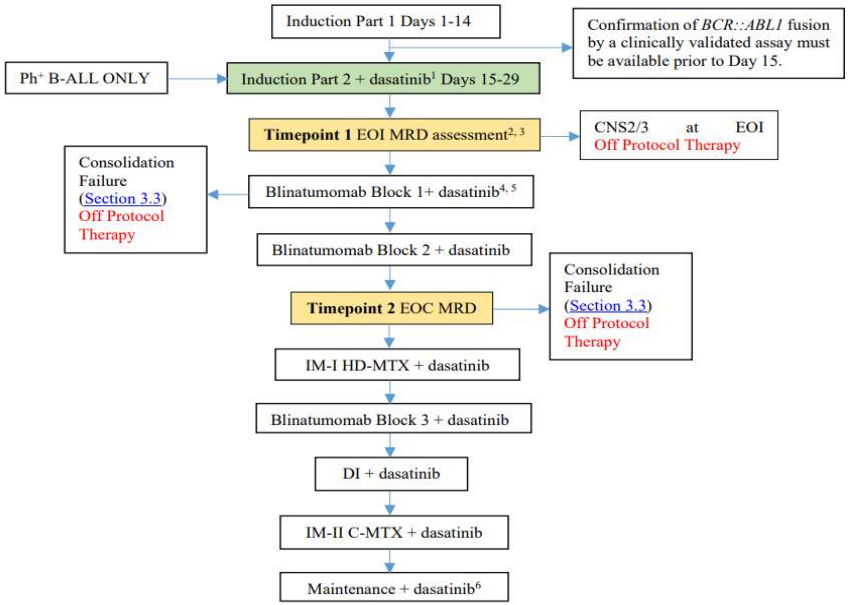
Treatment Trials posted May 2025

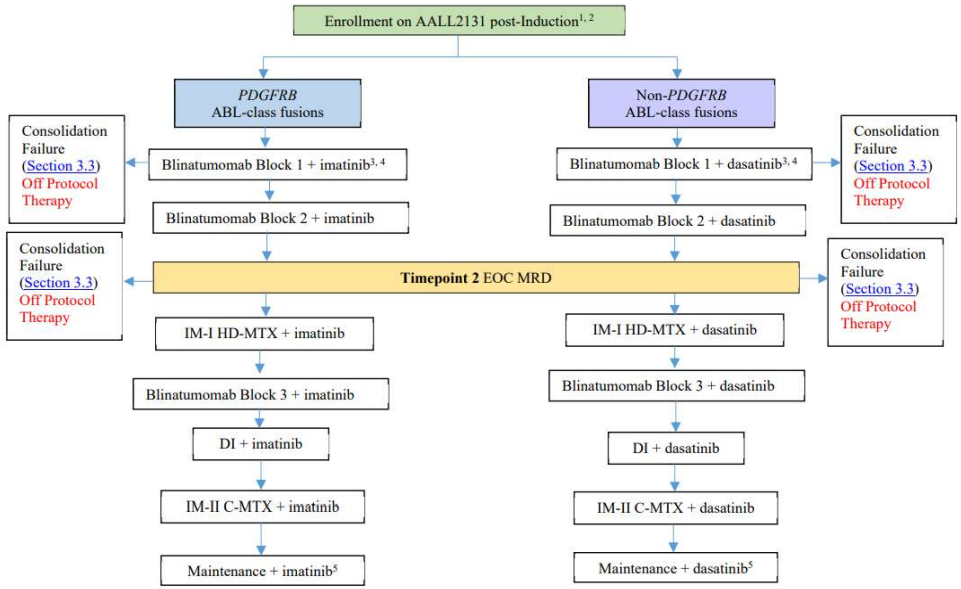
Research Base	Protocol #	Official Study Title	Indication/Disease	Planned Intervention	Abbreviated Eligibility Criteria Please refer to CTSU for the most recent version of the protocol.	Primary Objective	ClinicalTrials.gov NCT #	CTSU Activation Date	Approx. Target Accrual
COG	AALL2131	An International Pilot Study of Chemotherapy and Tyrosine Kinase Inhibitors with Blinatumomab in Patients with Newly-Diagnosed Philadelphia Chromosome-Positive or ABL-Class Philadelphia Chromosome-Like B-Cell Acute Lymphoblastic Leukemia	Newly-Diagnosed Philadelphia Chromosome-Positive or ABL-class Philadelphia Chromosome-Like B-cell Acute Lymphoblastic Leukemia	See Snippets below	**PVD: 3/25/2025** **Inclusion Criteria:** * must be >365 days and < 18 years (for AIEOP-BFM), >365 days and < 22 years (for COG) and >365 days and < 46 years (for ALLTogether sites) * Newly-diagnosed Ph+ or Ph-like ABL-class B-ALL. Leukemic blasts must express CD19 * Evidence of BCR::ABL1 should be documented by a clinically-validated assay prior to study entry on Day 15 from the first dose of vinCRIStine during Induction therapy. * Ph+ B-ALL must have previously started Induction therapy * Ph+ B-ALL have not received more than 14 days of systemic Induction therapy beginning with the first Induction dose of vinCRIStine * ABL-class Ph-like B-ALL must have previously completed 4 or 5 weeks of multiagent Induction chemotherapy * may have started either imatinib or dasatinib prior to study entry but should have received no more than 14 days of TKI for Ph+ B-ALL or no more than 35 days of TKI for ABL-class Ph-like B-ALL * have an ECOG scores of ≤ 2 or Karnofsky and Lansky performance scores ≥ 50% **Exclusion Criteria:** * Known history of chronic myeloid leukemia (CML) * ABL-class Ph-like B-ALL who are CNS2 or CNS3 at end of Induction phase * ALL developing after a previous cancer treated with cytotoxic chemo * Down syndrome (trisomy 21) * Prior treatment with TKIs before study entry with the exception of imatinib or dasatinib * known Charcot-Marie-Tooth disease See the protocol for CNS, HIV, organ, and marrow function parameters	* To estimate the 3-year event free survival (EFS) of children, adolescents, and young adults <25 years old with newly-diagnosed Ph+ (BCR::ABL1-rearranged) B-ALL who are treated with a modified Berlin-Frankfurt-Münster (mBFM) chemotherapy backbone that incorporates three cycles of blinatumomab without traditional consolidation chemotherapy in combination with continuous dasatinib. * To estimate the 3-year EFS of children, adolescents, and young adults <25 years old with newly-diagnosed ABL-class Ph-like B-ALL who are treated with a modified BFM chemotherapy backbone that incorporates three cycles of blinatumomab without traditional consolidation chemotherapy in combination with continuous imatinib for those with PDGFRB gene fusions or dasatinib for those without PDGFRB gene fusions. * To describe the safety and toxicity profile (infections, mucositis, neurotoxicity, cytokine release syndrome, hypogammaglobulinemia, therapy delays > 14 days, and treatment-related mortality) for patients with Ph+ or ABL-class Ph-like B-ALL treated on this novel chemo-immunotherapy backbone with continuous TKI.	NCT06124157	5/23/2025	222

