Registration

(registration, <registration>)

Registration

Subject Number

(patId, <patId>)

(Integer, Text)

Subject initials

(patInit, <patInit>)

(String, Text)

Eligibility

Sub Forms

Form A: Eligibility

Form A: Eligibility

Form A: Eligibility

(formA, <formA>)

Form A Eligibility

Date

(dateFormA, <dateFormA>)

(Date, Text)

(MMM-dd-yyyy)

Part A Initial Screening

Age >= 18 years old?

(eligA1, <eligA1>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Has a progressive life-limiting illness? (e.g., wouldn't be surprised if person passed away within the next year)

(eligA2, <eligA2>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

On statin medication for >= 3 months?

(eligA3, <eligA3>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Life expectancy of at least 1 month?

(eligA4, <eligA4>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Speak and read English?

(eligA5, <eligA5>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Inadequate cognitive status by report (e.g. Dementia)?

(eligA6, <eligA6>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Barrier to approaching patient?

(eligA7, <eligA7>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Part B Barriers to Participation

 (complete if eligible per Part A)

Primary treating physician willing to have patient enrolled?　☐ No (0)

(eligB1, <eligB1>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown/NA (9)

Physician

(eligB1Phys, <eligB1Phys>)

(String, Text)

Date

(eligB1Date, <eligB1Date>)

(Date, Text)

(MMM-dd-yyyy)

Declining functional status within the last 3 months and current AKPS below 80.

(eligB2, <eligB2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown/NA (9)

Requires ongoing therapy with statin drugs due to active CVD or sufficient risk of CVD?

(eligB3, <eligB3>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown/NA (9)

Contraindications to continuing or discontinuing statins?

(eligB4, <eligB4>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown/NA (9)

Adequately intact cognitive status (<5 errors)

(eligB5, <eligB5>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown/NA (9)

Signed HIPPA A (Recruitment) form

(eligB6, <eligB6>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown/NA (9)

Patient willing to discuss potential participation?

(eligB7, <eligB7>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown/NA (9)

Other Barrier to participation (e.g. family)

(eligB8, <eligB8>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown/NA (9)

Indication for Other Barrier to participation (specify)

(eligB8txt, <eligB8txt>)

(String, Text)

Does the patient meet all the Part B eligibility criteria?

(eligB9, <eligB9>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Part C- Consent

(complete if eligible per Part B)

Patient provides informed consent?
(eligC1, <eligC1>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ NA (9)

Does consent form have a valid signature?
(eligC2, <eligC2>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ NA (9)

Date of consent
(DateConsent, <DateConsent>)
(Date, Text)

(MMM-dd-yyyy)

Part D - Supplemental Information

(Complete for all patients screened and eligible after Part A.)

Age (years)
(eligAge, <eligAge>)
(Integer, Text)

History of cardiovascular disease
(eligCVD, <eligCVD>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

If yes, specify CVD type
(cvdType, <cvdType>)
(Integer, Select)

Acute coronary syndrome (1)
Coronary artery disease (2)
Angina (3)
Myocardial infarction (4)
Congestive heart failure (5)
Peripheral vascular disease (6)
Transient ischemic attack (7)
Stroke or cerebrovascular accident (8)
Carotid artery stenosis (9)
Other CVD (10)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(eligAKPS, <eligAKPS>)
(Integer, Select)

100 Normal; no complaints; no evidence of disease (100)
90 Able to carry on normal activity; minor signs or symptoms (90)
80 Normal activity with effort; some signs or symptoms of

disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

SPMSQ (Total Errors)

(eligSPMSQ, <eligSPMSQ>)

(Integer, Text)

Form A: Eligibility

(formANew, <formANew>)

Form A Eligibility

Date	
(dateFormA, <dateFormA>)	(MMM-dd-yyyy)
(Date, Text)	

Part A Initial Screening

Age >= 18 years old?
(eligA1, <eligA1>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Has a progressive life-limiting illness? (e.g., wouldn't be surprised if person passed away within the next year)
(eligA2New, <eligA2New>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

On statin medication for >= 3 months?
(eligA3, <eligA3>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Life expectancy of at least 1 month?
(eligA4, <eligA4>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Communicate and read English?
(eligA5New, <eligA5New>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Inadequate cognitive status by report (e.g. dementia, delirium, altered consciousness)?
(eligA6New, <eligA6New>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Barrier to approaching patient?
(eligA7, <eligA7>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Part B Barriers to Participation

(complete if eligible per Part A)

Primary treating physician willing to have patient enrolled?
(eligB1, <eligB1>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Physician
(eligB1Phys, <eligB1Phys>)
(String, Text)

Date
(eligB1Date, <eligB1Date>)
(Date, Text)

(MMM-dd-yyyy)

Declining functional status within the last 3 months and current AKPS below 80.
(eligB2, <eligB2>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Requires ongoing therapy with statin drugs due to active CVD or sufficient risk of CVD?
(eligB3, <eligB3>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Contraindications to continuing or discontinuing statins?
(eligB4, <eligB4>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Adequately intact cognitive status (<5 errors)
(eligB5, <eligB5>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Signed HIPPA A (Recruitment) form
(eligB6, <eligB6>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Patient willing to discuss potential participation?
(eligB7, <eligB7>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Other Barrier to participation (e.g. family)
(eligB8, <eligB8>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown/NA (9)

Indication for Other Barrier to participation (specify)
(eligB8txt, <eligB8txt>)
(String, Text)

Does the patient meet all the Part B eligibility criteria?
(eligB9New, <eligB9New>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Part C- Consent

(complete if eligible per Part B)

Patient (or legally authorized representative [LAR])
provides informed consent?
(eligC1New, <eligC1New>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ NA (9)

Does consent form have a valid signature?
(eligC2New, <eligC2New>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ NA (9)

Date of consent
(DateConsentNew, <DateConsentNew>)
(Date, Text)

(MMM-dd-yyyy)

Part D - Supplemental Information

(Complete for all patients screened and eligible after Part A.)

Age (years)
(eligAge, <eligAge>)
(Integer, Text)

History of cardiovascular disease
(eligCVD, <eligCVD>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

If yes, specify CVD type
(cvdType, <cvdType>)
(Integer, Select)

Acute coronary syndrome (1)
Coronary artery disease (2)
Angina (3)
Myocardial infarction (4)
Congestive heart failure (5)
Peripheral vascular disease (6)
Transient ischemic attack (7)
Stroke or cerebrovascular accident (8)
Carotid artery stenosis (9)
Other CVD (10)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(eligAKPS, <eligAKPS>)
(Integer, Select)

100 Normal; no complaints; no evidence of disease (100)
90 Able to carry on normal activity; minor signs or
symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

SPMSQ (Total Errors)

(eligSPMSQ, <eligSPMSQ>)

(Integer, Text)

Information on Cognitively Impaired Study Participants

SPMSQ (Items Attempted)

(SPMSQAttempted, <SPMSQAttempted>)

(Integer, Select)

0 (0)

1 (1)

2 (2)

3 (3)

4 (4)

5 (5)

6 (6)

7 (7)

8 (8)

9 (9)

10 (10)

Relationship of the Legally Authorized Representative to the Patient (check the category that fits best):

(eligE1, <eligE1>)

(Integer, RadioCheckbox)

☐ Health Care Power of Attorney (0)

☐ Next of Kin (1)

☐ Guardian (2)

☐ Other (9)

If "Other", specify:

(eligE1Txt, <eligE1Txt>)

(String, Text)

Diagnosis of Dementia?

(eligE2a, <eligE2a>)

☐ None noted (0)

☐ Yes (1)

(Integer, RadioCheckbox)

If yes, source of Dementia Diagnosis (choose one):

(eligE2b, <eligE2b>)

(Integer, Select)

Medical Record (0)

Clinician (e.g., MD, RN, PT) Report (1)

Other Source (9)

If "Other Source", specify:

(eligE2Txt, <eligE2Txt>)

(String, Text)

Diagnosis of Delirium?   ☐ None noted (0)

(eligE3a, <eligE3a>)   ☐ Yes (1)

(Integer, RadioCheckbox)

If yes, source of Delirium Diagnosis (choose one):

(eligE3b, <eligE3b>)

(Integer, Select)

Medical Record (0)

Clinician (e.g., MD, RN, PT) Report (1)

Other Source (9)

If "Other Source", specify:

(eligE3Txt, <eligE3Txt>)

(String, Text)

Diagnosis of Altered Consciousness?   ☐ None noted (0)

(eligE4a, <eligE4a>)   ☐ Yes (1)

(Integer, RadioCheckbox)

If yes, source of Altered Consciousness Diagnosis (choose

one):

(eligE4b, <eligE4b>)

(Integer, Select)

Medical Record (0)

Clinician (e.g., MD, RN, PT) Report (1)

Other Source (9)

If "Other Source", specify:

(eligE4Txt, <eligE4Txt>)

(String, Text)

Baseline

Sub Forms

Form B: Part A, B

Form B: Part C

Form B: Part C

Form B: Part D

Form B: Part E, F

Form B: Part G, H

Form F: Baseline Part A, B-Q2, and C

Form F: Baseline Part A, B-Q2, and C

Form H: Medications Summary

Form I:McGill QOL questionnaire

Form J: ESAS

Form B: Part A, B

(formBab, <formBab>)

Form B - Baseline Information

Date

(dateFormB, <dateFormB>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Demographic Information

Year of Birth (yyyy)

(yob, <yob>)

(Integer, Text)

Sex

(sex, <sex>)

(Integer, RadioCheckbox)

☐ Male (1)
☐ Female (2)

Education (What is the highest grade or level of schooling completed?)

(educations, <educations>)

(Integer, Select)

1-8 years (grade school) (1)

9-12 years (did not graduate from high school or get GED diploma) (2)

High school graduate or GED diploma, but no college classes or training after high school (3)

Training after high school (other than college) (4)

Some college (5)

2-year or 4-year college graduate (6)

Attended or completed graduate school (7)

Unknown (99)

Ethnicity (by patient report)

(ethnicity, <ethnicity>)

(Integer, Select)

Hispanic or Latino of any race (1)

Not Hispanic or Latino (2)

Unknown (99)

Race (by patient report, check all that apply)

(race, <race>)

(String, MultiCheckbox)

☐ White (1)
☐ Black or African American (2)
☐ Asian (3)
☐ Native Hawaiian or Pacific Islander (4)
☐ American Indian or Alaska Native (5)
☐ Other - specify below (9)
☐ Refused (88)

☐ Unknown (99)

Race Other (specify)

(raceOth, <raceOth>)

(String, Text)

Primary Insurance Status (choose one)

(insurance, <insurance>)

(Integer, Select)

Medicare (1)

Medicaid (2)

Private (Commercial) Insurance (3)

Other (includes TriCare, DOD, VA, Indian Health Care) (4)

Uninsured (5)

Missing (9)

Part B - Current Primary Diagnosis

Primary Diagnosis (see Charlson Index for definitions)

(priDx, <priDx>)

(Integer, Select)

1 AIDS (1)

2 Cerebrovascular Disease (2)

3 COPD (3)

4 Congestive Heart Failure (4)

5 Myocardial Infarction (5)

6 Peripheral Vascular Disease (6)

7 Connective Tissue Disease (7)

8 Dementia (8)

9 Hemiplegia (9)

10 Ulcer Disease (10)

11 Diabetes (uncomplicated) (11)

12 Diabetes (with end organ damage) (12)

13 Chronic Liver Disease (mild) (13)

14 Chronic Liver Disease (moderate or severe) (14)

15 Renal Disease (15)

16 Leukemia (16)

17 Malignant Lymphoma (17)

18 Malignant Solid Tumor without Mets (18)

19 Malignant Solid Tumor with Mets (19)

99 Primary Diagnosis Other(specify below) (99)

Primary Diagnosis Other (specify)

(priDxOth, <priDxOth>)

(String, Text)

ICD-9 Code (3 digit)

(priDxICD9, <priDxICD9>)

(Integer, Text)

Initial Date of Diagnosis (mmm-dd-yyyy UNK-UK-yyyy)

(datePriDx, <datePriDx>)

(PartialDate, PartialDate)

(MMM[UNK]-dd[UK]-yyyy)

Form B: Part C

(formBc, <formBc>)

Form B Baseline Information

Part C - Co-morbidity (Charlson Index)

Indicate whether the medical records or patient history indicates any of the following conditions exist. A response is required for each condition.

