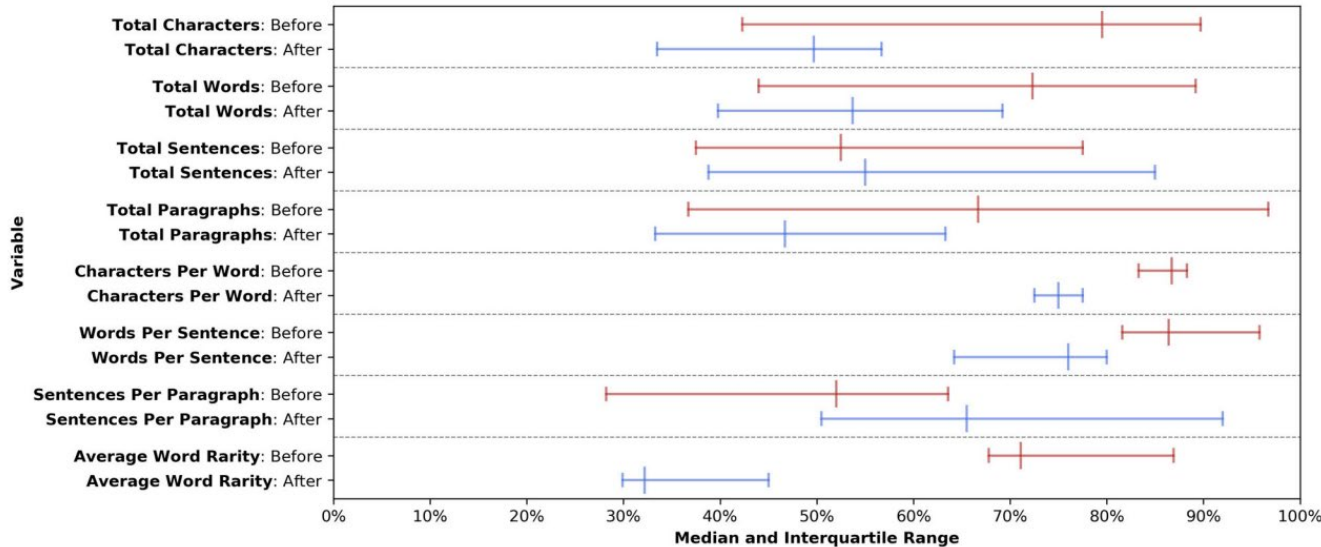
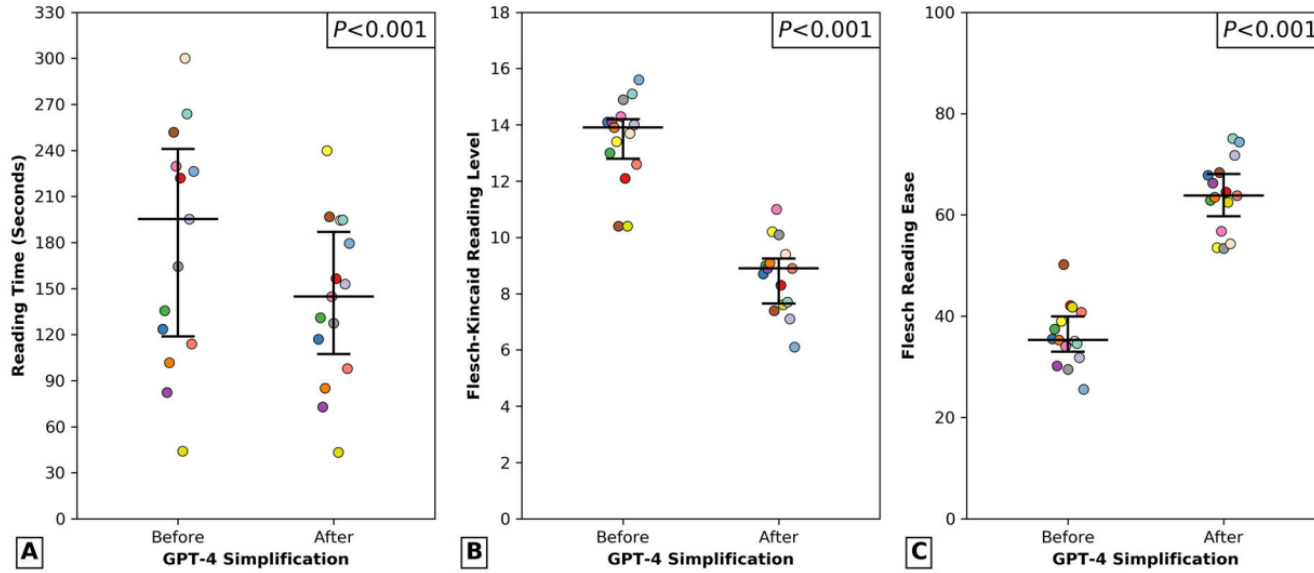
# Bridging the literacy gap for surgical consents: an AI-human expert collaborative approach



