State of the HRPP

Where we were, where we're going…

Research Matters

February 20, 2024

Rhonda Oilepo, MS, CIP, CHRC, CHPC
AVP, Human Research Administration
Human Research Protection Program

UT Southwestern Medical Center

Agenda

- HRPP Overview
- 2023 Performance
- Challenges, Changes, Accomplishments
- Current projects
- Initiatives for 2024

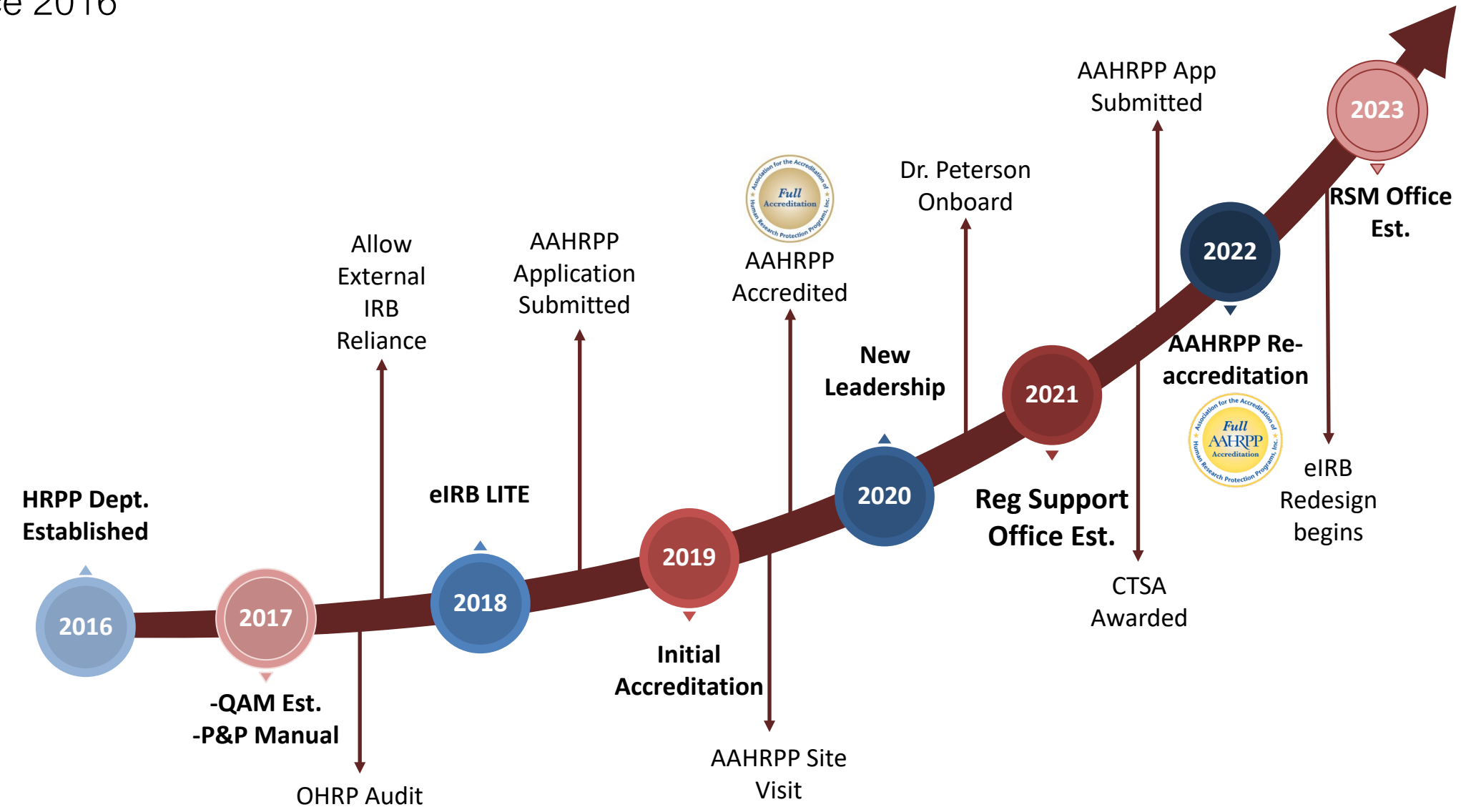
Human Research Protection Program Components

UT Southwestern Medical Center

UT Southwestern Medical Center

UT Southwestern HRPP Timeline

Since 2016



Human Research Institutional Official

Eric Peterson, MD, MPH

Vice Provost, Senior Associate Dean of Clinical Research, and VP Health System Research

Office of Clinical Research

Bhanu Pappu, PhD

Associate VP, Clinical Research

Human Research Protection Program

Rhonda Oilepo, MS, CIP, CHRC, CHPC

Assistant VP, Human Research Administration

- Clinical Research Education
- Office of Clinical Trial Management
- Clinical Research Unit (CRU)
- IRB Office
- Regulatory Support Office
- Regulatory Monitoring and QA

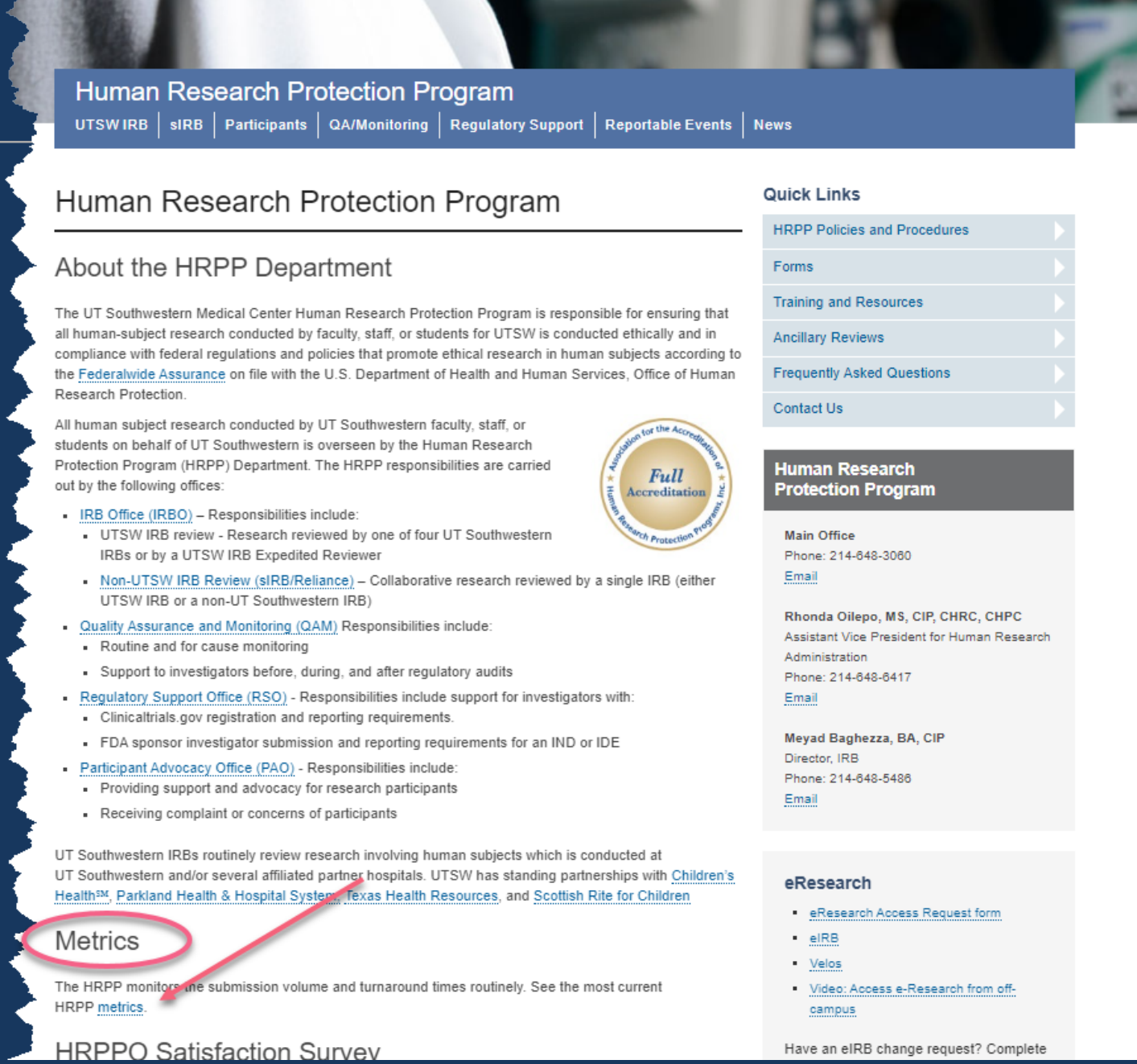
HRPP Departmental Offices

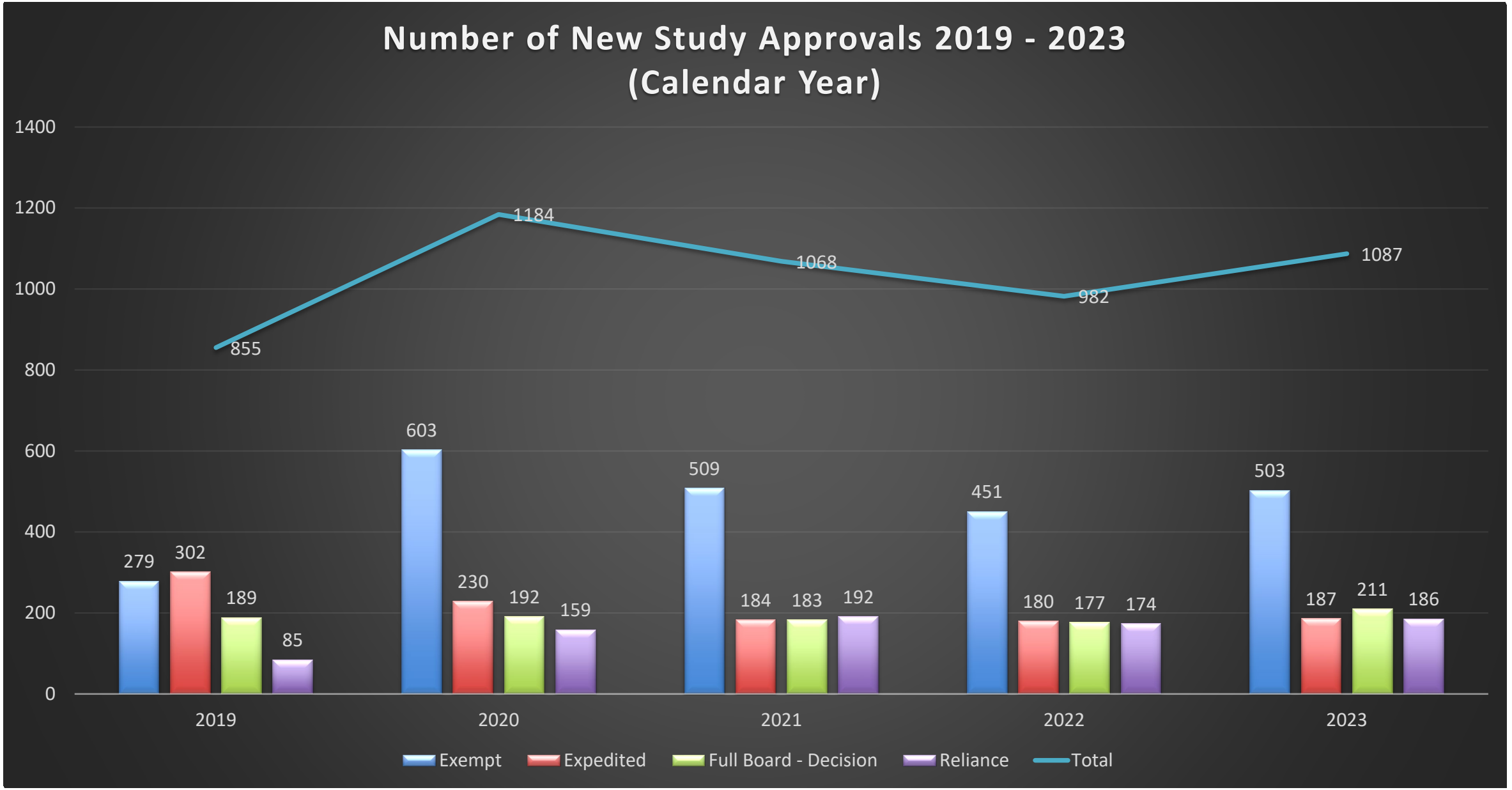
- HRPP Department
  - IRB Office
    - Research Review
    - Privacy Board
    - Federal Reporting
    - Agreements
    - Recordkeeping
  - Regulatory Support and Monitoring (RSM)
    - Quality Assurance & Monitoring (QAM)
      - Study Monitoring
      - FDA Audits
      - IRB Quality
    - Regulatory Support Office (RSO)
      - FDA Submissions
      - ClinicalTrials.gov
  - Administration
    - HRPP Fees
    - CRC Education
    - Ethics Education

