

## PATIENT REGISTRY

# Registry and Biobank for the collection of clinical data and biomaterial from adult ALL patients

Protocol Number: AGMT-ALL Reg

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### Protocol Synopsis:

<b>Indication:</b>	Adult acute lymphoblastic leukemia (ALL)	<b>Objective:</b>	Data collection regarding diagnosis, therapy and progression of disease for Austrian ALL patients older than 18 years
<b>Planned sample size:</b>	70 patients per year	<b>Biobank:</b>	Within the ALL registry biomaterial should be collected at diagnosis and once a year for 5 years and at relapse.
<b>Design:</b>	retrospective and prospective, observational, multicenter research initiative		
<b>Recruitment:</b>	First patient in (FPI): Q2 2012		

### Design:

In Austria approximately 70 patients are diagnosed with adult ALL per year and are treated in up to 17 institutes. Obviously there is a need to collect all data possible in order to harmonize diagnosis and treatment and to make optimal therapy available for every Austrian patient. Therefore information on these patients should be prospectively collected, analysed and used for the generation of treatment protocols by a specialized study group.

The Austrian ALL study group has been founded to take over this task. As a first step a registry with a standardized data set including diagnosis, therapy and outcome should be implemented.

This study is a registry and not an interventional clinical study. However, in order to achieve a maximum of data harmonisation it is recommended that patients are treated according to a standardized international protocol endorsed by the EWALL (European Working group for Adult Lymphoblastic Leukemia).

Associated with the registry a central biobank should be established for the collection of peripheral blood and bone marrow. During the last years the utility of molecular cytogenetics in adult ALL is an emerging topic. Several prognostic markers have been discovered and new targeted drugs are available. The use of molecular diagnosis in disease monitoring, risk stratification and the use of target orientated therapies are increasingly important in patient management of ALL. These diagnosis tools are currently not implemented in Austria. For that reason there are many open questions in adult ALL and the new prospects leave clinicians with uncertainty about how to optimally manage adult patients with ALL. A centralized and standardized diagnosis program is needed to assure quality.

### Biobank:

Biomaterial should be collected in a biobank to be used in ALL related research projects. As a basis for future research, the collection of biomaterial will help medical scientists to develop targeted therapies and to detect molecular targets for new therapies. A centralized biobank is the appropriate tool to collect these materials under strict ethical and legal regulations.

The collection of biomaterial is not categorically connected to the registry. Material should be obtained during clinical routine.

Within the ALL registry biomaterial should be collected at diagnosis, once a year for five years and at relapse.

### Inclusion Criteria:

- Signed written informed consent
- Male or female  $\geq 18$
- Acute lymphoblastic leukaemia (all types according to WHO classification 2008)
- Diagnosis of specific NHL subtypes (WHO classification):
  - B-lymphoblastic lymphoma
  - T-lymphoblastic lymphoma
  - Burkitt's lymphoma
  - Aggressive lymphoma with c-myc translocation
  - Other high risk lymphomas treated with ALL protocols

Due to the non-interventional design of the registry there are no exclusion criteria.

### Assessments:

- Collect informed consent
- Registration of the patient at first diagnosis
- Documentation during therapy at regular intervals every 6 months
- Documentation of response
- Follow up once a year for 5 years
- Documentation of relapse and following therapies

### Status (as of March 2017):

No	Zentrum	Patienten
01	PMU Salzburg / III. Med	7
02	AKH MUW / Med. I Hämatologie	103
03	Klinikum Wels Grieskirchen / Med. IV	17
04	KH Elisabethinen Linz / I. Interne	13
05	Kepler UK, Med Campus III./ Interne 3	12
06	Hanusch KH Wien / III. Med	0
07	LKH Feldkirch / Interne E	3
08	Kaiser-Franz-Josef Spital Wien	11
09	KH Hietzing	0
10	LKH Hochsteiermark	0
11	BHS Linz	0
	<b>TOTAL</b>	<b>166</b>