Rohaid Ali <sup>1,2,10</sup> , Ian D. Connolly<sup>3,10</sup>, Oliver Y. Tang <sup>1,10</sup>, Fatima N. Mirza <sup>4</sup>, Benjamin Johnston <sup>5</sup>, Hael F. Abdulrazeq<sup>1,2,10</sup>, Rachel K. Lim<sup>6</sup>, Paul F. Galamaga<sup>7</sup>, Tiffany J. Libby<sup>4</sup>, Neel R. Sodha<sup>6</sup>, Michael W. Groff<sup>5</sup>, Ziya L. Gokaslan<sup>1,2</sup>, Albert E. Telfeian<sup>1,2</sup>, John H. Shin<sup>3</sup>, Wael F. Asaad <sup>1</sup>, James Zou<sup>8,9</sup> & Curtis E. Doberstein<sup>1,2</sup>

*To quantitatively and qualitatively investigate the application of the GPT-4 to assess and transform surgical consent forms into a more accessible reading level in an efficient, standardized, and effective manner*

# Simplifying consent forms



## Bridging the literacy gap for surgical consents: an AI-human expert collaborative approach

Rohaid Ali<sup>1,2,10</sup>, Ian D. Connolly<sup>3,10</sup>, Oliver Y. Tang<sup>1,10</sup>, Fatima N. Mirza<sup>4</sup>, Benjamin Johnston<sup>5</sup>, Hael F. Abdulrazeq<sup>1,2,10</sup>, Rachel K. Lim<sup>6</sup>, Paul F. Galamaga<sup>7</sup>, Tiffany J. Libby<sup>4</sup>, Neel R. Sodha<sup>8</sup>, Michael W. Groff<sup>9</sup>, Ziya L. Gokaslan<sup>1,2</sup>, Albert E. Telfeian<sup>1,2</sup>, John H. Shin<sup>2</sup>, Wael F. Asaad<sup>1</sup>, James Zou<sup>8,9</sup> & Curtis E. Doberstein<sup>1,2</sup>

Check for updates

- GPT4 can enhance consent forms, significantly improving readability without sacrificing clinical detail
- This has been extended to consent process in clinical trials

HEALTH CARE ACCESS, EQUITY, AND DISPARITIES

109



Poster Session

## **Improving clinical trial consent form readability through artificial intelligence.**

Henry Kazunaru Litt, Emma Greenstreet Akman, Dame Idossa, Narjust Florez, Ana I. Velazquez Manana; University of California, San Francisco, San Francisco, CA; University of Minnesota, Minneapolis, MN; Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA

*To assess whether ChatGPT-4 could simplify clinical trial information from informed consent forms using data from NIH-funded clinical trials in cancer*

