Leveraging AI to Advance Clinical Trial Innovation: Our approach (from your friends at the NCI)

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Clinical Director, National Cancer Institute

NIH NATIONAL CANCER INSTITUTE

A Globalizing Clinical Trials Landscape

Image generated using ChatGPT

Global Expansion of Clinical Trials Calls for Greater Operational Efficiency

Startup Timelines

Longer site activation driven by administrative processes

Documentation Burden

High volume of required materials across approvals and sites

Language & Accessibility

Multilingual, patient-accessible content complexity

- Operational efficiency is becoming an increasingly important factor for trials
- Operational processes must scale with global clinical trial activity
- Documentation and language requirements add operational complexity

ARTI Initiative: AI for Research & Translational Informatics

Umit Topaloglu

Center for Biomedical Informatics and Information Technology (CBIIT)

Branch Chief: Clinical & Translational Informatics Branch

Tanna Nelson

Center for Biomedical Informatics and Information Technology (CBIIT)

Federal Lead

ARTI Program management

Clinical Informaticist

Prototype development

James Gulley

Co-Director, Center for Immuno-Oncology, CCR, NCI

& Clinical Director, National Cancer Institute

Clinical lead

NCI project champion & stakeholder connector

Kai-Ling Chen

Computer Scientist

Project management

Technical liaison

Operational design & execution

Brian Park

Contracting Engineer

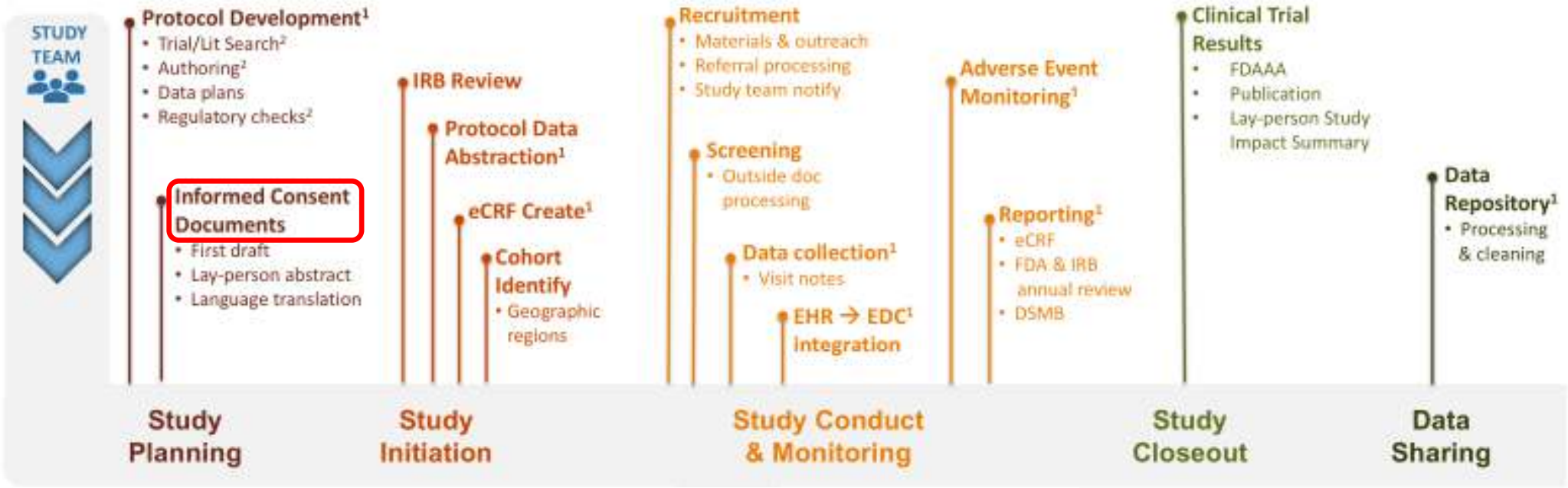
Computer scientist

Technical lead

Prototype development

Operational design & execution

AI Opportunities Within the Clinical Trials Ecosystem



LEGEND:
[1]Items involving CDEs
[2]Collaboration with CRISPI


SYSTEM SAFETY & EFFICACY
• Protecting from unsafe or ineffective systems.
Automated Check-in-progress
1
PRIVACY-BY-DESIGN SAFEGUARDS
• Safeguarding privacy: are hardwired into the design.
4
TASK-CALIBRATED DESIGN
2
OUR AI DESIGN PRINCIPLES: SIX CORE COMMITMENTS
Building Trust, Equity, and Control into Artificial Intelligence
CLEAR & PLAIN-LANGUAGE DECLARATIONS
5
EQUITABLE & FAIR DESIGN
3
Bias Filter
6
AI
OPT-OUT ABILITY & HUMAN ALTERNATIVES
AI PATH
HUMAN ALTERNATIVE
COMMITMENT TO ETHICAL & TRANSPARENT AI
OUR COMMITMENT: Building Trust & Safety into Every AI Interaction.

