



The Role of the Research Nurse in Clinical Trials

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About the Presenter



Professional Background

Claudia Grandas BSN, RN, CCRP



Current Position

Clinical Research Nurse 3 –
Lymphoma Team



Institution

Sylvester Cancer Center – University of Miami

Research Nurse Role Development



Historical Background

Evolution of the research nurse position



SCCC Role Establishment

Clinical Research Nurse formalized in 2018

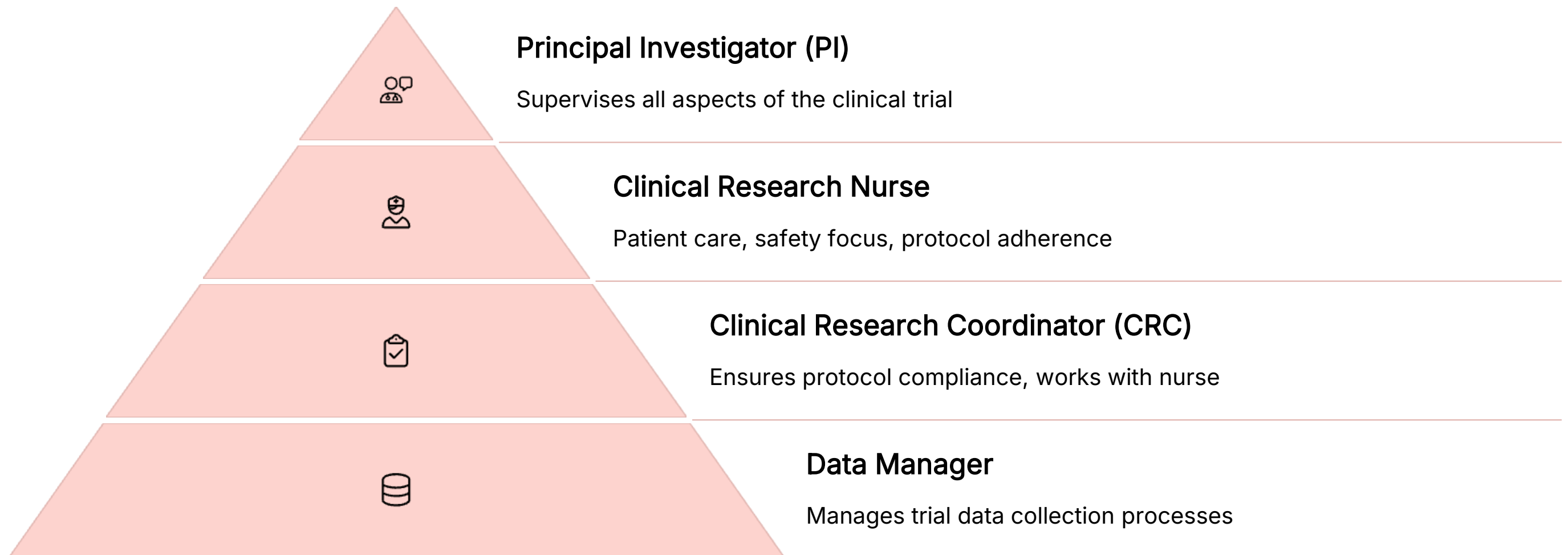


NCI Designation

Achieved in 2019, renewed in 2024



Clinical Trial Team Structure



Clinical Trial Workflow Overview



Pre-Screening & Enrollment

Patient identification and consent process



Baseline Evaluation

Initial assessments before treatment begins



Treatment Administration

Protocol-guided interventions and monitoring



Documentation & Communication

Accurate record-keeping and team updates



Patient Monitoring & Follow-up

Ongoing assessment of outcomes and safety

Patient Prescreening and Enrollment

1

Informed Consent

Support PI in consent process. Explain study details to patients.

2

Screening Coordination

Schedule necessary labs and procedures with CRC.

3

Eligibility Documentation

Assist with forms and protocol requirements.

