The Life Raft Group is conducting a research program in collaboration with TDM Pharmaceutical Research, a CLIA-certified laboratory, to monitor both CML and GIST patients who are currently on branded Gleevec and who plan to transition to generic imatinib.

**BACKGROUND**
Imatinib Blood Level Testing (BLT) is a method of determining the trough level, or lowest level, of the drug in the blood. Research suggests there may be a relationship between the trough levels of imatinib and clinical benefit in CML & GIST. Numerous factors can affect this level, including body metabolism, dosage prescribed, and drug-drug interactions. Research has suggested that a level of 1100 ng/ml may be the therapeutic level, or optimal threshold for drug efficacy. Further research is being devoted to further investigate the relationship between imatinib exposure and efficacy to develop guidelines for the potential of BLT use in clinical practice.

**WHY THIS TESTING IS IMPORTANT TO CONSIDER FOR YOUR PATIENTS**
- Informs you of variation in drug levels for a patient who switches between brand and generic. This could be a beneficial indicator to track patient response to therapy.
- Provides you with another tool to monitor disease and side effects.
- Allows you to optimize clinical outcomes by developing individualized treatment plans.

**ELIGIBILITY**
- Patients must reside in the United States.
- Patients must understand that their insurance may being billed for the testing twice (once while on brand and once while on generic).
- Patients must enroll in the LRG Patient Registry if they have not already done so: https://liferaftgroup.org/life-raft-group-membership-application-form/
- Please be advised other inclusion criteria may apply.

**IMPORTANT DOCUMENTATION**
The following materials can be found on The Life Raft Group website: https://liferaftgroup.org/generics-research-program/. Please read and fill out the information to ensure the test be done properly:
- Plasma Level Testing Service Sample Submittal Form
- Informed Consent
- Patient Instructions
- Instructions for Sample Collection and Handling

**NOTE:** Most standard labs should have the required materials to collect and ship the samples. If the laboratory does not have the specific tubes, then any tube can be used. For more information about this procedure, please contact TDM at 302-832-1008 or support@TDMRxResearch.com. To learn more about the research study or to enroll, please contact Michelle Durborow at mdurborow@liferaftgroup.org.

**REFERENCES**
PHYSICIAN INSTRUCTIONS

To have this test done properly, make sure to complete the steps below. If you have questions about this procedure, please contact TDM Lab at 302-832-1008 or support@TDMRxResearch.com.

1. PROPER EQUIPMENT: All the materials necessary for blood testing should be available in a standard laboratory. In case materials are not available, the LRG can send a kit including tubes, needles, packaging and shipping labels. The blood draw procedure calls for a centrifuge to separate the plasma from the blood. The procedure calls for direct venipuncture from a forearm vein, but if your patient has a port, blood can be collected from the port. Please make sure the port is properly flushed and prepped before using and discard the first 1 to 2 ml of blood before collecting the blood in the tube.

2. DOCUMENTATION: Please have patient fill out the LRG informed consent form and the TDM Plasma Level Testing Service Sample Submittal Form prior to the appointment. In addition, a photocopy of both sides of the patient’s insurance card must accompany this form. The laboratory should ship these documents along with the plasma sample to the address provided:

TDM Pharmaceutical Research
100 Biddle Ave, Suite 202
Newark, DE 19702

3. TIMING THE APPOINTMENT: The testing protocol requires the blood be drawn 3 hours before the next dose. Please be sure to take this into account while scheduling your patient’s appointment. For example, if they take their dose at 2:00pm every day, please be sure the blood draw takes place between 11:00am to 2:00pm and they have NOT taken their next dose until the testing has been performed. In circumstances where an appointment cannot be made in that 3-hour window, the blood draw can be taken up to 3 hours after the scheduled time for dosage, as long as the next dose has NOT been taken, making the range for testing 11:00 – 5:00pm. Office hours may be an issue if they take their medication during early or late hours of the day. If they cannot get an appointment in a 3-hour window, you may want to speak to them about changing the time they take their dose to make it possible to perform the test during office hours. Please make certain the patient is on the new dose schedule for one week leading up to the testing.

NOTE: If the patient takes the medication twice per day, the 3-hour window changes to a 2-hour window.

4. TESTING DAY: No fasting or other precautions have to be taken. Having all of the prior steps completed, the testing should go smoothly. It is a relatively simple procedure. The blood is drawn, centrifuged, and the plasma that is separated from the blood is collected and sent to the testing site where various procedures determine the trough level of imatinib in the patient’s blood.

5. SHIPPING DAY: Samples should not be shipped to TDM on Friday or Saturday.

6. OBTAINING RESULTS: Results will be sent back to you via internet or fax. Timeframe may vary based on number of samples that come into the laboratory.

Thank you for helping the CML & GIST patient community by participating in this research program. Please feel free to contact the Life Raft Group at (973) 837-9092 or liferaft@liferaftgroup.org if you have any questions about our efforts to help the CML & GIST community. Please contact TDM Laboratory at 302-832-1008 or support@TDMRxResearch.com for more information about the testing procedure.