

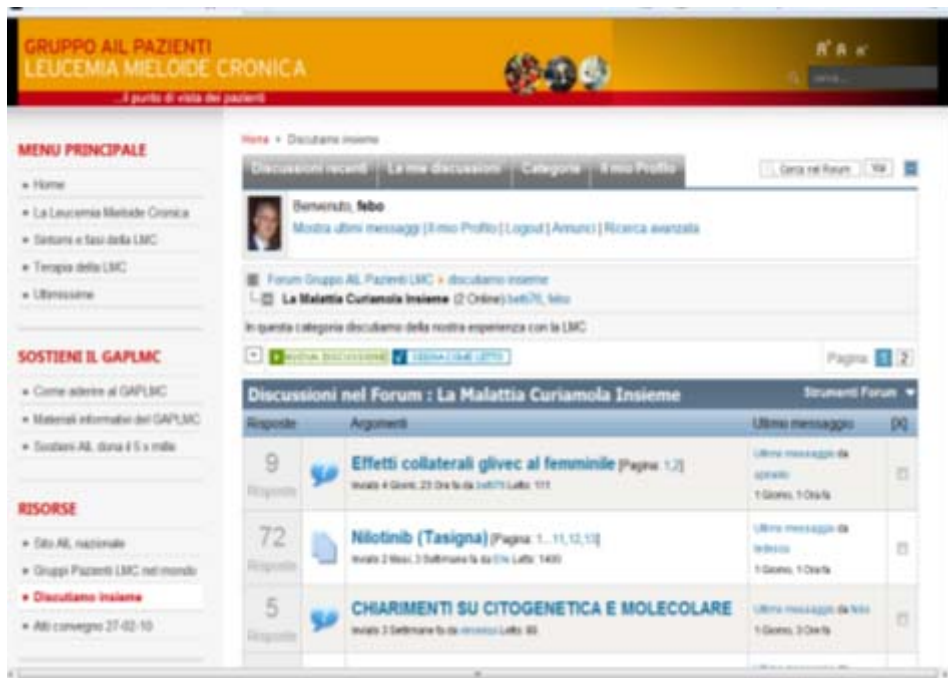
**Patient Reported Outcomes in
Chronic Myeloid Leukemia
GIMEMA QoL – CML0310**

Presented by

Gruppo ALL Pazienti LMC

Italy

Background



www.ailpazienti.it/lmconline is the first portal dedicated to Italian patients with chronic myeloid leukemia. A website built by patients for patients.

The forum, accessible to registered users, is a virtual meeting place for the Italian people with CML. A place where people meet someone else with the same disease to exchange their experiences.

The forum is the place where the people talk about of the their own QoL.

Only through the patients involvement in the development of a QoL questionnaire, the patient is able to give voice to how the disease or the treatment affect his personal QoL.

No one, outside of the patient, is able to make assumptions about the effects of therapy on some areas of his wellness.

Forum: general statistics

Total users	183
Answers	457
Discussions	26

Objective and Rationale



■ Objective of the study:

To support the development of an internationally validated **Quality of Life and symptom Burden Questionnaire** for Chronic Myeloid Leukemia (CML) Patients.

This Questionnaire will eventually be used in cancer clinical trials and routine clinical practice.

This Questionnaire will “formally” bring the unique patient’s perspective into the “clinical arena” and will facilitate clinicians and patients making more informed treatment-decisions.

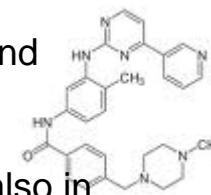
■ Project Rationale

No patient-reported instrument is as yet available to be used for CML patients.

Patients’ perspective is unique and should always be measured with methodologically sound instruments that are devised for such purpose (Food and Drug Administration-FDA, 2009).

New drugs, will have to be evaluated not only in terms of traditional clinical outcomes but also in terms of impact on patient-reported quality of life.

As stated by the FDA: “some treatment effects are known only to the patient” (FDA, 2009)



Brief description



- This research Project is lead by the “Italian Group for Adult Hematologic Diseases” (**GIMEMA**) and the “European Organization for Research and Treatment of Cancer” (**EORTC**) “**Quality of Life Group**”.
- It will be developed according to the highest methodological standards and complaint with international guidelines in this area (e.g. FDA, and EORTC QLG)
- Patients will be invited to participate in the survey after a brief description of the project and the survey will be posted on our website: www.ailpazienti.it/lmconline
- Data Collected through this method will be used to support the main analysis of the research project.
- The following countries have already committed to Participate: **Italy, UK, Norway, Germany, Greece, Netherlands, Austria, Taiwan and Australia.**



Basic steps of implementation



■ Questionnaire Development Process consists of 4 Phases.

Phase 1: Identify a list of relevant QL issues through:

- (i) Literature searches
- (ii) Interviews with Patients


Phase 2: Operationalise the issues into questions

Phase 3: Pretesting the questionnaire for acceptability and relevance

Phase 4: International Psychometric testing of the module



This has already been completed and patients will be asked to rate how relevant some health issues are for them.



Symptoms (disease and treatment related)	37 items
Psychosocial	17 items
Infertility	1 items
Body image	4 items
Adherence to therapy	9 items
Satisfaction	5 items

Basic steps of implementation



■ Phase 1: patients' interview

CML Patients

From CML advocacy web sites



Recruited on
CML advocacy web site

Online survey



Data to be used to support
main analyses

From Research centers



Recruited by local
investigators in their own
research centers



Main analysis

Surveys Elaboration

End of Phase 1

Preliminary Questionnaire !



Basic steps of implementation



- This project is open to all those interested in collaborating with us and warmly welcome any additional support and feedback from others.
- Is taking off the ground shortly and will continue until the development of a methodologically sound internationally validated questionnaire to evaluate quality of life in CML patients.
- Contact details of leading Investigators of the Project:

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Prof. Michele Baccarani

Director of the Department of Hematology
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Conclusions



- This project is transferable easily to other CML PG that are using a website and a forum to facilitate the experiences sharing between patients.
- The project is too usable to other PG on other pathologies, after appropriate adjustments.

How contact us



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