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Driving value in Clinical Trial Transparency publications

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Agenda

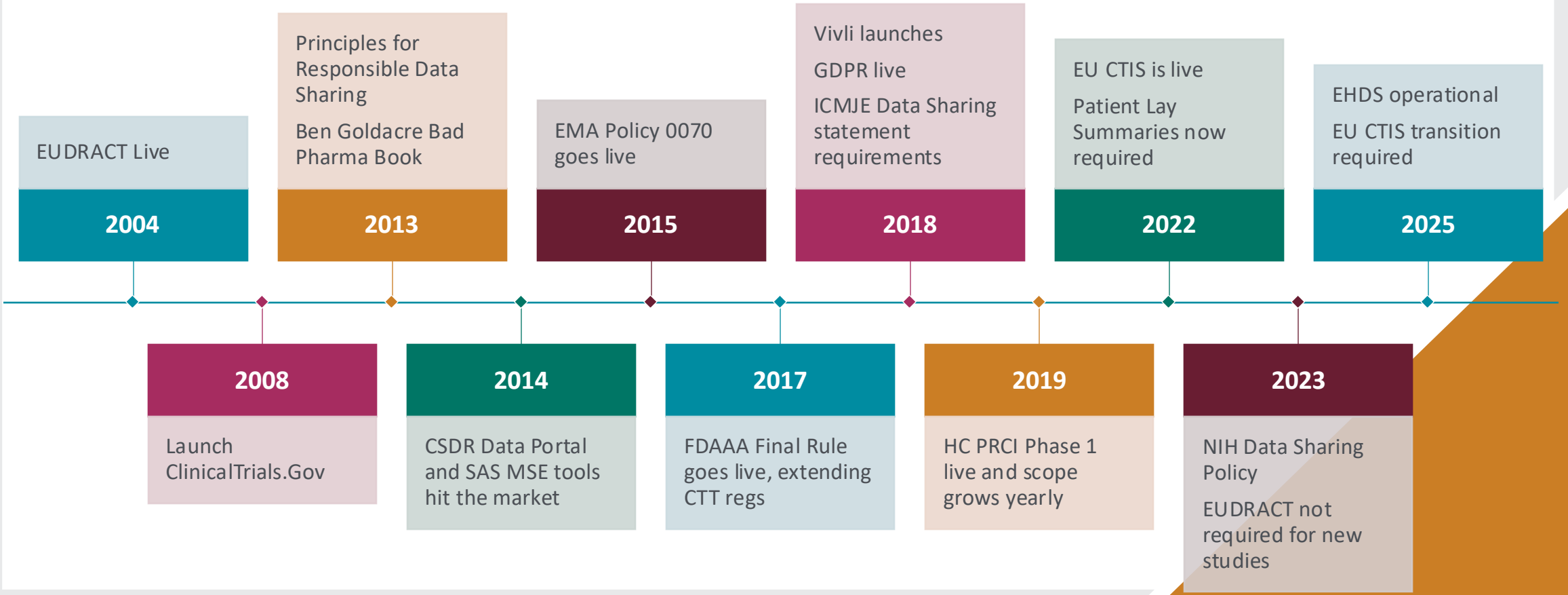
The Value and Cost of Clinical Trial Transparency.

Considering Anonymization beyond the technical controls when sharing Individual patient level data.

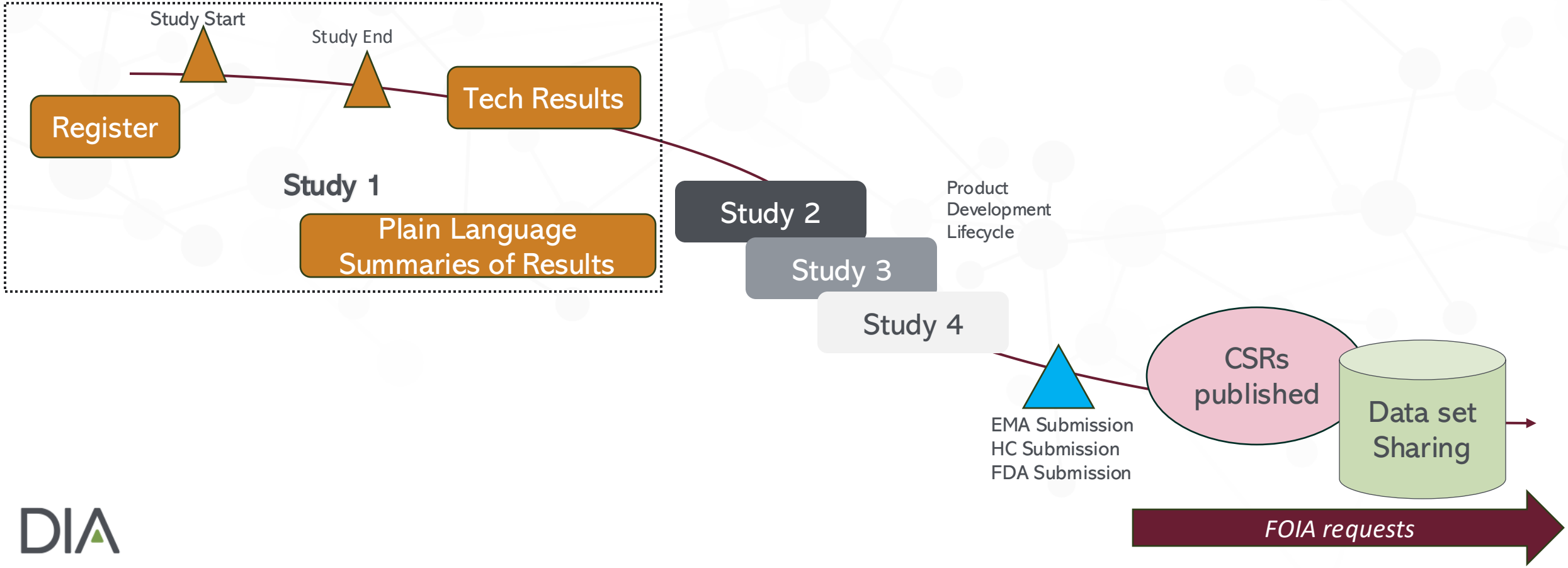
The human perspective of clinical trial transparency and privacy.

