RECOMMENDED Monitoring plan
SWENOTECA ABC-study

MONITOR:

- All sites in each country will be monitored by a study trained monitor who has experience from clinical trials and GCP in general.
- The monitor(s) cannot participate in the trial - or have contact with any of the patients through his or hers work in the clinic.
- Monitor from own organization is recommended.
- The study uses treatment already implemented in the clinical setting of testicular cancer patients, and the aim will be to guide the use of the eCRF and assure accurate inclusion in the study.
- There will be performed a final monitoring with focus on the endpoints of the study before publishing of results.

TIMING OF MONTORING:

- Recommended one time during the initial face of the study, e.g., after five patients have been locally included in the study.
- Further monitoring may be performed if deemed warranted by the study management.
- If major protocol violations and GCP non-compliance issues, additional monitoring visits may be performed. Furthermore, 100 % source data verification may be performed for all patients and the site may be closed. This will be decided by the principal investigators based upon the monitor-report.

TO BE PERFORMED DURING MONITORING VISIT:

- Check patient logs.
- Source-data verification
    - Informed consents
    - Eligibility criteria
    - Reported SAEs
    - Study treatment administered.