



Embracing Use of Technology in Clinical Research

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Research Navigator, University of Vermont





thank you



Chat Storm

Type in technologies you use as a research coordinator



Chat Storm

How do you feel when you are faced with having to learn a new software system?




Technophobia

The fear of technology, is the intense fear or dislike of advanced technology or complex devices, especially computers.

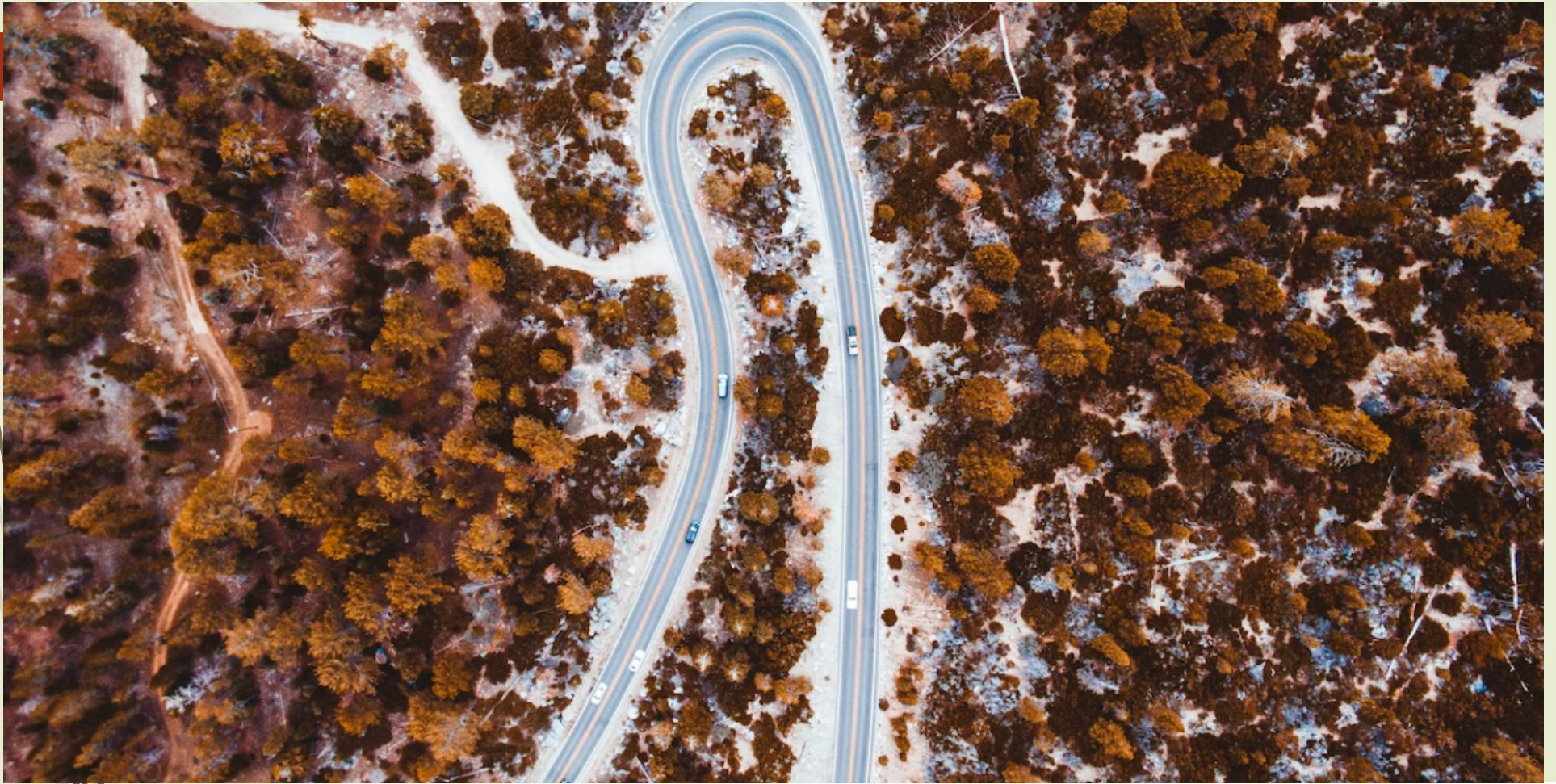
Technophobia is surprisingly common. Some experts believe that we all experience at least a small amount of nervousness when confronted with new technology. In today's rapidly changing world, it can be easy to feel out of touch.



 CBS THIS MORNING



The more we're willing to embrace the suck and try new things, the more new things we're willing to try.





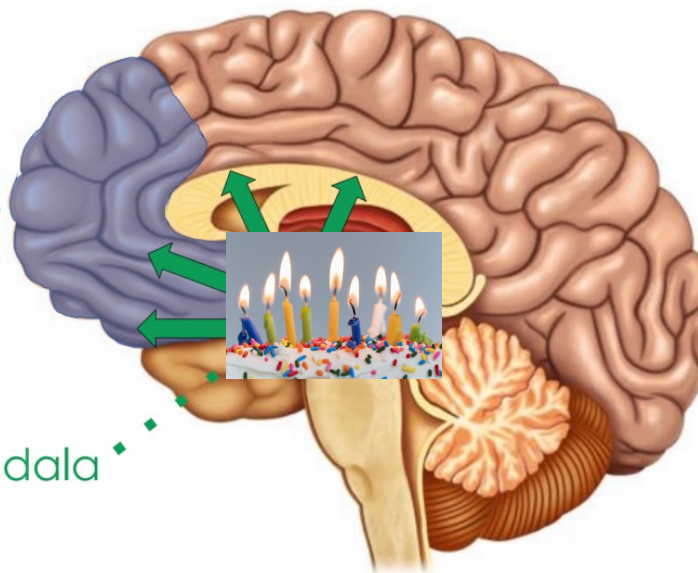
It's Okay to Take a Minute

Hijacked?

Hijack

Prefrontal
Cortex

Amygdala







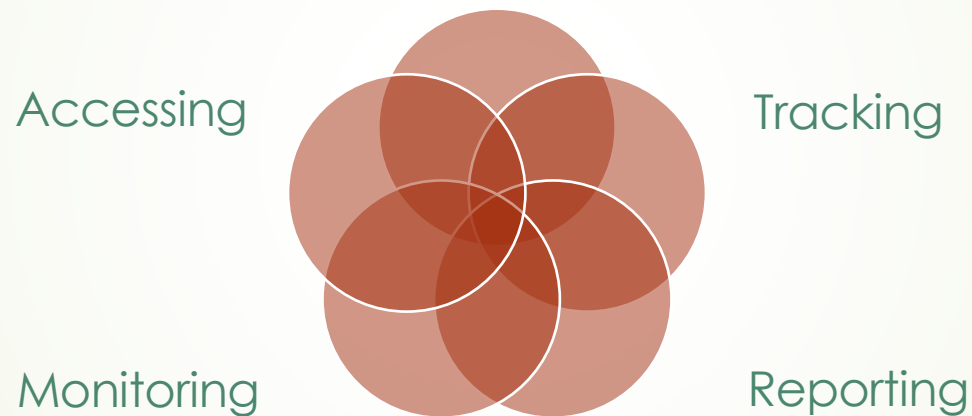
Electronic Systems – Advantages

Maximize features that minimize errors

- Alerts
- Audit Trail
- Automation
- Calculation
- eConsent
- Field Validation
- Logic
- Permissions
- Queries
- Remote Data Capture
- Reports
- Scheduling/Calendars

Clinical Trials Management System (CTMS)

CTMS provides a Centralized and Systematic way of



clinical trial information



Electronic Data Capture (EDC) vs CTMS

EDC (REDCap)