Clinical Trial Transparency Value Today.

Clinical Trial Transparency Regulations, Policies, and best practices have multiplied over the last decade



The Clinical Trial Transparency regulations and best practices include many public disclosure points.



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The number of disclosure channels to meet regulations and best practices continues to grow.

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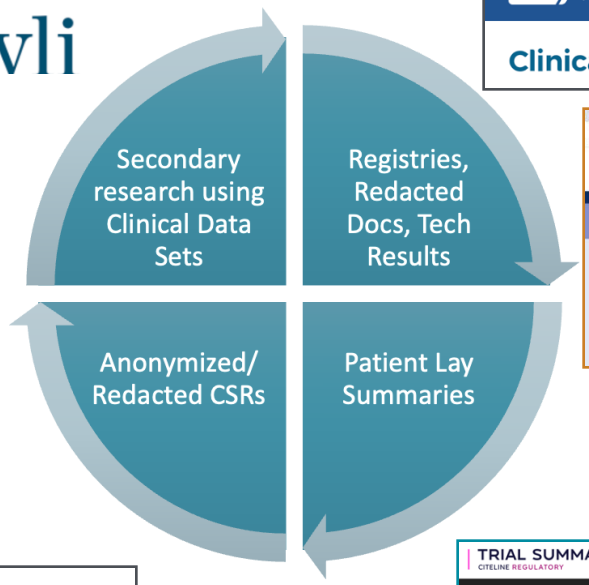
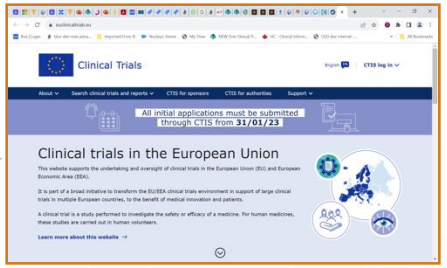
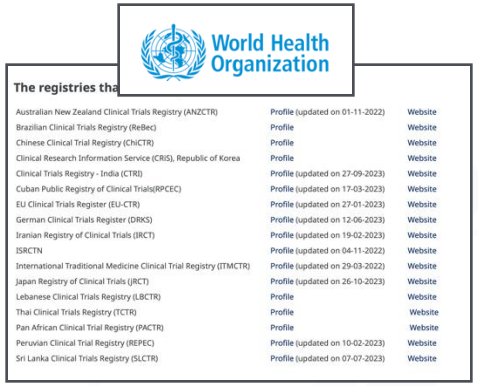
Clinical Study Data Request







…. How much of this is generating value for public health?

What is the value of Clinical Trial Transparency?

RESEARCH ACCESS: Ensure access and dissemination to clinical research globally.

ENHANCE PUBLIC HEALTH OUTCOMES: Transparency demonstrates a commitment to science and the health of the public, reducing repeat research and enabling more research findings.

