# Accompanied Visit Checklist

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| Study and Personnel Details |
| **Study Reference:**  | **Study Site:**  |
| **Monitor’s Name:**  | **Position:**  |
| **Reviewer’s Name:**  | **Position:**  |
| **Visit Date:** |
| **Study Site Personnel Present:**  |
| **Type of Study Site Visit: (tick as appropriate)**[ ]  Pre-Study [ ]  Initiation [ ]  Monitoring [ ]  Closure [ ]  Other (Specify): |
| **Purpose of Study Site Visit: (tick as appropriate)**[ ]  Quality [ ]  Training [ ]  Monitor sign off [ ]  Other (Specify): |
| Objectives of Visit *(to be completed in advance of visit with input from Line Manager)* |
| **Monitor’s Objectives for Visit** |
| **Monitoring tasks to be done:**  |
|  |
| **Topics for discussion with Principal Investigator:**  |
|  |
| **Topics for discussion with Study Site personnel:**  |
|  |
| **Other:**  |
| **Reviewer’s Objectives for Visit** |
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| **Topics for discussion with Principal Investigator:**  |
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| **QC Review tasks to be completed:**  |
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| **Areas for Support / Development of Monitor:**  |
|  |
| **Other:**  |
|  |
| Observations |
| **Quality Issues** *Record quality issues requiring urgent attention / that need to be brought to the attention of Line Management / CPrM / etc.* |
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| **Monitor’s preparation to achieve objectives for the study site visit.***Include awareness of study site issues, therapy area/protocol knowledge, all materials and info to hand etc.* |
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| **Monitor’s performance of monitoring tasks.** *Include adherence to SOPs, use of tracking systems, organising and prioritising work, management of documentation, accuracy, cross-referencing between CRF modules, methodology for SDV, checking consents etc. Include suggestions for best practice, development/training needs, compliance issues etc.* |
| [ ]  Consent Issues | [ ]  Protocol Deviations | [ ]  Monitoring Plan Compliance |
|  |
| **Monitor’s discussions with Investigator and Study Site personnel.** *Include interpersonal & communication skills, discussions on study targets and action plans, use of study site management plans / contingency, problem solving, negotiation skills, non-study issues, product discussions. Include suggestions for sharing as best practice, development/training needs etc.* |
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| **Assessment of achievement of Monitor’s objectives for visit.** |
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| **QC Review observations.** |
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| **Observations relating to areas for support/development of Monitor noted in objectives.** |
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| **Assessment of achievement of Reviewer’s objectives for visit.** |
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| Monitor’s Comments |
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| **Follow up of actions** *(where applicable, to be discussed with Line Manager and reviewer, and completed by Monitor)* |
| **Actions /training needs** | **Comment** | **Date completed/to be completed**  |
|  |  |  |
|  |  |  |
| **Signatures** |
| **Monitor:** |  | **Date:** |  |
| **Reviewer:** |  | **Date:** |  |
| **Report copied to:****(Governance Manager)** |  |