

Navigating the Pitfalls of Research Compliance Auditing



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- We have no conflicts of interest related to this presentation.
- The opinions expressed are our own and do not necessarily reflect the views of our employers, colleagues, or friends.
- The information, thoughts, and opinions provided here are not legal advice: consult your institution's legal, compliance, and other appropriate leaders and, at their discretion, your local Medicare Administrative Contractor (MAC), for any specific billing questions or issues.

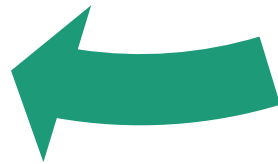
Home of
Florida's
largest clinical
cancer
research unit



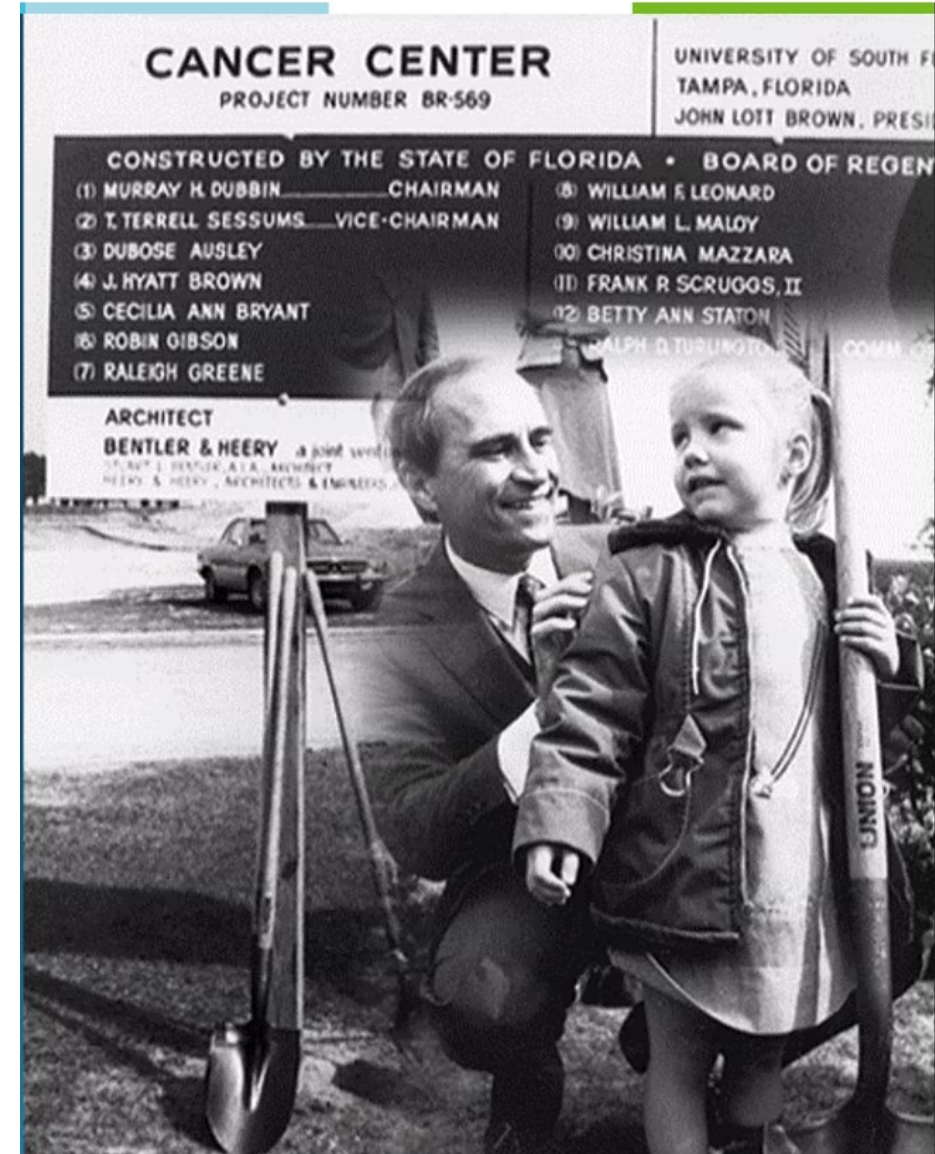
Established by
the Florida
legislature in
1981



Named after
H. Lee Moffitt,
former Florida
speaker of the
house



**One of only 52
NCI
designated
cancer centers**



Research

Moffitt's research focuses on cutting-edge discoveries that can be rapidly translated into improved diagnostic, preventive and therapeutic advances.

\$339M+

Global & Extramural Funding

\$588M+

State, Federal & Commercial
Grants

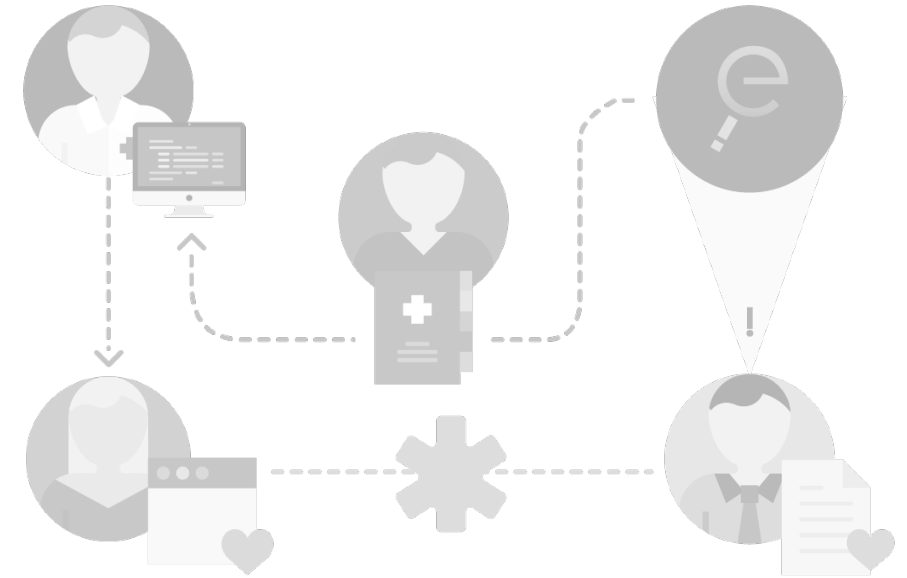
1. Cancer Biology and Evolution
2. Cancer Epidemiology
3. Health Outcomes and Behavior
4. Immuno-Oncology
5. Molecular Medicine



Research Impact

> 100 Observational protocols & > 27,000 observational accruals

1,727 +
Clinical Trial Accruals Annually



600+ Active Interventional Trials

40% Overall Accruals to Investigator-initiated studies

Future

Moffitt Cancer Center introduces “Speros FL,” Its 775-acre Pasco County Global Innovation Center

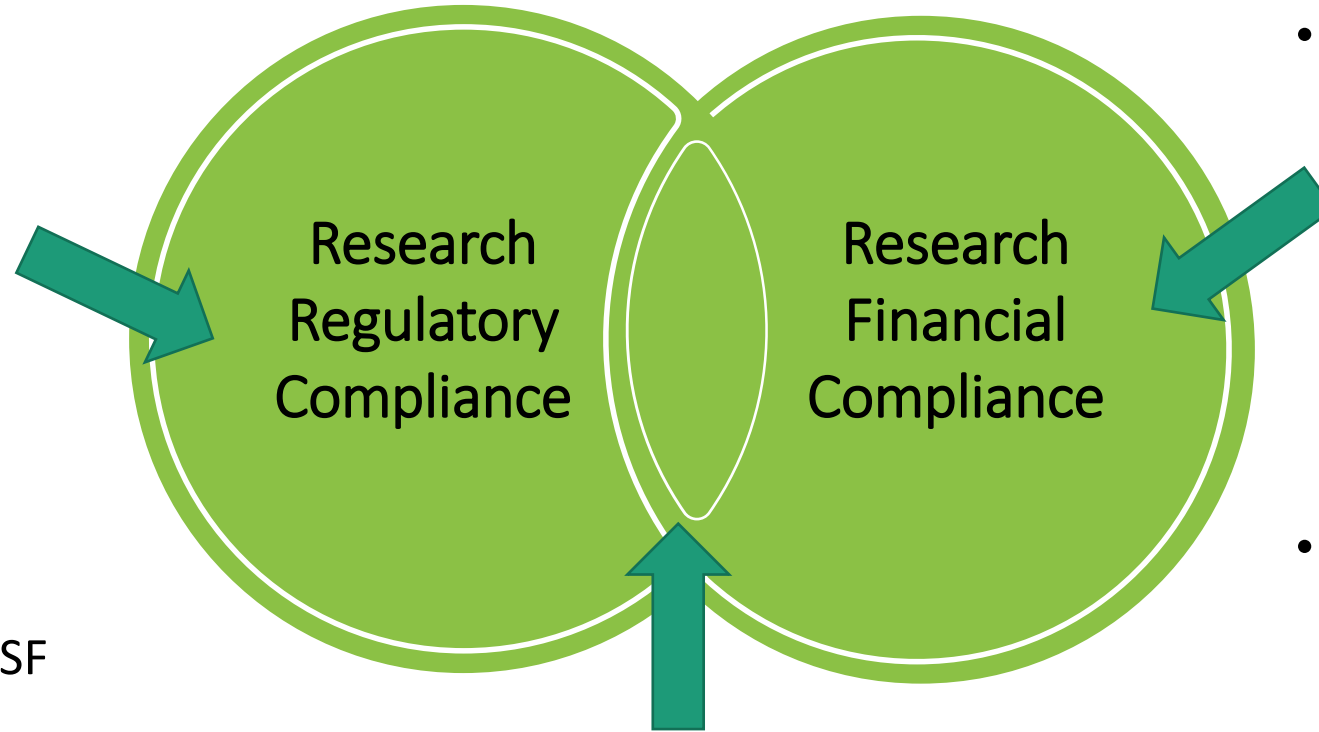
Featuring 16 million square feet of lab, office, manufacturing and clinical space, with potential to add classrooms, teaching kitchens, health clubs and a performing arts center.