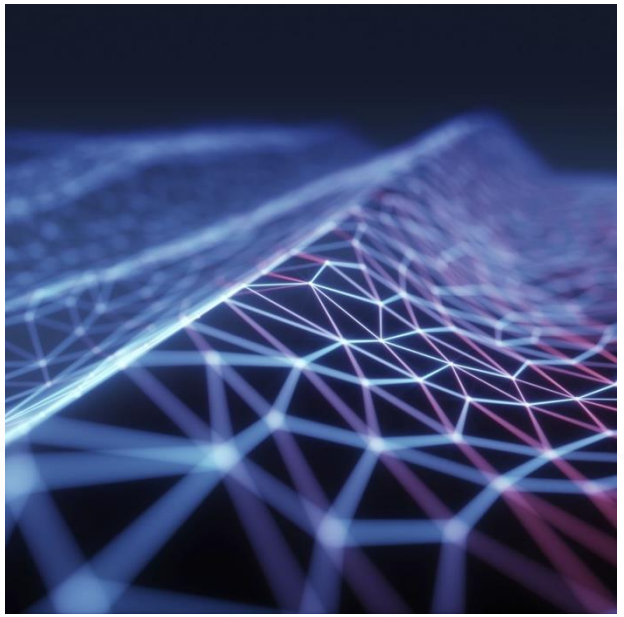
PATIENT CENTRICITY: Safe data sharing respects the patients' valuable contribution to science by enabling the data gathered for a single study to be reused to supports additional research.

JOURNAL PUBLICATIONS: Data sharing or data access is increasingly required to publish in high profile scientific journals.

FOSTER TRUST: Surveys report that the Pharmaceutical industry is trusted less then tobacco companies. Transparency enhances trust in clinical research and the medicines available to patients.

SUPPORT EQUITY: Through transparency sponsors demonstrate they engage diverse groups and evaluate treatment across diverse populations.

REDUCE WASTE: Eliminate the need to re-run the same trials saves money and allows focus on answer subsequent research questions.



I asked a group of Transparency Professions @CTT DIA 2024…

What is the value of transparency?

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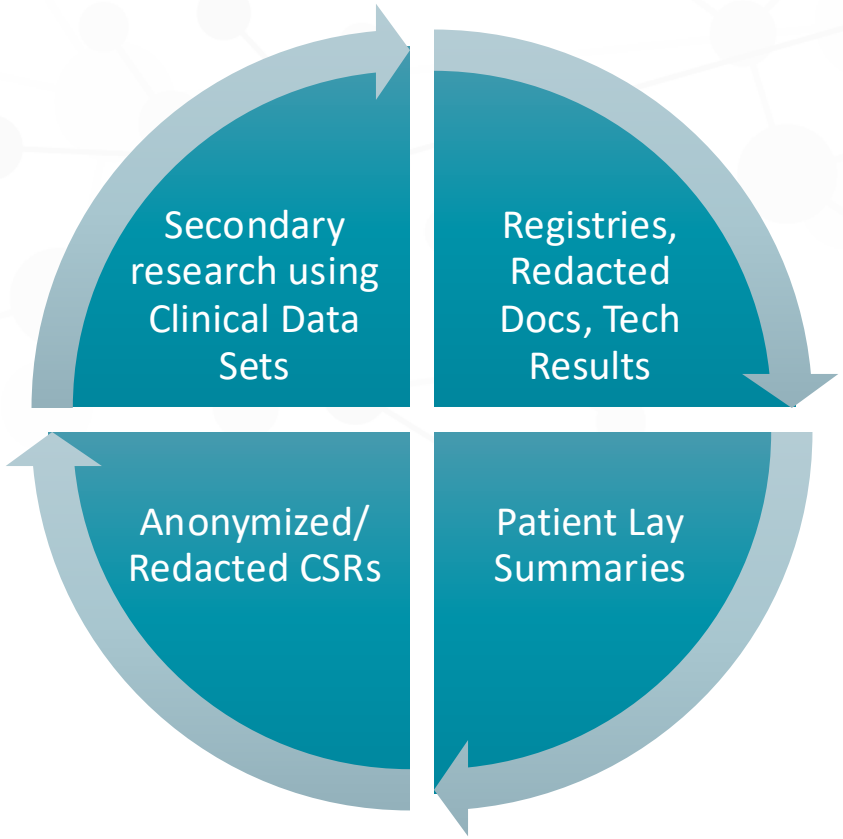
Then I asked the same group of experts…..

What is the cost of clinical trial transparency?

Which Transparency Disclosures cost the most?



Ask your Transparency Team.
They will tell you.

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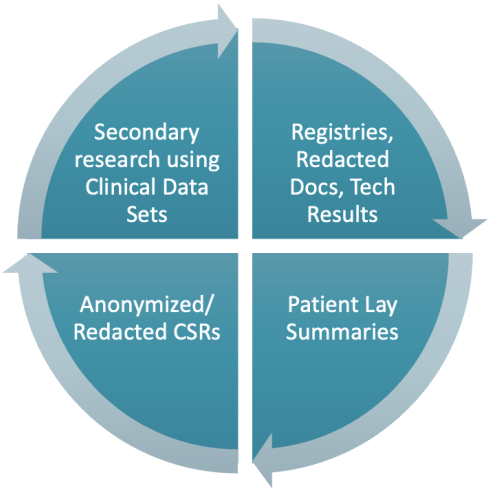
Be Purposeful with your policies and processes!



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The Value and Cost of Clinical Trial Transparency.

