# Clinical Trials Data KIT - Document 24

# A Biospecimen Collection Study of Leukapheresis-Derived Circulating Tumor Cells, Immune Cells, and Progenitor Cells.

## Clinical Trial: https://clinicaltrials.gov/study/NCT00571389

"eligibilityCriteria": "Inclusion Criteria for Biospecimen(s) collection:\n\nCancer Cohort Inclusion Criteria:\n\n1. Male or Female Adult \u2265 18 years of age.\n2. Histological diagnosis of any solid tumor type and at any stage of disease progression including in the neoadjuvant/presurgical setting, adjuvant setting, or considered in remission.\n3. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 3 (see Appendix 2) and an estimated life expectancy of at least 3 months.\n4. Subject or subject's legal representative provides written informed consent.\n5. Negative serology screening test for HIV, Hepatitis B surface antigen, and Hepatitis C antibody, or negative reflex PCR test result for HIV, Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV)\n6. Additional eligibility criteria need to be met for leukapheresis collection:\n\n \* ECOG Performance Status of 0 or 1 (see Appendix 2)\n \* WBC \u22652000/\u03bcL\n \* Neutrophils \u22651000/\u03bcL\n \* Platelets \u2265100x103/\u03bcL\n \* Hemoglobin \u22659 g/dL\n \* Creatinine \u22642.5 x ULN\n \* AST \u22642.5 x ULN without, and \u2264 5 x ULN with hepatic metastases\n \* Bilirubin \u22642 x ULN (except patients with Gilbert's syndrome, who must have total bilirubin \u2264 3.0 mg/dL)\n \* Negative urine pregnancy test for women of childbearing potential\n\nHealthy Volunteer Cohort Inclusion Criteria:\n\n1. Male or Female Adult \u2265 18 years of age.\n\n \u25aa Pediatric healthy volunteers from 5-17 years of age, with suspected or confirmed COVID-19 diagnosis by laboratory test will be eligible to participate in minimally invasive biospecimen collection procedures, as long as written parental consent has been obtained, and if applicable and technologically able, child assent. Minimally invasive biospecimen collection procedures allowed for pediatric participation include swabs (nasal, NP and OP), microcapillary sampling, and saliva or urine collection.\n2. Healthy volunteers are eligible, including the following:\n\n \* History of autoimmune disease or inflammatory disorder considered clinically stable by the Principal Investigator or treating physician's discretion.\n \* Suspected or diagnosed COVID-19 disease by laboratory test, whether in the acute, sub-acute or convalesced state.\n \* Employees of the study site(s) or BioCytics, as long as fulfilment of inclusion criteria 3.c is obtained.\n3. Subject or subject's legal representative provides written informed consent.\n4. Negative serology screening test for HIV, Hepatitis B surface antigen, and Hepatitis C antibody, or negative reflex PCR test result for HIV, HBV, and HCV.\n5. Additional eligibility criteria need to be met for leukapheresis collection:\n\n \* Must be \u2265 18 years of age.\n \* WBC \u22652000/\u03bcL\n \* Neutrophils \u22651000/\u03bcL\n \* Platelets \u2265100x103/\u03bcL\n \* Hemoglobin \u22659 g/dL\n \* Creatinine \u22642.5 x ULN\n \* AST \u22642.5 x ULN\n \* Bilirubin \u22642 x ULN (except patients with Gilbert's syndrome, who must have total bilirubin \u2264 3.0 mg/dL)\n \* Negative urine pregnancy test for women of childbearing potential\n\n2.3.4. Exclusion Criteria\n\n1. Subjects with active infection requiring therapy (fever, localizing source) will be excluded until the infection resolves.\n\n a. This excludes subjects with suspected or confirmed COVID-19 by laboratory test while in the acute and sub-acute phase of viremia.\n2. Underlying medical condition that, in the Principal Investigator's or treating oncologist's opinion, will obscure the interpretation of the patient's safety.\n3. Confirmed positive reflex PCR test result for HIV, Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV).",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "5 Years",  
"stdAges": [  
"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "The population of patients to be enrolled for this study will consist of two cohorts: 1) cancer patients, and to a lesser extent 2) healthy volunteers.",

Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
The criteria state that patients with \*\*any solid tumor type and at any stage\*\* are eligible. A KIT gene mutation is associated with certain types of solid tumors (e.g., gastrointestinal stromal tumors (GIST), some melanomas). Therefore, \*\*a patient \*could\* be eligible\*\* if they have a solid tumor driven by a KIT mutation, provided they also meet the other inclusion criteria (age, performance status, bloodwork, etc.) and don't meet any exclusion criteria. The trial doesn't specifically exclude patients based on the presence or absence of a KIT mutation.