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| *Institution Name*Clinical Trials Patient Assessment Record (PAR)CTC VERSION 3Date of visit: \_\_\_\_\_\_\_\_\_ (D/M/Y) Cycle: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Disease Site: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Clinical Trial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Assessment Period: from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Current Weight: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ kgVital Signs: T: \_\_\_\_ P: \_\_\_\_\_ R: \_\_\_\_\_ BP: \_\_\_\_\_\_ | Addressograph |
| **MEDICATIONS**: NONE NO CHANGES CHANGES **(complete medication record)** |
| **TOXICTY CRITERIA**CTG VERSION 3 | **1** | **2** | **3** | **4** | **5** |  Relation To  Protocol Therapy\* |
| DERMATOLOGICAL/SKIN |
| Hair Loss/ALOPECIAStart \_\_\_\_\_\_\_\_/Stop\_\_\_\_\_\_\_\_ | Thinning or patchy | Complete | \_\_\_ | \_\_\_ | \_\_\_ |  |
| INJECTION SITE REACTIONStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_\_ | Pain, itching or erythema | Pain or swelling, with inflammation or phlebitis | Ulceration/ necrosis severe or prolonged requiring surgery | \_\_\_ | \_\_\_ |  |
| RASH/DESQUAMATIONStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_\_ | Macular/papular eruption or erythema without associated symptoms | Macular or popular eruption or erythema with pruritis or other associated symptoms: localized desquamation or other lesions covering <50% of BSA | Severe,generalized erythroderma or macular,papular or vesicular eruption;desquamation covering >50% BSA | Generalized exfoliative, ulcerative, or bullous dermatitis. | Death |  |
| RASH ASSOCIATED WITH RADIATIONStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_\_ | Faint erythema or dry desquamation | Moderate to brisk erythema patchy, moist desquamation, mostly confined to skin folds and creases; moderate edema | Moist desquamation; other than skin folds and creases;bleeding induced by minor trauma or abrasion | Skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site | Death |  |
| RASH-HAND-FOOT SKIN REACTIONStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Minimal skin changes or dermatitis (e.g. erythema) without pain | Skin changes (e.g. peeling,blisters,bleeding,edema) or pain, not interfering with function | Ulcerative dermatitis or skin changes with pain interfering with function | \_\_\_ | \_\_\_ |  |
| CONSTITUTIONAL SYMPTOMS/INFECTION |
| FATIGUEStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild fatigue over baseline | Moderate or causing difficulty performing some ADL | Severe fatigue interfering with ADL | Disabling | \_\_\_ |  |
| INSOMNIAStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Occasional difficulty sleeping, not interfering with function | Difficulty sleeping interfering with function but not with activities of daily living | Frequent difficulty sleeping, interfering with activities of daily living | Disabling | \_\_\_ |  |
| RIGORS/CHILLSStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild | Moderate, narcotics indicated | Severe or prolonged, not responsive to narcotics | \_\_\_ | \_\_\_ |  |
| FEVER (in the absence of neutropenia where neutropenia is defined as ANC<1.0 x 109 /L)Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | 38.0 – 39.0°C (100.4 – 102.2°F | >39.0 – 40.0°C (102.3 – 104.0°F) | >40.0°C (104°F) for ≤ 24 hrs | >40.0°C (104°F)>24hrs | Death |  |
| FEBRILE NEUTROPENIA (fever of unknown origin with ANC <1.0 and Temp ≥ 38. 5Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | \_\_\_ | \_\_\_ | Present | Life-threatening consequences(e.g. septic shock,hypotension, acidosis, necrosis).) | Death |  |
| INFECTION (documented clinically or microbiologically) with grade 3 or 4 neutrophils0ANC<1.0 x 109 /L Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | \_\_\_ | Localized, local intervention indicated | IVantibiotic,antifungal or antiviral intervention indicated,interventional radiology or operative intervention indicated | Life threatening consequences ( e.g. septic shock, hypotension acidosis, necrosis). | Death |  |

