PreVent-ACaLL instruction

Reporting of protocol deviations **TMF/ISF section 19**

In all clinical trials, there can be deviations from the protocol. Some deviations are important for the patient's safety or the quality of the trial data. It is therefore important to report these deviations. The study coordinator (SC)/principle investigator (PI) is responsible for reporting protocol deviations to sponsor through REDCap. Those protocol deviations that must be reported to sponsor are listed below:

1. Patient enrolled into the study even though it's been more than 1 year from CLL diagnosis to randomization
2. Patient enrolled into the study even though it's been more than 42 days from signed informed consent (main study) to randomization
3. Patient enrolled into the study even though it's been more than 14 days from randomization to start of study treatment
4. No pregnancy test result was collected before start of study treatment
5. Collected pregnancy test were older than 7 days before start of study treatment
6. Incorrect dose of study treatment prescribed or dispensed to the participant
7. Participant did not ingest the fully assigned study treatment
8. Visit window was not kept within timeframe
9. Study data were collected from the patient before informed consent were signed

Each protocol deviation must be reported in the eCRF "Protocol Deviation" in REDCap. When the form is saved, sponsor will automatically be informed about the deviation. You can always contact sponsor (chip-prevent.rigshospitalet@regionh.dk) if you find reported protocol deviation serious or repeated at your site. Sponsor is always happy to help if something in the protocol is not clear or your site needs further training in specific areas of the protocol. Sponsor can also reach out to site if sponsor finds specific protocol areas necessary to be trained again.

Please see current version of the 'PreVent-ACaLL REDCap Guide' for further details on how to report protocol deviations in REDCap.

Thank you!