“Speros” - a derivative of “Sperare,” meaning “to hope” or “to look forward to”



Moffitt Research Compliance

- Study Audits
- Research Misconduct
- Research Data Concerns
- Research Record Retention & Disposal
- Academic Collaboration – USF
- More!



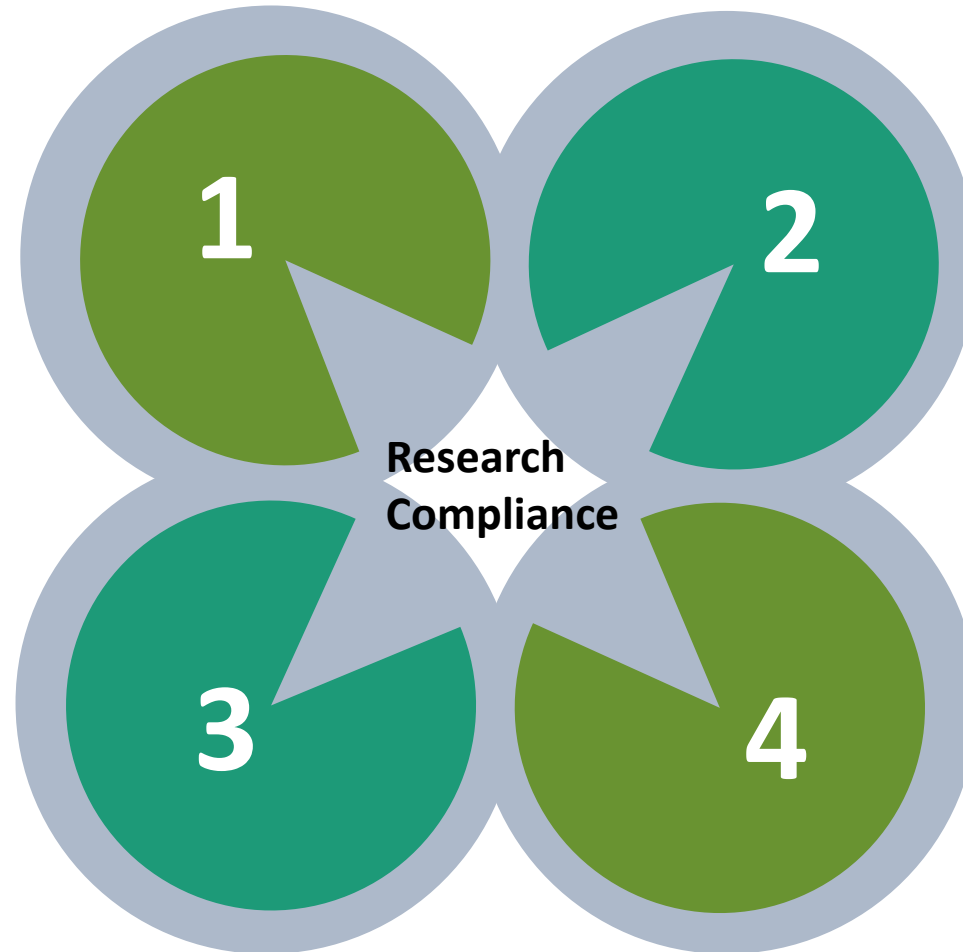
- Research Operations
- Research Finance
- Office of Sponsored Research
- Clinical Trials Business Office
- Revenue Cycle
- Research Leadership

- Research Financial Audits
 - Study Start-up
 - Research Finance
 - Clinical Research Billing
 - Informed consent & subject injury
- Grants Management
 - Budgeting
 - Subawards
 - Cost allocation
- Education
- More!

Moffitt Research Compliance Program

CORE FUNCTION

Policies
Education
Audits
Guidance Requests
Emerging Issues



CROSS-OVER WITH OTHER AREAS OF COMPLIANCE

Billing & Coding
Privacy
COI & Foreign Influence

COLLABORATIONS WITH OTHER INSTITUTIONAL DEPTS

Revenue Cycle
Research Compliance Attorney
Internal Audit

Research Operations

- Research Leadership
- Clinical Trials Office
- Non-Therapeutics Research Office
- Research Finance & OSR
- Clinical Trials Business Office

OTHER REGULATORY COMPLIANCE

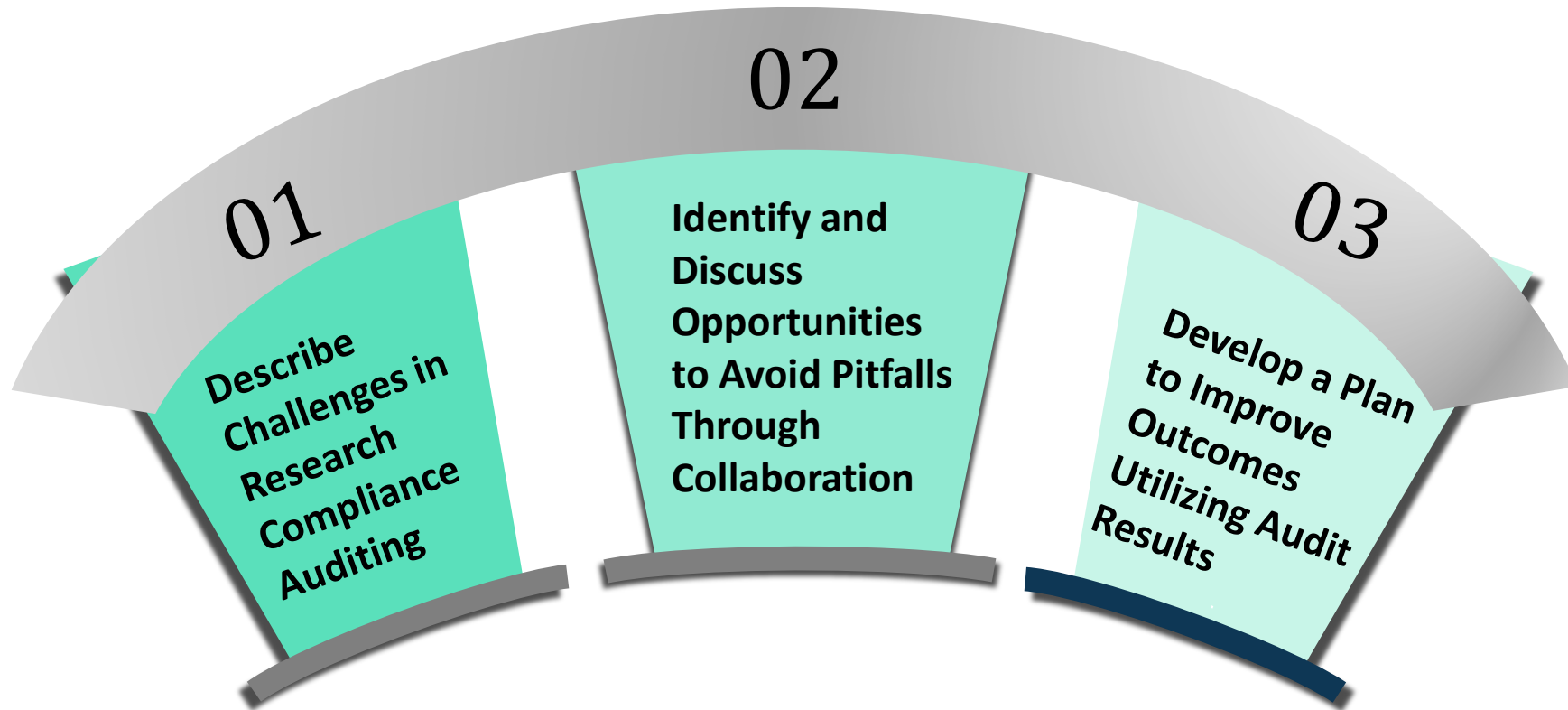
Research Misconduct
Research Data Concerns
Research Record Retention & Disposal
Academic Collaboration - USF

Audience Discussion



- How many of you conduct Research Regulatory Audits?
- How many of you conduct Research Finance/Clinical Research Billing Audits?
- How many of you conduct both types of audits?
- How many of you are new to research (less than 1 year)?
- How many of you have 10 or more employees that report to you?
- How many of you have between 2 & 9 employees?
- How many of you are the sole employee of the department?

