CLL2000: Pocket Card

What is CLL2000?

A **prospective, observational, multicenter study** by the German CLL Study Group (GCLLSG)

Indication: Studying long-term data of patients with CLL/SLL who received first-line treatment within the CLL2-GIVe, CLL13, CLL14, or CLL17 clinical trials

Primary endpoint:

- Overall survival (OS) after start of first-line treatment in the aforementioned trials

Secondary endpoints:

- Progression-free survival (PFS), time to next CLL treatment (TTNT), and treatment-free survival (TFS) after start of first-line treatment
- OS, PFS, TTNT, and TFS after start of second-line treatment
- Quality of life (QoL)
- Safety (types, frequencies and follow-up adjusted incidence rates of second primary malignancies and Richter Transformation from start of first-line treatment as well as causes of death)

Exploratory endpoints:

- MRD levels, analyses of biomarkers

Who is eligible?

Patients with the following criteria:

- Signature of informed consent
- Documented diagnosis of CLL/SLL at time point of inclusion in a first-line study of the GCLLSG (development of RT is not an exclusion criterion)
- First-line treatment was administered within one of the aforementioned studies of the GCLLSG
- Patients that already participate in a country-specific registry are also eligible
- Willingness and ability to comply with data collection (only once a year)

Why did we start this effort?

We are interested in understanding what happens to patients after they complete first-line therapy for CLL. Whether they received a fixed-duration regimen or remain on continuous treatment, we aim to capture their long-term outcomes. This includes data on survival, patient-reported outcomes, and the occurrence of secondary malignancies or Richter’s Transformation. By following patients beyond the original trial period, we hope to gain meaningful insights into the impact of first-line therapies over time.

How does CLL2000 differ from a registry?

While CLL2000 may seem similar to a registry, the key difference is our focus. In CLL2000, we are following a specific group of patients who received their first-line treatment as part of a GCLLSG trial. This means we are not just gathering general data, but closely tracking how these patients do over time: what treatments they receive next, how their disease evolves, and what kind of other relevant events occur. Having the possibility to connect the long-term data to each patient’s parent trial, we will be able to run longitudinal analyses within a pre-defined patient population to avoid bias. This approach will ensure a clearer picture of how treatment strategies play out in the long-term. However, for this effort to come to term, it is crucial that we include as many eligible patients as possible from the parent trials. Although enrolling a single patient may seem like a lot of effort for a small contribution, even a single case from each center adds meaningful value to the overall outcome

How can you participate?

1. **Register your trial site:**
   - Register your trial site for the study at the relevant independent ethics committee/ review board and/ or other authorities as per national requirements. Please get in touch with the GCLLSG to clarify the procedure for your trial site.
2. **Register the patient:**
   - Check if a patient is eligible (respect inclusion and exclusion criteria)
   - Obtain informed consent(s)
   - Use the same Patient ID as in the parent trial
3. **Document once a year as part of the clinical routine:**
   - Routine clinical data: survival, disease status, subsequent treatments for CLL/Richter Transformation, concomitant events (e.g. second primary malignancy, death)
   - Quality of Life: EORTC QLQ-C30 questionnaire (the questionnaire should be completed during the visit at the site or at home, preferably within a week after the documented visit)
   - Optional: collect 30 ml blood sample during routine blood draw (if the patient has agreed to optional blood sampling) and send it to the central DCLLSG laboratory

   No additional visits and venous puncture outside of clinical routine are required!

Timeline at a Glance

- Duration: 60 months after start of recruitment
- First patient in: Q3/2025
- Follow-up: annually

To be kept in mind

- No interventions or treatments are given
- Follow-up is entirely routine clinical practice
- Participation does not affect patient care
- Easy, low-burden documentation
- Big impact on current evidence by providing real-world, long-term outcome data linked to first-line clinical trials

Would you like to give feedback? We are happy to connect:

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