

## Statement of Work

### **Task I.** Patient Recruitment

The Contractor shall identify and recruit between 20 and 80 new patients with HTLV-1 Associated Adult T-Cell Leukemia/Lymphoma (ATL) for inclusion in Phase I/II Clinical Trials of the Metabolism Branch, Center for Cancer Research, National Cancer Institute (NCI). It is anticipated the Contractor shall identify between 5 and 20 new patients per year). These Clinical Trials will be conducted by the Metabolism Branch, National Cancer Institute under protocols that have been approved by the Institutional Review Board (IRB) of the NCI, and under Investigational New Drug (IND) applications that have been approved by the Food and Drug Administration (FDA) of the Department of Health and Human Services (DHHS) of the U.S. Federal government.

- A. The contractor shall identify patients who meet the criteria specified by the Clinical Trials Protocols that the Metabolism Branch, National Cancer Institute (NCI) will provide.
- B. For all patients identified in A. above, contractor shall provide the patient's name and contact information (address, telephone, electronic mail, as applicable).
- C. Identified patients shall have a diagnosis of HTLV-1 associated Adult T-Cell Leukemia.
- D. It is preferable but not mandatory that identified patients shall not have received any Chemotherapy.
- E. Identified patients shall be evaluated for inclusion in NCI Clinical Trials. Perform testing, collect specimens and sera, and review clinical information of identified patients. Testing results, specimens, and sera shall be submitted in accordance with ARTICLE F.1. DELIVERIES. This shall include:
  - 1) Serology test results including testing for HTLV-1.
  - 2) Serum Chemistries to include: sodium, potassium, calcium, chloride, glucose, blood urea nitrogen, carbon dioxide, total bilirubin, creatinine, albumin, alkaline phosphatase, and AST/ALT liver function tests.
  - 3) Complete Blood Count to include platelets and leukocyte differential
  - 4) Pathological examination of peripheral blood, bone marrow, lymph node or tissue, as requested or specified by the clinical protocol applicable to the patient.
  - 5) Stool specimens for examination of parasitic burden
  - 6) Bone marrow, skin, and spinal cord specimens from autopsy of ATL patients if available.

**Task II.** Travel Assistance

- A. The Contractor shall provide travel assistance to patients selected for inclusion in NCI clinical trials. The NCI shall select patients for inclusion in NCI clinical trials and inform the Contractor of patients selected for inclusion in NCI clinical trials. This shall include, but is not limited to, assisting patients in obtaining VISA's, passports or other documentation required for travel to the NCI in Bethesda, Maryland, USA.
- B. The Contractor shall coordinate the travel of patients selected for inclusion in NCI clinical trials. This shall include, but is not limited to, providing transportation schedules and coordinating travel arrangements with NCI staff, and assisting patients in directions, etc, to the NCI.
- C. All patients selected for inclusion in NCI clinical trials shall be reimbursed for travel separate from this contract by the NCI.

**Task III.** Patient Monitoring

Contractor shall perform post-treatment patient care and monitoring of patients. The post treatment evaluations shall be performed not only on all newly referred patients, but also on patients in Jamaica with ATL (approximately 30) previously treated on Metabolism Branch CCR, NCI clinical protocols and FDA approved IND applications. For each patient enrolled in a NCI Clinical Trial, and in accordance with applicable laws, regulations, and the specific clinical trial protocol, the contractor shall:

- A. Monitor and record patient progress at intervals defined in the individual protocols, and as required by the reports section of this RFP.
- B. Collect and arrange for delivery to the National Cancer Institute, patient data, specimens, and biological materials which may include blocks and slides of paraffin-embedded tumor tissue and bone marrow and/or serum samples, as determined by the protocol or as requested by the Project Officer.
- C. Continue clinical treatment on individual patients per the patient's specific clinical protocol as required as requested by the Project Officer or the specific clinical protocol. This may include, but is not limited to, administration of any of the following agents as defined by and/or described in the clinical protocols: Cyclophosphamide, Doxorubicin, Vincristine, Prednisone, (CHOP), Zenapax(daclizumab), Bactrim DS, Fluconazole ,and Valganciclovir.
- D. Perform laboratory evaluations as specified in the specific clinical protocol.

- E. Deliver patient data as specified in the specific clinical protocol.
- F. Contact appropriate the Project Officer when a serious adverse event occurs to patients enrolled in a NCI Clinical Trial conducted under this contract. Initial notification may be by telephone or electronic mail. Provide all information required by FDA regulations for adverse events. Submit, within 72 hours of the event, a report which provides the following information, as applicable:

CHECK TIMING FOR SUBMISSION OF REPORT

- 1) Hospital admission and discharge
- 2) Event summary
- 3) Copies of lab reports related to the event
- 4) Copies of radiology report
- 5) Medication dose and date(s) of administration of medication