

European Treatment and Outcome Study

Universitätsklinikum Jena · Klinik Innere Medizin II · Postfach 07740 Jena, Germany

EUREKA Trial Center

cml@med.uni-jena.de eureka@med.uni-jena.de

Phone: +49 3641 9-396660 Fax: +49 3641 9-396669

Standardized assessment of deep molecular response in your CML patients

Your participation on the EUREKA registry

Dear colleague:

With this letter we want to invite you to participate in the **EUREKA registry** of the EUTOS program. EUREKA is a European registry on the assessment of deep molecular response in chronic phase CML patients after at least two years of therapy with tyrosine kinase inhibitors (TKI).

Purpose of the EUREKA registry

Standardized molecular monitoring and the precise detection of deep molecular response is a prerequisite for any attempt of treatment discontinuation in CML patients (MR^{4.5}). The sensitivity of BCR-ABL PCR has improved over the last years and a growing number of MR^{4.5} certificated labs is available.

In this registry, BCR-ABL transcript levels after at least two years of TKI therapy will be evaluated for the occurrence of deeper molecular response rates and its impact on the management of patients in a clinical practice setting outside of clinical trials. Improving the monitoring of deeper and sustained molecular responses is critical for the optimal management of BCR-ABL+ CML patients.

Sample and data collection

20 ml EDTA blood will be taken as part of the routine BCR-ABL monitoring of your patients. The blood sample (with full name), accompanied by the completed CRF form with some basic clinical parameters in anonymized format, should be sent to one of your local MR^{4.5}-certificated lab (addresses see CRF and distributed kits). Blood can be sent once or repeatedly from the same individual with at least 10 weeks interval between samples over a period of 2 years. The laboratory performing the analysis of the sample will be responsible for inserting the CRF form together with the results of the analysis to an eCRF that will be then submitted to the EUREKA database. You will receive a **report of the PCR result** from the MR^{4.5}-certificated lab.

How to participate in the EUREKA registry

If you care for CML patients with at least two years of TKI therapy we would warmly encourage you to include these patients into the EUREKA registry. Please get in contact with EUREKA Trial Center (eureka@med.uni-jena.de; Fax: +49-3641-9396669) for detailed information. The complete EUREKA protocol as well as declaration of consent and the CRF form with addresses of your local MR^{4.5}-certificated lab will be sent to you.

With kind regards,

Prof. Dr. Andreas Hochhaus for the EUREKA steering board

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