2023 Performance

IRB Metrics:

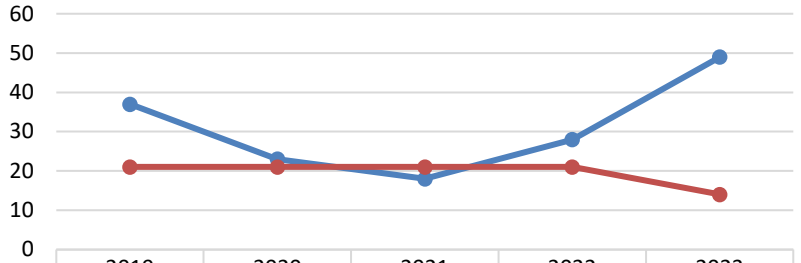
Available on the HRPP website




Number of New Study Approvals 2019 - 2023
(Calendar Year)
1400
1200
1000
800
600
400
200
0
855
1184
1068
982
1087
279
302
189
85
603
230
192
159
509
184
183
192
451
180
177
174
503
187
211
186
2019
2020
2021
2022
2023
Exempt
Expedited
Full Board - Decision
Reliance
Total

IRB Metrics – Turnaround time 2019-2023

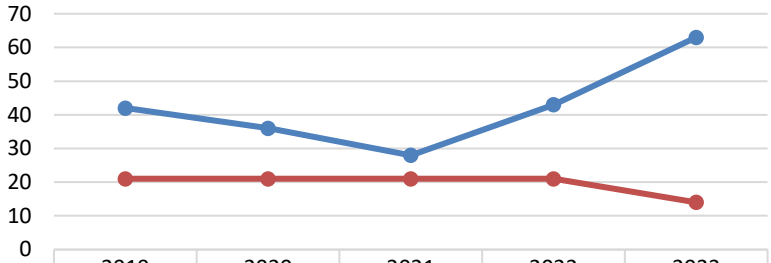
Exempt New Studies
Median Turnaournd in Calendar Days
(Submission to Final Approval



	2019	2020	2021	2022	2023
Exempt	37	23	18	28	49
Exempt Goal	21	21	21	21	14

Exempt Exempt Goal

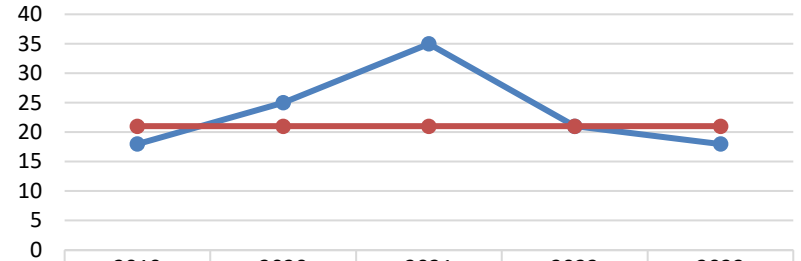
Expedited New Studies
Median Turnaournd in Calendar Days
(Submission to Final Approval)



	2019	2020	2021	2022	2023
Expedited	42	36	28	43	63
Expedited Goal	21	21	21	21	14

Expedited Expedited Goal

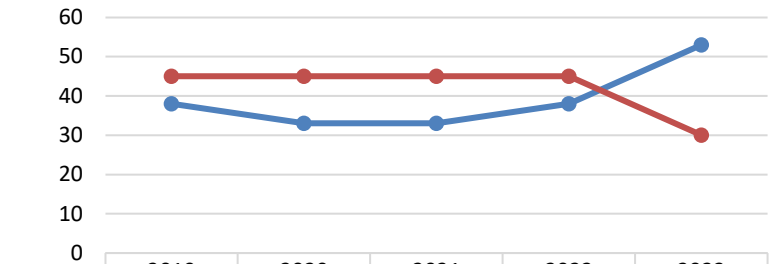
Reliance Studies Median Turnaournd in Calendar Days
(Submission to Final Approval)



	2019	2020	2021	2022	2023
Reliance	18	25	35	21	18
Reliance Goal	21	21	21	21	21

Reliance Reliance Goal

Full Board New Studies
Median Turnaournd in Calendar Days
(Submission to Final Approval)

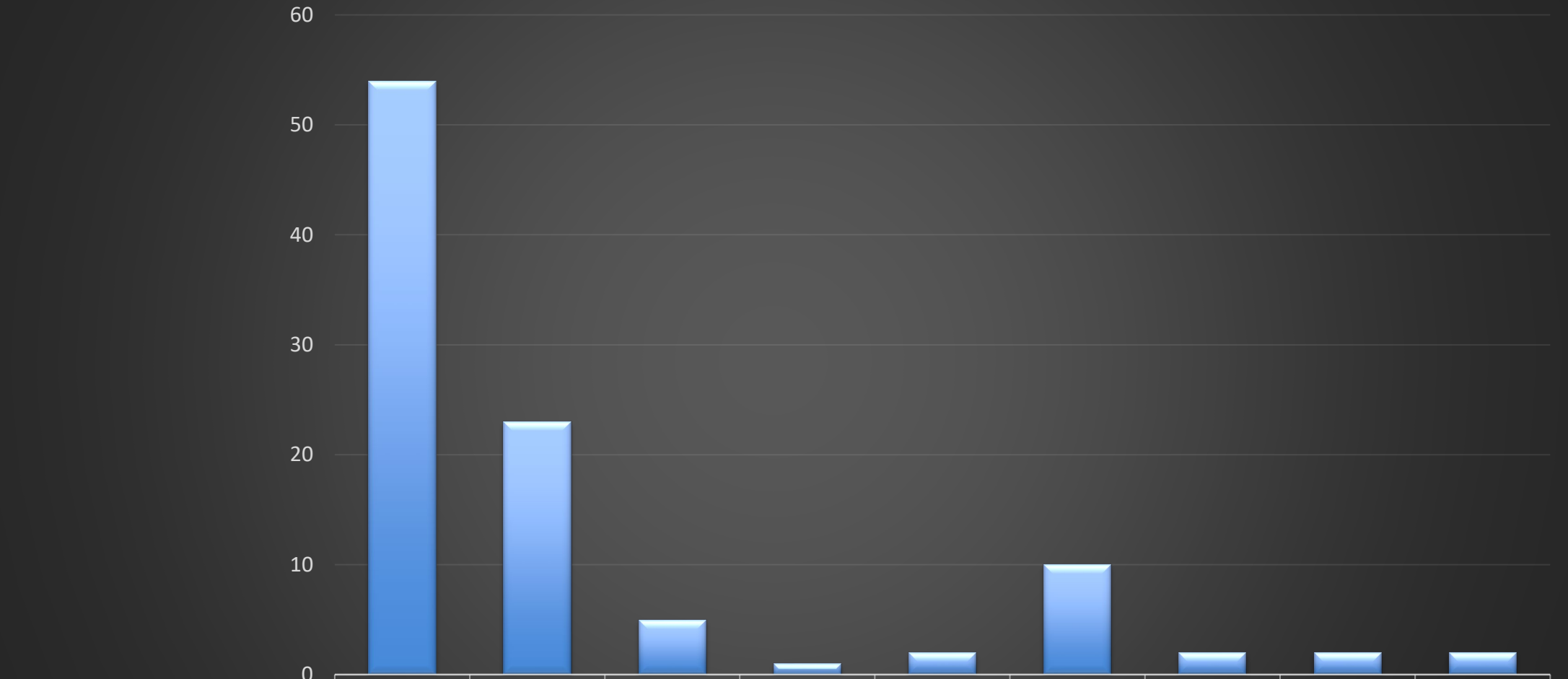


	2019	2020	2021	2022	2023
Full Board - Decision	38	33	33	38	53
Full Board Goal	45	45	45	45	30

