

YES	NO	Subjects Screening/Enrollment and Visit Data
<input type="checkbox"/>	<input type="checkbox"/>	All ICFs are signed and dated for all subjects and the process is fully documented in the source documents.
<input type="checkbox"/>	<input type="checkbox"/>	All subjects have received a copy of the signed and dated ICF.
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that all ongoing patients have signed and dated the latest approved version of ICF.
<input type="checkbox"/>	<input type="checkbox"/>	Site personnel involved in the informed consent process have been delegated this responsibility by the PI on the Delegation and Signature Log.
<input type="checkbox"/>	<input type="checkbox"/>	The "Screening" and "Enrollment" logs are completed.

YES	NO	Source Document Verification/CRF Entries
<input type="checkbox"/>	<input type="checkbox"/>	Source documents (SD) and other trial records (e.g., CRFs) for all enrolled subjects are available, accurate, complete, and current.
<input type="checkbox"/>	<input type="checkbox"/>	Subject's participation in the trial is clearly indicated in the source data.
<input type="checkbox"/>	<input type="checkbox"/>	Subject is eligible.
<input type="checkbox"/>	<input type="checkbox"/>	All entries in the CRF are checked against the original source data.
<input type="checkbox"/>	<input type="checkbox"/>	Data required by the protocol are reported accurately in the CRF/queries and are consistent with the source documents.
<input type="checkbox"/>	<input type="checkbox"/>	The source documents reflect all CRF data as well.
<input type="checkbox"/>	<input type="checkbox"/>	Verify at each visit any change in therapy or dosage.
<input type="checkbox"/>	<input type="checkbox"/>	Protocol deviations have been documented on site and reported to the IRB/IEC as required by the protocol/local regulations.
<input type="checkbox"/>	<input type="checkbox"/>	Any corrections to the CRF/queries are dated and initialed, and do not obscure the original entry. All corrections to the CRF must be made on the original CRF page. (In case an eCRF is used, this is not applicable as it is automatically audit-trailed.)
<input type="checkbox"/>	<input type="checkbox"/>	For electronically-stored source documents, print-outs of the electronic data can be used as source documents as long as they are certified by the investigator through date and signature.
<input type="checkbox"/>	<input type="checkbox"/>	All data queries have been resolved and source data verified when applicable.

<input type="checkbox"/>	<input type="checkbox"/>	In case of early withdrawal of a patient, carefully check that the reason for withdrawal indicated in the source documents matches with the entries in the CRF (example: withdrawal for Adverse Event X is reported in the source document → the same adverse event should be found back in the CRF).
<input type="checkbox"/>	<input type="checkbox"/>	Document all the subject's visits you have reviewed and/or CRF pages collected/approved.

YES	NO	Safety Review
<input type="checkbox"/>	<input type="checkbox"/>	Adverse events are being reported in accordance with the protocol/safety guidelines.
<input type="checkbox"/>	<input type="checkbox"/>	Review all concomitant medications, potential procedures, ongoing or newly diagnosed events, lab reports, radiology reports, symptoms, and missed visits for potential adverse events or serious adverse events (SAE).
<input type="checkbox"/>	<input type="checkbox"/>	The availability of any start and stop dates and the outcome of the events appear in the source documents and CRF. Ensure the intensity of the event and the relationship to the study drug is available in the source documents and CRF.
<input type="checkbox"/>	<input type="checkbox"/>	Pay close attention to prohibited medications during the course of the trial. In case prohibited medication has been taken by a subject, immediately contact the Sponsor/Study Physician as defined in the Monitoring Guidelines.
<input type="checkbox"/>	<input type="checkbox"/>	Check if adverse events reported as "serious" have been reported as SAEs in a timely manner. In case an SAE is detected that the PI did not previously identify, the monitor should notify the PI immediately and initiate the appropriate reporting procedures.