Consent Generation
&
Plain Language Research Summary

The Case for Change: AI-Assisted Informed Consent Generation

- Informed consent is the ethical and regulatory foundation of human subjects research

Comprehension	Respect/ Autonomy	Accessibility	Trust	Efficiency
				

AI-Solution Built for Compliance: Safety & Quality Safeguards

Incorporates safeguards to support compliance & patient-centered approaches

Required Language Preserved

NIH legal & regulatory language carried forward exactly as written

IRB Consent Library Integrated

Procedure descriptions & risk language drawn from NIH consent library when possible

Readability Standards Met

Meet Federal Plain Language guidelines

Cover Page Sets Use Expectation

First draft only – human review and refinement required

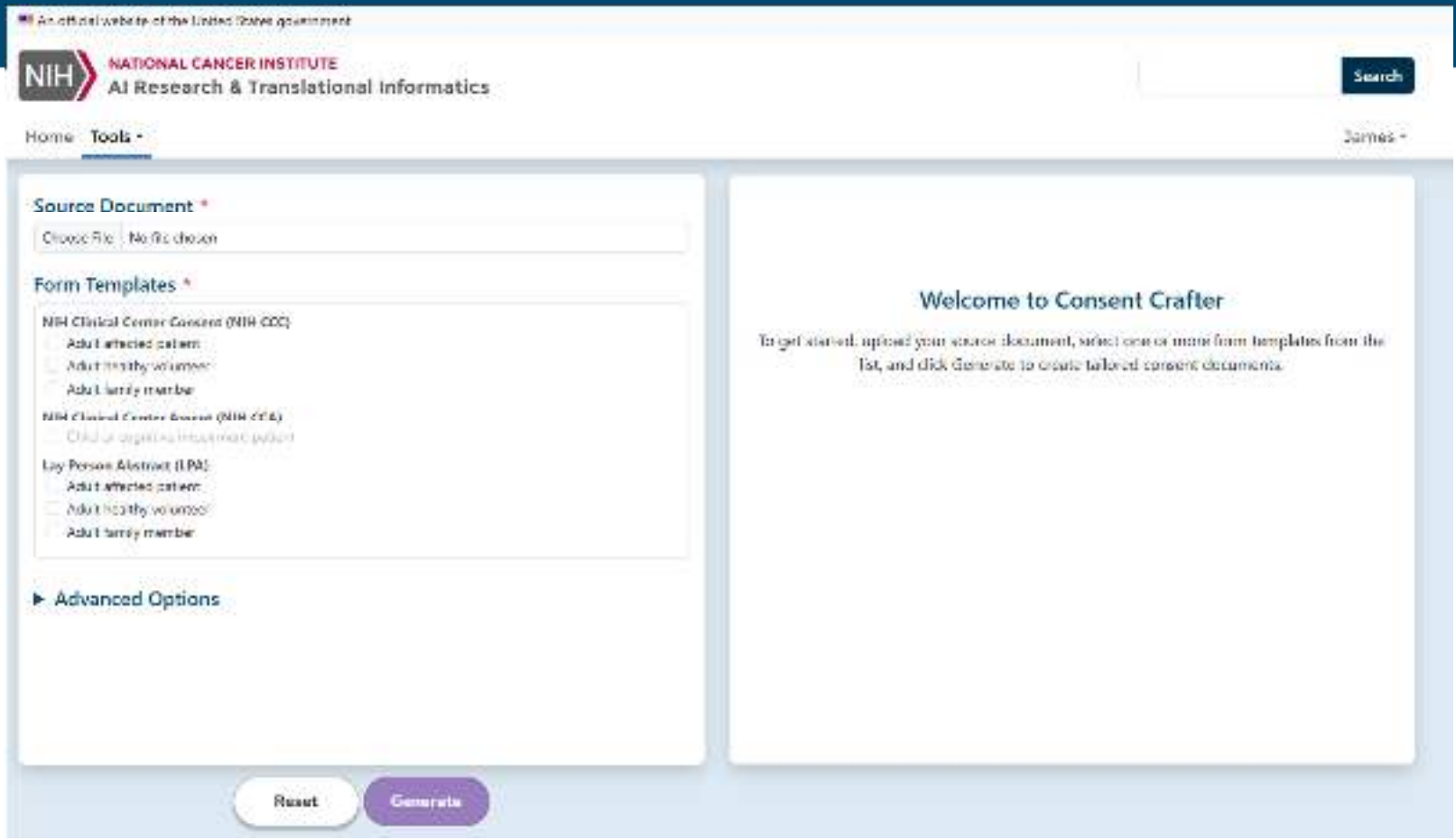
Inline Comments Provide Guidance

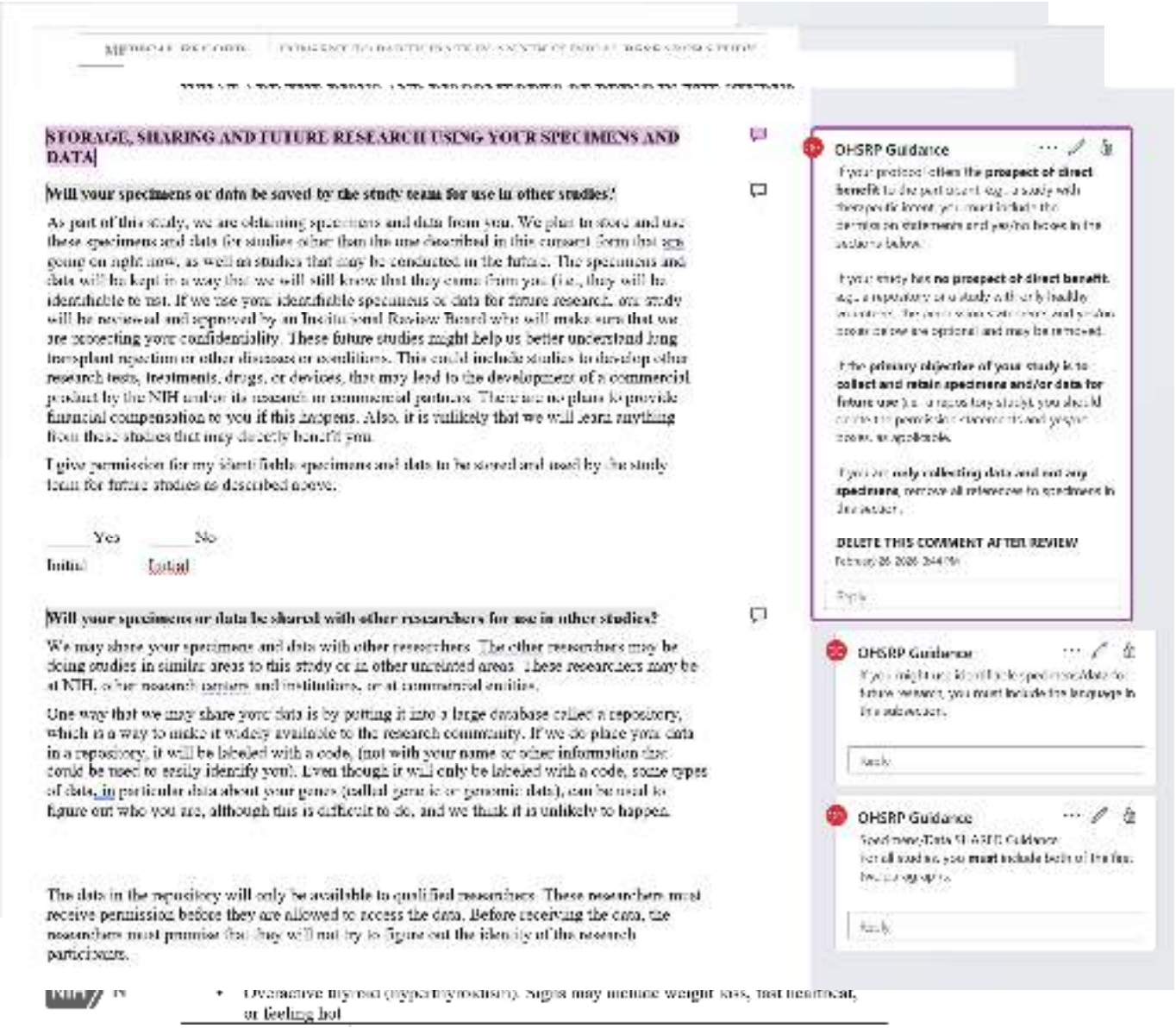
Highlights decision points for study teams