Full Board - Decision Full Board Goal

QA/Monitoring Metrics

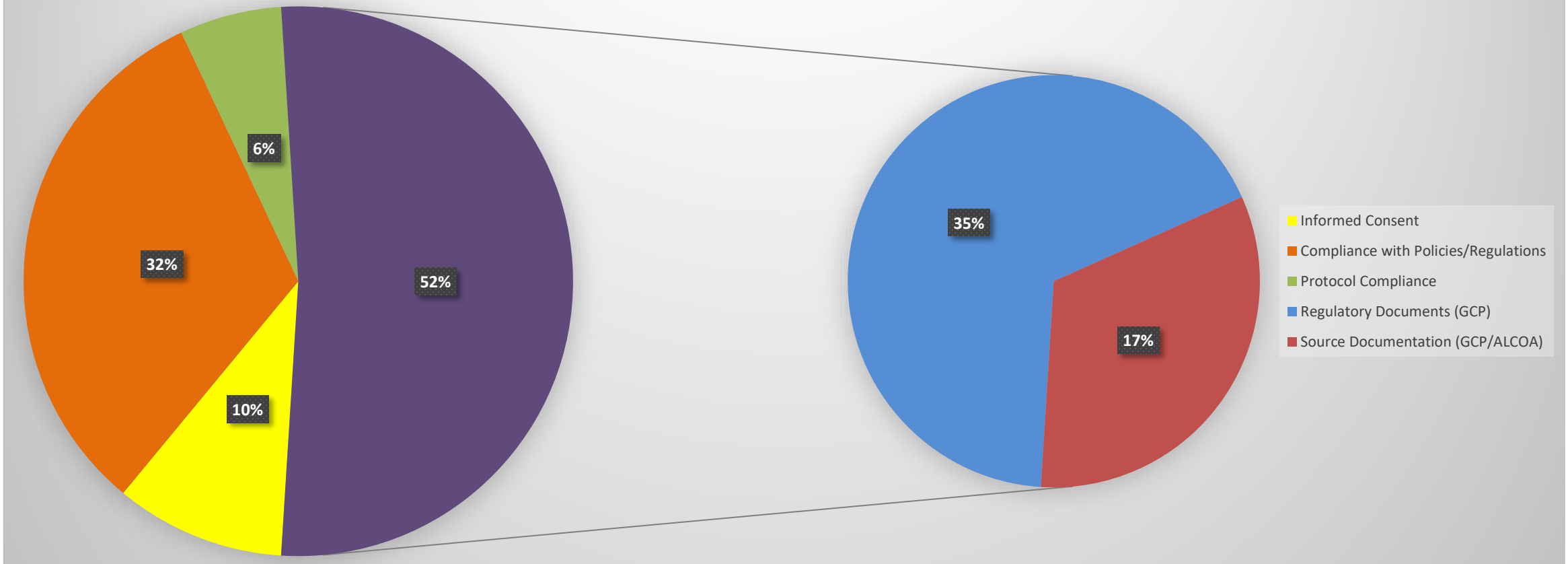
QAM Visits by Type
Calendar Year 2023 (n=101)



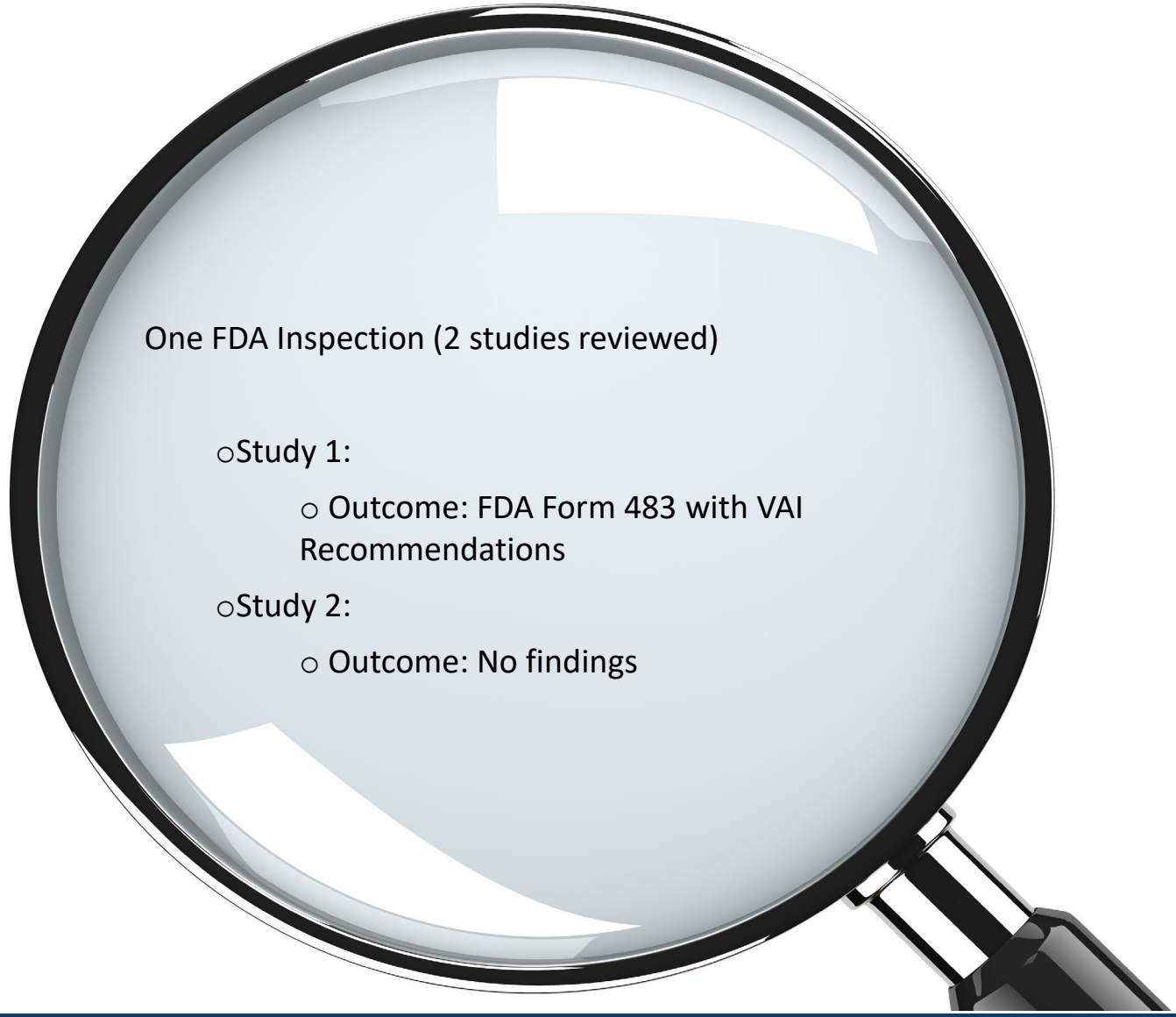
	Not-For-Cause	Sponsor-Investigator (SI) Monitoring	For-Cause	FDA Audit	FDA/Sponsor Audit Prep	Study Initiation Reviews	Focused Review	Follow-Up Reviews	Remote-to-Onsite Reviews (Remote)
Total Count of Visits Conducted	54	23	5	1	2	10	2	2	2

Observations by Deficiency Category

Calendar Year 2023



FDA Inspection Assistance in 2023



One FDA Inspection (2 studies reviewed)

- Study 1:
  - Outcome: FDA Form 483 with VAI Recommendations
- Study 2:
  - Outcome: No findings

