**Monitor’s responsibilities under ICH GCP**

The monitor(s) in accordance with the Sponsor’s requirements should ensure that the trial is conducted and documented properly by carrying out the following activities when relevant and necessary to the trial and the trial site:

1. Acting as the main line of communication between the Sponsor, the investigator or the investigator’s trial staff.
2. Verifying that the investigator has adequate qualifications and resources to conduct the trial safely and properly and that these remain adequate throughout the trial (e.g. facilities including laboratories, equipment and staff).
3. Verifying, for the investigational product(s):
   1. That storage times and conditions are acceptable, and that supplies are sufficient throughout the trial.
   2. That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).
   3. That subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s).
   4. That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.
   5. That the disposition of unused investigational product(s) at the trial sites or pharmacy complies with applicable regulatory requirement(s) and is in accordance with the sponsor.
4. Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.
5. Verifying that written informed consent was obtained before each subject's participation in the trial.
6. Ensuring that the investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).
7. Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.
8. Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution and have not delegated these functions to unauthorized individuals.
9. Verifying that the investigator is enrolling only eligible subjects.
10. Reporting the subject recruitment rate.
11. Verifying that source documents and other trial records are accurate, complete, kept up-to-date and maintained.
12. Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.
13. Checking the accuracy and completeness of the CRF entries, source documents and other trial-related records against each other. The monitor specifically should verify that:
    1. The data required by the protocol are reported accurately on the CRFs and are consistent with the source documents.
    2. Any dose and/or therapy modifications are well documented for each of the trial subjects.
    3. Adverse events, concomitant medications and inter-current illnesses are reported in accordance with the protocol on the CRFs.
    4. Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRFs.
    5. All withdrawals and dropouts of enrolled subjects from the trial are reported and explained on the CRFs.
14. Informing the investigator of any CRF entry error, omission, or illegibility. The monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialled by the investigator or by a member of the investigator's trial staff who is authorized to initial CRF changes for the investigator. This authorization should be documented.
15. Determining whether all adverse events (AEs) are appropriately reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, and the applicable regulatory requirement(s).
16. Determining whether the investigator is maintaining the essential documents.
17. Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.