

Participant ID	
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Initials of person 1 entering data	
Initials of person 2 entering data	

Staff 1 email	
Staff 2 email	

CONFIDENTIAL CASE REPORT FORM

Interventions for Sialorrhea in Motor Neuron Disease

Series 57

IMPACCT Trials Coordination Centre (ITCC)
UTS Rapid Program

A prospective observational study of palliative care and cancer symptom management

Interventions understanding the burden of the adverse effects.

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

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References:
<i>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</i>

(T₀) - Baseline Assessment

Date of Assessment

DD/MM/YYYY

What country are you located in?

Tick ✓	Country (<i>Tick one</i>)
<input type="radio"/>	Australia
<input type="radio"/>	USA
<input type="radio"/>	Other, please specify:

What is your clinical role?

Tick ✓	Roles (<i>Tick one</i>)
<input type="radio"/>	Palliative care clinician
<input type="radio"/>	MND/ALS clinician
<input type="radio"/>	Other, please specify:

Patient Demographics

Gender (*please tick*) Male Female Non-binary

Age (yrs)

Tick ✓	Type of MND (<i>please choose only one</i>)
<input type="radio"/>	Limb-onset
<input type="radio"/>	Bulbar-onset
<input type="radio"/>	Other - <i>Please specify:</i>
Tick ✓	Does this person have frontotemporal dementia?
<input type="radio"/>	Yes
<input type="radio"/>	No
Tick ✓	Does the patient have a PEG tube?
<input type="radio"/>	Yes
<input type="radio"/>	No
Tick ✓	Does the patient use non-invasive ventilation/BiPAP?
<input type="radio"/>	Yes
<input type="radio"/>	No

Tick ✓	Karnofsky Performance Scale (KPS)
<input type="radio"/>	100 - Normal; no complaints; no evidence of disease
<input type="radio"/>	90 - Able to carry on normal activity; minor sign of symptoms of disease
<input type="radio"/>	80 - Normal activity with effort; some signs or symptoms of disease
<input type="radio"/>	70 - Cares for self; unable to carry on normal activity or to do active work
<input type="radio"/>	60 - Requires occasional assistance but is able to care for most needs
<input type="radio"/>	50 - Requires considerable assistance and frequent medical care

<input type="radio"/>	40 – Disabled; requires special care and assistance
<input type="radio"/>	30 – Severely disabled; hospital admission is indicated although death not imminent
<input type="radio"/>	20 – Very sick; hospital admission necessary; active supportive treatment necessary
<input type="radio"/>	10 – Moribund; fatal processes progressing rapidly
<input type="radio"/>	0 - Dead
<input type="radio"/>	Not able to determine

Tick ✓	Place of Care (Tick one)
<input type="radio"/>	Inpatient acute hospital
<input type="radio"/>	Inpatient hospice/Palliative care unit
<input type="radio"/>	Outpatient clinic
<input type="radio"/>	Telemedicine
<input type="radio"/>	Home
<input type="radio"/>	Nursing home/Care facility
<input type="radio"/>	Other; Please specify here:

Sialorrhea Assessment

Salivation

0 1 2 3 4 Ungradable

ALSFRRS-R Criteria (modified)

0. Normal
1. Slight but definite excess of saliva in mouth; may have nighttime drooling
2. Moderately excessive saliva; may have minimal drooling
3. Marked excess of saliva with some drooling
4. Marked drooling; requires constant tissue or handkerchief

Intervention Details

Tick all that apply ✓	Interventions patient has <i>previously</i> tried or is currently using to manage sialorrhea (Tick all that apply)
<input type="checkbox"/>	<p>Suctioning</p> <p>If yes, is this intervention continuing? <input type="radio"/> Yes <input type="radio"/> No</p> <p>If you plan to stop the intervention or it has already been stopped, please select the reason:</p> <ul style="list-style-type: none"> <input type="radio"/> Due to toxicity <input type="radio"/> Lack of efficacy <input type="radio"/> Burden of treatment <input type="radio"/> Cost <input type="radio"/> Other. Please specify: _____