# Simplifying consent forms

## Improving clinical trial consent form readability through artificial intelligence.

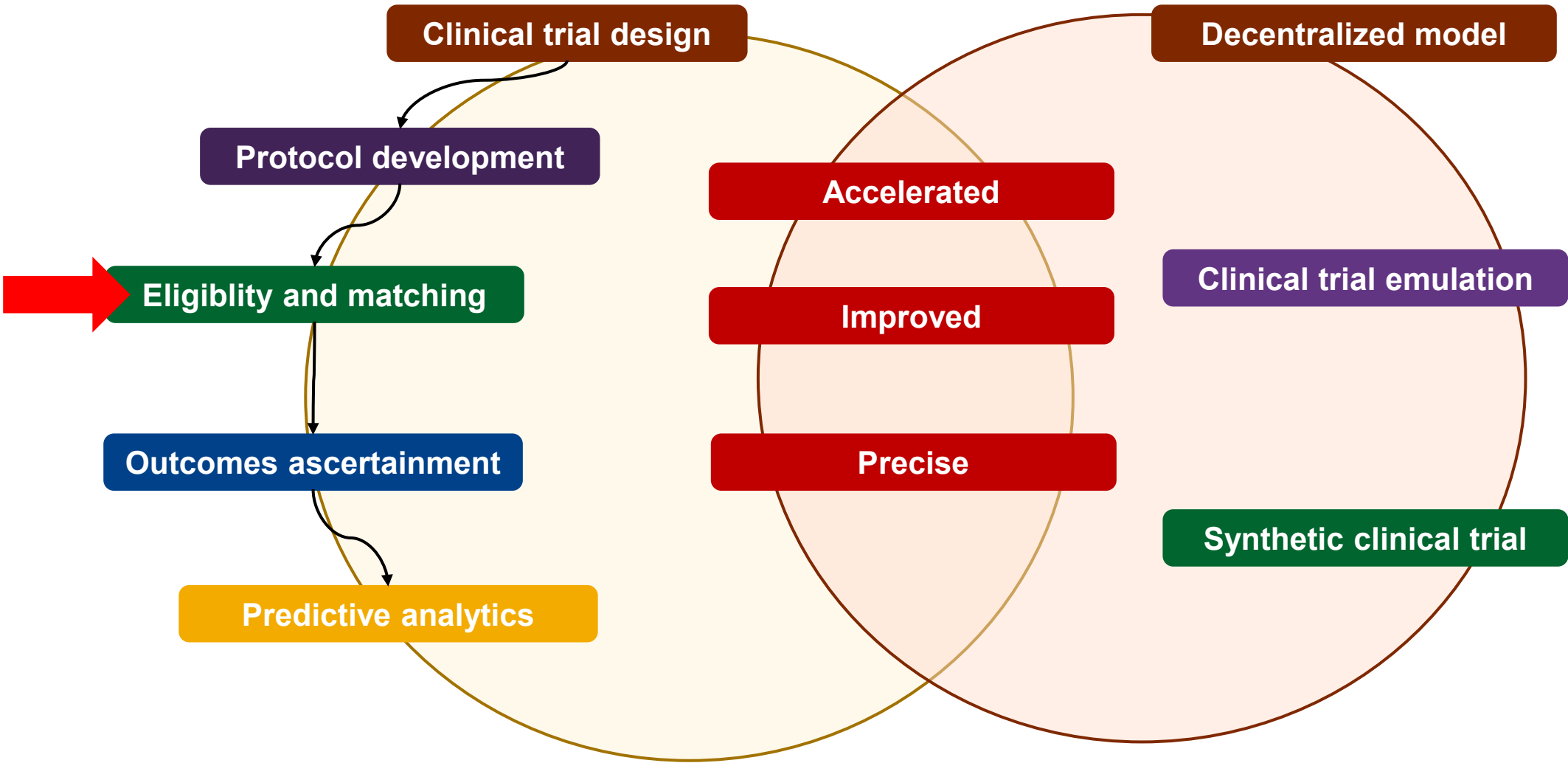
Henry Kazunaru Litt, Emma Greenstreet Akman, Dame Idossa, Narjust Florez, Ana I. Velazquez Manana; University of California, San Francisco, San Francisco, CA; University of Minnesota, Minneapolis, MN; Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA

### • Methods

- NIH-funded, clinical trials involving adults with the 14 most prevalent cancer types were included
- ChatGPT-4 was prompted to review each informed consent form (ICF) and answer (at the level 6<sup>th</sup> grade literacy) the following questions:
  - What **are the treatments** used in the clinical trial?
  - Has the treatment been used for other **types of cancer**?
  - What are **the risks and benefits of this treatment**?
  - What **side effects** should I expect and how will they be managed?
  - How **long** will I be in the clinical trial?
  - Will **I be able to get other treatment** if this doesn't work?
  - How will you know if the **treatment is working**?
  - Will the **clinical trial cost me** anything?

### • Results

- A total of 66 of the 70 ICFs (94.3%) were analyzed
- The mean text reading levels of its answers were
  - Flesch-Kincaid (FK) score: 6.2 (95% CI: 5.9-6.5)
  - Gunning-Fog (GF) score: 8.6 (95% CI: 8.2-8.9)
  - SMOG indices: 9.2 (95% CI: 8.9-9.4)
- ChatGPT-4's text responses had a significantly lower reading level compared to ICFs text for all three readability indices
  - (FK:  $p < 0.01$ , GF:  $p = 0.02$ , SMOG:  $p < 0.01$ ).





# Clinical Inflection Point Detection on the Basis of EHR Data to Identify Clinical Trial–Ready Patients With Cancer

Authors: Kenneth L. Kehl, MD, MPH  , Stefan Groha, PhD, Eva M. Lepisto, MA, MSc, Haitham Elmarakeby, PhD , James Lindsay, PhD ,

Alexander Gusev, PhD , Eliezer M. Van Allen, MD, Michael J. Hassett, MD, MPH , and Deborah Schrag, MD, MPH | [AUTHORS INFO & AFFILIATIONS](#)

Publication: JCO Clinical Cancer Informatics • Volume 5 • <https://doi.org/10.1200/CCI.20.00184>











*To develop a machine learning natural language processing model to identify inflection points in real time on the basis of serial imaging reports for each patient in an attempt to identify patients who are ready for clinical trials.*