Investigator-Editable Output

Editable Word document where study teams can take ownership before IRB submission

Consent Crafter





Consent Form Draft

- Ready for human review & refinement
- Headers and footers preserved
- All required information included
- 8th grade reading level
- OHSRP Guidance in comments
- Consent Library integration
- Study drug risks
- Highlight areas where decisions must be made

Please note: This is a first draft and will require modification

Protocol

Abbreviated Title: Atezolizumab Dosing
Version Date: 12/07/2020

Abbreviated Title: Atezolizumab Dosing
NIH Protocol #: IRB001559
CTEP Formulary #: FOR0016
Version Date: 12/07/2020
NCT Number: NCT00606138

Title: A Feasibility Multicenter Phase I Study of Therapeutic Drug Monitoring-Based Atezolizumab Dosing

Protocol Chair/
NCI Principal Investigator: James Gulley, MD, PhD
Center for Immuno-Oncology (CIO)
Center for Cancer Research (CCR)
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Bethesda, MD 20892
Phone: 301-480-0570
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Drug Name:	Atezolizumab (NSC 781608)	Atezolizumab PK assay
IND Number:	106513	Non-significant risk (NSR) device
Sponsor:	CCR	
Manufacturer:	Genentech F Hoffmann-La Roche	NCI Clinical Pharmacology Program (CPP)
Supplier:	Cancer Therapy Evaluation Program (CTEP), NCI	NCI CPP

Safety Monitoring Committee (SMC): NCI OSRO
Coordinating Center: CIO, CCR, NCI

1

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One page
4th grade
reading level

Ready for
human
review &
refinement

Lay-Person Summary

Project Title: Testing a Better Way to Give Cancer Drug Atezolizumab (NCT00606138)
Principal Investigators: Dr. James Gulley
Institute/Center: National Cancer Institute

What is the goal of this study?

This study tests if we can give a cancer drug in a new way. We want to see if we can use less drug but still fight cancer well.

Who can be in this study?

People who:
- are 18 years old or older
- have cancer that has spread
- can do daily tasks with little help
- have good enough organ function

What will happen during this study?

You will:
- get the cancer drug through a vein
- have blood drawn before each dose
- have scans every 12 weeks
- may have an optional tumor biopsy

How long will I be in this study?

- You will get treatment for up to 2 years.
- You will come to the clinic every 2 to 6 weeks for your drug, then every 3 months after 18 weeks.

What are some risks of this study?

You might:
- feel tired or weak
- get infections
- have nausea, vomiting, or diarrhea
- have pain or bruising from blood draws
- be exposed to radiation from scans

What are the benefits of this study?

For you: The drug may shrink your tumor or help with your cancer symptoms.

For others: This study may help us find better ways to give this drug to other people with cancer.

Do I have to be in this study?

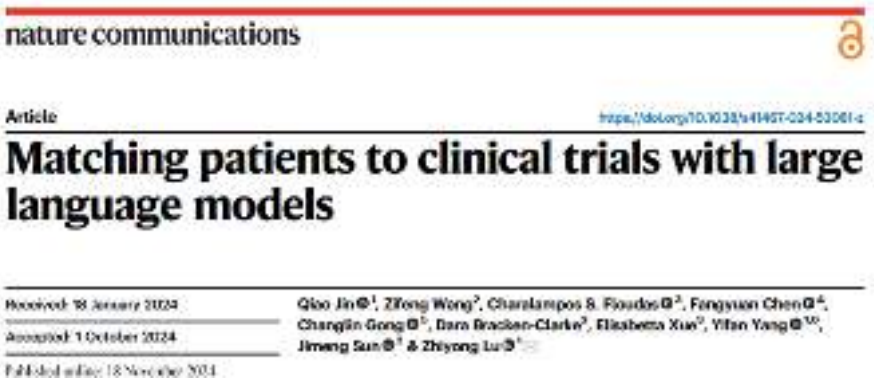
- **Your taking part in the study is voluntary.**
- **Withdrawal:** You can stop taking part at any time if you change your mind.
- **Alternatives:** You could get the standard cancer treatment your doctor suggests instead of joining this study.

Will I be paid or have costs in this study?

You will not be paid for this study, and costs depend on your local study site.

Please review more details on the next pages.

