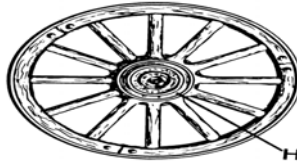


# The Coordinator: The Main Cog in the Wheel



Eileen Scheid, RN, MSN, MSCN,  
CCRC

University of Rochester



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# The Key to a Successful Trial

A coordinator who  
knows what  
they are doing.



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# Coordinator

- to make arrangements so that two or more people or groups of people can work together properly and well
- to act or work together properly and well
- to cause (two or more things) to be the same or to go together well : to cause (two or more things) to not conflict with or contradict each other

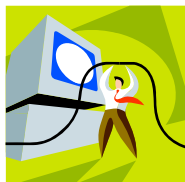
(Merriam-Webster on line dictionary)



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# Job Description

- Juggler
- Scheduler
- Recruiter
- Interpreter
- Typist
- Scribe

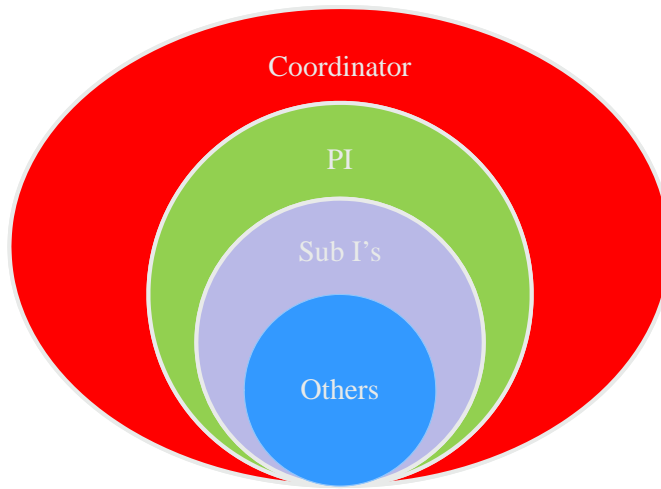


- Magician
- Mind reader
- Ability to hurry up and wait
- Facilitator
- Counselor



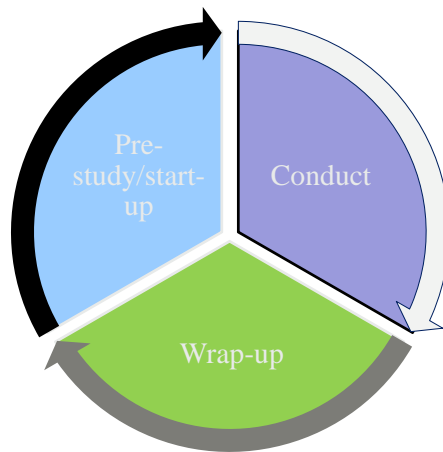
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# Making It Happen



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# Birth of a Study



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# Pre-study

Protocol evaluation

Is it feasible?

- subjects
- personnel
- facility & equipment

Examine timelines

Investigator meetings

Financially sound

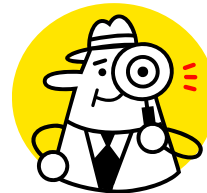
Time and resources



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# Site preparation

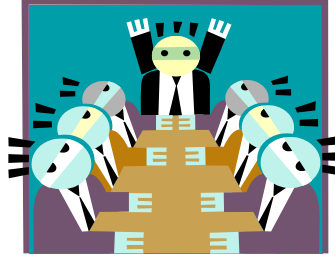
- Pre-study site assessment
- Proving your ability to do the study
- CV, Licenses, human subject protection
- Certifications for equipment
- Documentation of experience
- Past performance



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## IRB

- Who, when, and how
- Preparation and submission of documents
- Communication
- ICF modifications
- 1572
- Amendments



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## Start-up

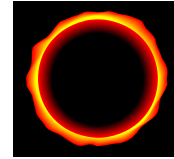
Patient recruitment:

- Locating **appropriate** subjects
- Screening tools
- Monitoring enrollment goals and modifying strategies
- Reaching out
  - Advertisement
  - Networking



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## Questions to answer



Are the planets aligned?

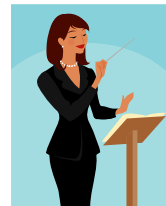
- Players/resources/patients scheduling
- Obtaining source documents
- Assessing for inclusion/exclusion criteria
- Length of visits
- Contact persons
- Visit space



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## Conducting the study

- Start with reasonable expectations
- Monitor compliance
- Ask for help
- Education
- Patient safety is the first priority



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# Communication

- Maintaining communication with
  - Sponsor/CRA
  - Monitors
  - Study staff
  - Ancillary staff



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## CRF/Source documentation

- If it is not documented it wasn't done!
- Correct data, accurate & complete
- Progress notes
- Subject logs
- Protocol deviations
- Retention



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## Adverse events

- Documentation
- Causality
- Follow-up
- SAE reports



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## Drug accountability

- Receipt and storage
- Dispensing logs
- Return
- Dispensing
- Drug ordering
- Pharmacy?
- randomization



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## Lab/Clinical Activities

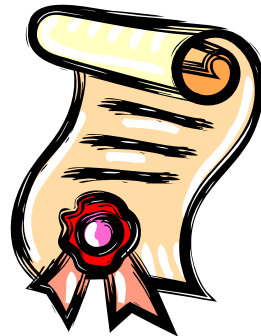
- Protocols
- Storage
- Lab kits
- Collection
- Shipment
- Standards
- Equipment



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## Certifications

- HSPP
- IATA
- CCRC
- MSCN
- GCP
- Raters:
  - EDSS
  - MSFC



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## Helpful websites

- <http://www.hhs.gov/ohrp>
- <http://www.FDA.gov>
- <http://www.ClinicalTrials.gov>



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## Code of Federal Regulations

- 21 CFR part 11, 50, 54,56,312,314,812,814
- 45 CFR part 46
  - Human subject protection
  - GCP: good clinical practice



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## Take home message



- The PI may be responsible for the conduct of the study, but it is the coordinator that makes the study possible.
- Recruitment and retention of study patients is directly related to the skill of the coordinator
- Organization, documentation and ability to multi-task are essential attributes.



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Thank you!



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