Objectives



Describe Challenges in Research Compliance Auditing

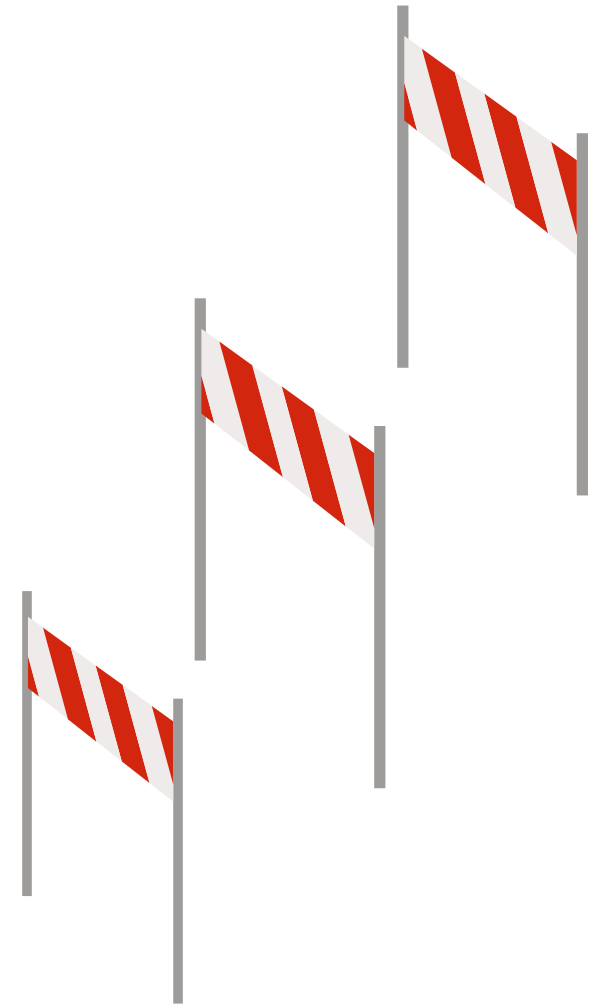
THAT WORD...

AUDIT



Challenges & Pitfalls to Successful Compliance Auditing

- Fearing the Audit
- Silos
- Lack of Communication
- Adherence to Good Clinical Practice
- FDA Inspection Readiness
- Clinical Research Billing Operations
- Lack of/Unclear Policies
- Lack of Institutional Compliance Support
- Staffing Issues
- Complex Processes/Procedures
- Competing Priorities
- Lack of Education/Training

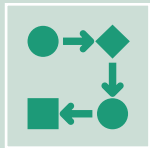


What more can you think of?



Identify Anticipated Pitfalls

Areas of prior failure
Auditor limitations
(knowledge/access)



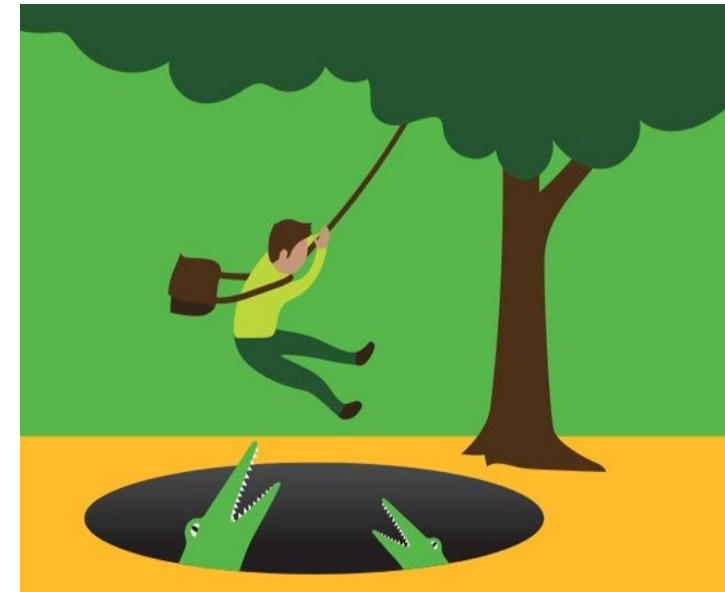
Follow the Data

Process start to finish
Use uniform
metrics/attributes



Expect the Unexpected

Unanticipated
findings inform the
most



Avoiding Pitfalls with Preparation

- Define Success
 - Clarify Scope limitations
 - Expectations
 - Adherence to federal regulations
 - Understand institutional risk tolerance
 - Risk reduction
 - Institutional policy or procedure conformity
 - Decreased non-compliance



Avoid Pitfalls by Planning



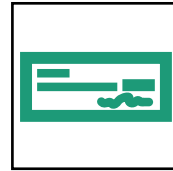
Define the audit

Scope,
population, date
range,
organization of
the fieldwork,
timeline



Audit Type

For Cause,
Limited Scope,
Full Scope



Audit Focus

Type of Audit



SCOPE

What are the
attributes of the
audit?

Are they clear to
stakeholders?



Randomization

Find the population
and then randomize
based on selected
criteria



Poor Metrics

Goals not clearly defined

Timelines

Difficulty measuring growth

What story does the data tell?

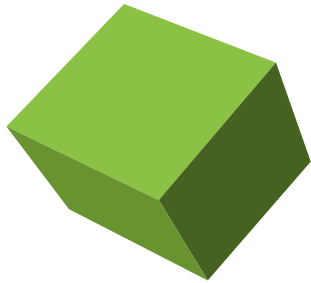
Are there actionable outcomes?

Will others understand the scope?

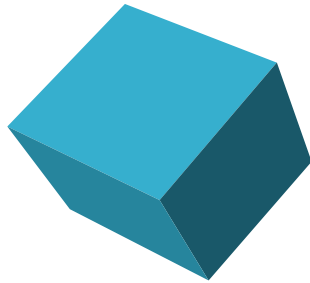
Delivery of findings

Polling Question #1

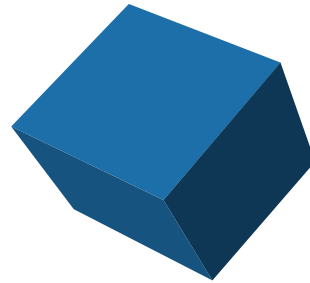
What are the Top Challenges/Pitfalls that You Face?



