Participant ID	

Initials of person 1 entering data	
Initials of person 2 entering data	

Staff 1 email	
Staff 2 email	

CONFIDENTIAL CASE REPORT FORM

Treatments for Muscle Cramps in Motor Neuron Disease/Amyotrophic Lateral Sclerosis

Series 63

IMPACCT Trials Coordination Centre (ITCC)
UTS Rapid Program

A prospective observational study of palliative care and cancer symptom management

Treatments understanding the burden of the adverse effects.

The case report form (CRF) is to be completed in compliance with
ITCC Standard Operating Procedures (SOP)

TABLE OF CONTENTS	PAGE NO.
T_0-Baseline	2
T_1 – 1-16 weeks post baseline	9
Treatment Cessation *(only complete if treatment is ceased during the study period. Otherwise leave blank).*	15
The Ad hoc pages only need to be completed if an unexpected harm occurs outside of the assessment timepoints.	
Ad hoc A	17
Ad hoc B	19
Ad hoc C	21

References:
Common Terminology Criteria for Adverse Events (CTCAE). Version 5.0. Published: November 27, 2017. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health, National Cancer Institute

(T_0) - Baseline Assessment	
Date of Assessment	DD/MM/YYYY

What country are you located in?	
Tick ✓	**Country** *(Tick one)*
◯	Australia
◯	USA
◯	Other - *Please specify*:
What is your clinical role?	
Tick ✓	**Roles** *(Tick one)*
◯	Palliative care clinician
◯	MND/ALS clinician
◯	Other - *Please specify*:

Patient Demographics	
Gender *(please tick)* ◯ Male ◯ Female ◯ Non-binary	
Age (yrs)	

Tick ✓	**Type of MND/ALS** *(please choose only one)*
◯	Limb-onset
◯	Bulbar-onset
◯	Other - *Please specify:*
Tick ✓	**Does this person have frontotemporal dementia?**
◯	Yes
◯	No
Tick ✓	**Does the patient have a PEG tube?**
◯	Yes
◯	No
Tick ✓	**Does the patient use non-invasive ventilation/BiPAP?**
◯	Yes
◯	No

Tick ✓	**Karnofsky Performance Scale (KPS)**
◯	100 – Normal; no complaints; no evidence of disease
◯	90 – Able to carry on normal activity; minor sign of symptoms of disease
◯	80 – Normal activity with effort; some signs or symptoms of disease
◯	70 – Cares for self; unable to carry on normal activity or to do active work
◯	60 – Requires occasional assistance but is able to care for most needs
◯	50 – Requires considerable assistance and frequent medical care
◯	40 – Disabled; requires special care and assistance

◯	30 – Severely disabled; hospital admission is indicated although death not imminent
◯	20 – Very sick; hospital admission necessary; active supportive treatment necessary
◯	10 – Moribund; fatal processes progressing rapidly
◯	0 – Dead
◯	Not able to determine

Tick ✓	**Place of Care** *(Tick one)*
◯	Inpatient acute hospital
◯	Inpatient hospice/Palliative care unit
◯	Outpatient clinic
◯	Telemedicine
◯	Home
◯	Nursing home/Care facility
◯	Other - *Please specify:*

Muscle Cramp Assessment

Muscle cramp

◯ No Symptom ◯ 1 ◯ 2 ◯ 3 ◯ Ungradable

NCI criteria
1. Mild pain
2. Moderate pain
3. Severe pain

How often do cramps occur?

◯ No symptom ◯ Less than daily ◯ Roughly once daily ◯ More than once daily

Treatment Details

Tick all that apply ✓	**Treatments patient has *previously* tried or is currently using to manage cramps** *(Tick all that apply)*
☐	**Gabapentin** If yes, is this treatment continuing? ◯ Yes ◯ No If you plan to stop the treatment or it has already been stopped, please select the reason: ◯ Due to toxicity ◯ Lack of efficacy ◯ Burden of treatment (e.g. pill burden) ◯ Cost ◯ Other - *Please specify*:
☐	**Carbamazepine** If yes, is this treatment continuing? ◯ Yes ◯ No If you plan to stop the treatment or it has already been stopped, please