1. AIDS

(charlson1, <charlson1>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (6)

2. CVD

(charlson2, <charlson2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

3. COPD

(charlson3, <charlson3>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

4. CHF

(charlson4, <charlson4>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

5. MI

(charlson5, <charlson5>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

6. PVD

(charlson6, <charlson6>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

7. Connective Tissue Disease

(charlson7, <charlson7>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

8. Dementia

(charlson8, <charlson8>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

9. Hemiplegia

(charlson9, <charlson9>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (2)

10. Ulcer disease

(charlson10, <charlson10>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

11. Diabetes (uncomplicated; no end organ damage)

(charlson11, <charlson11>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

12. Diabetes with end organ damage

(charlson12, <charlson12>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (2)

13. Chronic Liver Disease (mild)

(charlson13, <charlson13>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

14. Chronic Liver Disease (moderate or severe)

(charlson14, <charlson14>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (3)

15. Renal diseae (moderate or severe)

(charlson15, <charlson15>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (2)

16. Leukemia

(charlson16, <charlson16>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (2)

17. Malignant lymphoma

(charlson17, <charlson17>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (2)

18. Malignant solid tumor without mets

(charlson18, <charlson18>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (2)

19. Malignant solid tumor with mets

(charlson19, <charlson19>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (6)

Form B: Part C

(formBcNew, <formBcNew>)

Form B Baseline Information

Part C - Co-morbidity (Charlson Index)

Indicate whether the medical records or patient history indicates any of the following conditions exist. A response is required for each condition.

1. AIDS
(charlson1, <charlson1>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (6)

2. CVD
(charlson2, <charlson2>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

3. COPD
(charlson3, <charlson3>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

4. CHF
(charlson4, <charlson4>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

5. MI
(charlson5, <charlson5>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

6. PVD
(charlson6, <charlson6>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

7. Connective Tissue Disease
(charlson7, <charlson7>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

8. Dementia
(charlson8, <charlson8>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

9. Hemiplegia
(charlson9, <charlson9>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (2)

10. Ulcer disease
(charlson10, <charlson10>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

11. Diabetes (uncomplicated; no end organ damage)
(charlson11, <charlson11>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

12. Diabetes with end organ damage
(charlson12, <charlson12>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (2)

13. Chronic Liver Disease (mild)
(charlson13, <charlson13>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

14. Chronic Liver Disease (moderate or severe)
(charlson14, <charlson14>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (3)

15. Renal diseae (moderate or severe)
(charlson15, <charlson15>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (2)

16. Leukemia
(charlson16, <charlson16>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (2)

17. Malignant lymphoma
(charlson17, <charlson17>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (2)

18. Malignant solid tumor without mets
(charlson18, <charlson18>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (2)

19. Malignant solid tumor with mets
(charlson19, <charlson19>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (6)

20. Please describe any other diagnoses (ongoing conditions) not recorded above but noted in the medical record or reported by the patient or proxy.
(charlson20Txt, <charlson20Txt>)
(String, MultiLineText)

Form B: Part D

(formBd, <formBd>)

Form B: Baseline Information
Part D - Statin History

(Record generic name if single active ingredient or trade name if multiple active ingredients)

Name of current statin (Choose generic name if single active ingredient or trade name if multiple active ingredients)

(statinName, <statinName>)

(Integer, Select)

Advicor (Lovastatin + Niacin) (T) (1)

Altroprev (T) (2)

Caduet (Atorvastatin + Amlodipine) (T) (3)

Crestor (T) (4)

Lescol (T) (5)

Lescol XL (T) (6)

Lipitor (T) (7)

Livalo (T) (8)

Mevacore (T) (9)

Pravachol (T) (10)

Simcore (Simvastatin + Niacin) (T) (11)

Vyotrin (Simvastatin + Ezetimibe) (T) (12)

ZoCor (T) (13)

Other Trade 1, specify below (14)

Other Trade 2, specify below (15)

Other Trade 3, specify below (16)

Atorvastatin (G) (51)

Fluvastatin (G) (52)

Lovastatin (G) (53)

Pitavastatin (G) (54)

Pravastatin (G) (55)

Rosuvastatin (G) (56)

Simvastatin (G) (57)

Other Generic 1, specify below (58)

Other Generic 2, specify below (59)

Other Generic 3, specify below (60)

Current Statin Other Trade 1 (specify)

(statinOthT1, <statinOthT1>)

(String, Text)

Current Statin Other Trade 2 (specify)

(statinOthT2, <statinOthT2>)

(String, Text)

Current Statin Other Trade 3 (specify)

(statinOthT3, <statinOthT3>)

(String, Text)

Current Statin Other Generic 1 (specify)

(statinOthG1, <statinOthG1>)

(String, Text)

Current Statin Other Generic 2 (specify)

(statinOthG2, <statinOthG2>)

(String, Text)

Current Statin Other Generic 3 (specify)

(statinOthG3, <statinOthG3>)

(String, Text)

Typical daily dose (mg)

(statinDose, <statinDose>)

(Integer, Text)

Duration of Statin Use

(statinDur, <statinDur>)

(Integer, Select)

Less than 1 year (If < 3 months the patient is not eligible
for the trial) (1)

1-5 years (2)

Greater than 5 years (3)

Unknown (9)

Indication(s) for Statin Use: Hyperlipidemia

(statinInd1, <statinInd1>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Indication(s) for Statin Use: Hypercholesterolemia

(statinInd2, <statinInd2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Indication(s) for Statin Use: Hypertriglyceridemia

(statinInd3, <statinInd3>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Indication(s) for Statin Use: Hyperlipoproteinemia

(statinInd4, <statinInd4>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Indication(s) for Statin Use: Myocardial infarction (heart
attack) prophylaxis

(statinInd5, <statinInd5>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Indication(s) for Statin Use: Post Myocardial infarction (heart attack)
(statinInd6, <statinInd6>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Indication(s) for Statin Use: Unstable angina
(statinInd7, <statinInd7>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Indication(s) for Statin Use: Atherosclerosis
(statinInd8, <statinInd8>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Indication(s) for Statin Use: Peripheral and cerebrovascular disease
(statinInd9, <statinInd9>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Indication(s) for Statin Use: Stroke prophylaxis
(statinInd10, <statinInd10>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Indication(s) for Statin Use: Transient ischemic attack
(statinInd11, <statinInd11>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Indication(s) for Statin Use: Other, specify below
(statinInd12, <statinInd12>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Indication(s) for Statin Use: Unknown
(statinInd13, <statinInd13>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Indication for Statin Use Other (specify)
(statinIndTxt, <statinIndTxt>)
(String, Text)

Form B: Part E, F

(formBef, <formBef>)

Form B: Baseline Information

Part E - Height and Weight

Height (inches)

(heightIn, <heightIn>)

(Float, Text)

Weight (pounds)

(weightLb, <weightLb>)

(Float, Text)

Part F - Labs

(Note:Labs results must be in past 6 mos., preferable w/in < 4 wks from randomization)

Lab identifier for normal ranges

(labNormId, <labNormId>)

(String, Text)

Lipid Panel

Lipid Panel Date

(dateLipid, <dateLipid>)   (MMM-dd-yyyy)

(Date, Text)

Cholesterol Value (mg/dL)

(labChol, <labChol>)

(Float, Text)

Cholesterol Low Normal Range

(labChol1, <labChol1>)

(Float, Text)

Cholesterol High Normal Range

(labChol2, <labChol2>)

(Float, Text)

HDL Value (mg/dL)

(labHDL, <labHDL>)

(Float, Text)

HDL Low Normal Range

(labHDL1, <labHDL1>)

(Float, Text)

HDL High Normal Range

(labHDL2, <labHDL2>)

(Float, Text)

LDL Value (mg/dL)

(labLDL, <labLDL>)

(Float, Text)

LDL Low Normal Range

(labLDL1, <labLDL1>)

(Float, Text)

LDL High Normal Range

(labLDL2, <labLDL2>)

(Float, Text)

Triglycerides Value (mg/dL)

(labTrigl, <labTrigl>)

(Float, Text)

Triglycerides Low Normal Range

(labTrigl1, <labTrigl1>)

(Float, Text)

Triglycerides High Normal Range

(labTrigl2, <labTrigl2>)

(Float, Text)

Liver Function

Liver Function Date

(dateLFT, <dateLFT>)

(Date, Text)

(MMM-dd-yyyy)

Alkaline Phosphatase Value (U/L)

(labAlkPhos, <labAlkPhos>)

(Float, Text)

Alkaline Phosphatase Low Normal Range

(labAlkPhos1, <labAlkPhos1>)

(Float, Text)

Alkaline Phosphatase High Normal Range

(labAlkPhos2, <labAlkPhos2>)

(Float, Text)

AST Value (U/L)

(labAST, <labAST>)

(Float, Text)

AST Low Normal Range

(labAST1, <labAST1>)

(Float, Text)

AST High Normal Range

(labAST2, <labAST2>)

(Float, Text)

ALT Value (U/L)

(labALT, <labALT>)

(Float, Text)

ALT Low Normal Range

(labALT1, <labALT1>)

(Float, Text)

ALT High Normal Range

(labALT2, <labALT2>)

(Float, Text)

Other

Albumin Date

(dateAlbumin, <dateAlbumin>)

(Date, Text)

(MMM-dd-yyyy)

Albumin Value (g/dL)

(labAlbumin, <labAlbumin>)

(Float, Text)

Albumin Low Normal Range

(labAlbumin1, <labAlbumin1>)

(Float, Text)

Albumin High Normal Range

(labAlbumin2, <labAlbumin2>)

(Float, Text)

Creatinine Date

(dateCreat, <dateCreat>)

(Date, Text)

(MMM-dd-yyyy)

Creatinine Value (mg/dL)

(labCreat, <labCreat>)

(Float, Text)

Creatinine Low Normal Range

(labCreat1, <labCreat1>)

(Float, Text)

Creatinine High Normal Range

(labCreat2, <labCreat2>)

(Float, Text)

Creatine Kinase Date

(dateCKinase, <dateCKinase>)

(Date, Text)

(MMM-dd-yyyy)

Creatine Kinase Value (U/L)

(labCKinase, <labCKinase>)

(Float, Text)

Creatine Kinase Low Normal Range

(labCKinase1, <labCKinase1>)

(Float, Text)

Creatine Kinase High Normal Range

(labCKinase2, <labCKinase2>)

(Float, Text)

HbA1C Date

(dateHbA1c, <dateHbA1c>)

(Date, Text)

(MMM-dd-yyyy)

HbA1C Value (%)

(labHbA1c, <labHbA1c>)

(Float, Text)

HbA1C Low Normal Range

(labHbA1c1, <labHbA1c1>)

(Float, Text)

HbA1C High Normal Range

(labHbA1c2, <labHbA1c2>)

(Float, Text)

Form B: Part G, H

(formBgh, <formBgh>)