Project (study) Focused

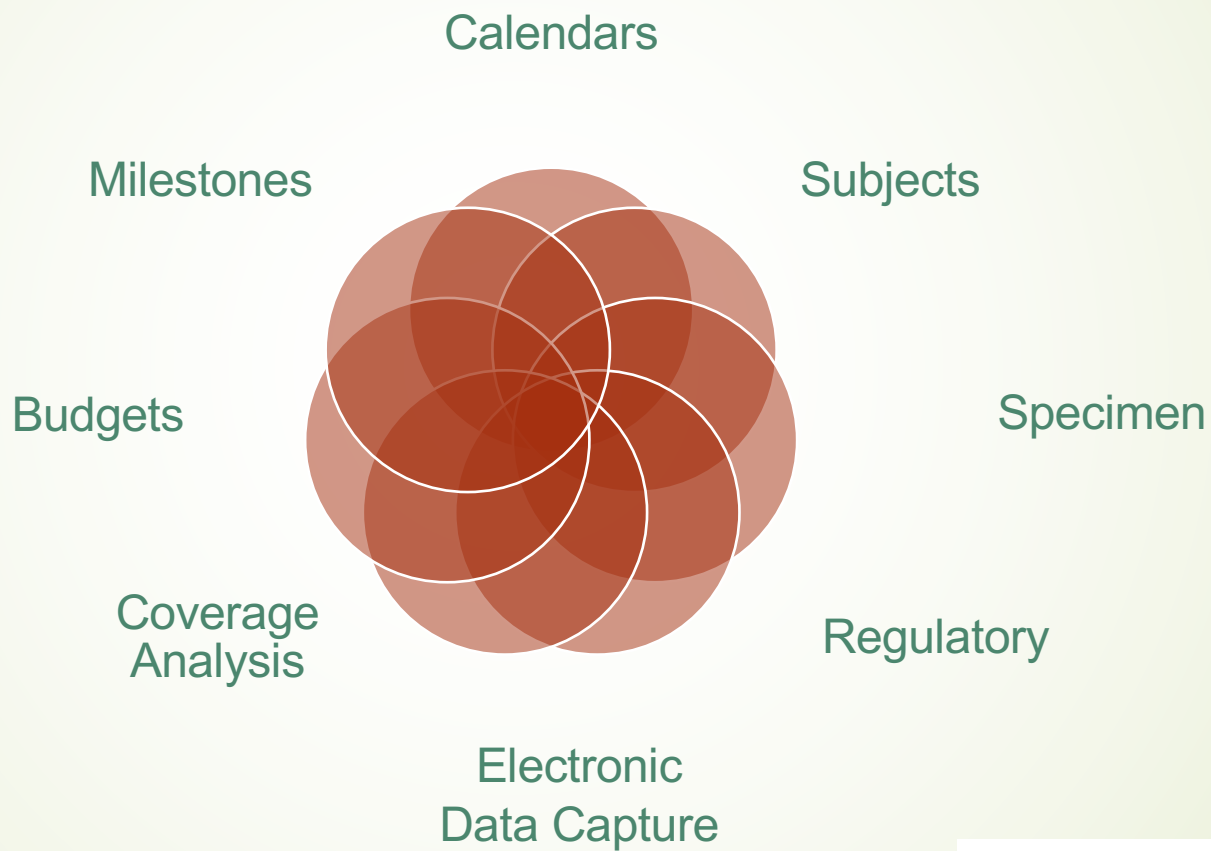
Collecting Data (CRF)

CTMS (OnCore)