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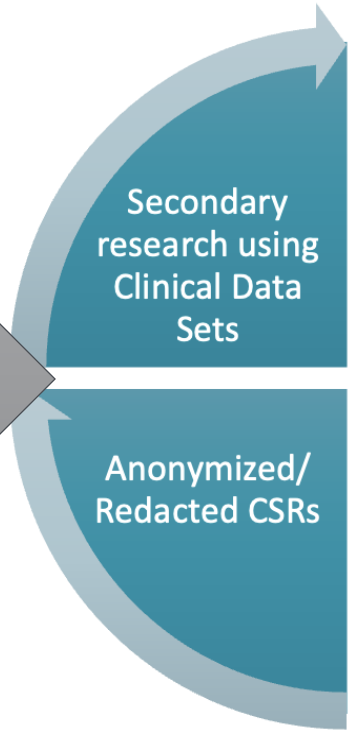
Clinical Trial Transparency Value Today.

To share data or documents, sponsors must first anonymize them.



Anonymization is contextual. It is more then how you transform data.

Contractual Controls

- Are users named?
- Are users legally liable to protect privacy?
- Are users held accountable with legal consequence?
- How long do they have access to the data?

Security controls

- Environment secure, monitored, etc.?
- Can data be combined with other data?
- Are users traceable?

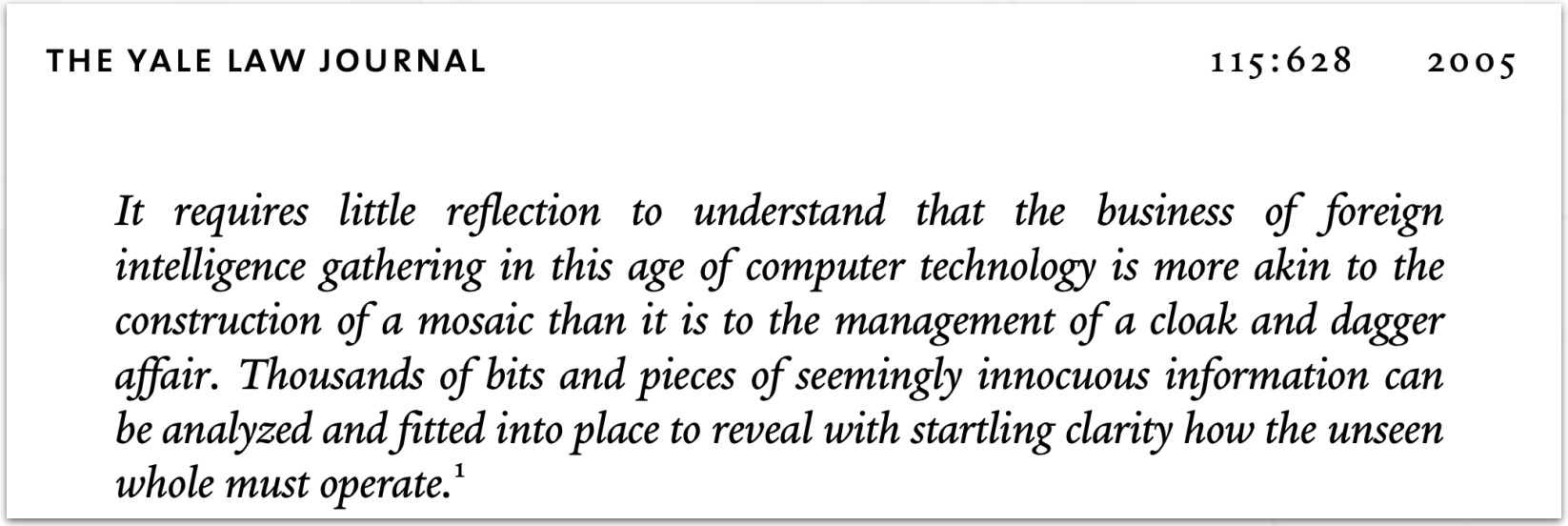
Technical Controls

- How is the data Anonymized?
- Measured risk or not?
- Is all data accounted for in the risk measurement such as adverse events and medical history?

Which controls are stronger when Sponsor Clinical Trial Documents are published on the portal?

”The Mosaic Theory”

“The “mosaic theory” describes a basic precept of intelligence gathering: Disparate items of information, though individually of limited or no utility to their possessor, can take on added significance when combined with other items of information. Combining the items illuminates their interrelationships and breeds analytic synergies, so that the resulting mosaic of information is worth more than the sum of its parts. “



THE YALE LAW JOURNAL 115:628 2005

It requires little reflection to understand that the business of foreign intelligence gathering in this age of computer technology is more akin to the construction of a mosaic than it is to the management of a cloak and dagger affair. Thousands of bits and pieces of seemingly innocuous information can be analyzed and fitted into place to reveal with startling clarity how the unseen whole must operate.[1]

Reference: https://www.yalelawjournal.org/pdf/358_fto38tb4.pdf

Technology and Data Access continue to grow at lightening pace

- More and more disclosures of the same patient data in different formats globally
  - CSRs published at multiple data cut offs, scientific publications, clinical trial registries, safety data reporting, etc.
- Patients publishing their own data on social media, not understanding it can be used to match locations and treatments in clinical trial datasets
- Public nonclinical sources, such as news reports and police reports make accessing anything unique or noteworthy easy
- Data marts are growing
  - A data mart is a subject-oriented database containing transactional data (rows and columns), which makes it easy to access, organize, and understand. It contains historical data brought together used to understand trends.
- Large Language Models make combination of data much easier

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The human perspective

Can a real person be identified with “anonymized” or ”de-identified” data?