Form B: Baseline Information

Part G - Patient Concerns

---

1. I have been previously told that I should never discontinue this medication.
(ptConcern1, <ptConcern1>)
(Integer, RadioCheckbox)

☐ Agree (1)
☐ Disagree (2)

2. I have been so careful to take this medication; stopping would mean that all that effort was wasted.
(ptConcern2, <ptConcern2>)
(Integer, RadioCheckbox)

☐ Agree (1)
☐ Disagree (2)

3. If I stop this medication, I will experience another problem in addition to those I already have.
(ptConcern3, <ptConcern3>)
(Integer, RadioCheckbox)

☐ Agree (1)
☐ Disagree (2)

4. If stop this medication, I will have fewer symptoms.
(ptConcern4, <ptConcern4>)
(Integer, RadioCheckbox)

☐ Agree (1)
☐ Disagree (2)

5. If I stop this medication, I will have a better quality of life.
(ptConcern5, <ptConcern5>)
(Integer, RadioCheckbox)

☐ Agree (1)
☐ Disagree (2)

6. If I stop this medication, I will spend less money on medications.
(ptConcern6, <ptConcern6>)
(Integer, RadioCheckbox)

☐ Agree (1)
☐ Disagree (2)

7. If I stop this medication, I may be able to stop other medications that I take.
(ptConcern7, <ptConcern7>)
(Integer, RadioCheckbox)

☐ Agree (1)
☐ Disagree (2)

8. Stopping this medication means that my doctor has given up on treating me.
(ptConcern8, <ptConcern8>)
(Integer, RadioCheckbox)

☐ Agree (1)
☐ Disagree (2)

9. Stopping this medication means that my doctor thinks I am about to die.

☐ Agree (1)
☐ Disagree (2)

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(ptConcern9, <ptConcern9>)

(Integer, RadioCheckbox)

Part H Smoking History

Have you smoked at least 100 cigarettes in your entire life? NOTE: 5 packs = 100 cigarettes

(smokeHx1, <smokeHx1>)

(Integer, Select)

Yes (1)

No (2)

Don't know/Not sure (7)

Refused (9)

Do you now smoke cigarettes every day, some days, or not at all?

(smokeHx2, <smokeHx2>)

(Integer, Select)

Every day (1)

Some days (2)

Not at all (3)

Don't know/Not sure (7)

Refused (9)

How old were you when you started smoking cigarettes? (yrs)

(smokeHx3, <smokeHx3>)

(Integer, Text)

On average how many cigarettes have you smoked per day since you started smoking? (per day)

(smokeHx4, <smokeHx4>)

(Integer, Text)

During the past 12 months, have you stopped smoking for one day or longer because you were trying to quit smoking?

(smokeHx5, <smokeHx5>)

(Integer, Select)

Yes (1)

No (2)

Don't know/Not sure (7)

Refused (9)

How long has it been since you last smoked cigarettes regularly?

(smokeHx6, <smokeHx6>)

(Integer, Select)

Within the past month(less than 1 month ago) (1)

Within the past 3 months (> 1 month but less than 3 months ago) (2)

Within the past 6 months (> 3 months but less than 6 months ago) (3)

Within the past year (> 6 months but less than 1 year ago) (4)

Within the past 5 years (> 1 year but less than 5 years ago) (5)

Within the past 10 years (>5 years but less than 10 years ago) (6)

10 years or more (7)

Never smoked regularly (8)

Don't know/Not sure (77)

Refused (99)

Form F: Baseline Part A, B-Q2, and C

(formFabq2cBS, formFabq2c)

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B -Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?
(hospice, <hospice>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown (9)

Receiving Palliative Care?
(palCare, <palCare>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown (9)

Has the patient taken any statin medications during the past week?
(statinUse, <statinUse>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?
(fuStatus2, <fuStatus2>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

What is the likelihood of you recommending your current health care to others?
(likelihood, <likelihood>)
(Integer, Select)

[⬇]

Very unlikely (1)
Somewhat unlikely (2)
Unsure (3)
Somewhat likely (4)
Very likely (5)

Form F: Baseline Part A, B-Q2, and C

(formFabq2cBSNew, formFabq2cNew)

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B -Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?
(hospice, <hospice>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown (9)

Receiving Palliative Care?
(palCare, <palCare>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown (9)

Has the patient taken any statin medications during the past week?
(statinUse, <statinUse>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?
(fuStatus2, <fuStatus2>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

What is the likelihood of you recommending your current health care to others?
(likelihood, <likelihood>)
(Integer, Select)

[   ] ▼

Very unlikely (1)
Somewhat unlikely (2)
Unsure (3)
Somewhat likely (4)
Very likely (5)

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Form H: Medications Summary

(formHsummaryBS, formHsummary)

Form H Medications

Were any non-statin medications taken in the past week?

(otherMeds, <otherMeds>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Total # regularly scheduled meds

(polyPharm1, <polyPharm1>)

(String, Text)

Total # PRN > 50% of days

(polyPharm2, <polyPharm2>)

(String, Text)

Total # PRN < 50% of days

(polyPharm3, <polyPharm3>)

(String, Text)

Form H: Medications

(formH, <formH>)

Form I:McGill QOL questionnaire

(formIBS, formI)

Form I: McGill Quality of Life Questionnaire (MQOLQ)

Part A

---

1. Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past two (2) days, the quality of my life has been:

(mqolqA1, <mqolqA1>)

(Integer, Text)

Part B - Physical Symptoms or Physical Problems

1a.Over the past two (2) days, one troublesome symptom has been:

(mqolqB1Txt, <mqolqB1Txt>)

(String, Text)

1b. How big a problem

(mqolqB1, <mqolqB1>)

(Integer, Text)

2a. Over the past two (2) days, another troublesome symptom has been:

(mqolqB2Txt, <mqolqB2Txt>)

(String, Text)

2b. How big a problem

(mqolqB2, <mqolqB2>)

(Integer, Text)

3a. Over the past two (2) days, a third troublesome symptom has been:

(mqolqB3txt, <mqolqB3txt>)

(String, Text)

3b. How big a problem

(mqolqB3, <mqolqB3>)

(Integer, Text)

---

4. Over the past two (2) days I have felt:

(mqolqB4, <mqolqB4>)

(Integer, Text)

Part C

1. Over the past two (2) days, I have been depressed:

(mqolqC1, <mqolqC1>)

(Integer, Text)

2. Over the past two (2) days, I have been nervous or worried:

(mqolqC2, <mqolqC2>)

(Integer, Text)

3. Over the past two (2) days, how much of the time did you feel sad?

(mqolqC3, <mqolqC3>)

(Integer, Text)

4. Over the past two (2) days, when I thought of the future, I was:

(mqolqC4, <mqolqC4>)

(Integer, Text)

5. Over the past two (2) days, my life has been:

(mqolqC5, <mqolqC5>)

(Integer, Text)

6. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life goals I have:

(mqolqC6, <mqolqC6>)

(Integer, Text)

7. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life to this point has been:

(mqolqC7, <mqolqC7>)

(Integer, Text)

8. Over the past two (2) days, I have felt that I have:

(mqolqC8, <mqolqC8>)

(Integer, Text)

9. Over the past two (2) days, I felt good about myself as a person.

(mqolqC9, <mqolqC9>)

(Integer, Text)

10. To me, the past two (2) days were:

(mqolqC10, <mqolqC10>)

(Integer, Text)

11. Over the past two (2) days, the world has been:

(mqolqC11, <mqolqC11>)

(Integer, Text)

12. Over the past two (2) days, I have felt supported:

(mqolqC12, <mqolqC12>)

(Integer, Text)

Part D

Was the response to Part D documented? (If yes, please attach the transcript.)

(mqolqD, <mqolqD>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Form J: ESAS

(formJBS, formJ)

Form J: Edmonton Symptom Assessment System (ESAS)

---

1. Pain

(esas1, <esas1>)

(Integer, Text)

2. Fatigue

(esas2, <esas2>)

(Integer, Text)

3. Nausea

(esas3, <esas3>)

(Integer, Text)

4. Depression

(esas4, <esas4>)

(Integer, Text)

5. Anxiousness

(esas5, <esas5>)

(Integer, Text)

6. Drowsiness

(esas6, <esas6>)

(Integer, Text)

7. Appetite

(esas7, <esas7>)

(Integer, Text)

8. Well-Being

(esas8, <esas8>)

(Integer, Text)

9. Breathing

(esas9, <esas9>)

(Integer, Text)

10. Muscle-Related Pain

(esas10, <esas10>)

(Integer, Text)

---

11. Weakness

(esas11, <esas11>)

(Integer, Text)

12. Headaches

(esas12, <esas12>)

(Integer, Text)

13. Fever

(esas13, <esas13>)

(Integer, Text)

Additional symptom - specify

(esas14Txt, <esas14Txt>)

(String, Text)

14. Specified symptom Rating

(esas14, <esas14>)

(Integer, Text)

Week 1

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk1, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[▾]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B and D

(formFabdWk1New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

⬇

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Form F Part D Important Events

(formFabdHEP, <formFabdHEP>)

Specify if the event was a hospital or ED admission or if the event was an invasive cardiovascular procedure

Please add a new form for each event.

Specify if the event was a hospital or ED admission or if the event was an invasive cardiovascular procedure

(hospEdProc, <hospEdProc>)

(Integer, RadioCheckbox)

☐ Hospital (1)
☐ Emergency Department (2)
☐ Invasive cardiovascular procedure (3)
☐ New cardiovascular event (4)
☐ Pneumonia (5)
☐ Venous thromboembolism (6)

Specify if the event is related to cardiovascular disease (CVD), dates and reason.

1-2 Specify if related to cardiovascular disease (CVD)

(cvdRelated, <cvdRelated>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

1-6 Start Date of Event (e.g. Admission / Procedure / Diagnosis Date of Pneumonia or DVT)

(admitProcDate, <admitProcDate>)

(Date, Text)

(MMM-dd-yyyy)

1-2 Discharge Date (hospital or ed only)

(dischDate, <dischDate>)

(Date, Text)

(MMM-dd-yyyy)

1-2 Hospital or ED admission Reason

(reason, <reason>)

(String, Text)

---

3 CV Procedure (choose one)

(cvProcTxt, <cvProcTxt>)

(Integer, Select)

Admission to a Coronary Care Unit (1)
Cardiac Catheterization (2)
Intra-aortic balloon pump (3)
Cardiac Valve Proc. valvuloplasty - Open surgery (4)
Cardiac Valve Proc. – valvuloplasty - Percutaneous or minimally invasive procedure (5)
Cardiac Valve Proc. – valve repair - Open surgery (6)
Cardiac Valve Proc. – valve repair - Percutaneous or minimally invasive procedure (7)

Cardiac Valve Proc. – valve replacement - Open surgery (8)

Cardiac Valve Proc. – valve replacement - Percutaneous or minimally invasive procedure (9)

Carotid Endarterectomy/Angioplasty - Open surgery (10)

Carotid Endarterectomy/Angioplasty - Percutaneous catheter ablation or minimally invasive procedure (11)

Coronary Angioplasty (PCI) (PTCA) - balloon angioplasty (12)

Coronary Angioplasty (PCI) (PTCA) - atherectomy (13)

Coronary Angioplasty (PCI) (PTCA) - laser angioplasty (14)

Coronary Angioplasty (PCI) (PTCA) - coronary or cardiac artery stent (15)

Coronary Angioplasty (PCI) (PTCA) - other Coronary Angioplasty procedure (16)

Coronary Artery Bypass Graft (CABG) (17)

Internal Cardioverter Defibrillator - Insertion (18)

Internal Cardioverter Defibrillator - Replacement (19)

Pacemaker Insertion (20)

Pacemaker Replacement (21)

Heart Transplant (22)

Other, Specify (99)

3 CV Procedure Other (specify)

(cvProcTxtSpfy, <cvProcTxtSpfy>)

(String, Text)

4 New cardiovascular event

(newCvdType, <newCvdType>)

(Integer, Select)

Acute coronary syndrome (1)

Coronary artery disease (2)

Angina (3)

Myocardial infarction (4)

Congestive heart failure (5)

Peripheral vascular disease (6)

Transient ischemic attack (7)

Stroke or cerebrovascular accident (8)

Carotid artery stenosis (9)

Other CVD (10)

4 Other (specify)

(newCvdTypeOther, <newCvdTypeOther>)

(String, Text)

Form F Part D Important Events

(formFabdHEPNew, <formFabdHEPNew>)

Specify if the event was a hospital or ED admission or if the event was an invasive cardiovascular procedure
Please add a new form for each event.