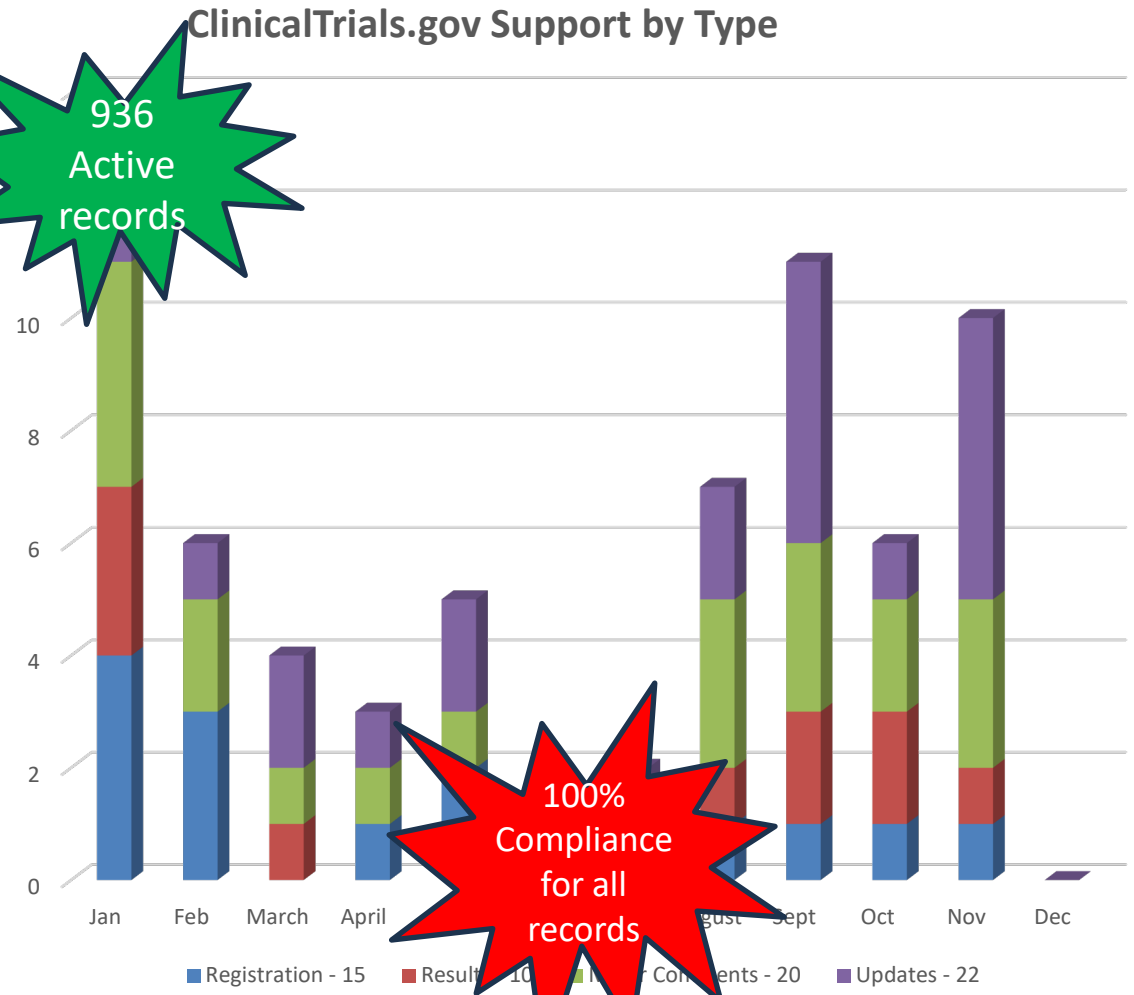
RSO Metrics

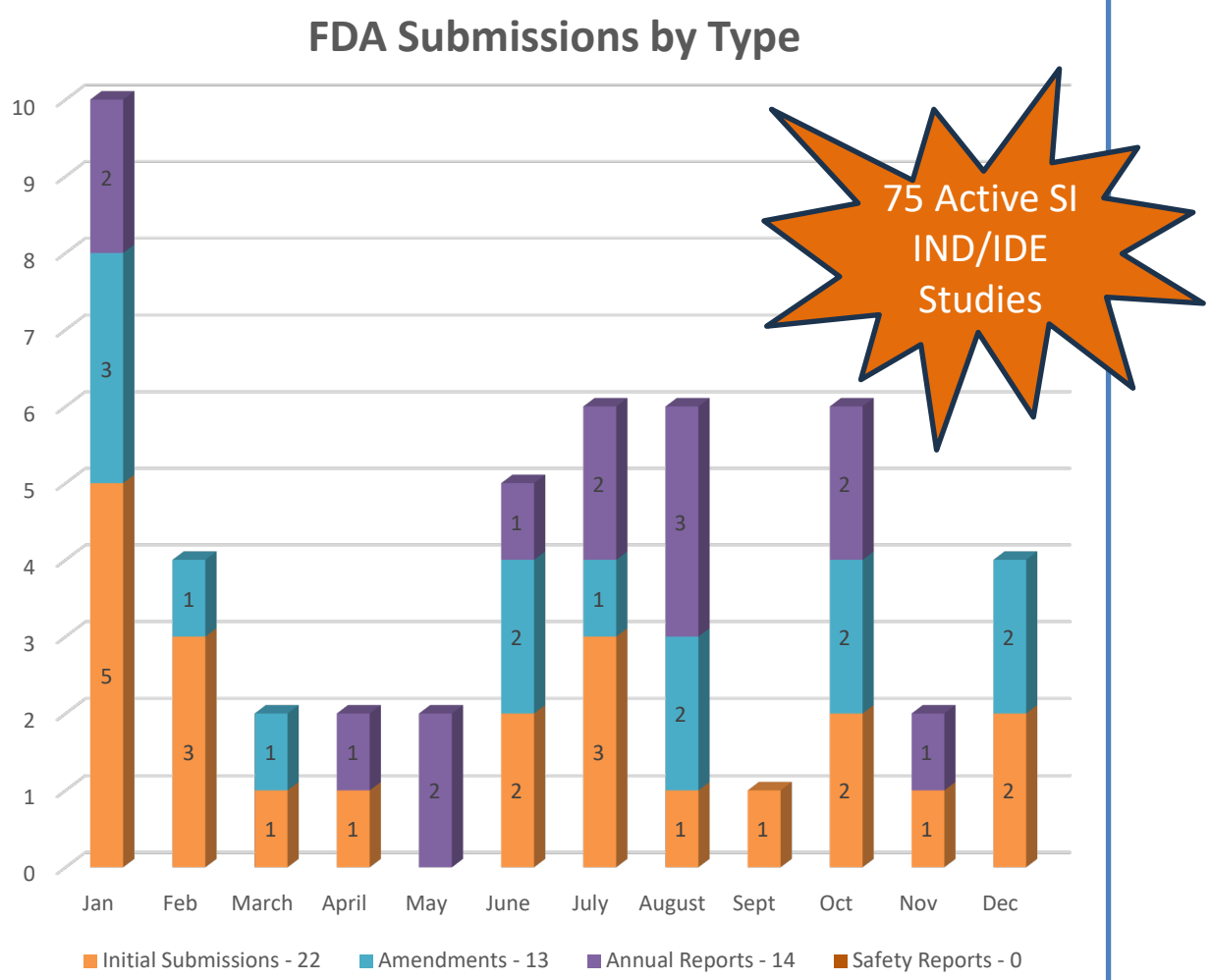
Metrics – Regulatory Support

936 Active records

100% Compliance for all records

75 Active SI IND/IDE Studies





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2023 Research Matters Survey Feedback

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Feedback Surveys Completed

Calendar Year 2023

(n=167)

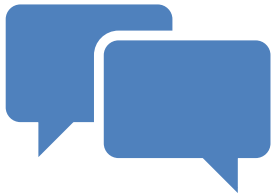
What are we doing well?

Information Sharing

Training and Education

Quality of Presentations and Materials

What can we do better?