Baseline and Pre-Treatment Evaluation



1

Medical History

Complete documentation in EMR system

2

Medication Reconciliation

EMR, patient report, physician notes

3

Lab Review

Check results, communicate abnormalities

4

Baseline Procedures

EKGs, vital signs, 6-minute walk test

Patient Care During Treatment



Direct Patient Care

Protocol-guided treatment administration



Adverse Event Monitoring

Identify and report within timeframes



Dose Modifications

Adjust per protocol requirements



Protocol Adherence

Follow Schedule of Assessments precisely



Treatment Planning and Administration



Sign Orders

SMART set or Preference List



Review Appointments

Coordinate with CRCs for scheduling



Medication Management

Release, document, review medication diaries

Data & Documentation Importance

Accurate Data Collection

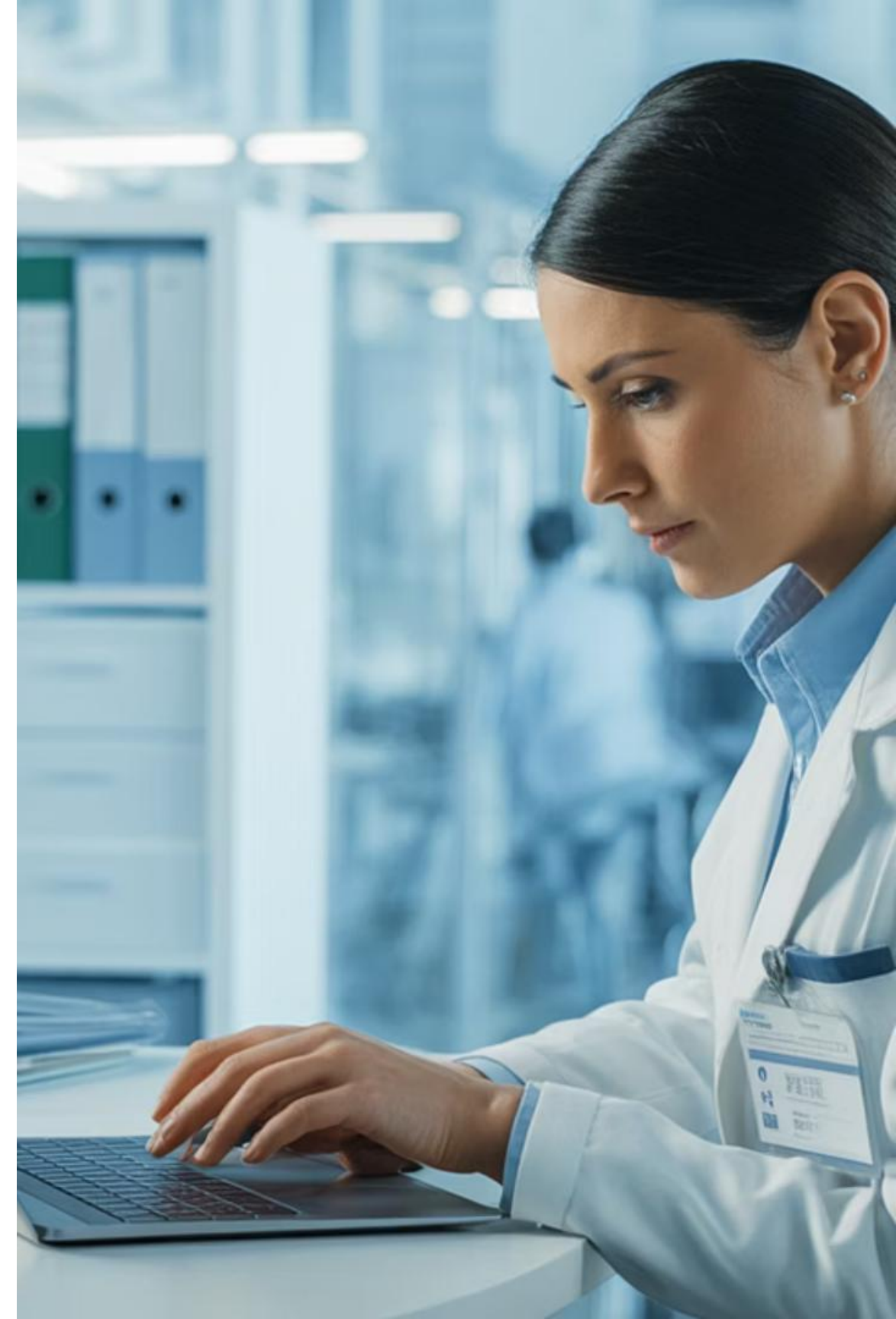
Record all patient
data per study
protocols