Specify if the event was a hospital or ED admission or if the event was an invasive cardiovascular procedure

(hospEdProcNew, <hospEdProcNew>)

(Integer, RadioCheckbox)

☐ Hospital (1)
☐ Emergency Department (2)
☐ Invasive cardiovascular procedure (3)
☐ New cardiovascular event (4)
☐ Pneumonia (5)
☐ Venous thromboembolism (6)

Specify if the event is related to cardiovascular disease (CVD), dates and reason.

1-2 Specify if related to cardiovascular disease (CVD)

(cvdRelated, <cvdRelated>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

1-6 Start Date of Event (e.g. Admission / Procedure / Diagnosis Date of Pneumonia or DVT)

(admitProcDate, <admitProcDate>)

(Date, Text)

(MMM-dd-yyyy)

1-2 Discharge Date (hospital or ed only)

(dischDateNew, <dischDateNew>)

(Date, Text)

(MMM-dd-yyyy)

1-2 Hospital or ED admission Reason

(reasonNew, <reasonNew>)

(String, Text)

3 CV Procedure (choose one)

(cvProcTxtNew, <cvProcTxtNew>)

(Integer, Select)

Admission to a Coronary Care Unit (1)
Cardiac Catheterization (2)
Intra-aortic balloon pump (3)
Cardiac Valve Proc. valvuloplasty - Open surgery (4)
Cardiac Valve Proc. – valvuloplasty - Percutaneous or minimally invasive procedure (5)
Cardiac Valve Proc. – valve repair - Open surgery (6)
Cardiac Valve Proc. – valve repair - Percutaneous or minimally invasive procedure (7)

Cardiac Valve Proc. – valve replacement - Open surgery (8)

Cardiac Valve Proc. – valve replacement - Percutaneous or minimally invasive procedure (9)

Carotid Endarterectomy/Angioplasty - Open surgery (10)

Carotid Endarterectomy/Angioplasty - Percutaneous catheter ablation or minimally invasive procedure (11)

Coronary Angioplasty (PCI) (PTCA) - balloon angioplasty (12)

Coronary Angioplasty (PCI) (PTCA) - atherectomy (13)

Coronary Angioplasty (PCI) (PTCA) - laser angioplasty (14)

Coronary Angioplasty (PCI) (PTCA) - coronary or cardiac artery stent (15)

Coronary Angioplasty (PCI) (PTCA) - other Coronary Angioplasty procedure (16)

Coronary Artery Bypass Graft (CABG) (17)

Internal Cardioverter Defibrillator - Insertion (18)

Internal Cardioverter Defibrillator - Replacement (19)

Pacemaker Insertion (20)

Pacemaker Replacement (21)

Heart Transplant (22)

Other, Specify (99)

3 CV Procedure Other (specify)

(cvProcTxtSpfyNew, <cvProcTxtSpfyNew>)

(String, Text)

4 New cardiovascular event

(newCvdType, <newCvdType>)

(Integer, Select)

Acute coronary syndrome (1)

Coronary artery disease (2)

Angina (3)

Myocardial infarction (4)

Congestive heart failure (5)

Peripheral vascular disease (6)

Transient ischemic attack (7)

Stroke or cerebrovascular accident (8)

Carotid artery stenosis (9)

Other CVD (10)

4 Other (specify)

(newCvdTypeOther, <newCvdTypeOther>)

(String, Text)

Week 2

Sub Forms

Form F: Part A, B, C and D

Form F: Part A, B, C and D

Form H: Medications Summary

Form I:McGill QOL questionnaire

Form J: ESAS

Form F: Part A, B, C and D

(formFWk2, formF)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)
(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)
(AKPS, <AKPS>)
(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?
(hospice, <hospice>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown (9)

Receiving Palliative Care?
(palCare, <palCare>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown (9)

Has the patient taken any statin medications during the past week?
(statinUse, <statinUse>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?
(fuStatus2, <fuStatus2>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

What is the likelihood of you recommending your current health care to others?
(likelihood, <likelihood>)

[dropdown ▼]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B, C and D

(formFWk2New, formFNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)   (MMM-dd-yyyy)

(Date, Text)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)

(AKPS, <AKPS>)

(Integer, Select)

[   ] ▼

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[   ] ▼

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Form H: Medications Summary

(formHsummaryWk2, formHsummary)

Form H Medications

Were any non-statin medications taken in the past week?

(otherMeds, <otherMeds>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Total # regularly scheduled meds

(polyPharm1, <polyPharm1>)

(String, Text)

Total # PRN > 50% of days

(polyPharm2, <polyPharm2>)

(String, Text)

Total # PRN < 50% of days

(polyPharm3, <polyPharm3>)

(String, Text)

Form I:McGill QOL questionnaire

(formIWk2, formI)

Form I: McGill Quality of Life Questionnaire (MQOLQ)

Part A

1. Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past two (2) days, the quality of my life has been:

(mqolqA1, <mqolqA1>)

(Integer, Text)

Part B - Physical Symptoms or Physical Problems

1a.Over the past two (2) days, one troublesome symptom has been:

(mqolqB1Txt, <mqolqB1Txt>)

(String, Text)

1b. How big a problem

(mqolqB1, <mqolqB1>)

(Integer, Text)

2a. Over the past two (2) days, another troublesome symptom has been:

(mqolqB2Txt, <mqolqB2Txt>)

(String, Text)

2b. How big a problem

(mqolqB2, <mqolqB2>)

(Integer, Text)

3a. Over the past two (2) days, a third troublesome symptom has been:

(mqolqB3txt, <mqolqB3txt>)

(String, Text)

3b. How big a problem

(mqolqB3, <mqolqB3>)

(Integer, Text)

4. Over the past two (2) days I have felt:

(mqolqB4, <mqolqB4>)

(Integer, Text)

Part C

1. Over the past two (2) days, I have been depressed:

(mqolqC1, <mqolqC1>)

(Integer, Text)

2. Over the past two (2) days, I have been nervous or worried:

(mqolqC2, <mqolqC2>)

(Integer, Text)

3. Over the past two (2) days, how much of the time did you feel sad?

(mqolqC3, <mqolqC3>)

(Integer, Text)

4. Over the past two (2) days, when I thought of the future, I was:

(mqolqC4, <mqolqC4>)

(Integer, Text)

5. Over the past two (2) days, my life has been:

(mqolqC5, <mqolqC5>)

(Integer, Text)

6. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life goals I have:

(mqolqC6, <mqolqC6>)

(Integer, Text)

7. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life to this point has been:

(mqolqC7, <mqolqC7>)

(Integer, Text)

8. Over the past two (2) days, I have felt that I have:

(mqolqC8, <mqolqC8>)

(Integer, Text)

9. Over the past two (2) days, I felt good about myself as a person.

(mqolqC9, <mqolqC9>)

(Integer, Text)

10. To me, the past two (2) days were:

(mqolqC10, <mqolqC10>)

(Integer, Text)

11. Over the past two (2) days, the world has been:

(mqolqC11, <mqolqC11>)

(Integer, Text)

12. Over the past two (2) days, I have felt supported:

(mqolqC12, <mqolqC12>)

(Integer, Text)

Part D

Was the response to Part D documented? (If yes, please attach the transcript.)

☐ No (0)

☐ Yes (1)

(mqolqD, <mqolqD>)

(Integer, RadioCheckbox)

Form J: ESAS

(formJWk2, formJ)

Form J: Edmonton Symptom Assessment System (ESAS)

---

1. Pain

(esas1, <esas1>)

(Integer, Text)

---

2. Fatigue

(esas2, <esas2>)

(Integer, Text)

---

3. Nausea

(esas3, <esas3>)

(Integer, Text)

---

4. Depression

(esas4, <esas4>)

(Integer, Text)

---

5. Anxiousness

(esas5, <esas5>)

(Integer, Text)

---

6. Drowsiness

(esas6, <esas6>)

(Integer, Text)

---

7. Appetite

(esas7, <esas7>)

(Integer, Text)

---

8. Well-Being

(esas8, <esas8>)

(Integer, Text)

---

9. Breathing

(esas9, <esas9>)

(Integer, Text)

---

10. Muscle-Related Pain

(esas10, <esas10>)

(Integer, Text)

---

11. Weakness

(esas11, <esas11>)

(Integer, Text)

12. Headaches

(esas12, <esas12>)

(Integer, Text)

13. Fever

(esas13, <esas13>)

(Integer, Text)

Additional symptom - specify

(esas14Txt, <esas14Txt>)

(String, Text)

14. Specified symptom Rating

(esas14, <esas14>)

(Integer, Text)

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Week 3

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk3, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

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Form F: Part A, B and D

(formFabdWk3New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

	⊞

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 4

Sub Forms

Form F: Part A, B, C and D

Form F: Part A, B, C and D

Form H: Medications Summary

Form I:McGill QOL questionnaire

Form J: ESAS

Form F: Part A, B, C and D

(formFWk4, formF)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[▼]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B, C and D
(formFWk4New, formFNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

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(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[⬍]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[⬍]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Form H: Medications Summary

(formHsummaryWk4, formHsummary)

Form H Medications

Were any non-statin medications taken in the past week?

(otherMeds, <otherMeds>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Total # regularly scheduled meds

(polyPharm1, <polyPharm1>)

(String, Text)

Total # PRN > 50% of days

(polyPharm2, <polyPharm2>)

(String, Text)

Total # PRN < 50% of days

(polyPharm3, <polyPharm3>)

(String, Text)

Form I:McGill QOL questionnaire

(formIWk4, formI)

Form I: McGill Quality of Life Questionnaire (MQOLQ)
Part A

1. Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past two (2) days, the quality of my life has been:

(mqolqA1, <mqolqA1>)

(Integer, Text)

Part B - Physical Symptoms or Physical Problems

1a.Over the past two (2) days, one troublesome symptom has been:

(mqolqB1Txt, <mqolqB1Txt>)

(String, Text)

1b. How big a problem

(mqolqB1, <mqolqB1>)

(Integer, Text)

2a. Over the past two (2) days, another troublesome symptom has been:

(mqolqB2Txt, <mqolqB2Txt>)

(String, Text)

2b. How big a problem

(mqolqB2, <mqolqB2>)

(Integer, Text)

3a. Over the past two (2) days, a third troublesome symptom has been:

(mqolqB3txt, <mqolqB3txt>)

(String, Text)

3b. How big a problem

(mqolqB3, <mqolqB3>)

(Integer, Text)

4. Over the past two (2) days I have felt:

(mqolqB4, <mqolqB4>)

(Integer, Text)

Part C

1. Over the past two (2) days, I have been depressed:

(mqolqC1, <mqolqC1>)

(Integer, Text)

2. Over the past two (2) days, I have been nervous or worried:

(mqolqC2, <mqolqC2>)

(Integer, Text)

3. Over the past two (2) days, how much of the time did you feel sad?

(mqolqC3, <mqolqC3>)

(Integer, Text)

4. Over the past two (2) days, when I thought of the future, I was:

(mqolqC4, <mqolqC4>)

(Integer, Text)

5. Over the past two (2) days, my life has been:

(mqolqC5, <mqolqC5>)

(Integer, Text)

6. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life goals I have:

(mqolqC6, <mqolqC6>)

(Integer, Text)

7. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life to this point has been:

(mqolqC7, <mqolqC7>)

(Integer, Text)

8. Over the past two (2) days, I have felt that I have:

(mqolqC8, <mqolqC8>)

(Integer, Text)

9. Over the past two (2) days, I felt good about myself as a person.

(mqolqC9, <mqolqC9>)

(Integer, Text)

10. To me, the past two (2) days were:

(mqolqC10, <mqolqC10>)

(Integer, Text)

11. Over the past two (2) days, the world has been:

(mqolqC11, <mqolqC11>)

(Integer, Text)

12. Over the past two (2) days, I have felt supported:

(mqolqC12, <mqolqC12>)

(Integer, Text)

Part D

Was the response to Part D documented? (If yes, please attach the transcript.)

