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| --- | --- | --- |
| Check list | Yes | No |
| **Site**1. Review study team training in sponsor SOP’s if applicable
2. Review CV’s and GCP certificates
3. Review Delegation log
4. Review any specific site training requirements/training in study protocol
5. eTMF review – site file and investigator files
6. Staff changes
7. Document amendments
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| **Data**1. Review patient compliance by reviewing any missing data
2. Review deviations log/violations
3. Review the source data verification for the Primary & Secondary end points or critical data points
4. Review time to data entry
5. Number of queries
6. Time to Query resolution
7. Error rate
8. Data outliers
9. Data trends
 |  |  |
| **Participants**1. Check screening and pre-screening patient numbers
2. Review patient recruitment levels against agreed targets
3. Look out for:
* Patient recruitment much higher or lower than expected
* High screen failure
* High discontinuation rate
1. Complete eligibility review if possible/recruitment of patient not fulfilling the key eligibility criteria
2. Review patient attendance dates/patients that consistently out of window period
3. Review Informed consent forms if possible
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| **Safety**1. Check sites showing higher or lower AE’s/SAE’s than other sites
2. Sites failing to report SAE’s within the specified timelines
3. Sites with significant numbers of patient discontinuing the study due to AE’s/SAE’s
4. Deviation and/or Non Compliance
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| **Study design/Methods**1. Sites not performing specific procedures on time/compliance
 |  |  |
| **Facilities/resources**1. Check if there are any issues relating to facilities or resources raised by the team – escalate to the sponsors if necessary
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| **Monitoring**1. Review of monitoring plan. Escalate to on-site monitoring/site visit based on any risks identified
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