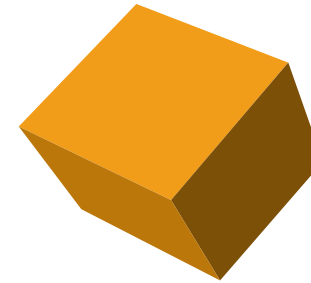
SILOS



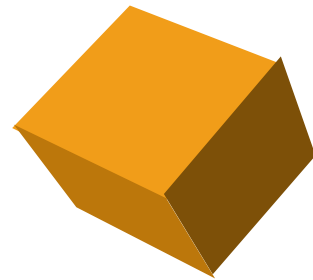
Lack of
Communication



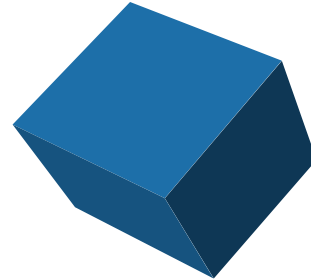
Lack of
Compliance
Support



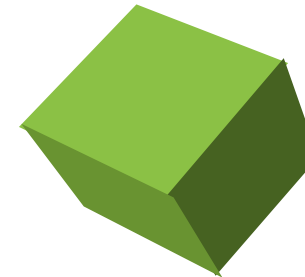
Staffing Issues



Unclear Policies

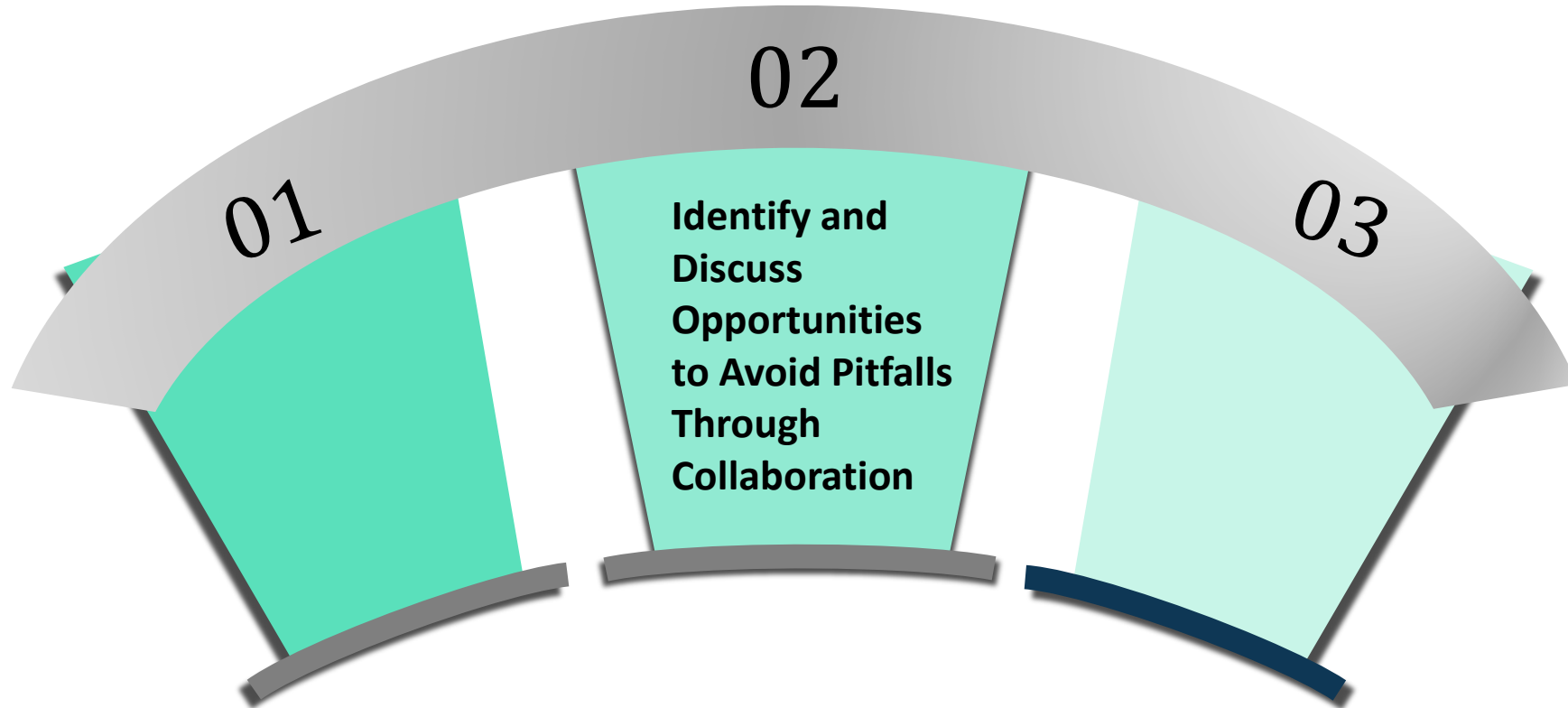


Complex
Procedures



Lack of
Education

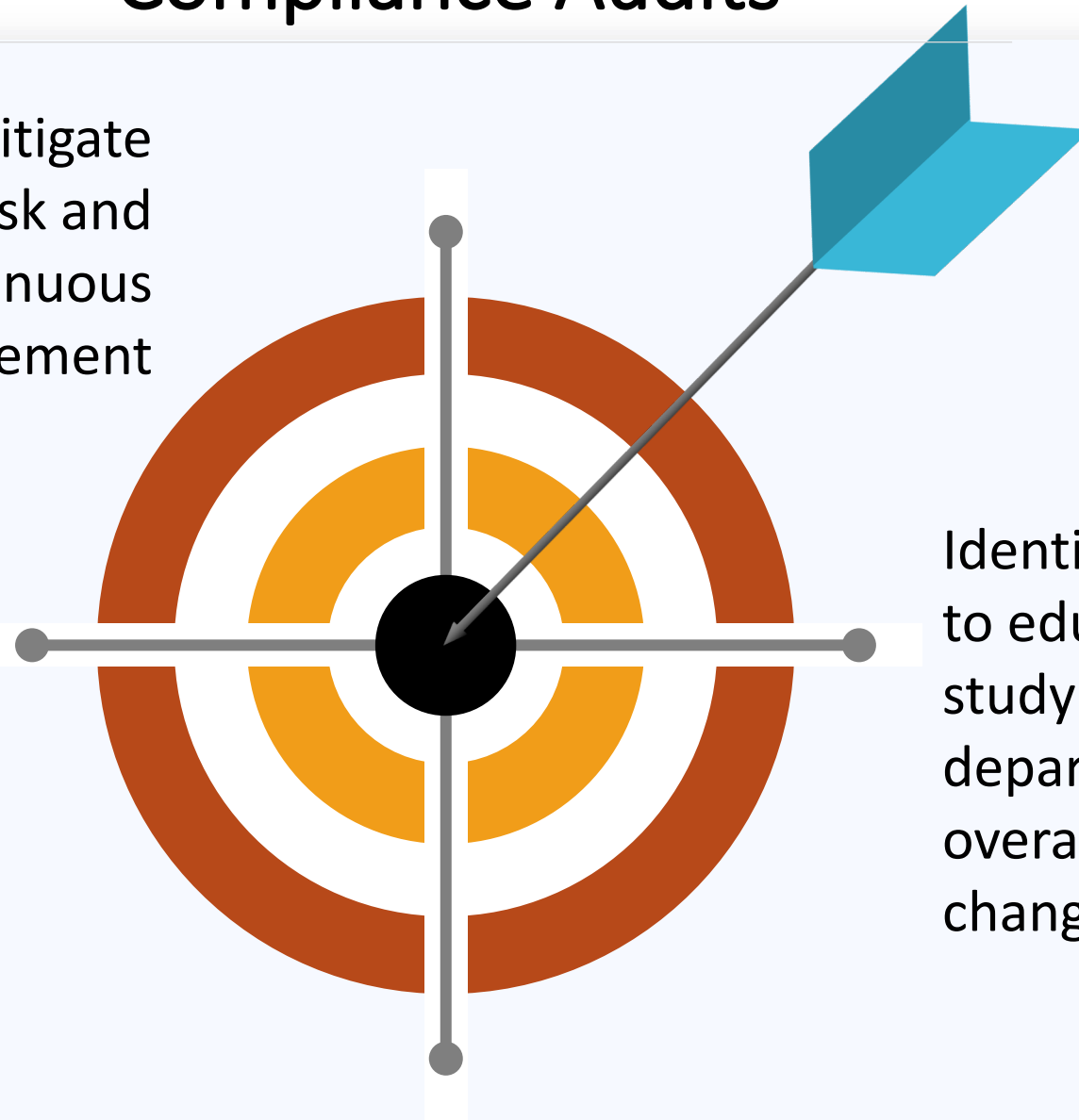
Objectives



Compliance Audits

Identify/mitigate institutional risk and foster continuous improvement

Ensure appropriate oversight, accurate financial decisions, process improvement, & regulatory compliance



Identify opportunities to educate individual study teams or departments & make overall institutional changes