☐ No (0)

☐ Yes (1)

(mqolqD, <mqolqD>)

(Integer, RadioCheckbox)

Form J: ESAS

(formJWk4, formJ)

Form J: Edmonton Symptom Assessment System (ESAS)

1. Pain

(esas1, <esas1>)

(Integer, Text)

2. Fatigue

(esas2, <esas2>)

(Integer, Text)

3. Nausea

(esas3, <esas3>)

(Integer, Text)

4. Depression

(esas4, <esas4>)

(Integer, Text)

5. Anxiousness

(esas5, <esas5>)

(Integer, Text)

6. Drowsiness

(esas6, <esas6>)

(Integer, Text)

7. Appetite

(esas7, <esas7>)

(Integer, Text)

8. Well-Being

(esas8, <esas8>)

(Integer, Text)

9. Breathing

(esas9, <esas9>)

(Integer, Text)

10. Muscle-Related Pain

(esas10, <esas10>)

(Integer, Text)

11. Weakness

(esas11, <esas11>)

(Integer, Text)

12. Headaches

(esas12, <esas12>)

(Integer, Text)

13. Fever

(esas13, <esas13>)

(Integer, Text)

Additional symptom - specify

(esas14Txt, <esas14Txt>)

(String, Text)

14. Specified symptom Rating

(esas14, <esas14>)

(Integer, Text)

Week 6

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk6, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEvent, <impEvent>)
(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)
☐ Yes (1)

Form F: Part A, B and D

(formFabdWk6New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

	▾

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

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Week 8

Sub Forms

Form F: Part A, B, C and D

Form F: Part A, B, C and D

Form H: Medications Summary

Form I:McGill QOL questionnaire

Form J: ESAS

Form F: Part A, B, C and D

(formFWk8, formF)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)
(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[　　　　　　　　　　　　　　▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[　　　　　　　　　　　　　　▼]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B, C and D

(formFWk8New, formFNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[⬇]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[⬇]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Form H: Medications Summary

(formHsummaryWk8, formHsummary)

Form H Medications

Were any non-statin medications taken in the past week?

(otherMeds, <otherMeds>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Total # regularly scheduled meds

(polyPharm1, <polyPharm1>)

(String, Text)

Total # PRN > 50% of days

(polyPharm2, <polyPharm2>)

(String, Text)

Total # PRN < 50% of days

(polyPharm3, <polyPharm3>)

(String, Text)

Form I:McGill QOL questionnaire

(formIWk8, formI)

Form I: McGill Quality of Life Questionnaire (MQOLQ)

Part A

1. Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past two (2) days, the quality of my life has been:

(mqolqA1, <mqolqA1>)

(Integer, Text)

Part B - Physical Symptoms or Physical Problems

1a.Over the past two (2) days, one troublesome symptom has been:

(mqolqB1Txt, <mqolqB1Txt>)

(String, Text)

1b. How big a problem

(mqolqB1, <mqolqB1>)

(Integer, Text)

2a. Over the past two (2) days, another troublesome symptom has been:

(mqolqB2Txt, <mqolqB2Txt>)

(String, Text)

2b. How big a problem

(mqolqB2, <mqolqB2>)

(Integer, Text)

3a. Over the past two (2) days, a third troublesome symptom has been:

(mqolqB3txt, <mqolqB3txt>)

(String, Text)

3b. How big a problem

(mqolqB3, <mqolqB3>)

(Integer, Text)

4. Over the past two (2) days I have felt:

(mqolqB4, <mqolqB4>)

(Integer, Text)

Part C

1. Over the past two (2) days, I have been depressed:
(mqolqC1, <mqolqC1>)
(Integer, Text)

2. Over the past two (2) days, I have been nervous or worried:
(mqolqC2, <mqolqC2>)
(Integer, Text)

3. Over the past two (2) days, how much of the time did you feel sad?
(mqolqC3, <mqolqC3>)
(Integer, Text)

4. Over the past two (2) days, when I thought of the future, I was:
(mqolqC4, <mqolqC4>)
(Integer, Text)

5. Over the past two (2) days, my life has been:
(mqolqC5, <mqolqC5>)
(Integer, Text)

6. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life goals I have:
(mqolqC6, <mqolqC6>)
(Integer, Text)

7. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life to this point has been:
(mqolqC7, <mqolqC7>)
(Integer, Text)

8. Over the past two (2) days, I have felt that I have:
(mqolqC8, <mqolqC8>)
(Integer, Text)

9. Over the past two (2) days, I felt good about myself as a person.
(mqolqC9, <mqolqC9>)
(Integer, Text)

10. To me, the past two (2) days were:

(mqolqC10, <mqolqC10>)

(Integer, Text)

11. Over the past two (2) days, the world has been:

(mqolqC11, <mqolqC11>)

(Integer, Text)

12. Over the past two (2) days, I have felt supported:

(mqolqC12, <mqolqC12>)

(Integer, Text)

Part D

Was the response to Part D documented? (If yes, please attach the transcript.)

(mqolqD, <mqolqD>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Form J: ESAS

(formJWk8, formJ)

Form J: Edmonton Symptom Assessment System (ESAS)

1. Pain

(esas1, <esas1>)

(Integer, Text)

2. Fatigue

(esas2, <esas2>)

(Integer, Text)

3. Nausea

(esas3, <esas3>)

(Integer, Text)

4. Depression

(esas4, <esas4>)

(Integer, Text)

5. Anxiousness

(esas5, <esas5>)

(Integer, Text)

6. Drowsiness

(esas6, <esas6>)

(Integer, Text)

7. Appetite

(esas7, <esas7>)

(Integer, Text)

8. Well-Being

(esas8, <esas8>)

(Integer, Text)

9. Breathing

(esas9, <esas9>)

(Integer, Text)

10. Muscle-Related Pain

(esas10, <esas10>)

(Integer, Text)

11. Weakness

(esas11, <esas11>)

(Integer, Text)

12. Headaches

(esas12, <esas12>)

(Integer, Text)

13. Fever

(esas13, <esas13>)

(Integer, Text)

Additional symptom - specify

(esas14Txt, <esas14Txt>)

(String, Text)

14. Specified symptom Rating

(esas14, <esas14>)

(Integer, Text)

Week 10

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk10, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of

Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEvent, <impEvent>)
(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)
☐ Yes (1)

Form F: Part A, B and D

(formFabdWk10New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

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50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 12

Sub Forms

Form F: Part A, B, C and D

Form F: Part A, B, C and D

Form H: Medications Summary

Form I:McGill QOL questionnaire

Form J: ESAS

Form F: Part A, B, C and D

(formFWk12, formF)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)
(AKPS, <AKPS>)
(Integer, Select)

[dropdown field]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

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50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?
(hospice, <hospice>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown (9)

Receiving Palliative Care?
(palCare, <palCare>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)
☐ Unknown (9)

Has the patient taken any statin medications during the past week?
(statinUse, <statinUse>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?
(fuStatus2, <fuStatus2>)
(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

What is the likelihood of you recommending your current health care to others?
(likelihood, <likelihood>)

[dropdown field]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B, C and D

(formFWk12New, formFNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[⬇]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

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40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[⬇]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Form H: Medications Summary

(formHsummaryWk12, formHsummary)

Form H Medications

Were any non-statin medications taken in the past week?

(otherMeds, <otherMeds>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Total # regularly scheduled meds

(polyPharm1, <polyPharm1>)

(String, Text)

Total # PRN > 50% of days

(polyPharm2, <polyPharm2>)

(String, Text)

Total # PRN < 50% of days

(polyPharm3, <polyPharm3>)

(String, Text)

Form I:McGill QOL questionnaire

(formIWk12, formI)

Form I: McGill Quality of Life Questionnaire (MQOLQ)

Part A

---

1. Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past two (2) days, the quality of my life has been:

(mqolqA1, <mqolqA1>)

(Integer, Text)

Part B - Physical Symptoms or Physical Problems

1a.Over the past two (2) days, one troublesome symptom has been:

(mqolqB1Txt, <mqolqB1Txt>)

(String, Text)

1b. How big a problem

(mqolqB1, <mqolqB1>)

(Integer, Text)

2a. Over the past two (2) days, another troublesome symptom has been:

(mqolqB2Txt, <mqolqB2Txt>)

(String, Text)

2b. How big a problem

(mqolqB2, <mqolqB2>)

(Integer, Text)

3a. Over the past two (2) days, a third troublesome symptom has been:

(mqolqB3txt, <mqolqB3txt>)

(String, Text)

3b. How big a problem

(mqolqB3, <mqolqB3>)

(Integer, Text)

---

4. Over the past two (2) days I have felt:

(mqolqB4, <mqolqB4>)

(Integer, Text)

Part C

1. Over the past two (2) days, I have been depressed:

(mqolqC1, <mqolqC1>)

(Integer, Text)

2. Over the past two (2) days, I have been nervous or worried:

(mqolqC2, <mqolqC2>)

(Integer, Text)

3. Over the past two (2) days, how much of the time did you feel sad?

(mqolqC3, <mqolqC3>)

(Integer, Text)

4. Over the past two (2) days, when I thought of the future, I was:

(mqolqC4, <mqolqC4>)

(Integer, Text)

5. Over the past two (2) days, my life has been:

(mqolqC5, <mqolqC5>)

(Integer, Text)

6. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life goals I have:

(mqolqC6, <mqolqC6>)

(Integer, Text)

7. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life to this point has been:

(mqolqC7, <mqolqC7>)

(Integer, Text)

8. Over the past two (2) days, I have felt that I have:

(mqolqC8, <mqolqC8>)

(Integer, Text)

9. Over the past two (2) days, I felt good about myself as a person.

(mqolqC9, <mqolqC9>)

(Integer, Text)

10. To me, the past two (2) days were:

(mqolqC10, <mqolqC10>)

(Integer, Text)

11. Over the past two (2) days, the world has been:

(mqolqC11, <mqolqC11>)

(Integer, Text)

12. Over the past two (2) days, I have felt supported:

(mqolqC12, <mqolqC12>)

(Integer, Text)

Part D

Was the response to Part D documented? (If yes, please attach the transcript.)