	select the reason: ○ Due to toxicity ○ Lack of efficacy ○ Burden of treatment ○ Cost ○ Other - *Please specify*:
☐	**Baclofen** If yes, is this treatment continuing or is there a plan to repeat the procedure in the future? ○ Yes ○ No If you plan to stop the treatment or it has already been stopped, please select the reason: ○ Due to toxicity ○ Lack of efficacy ○ Burden of treatment ○ Cost ○ Other - *Please specify*:
☐	**Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). Please specify:_____** If yes, is this treatment continuing or is there a plan to repeat the procedure in the future? ○ Yes ○ No If you plan to stop the treatment or it has already been stopped, please select the reason: ○ Due to toxicity ○ Lack of efficacy ○ Burden of treatment ○ Cost ○ Other - *Please specify*:
☐	**Mexiletine** If yes, is this treatment continuing or is there a plan to repeat the procedure in the future? ○ Yes ○ No If you plan to stop the treatment or it has already been stopped, please select the reason: ○ Due to toxicity ○ Lack of efficacy ○ Burden of treatment ○ Cost ○ Other - *Please specify*:
☐	**Quinine derivatives** If yes, is this treatment continuing or is there a plan to repeat the procedure in the future? ○ Yes ○ No If you plan to stop the treatment or it has already been stopped, please select the reason: ○ Due to toxicity ○ Lack of efficacy ○ Burden of treatment ○ Cost ○ Other - *Please specify*:
	Magnesium If yes, is this treatment continuing or is there a plan to repeat the

☐	procedure in the future? ○ Yes ○ No If you plan to stop the treatment or it has already been stopped, please select the reason: ○ Due to toxicity ○ Lack of efficacy ○ Burden of treatment ○ Cost Other - *Please specify*:
☐	**Non-pharmacological treatments (e.g. hydration, salt/solutes, stretching, massage, heat). Please specify:_____** If yes, is this treatment continuing or is there a plan to repeat the procedure in the future? ○ Yes ○ No If you plan to stop the treatment or it has already been stopped, please select the reason: ○ Due to toxicity ○ Lack of efficacy ○ Burden of treatment ○ Cost ○ Other. *Please specify*:
☐	**Other. Please specify:_____** If yes, is this treatment continuing or is there a plan to repeat the procedure in the future? ○ Yes ○ No If you plan to stop the treatment or it has already been stopped, please select the reason: ○ Due to toxicity ○ Lack of efficacy ○ Burden of treatment ○ Cost ○ Other. *Please specify*:

Tick ✓	**Which treatment(s) are you *commencing or adjusting today*?** *(Tick all that apply)*
☐	Gabapentin
☐	Carbamazepine
☐	Baclofen
☐	Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). *Please specify*: _____
☐	Mexiletine
☐	Quinine derivatives
☐	Magnesium

☐	Non –pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat). *Please specify*: _____
☐	Other. *Please specify*: _____

Dosing plan - Specify treatment: _____	
Specify formulation (Optional) *For magnesium and quinine derivatives e.g. tonic water, magnesium sulphate*	
Amount per dose *(in mg OR for quinine derivates in mL)*	

Tick ✓	**Frequency**
○	Daily ○ Regular/scheduled ○ As needed
○	BD/BID ○ Regular/scheduled ○ As needed
○	TDS/TID ○ Regular/scheduled ○ As needed
○	QID ○ Regular/scheduled ○ As needed
○	Other; *Please specify*:_____ ○ Regular/scheduled ○ As needed
Tick ✓	**Route of administration**
○	Oral or per PEG tube
○	Transdermal/Topical
○	Other; *Please specify*:_____

Additional dosing plan - Specify treatment: _____	
Specify formulation (Optional) *For magnesium and quinine derivatives e.g. tonic water, magnesium sulphate*	
Amount per dose *(in mg OR for quinine derivates in mL)*	

Tick ✓	**Frequency**
○	Daily ○ Regular/scheduled ○ As needed
○	BD/BID ○ Regular/scheduled ○ As needed
○	TDS/TID ○ Regular/scheduled ○ As needed
○	QID