System Focused

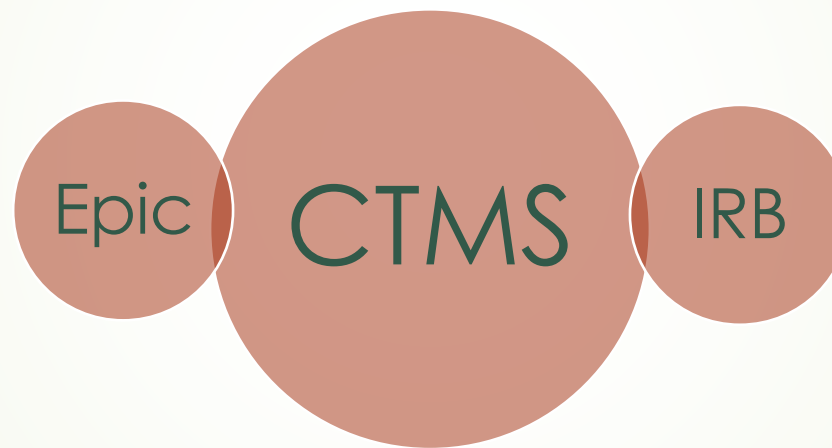
Overall Project
Management

CTMS Capabilities

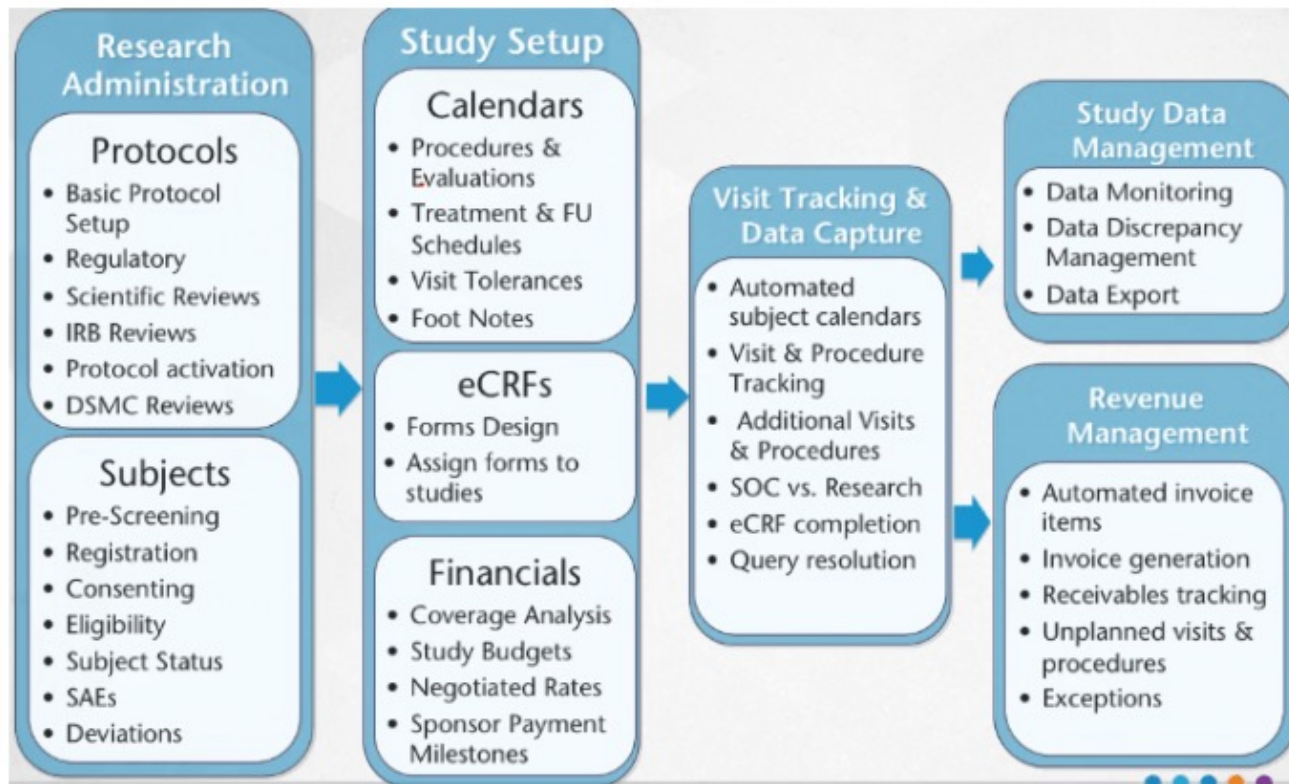




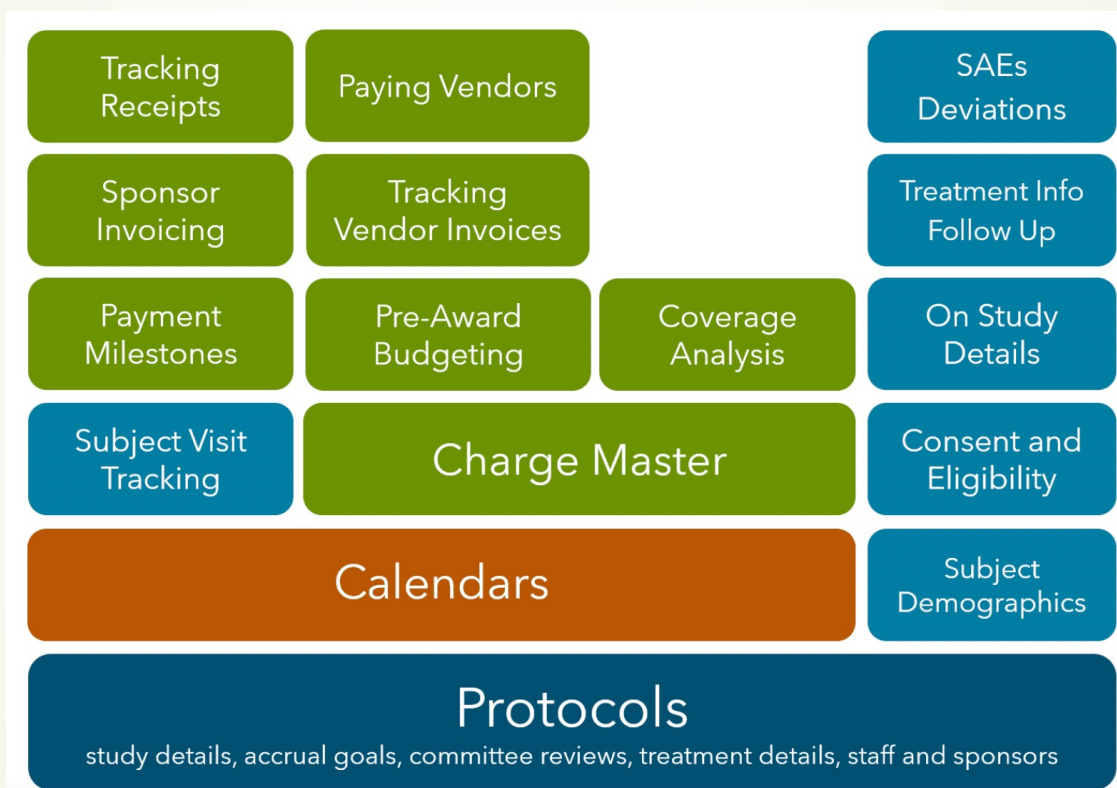
Talks to other systems



OnCore Generic Clinical Research Workflow



Clinical Trials Management System (CTMS)



★ PC Console

Protocol No.: **ONC0116**

Protocol Target Accrual: **1500**

RC Total Accrual Goal (Upper): **150**

Library: **Oncology**

Accrual To Date: **25**

PI: **Investigator, Irene**

Sponsor: **Bristol Myers Squibb**

Protocol Status: **OPEN TO ACCRUAL**

IRB Expiration: **02/01/2018**

Select Protocol

Type here to search

Details

Management

Staff

Sponsor

IND/IDE

ClinicalTrials.gov / CTRP

History

Main

Treatment

Institution

Accrual

Status

Reviews

Documents/Info

Risk Assessment

Eligibility

Protocol Calendar

Notifications

Conclusions

Annotations

Deviations

New Protocol

Protocol Details

Protocol No.

ONC0116

NCT Number

NCT00324805

Library

Oncology

Department

Oncology

Organizational Unit

Cancer Center

Title

A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (≥ 4 cm) - IIIA Non-small Cell Lung Cancer (NSCLC)

Short Title

Chemotherapy With or Without Bevacizumab in Treating Patients With Stage IB, Stage II, or Stage IIIA

Objectives

This randomized phase III trial studies chemotherapy and bevacizumab to see how well they work compared to chemotherapy alone in treating patients with stage IB, stage II, or stage IIIA non-small cell lung cancer that was removed by surgery. Drugs used in chemotherapy work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving more than one drug (combination chemotherapy) may kill more tumor cells. Monoclonal antibodies, such as bevacizumab, may interfere with the ability of tumor cells to grow and spread. Bevacizumab also may stop the growth of non-small cell lung cancer by blocking the growth of new blood vessels necessary for tumor growth. It is not yet known whether chemotherapy is more effective with or without bevacizumab in treating non-small cell lung cancer.

Phase

III

Scope

National

Age

Adults

Consent at Age of Majority

N/A

Drug Accountability

No

Investigator Initiated Protocol

Yes

Involves Therapy

Yes

Exclude Protocol on Web

No

Open For Affiliates Only

No

Summary Accrual Info. Only

No

Protocol Type

Treatment

Cancer Control

Yes

Cancer Prevention

No

Data Table 4 Report Type

Interventional

Registration Center

Involves Correlates or Companions

No

Data Monitoring

External

Adjuvant

No

Includes Specimen Banking?

No

Companion Study?

No

Multi-site Trial

Yes

Investigational Drug

No

Precision Trial

No

Precision Trial Classification

Investigational Device

No

Accrual Information

Protocol Target Accrual

1500

RC Total Accrual Goal (Lower)

150

RC Total Accrual Goal (Upper)

150

RC Annual Accrual Goal

50

Affiliate Accrual Goal

1350

Accrual Duration (Months)

36

Completion Dates

Primary Completion Date

08/05/2017 (Anticipated)