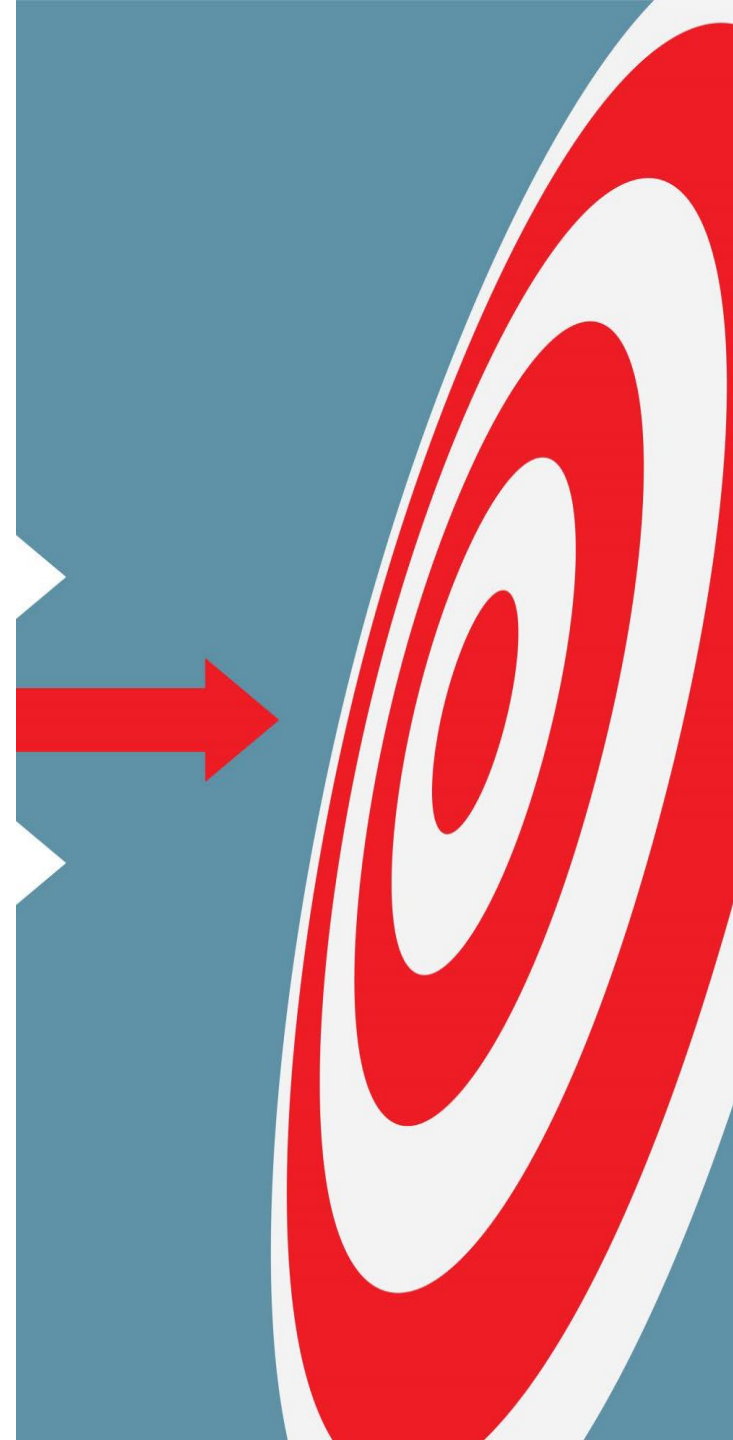
Goals of the Audit

- Identify the goal(s)
 - Testing controls (like classic Internal Audit)
 - Life of CRB
 - Identify cross-departmental process and communication gaps
 - For-cause
- Could be combination of goals
- Could be a risk assessment to level-set stratification
 - Never been audited
 - Significant institutional change
 - Corrective action controls post-change



Scope of the Audit

- For-cause
- Issues identified during Risk assessment
- Never been audited
- Significant institutional change
- Corrective action controls post-change
- Post audit monitoring



Opportunities to Avoid Pitfalls Through Collaboration

Staffing Issues

- Define true risk
- Audit Scope - Focused audit vs. full scoped audit
- Collaboration with individual QA initiatives
- Extend CAPA due dates



Opportunities to Avoid Pitfalls Through Collaboration

Organizational
Meetings

Education

Visibility

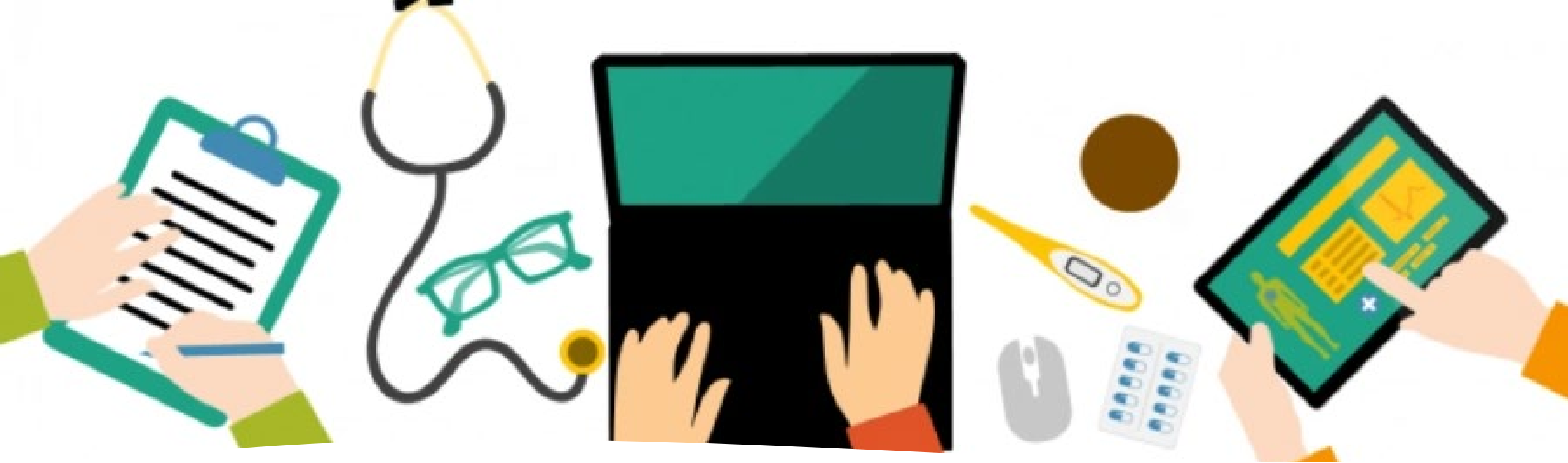
Compliance
Intranet



Institutional Compliance Support



What Do You Do
to Increase
Institutional
Compliance
Support?

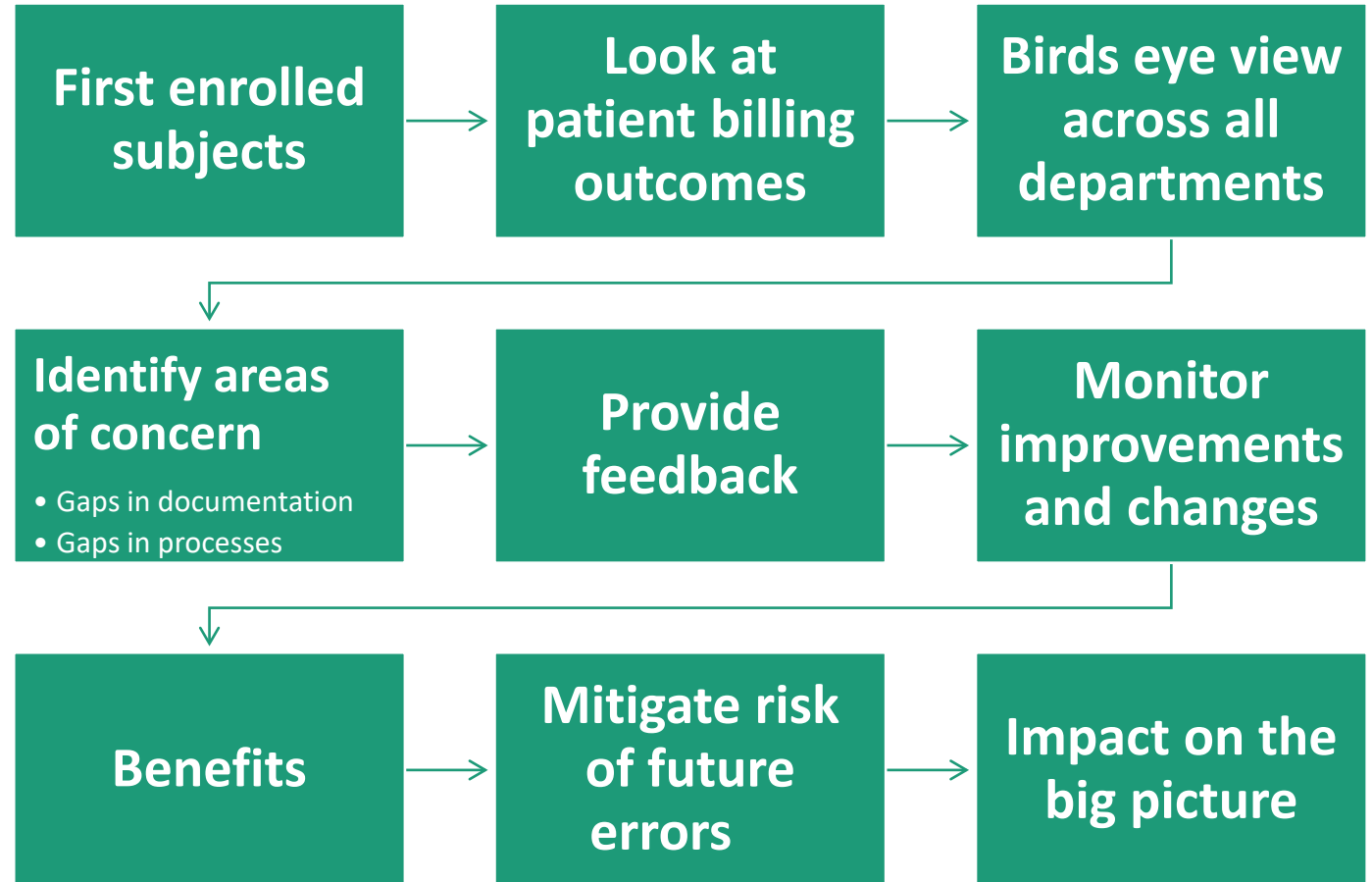


Opportunities to Avoid
Pitfalls Through
Collaboration – GCP &
FDA Readiness

- Helpful Documents & Expectations
- Education
- Involve other stakeholders
- Collaborative review for FDA readiness



First Participant Enrolled Reviews



DO THIS Before Claims Go Out!!!

