

	All Patients	Patients not on Enzyme Therapy			Patients on Enzyme Therapy		
	Upon Enrollment	Every 12 months	At time of an event	Baseline and every 6 months	Baseline and every 12 - 24 months	At time of an event or therapy change	
<b>General</b>							
Demographics	●						
Enzyme Activity	●						
Genotype	●						
Diagnosis	●						
Medical History	●	●		●			
Physical Examination	●						
<b>Fabry Disease Clinical Assessment <sup>A</sup></b>							
Cerebrovascular - TIA, Stroke	●	●	●	●		●	
Neurology - Sweating, Heat/Cold Intolerance, Pain	●	●		●			
Gastroenterology	●	●		●			
Cardiology	●	●	●	●		●	
ECHO <sup>B</sup>					● <sup>B</sup>		
ECG <sup>B</sup>					● <sup>B</sup>		
Renal - Dialysis, Transplant	●	●	●	●		●	
Skin	●	●		●			
Respiratory - Spirometry	●	●	●	●		●	
Ophthalmology	●	●	●		●	●	
<b>Vital Signs and Laboratory Tests</b>							
Height/Weight	●	●	●	●		●	
Blood Pressure	●	●	●	●		●	
Serum Creatinine and BUN	●	●	●	●		●	
Urinary Protein Excretion <sup>C</sup>	●	●	●	●		●	
GFR <sup>D</sup>	●	●	●	●		●	
<b>Specialized Tests</b>							
Plasma GL-3	Prior to the first infusion, then every 3 months for the first 18 months of treatment, then every 6 months thereafter.						
Antbody Testing	Prior to the first infusion, then every 3 months for the first 18 months of treatment, then every 6 months until a negative result is confirmed, and annually thereafter.						
Immune Complex Testing	If signs and symptoms of immune complex are evident, appropriate laboratory assessments for circulating immune complexes, such as Raji and C1q binding methods, will be undertaken in consultation with the Genzyme Safety Officer.						
<b>Pain/Quality of Life (QOL) <sup>E</sup></b>							
SF-36	●	●			●	●	
BPI-9	●	●			●	●	
Pediatric QOL Questionnaire	●	●			●	●	
<b>Enzyme Replacement Therapy Status</b>							
<b>Adverse Event Reporting</b>							
Ongoing/continuous monitoring with reporting through Genzyme Pharmacovigilance Department. Refer to Safety section of Protocol and Manual for specific reporting guidelines and instructions.							

<sup>A</sup> Relates to a series of questions of Fabry specific symptoms that are delineated in the CRFs attached. The Clinical Assessments represent the core Fabry-related disease manifestations that are assessed to stage disease progression over the life-long course of the disease. Physicians will determine the actual frequency of necessary assessments according to a patient's individualized need for medical care and routine follow-up.

<sup>B</sup> ECHO and ECG are recommended for patients ≥ 35 years of age every other year.

<sup>C</sup> 24 hour or first morning void urine for urine protein, creatinine and microalbumin

<sup>D</sup> GFR can be estimated using equations such as the MDRD equation for adults and Schwarz formula for children

<sup>E</sup> Ideally, Pain and QOL should be assessed at Baseline and every 12 months.