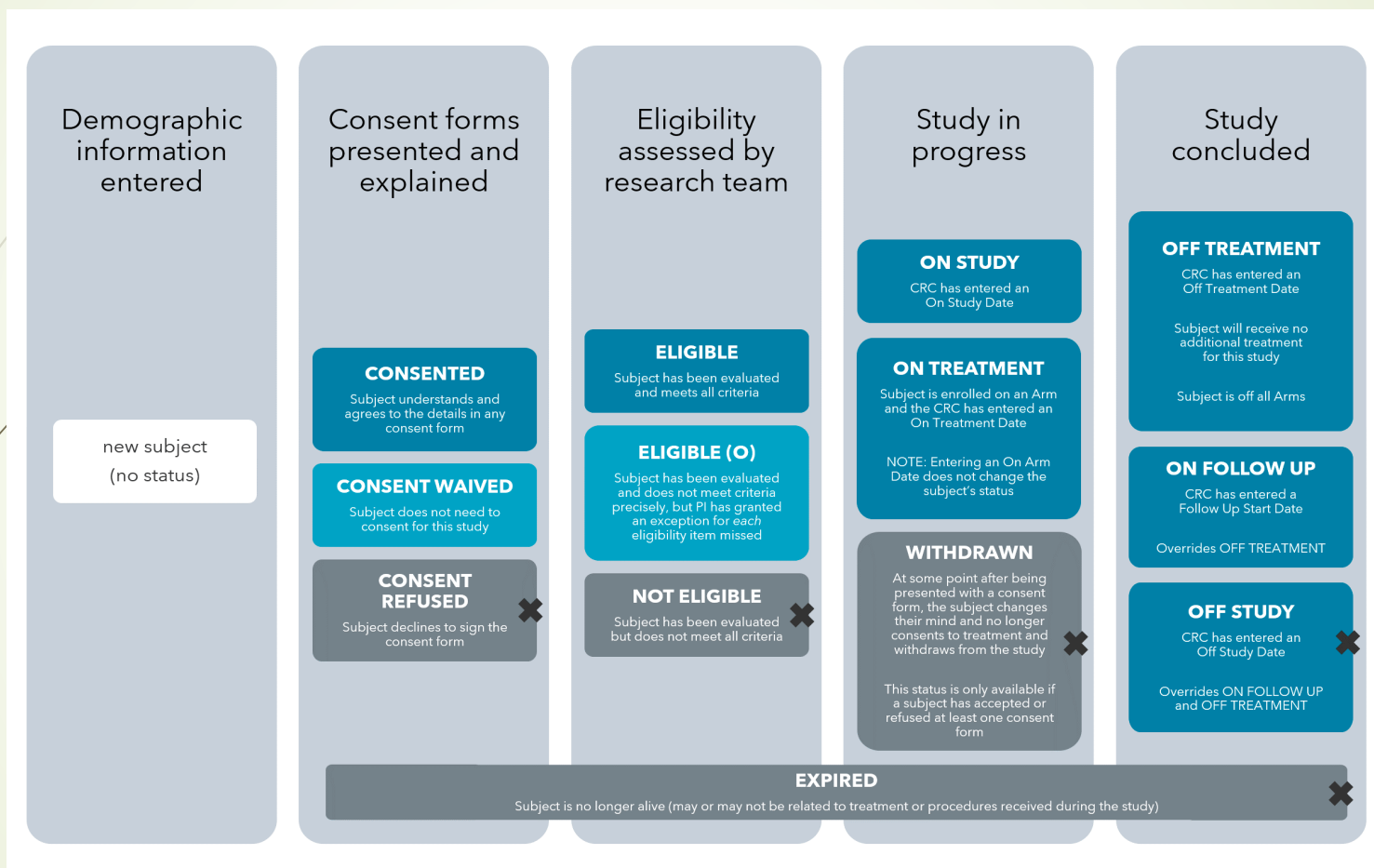
Study Completion Date

08/05/2018 (Anticipated)

Update

Lock Protocol

Subject Tracking





RESEARCH PROFESSIONALS NETWORK

Reporting

Why Do Sites Need a CTMS?

- ▶ Research Operations Management

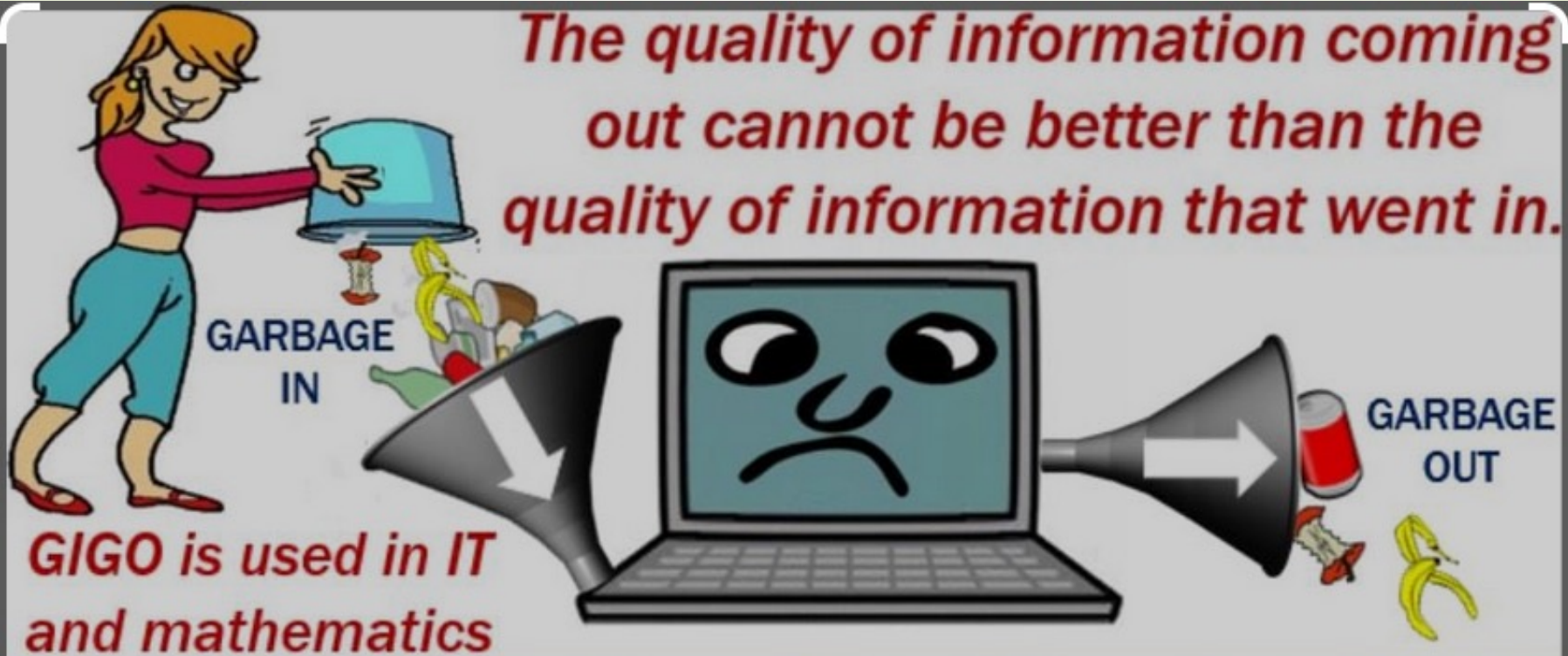
- ▶ Financial Management

- ◀ Reporting and Analytics

Enables a site to easily access data to confidently make strategic decisions. Sites leadership can identify trends and problem areas, and leverage actionable insights related to accrual, study activation, and effort.



The quality of information coming out cannot be better than the quality of information that went in.