Adverse Event Documentation

Maintain detailed
logs, report findings

Source Document Management

Provide necessary
documentation to
lead CRC



Data, Documentation and Communication

Record Maintenance

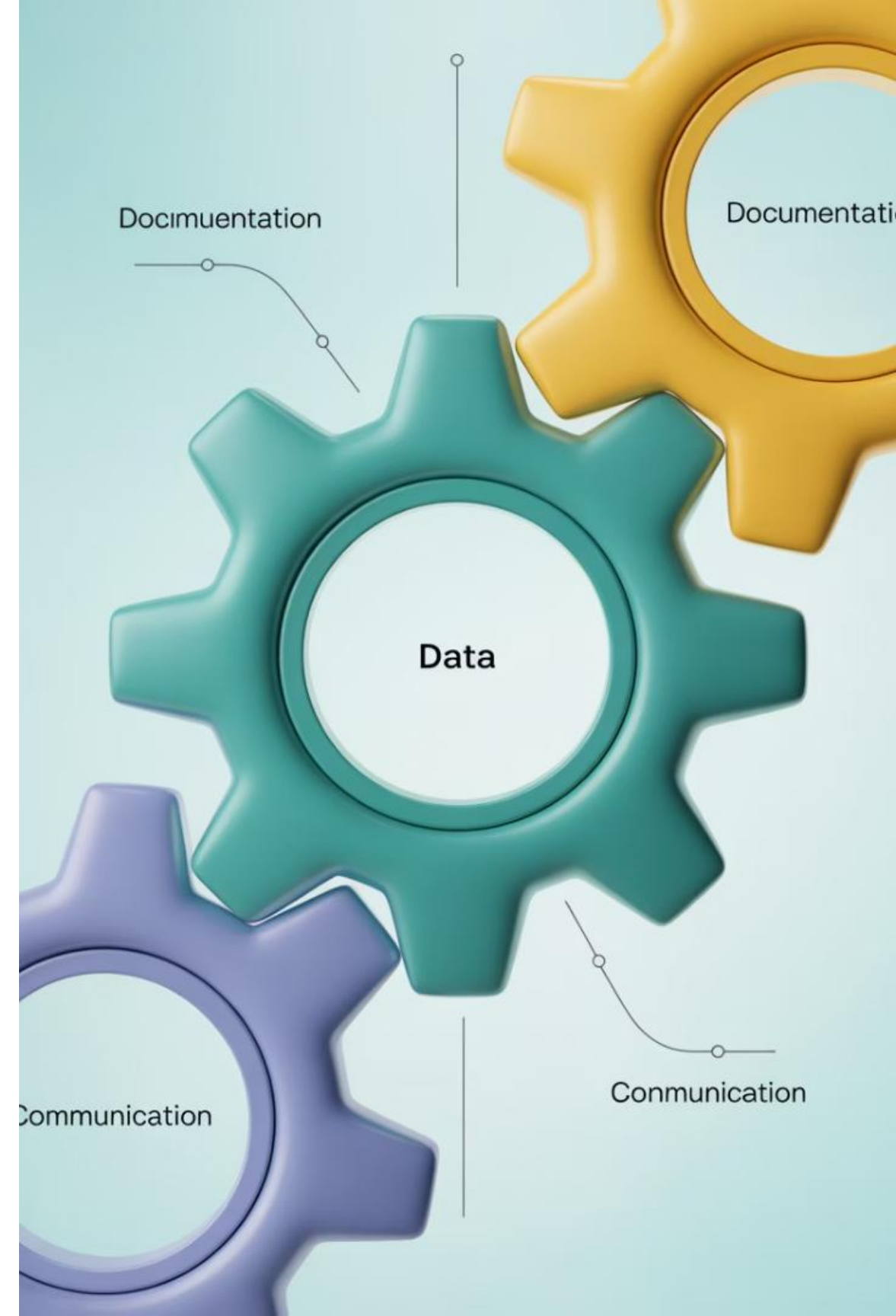
- Research info notes
- Concomitant Med Logs
- Medication diaries