If you have questions or want to join the study, contact Dr. James Gulley.
Email: gulleyj@mail.nih.gov | Phone: 301-480-0570



nature communications

Article

Matching patients to clinical trials with large language models

Qiao Jin, Zifeng Wang, Charalampos S. Floudas, Fangyuan Chen, Changlin Gong, Dara Bracken-Clarke, Elisabetta Xue, Yifan Yang, Jimeng Sun & Zhiyong Lu

Input

(Participant information **x** Trials catalog & Eligibility criteria)

Algorithm

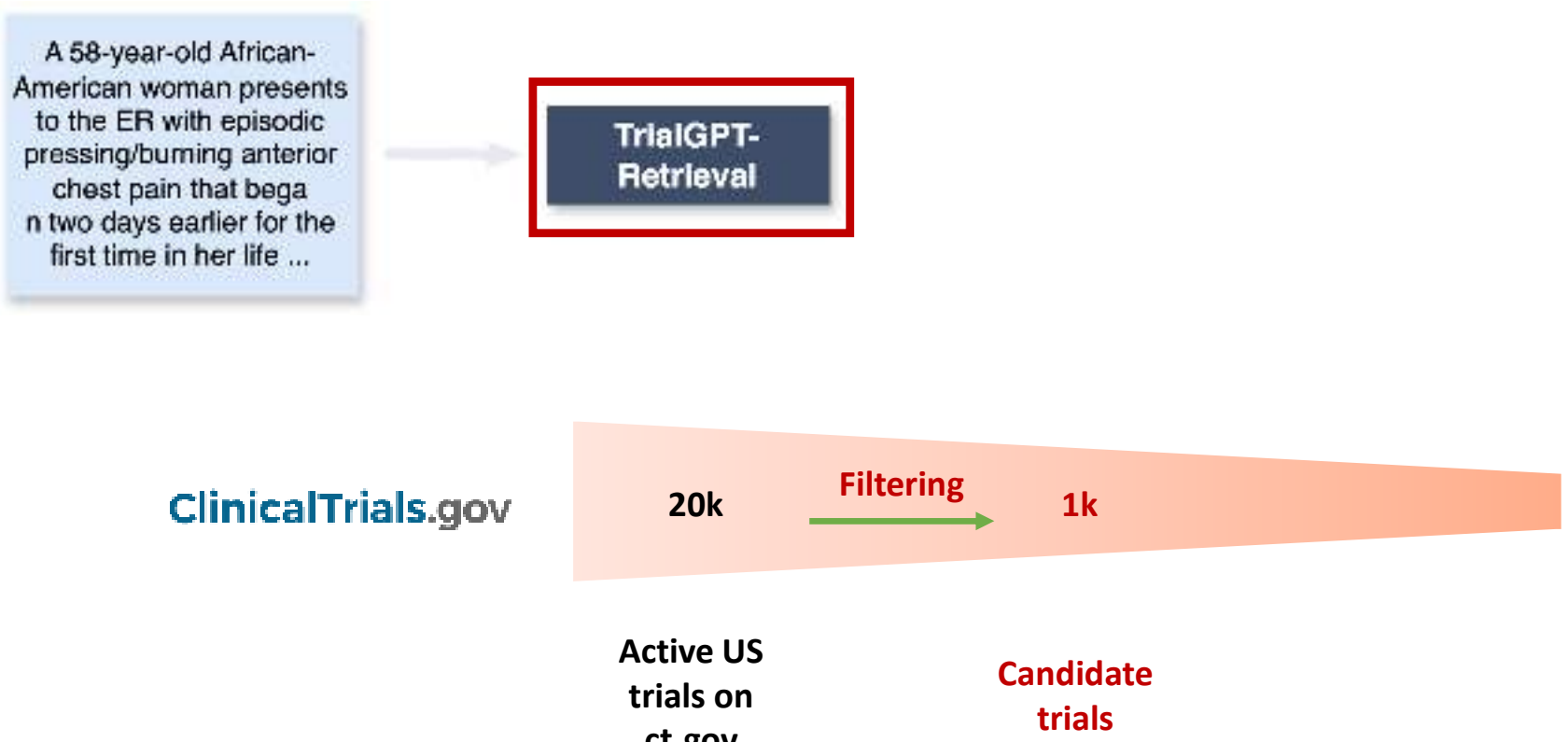
Output

Relevant trials

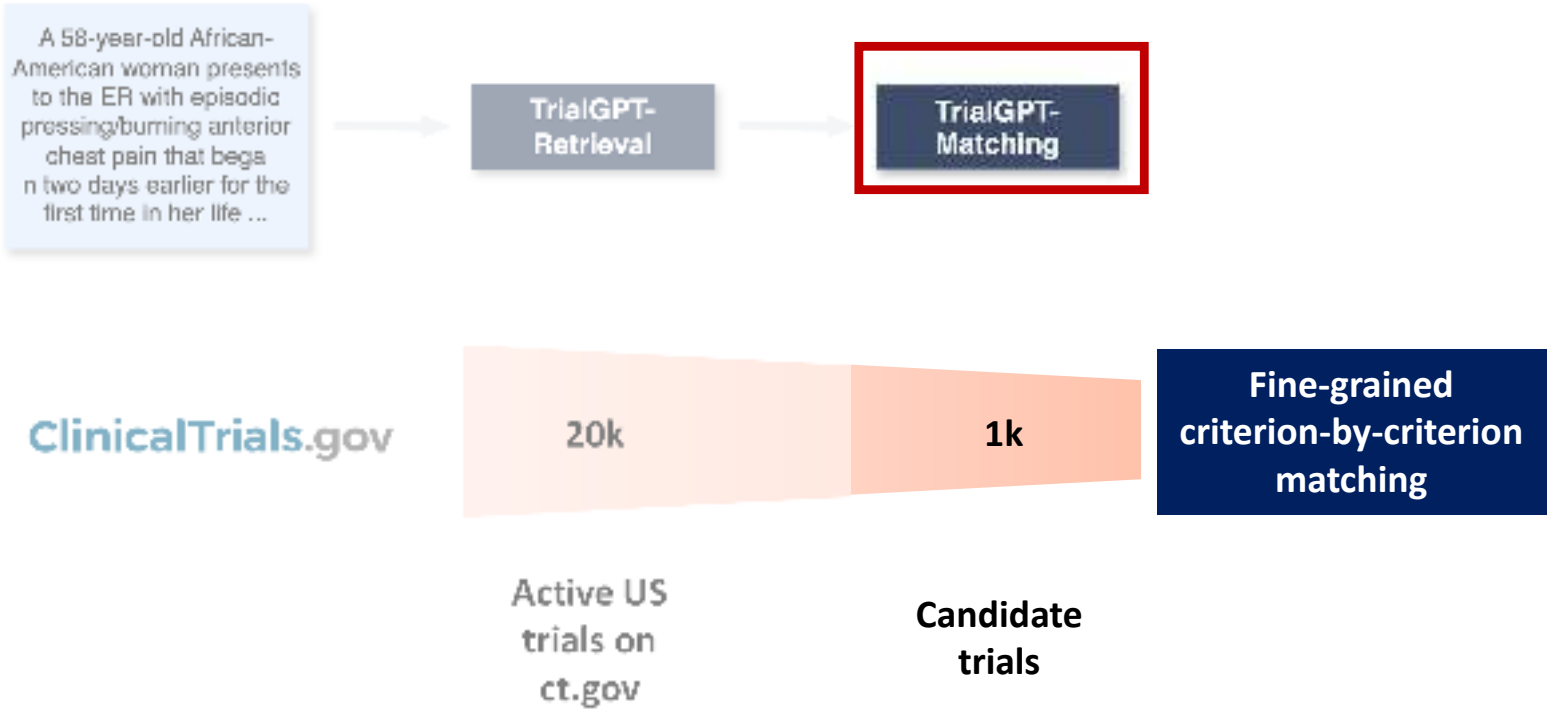
↓

Eligibility assessment

Step 1: Retrieval



Step 2: Matching

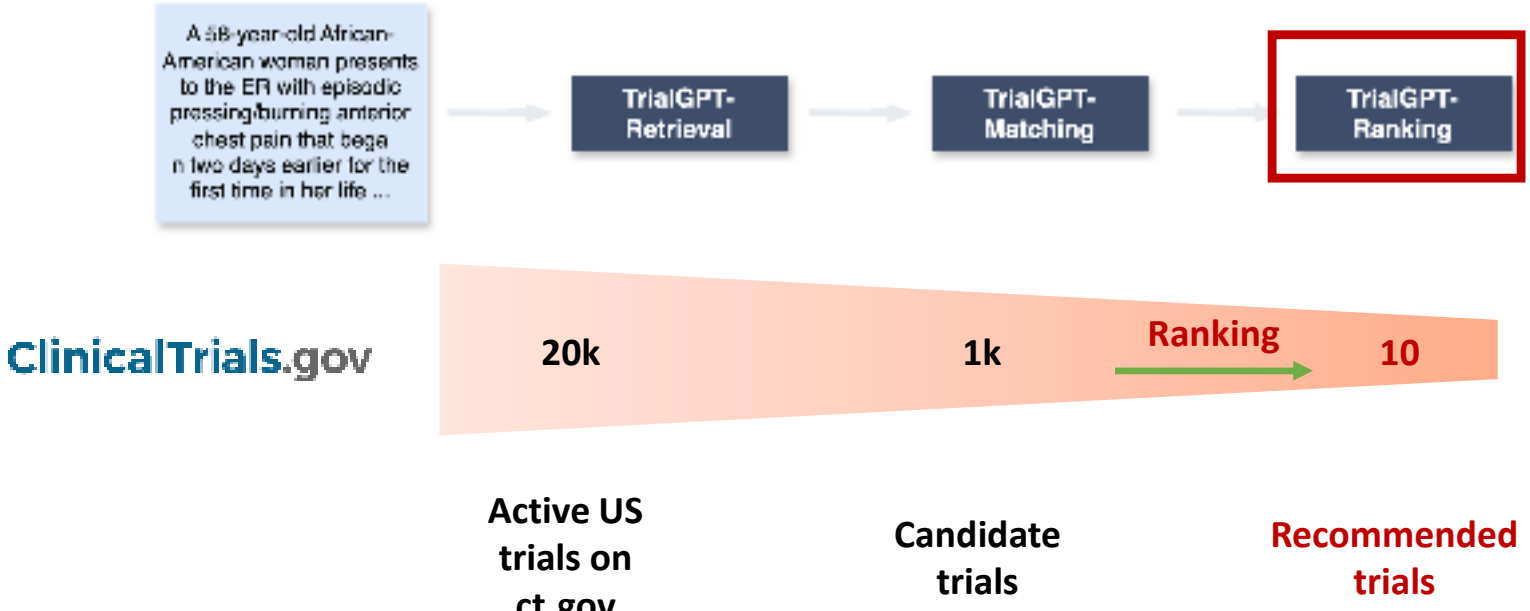


Matching example

Inclusion Criteria	Explanation	Evident Sentence IDs	Eligibility
Age >= 18 years	The patient is 53 years old, which is greater than 18 years.	0	included
Prior or suspected diagnosis of malignancy	The patient has a prior diagnosis of metastatic HR+ HER2+ breast cancer.	0	included
Brain metastases visible on contrasted magnetic resonance imaging (MRI) brain	The patient has brain metastases visible on MRI, as indicated by the increase in leptomeningeal enhancement.	5	included
Eastern Cooperative Oncology Group (ECOG) performance status =< 2 (Karnofsky >= 60%)	The patient's ECOG performance status is currently 1, which is less than or equal to 2.	7	included