☐ No (0)

☐ Yes (1)

(mqolqD, <mqolqD>)

(Integer, RadioCheckbox)

Form J: ESAS

(formJWk12, formJ)

Form J: Edmonton Symptom Assessment System (ESAS)

1. Pain

(esas1, <esas1>)

(Integer, Text)

2. Fatigue

(esas2, <esas2>)

(Integer, Text)

3. Nausea

(esas3, <esas3>)

(Integer, Text)

4. Depression

(esas4, <esas4>)

(Integer, Text)

5. Anxiousness

(esas5, <esas5>)

(Integer, Text)

6. Drowsiness

(esas6, <esas6>)

(Integer, Text)

7. Appetite

(esas7, <esas7>)

(Integer, Text)

8. Well-Being

(esas8, <esas8>)

(Integer, Text)

9. Breathing

(esas9, <esas9>)

(Integer, Text)

10. Muscle-Related Pain

(esas10, <esas10>)

(Integer, Text)

11. Weakness

(esas11, <esas11>)

(Integer, Text)

12. Headaches

(esas12, <esas12>)

(Integer, Text)

13. Fever

(esas13, <esas13>)

(Integer, Text)

Additional symptom - specify

(esas14Txt, <esas14Txt>)

(String, Text)

14. Specified symptom Rating

(esas14, <esas14>)

(Integer, Text)

Week 14

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk14, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date (dateFormF, <dateFormF>) (Date, Text)	(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)
(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

□ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEvent, <impEvent>)
(Integer, RadioCheckbox)

□ No(If no, then the answer to all the following questions should be no) (0)
□ Yes (1)

Form F: Part A, B and D

(formFabdWk14New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)

(AKPS, <AKPS>)

(Integer, Select)

⬇

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

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40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Week 16

Sub Forms

Form F: Part A, B, C and D

Form F: Part A, B, C and D

Form H: Medications Summary

Form I:McGill QOL questionnaire

Form J: ESAS

Form F: Part A, B, C and D

(formFWk16, formF)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date	
(dateFormF, <dateFormF>)	(MMM-dd-yyyy)
(Date, Text)	

Part A - Interview Information

Was the interview obtained?
(fuStatus, <fuStatus>)
(Integer, Select)

Yes (1)
No, could not contact within appropriate time window (2)
No, patient actively refused interview (3)
No, caregiver or family member refused interview (4)
No, administrative barrier (5)
No, other (specify below) (9)

Other (specify interview obtained)
(fuStatusTxt, <fuStatusTxt>)
(String, Text)

Who provided the information?
(fuWho, <fuWho>)
(Integer, Select)

Patient (1)
Professional caregiver (2)
Informal caregiver (family, friend, etc. who is giving care) (3)
Other (specify relationship below) (9)

Other (specify relationship:)
(fuWhotxt, <fuWhotxt>)
(String, Text)

Part B - Current Status

Is patient alive?
(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

	⬇

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

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50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

	⬇

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B, C and D

(formFWk16New, formFNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[dropdown ▼]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Form H: Medications Summary

(formHsummaryWk16, formHsummary)

Form H Medications

Were any non-statin medications taken in the past week?

(otherMeds, <otherMeds>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Total # regularly scheduled meds

(polyPharm1, <polyPharm1>)

(String, Text)

Total # PRN > 50% of days

(polyPharm2, <polyPharm2>)

(String, Text)

Total # PRN < 50% of days

(polyPharm3, <polyPharm3>)

(String, Text)

Form I:McGill QOL questionnaire

Form I: McGill Quality of Life Questionnaire (MQOLQ)

Part A

---

1. Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past two (2) days, the quality of my life has been:

(mqolqA1, <mqolqA1>)

(Integer, Text)

Part B - Physical Symptoms or Physical Problems

1a.Over the past two (2) days, one troublesome symptom has been:

(mqolqB1Txt, <mqolqB1Txt>)

(String, Text)

1b. How big a problem

(mqolqB1, <mqolqB1>)

(Integer, Text)

2a. Over the past two (2) days, another troublesome symptom has been:

(mqolqB2Txt, <mqolqB2Txt>)

(String, Text)

2b. How big a problem

(mqolqB2, <mqolqB2>)

(Integer, Text)

3a. Over the past two (2) days, a third troublesome symptom has been:

(mqolqB3txt, <mqolqB3txt>)

(String, Text)

3b. How big a problem

(mqolqB3, <mqolqB3>)

(Integer, Text)

4. Over the past two (2) days I have felt:

(mqolqB4, <mqolqB4>)

(Integer, Text)

Part C

1. Over the past two (2) days, I have been depressed:

(mqolqC1, <mqolqC1>)

(Integer, Text)

2. Over the past two (2) days, I have been nervous or worried:

(mqolqC2, <mqolqC2>)

(Integer, Text)

3. Over the past two (2) days, how much of the time did you feel sad?

(mqolqC3, <mqolqC3>)

(Integer, Text)

4. Over the past two (2) days, when I thought of the future, I was:

(mqolqC4, <mqolqC4>)

(Integer, Text)

5. Over the past two (2) days, my life has been:

(mqolqC5, <mqolqC5>)

(Integer, Text)

6. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life goals I have:

(mqolqC6, <mqolqC6>)

(Integer, Text)

7. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life to this point has been:

(mqolqC7, <mqolqC7>)

(Integer, Text)

8. Over the past two (2) days, I have felt that I have:

(mqolqC8, <mqolqC8>)

(Integer, Text)

9. Over the past two (2) days, I felt good about myself as a person.

(mqolqC9, <mqolqC9>)

(Integer, Text)

10. To me, the past two (2) days were:

(mqolqC10, <mqolqC10>)

(Integer, Text)

11. Over the past two (2) days, the world has been:

(mqolqC11, <mqolqC11>)

(Integer, Text)

12. Over the past two (2) days, I have felt supported:

(mqolqC12, <mqolqC12>)

(Integer, Text)

Part D

Was the response to Part D documented? (If yes, please attach the transcript.)

(mqolqD, <mqolqD>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Form J: ESAS

(formJWk16, formJ)

Form J: Edmonton Symptom Assessment System (ESAS)

1. Pain

(esas1, <esas1>)

(Integer, Text)

2. Fatigue

(esas2, <esas2>)

(Integer, Text)

3. Nausea

(esas3, <esas3>)

(Integer, Text)

4. Depression

(esas4, <esas4>)

(Integer, Text)

5. Anxiousness

(esas5, <esas5>)

(Integer, Text)

6. Drowsiness

(esas6, <esas6>)

(Integer, Text)

7. Appetite

(esas7, <esas7>)

(Integer, Text)

8. Well-Being

(esas8, <esas8>)

(Integer, Text)

9. Breathing

(esas9, <esas9>)

(Integer, Text)

10. Muscle-Related Pain

(esas10, <esas10>)

(Integer, Text)

11. Weakness

(esas11, <esas11>)

(Integer, Text)

12. Headaches

(esas12, <esas12>)

(Integer, Text)

13. Fever

(esas13, <esas13>)

(Integer, Text)

Additional symptom - specify

(esas14Txt, <esas14Txt>)

(String, Text)

14. Specified symptom Rating

(esas14, <esas14>)

(Integer, Text)

Week 18

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk18, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)
(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▾]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEvent, <impEvent>)
(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)
☐ Yes (1)

Form F: Part A, B and D

(formFabdWk18New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[⬇]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 20

Sub Forms

Form F: Part A, B, C and D

Form F: Part A, B, C and D

Form H: Medications Summary

Form I:McGill QOL questionnaire

Form J: ESAS

Form F: Part A, B, C and D
(formFWk20, formF)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)
(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[▼]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B, C and D

(formFWk20New, formFNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)   (MMM-dd-yyyy)

(Date, Text)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[dropdown ▼]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Form H: Medications Summary

(formHsummaryWk20, formHsummary)

Form H Medications

Were any non-statin medications taken in the past week?

(otherMeds, <otherMeds>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Total # regularly scheduled meds

(polyPharm1, <polyPharm1>)

(String, Text)

Total # PRN > 50% of days

(polyPharm2, <polyPharm2>)

(String, Text)

Total # PRN < 50% of days

(polyPharm3, <polyPharm3>)

(String, Text)

Form I:McGill QOL questionnaire

(formIWk20, formI)

Form I: McGill Quality of Life Questionnaire (MQOLQ)
Part A

1. Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past two (2) days, the quality of my life has been:

(mqolqA1, <mqolqA1>)

(Integer, Text)

Part B - Physical Symptoms or Physical Problems

1a.Over the past two (2) days, one troublesome symptom has been:

(mqolqB1Txt, <mqolqB1Txt>)

(String, Text)

1b. How big a problem

(mqolqB1, <mqolqB1>)

(Integer, Text)

2a. Over the past two (2) days, another troublesome symptom has been:

(mqolqB2Txt, <mqolqB2Txt>)

(String, Text)

2b. How big a problem

(mqolqB2, <mqolqB2>)

(Integer, Text)

3a. Over the past two (2) days, a third troublesome symptom has been:

(mqolqB3txt, <mqolqB3txt>)

(String, Text)

3b. How big a problem

(mqolqB3, <mqolqB3>)

(Integer, Text)

4. Over the past two (2) days I have felt:

(mqolqB4, <mqolqB4>)

(Integer, Text)

Part C

1. Over the past two (2) days, I have been depressed:

(mqolqC1, <mqolqC1>)

(Integer, Text)

2. Over the past two (2) days, I have been nervous or worried:

(mqolqC2, <mqolqC2>)

(Integer, Text)

3. Over the past two (2) days, how much of the time did you feel sad?

(mqolqC3, <mqolqC3>)

(Integer, Text)

4. Over the past two (2) days, when I thought of the future, I was:

(mqolqC4, <mqolqC4>)

(Integer, Text)

5. Over the past two (2) days, my life has been:

(mqolqC5, <mqolqC5>)

(Integer, Text)

6. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life goals I have:

(mqolqC6, <mqolqC6>)

(Integer, Text)

7. Over the past two (2) days, when I thought about my whole life, I felt that in achieving my life to this point has been:

(mqolqC7, <mqolqC7>)

(Integer, Text)

8. Over the past two (2) days, I have felt that I have:

(mqolqC8, <mqolqC8>)

(Integer, Text)

9. Over the past two (2) days, I felt good about myself as a person.

(mqolqC9, <mqolqC9>)

(Integer, Text)

10. To me, the past two (2) days were:

(mqolqC10, <mqolqC10>)

(Integer, Text)

11. Over the past two (2) days, the world has been:

(mqolqC11, <mqolqC11>)

(Integer, Text)

12. Over the past two (2) days, I have felt supported:

(mqolqC12, <mqolqC12>)

(Integer, Text)

Part D

Was the response to Part D documented? (If yes, please attach the transcript.)

(mqolqD, <mqolqD>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Form J: ESAS

(formJWk20, formJ)

Form J: Edmonton Symptom Assessment System (ESAS)

1. Pain

(esas1, <esas1>)

(Integer, Text)

2. Fatigue

(esas2, <esas2>)

(Integer, Text)

3. Nausea

(esas3, <esas3>)

(Integer, Text)

4. Depression

(esas4, <esas4>)

(Integer, Text)

5. Anxiousness

(esas5, <esas5>)

(Integer, Text)

6. Drowsiness

(esas6, <esas6>)

(Integer, Text)

7. Appetite

(esas7, <esas7>)

(Integer, Text)

8. Well-Being

(esas8, <esas8>)

(Integer, Text)

9. Breathing

(esas9, <esas9>)

(Integer, Text)

10. Muscle-Related Pain

(esas10, <esas10>)

(Integer, Text)

11. Weakness

(esas11, <esas11>)

(Integer, Text)

12. Headaches

(esas12, <esas12>)

(Integer, Text)

13. Fever

(esas13, <esas13>)

(Integer, Text)

Additional symptom - specify

(esas14Txt, <esas14Txt>)

(String, Text)

14. Specified symptom Rating

(esas14, <esas14>)

(Integer, Text)

Week 22

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk22, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)
(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEvent, <impEvent>)
(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)
☐ Yes (1)

Form F: Part A, B and D

(formFabdWk22New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date	
(dateFormF, <dateFormF>)	(MMM-dd-yyyy)
(Date, Text)	

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[   ] ⊞

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30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 24

Sub Forms

Form F: Part A, B, C and D

Form F: Part A, B, C and D

Form H: Medications Summary

Form I:McGill QOL questionnaire

Form J: ESAS

Form F: Part A, B, C and D

(formFWk24, formF)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

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(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)

(AKPS, <AKPS>)

(Integer, Select)

[dropdown]

100 Normal; no complaints; no evidence of disease (100)

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30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[dropdown]

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B, C and D

(formFWk24New, formFNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ Unknown, could not contact (9)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[   ] ▼

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30 Almost completely bedridden (30)

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10 Comatose or barely arousable (10)

0 Dead (0)

Part C - In-Depth Assessment

Enrolled in Hospice?