”Reidentification" refers to the process of taking de-identified personal information and using it to identify an individual.

This can happen by combining the de-identified data with other available information, potentially allowing someone to be recognized even if direct identifiers like names were removed initially.

This can be the result of combining seemingly anonymous data through various methods like cross-referencing with other datasets.

Yes, potentially.

What does the average person have to lose if the public can identify them in their personal health data?

Re-identifying individuals can have adverse impacts on human lives. For example:

If a participant's name or address is matched to research data, their landlord may refuse to renew their lease based on concerns for health and longevity

The information might negatively impact an employment or health insurance decision.

Individuals face invasion of privacy by an acquaintance or stranger.

It depends, but it could be a lot for some.

Is it really that personal?

Consider Patient Narratives in Clinical study reports

A Patient narrative:

- A detailed story of what happened in a clinical study for one real person.
- It includes sensitive details of medical history, medical treatments, and medical outcomes.
- Written for patients with notably unique experiences in a trial – adverse events, deaths, pregnancies, unique outcomes.
- Most challenging to anonymize.

Mocked up example

Participant ID: PPD

Reason for Narrative: Pregnancy

Subject experienced a treatment emergent AE of moderate pain at the site of the injection after receiving the second injection on Day 10. The pain lasted about half an hour. The investigator considered the AE mild and related to the study drug.

Subject experienced another treatment emergent AE of chlamydia on Day 23. The investigator considered this AE to be mild and unrelated to the study drug. The subject was diagnosed as pregnant on Day 23 and the site was notified.

Subject experienced treatment emergent AEs of pelvic pain and vaginal hemorrhage on Day 26. Three hours later, the subject had a treatment emergent AE of threatened abortion. All adverse events experienced on Day 26 were treated and resolved. The investigator considered them not to be study drug related.

The blind was broken on Day 30 due to pregnancy. Subject had been receiving study drug. The decision was made to leave the study and stop any further exposure to the study drug due to pregnancy.

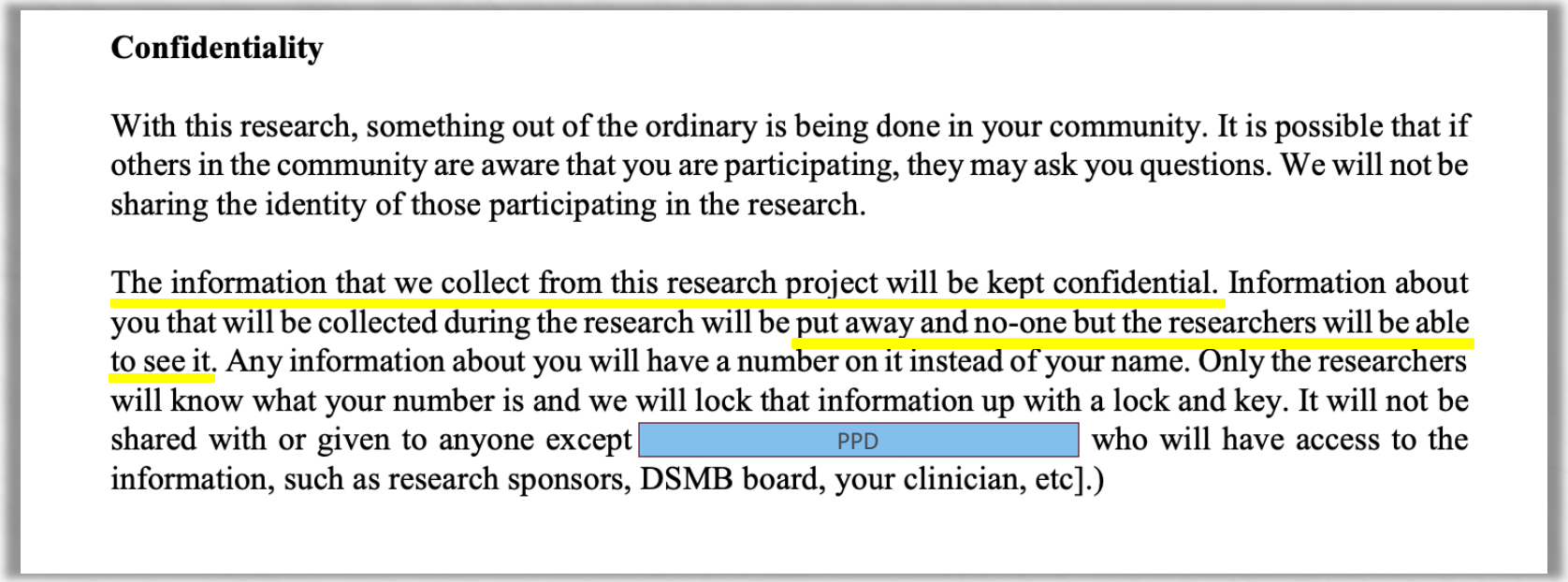
Subject was treated by primary care physician for pregnancy. The pregnancy resulted in a healthy baby PPD on PPD at PPD weeks. The baby had an Apgar score of 7 at minute 1 post-delivery. Baby was born with PPD No further details are available about the baby or mother.

