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Best Practices with Site Management, Efficient Data Entry and Quality Clinical Monitoring

A CRA's perspective

MedSource provides support for complex clinical trials. Whether a challenging therapeutic area or a sophisticated trial design, our highly experienced team excels at delivering results.

Management of the study site begins at the first study visit

1. Proper evaluation of a study site to ensure the study is a good fit
    a. Appropriate experienced staff to conduct the trial
    b. Sufficient time available by study staff
    c. Therapeutic area experience

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Management of the study site begins at the first study visit

2. Proper training during SIV to minimize errors with first subject screening and enrollment
    a. Up to date materials used in training
    b. Electronic Data Entry (EDC) system access request submitted, and then database data entry training

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Management of the study site begins at the first study visit

2. Proper training during SIV to minimize errors with first subject screening and enrollment
    c. Appropriate tools for the site to use during the study
        i. Forms templates
            - Delegation of Authority log, Investigational Product (IP) Accountability log, IP storage area temperature log
            - Many sites have their own – be flexible to use site's forms – less errors by site
        ii. Advertising templates – sponsor approved informational leaflet or brochure for potential subject, sponsor approved social media ad

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3. Up to date contact information from study site and project team – personnel changes
    a. Who at study site gets copied on IND Safety updates?
    b. Where is IP shipped to at the site?
    c. Who does study site personnel send enrollment log to at sponsor or CRO?
    d. Are there multiple central labs to receive different collected specimens?

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Make sure current versions of all documents are being used at study site

- Use an email reply requirement to make sure site got the documents
- Protocol
- Pharmacy manual
- Lab manual
- CRF Guidelines
- Forms updated to reflect current recipient – SAE, Enrollment

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CRF Guidelines

1. Have examples to address anticipated data entry issues
   a. Sophisticated databases now add or subtract CRFs depending on what data is entered at a specific point in the CRFs
   b. Example – Lesions identified at Baseline are issued numbers. Those numbers prepopulate CRFs of post baseline visits
   c. Example – automatic edit checks that should not exist – asking for the units of coagulation INR result

CRF Guidelines

2. Indicate the forms required for completion for subjects that are Screen Failures
3. Time and date format
4. FAQ instead of/in addition to updating CRF Guidelines
    a. When an issue not addressed in the Guidelines present itself, the answer can be entered into the FAQ for others to use going forward
    b. Better than a folder of emails in your Outlook or Apple Mail each addressing a single issue
    c. Someone has to maintain it, or it will be difficult to use

Push study management to define how to count study subjects, if it is not clear in the study plan

1. Completed subject – initial cycle of treatment? Defined follow up period?
2. Discontinued subject – Is Completed included in Discontinued, or is it separate?
3. End of Study – Is it associated with Complete or Discontinued?
4. Match with statistical plan if possible

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Study site staff best respond to CRAs who are perceived as experts

1. Don’t provide an answer unless you are sure of it
2. Admit when you don’t know something
3. Make sure the site staff understand, and continue to understand as the study progresses, what expectations are in terms of data entry and query resolution
4. Keep reference materials with you
    a. Protocol
    b. CRF Guidelines
5. Various manuals

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Data management metrics reports can be helpful to the CRA prior, during, and after the site visit

Track status of expected CRF completion

Number of queries pending

Calculated expected visit dates helps to quickly determine out of visit window deviations

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FDA – “Monitoring is a quality control tool for determining whether study activities are being carried out as planned, so that deficiencies can be identified and corrected.”

Questions?

cgall@medsource.com

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