(hospice, <hospice>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Receiving Palliative Care?

(palCare, <palCare>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

☐ Unknown (9)

Has the patient taken any statin medications during the past week?

(statinUse, <statinUse>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Is the patient willing and available to complete the McGill QOL and ESAS of the interview?

(fuStatus2, <fuStatus2>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

What is the likelihood of you recommending your current health care to others?

(likelihood, <likelihood>)

[   ] ▼

Very unlikely (1)

Somewhat unlikely (2)

(Integer, Select)

Unsure (3)

Somewhat likely (4)

Very likely (5)

Part D - Important Events

Was the patient admitted to the hospital, an Emergency Department or undergone and invasive cardiovascular procedure since the last follow-up?

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Form H: Medications Summary

(formHsummaryWk24, formHsummary)

Form H Medications

Were any non-statin medications taken in the past week?

(otherMeds, <otherMeds>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Total # regularly scheduled meds

(polyPharm1, <polyPharm1>)

(String, Text)

Total # PRN > 50% of days

(polyPharm2, <polyPharm2>)

(String, Text)

Total # PRN < 50% of days

(polyPharm3, <polyPharm3>)

(String, Text)

Form I:McGill QOL questionnaire

(formIWk24, formI)

Form I: McGill Quality of Life Questionnaire (MQOLQ)

Part A

1. Considering all parts of my life – physical, emotional, social, spiritual, and financial – over the past two (2) days, the quality of my life has been:

(mqolqA1, <mqolqA1>)

(Integer, Text)

Part B - Physical Symptoms or Physical Problems

1a.Over the past two (2) days, one troublesome symptom has been:

(mqolqB1Txt, <mqolqB1Txt>)

(String, Text)

1b. How big a problem

(mqolqB1, <mqolqB1>)

(Integer, Text)

2a. Over the past two (2) days, another troublesome symptom has been:

(mqolqB2Txt, <mqolqB2Txt>)

(String, Text)

2b. How big a problem

(mqolqB2, <mqolqB2>)

(Integer, Text)

3a. Over the past two (2) days, a third troublesome symptom has been:

(mqolqB3txt, <mqolqB3txt>)

(String, Text)

3b. How big a problem

(mqolqB3, <mqolqB3>)

(Integer, Text)

4. Over the past two (2) days I have felt:

(mqolqB4, <mqolqB4>)

(Integer, Text)

Part C

1. Over the past two (2) days, I have been depressed:
(mqolqC1, <mqolqC1>)
(Integer, Text)

2. Over the past two (2) days, I have been nervous or
worried:
(mqolqC2, <mqolqC2>)
(Integer, Text)

3. Over the past two (2) days, how much of the time did
you feel sad?
(mqolqC3, <mqolqC3>)
(Integer, Text)

4. Over the past two (2) days, when I thought of the future,
I was:
(mqolqC4, <mqolqC4>)
(Integer, Text)

5. Over the past two (2) days, my life has been:
(mqolqC5, <mqolqC5>)
(Integer, Text)

6. Over the past two (2) days, when I thought about my
whole life, I felt that in achieving my life goals I have:
(mqolqC6, <mqolqC6>)
(Integer, Text)

7. Over the past two (2) days, when I thought about my
whole life, I felt that in achieving my life to this point has
been:
(mqolqC7, <mqolqC7>)
(Integer, Text)

8. Over the past two (2) days, I have felt that I have:
(mqolqC8, <mqolqC8>)
(Integer, Text)

9. Over the past two (2) days, I felt good about myself as a
person.
(mqolqC9, <mqolqC9>)
(Integer, Text)

10. To me, the past two (2) days were:

(mqolqC10, <mqolqC10>)

(Integer, Text)

11. Over the past two (2) days, the world has been:

(mqolqC11, <mqolqC11>)

(Integer, Text)

12. Over the past two (2) days, I have felt supported:

(mqolqC12, <mqolqC12>)

(Integer, Text)

Part D

Was the response to Part D documented? (If yes, please attach the transcript.)

(mqolqD, <mqolqD>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Form J: ESAS

Form J: Edmonton Symptom Assessment System (ESAS)

1. Pain

(esas1, <esas1>)

(Integer, Text)

2. Fatigue

(esas2, <esas2>)

(Integer, Text)

3. Nausea

(esas3, <esas3>)

(Integer, Text)

4. Depression

(esas4, <esas4>)

(Integer, Text)

5. Anxiousness

(esas5, <esas5>)

(Integer, Text)

6. Drowsiness

(esas6, <esas6>)

(Integer, Text)

7. Appetite

(esas7, <esas7>)

(Integer, Text)

8. Well-Being

(esas8, <esas8>)

(Integer, Text)

9. Breathing

(esas9, <esas9>)

(Integer, Text)

10. Muscle-Related Pain

(esas10, <esas10>)

(Integer, Text)

11. Weakness

(esas11, <esas11>)

(Integer, Text)

12. Headaches

(esas12, <esas12>)

(Integer, Text)

13. Fever

(esas13, <esas13>)

(Integer, Text)

Additional symptom - specify

(esas14Txt, <esas14Txt>)

(String, Text)

14. Specified symptom Rating

(esas14, <esas14>)

(Integer, Text)

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Week 28

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk28, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[⬇]

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30 Almost completely bedridden (30)

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10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B and D
(formFabdWk28New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[dropdown ▼]

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10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 32

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk32, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

□ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[⬍]

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0 Dead (0)

Part D - Important Events

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(impEvent, <impEvent>)
(Integer, RadioCheckbox)

□ No(If no, then the answer to all the following questions should be no) (0)
□ Yes (1)

Form F: Part A, B and D

(formFabdWk32New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[⬇]

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Part D - Important Events

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(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 36

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdW36, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date	
(dateFormF, <dateFormF>)	(MMM-dd-yyyy)
(Date, Text)	

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEvent, <impEvent>)
(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)
☐ Yes (1)

Form F: Part A, B and D

(formFabdW36New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 40

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk40, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

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60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEvent, <impEvent>)
(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)
☐ Yes (1)

Form F: Part A, B and D

(formFabdWk40New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

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60 Requires occasional assistance but is able to care for most of his or her needs (60)

50 Requires considerable assistance and frequent medical care (50)

40 In bed more than 50% of the time (40)

30 Almost completely bedridden (30)

20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 44

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdWk44, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)
(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

90 Able to carry on normal activity; minor signs or symptoms (90)

80 Normal activity with effort; some signs or symptoms of disease (80)

70 Cares for self; unable to carry on normal activity or to do active work (70)

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20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B and D

(formFabdWk44New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[dropdown ▼]

100 Normal; no complaints; no evidence of disease (100)

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30 Almost completely bedridden (30)

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10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEventNew, <impEventNew>)

(Integer, RadioCheckbox)

☐ No / not that I know of (0)

☐ Yes (1)

Week 48

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

(formFabdW48, formFabd)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[▼]

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80 Normal activity with effort; some signs or symptoms of disease (80)

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20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B and D

(formFabdW48New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status)
(choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

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20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Week 52

Sub Forms

Form F: Part A, B and D

Form F: Part A, B and D

Form F: Part A, B and D

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWho, <fuWho>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, etc. who is giving care)

(3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxt, <fuWhotxt>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)

(AKPS, <AKPS>)

(Integer, Select)

[▾]

100 Normal; no complaints; no evidence of disease (100)

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20 Totally bedridden and requiring extensive nursing care by professionals and/or family (20)

10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?

(impEvent, <impEvent>)

(Integer, RadioCheckbox)

☐ No(If no, then the answer to all the following questions should be no) (0)

☐ Yes (1)

Form F: Part A, B and D

(formFabdW52New, formFabdNew)

Sub Forms

[Form F Part D Important Events]

Form F - Follow-up Interview

Date

(dateFormF, <dateFormF>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Interview Information<HR

Was the interview obtained?

(fuStatus, <fuStatus>)

(Integer, Select)

Yes (1)

No, could not contact within appropriate time window (2)

No, patient actively refused interview (3)

No, caregiver or family member refused interview (4)

No, administrative barrier (5)

No, other (specify below) (9)

Other (specify interview obtained)

(fuStatusTxt, <fuStatusTxt>)

(String, Text)

Who provided the information?

(fuWhoNew, <fuWhoNew>)

(Integer, Select)

Patient (1)

Professional caregiver (2)

Informal caregiver (family, friend, proxy, etc. who is giving care) (3)

Other (specify relationship below) (9)

Other (specify relationship:)

(fuWhotxtNew, <fuWhotxtNew>)

(String, Text)

Part B - Current Status

Is patient alive?

(fuAlive, <fuAlive>)

(Integer, RadioCheckbox)

☐ No (Provide dates and cause of death in Form Z: End of Study and Mortality) (0)

☐ Yes (1)

☐ Unknown, could not contact (9)

Australia-modified Karnofsky Performance Status (AKPS) (choose only one)

AKPS (Australia-modified Karnofsky Performance Status) (choose one)
(AKPS, <AKPS>)
(Integer, Select)

[▼]

100 Normal; no complaints; no evidence of disease (100)

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30 Almost completely bedridden (30)

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10 Comatose or barely arousable (10)

0 Dead (0)

Part D - Important Events

Please add a new form for each event.

(Complete weekly, weeks 1-4, then on even weeks, weeks 5-24, then every four weeks until week 52) information may be obtained from patient or caregiver.

Since the last follow up visit, has the patient experienced any of the following: admission to the hospital, visit to an Emergency Department, an invasive cardiovascular procedure, a cardiovascular event, pneumonia, and/or venous thromboembolism?
(impEventNew, <impEventNew>)
(Integer, RadioCheckbox)

☐ No / not that I know of (0)
☐ Yes (1)

Adverse Events Summary

(aeSummary, <aeSummary>)

Sub Forms

[Form W and X: Reportable Adverse Events]

Were there any adverse events?

Did the patient experience any reportable Adverse Events

(aeyn, <aeyn>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

PCRC1001 Annotated eCRF Version 3.00 26 July 2012 FINAL

Form W and X: Reportable Adverse Events

(formWX, <formWX>)

Form X: Adverse Events

What is NOT an AE (i.e., for what things do you NOT need to fill out this form):

• Related to any documented underlying illness for this patient (as captured on baseline enrollment form) (i.e., obvious progression of the underlying disease)

• Predefined study outcomes: cardiovascular event, venous thromboembolism, pneumonia (captured on Form F, Part D)

Pt Incident #

(aeIncNo, <aeIncNo>)

(Integer, Text)

---

1. Is this an Initial Event or Follow-up on a Previous Event?

(reportType, <reportType>)

(Integer, RadioCheckbox)

☐ Initial event (1)

☐ Follow-up on a previous event (2)

Date of AE (Enter original date if a follow-up report)

(dateOnset, <dateOnset>)

(Date, Text)

(MMM-dd-yyyy)

---

2. Brief description (Diagnosis or Signs and Symptoms):

(diagnosis, <diagnosis>)

(String, Text)

---

3. Seriousness (Grade)

(grade, <grade>)

(Integer, Select)

Mild (1)

Moderate (2)

Severe (3)

Life Threatening (4)

Death (5)

---

4. Outcome

(outcome, <outcome>)

(Integer, RadioCheckbox)

☐ Resolved (1)

☐ Ongoing (2)

☐ Death (3)

Date AE Resolved

(dateResolved, <dateResolved>)

(Date, Text)

(MMM-dd-yyyy)

If the response to Question 3 above is #3, #4 or #5, then the adverse event is SERIOUS. Please complete the following section about SERIOUS AEs. Otherwise, the form is complete at this point.

