

## **Non-technical Abstract:**

This is a clinical trial (a type of research study) for patients with chronic myelogenous leukemia (CML), who have been treated for some time with an oral drug called imatinib mesylate (Gleevec). However, despite treatment with imatinib, there is still the presence of CML in the patient's blood or bone marrow. The purpose of the proposed study is to test the safety of a new investigational vaccine against CML and to see what effects it has on CML. This study is designed to test the ability to a vaccine against CML. This vaccine is made from GM-K562 cells. These cells are derived from K562 cells (which are CML cells) which have been altered in the laboratory to secrete GM-CSF. GM-CSF is a hormone that stimulates the immune system. These cells have the ability to secrete GM-CSF in effort to stimulate the immune system, but have been treated so that they do not have the ability to grow. These cells have been frozen away in our cell bank until thawed for clinical use. Similar vaccine trials using GM-CSF have been conducted in patients with other types of cancer. This is the first time that GM-K562 cells will be utilized in a clinical trial. GM-K562 cells are different from other K562 cells that have been previously modified to secrete GM-CSF in that GM-CSF expression is achieved by using a different plasmid expression vector. Data presented in publications have demonstrated that there are no significant side effects in receiving GM-CSF based cancer vaccines. Three different doses of GM-K562 cells will be tested in this trial. The first ten patients enrolled will receive the lowest dose. If this is well tolerated, then the next ten patients will receive the middle dose. If this is well tolerated, then the next ten patients will receive the highest dose. Once assigned to a dose, you will receive that same dose throughout your participation in this trial. Patients will continue to take their current dose of imatinib mesylate but in addition, will also receive a vaccine made from GM-K562 cells. Patients on this study will receive vaccination shots weekly under the skin for 3 weeks for three vaccinations, then every other week for three vaccinations, and then every month for three vaccinations until they have received a total of 9 vaccinations. Each vaccination may consist one to several shots placed under the skin on your forearms, thighs, or trunk areas, and the sites will rotate per vaccine.