PreVent-ACaLL instruction

Enrollment procedure **TMF/ISF section 19**

This instruction lists the procedures and time frames for enrollment of patients for the PreVent-ACaLL study (incl. pre-screening). It is important to abide by these time points to assure that patients won't fail enrollment due to long time between CLL diagnosis and possible enrollment.

Reporting of pre-screening data, running of CLL-TIM algorithm, potential enrollment (for high risk, high confidence) incl. screening visit must be done as quick as possible.

1. Patient is diagnosed with CLL
2. Patient sign pre-screening informed consent
3. All available/needed pre-screening tests and data are reported in REDCap eCRF "PreVent-ACaLL – pre-screening". Time frame: Maximum one month for entering of all pre-screening data from CLL diagnosis.
4. CLL-TIM algorithm is run in REDCap,
5. Data is verified by sponsor within 24 hours
6. If the pre-screening result is **high risk, high confidence**, contact the patient as soon as possible to plan a visit for information about the randomized part of the project in written and orally by the principal investigator or sub-investigator.
7. If the pre-screening result is one of the below-mentioned, the participant must be created in the **low-risk category** in the REDCap project "PreVent-ACaLL – pre-screening":
    - Low risk, low confidence
    - Low risk, high confidence
    - High risk, low confidence
8. Minimum 24 hours and maximum one week after information visit, the patient must be contacted by either principal investigator, sub-investigator or project nurse to clarify any remaining questions from the patient and to plan whether the patient agrees to be enrolled in the study.
    a. If the patient agrees to be enrolled, date for screening/baseline visit must be arranged as soon as possible. The screening/baseline visit must be planned minimum one week ahead since central labs need to be informed and plan for sample management.

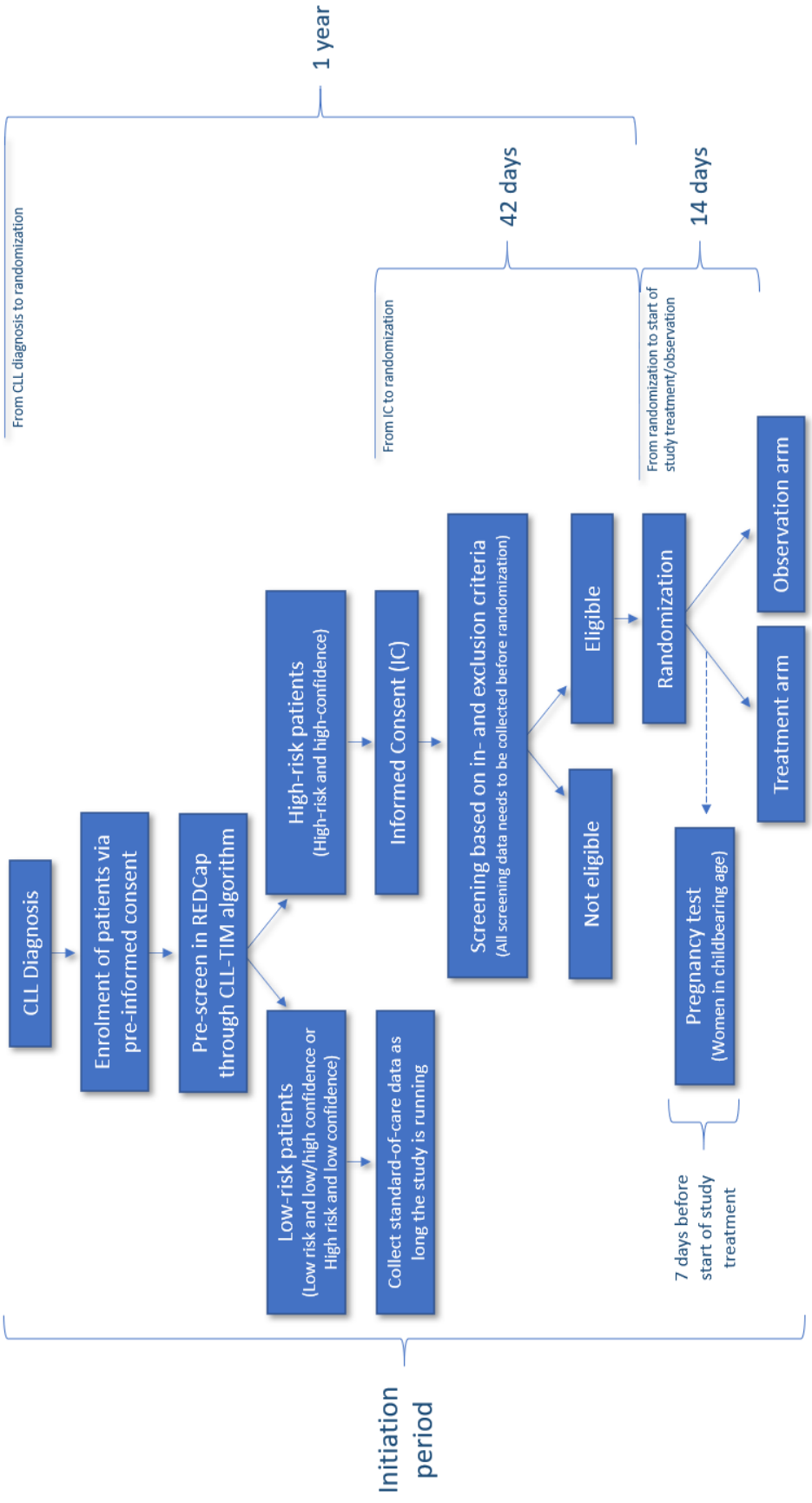
       Please assure that CT scan and bone marrow as well as the other screening tests are performed (please see Schedule of Assessments).

       OBS maximum 42-day screening period (from informed consent to randomization), randomization no later than 1 year after diagnosis of CLL, start of treatment/observation no later than 14 days after randomization (see Initiation Flowchart on next page).

       Sponsor will ship needed study kit(s) to your site when a patient is pre-screened as high/high.

    b. If the patient is not being enrolled into the study, please complete the eCRF "CLL-TIM assessment" including giving the reason for why the patient is not being enrolled.

Thank you!


1 year
42 days
14 days
From CLL diagnosis to randomization
From IC to randomization
From randomization to start of study treatment/observation
CLL Diagnosis
Enrolment of patients via pre-informed consent
Pre-screen in REDCap through CLL-TIM algorithm
High-risk patients
(High-risk and high-confidence)
Low-risk patients
(Low risk and low/high confidence or High risk and low confidence)
Informed Consent (IC)
Collect standard-of-care data as long the study is running
Screening based on in- and exclusion criteria
(All screening data needs to be collected before randomization)
Eligible
Not eligible
Randomization
Observation arm
Treatment arm
Pregnancy test
(Women in childbearing age)
7 days before start of study treatment
Initiation period