	○ Regular/scheduled ○ As needed
○	Other; *Please specify*:_____ ○ Regular/scheduled ○ As needed
Tick ✓	**Route of administration**
○	Oral or per PEG tube
○	Transdermal/Topical
○	Other; *Please specify*:_____

Additional dosing plan - Specify treatment: _____	
Specify formulation (Optional) *For magnesium and quinine derivatives e.g. tonic water, magnesium sulphate*	
Amount per dose *(in mg OR for quinine derivates in mL)*	
Tick ✓	**Frequency**
○	Daily ○ Regular/scheduled ○ As needed
○	BD/BID ○ Regular/scheduled ○ As needed
○	TDS/TID ○ Regular/scheduled ○ As needed
○	QID ○ Regular/scheduled ○ As needed
○	Other; *Please specify*:_____ ○ Regular/scheduled ○ As needed
Tick ✓	**Route of administration**
○	Oral or per PEG tube
○	Transdermal/Topical
○	Other; *Please specify*:_____

Baseline Harm Assessment *(Please grade all harms)*

Confusion

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Mild disorientation
2. Moderate disorientation
3. Severe disorientation
4. Life-threatening consequences; treatment indicated

Constipation

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification or enema
2. Persistent symptoms with regular use of laxatives or enemas
3. Obstipation with manual evacuation indicated
4. Life-threatening consequences; urgent treatment indicated

Diarrhea

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline
3. Increase of >=7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline
4. Life-threatening consequences; urgent treatment indicated

Drowsiness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation
3. Obtundation or stupor
4. Life threatening consequences; urgent treatment indicated

Unsteadiness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement
3. Severe unsteadiness or sensation of movement

Other *(only if applicable – can be related or unrelated to the treatment)*

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Additional other *(only if applicable – can be related or unrelated to the treatment)*

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

T_1 – 1-16 weeks after baseline survey

Date of Assessment	DD/MM/YYYY

Tick ✓	**T_1: Assessed/Not assessed reason**
◯	Assessed today *(continue to complete T_1)* OR
◯	Died *(record date of death below)*
◯	Treatment ceased prior to assessment *(complete treatment cessation form)*
◯	Not able to reach patient
◯	Patient too unwell for reassessment of cramps
◯	Other

Date of Death*	DD/MM/YYYY

End survey here

Muscle Cramp Assessment

Muscle cramp

◯ No Symptom ◯ 1 ◯ 2 ◯ 3 ◯ Ungradable

NCI criteria
1. Mild pain 2. Moderate pain, 3. Severe pain

How often do cramps occur?
◯ No symptom ◯ Less than daily ◯ Roughly once daily ◯ More than once daily

In your subjective assessment as a clinician, has cramping improved or resolved?
◯ No ◯ Improved/Partial resolution ◯ Complete resolution ◯ Not applicable

T_1 Follow-Up Harm Assessment *(Please grade each of the following potential harms)*

Confusion

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Mild disorientation 2. Moderate disorientation 3. Severe disorientation 4. Life-threatening consequences; treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Constipation

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification or enema 2. Persistent symptoms with regular use of laxatives or enemas 3. Obstipation with manual evacuation indicated 4. Life-threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Diarrhea

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline 2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline 3. Increase of >=7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline 4. Life-threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Drowsiness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness 2. Moderate sedation 3. Obtundation or stupor 4. Life threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Unsteadiness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement 3. Severe unsteadiness or sensation of movement
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Other *(only if applicable – can be related or unrelated to the treatment)*

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Additional other *(only if applicable – can be related or unrelated to the treatment)*

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Tick ✓	**Which side effect/harm is the <u>most</u> troublesome?** *(Tick one only)*
○	Confusion
○	Constipation
○	Diarrhea
○	Drowsiness
○	Unsteadiness
○	Other
○	Additional Other
○	Not applicable

