**Checklist of actions required for on-site monitoring visits:**

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| --- | --- |
| Discuss appropriate visit dates/times with PI/Research Nurse |  |
| Write and send monitoring visit letter to site |  |
| Prepare trial-specific monitoring visit checklists:   * ISF checklist * Consent & eligibility checklist * SDV checklist |  |
| Print out relevant number of each monitoring visit checklist |  |
| Review previous monitoring visit reports to confirm if there are any outstanding actions that should be followed up at this visit |  |
| Review patient records – check for missing CRFs/queries raised but not yet resolved |  |
| Take following information/documentation on visit:   * Copy of protocol * All relevant checklists (see above) * Document version histories * List of comments/queries from review of previous reports * Pens, post-it notes, etc. |  |
| Carry out monitoring visit – ensure you complete:   * Clinic   + ISF review   + Patient consent review   + Patient eligibility review   + Adverse event & SAE reporting review   + CRF completion up to and including 30 day follow-up   + CRF completion 1 year follow-up (if close-out visit) * Close-out meeting   + Discuss main findings with PI   + Discuss specific ISF/patient data findings with Research Nurse/Data Manager   + Complete site visit log |  |
| Write monitoring visit report |  |
| Send monitoring visit report to site listing all findings and actions required |  |