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| TOXICTY CRITERIACTG VERSION 3 | **1** | **2** | **3** | **4** | **5** | **Relation****To****Protocol****Therapy \*** |
| GASTROINTESTINAL/ NUTRITIONAL |
| ANOREXIAStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Loss of appetite without alteration in eating habits | Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated | Associated with significant weight loss or malnutrition( e.g. inadequate oral caloric and/or fluid intake); IV fluids, tube feedings or TPN indicated. | Life threatening consequences | Death |  |
| NAUSEAStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | 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 | Death |  |
| VOMITINGStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | 1 episode in 24 hrs. | 2-5 episodes in 24 hours ; IV fluids indicated < 24hrs | >6 episodes in 24 hours ; IV fluids, or TPN indicated ≥ 24hrs. | Life threatening consequences | Death |  |
| CONSTIPATIONStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Occasional or intermittent symptoms; occasional use of stool softeners, laxatives dietary modification, or enema. | Persistant symptoms with regular use of laxatives or enemas indicated. | \_\_\_ | \_\_\_ | \_\_\_ |  |
| TASTE ALTERATION Start \_\_\_\_/Stop\_\_\_\_\_\_\_\_\_\_\_\_\_ | Altered taste but no but no change in diet | Altered taste with change in diet, unpleasant taste, loss of taste | \_\_\_ | **\_\_\_** | **\_\_\_** |  |
| STOMATITIS/MUCOSITIS(clinical exam / pt history)Start\_\_\_\_\_\_\_/Stop\_\_\_\_\_\_\_\_\_\_ | Erythema of the mucosa | Patchy ulcerations or pseudomembranes | Confluent ulcerations or pseudomembranes; bleeding with minor trauma | Tissue necrosis;significant spontaneous bleeding; life threatening consequences | Death |  |
| DIARRHEAStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Increase of <4 stools/day over baseline; mild increase in ostomy outpur compared to baseline | Increase of 4-6 stools per day over baseline;IV fluids indicated <24hrs;moderate increase in ostomy out put compared to baseline;not interfering with ADL> | Increase of > 7 stools/day over baseline; incontinence;IV fluids ≥hrs;hospitalization;severe increase in ostomy output compared to baseline;interfering with ADL. | Life threatening consequences (e.g. hemodynamic collapse). | Death |  |
| DEHYDRATIONStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Increased oral fluids indicated;dry mucous membranes; diminished skin turgor | IV fluids indicated <24 hrs | IV fluids indicated ≥ 24 hrs | Life-threatening consequences (e.g. hemodynamic collapse) | Death |  |
| DYSPHAGIA(difficulty swallowing)Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Symptomatic, able to eat regular diet | Symptomatic and altered eating/swallowing ( e.g. altered dietary habits,oral supplements);IV fluids indicated <24hrs. | Symptomatic and severly altered eating/swallowing (e.g. inadequate oral caloric or fluid intakeO;IV fluids, tube feedings,or TPN indicated ≥ 24hrs. | Lifethreatening consequences ( e.g. obstruction, perforation). | Death |  |
| **RENAL/GENITOURINARY OR ENDOCRINE** |
| URINARY (frequency/urgency)Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ |  Increase in frequency or nocturia up to 2x normal; enuresis | Increase> 2x normal but < hourly | >1 x/hr, urgency; catheter indicated | \_\_\_ | \_\_\_ |  |
| HOT FLASHES N/A Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild | Moderate | Interferring with ADL | \_\_\_ | \_\_\_ |  |