What is the intended plan based on today's assessment?	
Tick ✓	**Treatment changes** *(Tick all that apply)*
☐	No change to treatment regimen/continue current dose(s)
☐	Dose decreased***** **Specify which treatment:** ◯ Gabapentin ◯ Carbamazepine ◯ Baclofen ◯ Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). *Please specify*:_____ ◯ Mexiletine ◯ Quinine derivatives ◯ Magnesium ◯ Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat). *Please specify*:_____ ◯ Other. *Please specify*:_____
☐	Dose increased***** **Specify which treatment:** ◯ Gabapentin ◯ Carbamazepine ◯ Baclofen ◯ Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). Please specify:_____ ◯ Mexiletine ◯ Quinine derivatives ◯ Magnesium ◯ Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat). *Please specify*:_____ ◯ Other. *Please specify*:_____
☐	Treatment ceased *(Complete treatment cessation form)*
☐	New treatment*****. *Please specify here:* _____ _____

****If dose has <u>decreased</u> or <u>increased</u>, or <u>new treatment</u> is commenced, please complete the following table:***

New dosing plan at time of treatment adjustment or commencement of new treatment	
Please indicate which treatment is being adjusted or commenced	◯ Gabapentin ◯ Carbamazepine ◯ Baclofen ◯ Other muscle relaxants (e.g. cyclobenzaprine, tizanidine) *Please specify*:_____ ◯ Mexiletine ◯ Quinine derivatives ◯ Magnesium ◯ Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat). *Please specify*: _____ ◯ Other. *Please specify*: _____
Specify formulation (Optional) *For magnesium and quinine derivatives e.g. tonic water, magnesium sulphate*	

Amount per dose *(in mg OR for quinine derivates in mL)*	
Tick ✓	**Frequency**
○	Daily ○ Regular/scheduled ○ As needed
○	BD/BID ○ Regular/scheduled ○ As needed
○	TDS/TID ○ Regular/scheduled ○ As needed
○	QID ○ Regular/scheduled ○ As needed
○	Other; *Please specify*: _____ ○ Regular/scheduled ○ As needed
Tick ✓	**Route of administration**
○	Oral/PEG tube
○	Transdermal/Topical
○	Other - *Please specify*:

Additional new dosing plan at time of treatment adjustment or commencement of new treatment	
Please indicate which treatment is being adjusted or commenced	○ Gabapentin ○ Carbamazepine ○ Baclofen ○ Other muscle relaxants (e.g. cyclobenzaprine, tizanidine) *Please specify*:_____ ○ Mexiletine ○ Quinine derivatives ○ Magnesium ○ Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat). *Please specify*: _____ ○ Other. *Please specify*: _____
Specify formulation (Optional) *For magnesium and quinine derivatives e.g. tonic water, magnesium sulphate*	
Amount per dose *(in mg OR for quinine derivates in mL)*	
Tick ✓	**Frequency**
○	Daily ○ Regular/scheduled ○ As needed
○	BD/BID ○ Regular/scheduled ○ As needed
○	TDS/TID ○ Regular/scheduled ○ As needed
○	QID

	○ Regular/scheduled ○ As needed
○	Other; *Please specify*: _____ ○ Regular/scheduled ○ As needed
Tick ✓	**Route of administration**
○	Oral/PEG tube
○	Transdermal/Topical
○	Other - *Please specify*:

Treatment Cessation *(complete this page if treatment was ceased at any point during the study period)*	
Date of Assessment (Medication Cessation)	DD/MM/YYYY

Tick ✓	**Which treatment(s) ceased?** *(Tick all that apply)*
☐	Gabapentin
☐	Carbamazepine
☐	Baclofen
☐	Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). *Please specify:*
☐	Mexiletine
☐	Quinine derivatives
☐	Magnesium
☐	Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat)
☐	Other - *Please specify:*

Tick ✓	**Reason treatment was ceased.** **If more than one ceased, specify treatment: _____**
○	Cramping resolved - *Please indicate date symptom resolved:* DD/MM/YYYY
○	Due to toxicity - *Please record NCI grade below**
○	Lack of efficacy
○	Burden of treatment
○	Cost
○	Other - *Please specify:*

Reason due to toxicity – Record grade below

Please specify symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Tick one ✓	**Additional reason treatment was ceased.** **If more than one ceased, specify treatment: _____**
○	Cramping resolved - *Please indicate date symptom resolved:* DD/MM/YYYY
○	Due to toxicity - *Please record NCI grade below**
○	Lack of efficacy