Have we asked patients how they feel about having their medical history, medical treatments and medical outcomes published?

Informed Consent is required for every clinical trial

Sponsors promise patients to protect their privacy when they agree to participate in a clinical trial.

Example:
W.H.O Template
and Clinicaltrials.gov
sample ICF



Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except PPD who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

Patient trust is critical to enable clinical research to continue.

Personal Privacy and Information Access are a balancing act.

HJ Heinz Co of Canada Ltd v. Canada 2006

The Supreme Court of Canada's leading decision on Privacy and Access to Information makes it clear that Privacy is the top priority.

- "It is apparent from the scheme and the legislative histories of the Access Act and the Privacy Act that the combined purpose of the two statutes is to strike a careful balance between privacy rights and the right of access to information. However, within this balanced scheme, **the Acts afford greater protection to personal information.**"
- "in a situation involving personal information about an individual, the right to privacy is paramount over the right of access to information...".[3]
- These statements were made about the interplay between the *Privacy Act* and the *Access to Information Act in the decision document.*
- The same principles should apply to clinical patient data in the *Public Release of Clinical Information*.

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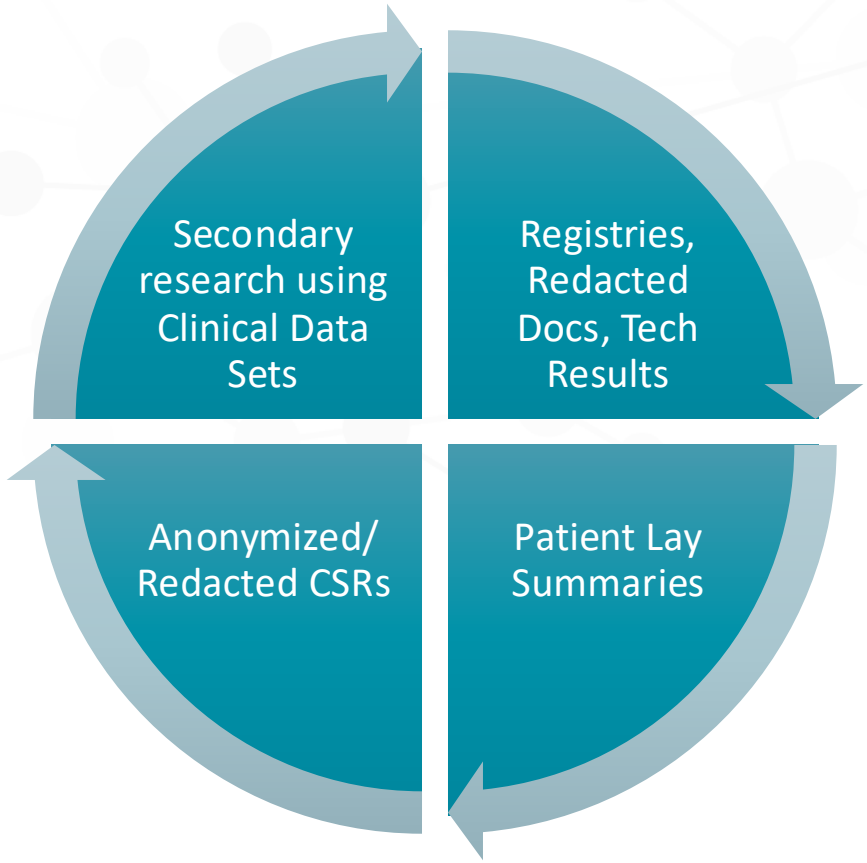
There's a lot of Transparency happening. What is creating the most value for patients and the public?



This is a great discussion topic for policy and strategy.