# Clinical trial matching

ARTICLE OPEN



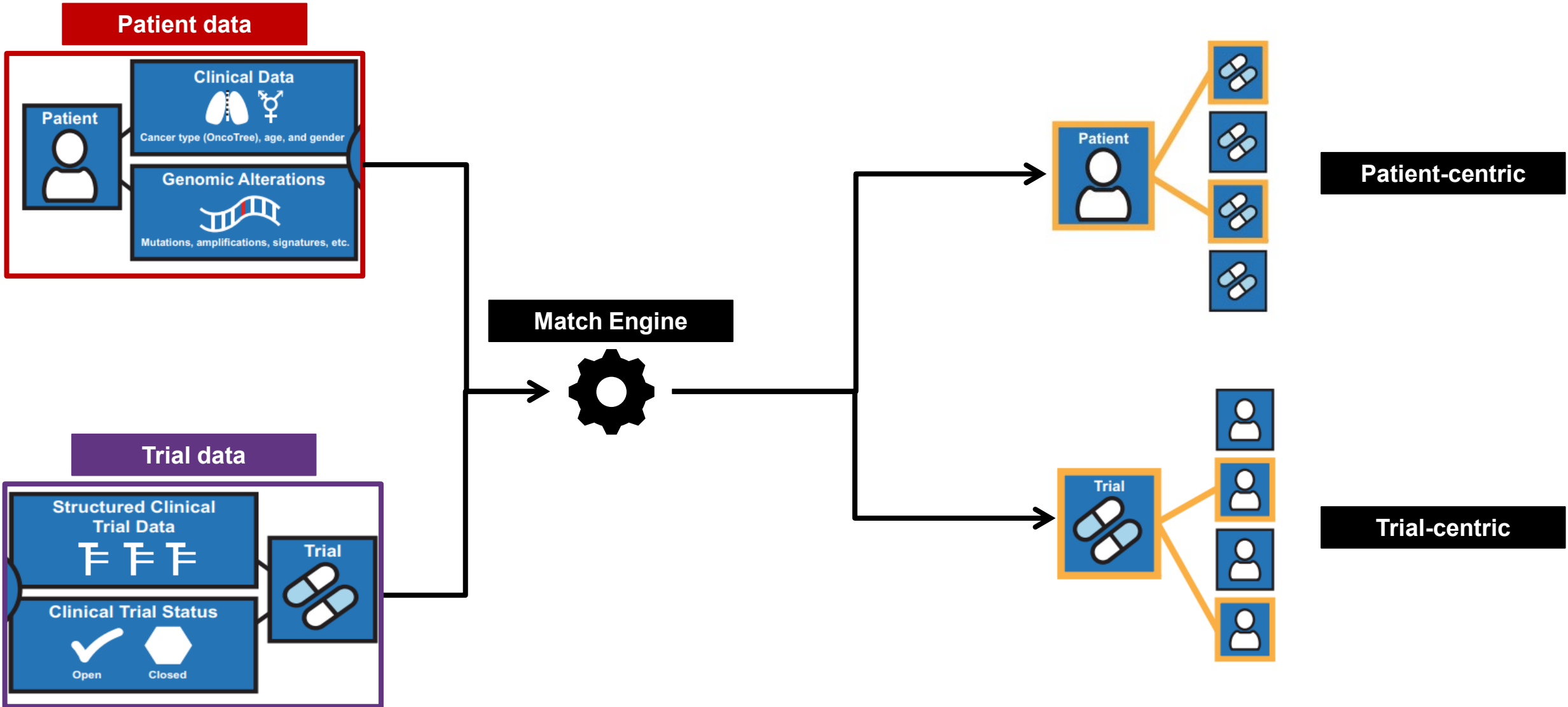
# MatchMiner: an open-source platform for cancer precision medicine

Harry Klein <sup>1</sup>✉, Tali Mazor <sup>1</sup>✉, Ethan Siegel<sup>1</sup>, Pavel Trukhanov <sup>1</sup>, Andrea Ovalle<sup>1</sup>, Catherine Del Vecchio Fitz <sup>1</sup>, Zachary Zwiesler<sup>1</sup>, Priti Kumari<sup>1</sup>, Bernd Van Der Veen<sup>2</sup>, Eric Marriott <sup>1</sup>, Jason Hansel<sup>1</sup>, Joyce Yu<sup>1</sup>, Adem Albayrak<sup>3</sup>, Susan Barry<sup>4</sup>, Rachel B. Keller <sup>5</sup>, Laura E. MacConaill<sup>6</sup>, Neal Lindeman<sup>6</sup>, Bruce E. Johnson<sup>5</sup>, Barrett J. Rollins<sup>5,7</sup>, Khanh T. Do <sup>5,7</sup>, Brian Beardslee<sup>5</sup>, Geoffrey Shapiro<sup>5,7</sup>, Suzanne Hector-Barry<sup>5</sup>, John Methot <sup>3</sup>, Lynette Sholl<sup>6</sup>, James Lindsay <sup>1</sup>, Michael J. Hassett <sup>5</sup> and Ethan Cerami<sup>1</sup>