TrialGPT-Matching Output

Step 3: Ranking

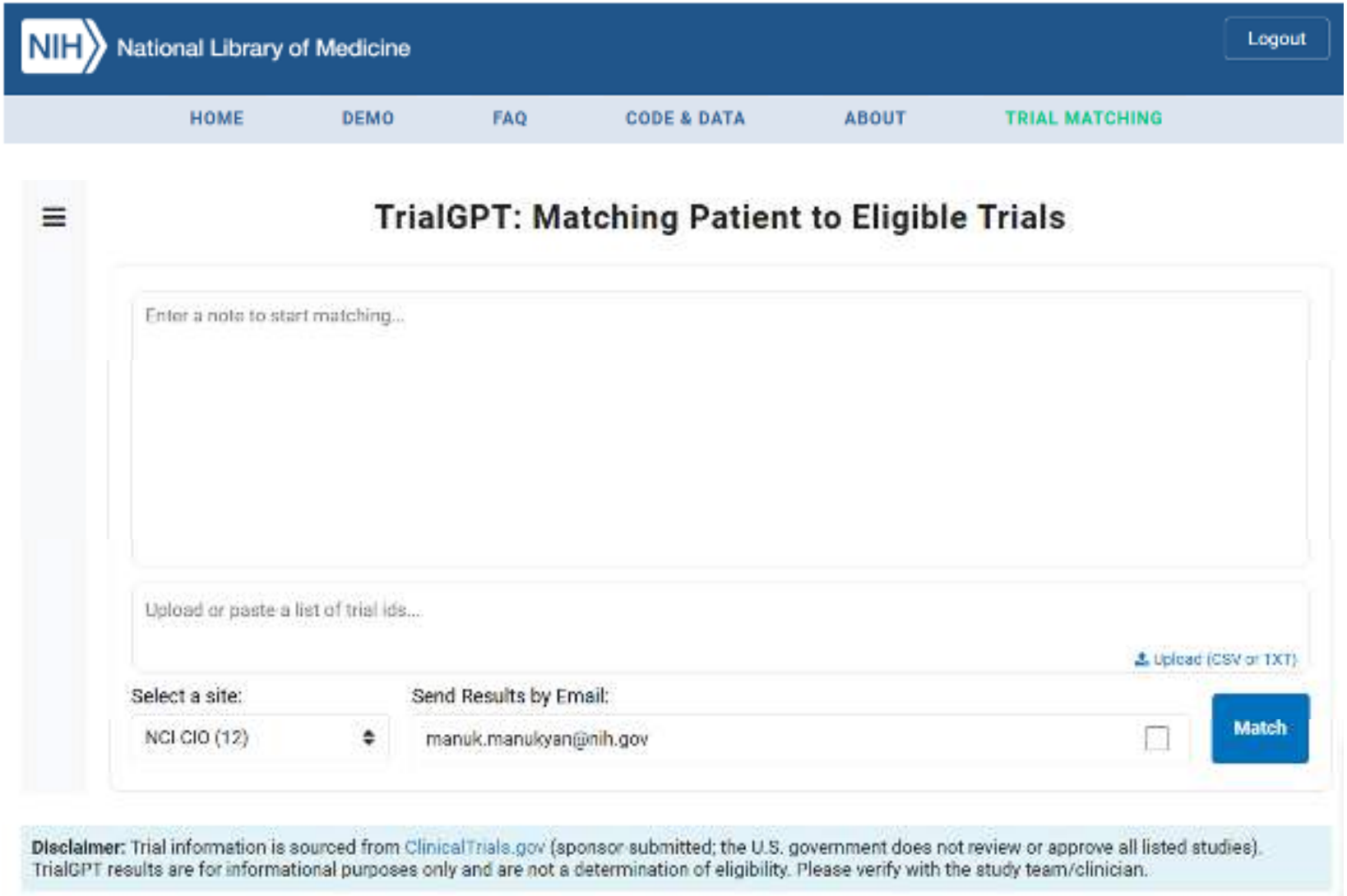


Ranking example

Patient ID: 1

Trial ID	Clinical Trial Title	Score	Summary
NCT06324357	Beamion BCGC-1: A Study to Find a Suitable Dose of Zongertinib in Combination With Trastuzumab Deruxtecan or With Trastuzumab Emtansine and to Test Whether it Helps People With Different Types of HER2+ Cancer That Has Spread	85	The patient meets the main diagnosis criterion and several key inclusion criteria, with no exclusion criteria met.
NCT03321045	Positron Emission Tomography (PET) Imaging With Zirconium 89 (89Zr) Trastuzumab for Prediction of HER2 Targeted Therapy Effectiveness	85	The patient meets the main diagnosis criterion and most of the inclusion criteria, with no exclusion criteria mentioned.
NCT04419532	A Phase 1, First In Human Study of DS-1055a in Subjects With Relapsed or Refractory Locally Advanced or Metastatic Solid Tumors	85	The patient meets the main diagnosis criterion and several other key inclusion criteria, but there is insufficient information on organ function and ability to provide informed consent.

Trial-level Score by TrialGPT-Ranking


NIH
National Library of Medicine
Logout
HOME
DEMO
FAQ
CODE & DATA
ABOUT
TRIAL MATCHING
TrialGPT: Matching Patient to Eligible Trials
Enter a note to start matching...
Upload or paste a list of trial ids...
Upload (CSV or TXT)
Select a site:
NCI CIO (12)
Send Results by Email:
manuk.manukyan@nih.gov
Match
Disclaimer: Trial information is sourced from ClinicalTrials.gov (sponsor submitted; the U.S. government does not review or approve all listed studies). TrialGPT results are for informational purposes only and are not a determination of eligibility. Please verify with the study team/clinician.


Manual Protocol Life Cycle Takes 12 Months to Open
1 Month
1 Month
2 Month
3 Month
6 Month
9 Month
12 Months
1 Scientific Review
2 Regulatory Review
3 Final Steps
4 Enrollment
1 Month
12 Months

Questions?