

Keys to effective Project Management in Clinical Research

The Role of the CRA in the successful
management of a Clinical Trial



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What is a project?

- Unique set of activities and tasks
- Defined beginning and end
- Requires people to work together across organizational boundaries
- To achieve a specific objective

Clinical Project - Phases

- From the time the project is awarded, to the completion of project work and close-out, the project is managed by following the required steps.
- Most projects go through a life cycle with well defined stages
 - start-up - Start -SIV
 - conduct - SIV to LPO
 - close-out - LPO to DBL

Project Management

- Project management
 - Project manager: manages trial at global level
- Clinical Operations:
 - Lead CRA manages the clinical operations activities at global or regional level
 - CRA: project manager for their sites and country activities



Managing a study

What do YOU do when given a study to manage?

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PANIC !!!!!!!!



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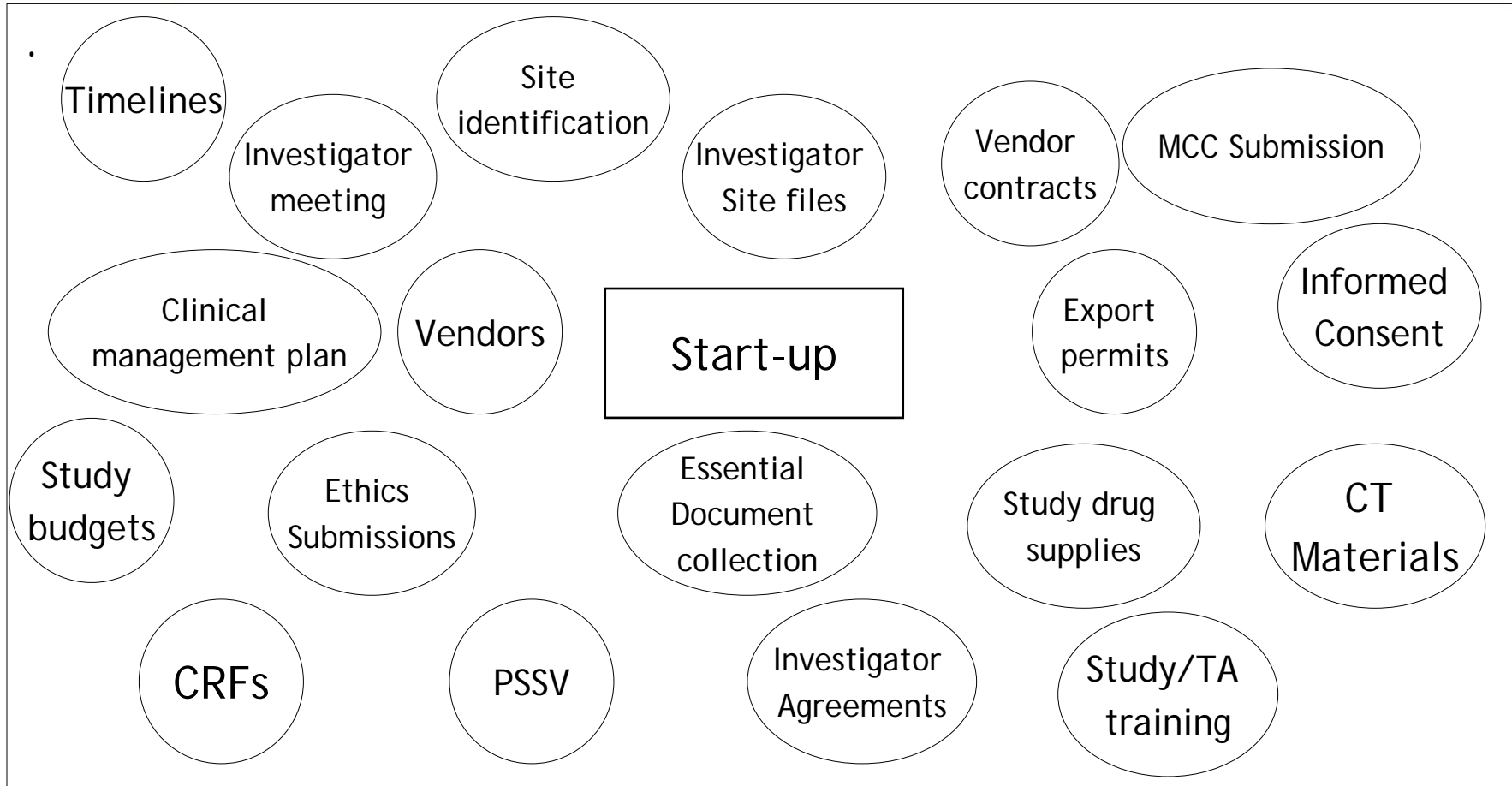
PLAN