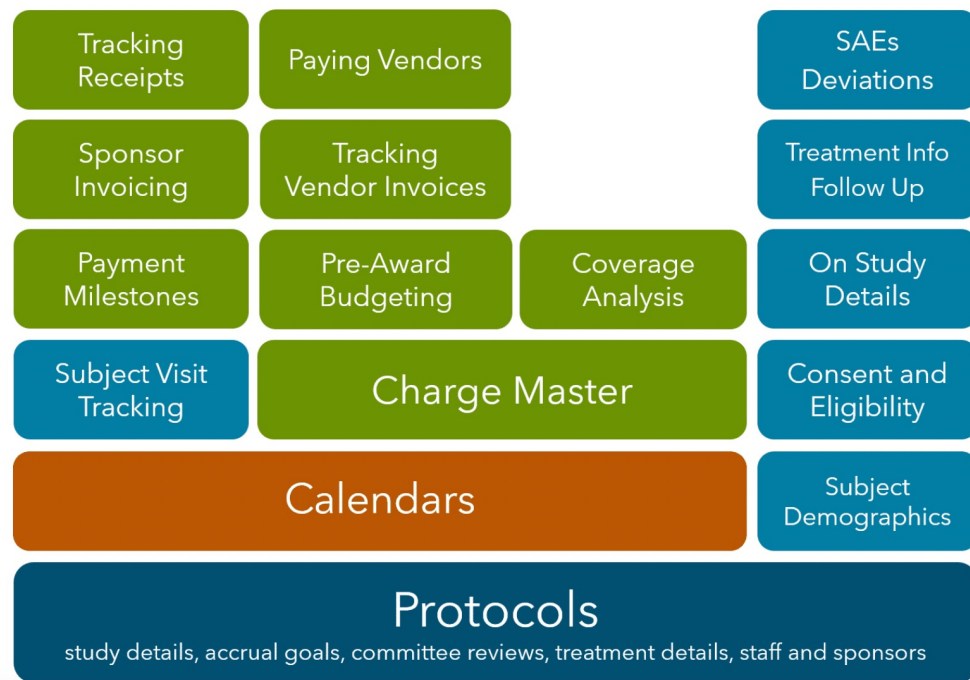


GIGO is used in IT and mathematics

Garbage In, Garbage Out



How does a CTMS help **ME?**

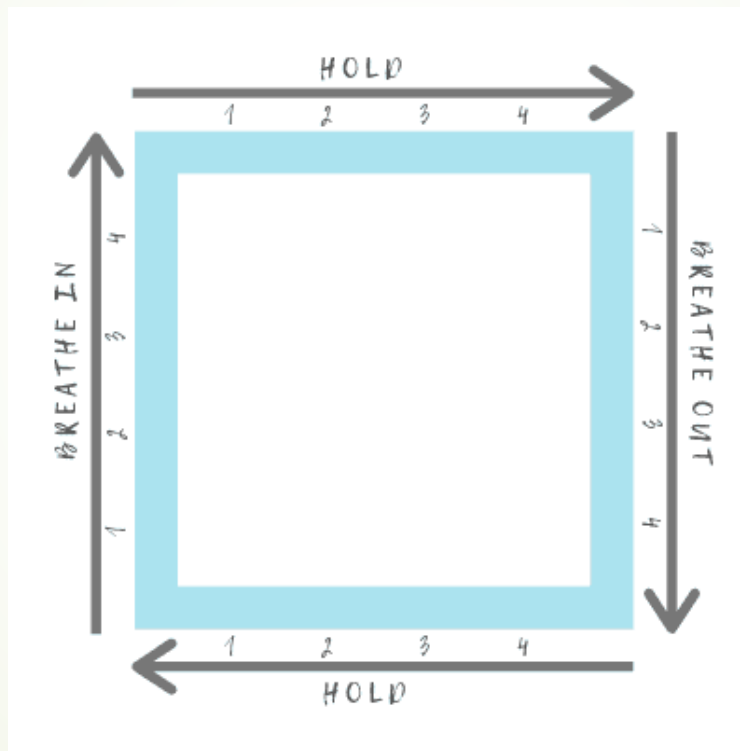




Why is visit tracking so important?

- Financial/budgeting
- Consistency across team/institution
- Leave, illness, or turnover

Square Breathing



A lush green forest scene with tall trees and sunlight filtering through the canopy. A semi-transparent gray square is centered on the image, containing the number '2' and the word 'Hold'. A small red pushpin is visible on the right edge of the gray box.

2

Hold

CONSCIOUSWORKS

eRegulatory

Integrating a clinical trial management system (CTMS) enables the regulatory team to pull protocol details and place them into eReg.



saves trees 🌲 and time ⌚

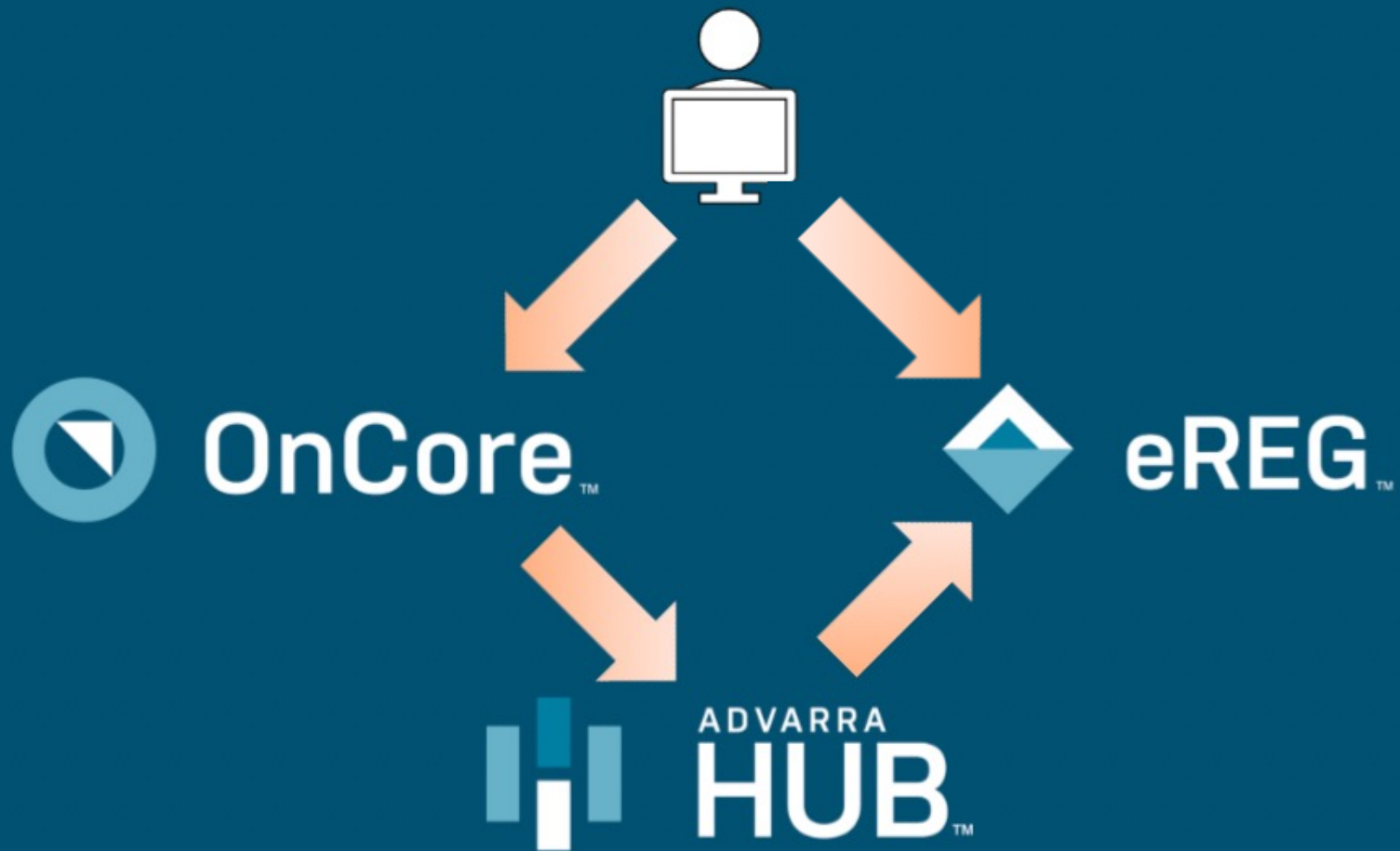
ensures consistency between platforms

- documents filed and signed in eReg, made available in CTMS.

