

Relapse Capture Log Definitions

Refractory disease – disease not responsive to current therapy based on clinical, radiologic, or bone marrow evaluation as dictated by a protocol if the child is on protocol (or as per off study criteria for a child being treated as per a protocol) or by the treating physician if the child is being treated off protocol. On or as per a protocol, this would mean meeting criteria that the child would need to come off protocol. If the child is then either enrolled on a subsequent study, DVL or otherwise, or given a different treatment and remains refractory, this would count as a second or subsequent independent “refractory”.

Progressive disease – disease not responsive to current therapy with evidence of further disease progression by clinical, radiologic or bone marrow evaluation as dictated by a protocol (RECIST CRITERIA) if the child is on protocol (or as per off study criteria for a child being treated as per a protocol) or by the treating physician if the child is being treated off protocol. On or as per a protocol, this would mean meeting criteria that the child would need to come off protocol. If the child is then either enrolled on a subsequent study, DVL or otherwise, or given a different treatment and continues to progress, this would count as a second or subsequent independent “progression”.

Patients may go from refractory to progressive based on clinical, radiologic or bone marrow evidence of disease progression.