Project Phases

- Start-up
 - start - SIV
- Conduct
 - SIV to LPO
- Close-out
 - LPO - database lock

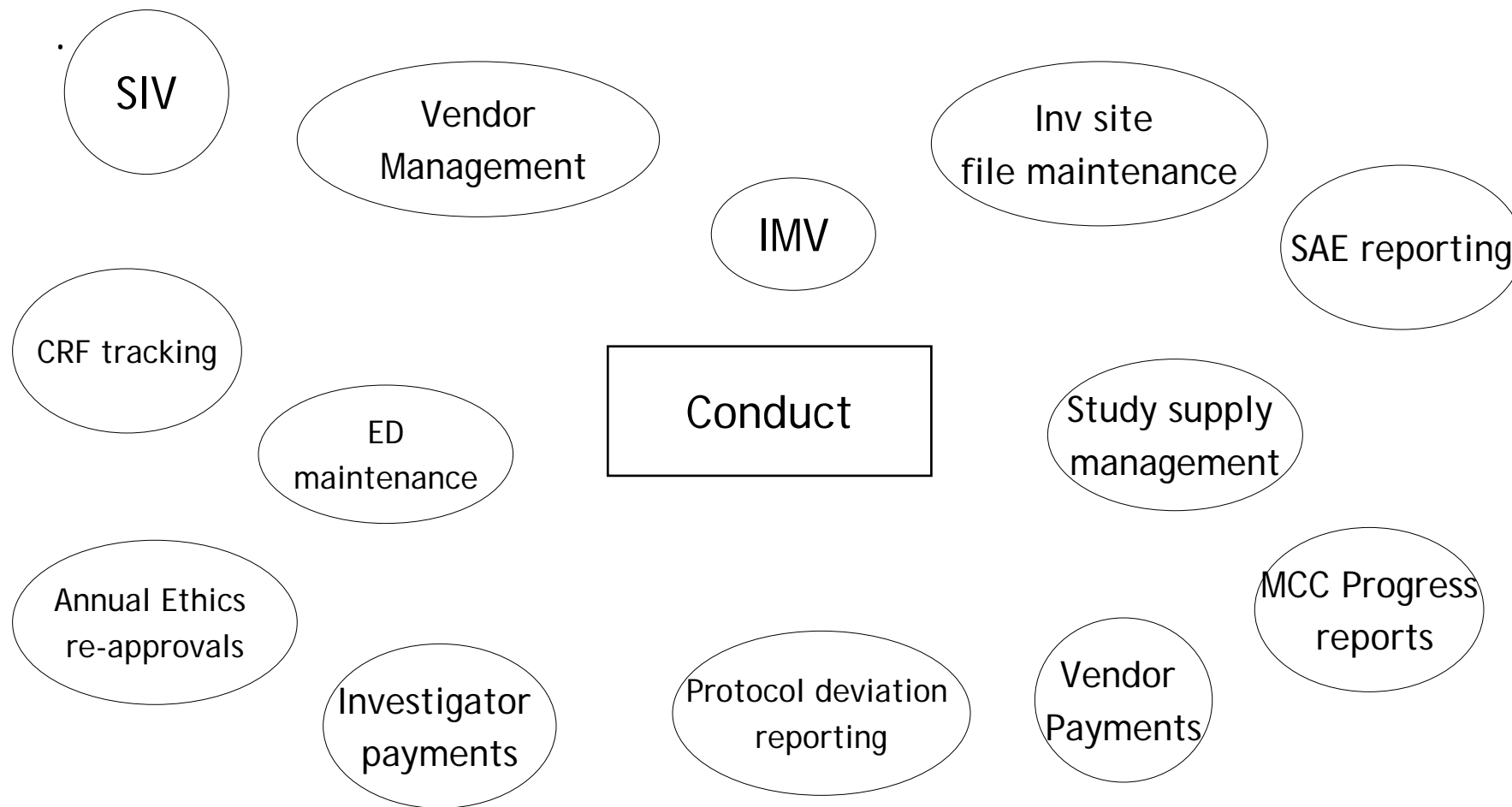
Start-up Phase



Start-up phase

- Large volume of work done in first 3-6 months
- High Pressure
- Planning and teamwork essential