Additional Collaboration Strategies

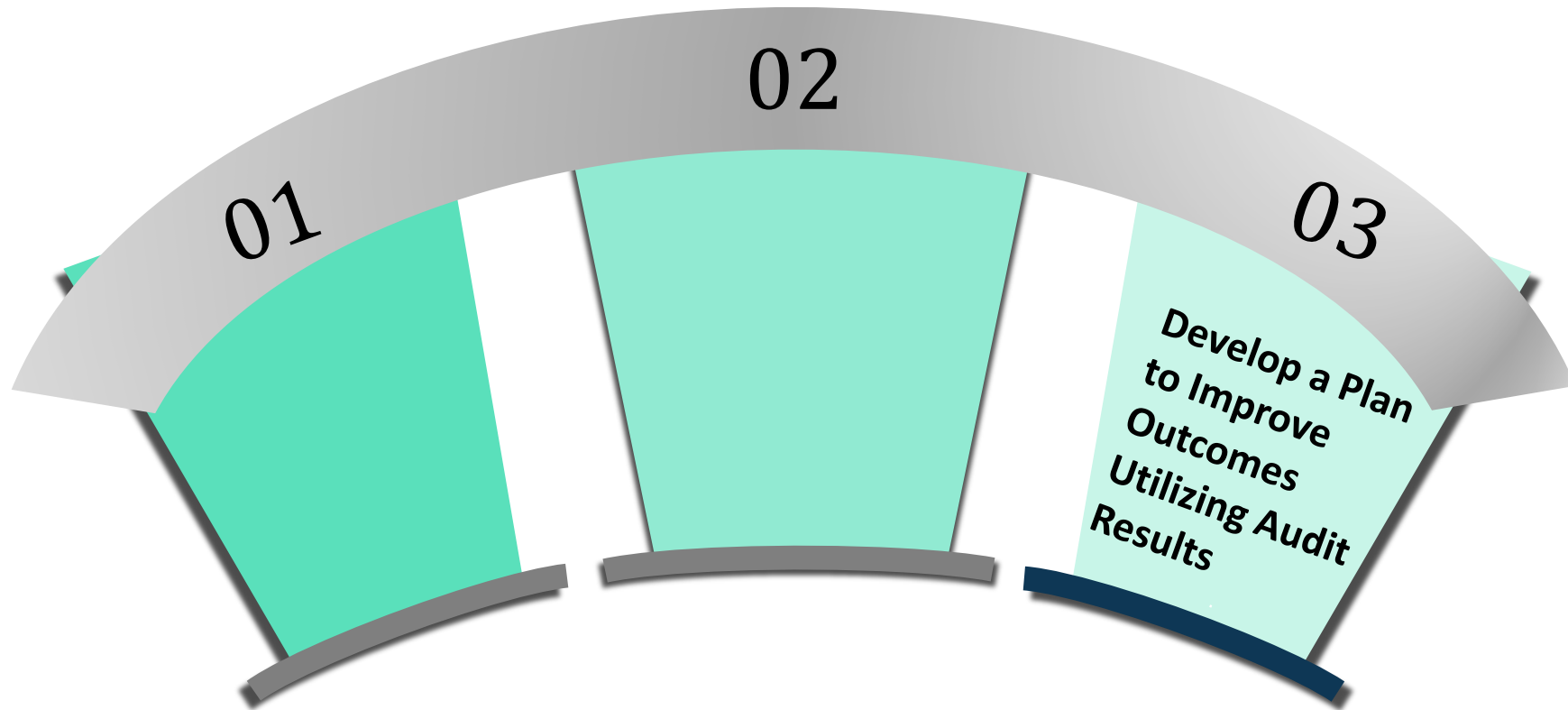
- Meet Regularly with Teams to Walk through Scenarios
 - Clarity
 - Understanding
 - Teaching Moment
- Ask Questions
- Be Present and Available
- Provide Support
- Transparency
- Provide References and Resources
- Remind Stakeholders: Findings are not punitive from a compliance audit!



Compliance Dept Collaborations

GCP	RBC
Subjects given study assessments not approved by the sponsor	Billed to payer with incorrect coding; billed to sponsor; loss of revenue
Discrepancies in drug reconciliation	Incorrect quantity charged to payer or sponsor
Treating physician not listed, not recognized or compensated	Inappropriate allocation of funds
Wrong dates entered for screening tests and/or other study related assessments	Triggers billing that could go to wrong payer with incorrect coding; loss or revenue
Not certifying/documenting visits	Delays in Revenue Cycle Reviews, potential for incorrect billing and payers, increases risk of double billing
Tests not required for study that are done anyway	Incorrect billing; loss of revenue
Pregnancy test done on women of none childbearing potential, i.e. hysterectomy	Unnecessary service; not billable to Medicare
Discrepancies/unable to find drug administration start/stop	Sponsor paid items could get billed to a payer incorrectly
Items and services that are “confirmatory”	Imaging done to confirm tumor progression or response outside of recommendations in guidelines - could trigger incorrect billing
Identify items and services unnecessarily repeated to fit the protocol’s screening or other windows	If a patient has had a procedure that is “just outside” the protocol window, not billable without sponsor approval (should be in the CTA)
Missing source documentation	Verification missing; incorrect billing
Using an unapproved or inaccurate ICF	Billing review inconsistencies leading to incorrect billing
Missed scans/procedures	Invoicing issues; incorrect billing; loss of revenue
DOA Log Discrepancy	Incorrect billing or funds transfers

Objective



Foundations to Successful Auditing

Leadership Buy In/C Suite Support



- Needs to come from the top!
- Organizational culture

Communication & Collaboration

Written Policies & Procedures

- Are they updated?
- Who reviews them?

Training & Education

- Do staff know what to do?
- Who tracks training & education?

