

BMT CTN 0101 Research Sample Types and Collection Schedule

Research Sample Purpose	Sample Type	Sample Aliquot Volume & Quantity	DATES SAMPLES OBTAINED
Pharmacokinetics	Plasma (heparin)	1.0-3.5 mL 1 aliquot	Day 14 & 28 of therapy, at onset of serious suspected drug toxicities as delineated in Section 2.4.6 and at onset of possible, presumptive, probable or proven infection (prior to start of antifungal therapy).
Investigational Fungal Diagnostic Assays	Serum	1.0-3.5 mL 1 aliquot	2x/week from Day 0 to Day 60. After Day 60, samples will be collected once per week until Day 100 unless one of the following is met: (1) patient received a T cell depleted transplant and received post-transplant GVHD prophylaxis, or (2) patient is on steroids, or (3) patient has or has had acute GVHD requiring systemic therapy. These patients will provide samples 2x/week until Day 100. Samples will also be collected at onset of possible fungal infection and 2x/week in patients receiving an empirical trial of amphotericin B or caspofungin for possible invasive fungal infection. For patients with presumptive, probable or proven aspergillus infection, 2x/week for 4 weeks and then once every 2 weeks for 8 weeks for a total of 12 samples, and then 1-2x/week until Day 100.
	Whole Blood (heparin)	1.0-4.5 mL 1 aliquot	
Donor SNP Testing (related donors)	Whole Blood or Stem Cell Product Aliquot (heparin)	2.0-4.5 mL 1-2 aliquots	At baseline prior to transplant.
Investigational Monitoring of Treatment Galactomannan Assays	Serum	1.0-3.5 mL 1 aliquot	For patients with presumptive, probable or proven aspergillus infection, at onset and 2x/week for 4 weeks and then once every two weeks for a total of 12 samples.
Investigational Galactomannan Assays of BAL (bronchoalveolar lavage)	1 mL BAL	1.0 mL 1 aliquot	Anytime bronchoscopy is performed.
Investigational Future Testing	Serum	0.5-2.5 mL 1-2 aliquots	Baseline.

Note 1: Sample aliquot processing was performed by the clinical sites. Frozen sample aliquots were periodically batch-shipped to the NHLBI Repository. All repository samples are being stored at -80°C.