



TUMOR MEASUREMENTS

Check the response evaluation system required by the protocol: WHO RECIST Other: _____

Method of assessment* ▶▶▶▶▶									
DATE dd/mm/yy ▶▶▶▶▶	LESIONS	INITIAL MEASUREMENTS mm X mm	*	1 st . MEASUREMENTS mm X mm	*	2 nd . MEASUREMENTS mm X mm	*	3 rd . MEASUREMENTS mm X mm	*
	A								
	B								
	C								
	D								
	E								
	F								
	G								
	H								
	I								
	J								
		Response to target lesion °							
NON TARGET LESIONS		Response to Non target lesions °°							
Present at baseline ?	Y/N	New lesions observed		Y / N		Y / N		Y / N	
Overall RESPONSE °°° ▶									

Method of assessment* ▶▶▶▶▶											
DATE ▶	TARGET LESIONS **	4 th MEASUREMENTS mm X mm	*	5 th MEASUREMENTS mm X mm	*	6 th MEASUREMENTS mm X mm	*	7 th MEASUREMENTS mm X mm	*	8 th MEASUREMENTS mm X mm	*
	A										
	B										
	C										
	D										
	E										
	F										
	G										
	H										
	I										
	J										
	Response to - target lesions °										
	Response to non target lesion °°										
	New lesions	Y / N		Y / N		Y / N		Y / N		Y / N	
	Overall RESPONSE °°° ▶										

*** METHODS OF ASSESSMENT:**
 1) Physical Examination 2) Chest X-Ray 3)conventional CT-Scan
 4) spiral CT scan 5) MRI 6) Echography 7) Bone scan 8) Tumor Markers 9) Other

**Guidelines for indications to body drawings:
Target lesions should be marked **TL** on the body drawings
Non Target lesions should be marked **NLT** on the body drawings

° Target lesion :
 WHO / RECIST: CR/PR/NC/PD

°° Non Target Lesion :
 WHO: CR/PR/NC/PD
 RECIST: CR/ non CR non PD/ PD

°°° Overall response:
 WHO / RECIST: CR/PR/NC/PD



Guidelines for toxicity version 3.0 (august 2006)

Please add a copy of the required toxicity scale according to the protocol. (see annex in protocol) Electronic version of the NCI-CTC available at: <http://ctep.cancer.gov/forms/CTCAEv3.pdf>