*To describe MatchMiner's capabilities (an open-source platform to computationally match genomically profiled cancer patients to PM trials), outline its deployment, and characterize its impact on PM trial enrollment*

# Clinical trial “matching”

- MatchMiner**

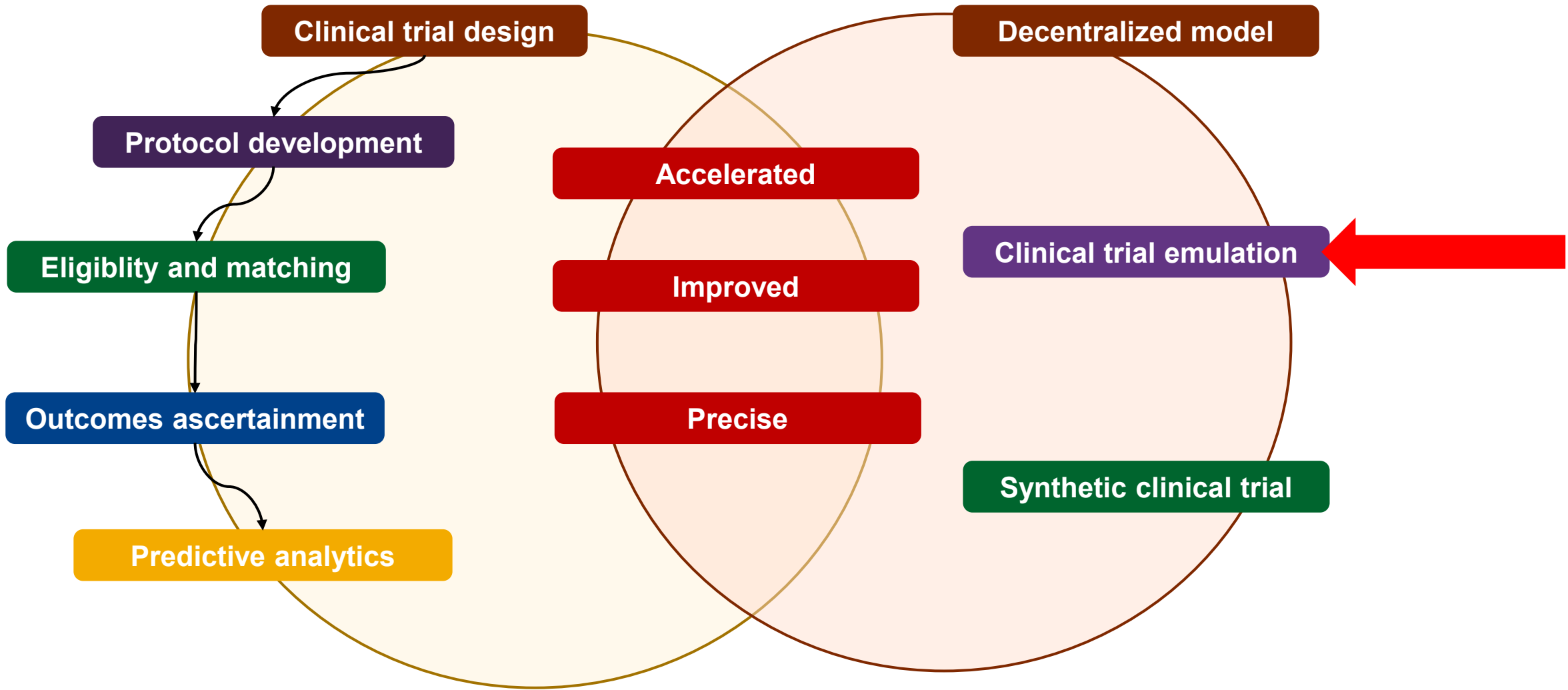


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MatchMiner: an open-source platform for cancer precision medicine