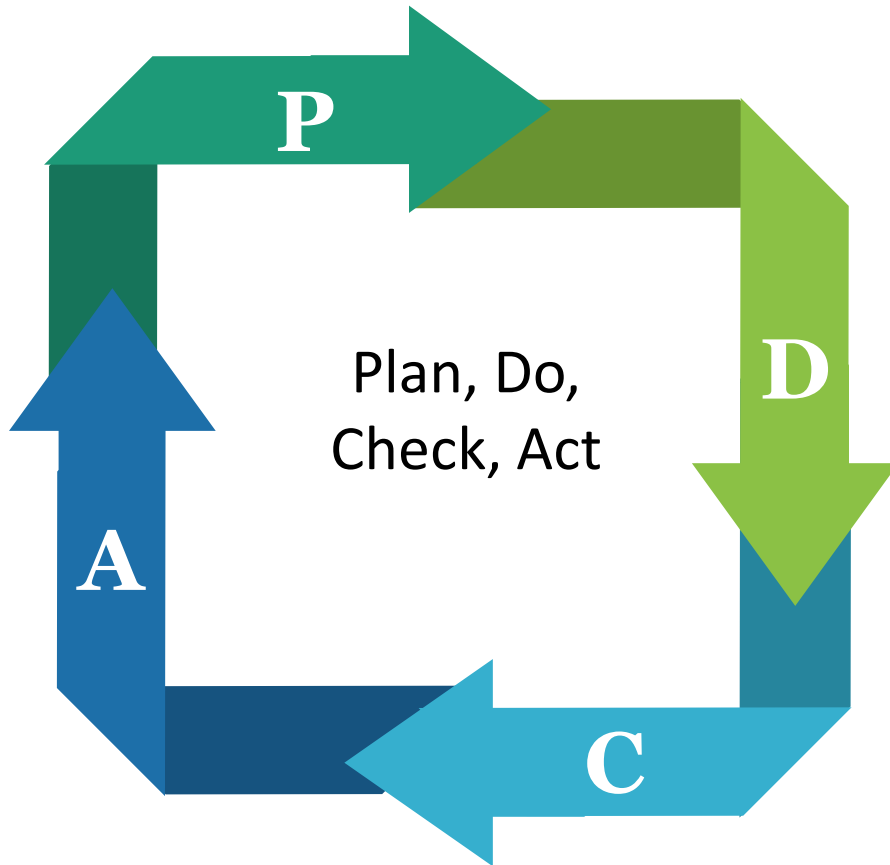
Enforcement

Response & Corrective Actions

- Periodic Reviews

Monitoring & Auditing

Outcome Improvements Using Audit Results



Plan

Plan and Identify Risk

Do

Implement a plan

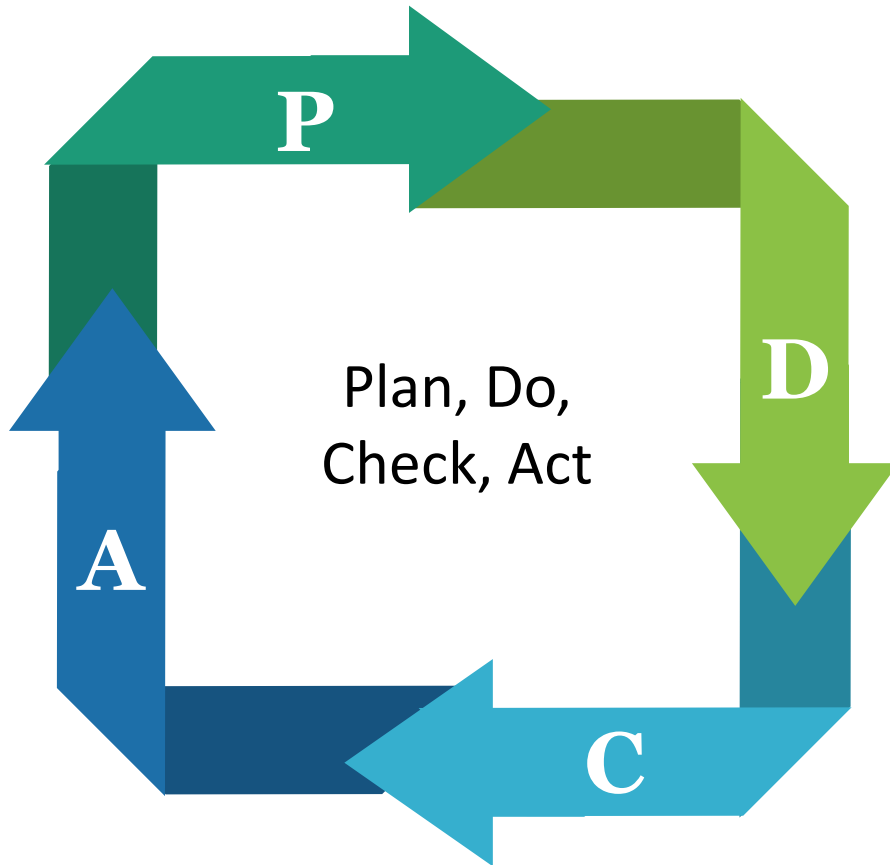
Check

Measure performance through auditing, monitoring, QA

Act

Review Performance- Benchmark, implement change

Outcome Improvements Using Audit Results

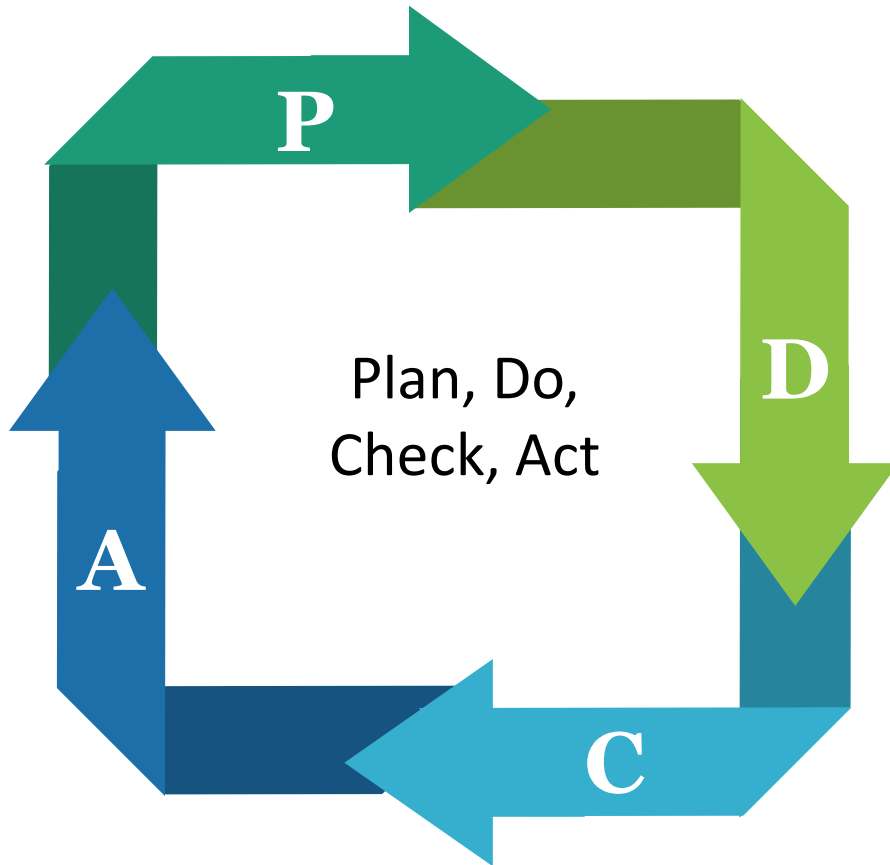


Plan

- Understand the problem & where it went wrong.
- How much improvement?
- How to implement change?
- When to implement change?
- How to measure the impact of change.
- What will be affected by change?

Take **HOT** issues to compliance!

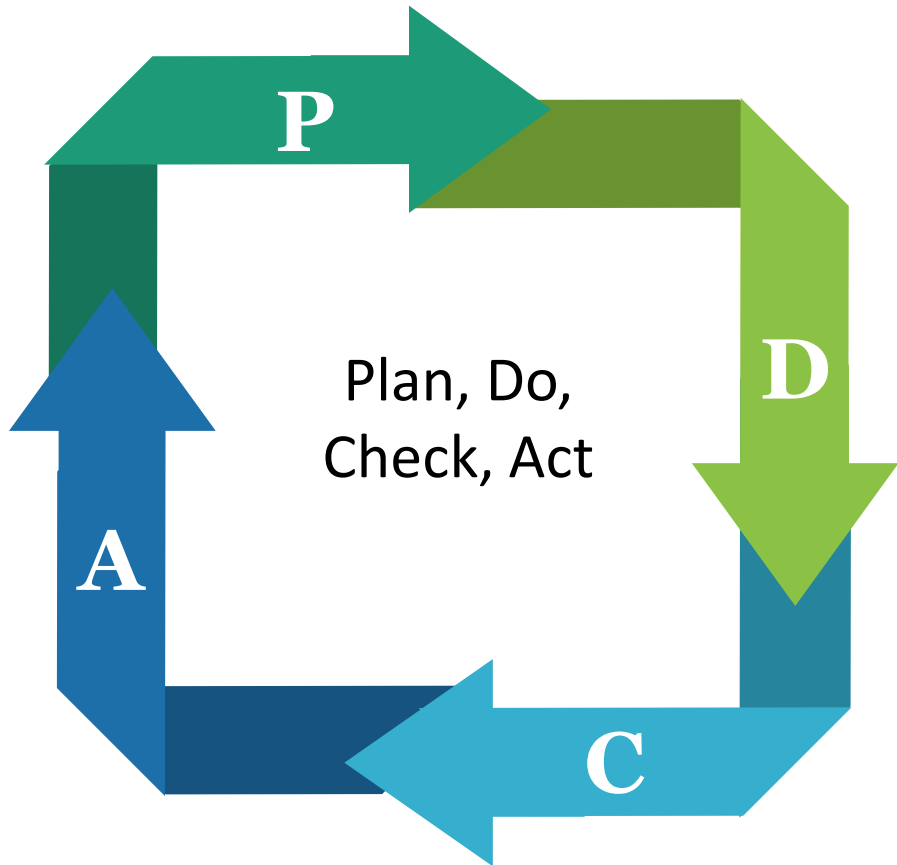
Outcome Improvements Using Audit Results



Do

- Implement the change
- Identify those affected by change
- Solicit buy-in to ensure effective change

