fondazione GIMEMA onlus
per la promozione e lo sviluppo della ricerca scientifica sulle malattie ematologiche.

ELN European LeukemiaNet

Mid to **L**ong-term Quality of Life **E**ffects **O**f imati**NI**b v*ersus* **DAS**atinib in Chronic Myeloid Leukemia Patients (LEONIDAS**)**

GIMEMA QoL-CML0713

GIMEMA QoL-CML0713 : Study Synopsis

Date 26.03.2014	*Version #1.0*

This protocol has been written and will be conducted in respect of the Helsinki Declaration, and of applicable national regulations

Study Responsabilities:

For GIMEMA Foundation:

Sponsor according to European Directives:	GIMEMA Foundation, Rome
Study Coordinator	Fabio Efficace
Study Co-coordinator	Gianantonio Rosti
Coordinating Center:	GIMEMA Data Center
Writing Committee:	Fabio Efficace, Gianantonio Rosti, Susanne Saussele, Marco Vignetti, Michele Baccarani
Advisory Board, CML Advocates Network:	Giora Sharf, Felice Bombaci
Project Management:	Laura Cannella, GIMEMA Data Center, Rome
In collaboration with:	ELN and CML Advocates Network
Legal representative of the GIMEMA Foundation:	Pr. Franco Mandelli

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Study Synopsis

Title:

Mid to Long-term Quality of Life Effects Of imatiNIb versus DASatinib in Chronic Myeloid Leukemia Patients (LEONIDAS)

Objectives:

Primary:

To compare the impact of therapy on daily life in Chronic Phase-Chronic Myeloid Leukemia patients (CP-CML) treated with first line therapy with dasatinib vs those receiving first line therapy with imatinib.

Secondary:

- To investigate QoL and symptoms burden differences between treatment groups;
- To examine adherence to treatment by type of therapy;
- To study the relationship between information provision, QoL profile and adherence to therapy;
- To compare the reporting of treatment related symptoms between patients and their treating physicians.

Design and Outcomes:

This is a cross-sectional and international matched case-control study run by the GIMEMA and the ELN. All data will be centrally collected and analyzed at the GIMEMA Data Center in Rome (Italy). Patients reported outcomes will be collected using internationally validated questionnaires (including the EORTC QLQ-C30 EORTC QLQ-CML 24 and –EORTC QLQ- INFO 25).

Population:

Inclusion criteria:

- Age of 18 years old or more at the time of study entry;
- Diagnosis of Philadelphia chromosome positive and/or BCR-ABL positive chronic myeloid leukemia (CP-CML) confirmed by pathological and cytogenetic/molecular analysis;
- CP-CML patients with already achieved CCyR (as documented by chromosome banding analysis of marrow cell metaphases) or in MMR (≤0.1% BCR-ABL IS);
- First line treatment with either dasatinib or imatinib for no more than 3 years;
- Written informed consent.

Exclusion criteria :

- Major cognitive deficits or psychiatric problems hampering a self-reported evaluation;
- Not speaking and reading the language of the participating country;
- Having received any CML treatment prior to imatinib or dasatinib therapy for more than three months.

Sample Size

According with study design and primary objective, the actual sample size required is 128 patients per dasatinb group and, 351 patients per imatinib group.