Next Generation Sequencing (NGS) and Droplet Digital PCR mutation testing project for optimal monitoring of your CML and Ph+ ALL patients

OVERALL OBJECTIVE

Early determination of the occurence of mutations in the kinase domain of the BCR-ABL gene in CML who are in the "warning" or "failure" zone during current TKI therapy (ELN 2013 guidelines) and Ph+ ALL patients as from diagnosis.

RATIONALE

Next Generation Sequencing (NGS) and Droplet Digital PCR (ddPCR) are sensitive detection techniques which can contribute to early detection of treatment failure and therefore guide optimal treatment.

NGS will be used in CML and ALL patients to screen for mutations in the bcr-abl kinase domain. Droplet Digital PCR is an even more sensitive technique and will be used in both CML and Ph+ ALL to screen for 3 the most common mutations, representing 75% of all mutations in the bcr-abl kinase domain: T315I, E255K and Y253H. (Soverini, 2014)

INCLUSION CRITERIA

CML patients with failure or warning to their current TKI therapy - all lines of therapy (ELN guidelines 2013)
Ph+ ALL patients from diagnosis and/or at molecular relapse - all lines of therapy. Monitoring when clinically appropriate.

SAMPLE PROCEDURE

- preferred: 10 to 20 µl cDNA (at room temperature)
- or: 1 µg RNA (or at least 15 µl if < 1 µg) RNA (at – 20°C)
- or: 3 ml of EDTA (at room temperature)

SHIP TO (PREFERABLY WITHIN 48 HOURS)

IPG - Dr. Pascal Vannuffel / Dr. Céline De Rop
NGS project
Avenue George Lemaître 25
6041 Gosselies (Belgium)

PLEASE COMPLETE THIS SECTION WITH NECESSARY DATA

Patient ID: ..... Sample ID: ..... Sample date: .....

Sample source: ☐ peripheral blood ☐ bone marrow

Diagnosis: ☐ CP-CML ☐ BP-CML ☐ AP-CML ☐ Ph+ ALL

% BCR-ABL$_{IS}$ transcript level: .....

If Ph+ ALL, specify isoform of BCR-ABL: ☐ P210 ☐ P190

Prior TKI treatment(s): .....

Confirm that there is NO suspected lack of adherence ☐ Yes

Doctor: .....

E-mail: .....

Institution: .....

City: .....

Additional information if possibly relevant: .....

IMPORTANT

- If questions, do not hesitate to call or e-mail one of the investigators
- We will also be pleased to explain the project during a Hemato Staff meeting in your hospital
- The samples will be analyzed and results will be reported to you within 2 weeks
- The analysis of samples via this Project does not substitute for the analysis of samples performed in your routine clinical practice
- The costs of sample analysis are covered by the project
- This project is supported by an unrestricted educational grant from Incyte Biosciences Benelux

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