

## **KURZPROTOKOLL** **EsPhALL Imatinib Obs**

<b>Öffentlicher Titel</b>	Register neu diagnostizierter Philadelphia-positiver ALL bei Kindern
<b>Wissenschaftl. Titel</b>	A European observational registry collecting efficacy and safety data in newly diagnosed pediatric Philadelphia positive (Ph+) Acute Lymphoblastic Leukemia (ALL) patients treated with chemotherapy + imatinib (+/-) hematopoietic stem cell treatment (+/-)HSCT)
<b>Kurztitel</b>	EsPhALL Imatinib Obs
<b>Studienart</b>	multizentrisch, prospektiv, offen/unverblindet, einarmig, Register
<b>Studienphase</b>	Phase IV
<b>Erkrankung</b>	Kinder: Leukämien und Lymphome: Neu diagnostiziert / de novo
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Documented, newly diagnosed Philadelphia Chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) (a) Recorded presence of t(9;22)(q34;q11) is required e.g. determined via institutional cytogenetics or FISH and/ or of the presence of BCR-ABL fusion transcript identified by RT-PCR or FISH. Recorded presence of t(9;22)(q34;q11) is required e.g. determined via institutional cytogenetics or FISH and/ or of the presence of BCR-ABL fusion transcript identified by RT-PCR or FISH.</li><li>- Enrolled into this registry within 6 months of diagnosis or enrolled in a clinical trial within 6 months of diagnosis, although no earlier than Jan-2012.</li><li>- Previously treated or currently on treatment with any chemotherapy regimen + imatinib (of an HA-approved formulation or HA-approved Gleevec generic) ± HSCT.</li><li>- Written informed consent obtained prior to any information being entered into the registry (parent / legal guardian consent, where applicable) (a) Assent from a patient enrolled as a minor by parent / legal guardian consent must be obtained wherever possible. Obvious child dissent must be respected; (b) A patient enrolled as a minor by parent / legal guardian consent must be re-consented as an adult upon reaching the legal age of maturity during the course of the registry (legal age of maturity defined by local regulations); (c) Patients fulfilling the inclusion criteria, but who have died prior to registry opening and without the opportunity to give consent, may still be eligible for inclusion, subject to local requirements regarding the consent process.</li><li>- Male or female, pediatric patients aged greater than 1 year (<math>\geq 365</math> days) and less than 18 years old (<math>&lt; 17</math> years, 365 days) at diagnosis.</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- There are no exclusion criteria for this non-interventional study.</li><li>- Patients may voluntarily withdraw from the registry at any time.</li></ul>
<b>Alter</b>	1 - 17 Jahre
<b>Molekularer Marker</b>	BCR-ABL1
<b>Prüfzentren</b>	<b>Universitätsklinikum Frankfurt</b> (Rekrutierung beendet) Klinik für Kinder- und Jugendmedizin Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med Thomas Klingebiel Tel: 069 6301-5094 Fax: 069 6301-6700 <a href="mailto:Thomas.Klingebiel@kgu.de">Thomas.Klingebiel@kgu.de</a>
<b>Sponsor</b>	Novartis Pharma