Communication Improvement

Respond timely to emails

Communicate required study changes clearly

Technology and System Enhancement

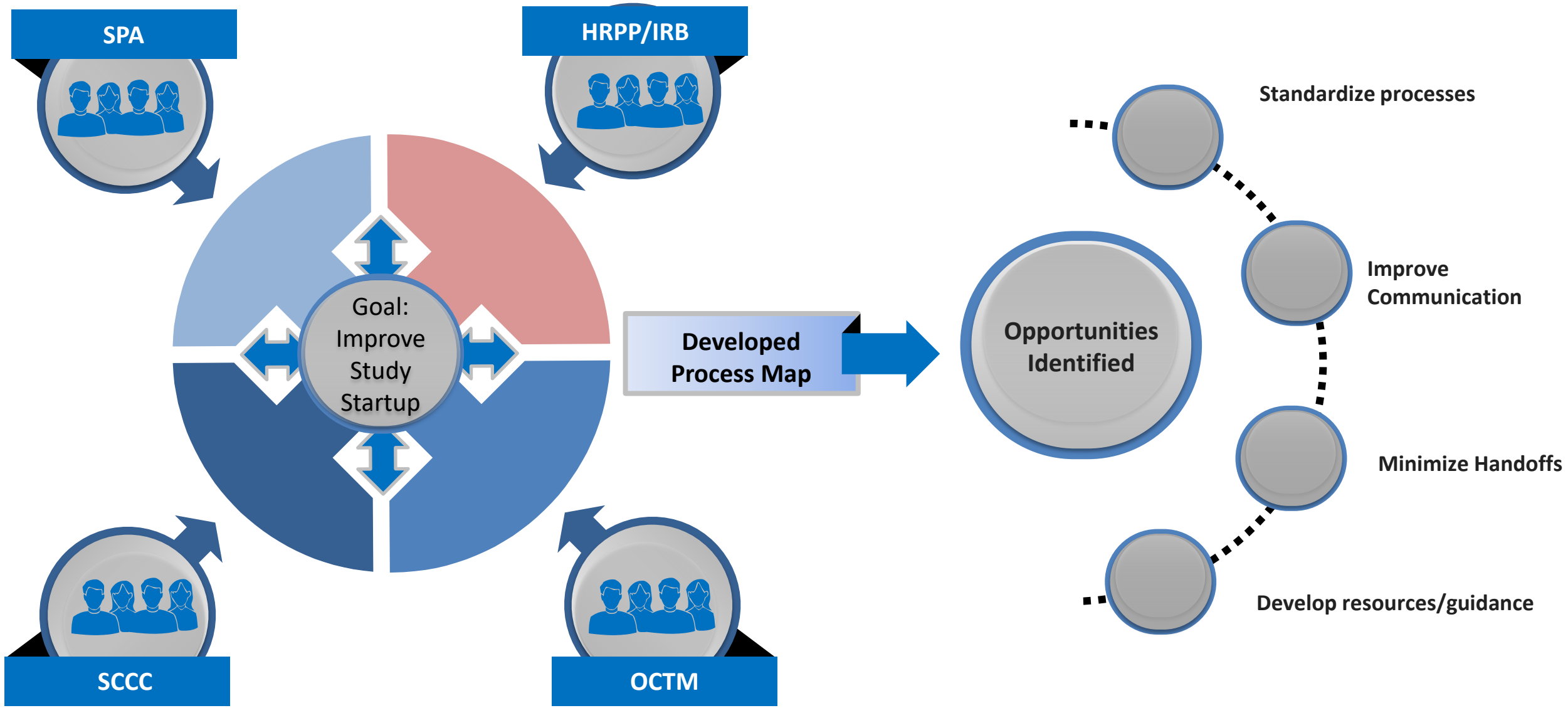
Website

Forms

eIRB System

Study Startup - QI Project

Supported by CTSA, Office of Clinical Research



Challenges, Changes, and Accomplishments

Challenges

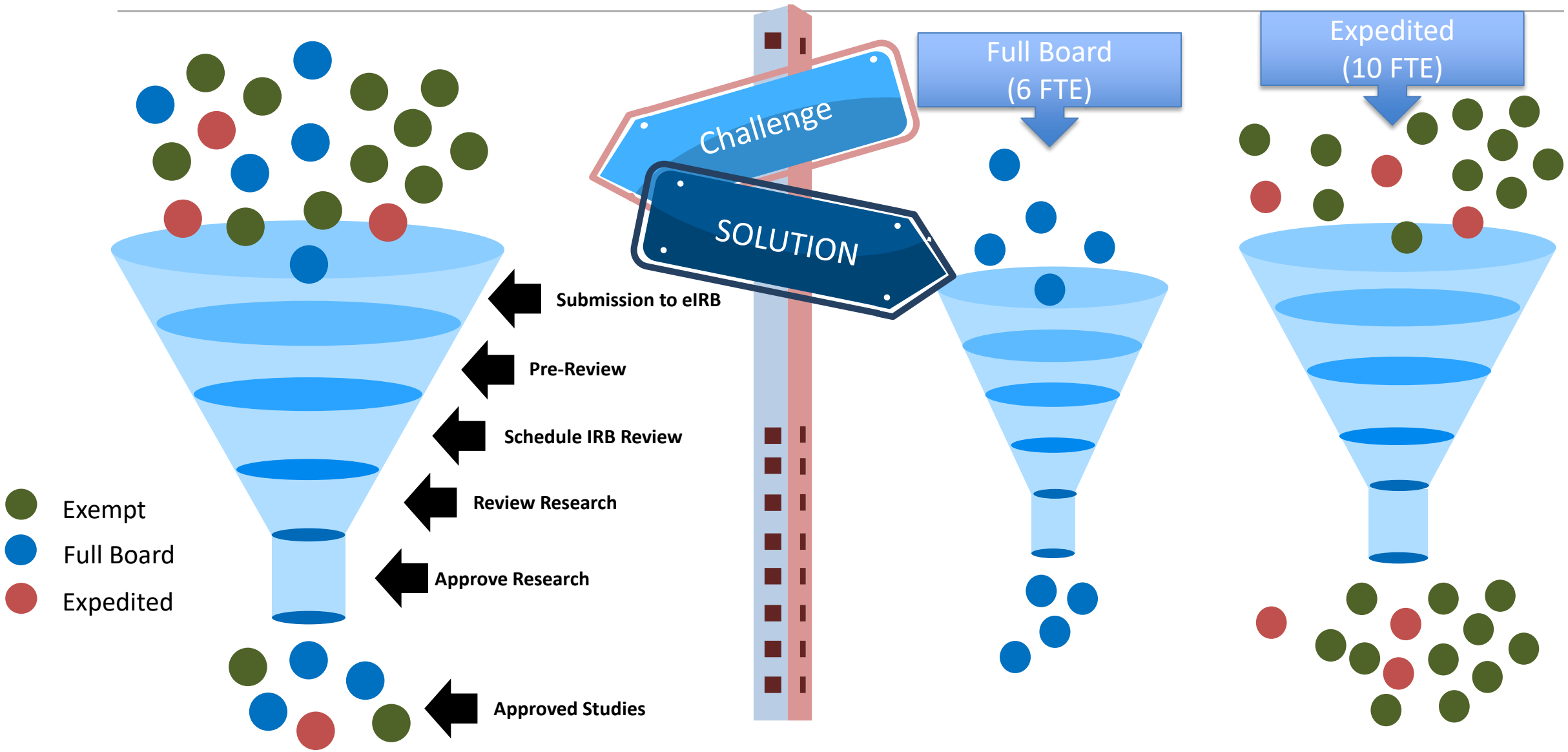
2023 Challenges

STAFF VACANCIES

STUDY BACKLOG

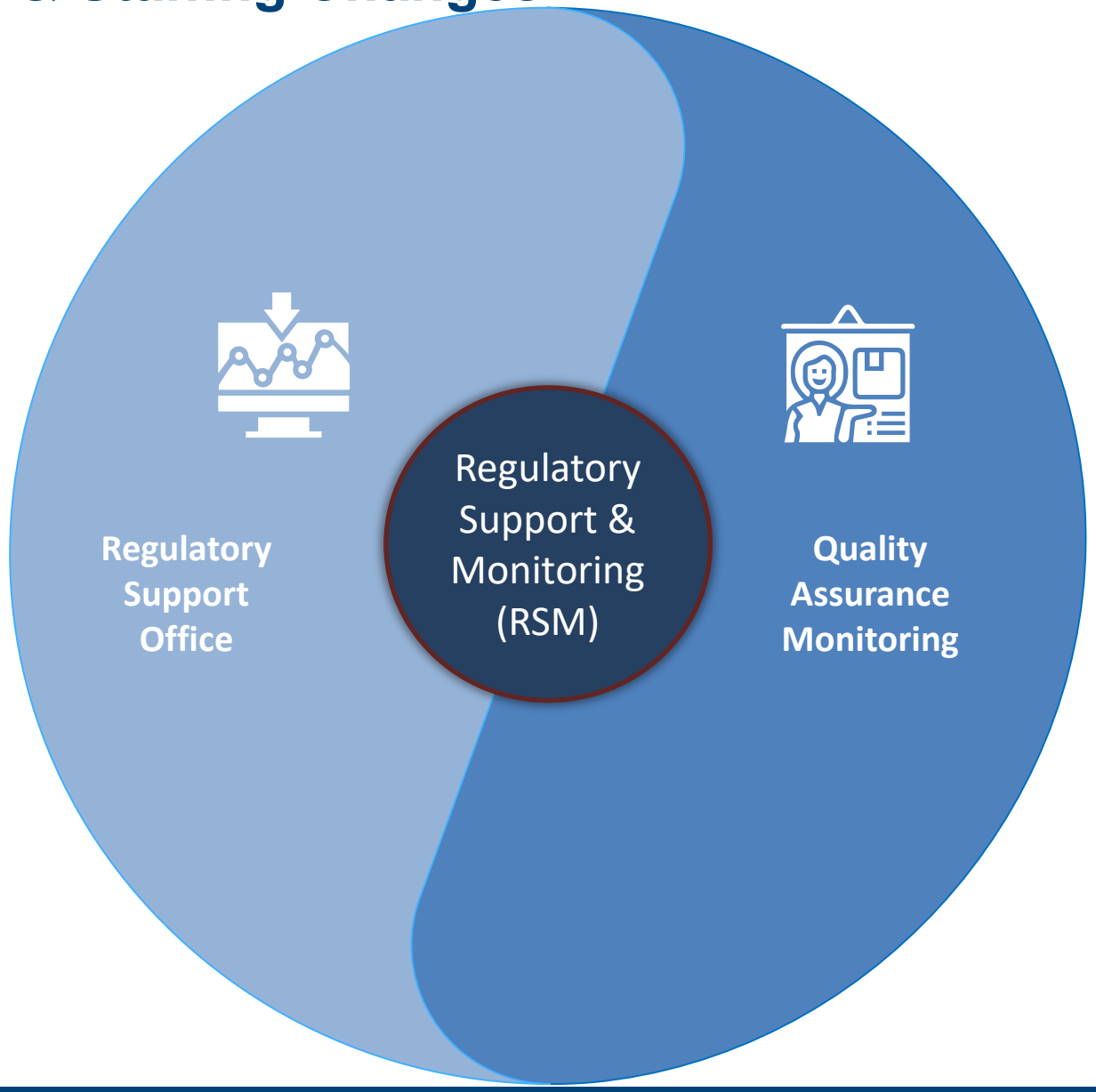
DECREASED IRB TURNAROUND TIMES

2023 IRB Backlog



Change

Office & Staffing Changes



Personnel Changes

Kimberly Mapes
Director, Regulatory Support and Monitoring
(new office)

Erik Soliz
IRB Manager
(new position)

Hend Nadim
HRPP Program Manager - Expedited
(Replaced Chuck Akers *retired*)

Manali Thakkar
HRPP Program Manager - Full Board
(Replaced Kimberly Mapes *promoted*)

Tara Garcia
HRPP Program Manager - Full Board
(new position)

Sandra Morones
Clinical Research Educator
Moved to OCR
(still affiliated with HRPP)

Raj Varadarajan
Regulatory Scientist
Moved to Pediatrics – Gene Therapy
(no longer with HRPP)

Accomplishments

2023 Accomplishments

Key Achievements

Decreased Non-Committee Turnaround

Restructured IRB Office
Exempt 12 days (Nov ‘23)
Expedited 20 Days (Nov ‘23)

3

Cleared IRB Backlog

Hired Advarra (short term)
Cleared >370 minimal risk submissions

2

Study Initiation Reviews (QAM)

Early QA review of studies
June 2023

4

FDA Inspection - IRB

No findings
February 2023

1

CRC Foundations Course

Courses, videos, handbook
July 2023

5

Clinical Research Education – Feedback

"…there was no clear training plan or format, I was trained by the person who was retiring but she was ill equipt to ensure all necessary training was advised…"

"While this training was very informative and helpful, I could have used it **much earlier** in my time here."

"…the training was laid out in an **understandable fashion** and continued to build on the foundation of the original courses. It was great to see repeating information that would jog my memory because it helped me with progressing toward more knowledge in latter courses".

"There should be **hands on training/classes** available when needed."

"…in the interest of uniformity, this training should be mandatory for everyone involved in research, no matter how long they have been on staff"

*"…a **condensed version** of the take home points for each module that can be saved for future reference would be excellent"*

*"There should be a **lead contact person** who has experience in clinical research who can help with questions, concerns or percept new employees and others when help is needed"*