Harry Klein<sup>1</sup>, Tali Mazor<sup>1,2,3</sup>, Ethan Siegel<sup>1</sup>, Pavel Trukhanov<sup>4</sup>, Andrea Ovalle<sup>1</sup>, Catherine Del Vecchio Fitz<sup>5</sup>, Zachary Zwiesler<sup>1</sup>, Priti Kumari<sup>1</sup>, Bernd Van Der Veen<sup>2</sup>, Eric Marriott<sup>6</sup>, Jason Hansel<sup>1</sup>, Joyce Yu<sup>1</sup>, Adem Albayrak<sup>3</sup>, Susan Barry<sup>4</sup>, Rachel B. Keller<sup>6</sup>, Laura E. MacConaill<sup>6</sup>, Neal Lindeman<sup>6</sup>, Bruce E. Johnson<sup>5</sup>, Barrett J. Rollins<sup>5,7</sup>, Khanh T. Do<sup>5,7</sup>, Brian Beardslee<sup>5</sup>, Geoffrey Shapiro<sup>5,7</sup>, Suzanne Hector-Barry<sup>2</sup>, John Methot<sup>8</sup>, Lynette Sholl<sup>6</sup>, James Lindsay<sup>9</sup>, Michael J. Hassett<sup>6</sup> and Ethan Cerami<sup>1</sup>



Article

# Evaluating eligibility criteria of oncology trials using real-world data and AI

<https://doi.org/10.1038/s41586-021-03430-5>

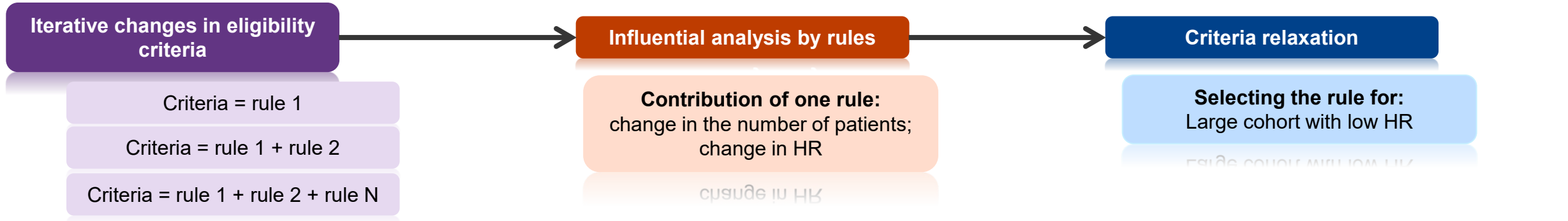
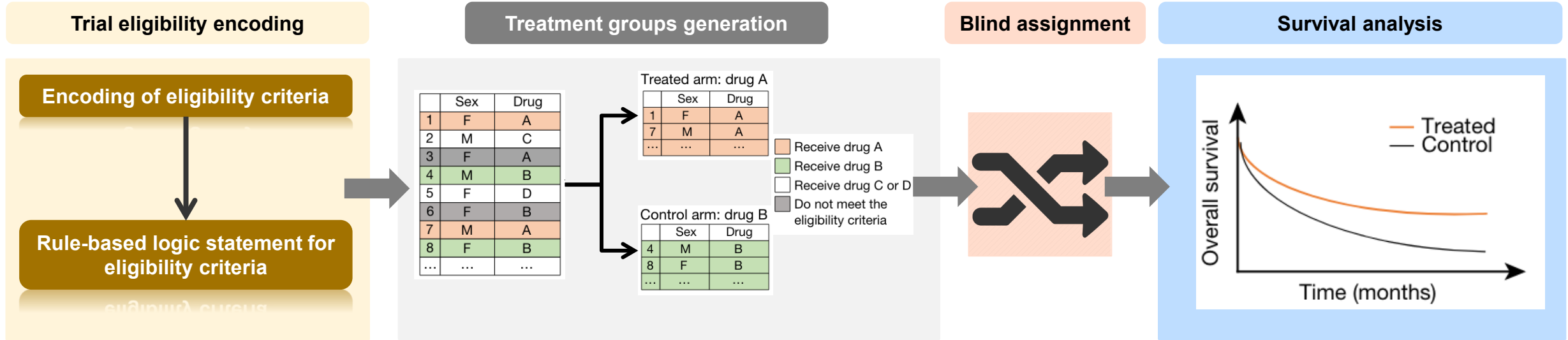
Received: 24 August 2020

Ruishan Liu<sup>1</sup>, Shemra Rizzo<sup>2</sup>, Samuel Whipple<sup>2</sup>, Navdeep Pal<sup>2</sup>, Arturo Lopez Pineda<sup>2</sup>,  
Michael Lu<sup>2</sup>, Brandon Arnieri<sup>2</sup>, Ying Lu<sup>3</sup>, William Capra<sup>2</sup>, Ryan Copping<sup>2</sup>✉ & James Zou<sup>1,3,4,5</sup>✉

*To systematically evaluate the effect of different eligibility criteria on cancer trial populations and outcomes with real-world data using the computational framework of Trial Pathfinder*