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| TOXICTY CRITERIACTG VERSION 3 | **1** | **2** | **3** | **4** | **5** | **Relation****To****Protocol****Therapy \*** |
| **SEXUAL/REPRODUCTIVE FUNCTION** |
| ERECTILE DYSFUNCTIONStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Decrease in erectile function (frequency /rigidity of erections) but erectile aids not indicated | Same as Grade I with erectile aids indicated | Decrease in erectile function (frequency /rigidity of erections) but erectile aids not helpful, penis prosthesis indicated | \_\_\_ | --- |  |
| EJACULATORY DYSFUNCTIONStart\_\_\_\_\_\_\_/Stop\_\_\_\_\_\_\_\_\_ | Diminished ejaculation | An ejaculation or retrograde ejaculation | \_\_\_ | \_\_\_ | \_\_\_ |  |
| IRREGULAR MENSES N/A (change from baseline) Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | 1-3 months without menses | > 3-6 months without menses but continuing menstrual cycles | Persistent amenorrhea for .6 months | \_\_\_ | \_\_\_ |  |
| LIBIDO Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Decrease in interest but not affecting relationship; intervention not indicated | Decrease in interest and adversely affecting relationship; intervention indicated | \_\_\_ | \_\_\_ | \_\_\_ |  |
| VAGINAL DRYNESS/DISCHARGE Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild | Interfering with sexual function, dyspareunia; intervention indicated | \_\_\_ | \_\_\_ | \_\_\_ |  |
| NEUROLOGY |
| MOOD ALTERATION: Select:-Agitation-Anxiety-Depression-EuphoriaStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild mood alteration not interfering with function | Moderate mood alteration interfering with function, but not with ADL; medication indicated | Severe mood alteration interfering with ADL | Suicidal ideation : danger to self or others | Death |  |
| NEUROPATHY – MOTORStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | 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 indicated | Life-threatening ;disabling (e.g. paralysis) | Death |  |
| NEUROPATHY – SENSORYStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Asymptomatic; Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function | Sensory alteration or parasthesia (including tingling); interfering with function, but not interfering with ADL | Sensory alteration or paresthesia interfering with ADL | Disabling | Death |  |
| OCULAR/VISUAL |
| DRY EYE Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild, not requiring intervention | Symptomatic, interfering with function but not interfering with ADL; medical intervention indicated | Symptomatic or decrease in visual acuity interfering with ADL; surgical intervention indicated | \_\_\_ | \_\_\_ |  |
| WATERY EYE (TEARING)Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Symptomatic, intervention not indicated | Symptomatic, interfering with function but not with ADL | Symptomatic, interfering with activities of daily living | \_\_\_ | \_\_\_ |  |
| AUDITORY |
| HearingPatients without baseline audiogram and not enrolled in a monitoring programStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | \_\_\_ | Hearing loss not requiring a hearing aid or intervention(i.e. not interfering with ADL) | Hearing loss requiring hearing aid or intervention (i.e. interfering with ADL) | Profound bilateral hearing loss (>90dB) | Severe hearing loss –1 or both ears(deaf), not correc- table |  |
| TOXICTY CRITERIACTG VERSION 3 | **1** | **2** | **3** | **4** | **5** | **Relation****To****Protocol****Therapy \*** |
| PAIN |  |  |  |  |  |  |
| HEADACHEStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild pain not interfering with function | Moderate pain: pain or analgesics interfering with function, but not with ADL | Severe pain: pain or analgesics severely interfering with ADL | Disabling | \_\_\_ |  |
| ABDOMINAL PAIN Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild pain not interfering with function | Moderate pain: pain or analgesics interfering with function, but not with ADL | Severe pain: pain or analgesics severely interfering with ADL | Disabling | \_\_\_ |  |
| JOINT PAINStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild pain not interfering with function | Moderate pain: pain or analgesics interfering with function, but not with ADL | Severe pain: pain or analgesics severely interfering with ADL | Disabling | \_\_\_ |  |
| MUSCLE PAINStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild pain not interfering with function | Moderate pain: pain or analgesics interfering with function, but not with ADL | Severe pain: pain or analgesics severely interfering with ADL | Disabling | \_\_\_ |  |
| BONE PAINStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild pain not interfering with function | Moderate pain: pain or analgesics interfering with function, but not with ADL | Severe pain: pain or analgesics severely interfering with ADL | Disabling | \_\_\_ |  |
| TUMOR PAIN Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild pain not interfering with function | Moderate pain: pain or analgesics interfering with function, but not with ADL | Severe pain: pain or analgesics severely interfering with ADL | Disabling | \_\_\_ |  |
| PAIN \_ OTHERStart\_\_\_\_\_\_\_/Stop\_\_\_\_\_\_\_\_ | Mild pain not interfering with function | Moderate pain: pain or analgesics interfering with function, but not with ADL | Severe pain: pain or analgesics severely interfering with ADL | Disabling | \_\_\_ |  |
| PULMONARY/CARDIOVASCULAR OR LYMPHATICS |
| COUGHStart \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Symptomatic, non-narcotic medication only indicated | Symptomatic and narcotic medication indicated | Symptomatic and significantly interfering with sleep or ADL | \_\_\_ | \_\_\_ |  |
| DYSPNEA (shortness of breath)Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Dyspnea on exertion but can walk 1 flight of stairs without stopping | Dyspnea on exertion on exertion but unable to walk 1 flight of stairs or 1 city block without stopping | Dyspnea with ADL | Dyspnea at rest; intubation/ventilator indicated | Death |  |
| VOICE CHANGES/STRIDOR/ LARYNX (hoarseness, loss or alteration in voice, laryngitis)Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ | Mild or intermittent hoarseness or voice change, but fully understandable | Moderate or persistent voice changes may require occasional repetition but understandable on telephone | Severe voice changes including whispered speech: may require face-to-face contact for understandability; requires voice aid for ≤50% of communication | Disabling: non-understandable voice or aphonic: requires voice aid for >50% of communication or requires>50% written communication | Death |  |
| EDEMALimbSee manual for other types of edemaStart\_\_\_\_\_\_\_/Stop\_\_\_\_\_\_\_\_\_\_ | pitting edema; swelling or obscuration of anatomic architecture on close inspection;5-10% inter limb discrepancy in volume or circumference at point of greatest visible difference;  | Readily apparent deviation from normal anatomic contour; readily apparent obscuration of anatomic architecture;>10-30% inter limb discrepancy | >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 | Death |  |