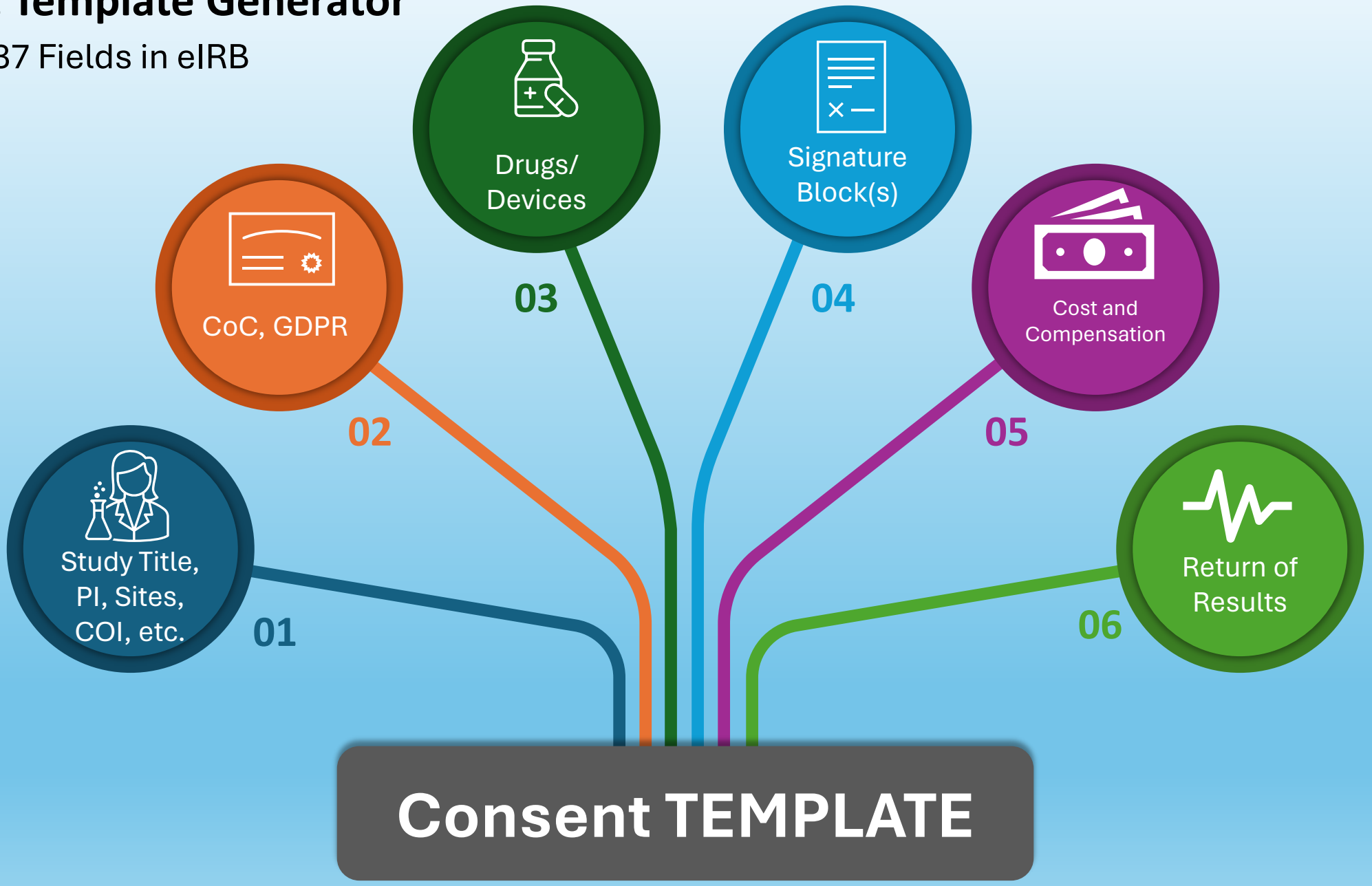
Current Projects

Consent Template Generator

Supported by CTSA

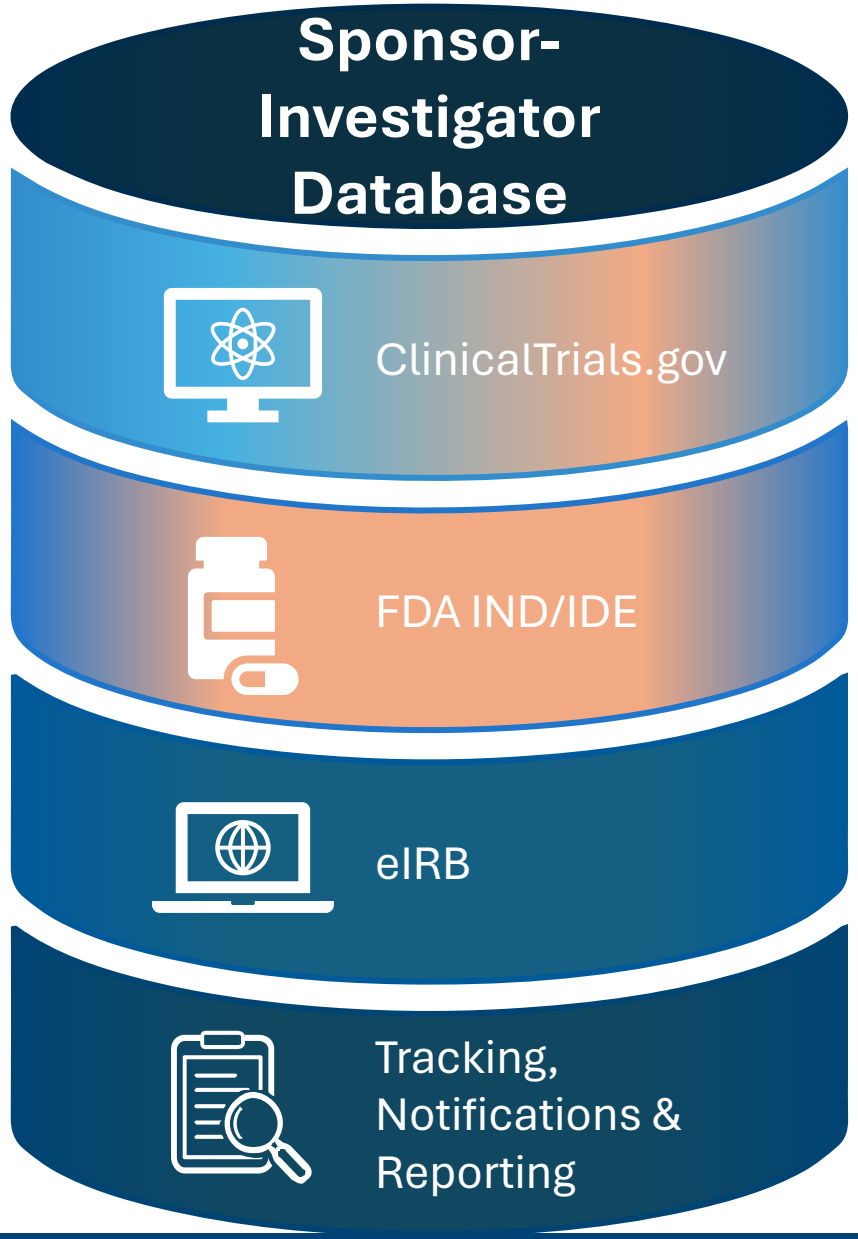
Consent Template Generator

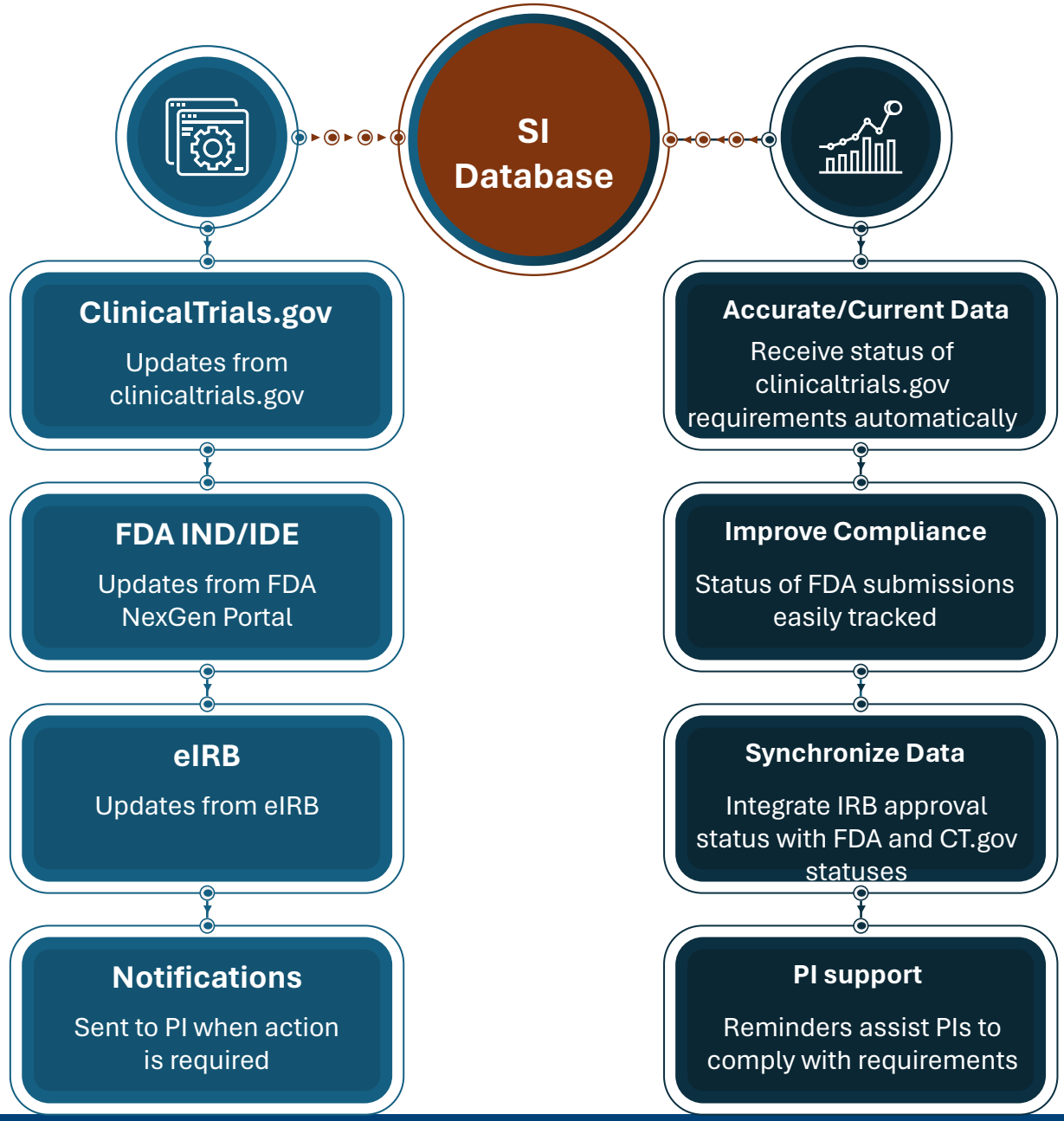
Linked to 37 Fields in eIRB



SI Database

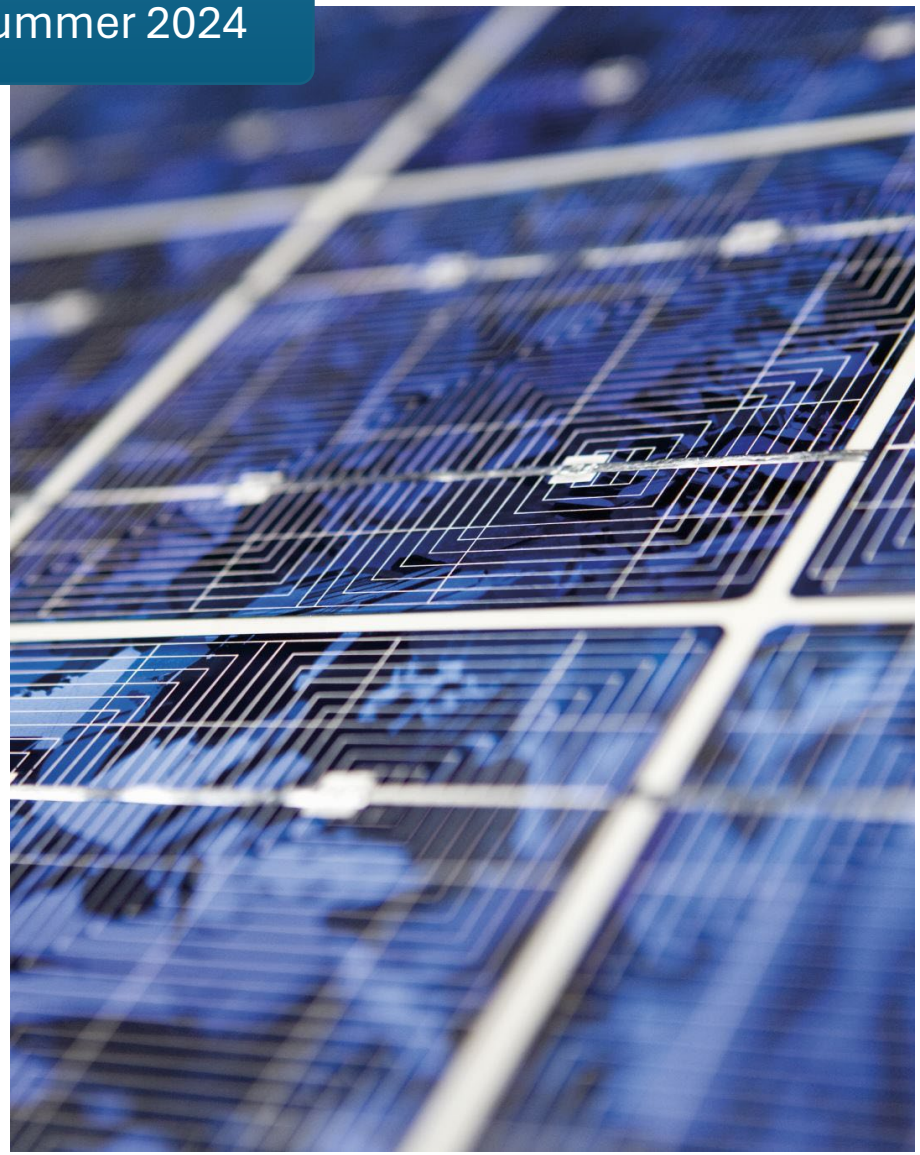
Supported by CTSA


Sponsor-Investigator Database
ClinicalTrials.gov
FDA IND/IDE
eIRB
Tracking, Notifications & Reporting


SI Database
ClinicalTrials.gov
Updates from clinicaltrials.gov
FDA IND/IDE
Updates from FDA NexGen Portal
eIRB
Updates from eIRB
Notifications
Sent to PI when action is required
Accurate/Current Data
Receive status of clinicaltrials.gov requirements automatically
Improve Compliance
Status of FDA submissions easily tracked
Synchronize Data
Integrate IRB approval status with FDA and CT.gov statuses
PI support
Reminders assist PIs to comply with requirements

eIRB System

Coming Soon
Summer 2024



eIRB system redesign

FEATURE

- Submission in eIRB
- CRU Approval changes
- Leverage REDCap for non-eIRB users
- Includes all project types
- Eliminate most Word attachments
- Notifications to ad-hoc email addresses

FEATURE

- sIRB Portal
- Improved Document Management
- Integration with eGrants, eAgreements
- Reliance Request Activity
- Modification to study SmartForm
- Auto-generated letters for NHR Projects (form Y1)