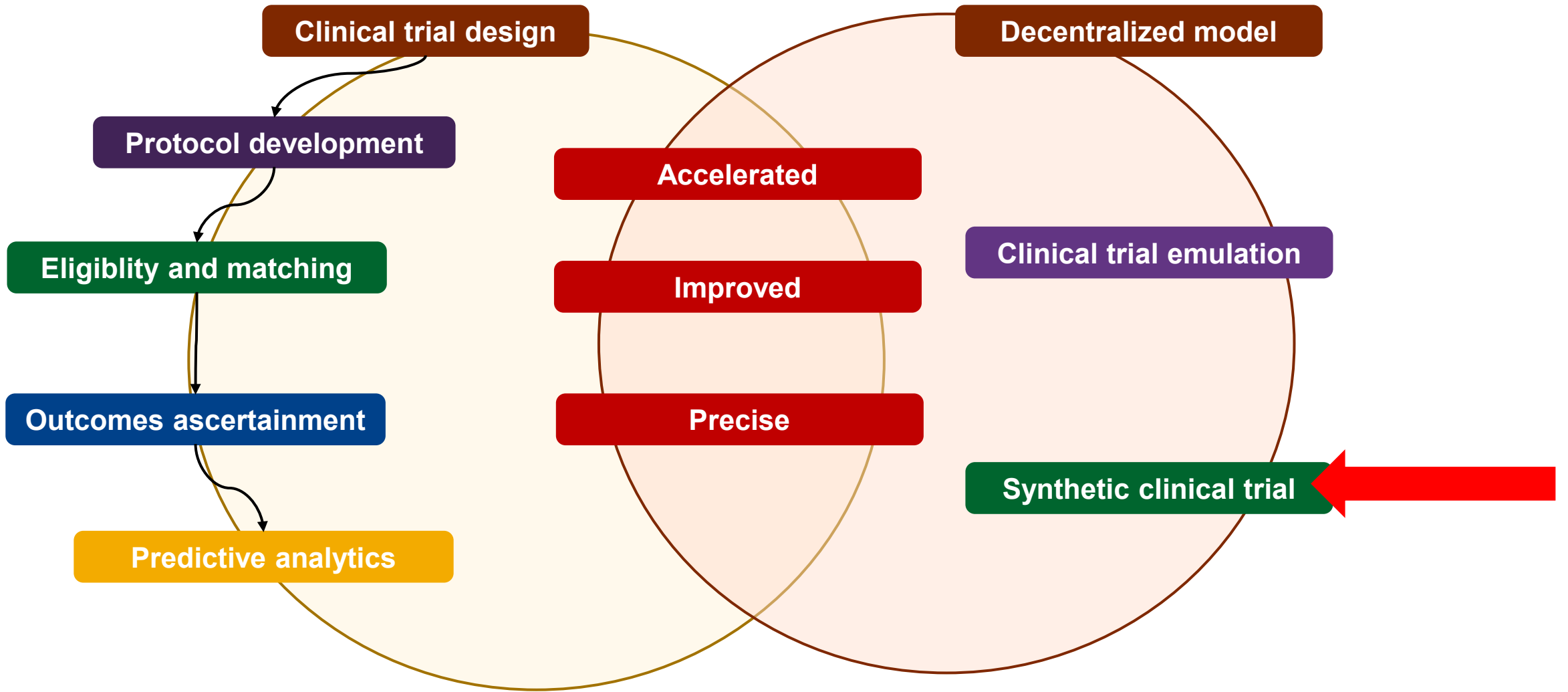
# Clinical trial emulation

- Computational framework of Trial Pathfinder**



Upon broadening the restrictive criteria:

- The pool of eligible patients **more than doubled** on average
- The hazard ratio of the overall survival **decreased** by an average of 0.05





Article | [Open access](#) | Published: 20 March 2024

## Mimicking clinical trials with synthetic acute myeloid leukemia patients using generative artificial intelligence

[Jan-Niklas Eckardt](#) , [Waldemar Hahn](#), [Christoph Röllig](#), [Sebastian Stasik](#), [Uwe Platzbecker](#), [Carsten Müller-Tidow](#), [Hubert Serve](#), [Claudia D. Baldus](#), [Christoph Schliemann](#), [Kerstin Schäfer-Eckart](#), [Maher Hanoun](#), [Martin Kaufmann](#), [Andreas Burchert](#), [Christian Thiede](#), [Johannes Schetelig](#), [Martin Sedlmayr](#), [Martin Bornhäuser](#), [Markus Wolfien](#) & [Jan Moritz Middeke](#)

[npj Digital Medicine](#) **7**, Article number: 76 (2024) | [Cite this article](#)

*To investigate how closely the synthetic data generated by generative artificial intelligence models resembles the real trial data aligning baseline characteristics and patient outcome*

# Clinical trial emulation with Synthetic data

Two state of the art generative models were used:

- **CTAB-GAN+** → builds upon the Generative Adversarial Network (GAN) architecture, consisting of two interlinked neural networks – the generator and the discriminator
- **Normalizing Flows (NFlow)** → comprises a sequence of invertible transformations, starting from a simple base distribution.