○	Burden of treatment
○	Cost
○	Other - *Please specify:*

Reason due to toxicity – Record grade below

Please specify symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

What treatment did you subsequently initiate following the cessation of the medication? *(Tick all that apply)*

Tick✓	Treatments
☐	Gabapentin
☐	Carbamazepine
☐	Baclofen
☐	Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). *Please specify:*
☐	Mexiletine
☐	Quinine derivatives
☐	Magnesium
☐	Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat)
☐	Other - *Please specify:*

Ad hoc A - Unscheduled Harm/Toxicity Assessment

Date of Assessment	dd/mm/yyyy

Unscheduled harm/toxicity due to which treatment? (Please tick)	
○	Gabapentin
○	Carbamazepine
○	Baclofen
○	Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). *Please specify:*
○	Mexiletine
○	Quinine derivatives
○	Magnesium
○	Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat)
○	Other - *Please specify:*

Confusion

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Mild disorientation 2. Moderate disorientation 3. Severe disorientation 4. Life-threatening consequences; treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Constipation

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification or enema 2. Persistent symptoms with regular use of laxatives or enemas 3. Obstipation with manual evacuation indicated 4. Life-threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Diarrhea

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline 2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline

3. Increase of >=7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline 4. Life-threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Drowsiness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Mild but more than usual drowsiness or sleepiness 2. Moderate sedation 3. Obtundation or stupor 4. Life threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Unsteadiness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement 3. Severe unsteadiness or sensation of movement
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Other *(only if applicable – can be related or unrelated to the treatment)*

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Additional other *(only if applicable – can be related or unrelated to the treatment)*

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment	dd/mm/yyyy

Unscheduled harm/toxicity due to which treatment? (Please tick)	
○	Gabapentin
○	Carbamazepine
○	Baclofen
○	Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). *Please specify*:
○	Mexiletine
○	Quinine derivatives
○	Magnesium
○	Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat)
○	Other - *Please specify:*

Confusion

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Mild disorientation 2. Moderate disorientation; 3. Severe disorientation; limiting self care ADL 4. Life-threatening consequences; treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Constipation

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification or enema 2. Persistent symptoms with regular use of laxatives or enemas; 3. Obstipation with manual evacuation indicated; 4. Life-threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Diarrhea

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline

2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; 3. Increase of >=7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL 4. Life-threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Dizziness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; 3. Severe unsteadiness or sensation of movement; limiting self care ADL
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Fatigue

○ No Symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; 3. Fatigue not relieved by rest; limiting self care ADL
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Other *(only if applicable – can be related or unrelated to the treatment)*

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Additional other *(only if applicable – can be related or unrelated to the treatment)*

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment	dd/mm/yyyy

Unscheduled harm/toxicity due to which treatment? (Please tick)	
○	Gabapentin
○	Carbamazepine
○	Baclofen
○	Other muscle relaxants (e.g. cyclobenzaprine, tizanidine). *Please specify*:
○	Mexiletine
○	Quinine derivatives
○	Magnesium
○	Non – pharmacological (e.g. hydration, salt/solutes, stretching, massage, heat)
○	Other - *Please specify:*

Confusion

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Mild disorientation 2. Moderate disorientation 3. Severe disorientation 4. Life-threatening consequences; treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Constipation

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification or enema 2. Persistent symptoms with regular use of laxatives or enemas 3. Obstipation with manual evacuation indicated 4. Life-threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Diarrhea

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline 2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline

3. Increase of >=7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline 4. Life-threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Drowsiness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria 1. Mild but more than usual drowsiness or sleepiness 2. Moderate sedation 3. Obtundation or stupor 4. Life threatening consequences; urgent treatment indicated
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Unsteadiness

○ No Symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement 3. Severe unsteadiness or sensation of movement
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Other *(only if applicable – can be related or unrelated to the treatment)*

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No

Additional other *(only if applicable – can be related or unrelated to the treatment)*

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death
If grading 1 or more, do you think this is attributable to treatment commenced for cramps? ○ Yes ○ No