Outcome Improvements Using Audit Results



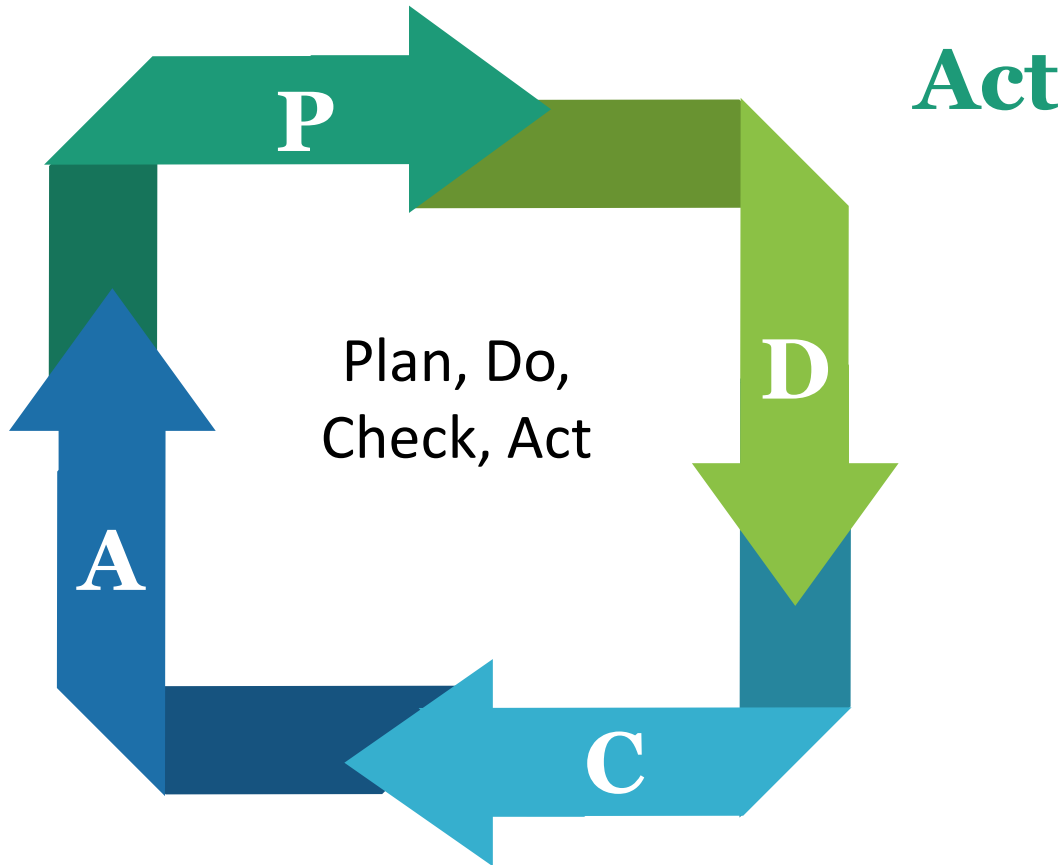
Check

- Document & evaluate the change
- Was it enough?

Examples:

Seek input from end users for gaps in processes

Outcome Improvements Using Audit Results



- **No improvement** – return to Plan and consider new options
- **Improvement** – evaluate if enough and return to Plan if needed
- Solicit feedback
- Update documentation & training
- Sustain the gain – Monitor & revisit improvement
- Benchmark/Trends/Metrics

Examples

Prospective or in real-time QA

Retrospective QA

Root Cause Examples – Clinical Research Billing

Charge Post Error – Token charge missing

Order Error – Billing designation listed on the research order form

CA Error – Procedures are missing that are identified in the protocol

CTMS Build Error – Procedures missing footnotes

CTMS Data Entry Error – Procedure occurrence date does not match the result date within the EMR

Charge Review Error – Improperly reversing a charge to bill research when listed as routine care on the CA

HB Process Errors – Identification that overnight scripts are failing within the HB system

PB Process Errors – Identification that automation of dx z00.6 is failing within the PB system

Charge Post Error	Order Error	CA Error	OnCore Build Error	OnCore Data Entry Error	Charge Review Error	HB Process Errors	PB Process Errors	Comment
▼	▼	▼	▼	▼	▼	▼	▼	▼



Case Study

Background



Protocol requires “Total Bilirubin (Fractionated).”



The calendar team has noted that total bilirubin is part of the CMP.



The coverage analyst notes that the CMP is routine for this population.



The study team and PI reviews the coverage analysis and signs off.



After final approval, study goes live.

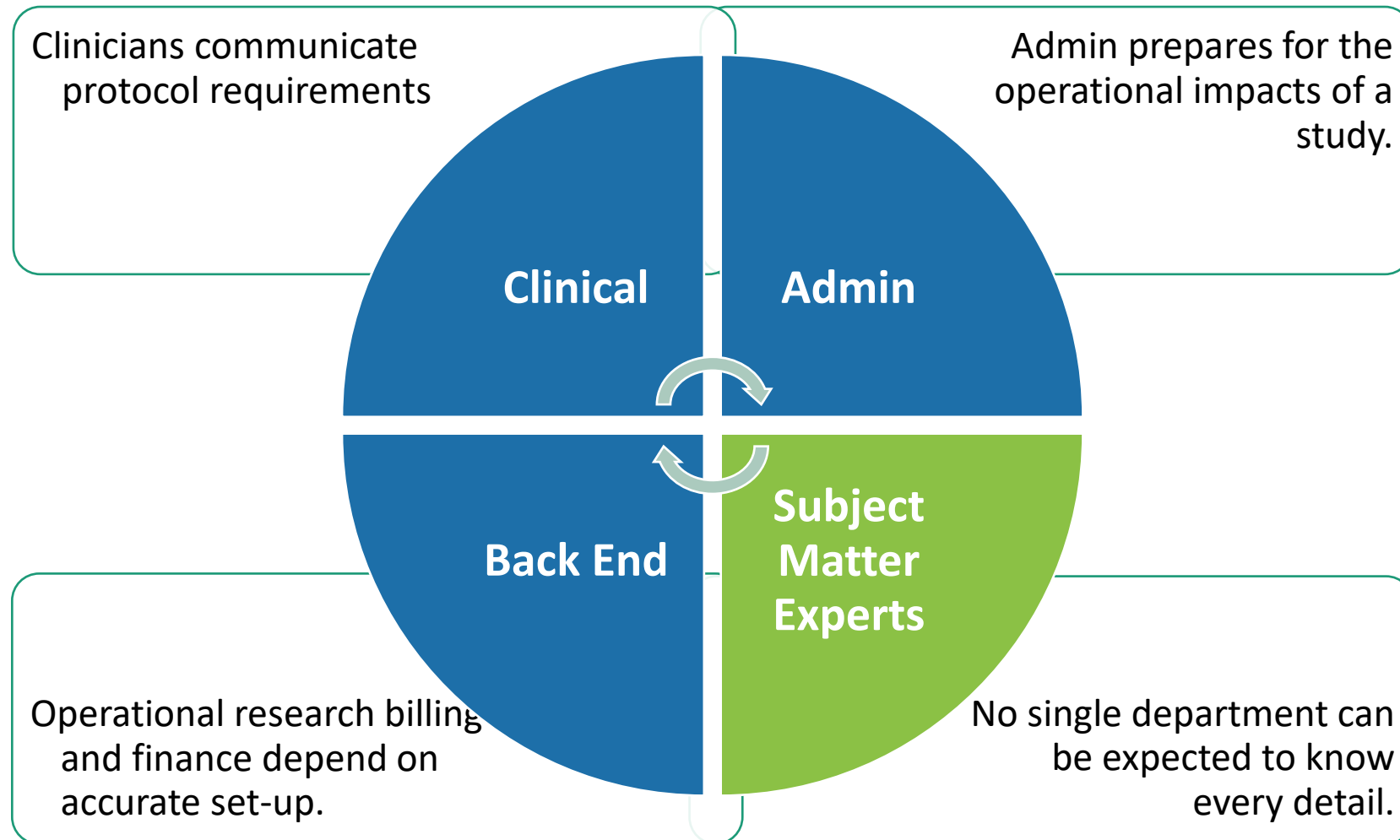
Situation

- The first subject reaches the visit requiring the Fractionated Total Bilirubin, the nurse coordinator orders a direct and indirect bilirubin in addition to the CMP.
- The billing team sees these charges and releases them as not research related because they were not identified on the CA, and the coordinator only certified total bilirubin.
- During an audit, it was identified as a finding that the additional bilirubin charges were ordered specifically to satisfy the protocol requirements. After reaching out to the lab, it was confirmed “fractionated” Bilirubin requires all 3 labs to satisfy protocol requirements.

What went wrong?

- The calendar builder entered exactly what was in the time and events table without catching the “fractionated” part in the protocol.
- Study team and PI missed this line item during their review of the calendar/coverage analysis and signed off.
- The billing review team did not question the discrepancy of the charges vs. the research order and billed the charges as unrelated to research.

Improvement: Teams needed to do more comprehensive reviews up front and talk across departments.

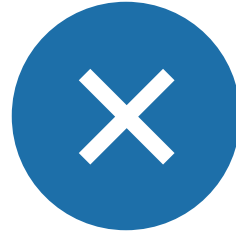




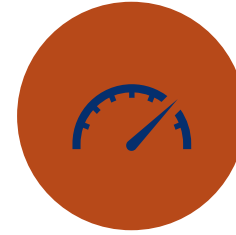
Feedback



Corrective
Actions



Preventative
Actions



Monitor
Progress



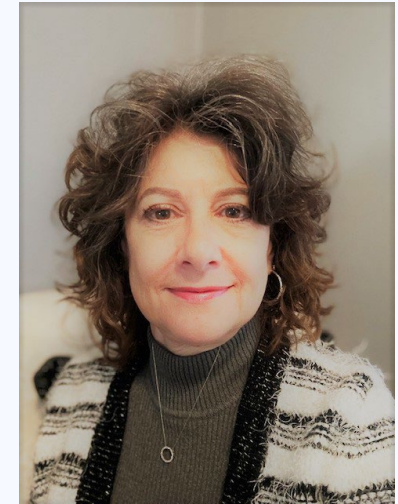
Improvement
Initiatives



Benchmark &
Develop
Metrics



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