## Mimicking clinical trials with synthetic acute myeloid leukemia patients using generative artificial intelligence

Jan-Niklas Eckardt<sup>1</sup>, Waldemar Hahn, Christoph Röhlig, Sebastian Stasik, Uwe Platzbecker, Carsten Müller-Tidow, Hubert Serve, Claudia D. Baldus, Christoph Schliemann, Kerstin Schäfer-Eckart, Maher Hanoun, Martin Kaufmann, Andreas Burchert, Christian Thiede, Johannes Schetelig, Martin Sedlmayr, Martin Bornhäuser, Markus Wolfen & Jan Moritz Middeke

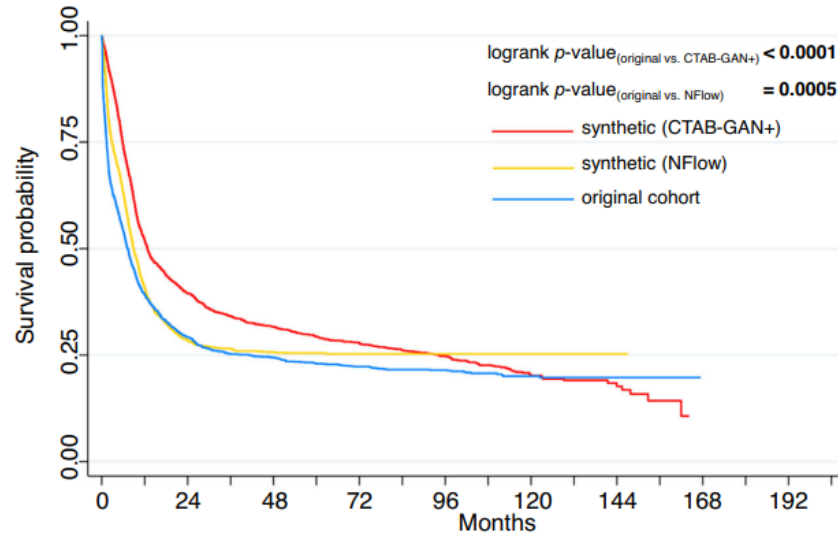
*npj Digital Medicine* 7, Article number: 76 (2024) | [Cite this article](#)

### Large language models for synthetic trial data?

Synthetic clinical data

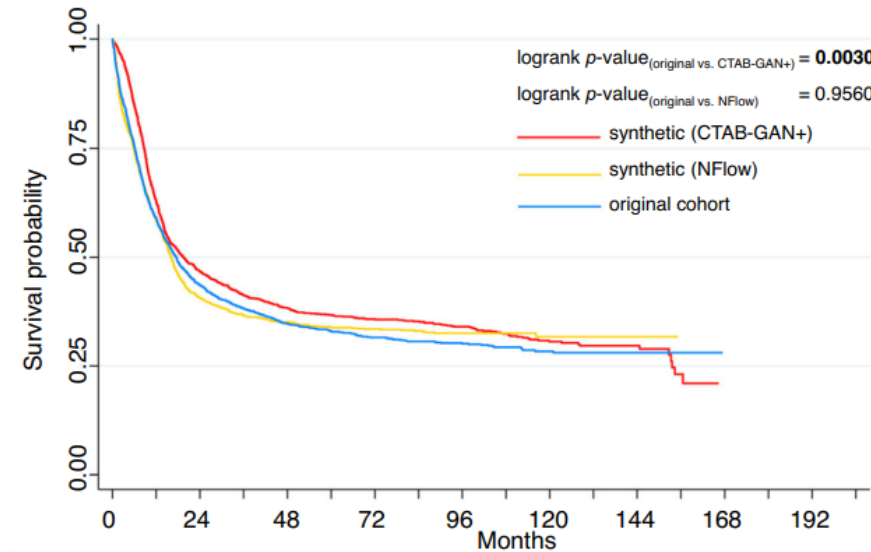
Synthetic control arms

Event-free survival



Numbers at risk								
	0	24	48	72	96	120	144	168
real	1606	454	292	238	161	68	27	0
CTAB+	1606	590	407	313	210	97	23	0
NFlow	1606	418	315	227	84	20	1	0

Overall survival



Numbers at risk								
	0	24	48	72	96	120	144	168
real	1606	671	398	324	217	96	30	0
CTAB+	1606	699	467	364	257	128	41	0
NFlow	1606	590	407	285	116	34	4	0

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# QUESTIONS & ANSWERS

