



CRO oversight - seen from NORMA

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- Negotiation/Preliminary work
- Maintenance phase
- Closure phase



Negotiation/Preliminary work

- Request for Information (RFI)
 - General information (e.g. Services, Internal structure)
- Request for Proposal (RFP)
 - Detailed price list and planned time for defined tasks
 - Qualifications (e.g. job descriptions)
 - FTE
- Request for Quality Assessment (RFQ)
 - More detailed information

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Negotiation/Preliminary work cont.

- Very detailed contracts
 - Very precise and detailed description of the tasks
 - NORMA check list (contract content)
 - Responsibility (SOPs/study specific tasks/training etc.)
- Preferred/strategic partnership
 - Shared goals
 - Shared technology
 - Proactive Resource Management

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Negotiation/Preliminary work cont.

- F2F (TC) Meeting with Sponsor in start up phase
 - Match the personality demand/qualifications with sponsor demand
 - Communication lines (who, when, why, how)
 - For each Sponsor one line into CO in NORMA (+/- Contract manager)
 - Reporting line in the maintenance phase
 - Escalation Plan
 - Other Expectations (formal + informal)
 - Relationship
- Acceptance of blinded CV (very detailed CV)
- F2F meeting or unblinded CV

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Maintenance

- Selection responsibility at NORMA:
 - Selection list reviewed and accepted by line manager
 - All pre-study visit (qualification visit) reports and CV of the principal investigators reviewed and accepted by line manager
 - Check list for green light (signed by 2 people)
- Review of monitoring reports as needed (line manager)
- Follow-up with CRAs as needed (line manager)
- Co-monitoring (QA + QC) incl. report

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Maintenance

- 3-4 Sponsor-Manager meetings per year (outsourced/NORMA/Home based staff)
 - Support sponsor goals
 - Support CRA
 - Follow-up of KPIs
- CRA – Manager meetings (F2F, TC, Skype) as needed
 - APR x 2 yearly
 - Training/support/development of CRA
 - Co-monitoring (training/GCP etc.)

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Maintenance

- KPIs/Metrix
 - NORMA KPIs
 - Monitoring Visits acc. to Monitoring Plan
 - Mon. Report acc. to Sponsor demand or NORMA SOPs
 - Actual Recruitment according to Recruitment Plan (Committed patients \leq Actual Patients)
 - NORMA Week Reports and Travel Reports acc. to timelines
 - No critical findings related to NORMA in Inspections and Audits
 - Turnover rate
 - Number of Co-monitoring visits according to applicable SOPs
 - Time from Medication Release time to PPFV (first patient first visit)
 - Sponsor KPIs/Metrix

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Maintenance

- QC
 - Co-monitoring (following SOPs/protocol etc. if possible)
 - Report reading (accord. to SOPs)
 - Training Record updates/deadlines
- QA
 - NORMA Audit plan
 - NORMA SOPs with update/review
 - Training Plan: New hired and maintenance plan
 - Company processes with update/review
 - Audits of NORMAs External Collaborators

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Maintenance

- Sponsors with several NORMA CRAs have "their own" manager, who knows the sponsor SOPs and systems
- High flexibility as line managers is used as a human resource (Partly manager - partly senior CRA)

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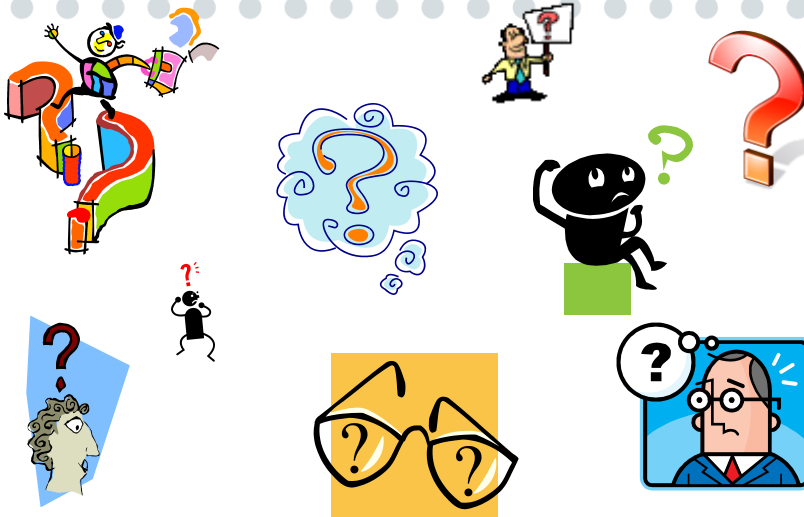
Closure phase

- Summary of collaboration with sponsor
 - Lesson learned
 - Good issues
 - Issues for Improvement
 - Conclusion

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Questions



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