REDCap Part 11

REDCap 21 CFR Part 11 Certification

FDA Requirement

Collection and storage electronic data

- *Not certified for electronic signatures (e.g., informed consent)*

Requires additional training by study teams

iMed Consent

iMed Consent

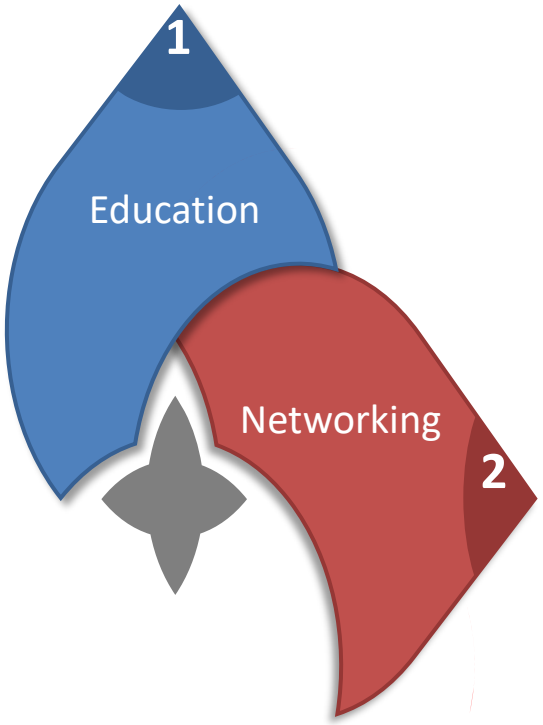
- Epic-housed application
- Allows for electronic consenting of patients
- HIPAA compliant
- 21 CFR Part 11 Compliant
- Captures electronic signatures
- Signed informed consent immediately stored in participant's Epic medical record
- Point-of-care and mobile sign capabilities

Clinical Research Coordinator Education and Events

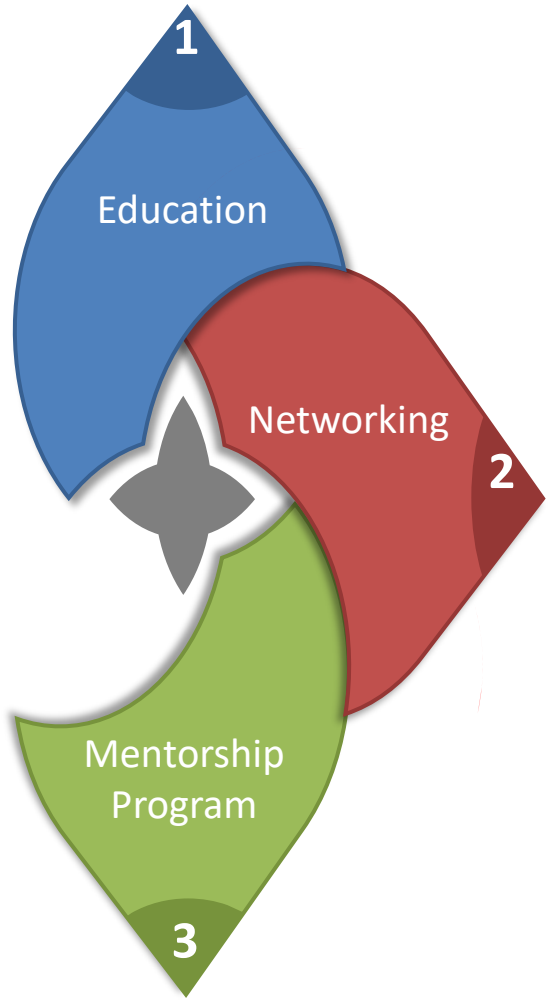
Supported by CTSA

Clinical Research Coordinator Workforce Development

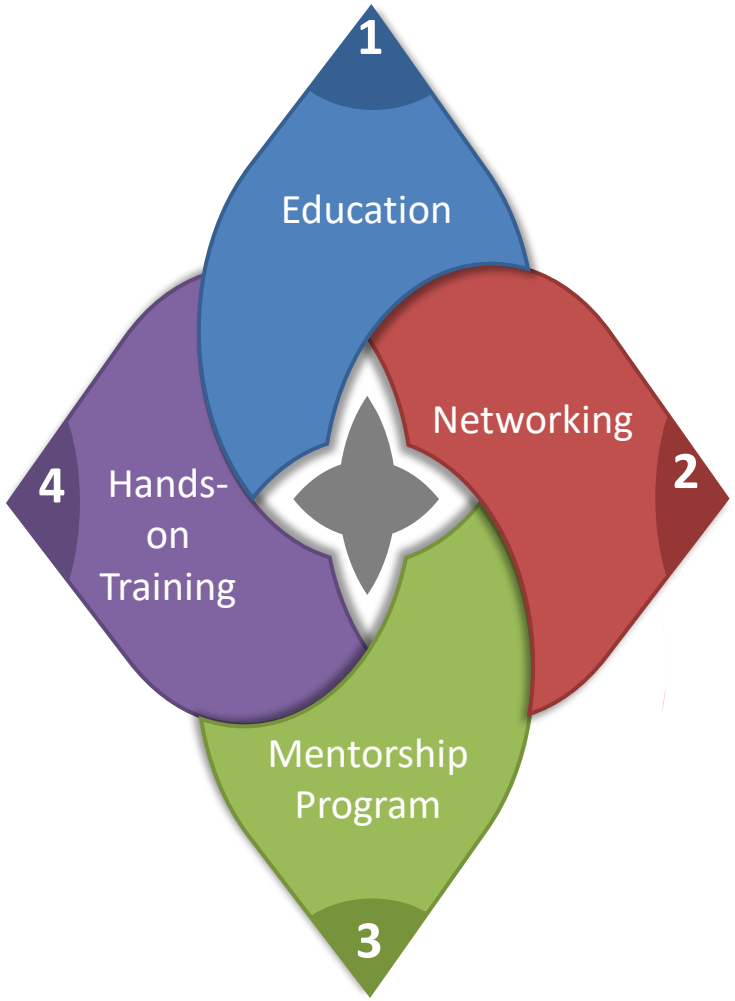
Clinical Research Coordinator Workforce Development



Clinical Research Coordinator Workforce Development

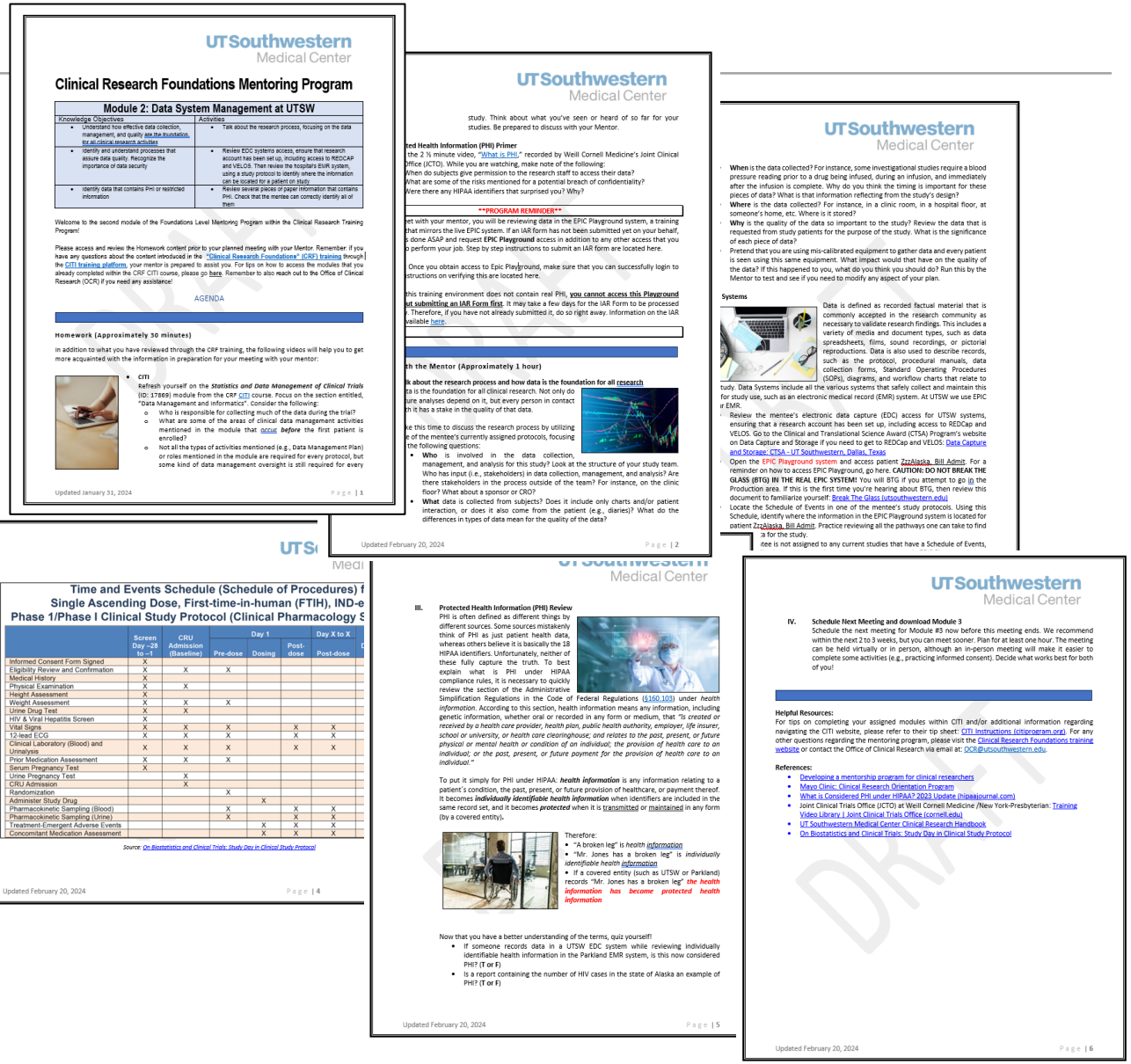


Clinical Research Coordinator Workforce Development



CRC Mentorship Program

- Mentee/Mentor Matching
- 4 month Program
- Six Modules
- Activity booklet for each module
- Hands on learning
- Networking



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Clinical Research Foundations Mentoring Program

Module 2: Data System Management at UTSW

Knowledge Objectives	Activities
• Understand how effective data collection, management, and quality are the foundation for all clinical research activities	• Talk about the research process, focusing on the data
• Identify and understand processes that assure data quality. Recognize the importance of data security	• Review EDC systems access, ensure that research account has been set up, including access to REDCAP and VELOS. Then review the hospital's EMR system, using a study protocol to identify where the information can be located for a patient on study
• Identify data that contains PHI or restricted information	• Review several pieces of paper information that contains PHI. Check that the mentee can correctly identify all of them

Welcome to the second module of the Foundations Level Mentoring Program within the Clinical Research Training Program!