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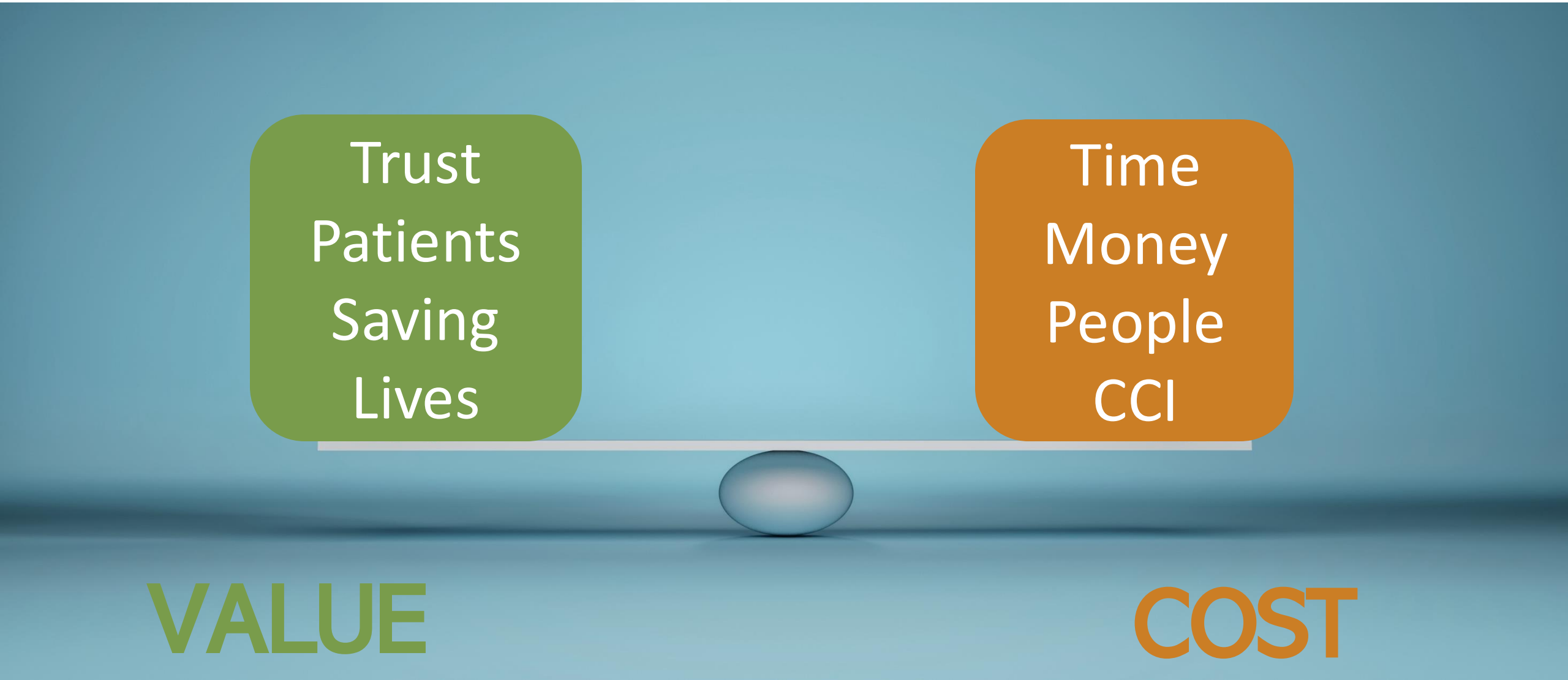
Purposeful Clinical Trial Transparency delivers value to the health care ecosystem and manages costs.



Overview of this study

Why was the research needed?

Researchers are looking for a better way to treat migraine. Before a drug is available for all patients, researchers do clinical studies to find out how it works and how safe it is.

What treatments did the participants receive?

The participants in this study received LY3451838 or a placebo. A placebo looks like a drug but does not have any drug in it.

What were the results of this study?

The main question the researchers wanted to answer in this study was:

- **Did LY3451838 reduce the number of days participants had migraine headaches?**

  No. Overall, the researchers found that the participants who received LY3451838 had about the same number of migraine headache days compared to those who received the placebo.

More details about the results of this study are included later in this summary.

What medical problems did the doctors report as possibly related to the study treatment?

There were 2.6% of participants who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 1 out of 38 participants.

More details about the medical problems from this study are included later in this summary.

Where can I learn more about this study?

Plain Language Summaries

Patient Plain Language Summaries of clinical studies started to appear at the conclusion of studies nearly a decade ago, and *patients like them*.

- Standardized way to provide an easy-to-understand summary of completed clinical research.
- Established standards.
- Patient reviewers are typically involved.
- Thousands have been published to help the public better understand research and treatment options.