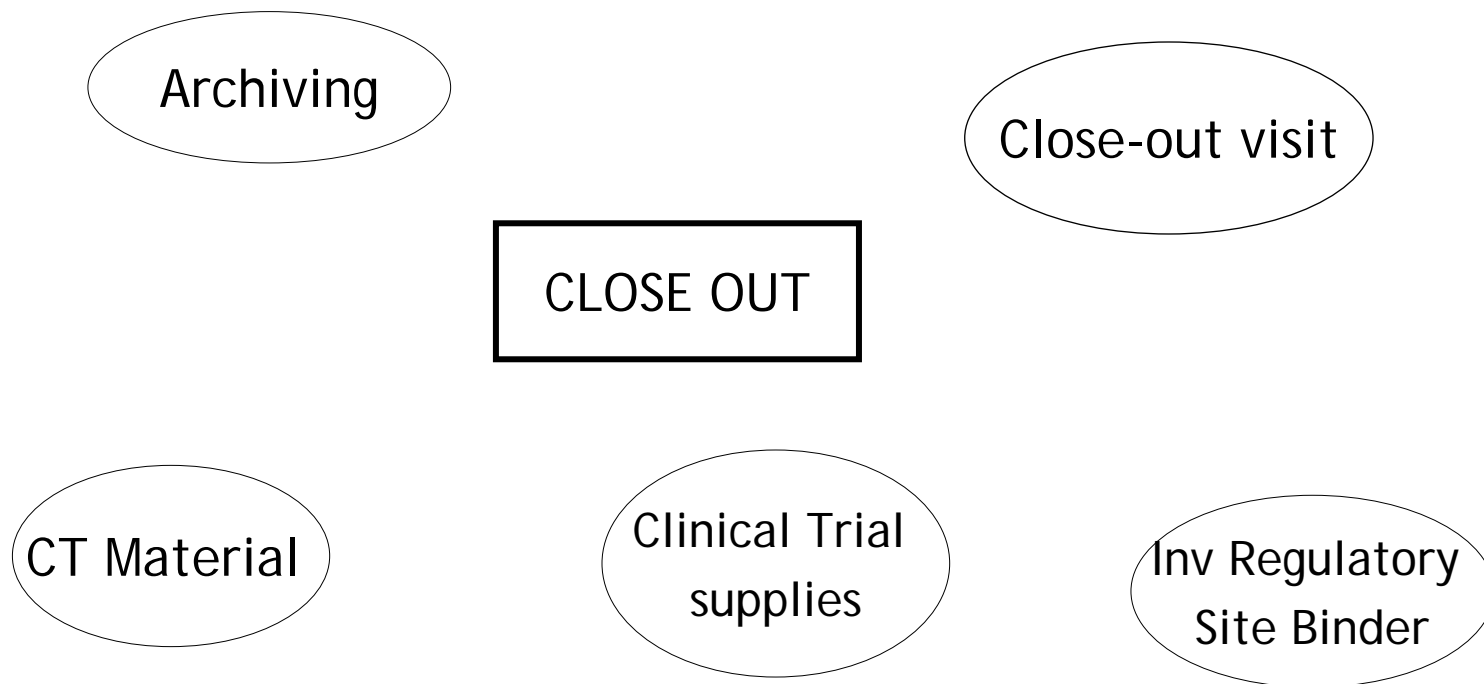
Conduct Phase



Conduct phase

- Large volume spread out over longer period of time
- Peaks and troughs
- Pressure less intense
- Planning and teamwork still essential

Close-out Phase



Close-out phase

- Smaller volume - tidying up
- Often no definite timelines
- Teamwork **STILL** essential

What should be done first?

- Numerous tasks in all phases- What should be done first?
- Develop a Plan
- How?
 - Order of tasks and activities
 - Deadlines
 - Project team deliverables

Start-up

- Timelines
 - study start, FPI, enrolment, treatment
 - Submission dates - MCC and ECs
- Site Identification
 - Medical Director, Marketing, Colleagues, SRQ, feasibility, internal database, FRIENDS in the industry
- Therapeutic Area training
- PSSV
 - Very important visit
 - Be well prepared, know the protocol and what is required for the study.

- Essential Document Collection
- ICF
 - Prepare country specific
 - Prepare Ethics Committee specific
- MCC Submission
- Study / Investigator Budget - Draft
- Ethics Submissions
- Investigator Contracts

Start-up

- Vendors – Laboratories, ECG, Radiology
 - Identification
 - Quotes
 - Contracts
- Study Drug supplies and CT Material
- Investigator site files

- Monitoring
 - Booking appointment early
 - Plan IMVs for less stress
 - IMV report - get it done ASAP
- CRF tracking - Critical
- Study supplies
 - Check at each IMV
 - Set-up system with site to get advance notice
- Payments - Inv and vendors
 - set-up tracking system

Conduct

- Draw up plan with due dates for:
 - MCC progress reports
 - Annual Ethics renewals
 - Medical license renewals
 - Medical Insurance renewals

Close-out

- Often forgotten or not done properly
- Close-out Visit
 - Not just another IMV
- What happens to study drug?
- What happens to Study materials
- Archiving

CRAs are more than just monitors

- Remember
 - You manage people
 - You manage plans
 - You manage deadlines
 - You manage teams
- Use all that is available to you to do this successfully