Please access and review the Homework content prior to your planned meeting with your Mentor. Remember if you have any questions about the content introduced in the "Clinical Research Foundations" (CRF) training through the CITI training platform, your mentor is prepared to assist you. For tips on how to access the modules that you already completed within the CRF CITI course, please go here. Remember to also reach out to the Office of Clinical Research (OCR) if you need any assistance!

AGENDA

Homework (Approximately 30 minutes)

In addition to what you have reviewed through the CRF training, the following videos will help you to get more acquainted with the information in preparation for your meeting with your mentor:

- **CITI**
  Refresh yourself on the ***Statistics and Data Management of Clinical Trials*** (ID: 17869) module from the CRF CITI course. Focus on the section entitled, "Data Management and Informatics". Consider the following:
  - Who is responsible for collecting much of the data during the trial?
  - What are some of the areas of clinical data management activities mentioned in the module that occur ***before*** the first patient is enrolled?
  - Not all the types of activities mentioned (e.g., Data Management Plan) or roles mentioned in the module are required for every protocol, but some kind of data management oversight is still required for every

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study. Think about what you've seen or heard of so far for your studies. Be prepared to discuss with your Mentor.

ted Health Information (PHI) Primer

the 2 ½ minute video, "What is PHI," recorded by Weill Cornell Medicine's Joint Clinical Office (JCTO). While you are watching, make note of the following:
When do subjects give permission to the research staff to access their data?
What are some of the risks mentioned for a potential breach of confidentiality?
Were there any HIPAA identifiers that surprised you? Why?

****PROGRAM REMINDER****

et with your mentor, you will be reviewing data in the EPIC Playground system, a training that mirrors the live EPIC system. If an IAR form has not been submitted yet on your behalf, s done ASAP and request **EPIC Playground** access in addition to any other access that you o perform your job. Step by step instructions to submit an IAR form are located here.

Once you obtain access to Epic Playground, make sure that you can successfully login to structions on verifying this are located here.

his training environment does not contain real PHI, **you cannot access this Playground ut submitting an IAR Form first**. It may take a few days for the IAR Form to be processed . Therefore, if you have not already submitted it, do so right away. Information on the IAR vailable here.

th the Mentor (Approximately 1 hour)

k about the research process and how data is the foundation for all research
ta is the foundation for all clinical research. Not only do ure analyses depend on it, but every person in contact h it has a stake in the quality of that data.

ke this time to discuss the research process by utilizing e of the mentee's currently assigned protocols, focusing the following questions:

- **Who** is involved in the data collection, management, and analysis for this study? Look at the structure of your study team. Who has input (i.e., stakeholders) in data collection, management, and analysis? Are there stakeholders in the process outside of the team? For instance, on the clinic floor? What about a sponsor or CRO?
- **What** data is collected from subjects? Does it include only charts and/or patient interaction, or does it also come from the patient (e.g., diaries)? What do the differences in types of data mean for the quality of the data?

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- **When** is the data collected? For instance, some investigational studies require a blood pressure reading prior to a drug being infused, during an infusion, and immediately after the infusion is complete. Why do you think the timing is important for these pieces of data? What is that information reflecting from the study's design?
- **Where** is the data collected? For instance, in a clinic room, in a hospital floor, at someone's home, etc. Where is it stored?
- **Why** is the quality of the data so important to the study? Review the data that is requested from study patients for the purpose of the study. What is the significance of each piece of data?
- Pretend that you are using mis-calibrated equipment to gather data and every patient is seen using this same equipment. What impact would that have on the quality of the data? If this happened to you, what do you think you should do? Run this by the Mentor to test and see if you need to modify any aspect of your plan.

Systems

Data is defined as recorded factual material that is commonly accepted in the research community as necessary to validate research findings. This includes a variety of media and document types, such as data spreadsheets, films, sound recordings, or pictorial reproductions. Data is also used to describe records, such as the protocol, procedural manuals, data collection forms, Standard Operating Procedures (SOPs), diagrams, and workflow charts that relate to tudy. Data Systems include all the various systems that safely collect and maintain this for study use, such as an electronic medical record (EMR) system. At UTSW we use EPIC r EMR.

- Review the mentee's electronic data capture (EDC) access for UTSW systems, ensuring that a research account has been set up, including access to REDCap and VELOS. Go to the Clinical and Translational Science Award (CTSA) Program's website on Data Capture and Storage if you need to get to REDCap and VELOS: Data Capture and Storage: CTSA - UT Southwestern, Dallas, Texas
- Open the EPIC Playground system and access patient ZzzAlaska, Bill Admit. For a reminder on how to access EPIC Playground, go here. **CAUTION: DO NOT BREAK THE GLASS (BTG) IN THE REAL EPIC SYSTEM!** You will BTG if you attempt to go in the Production area. If this is the first time you're hearing about BTG, then review this document to familiarize yourself: Break The Glass (utsouthwestern.edu)
- Locate the Schedule of Events in one of the mentee's study protocols. Using this Schedule, identify where the information in the EPIC Playground system is located for patient ZzzAlaska, Bill Admit. Practice reviewing all the pathways one can take to find a for the study.

tee is not assigned to any current studies that have a Schedule of Events,

UTS… Medi…

Time and Events Schedule (Schedule of Procedures) f
Single Ascending Dose, First-time-in-human (FTIH), IND-e
Phase 1/Phase I Clinical Study Protocol (Clinical Pharmacology S

	Screen Day −28 to −1	CRU Admission (Baseline)	Day 1			Day X to X	
			Pre-dose	Dosing	Post-dose	Post-dose	D
Informed Consent Form Signed	X						
Eligibility Review and Confirmation	X	X	X				
Medical History	X						
Physical Examination	X	X					
Height Assessment	X						
Weight Assessment	X	X	X				
Urine Drug Test	X	X					
HIV & Viral Hepatitis Screen	X						
Vital Signs	X	X	X		X	X	
12-lead ECG	X	X	X		X	X	
Clinical Laboratory (Blood) and Urinalysis	X	X	X		X	X	
Prior Medication Assessment	X	X	X				
Serum Pregnancy Test	X						
Urine Pregnancy Test		X					
CRU Admission		X					
Randomization			X				
Administer Study Drug				X			
Pharmacokinetic Sampling (Blood)			X		X	X	
Pharmacokinetic Sampling (Urine)			X		X	X	
Treatment-Emergent Adverse Events				X	X	X	
Concomitant Medication Assessment				X	X	X	

Source: On Biostatistics and Clinical Trials: Study Day in Clinical Study Protocol

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III. Protected Health Information (PHI) Review

PHI is often defined as different things by different sources. Some sources mistakenly think of PHI as just patient health data, whereas others believe it is basically the 18 HIPAA identifiers. Unfortunately, neither of these fully capture the truth. To best explain what is PHI under HIPAA compliance rules, it is necessary to quickly review the section of the Administrative Simplification Regulations in the Code of Federal Regulations (§160.103) under *health information*. According to this section, health information means any information, including genetic information, whether oral or recorded in any form or medium, that *"Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."*

To put it simply for PHI under HIPAA: ***health information*** is any information relating to a patient's condition, the past, present, or future provision of healthcare, or payment thereof. It becomes ***individually identifiable health information*** when identifiers are included in the same record set, and it becomes ***protected*** when it is transmitted or maintained in any form (by a covered entity).

Therefore:
- "A broken leg" is *health information*
- "Mr. Jones has a broken leg" is *individually identifiable health information*
- If a covered entity (such as UTSW or Parkland) records "Mr. Jones has a broken leg" ***the health information has become protected health information***

Now that you have a better understanding of the terms, quiz yourself!
- If someone records data in a UTSW EDC system while reviewing individually identifiable health information in the Parkland EMR system, is this now considered PHI? **(T or F)**
- Is a report containing the number of HIV cases in the state of Alaska an example of PHI? **(T or F)**

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IV. Schedule Next Meeting and download Module 3

Schedule the next meeting for Module #3 now before this meeting ends. We recommend within the next 2 to 3 weeks, but you can meet sooner. Plan for at least one hour. The meeting can be held virtually or in person, although an in-person meeting will make it easier to complete some activities (e.g., practicing informed consent). Decide what works best for both of you!

Helpful Resources:
For tips on completing your assigned modules within CITI and/or additional information regarding navigating the CITI website, please refer to their tip sheet: CITI Instructions (citiprogram.org). For any other questions regarding the mentoring program, please visit the Clinical Research Foundations training website or contact the Office of Clinical Research via email at: OCR@utsouthwestern.edu.

References:
- "Developing a mentorship program for clinical researchers
- Mayo Clinic: Clinical Research Orientation Program
- What is Considered PHI under HIPAA? 2023 Update (hipaajournal.com)
- Joint Clinical Trials Office (JCTO) at Weill Cornell Medicine /New York-Presbyterian: Training Video Library | Joint Clinical Trials Office (cornell.edu)
- UT Southwestern Medical Center Clinical Research Handbook
- On Biostatistics and Clinical Trials: Study Day in Clinical Study Protocol

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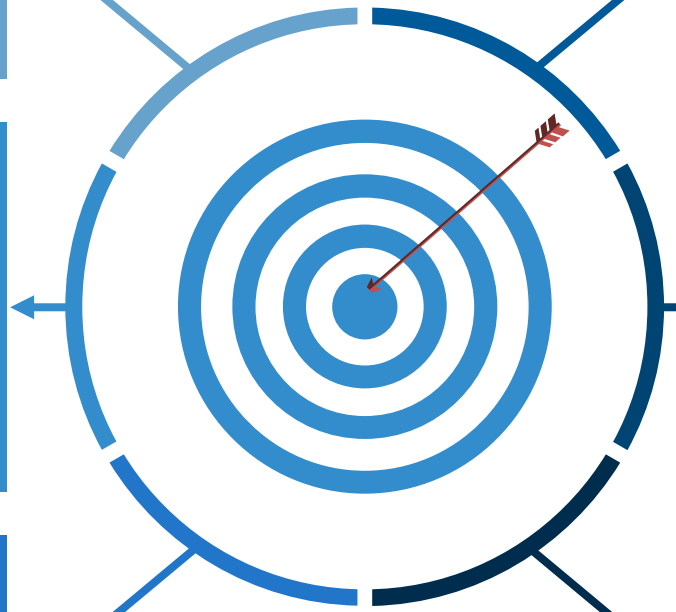
2024: What's next?

2024 Initiatives

- eIRB New System
- Consent Template Generator
- iMed Consent
- REDCap Part 11
- CRC Education and Events
- Decrease in Study Startup Times



Have ideas for future Research Matters topics?

Let us know!

HRPP@UTSouthwestern.edu

Thank you!

- **We'd love to hear your feedback.** We invite you to provide your evaluation of Research Matters and of the Human Research Protection Program.

- Visit: https://ais.swmed.edu/redcap/surveys/?s=3PRJFCFJJW