- centrally manage documents

- centrally manage multi-site protocols

- receive documents from sponsor/coordinating center directly in the protocol inbox, making filing and organization easier as well



Protocol



eREG

Menu

Regulatory Templates

Protocols

Sign Documents

Favorite Protocols

★	🔗	🔒	Protocol Number ↑	Study Site ↑
★			MULTIP1-KDS	Multi-Site
★			PROT-DOA-KDS	Fitchburg Clinic
★			PROT01-KDS	UMC - Wisconsin Cancer Institute

Protocols > STUDY15438

Select Protocol

Document Inbox

Overview

Summary

Details

Organizations

Staff

Staff Training

Protocol

Delegation of Authority

Other Documents

Informed Consent Documentation

IRB Approvals and Correspondence

Screening/Enrollment Log

Serious Adverse Events
(SAE)/Unanticipated Problem
Documents

Protocol Deviation Form or Memo

Data and Safety Monitoring
Documents






Case Report Forms/Source
Documents

Delegation of Authority Log

Easy Credential sharing

Credentials

+ New Document ▼

Credential Type ↑	Versions	Document Name	Effective Date ↑	Valid Until ↑	Signature Status	
Curriculum Vitae	2	Madden, Katrina 9 8 2021.pdf 	08 Sep 2021	07 Sep 2023	N/A	+ New Version ✕ Delete
eReg Training	2	KMadden_eregtrain2.pdf 	18 Mar 2021		N/A	+ New Version ✕ Delete
Good Clinical Practice Training	2	Madden, Katrina CITI GCP 2023 - 03 20 2026.pdf 	20 Mar 2023	20 Mar 2026	N/A	+ New Version ✕ Delete
Human Subjects Protection Training	3	Madden, Katrina CITI G1 Biomed 2023 - 3 6 26.pdf 	06 Mar 2023	06 Mar 2026	N/A	+ New Version ✕ Delete
Signature Sample	1	Madden, K sig.jpeg 	08 Mar 2021		N/A	+ New Version ✕ Delete

Email documents for filing

★ Protocol: STUDY11554

Actions ▾

Expand All | Collapse All

Email (4) ▾

Refresh Inbox

Document Name ↑		Received Date ↓	Sender	
No subject	📎	20 Apr 2023	Katrina Madden	✓ Review and File ✕ Reject
No subject (Benitez IAM v2.0 Consent Form ...)	📎	20 Apr 2023	Katrina Madden	✓ Review and File ✕ Reject
No subject (Benitez IAM v2.0 Consent_stamp...)	📎	20 Apr 2023	Katrina Madden	✓ Review and File ✕ Reject
No subject (IAM_UBACC_v1.1_tc_20MAR2023.do...)	📎	20 Apr 2023	Katrina Madden	✓ Review and File ✕ Reject

Review and File

Section * Informed Consent Documentation x ▾

Requirement * IRB-approved Informed Consents x ▾

New Version of Existing Document ⓘ

Document Name * Benitez IAM v2.0 Consent Form Co-P_starr

Effective Date 16 Mar 2023

Valid Until

✓ File Cancel

Review and File

Section * Other Documents x ▾

Requirement * Other study documents x ▾

New Version of Existing Document ⓘ

Document Name * IAM_UBACC_v1.1_tc_20MAR2023.docx

Effective Date 16 Mar 2023

Valid Until

✓ File Cancel

Document sign offs

Create Credential Version ✕

Credential Type * Curriculum Vitae

File * Katrina Madden CV - 4.11.2023.docx

Document Name * Katrina Madden CV - 4.11.2023.docx

Effective Date

Valid Until

Signature Requirement * ☐ Electronic Signature
☐ Wet Signature
☐ None

Create Credential Version ✕

Credential Type * Curriculum Vitae

File * Katrina Madden CV - 4.11.2023.pdf

Document Name * Katrina Madden CV - 4.11.2023.pdf

Effective Date

Valid Until

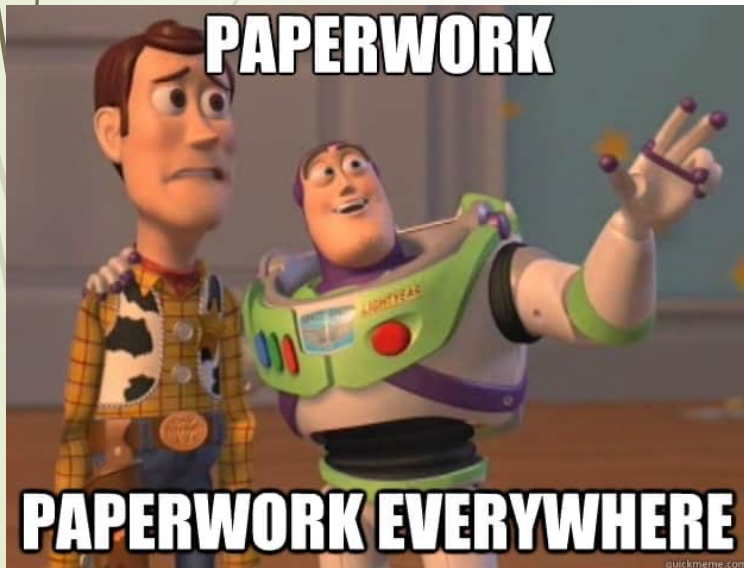
Signature Requirement * ☒ Electronic Signature
☐ Wet Signature
☐ None

Due Date

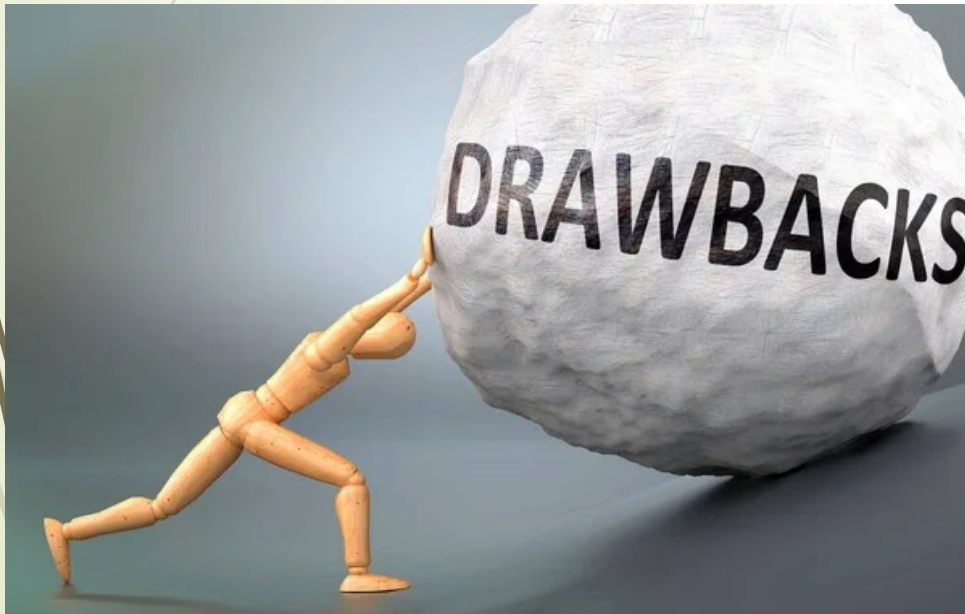
Notes to Signer

Notify Now ⓘ *

Benefits



- 21 CFR Part 11-compliant electronic signatures
- Remote signing
- Electronic Delegation of Authority
- Regulatory templates
- Email integration
- Storage for INDs/IRB Approvals/SOPs
- Monitor Review sessions




- Institution templates
- Search for answers
- Some features may not be available to you
- Training required for users

Recruitment



Planning
+
Workflows
+
Tracking Enrollment
Goals
=
Improved
Recruitment





To begin with the end in mind means to start with a clear understanding of your destination. It means to know where you're going so that you better understand where you are now and so that the steps you take are always in the right direction.