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| TOXICTY CRITERIACTG VERSION 3 | **1** | **2** | **3** | **4** | **5** | **Relation****To****Protocol****Therapy \*** |
| OTHER |  |  |  |  |  |  |
| Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ |  |  |  |  |  |  |
| Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ |  |  |  |  |  |  |
| Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ |  |  |  |  |  |  |
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| Start \_\_\_\_\_\_\_/Stop \_\_\_\_\_\_\_\_ |  |  |  |  |  |  |

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| COMPLIANCE |
| STUDY MEDICATIONN/A | Start\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Stop\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Missed doses (add dates) | PILL COUNT- | COMMENTS- |
| DIARY REQUIREDN/A | Yes | No | Diary Returned Yes No | Reviewed  | New Diary Given  |
| QUESTIONNAIRE(S) N/A  | Yes | No | COMMENTS |
| COMMENTS:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**PREFORMANCE STATUS SCALES/SCORES (circle appropriate score)**

## ECOG/Zubrod scale

 0 Asymptomatic and fully active

1. Symptomatic; fully ambulatory; restricted in physically strenuous activity

 2 Symptomatic; ambulatory; capable of self –care; more

Than 50% of waking hours are spent out of bed

1. Symptomatic; limited self-care; spends more than 50% of time in bed, but not bedridden

 4 Completely disabled; no self-care; bedridden

## Karnofsky Scale

100 No complaints, no evidence of evidence

 90 Able to carry on normal activity, minor signs or symptoms of disease

80 Some signs or symptoms of disease, carries on normal activity with some effort

 70 Cares for self, unable to carry on normal activity or to do active work

 60 Requires occasional assistance but is able to care for most personal needs

 50 Requires considerable assistance and frequent medical care

 40 Disabled, requires special care and assistance

 30 Severely disabled, hospitalization indicated although death not imminent

 20 Very sick: hospitalization necessary, requires active supportive treatment

 10 Moribund: fatal processes progressing rapidly

 0 Dead

Nurse: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(person who completed the form)