EXPERIMENTAL DESIGN SCHEMA FOR PH+ B-ALL



[1] Administer dasatinib continuously throughout protocol unless otherwise noted.
[2] Patients with M1 marrow at EOI proceed to post-Induction therapy when peripheral counts recover. Patients with M2/M3 marrow at EOI proceed to post-Induction therapy immediately, irrespective of hematologic values.
[3] Patients who are CNS2/3 at the EOI must come off protocol.
[4] Patients with persistent testicular disease will receive 2400 cGy testicular RT in 12 fractions.
[5] Patients with M2/M3 marrow at EOI or EOI MRD ≥ 5% should have a bone marrow assessment following the first cycle of blinatumomab plus TKI.
[6] Patients who are CNS3 at diagnosis and clear their CNS disease by EOI will receive CRT 1800 cGy in 10 fractions during Maintenance therapy if patient is ≥ 48 months of age at the time of CRT. CRT is optional for CNS3 for patients who are < 48 months of age at the time of CRT.

EXPERIMENTAL DESIGN SCHEMA FOR ABL-CLASS PH-LIKE B-ALL



[1] Imatinib (for *PDGFRB* fusions) or dasatinib (non-*PDGFRB* ABL-class fusions such as non-*BCR ABL1, ABL2* or *CSF1R* gene fusions) are allowed to start during Induction as soon as the ABL-class gene fusion is identified prior to study enrollment.
[2] Patients with M1 marrow at EOI proceed to post-Induction therapy when peripheral counts recover. Patients with M2/M3 marrow at EOI proceed to post-Induction therapy immediately, irrespective of hematologic values.
[3] Patients with persistent testicular disease will receive 2400 cGy testicular RT in 12 fractions.
[4] Patients with M2/M3 marrow at EOI or EOI MRD ≥ 5% should have a bone marrow assessment following the first cycle of blinatumomab plus TKI.
[5] Patients who are CNS3 at diagnosis and clear their CNS disease by EOI will receive CRT 1800 cGy in 10 fractions during Maintenance therapy if patient is ≥ 48 months of age at the time of CRT. CRT is optional for CNS3 for patients who are < 48 months of age at the time of CRT.