— *Stephen Covey* —

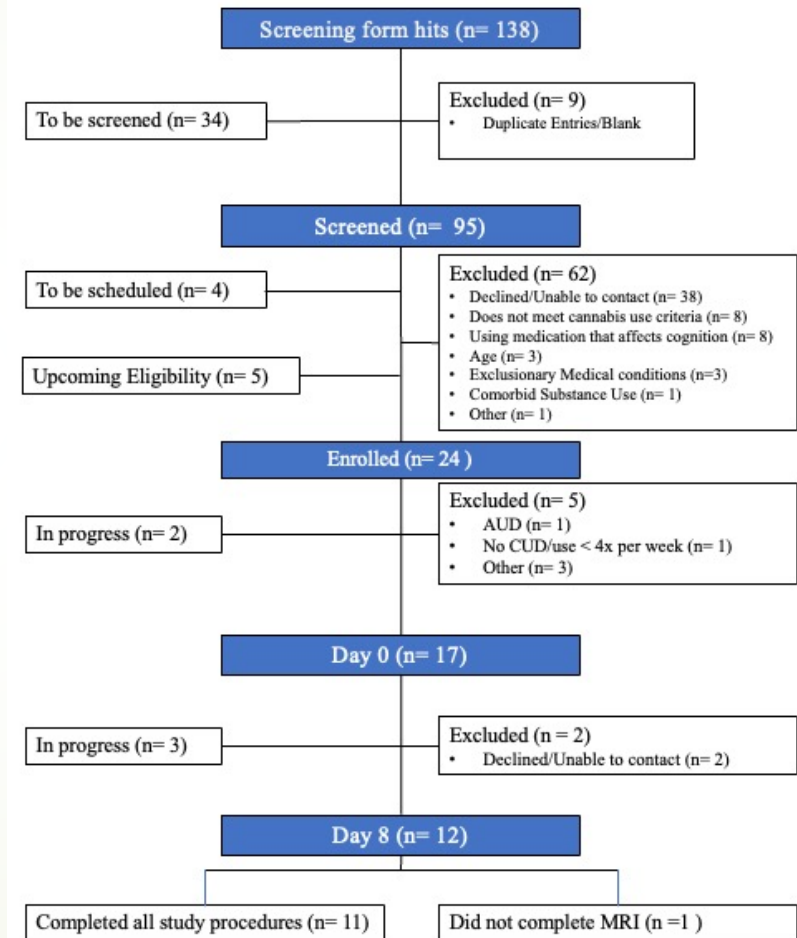
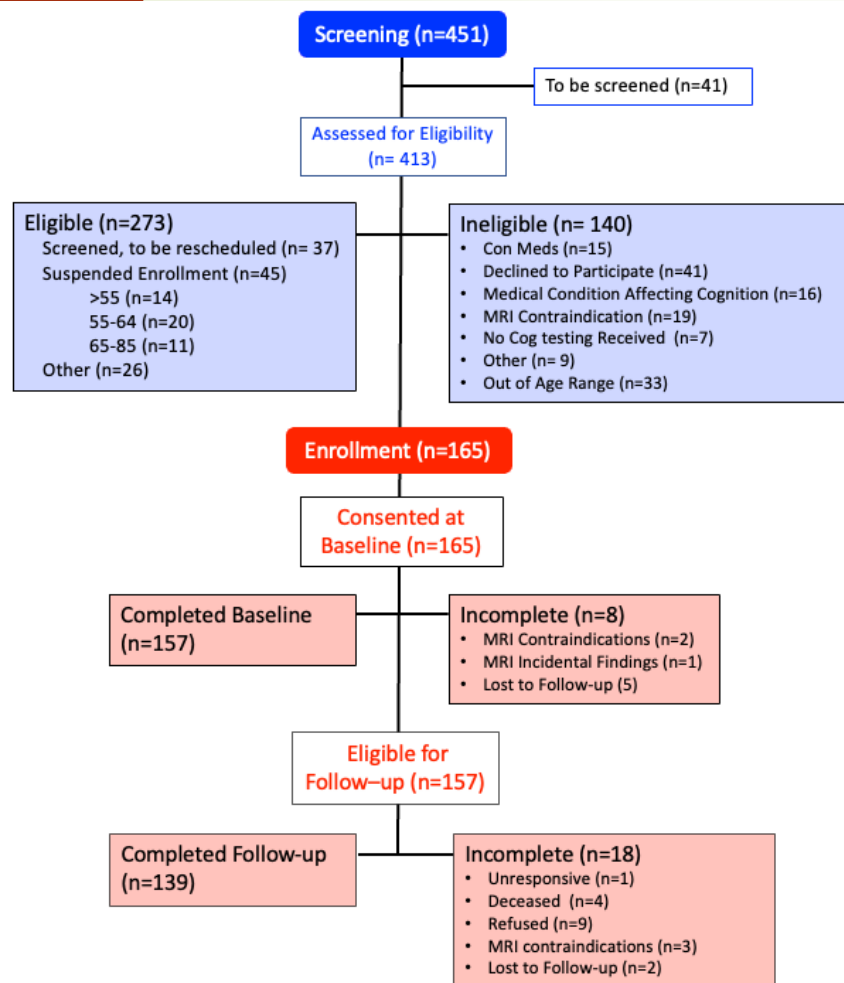


RedCap Recruitment

Pre-screening/Screening
Eligibility
Scheduling
eConsent

- capture details
- meet recruitment goals
- easy Consort Diagrams

Consort Diagram



2023	Project Year 1														projected in blue
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Total		actual in green
Wave 1 48mo Goal			12	11	7	6	6	6	6	6	6	4	70		
Wave 2 BL Goal					8	5	5	5	4	5	5	4	41		
Wave 1 48mo Actual													0		
Wave 2 BL Actual													0		
2024	Project Year 2														
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Total		
Wave 1 48mo Goal	6	6	6	6	6	6	6	6	6	6	6	4	70	140	Wave 1 48mo Goal
Wave 2 BL Goal	5	5	4	6	6	6	4	6	4	4	5	4	59	100	Wave 2 BL Goal
Wave 1 48mo Actual													0	0	Wave 1 48mo Actual
Wave 2 BL Actual													0	0	Wave 2 BL Actual
2025	Project Year 3														
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Total		
Wave 1 72mo Goal	5	6	5	6	5	6	6	6	6	6	6	4	67		
Wave 2 24mo Goal	4	4	4	4	4	4	4	4	4	4	4	4	48		
Wave 1 72mo Actual													0		
Wave 2 24mo Actual													0		
2026	Project Year 4														
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Total		
Wave 1 72mo Goal	7	6	6	7	6	7	7	6	6				58	129	Wave 1 72mo Goal
Wave 2 24mo Goal	3	4	4	3	4	3	3	4	4	4	4	4	44	92	Wave 2 24mo Goal
Wave 1 Actual														0	Wave 1 72mo Actual
Wave 2 Actual													0	0	Wave 2 24mo Actual



Recruitment in CTMS

➤ CTMS

- Screening
- Eligibility
- Consent tracking

- meet recruitment goals
- easily share with monitors
- share recruitment successes with Sponsors for new trials

Texting



Texting





21 CFR Part 11 Compliance

IT Level

- regular systems upgrades
- daily backups
- secure logins
- system validation

Protocol Level

- standard operating procedures
- protect the collection and maintenance of data
- ensure the proper delegation of study specific roles and responsibilities to members of the study team
- instituting policies and procedures for the necessary training and oversight required throughout the study's operation