Data Management

- Implement collection processes
- Assist with query resolution
- Review questionnaires

Team Communication

- Research team updates
- Manage clinical trial hotline
- Interdepartmental coordination



Patient Monitoring and Follow-Up

Adverse Event Surveillance

Monitor for AEs, SAEs, report to clinical team

Report Review

Examine adverse event reports, team communication

Detailed Record Keeping

Maintain visit documentation, AEs, medications

Efficacy Assessment

Collect data to evaluate intervention effectiveness



Discharge Process Responsibilities

1

Appointment Review

Ensure patient understanding of follow-up schedule

2

Check-Out Coordination

Work with clinic or infusion unit nurses

3

Schedule Coordination

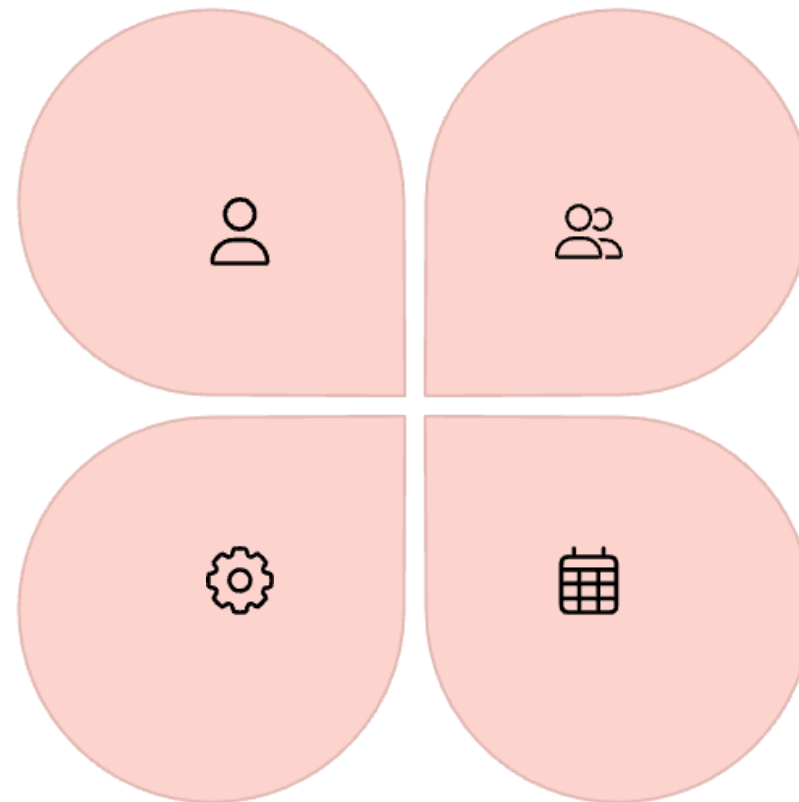
Collaborate with CRC on protocol-required visits



Collaborative Settings

Study Team Collaboration

Work with PI, Sub-Is, CRCs, data managers



Multidisciplinary Interaction

Coordinate across healthcare departments

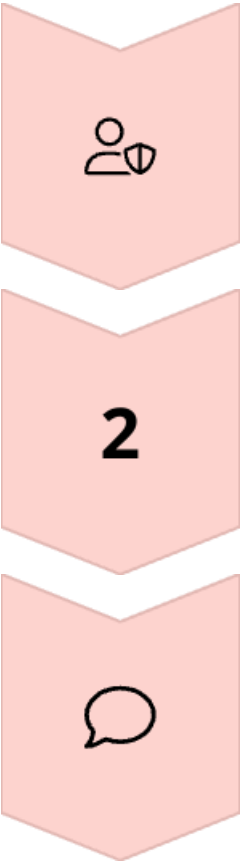
Problem Solving

Resolve daily challenges for smooth operations

Meeting Participation

Huddles, PI oversight, sponsor calls, SIVs

Key Takeaways



Critical in Patient Care

Ensures safety and comfort throughout trial

Central to Data Accuracy

Documentation from enrollment through follow-up

Communication is Key

Collaboration ensures protocol compliance





Thank You!



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