Was this event serious?

(saeYn, <saeYn>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

5. Other Notes:

(saeNotesTxt, <saeNotesTxt>)

(String, MultiLineText)

6. Classification of SAE:

(saeType, <saeType>)

(Integer, RadioCheckbox)

☐ Hospitalization/prolonged hospitalization (1)

☐ Disability (2)

☐ Serious and/or unexpected reactions (3)

☐ Death (4)

☐ Congenital anomaly or birth defect (5)

☐ Life threatening (6)

7. If death, specify cause and date:

Cause of death:

(deathCauseTxt, <deathCauseTxt>)

(String, Text)

Date of death

(dateDeath, <dateDeath>)

(Date, Text)

(MMM-dd-yyyy)

8. Is event related to participation in the trial? (This question documents the physician's opinion of the causal link between participation in the trial and the event.)

(related, <related>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

9. Is this SAE a Suspected Unanticipated Serious Adverse Reaction (SUSAR)?

(irbReport, <irbReport>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Answer the following question if the event is a SUSAR (Suspected Unanticipated Serious Adverse Reaction).

Date SUSAR reported to IRB

(dateIrbReport, <dateIrbReport>)

(Date, Text)

(MMM-dd-yyyy)

Event Classification Committee Report on SAEs Summary

(formYSummary, <formYSummary>)

Sub Forms

[Event Classification Committee Report on SAEs]

Were there any adverse events reviewed by the Event Classification Committee?

Were there any events reviewed by the PCRC Event Classification Committee?

(eccReview, <eccReview>)

(Integer, RadioCheckbox)

☐ No (0)
☐ Yes (1)

Event Classification Committee Report on SAEs

(formY, <formY>)

Event Classification Committee Report on SAEs

To be completed by the ECC

Pt Incident #

(aeIncNo, <aeIncNo>)

(Integer, Text)

Date of Onset

(dateOnsetFormY, <dateOnsetFormY>)

(Date, Text)

(MMM-dd-yyyy)

Date reviewed

(eccDate, <eccDate>)

(Date, Text)

(MMM-dd-yyyy)

Did the Event Classification Committee agree with the site PIs assessment of Expectedness?

(eccAgreeExpec, <eccAgreeExpec>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Expectedness

(eccExpec, <eccExpec>)

(Integer, RadioCheckbox)

☐ Expected (1)

☐ Unexpected (2)

Did the Event Classification Committee agree with the site PIs assessment of Attribution?

(eccAgreeAttrib, <eccAgreeAttrib>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Attribution/Relationship to trial

(eccAttrib, <eccAttrib>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

Form Z: End of Study and Mortality

(formZ, <formZ>)

Form Form Z End of Study and Mortality

Date

(dateFormZ, <dateFormZ>)

(Date, Text)

(MMM-dd-yyyy)

Part A - Survival status

Survival status

(status, <status>)

(Integer, Select)

Dead (0)

Alive (1)

Consent for survivor follow-up withdrawn (2)

Lost to follow-up (3)

Date of Death or Date of last contact (if alive)

(dateLfu, <dateLfu>)

(Date, Text)

(MMM-dd-yyyy)

If death has occurred, was cause of death due to cardiovascular disease?

(deathCVD, <deathCVD>)

(Integer, RadioCheckbox)

☐ No (0)

☐ Yes (1)

If death has occurred, specify cause

(deathTxt, <deathTxt>)

(String, Text)

Part B - Compliance to Randomization Assignment (Answer either continuation or discontinuation question)

For patients assigned to continuation arm: Did the patient discontinue statin medication?

(statinComp1, <statinComp1>)

(Integer, Select)

No, completed study per assignment (0)

Yes, due to gastrointestinal side effects (1)

Yes, due to myopathy (2)

Yes, contraindicated based on labs indicating renal or liver compromise (3)

Yes, other - specify below (9)

Yes, discontinue statin medication Other (specify)

(statinComp1Txt, <statinComp1Txt>)

(String, Text)

If yes, specify date discontinued

(dateStatinComp1, <dateStatinComp1>)

(Date, Text)

(MMM-dd-yyyy)

For patients assigned to discontinuation arm: Did the patient continue or restart statins during the trial?
(statinComp2, <statinComp2>)
(Integer, Select)

No, completed study per assignment (0)

Yes, never discontinued (1)

Yes, restarted due to cardiovascular event (2)

Yes, other - specify below (9)

Yes, continue or restart Other (specify)
(statinComp2txt, <statinComp2txt>)
(String, Text)

If yes, specify date continue or restart statin:
(dateStatinComp2, <dateStatinComp2>)
(Date, Text)

(MMM-dd-yyyy)

Part C - Willingness to continue assessments contrbuting follow-up information

Patient assessment prior to death or 12 months post randomization:
(willing, <willing>)
(Integer, Select)

Yes, completed follow-up (0)

No, patient refusal to continue follow-up assessments (1)

No, patient's family requested discontinuation of follow-up (2)

No, patient's physician/health care provider requested discontinuation of follow-up (3)

No, patient unable to continue participation due to cognitive impairment (4)

No, adverse event requires discontinuation of follow-up (5)

No, initally eligibility determined to be incorrect (6)

No, other. Specify below (9)

Asessment No, other. (Specify)
(willingTxt, <willingTxt>)
(String, Text)

If no, extent and date of withdrawal from follow-up
(withdraw, <withdraw>)
(Integer, Select)

Discontinue telephone assessment but willing to allow access to medical records and survival information (1)

No follow-up information (2)

Date of withdrawal
(dateWithdraw, <dateWithdraw>)
(Date, Text)

(MMM-dd-yyyy)

Form Architecture

Record

- (1) Registration
- (2) Eligibility
    - (1) *Form A: Eligibility*
    - (2) Form A: Eligibility
- (3) Baseline
    - (1) Form B: Part A, B
    - (2) *Form B: Part C*
    - (3) Form B: Part C
    - (4) Form B: Part D
    - (5) Form B: Part E, F
    - (6) Form B: Part G, H
    - (7) *Form F: Baseline Part A, B-Q2, and C*
    - (8) Form F: Baseline Part A, B-Q2, and C
    - (9) Form H: Medications Summary
    - (10) Form I:McGill QOL questionnaire
    - (11) Form J: ESAS
- (4) Week 1
    - (1) *Form F: Part A, B and D*
        - [*Form F Part D Important Events*]
    - (2) Form F: Part A, B and D
        - [Form F Part D Important Events]
- (5) Week 2
    - (1) *Form F: Part A, B, C and D*
        - [*Form F Part D Important Events*]
    - (2) Form F: Part A, B, C and D
        - [Form F Part D Important Events]
    - (3) Form H: Medications Summary
    - (4) Form I:McGill QOL questionnaire
    - (5) Form J: ESAS
- (6) Week 3
    - (1) *Form F: Part A, B and D*
        - [*Form F Part D Important Events*]
    - (2) Form F: Part A, B and D
        - [Form F Part D Important Events]
- (7) Week 4
    - (1) *Form F: Part A, B, C and D*
        - [*Form F Part D Important Events*]
    - (2) Form F: Part A, B, C and D
        - [Form F Part D Important Events]

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(3) Form H: Medications Summary

(4) Form I:McGill QOL questionnaire

(5) Form J: ESAS

(8) Week 6

(1) *Form F: Part A, B and D*

[*Form F Part D Important Events*]

(2) Form F: Part A, B and D

[Form F Part D Important Events]

(9) Week 8

(1) *Form F: Part A, B, C and D*

[*Form F Part D Important Events*]

(2) Form F: Part A, B, C and D

[Form F Part D Important Events]

(3) Form H: Medications Summary

(4) Form I:McGill QOL questionnaire

(5) Form J: ESAS

(10) Week 10

(1) *Form F: Part A, B and D*

[*Form F Part D Important Events*]

(2) Form F: Part A, B and D

[Form F Part D Important Events]

(11) Week 12

(1) *Form F: Part A, B, C and D*

[*Form F Part D Important Events*]

(2) Form F: Part A, B, C and D

[Form F Part D Important Events]

(3) Form H: Medications Summary

(4) Form I:McGill QOL questionnaire

(5) Form J: ESAS

(12) Week 14

(1) *Form F: Part A, B and D*

[*Form F Part D Important Events*]

(2) Form F: Part A, B and D

[Form F Part D Important Events]

(13) Week 16

(1) *Form F: Part A, B, C and D*

[*Form F Part D Important Events*]

(2) Form F: Part A, B, C and D

[Form F Part D Important Events]

(3) Form H: Medications Summary

(4) Form I:McGill QOL questionnaire

(5) Form J: ESAS

(14) Week 18

    (1) *Form F: Part A, B and D*

        [*Form F Part D Important Events*]

    (2) Form F: Part A, B and D

        [Form F Part D Important Events]

(15) Week 20

    (1) *Form F: Part A, B, C and D*

        [*Form F Part D Important Events*]

    (2) Form F: Part A, B, C and D

        [Form F Part D Important Events]

    (3) Form H: Medications Summary

    (4) Form I:McGill QOL questionnaire

    (5) Form J: ESAS

(16) Week 22

    (1) *Form F: Part A, B and D*

        [*Form F Part D Important Events*]

    (2) Form F: Part A, B and D

        [Form F Part D Important Events]

(17) Week 24

    (1) *Form F: Part A, B, C and D*

        [*Form F Part D Important Events*]

    (2) Form F: Part A, B, C and D

        [Form F Part D Important Events]

    (3) Form H: Medications Summary

    (4) Form I:McGill QOL questionnaire

    (5) Form J: ESAS

(18) Week 28

    (1) *Form F: Part A, B and D*

        [*Form F Part D Important Events*]

    (2) Form F: Part A, B and D

        [Form F Part D Important Events]

(19) Week 32

    (1) *Form F: Part A, B and D*

        [*Form F Part D Important Events*]

    (2) Form F: Part A, B and D

        [Form F Part D Important Events]

(20) Week 36

    (1) *Form F: Part A, B and D*

        [*Form F Part D Important Events*]

    (2) Form F: Part A, B and D

        [Form F Part D Important Events]

(21) Week 40

(1) *Form F: Part A, B and D*

    [*Form F Part D Important Events*]

(2) Form F: Part A, B and D

    [Form F Part D Important Events]

(22) Week 44

(1) *Form F: Part A, B and D*

    [*Form F Part D Important Events*]

(2) Form F: Part A, B and D

    [Form F Part D Important Events]

(23) Week 48

(1) *Form F: Part A, B and D*

    [*Form F Part D Important Events*]

(2) Form F: Part A, B and D

    [Form F Part D Important Events]

(24) Week 52

(1) *Form F: Part A, B and D*

    [*Form F Part D Important Events*]

(2) Form F: Part A, B and D

    [Form F Part D Important Events]

(25) Adverse Events Summary

    [Form W and X: Reportable Adverse Events]

(26) Event Classification Committee Report on SAEs Summary

    [Event Classification Committee Report on SAEs]

(27) Form Z: End of Study and Mortality