Have a Back-up Plan





Electronic Data Destruction

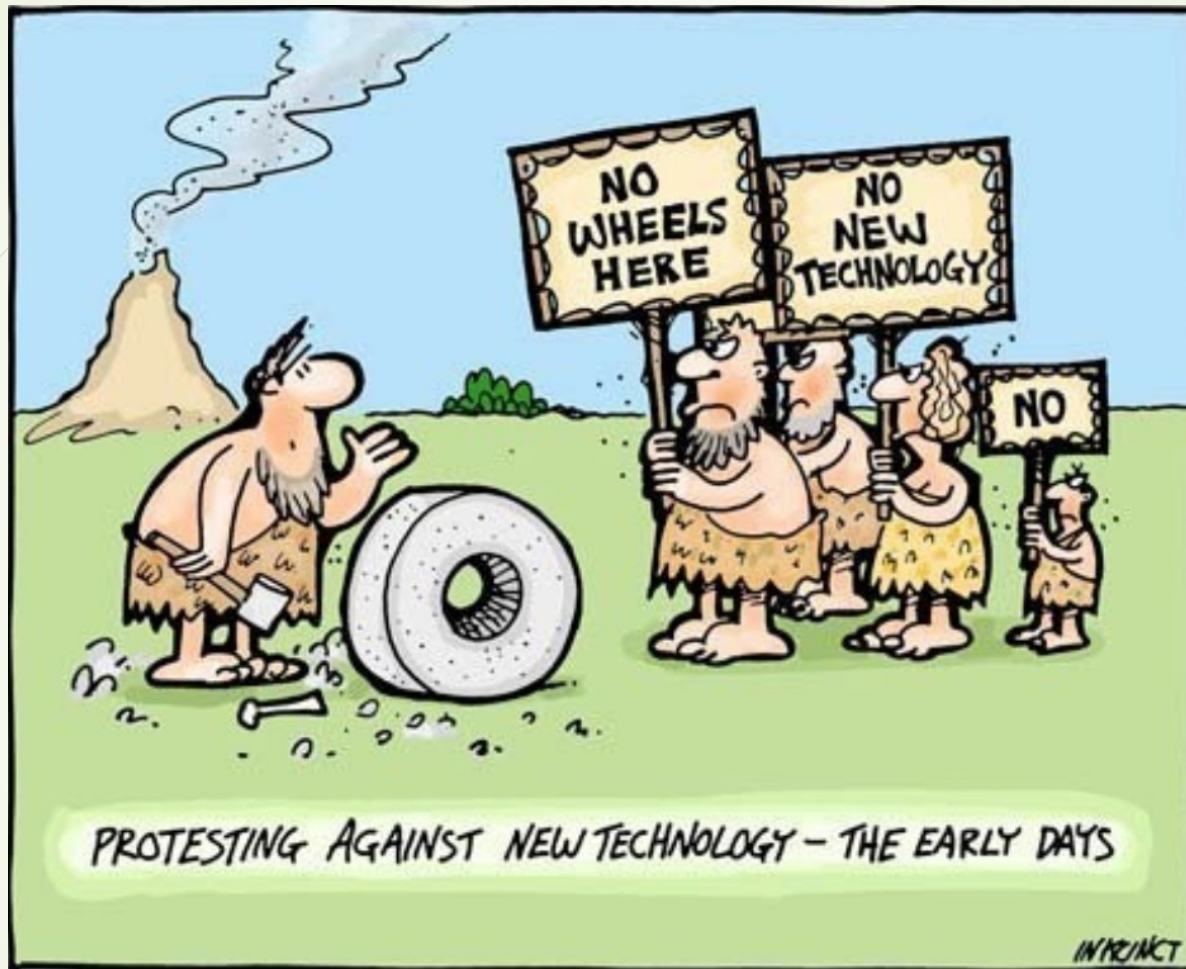
Destruction of Research Data

When researchers decide that research data should no longer be maintained, the data should be thoroughly and completely destroyed. Effective destruction ensures that research data cannot be extracted or reconstructed. Many document storage companies now offer onsite shredding and secure destruction of written and electronic media.

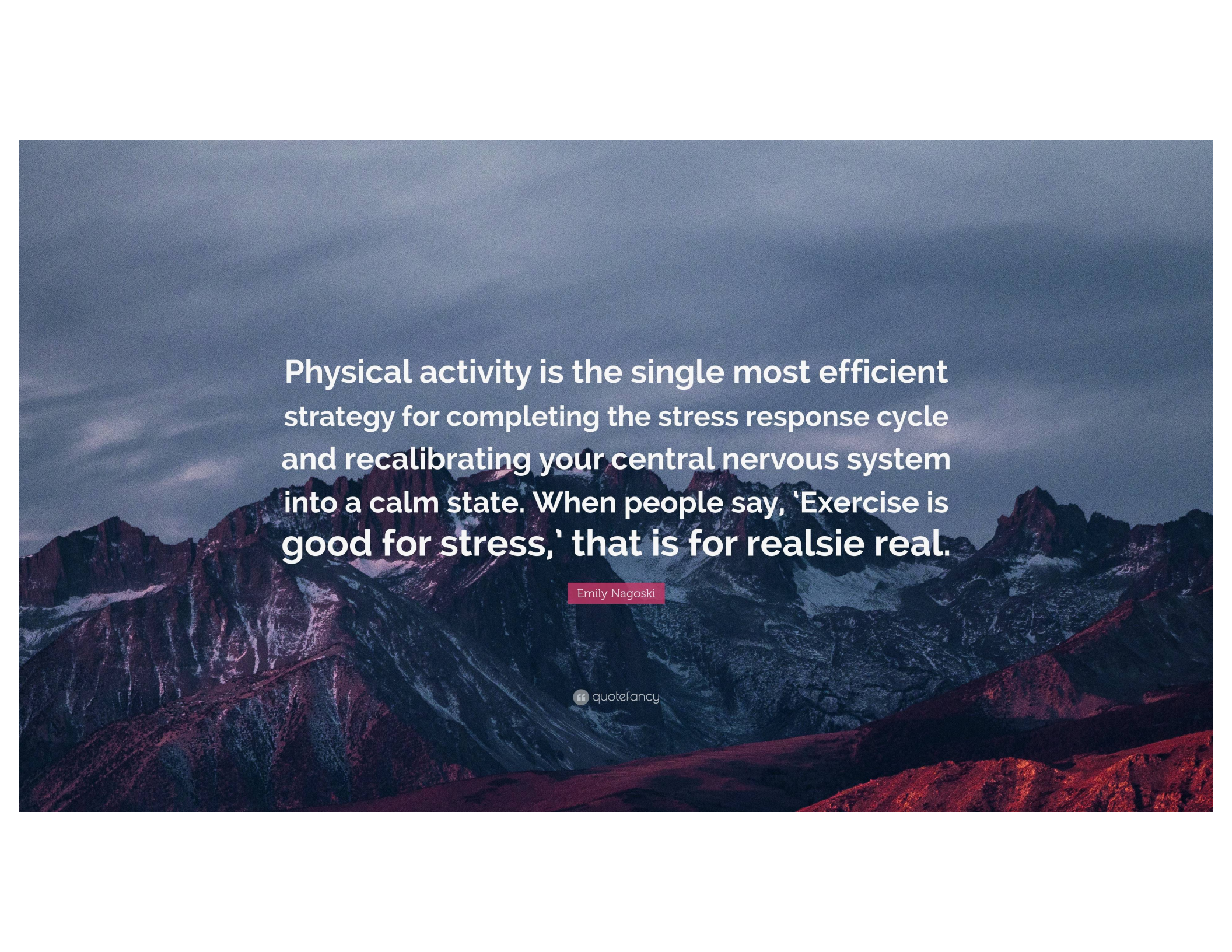
For electronic research data, the IRB advises researchers to contact either the College of Medicine Technology Services COMTS or Enterprise Technology Services (ETS) to assist with development of an adequate data destruction plan, as simply deleting the data files is insufficient.

I have a hard time
asking for help.





4/06 2007-346 © INKCINCT Cartoons www.inkcinct.com.au




Physical activity is the single most efficient strategy for completing the stress response cycle and recalibrating your central nervous system into a calm state. When people say, 'Exercise is good for stress,' that is for realsie real.

Emily Nagoski

quote fancy

Legs up the wall





“When we get to the point that we only
do things that we’re already good at
doing, we stop growing.”

~Brené Brown



Questions?