Scientific Publications provide valuable insights learned from clinical research to further healthcare

	What is available	Scientific Output
Vivli	**7,500 datasets; 4.1 M patients 1,172 data requests***	**329 Publications, 1014 citations**
CSDR	757 proposals*	129 Publications
YODA	**435 data requests***	**105 Data Published**
DataSphere	205 datasets; 260,000 patients	135 Peer Reviewed Publications

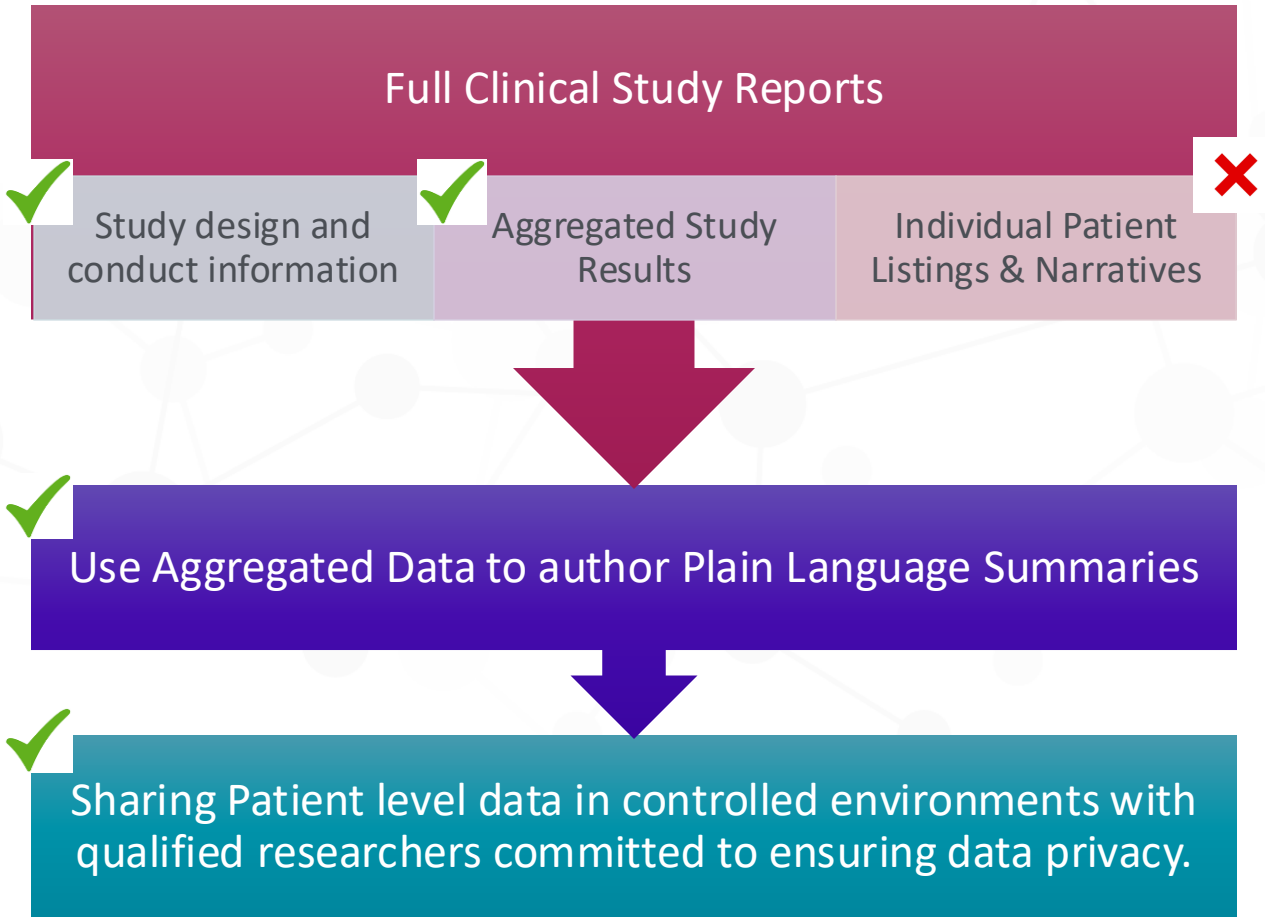
Stats from 2024 as published on sites

Clinical Study Data Set Sharing

Controlled data sharing with researchers has *yielded significant scientific insight* as demonstrated by the number of publications.

- Controlled data sharing allows sponsors a chance to better meet the data utility needs of researchers
- Increased security and contractual controls, means that sponsors don't need to transform the data so much to still call it anonymized.

Clinical Study Reports



Clinical Study Reports are technical documents written for scientific and medical experts.

- Clinical study reports contain information about the study design, treatments, how data is collected and analyzed, and other information about the therapy being researched
- CSRs also include individual and aggregated results data.

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CONCLUSIONS

How do we drive value with clinical trial transparency?

Purposeful transparency is the target; focus on the value-add activities, making the most of limited and valuable resources.

Clinical Study Report body provides transparency of the research approach, design, etc. and can be safely shared whilst protecting patient privacy.

Sharing data sets (IPLD) with qualified researchers in controlled environments which include strong contract and security controls drives value for public health.

Plain language summaries of clinical trials benefit the public and patients, serving as an easy-to-understand summary of the clinical research.

Compliant and **timely study registrations** bring trust to the ecosystem.


Questions?