Toxicity	Grade			
	1	2	3	4
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition; IV fluids indicated <24 hrs	Inadequate oral caloric or fluid intake; IV fluids, tube feedings, or TPN indicated ≥24 hrs	Life-threatening consequences
Vomiting	1 episode in 24 hrs	2-5 episodes in 24 hrs; IV fluids indicated < 24 hrs	≥6 episodes in 24 hours; IV fluids or TPN indicated ≥ 24 hrs	Life-threatening consequences
Anorexia	Loss of appetite without alteration in eating habits	Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated	Associated with significant weights loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); IV fluids, tube feedings or TPN indicated.	Life-threatening consequences
Constipation	Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema	Persistent symptoms with regular use of laxatives or enemas indicated	Symptoms interfering with ADL*; obstipation with manual evacuation indicated	Life-threatening consequences (e.g., obstruction, toxic megacolon)
Diarrhea	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 – 6 stools per day over baseline; IV fluids indicated <24hrs; moderate increase in ostomy output compared to baseline; not interfering with ADL*	Increase of ≥7 stools per day over baseline; incontinence; IV fluids ≥24 hrs; hospitalization; severe increase in ostomy output compared to baseline; interfering with ADL*	Life-threatening consequences (e.g., hemodynamic collapse)
Mucositis/stomatitis (clinical exam) <i>Select: Anus, Esophagus, Large bowel, Larynx, Oral cavity, Pharynx, Rectum, Small bowel, Stomach, Trachea</i>	Erythema of the mucosa	Patchy ulcerations or pseudomembranes	Confluent ulcerations or pseudomembranes; bleeding with minor trauma	Tissue necrosis; significant spontaneous bleeding; life-threatening consequences
Mucositis/stomatitis (functional/symptomatic) <i>Select: Anus, Esophagus, Large bowel, Larynx, Oral cavity, Pharynx, Rectum, Small bowel, Stomach, Trachea</i>	Upper aerodigestive tract sites; Minimal symptoms, normal diet; minimal respiratory symptoms but not interfering with function Lower GI sites; Minimal discomfort, intervention not indicated	Upper aerodigestive tract sites; Symptomatic but can eat and swallow modified diet; respiratory symptoms interfering with function but not interfering with ADL* Lower GI sites; Symptomatic, medical intervention indicated but not interfering with ADL*	Upper aerodigestive tract sites; Symptomatic and unable to adequately aliment or hydrate orally; respiratory symptoms interfering with ADL* Lower GI sites; Stool incontinence or other symptoms interfering with ADL*	Symptoms associated with life-threatening consequences
Alopecia	Thinning or patchy	Complete	-	-
Rash/desquamation	Macular or papular eruption or erythema without associated symptoms	Macular or papular eruption or erythema with pruritus or other associated symptoms; localized desquamation or other lesions covering <50% of body surface area (BSA)	Severe, generalized erythroderma or macular, papular or vesicular eruption; desquamation covering ≥50% BSA	Generalized exfoliative, ulcerative, or bullous dermatitis
Nail changes	Discoloration; ridging (koilonychia); pitting	Partial or complete loss of nail(s); pain in nailbed(s)	Interfering with ADL*	-
Infection with normal ANC or Grade 1 or 2 neutrophils	-	Localized, local intervention indicated	IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated	Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)
Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC <1.0 x 10 ⁹ /L, fever ≥38.5°C)	-	-	Present	Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)
Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia neutrophils (ANC <1.0 x 10 ⁹ /L)	-	Localized, local intervention indicated	IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated	Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)
Neuropathy- motor	Asymptomatic, weakness on exam/testing only	Symptomatic weakness interfering with function, but not interfering with ADL*	Weakness interfering with ADL*; bracing or assistance to walk (e.g., cane or walker) indicated	Life-threatening; disabling (e.g., paralysis)
Neuropathy-sensory	Asymptomatic; loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	Sensory alteration or paresthesia (including tingling), interfering with function, but not interfering with ADL*	Sensory alteration or paresthesia interfering with ADL*	Disabling
Dizziness	With head movements or nystagmus only; not interfering with function	Interfering with function, but not interfering with ADL*	Interfering with ADL*	Disabling
Cardiac left ventricular diastolic function	Asymptomatic diagnostic finding; intervention not indicated	Asymptomatic, intervention indicated	Symptomatic CHF responsive to intervention	Refractory CHF, poorly controlled; intervention such as ventricular assist device or heart transplant indicated
Cardiac left ventricular systolic function	Asymptomatic, resting ejection fraction (EF) <60 – 50%; shortening fraction (SF) <30 – 24%	Asymptomatic, resting; EF <50 – 40%; SF <24 – 15%	Symptomatic CHF responsive to intervention; EF <40 – 20% SF <15%	Refractory CHF or poorly controlled; EF <20%; intervention such as ventricular assist device, ventricular reduction surgery, or heart transplant indicated
Edema: head and neck	Localized to dependent areas, no disability or functional impairment	Localized facial or neck edema with functional impairment	Generalized facial or neck edema with functional impairment (e.g., difficulty in turning neck or opening mouth compared to baseline)	Severe with ulceration or cerebral edema; tracheotomy or feeding tube indicated
Edema: limb	5 – 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection; pitting edema	>10 – 30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour	>30% inter-limb discrepancy in volume; lymphorrhea; gross deviation from normal anatomic contour; interfering with ADL*	Progression to malignancy (i.e., lymphangiosarcoma); amputation indicated; disabling
Edema: trunk/genital	Swelling or obscuration of anatomic architecture on close inspection; pitting edema	Readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour	Lymphorrhea; interfering with ADL*; gross deviation from normal anatomic contour	Progression to malignancy (i.e., lymphangiosarcoma); disabling
Edema: viscera	Asymptomatic; clinical or radiographic findings only	Symptomatic; medical intervention indicated	Symptomatic and unable to aliment adequately orally; interventional radiology or operative intervention indicated	Life-threatening consequences
Fatigue (lethargy, malaise, asthenia)	Mild fatigue over baseline	Moderate or causing difficulty performing some ADL*	Severe fatigue interfering with ADL*	Disabling

*ADL = Activities of Daily Living.