YES	NO	Investigational Product (IP)/ Study Supplies
<input type="checkbox"/>	<input type="checkbox"/>	Only authorized personnel have access to the IP and can distribute it to the subject. This should be documented on the signature and delegation list.
<input type="checkbox"/>	<input type="checkbox"/>	Check the tracking of IP at the site and recording of the IP on the accountability logs.
<input type="checkbox"/>	<input type="checkbox"/>	Perform IP accountability/inventory at site and subject level. Document any discrepancies identified. Double check that the information is consistent with the entries in the CRF and what is written in the source documents.
<input type="checkbox"/>	<input type="checkbox"/>	Check the temperature log to ensure that the storage conditions of the IP are within the ranges defined for the product. In case of temperature excursion, contact the Sponsor and

		follow any procedures identified on temperature excursions.
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that the expiration date of the IP present on site is still within acceptable range. If not, ensure new IP is sent to the site. Ensure that there are always sufficient supplies on site.
<input type="checkbox"/>	<input type="checkbox"/>	Ensure records of receipt, use, and return of IP are complete and accurate at the site. When applicable, ensure that unused IP is destroyed according to regulatory and client-specific requirements. IP destruction can only be done upon written approval of the sponsor.
<input type="checkbox"/>	<input type="checkbox"/>	If IP is destroyed, ensure a certification of IP destruction is available at the site.
<input type="checkbox"/>	<input type="checkbox"/>	If using an Interactive Voice/Web Response System, compare the electronic listing to the CRF, source documents, and IP Accountability Log.
<input type="checkbox"/>	<input type="checkbox"/>	Check for any potential code break (only applicable if blinded study).
<input type="checkbox"/>	<input type="checkbox"/>	At each monitoring visit, make copies of all of the above documents to keep your filing up-to-date.

YES	NO	Review/Collection of Essential Documents
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that the Investigator's site file contains all current essential documents. Replace expired documents with new documents as needed.
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that the Delegation and Responsibilities Signature Log is always up to date.
<input type="checkbox"/>	<input type="checkbox"/>	In case of new team member, ensure that all the documents are collected (CV, Financial Disclosure Form, GCP certification, updated FDA 1572, etc.).
<input type="checkbox"/>	<input type="checkbox"/>	Check that new documents that require submissions to the IRB have been appropriately submitted and approved (where applicable).
<input type="checkbox"/>	<input type="checkbox"/>	Sign the Site Visit Log each day of a site visit.

YES	NO	Study Personnel/Site Facilities
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that the PI and staff are performing specified functions in accordance with the protocol and the client's requirements, and that the PI is providing adequate oversight.
<input type="checkbox"/>	<input type="checkbox"/>	In case tasks are delegated by the PI, ensure that delegates are appropriately qualified

		and trained.
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that materials for the study are always used in the appropriate fashion and maintained on a regular basis.
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that the site always keeps the study files in an appropriate and confidential way.
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that the site is still acceptable.
<input type="checkbox"/>	<input type="checkbox"/>	Visit on a regular basis all departments involved into the trial and document this into your visit report.

YES	NO	Meeting with PI and Site Staff
<input type="checkbox"/>	<input type="checkbox"/>	Ensure that all your findings detected during the visit are shared and discussed with the PI and site staff during the visit. If the PI is not available that day, ensure that the Follow-up letter clearly identifies all the issues and action to be taken. When appropriate, do not hesitate to personally contact the PI after your visit in case you did not had the chance to meet him/her.
<input type="checkbox"/>	<input type="checkbox"/>	Address all the deviations you noted and ensure appropriate retraining of the site where needed.
<input type="checkbox"/>	<input type="checkbox"/>	Ensure the site understands all the actions they need to follow-up on after the visit.
<input type="checkbox"/>	<input type="checkbox"/>	Keep the site informed on every aspect of the trial, and not only on the site-specific situation. It may be of interest and encouragement for sites to know the general status of the trial.