|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Study Title and Status | | | | | | |
|  | | 1. Short Title | Please insert your trial’s short title according to the protocol. | | | | | |
|  | | 1. Brief Title | Please insert a brief and plain title for your trial. | | | | | |
|  | | 1. Scientific Title\* | Please insert the full scientific title of your trial. | | | | | |
|  | | 1. Recruitment Status\* |  | | | | | |
|  |  | Responsible Person/Center | | | | | | |
|  | | 1. Trialgroup\* |  | | | | | |
|  | | other | Please add additional study groups. | | | | | |
|  | | 1. Coordinating Investigator\* | Name (Degree, first name, surname) of public contact | | | | | |
|  | | Institute | Institute | | | | | |
|  | | Department | Department | | | | | |
|  | | Address | Address | | | | | |
|  | | Phone | Phone | | | | | |
|  | | FAX | FAX | | | | | |
|  | | Email | Email address | | | | | |
|  | | other | Additions | | | | | |
|  |  | Disease | | | | | | |
|  | | 1. Disease and Subform\* | Please select the type of leukemia and subform. | | | | | |
|  | | ALL | Y/N | All subtypes | | | Y/N | B-Precursor ALL |
|  | | Y/N | T-ALL/T-LBL | | | Y/N | Mature B-ALL/NHL |
|  | | Y/N | BCR-ABL+ | | |  |  |
|  | | Y/N | other | | | | |
|  | | AML | Y/N | All subtypes | | | Y/N | All subtypes accept APL |
|  | | Y/N | APL | | |  |  |
|  | | Y/N | other | | | | |
|  | | CLL | Y/N | All stages | | | Y/N | Stage 0 |
|  | | Y/N | Stage I | | | Y/N | Stage II |
|  | | Y/N | Stage III | | | Y/N | Stage IV |
|  | | Y/N | other | | | | |
|  | | CML | Y/N | All subtypes | | | Y/N | Chronic phase |
|  | | Y/N | Blast crisis | | | Y/N | Accelerated phase |
|  | | Y/N | Intolerant/resistant to one TKI | | | | |
|  | | Y/N | other | | | | |
|  | | MDS | Y/N | All subforms | | | Y/N | RCUD (RA/RN/RT) |
|  | | Y/N | RARS | | | Y/N | RCMD |
|  | | Y/N | MDS-U | | | Y/N | MDS with del5q |
|  | | Y/N | RAEB I | | | Y/N | RAEB II |
|  | | Y/N | CMML I | | | Y/N | CMML II |
|  | |  | Y/N | RARS-T | | |  |  |
|  | |  | Y/N | other | | | | |
|  | | MPD | Y/N | All subforms | | | Y/N | ET |
|  | | Y/N | PMF | | | Y/N | PV |
|  | | Y/N | other | | | | |
|  | | 1. Stage of Disease\* | Y/N | de novo | | | Y/N | relapsed/refractory |
|  | |  | Y/N | MRD positive | | |  |  |
|  | | other | Please insert additional stages. | | | | | |
|  |  | Study Design | | | | | | |
|  | | 1. Design\* | Y/N | open | | | Y/N | doubleblind |
|  | | Y/N | single-group | | | Y/N | double-group |
|  | | Y/N | randomised | | | Y/N | prospektive |
|  | | Y/N | monocentric | | | Y/N | multicentric |
|  | | other | Type design additions | | | | | |
|  | | 1. Phase\* |  | | | | | |
|  | | other | Please insert an additional study phase if needed. | | | | | |
|  | | 1. Type of Therapy/Trial\* | Y/N | Treatment study | | | Y/N | Supportive care |
|  | | Y/N | Stem cell transplantation | | | Y/N | Registry/observational study |
|  | | Y/N | Diagnostics/biomarker study | | | Y/N | Project |
|  | | Y/N | Trial for patients unfit for an intensive therapy | | | | |
|  | | other | Please insert additional types of therapy. | | | | | |
|  |  | Study Details |  | |  | | | |
|  | | 1. Recruiting Coutries | Please name countries from which participants will be, are planned to be, or have been recruited. | | | | | |
|  | | 1. Estimated Enrollment | Please name the estimated enrollment. | | | | | |
|  | | 1. Age\* |  | | | | | |
|  | | other | others, additions | | | | | |
|  | | 1. Start of Recruitment\* | Please enter the date (dd.mm.yyyy). | | | | | |
|  | | 1. Study Registries and Numbers | clinicaltrials.gov | | | NCTNumber | | |
|  | | EudraCT | | | Number | | |
|  | |  | other registry | | | Number | | |
|  | | 1. Intervention overview | Please provide an overview on the intervention. This field is optional! Do not enter precise dosage specifications. | | | | | |
|  | | 1. Remark | Here you may include any remarks. | | | | | |
|  | | 1. Aims | Please provide details on the aims of your study. | | | | | |
|  | | 1. Primary and Secondary Outcome Measures | Please name the primary and secondary outcome measures (optional). | | | | | |
|  | | 1. Inclusion Criteria\* | Please provide details on the inclusion criteria. | | | | | |
|  | | 1. Exclusion Criteria\* | Please provide details on the exclusion criteria. | | | | | |
|  |  | Contact |  | | | | | |
|  | | 1. Scientific Contact | Name (Degree, first name, surname) of scientific contact | | | | | |
|  | | Institut | Institute | | | | | |
|  | | Department | Department | | | | | |
|  | | Address | Address | | | | | |
|  | | Phone | Phone | | | | | |
|  | | FAX | FAX | | | | | |
|  | | Email | Email address | | | | | |
|  | | other | Additions | | | | | |
|  | | 1. Contact for administrative issues | Name (Degree, first name, surname) of public contact | | | | | |
|  | | Institut | Institute | | | | | |
|  | | Department | Department | | | | | |
|  | | Address | Address | | | | | |
|  | | Phone | Phone | | | | | |
|  | | FAX | FAX | | | | | |
|  | | Email | Email address | | | | | |
|  | | other | Additions | | | | | |
|  | | 1. Other Contact | e.g. study nurses | | | | | |
|  | | Name | Name (Degree, first name, surname) of contact | | | | | |
|  | | Institut | Institute | | | | | |
|  | | Department | Department | | | | | |
|  | | Address | Address | | | | | |
|  | | Phone | Phone | | | | | |
|  | | FAX | FAX | | | | | |
|  | | Email | Email address | | | | | |
|  | | other | Additions | | | | | |
|  | | 1. Additional Contact | Please fill in additional contacts (Name, Institute, Department, contact data). | | | | | |
|  | | 1. Contact Labs/Diagnostics | Contact for lab/diagnostics (Name, Institute, Department, contact data) | | | | | |
|  |  | Funding |  | | | | | |
|  | | 1. Source of monetary Support | Major source(s) of monetary or material support for the trial (e.g., funding agency, foundation, company). | | | | | |
|  | | 1. Sponsors | Primary sponsor: Individual, organisation, group or other legal person taking on responsibility for securing the arrangements to initiate and/or manage this study | | | | | |
|  | | Secondary sponsor: Additional individuals, organisations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. | | | | | |
|  | | 1. Seal of Approval | Seal of approval | | | | | |

Please send the fully completed form to the European Leukemia Information Center [ELIC@em.uni-frankfurt.de](mailto:ELIC@em.uni-frankfurt.de).