<input type="checkbox"/>	<p>Glycopyrrolate</p> <p>If yes, is this intervention continuing? <input type="radio"/> Yes <input type="radio"/> No</p> <p>If you plan to stop the intervention or it has already been stopped, please select the reason:</p> <ul style="list-style-type: none"> <input type="radio"/> Due to toxicity <input type="radio"/> Lack of efficacy <input type="radio"/> Burden of treatment <input type="radio"/> Cost <input type="radio"/> Other. Please specify: _____
<input type="checkbox"/>	<p>Scopolamine patch</p> <p>If yes, is this intervention continuing? <input type="radio"/> Yes <input type="radio"/> No</p> <p>If you plan to stop the intervention or it has already been stopped, please select the reason:</p> <ul style="list-style-type: none"> <input type="radio"/> Due to toxicity <input type="radio"/> Lack of efficacy <input type="radio"/> Burden of treatment <input type="radio"/> Cost <input type="radio"/> Other. Please specify: _____
<input type="checkbox"/>	<p>Atropine drops</p> <p>If yes, is this intervention continuing? <input type="radio"/> Yes <input type="radio"/> No</p> <p>If you plan to stop the intervention or it has already been stopped, please select the reason:</p> <ul style="list-style-type: none"> <input type="radio"/> Due to toxicity <input type="radio"/> Lack of efficacy <input type="radio"/> Burden of treatment <input type="radio"/> Cost <input type="radio"/> Other. Please specify: _____
<input type="checkbox"/>	<p>Tricyclic antidepressants (e.g. amitriptyline)</p> <p>If yes, is this intervention continuing? <input type="radio"/> Yes <input type="radio"/> No</p> <p>If you plan to stop the intervention or it has already been stopped, please select the reason:</p> <ul style="list-style-type: none"> <input type="radio"/> Due to toxicity <input type="radio"/> Lack of efficacy <input type="radio"/> Burden of treatment <input type="radio"/> Cost <input type="radio"/> Other. Please specify: _____
<input type="checkbox"/>	<p>Salivary gland botox</p> <p>If yes, is this intervention continuing or is there a plan to repeat the procedure in the future? <input type="radio"/> Yes <input type="radio"/> No</p> <p>If you plan to stop the intervention or it has already been stopped, please select the reason:</p> <ul style="list-style-type: none"> <input type="radio"/> Due to toxicity <input type="radio"/> Lack of efficacy <input type="radio"/> Burden of treatment <input type="radio"/> Cost <input type="radio"/> Other. Please specify: _____
	<p>Other (e.g. radiotherapy, surgery, hyoscyamine, dietary changes etc.) Please specify: _____</p>

<input type="checkbox"/>	If yes, is this intervention continuing? <input type="radio"/> Yes <input type="radio"/> No If you plan to stop the intervention or it has already been stopped, please select the reason: <input type="radio"/> Due to toxicity <input type="radio"/> Lack of efficacy <input type="radio"/> Burden of treatment <input type="radio"/> Cost <input type="radio"/> Other. Please specify: _____
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Tick ✓	Which intervention(s) are you <i>commencing or adjusting today?</i> (Tick all that apply)
<input type="checkbox"/>	Glycopyrrolate
<input type="checkbox"/>	Scopolamine
<input type="checkbox"/>	Atropine drops
<input type="checkbox"/>	Tricyclic antidepressants (e.g. amitriptyline)
<input type="checkbox"/>	Salivary gland botox
<input type="checkbox"/>	Other (e.g. radiotherapy, surgery, hyoscyamine, dietary changes etc.). Please specify:

Dosing plan - Specify intervention: _____	
Amount per dose (mg)	
Tick ✓	Frequency
<input type="radio"/>	Daily <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	BD/BID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	TDS/TID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	QID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Continuous <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Other; please specify: <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
Tick ✓	Route of administration
<input type="radio"/>	Oral or per PEG tube
<input type="radio"/>	Transdermal/Topical

<input type="radio"/>	Subcutaneous
<input type="radio"/>	Nebulised
<input type="radio"/>	IV
<input type="radio"/>	Other; please specify:

Additional dosing plan - Specify intervention: _____	
Amount per dose (mg)	
Tick ✓	Frequency
<input type="radio"/>	Daily <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	BD/BID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	TDS/TID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	QID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Continuous <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Other; please specify: <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
Tick ✓	Route of administration
<input type="radio"/>	Oral or per PEG tube
<input type="radio"/>	Transdermal/Topical
<input type="radio"/>	Subcutaneous
<input type="radio"/>	Nebulised
<input type="radio"/>	IV
<input type="radio"/>	Other; please specify:

Additional dosing plan - Specify intervention: _____	
Amount per dose (mg)	
Tick ✓	Frequency
<input type="radio"/>	Daily <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	BD/BID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	TDS/TID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed

<input type="radio"/>	QID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Continuous <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Other; please specify: <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
Tick ✓	Route of administration
<input type="radio"/>	Oral or per PEG tube
<input type="radio"/>	Transdermal/Topical
<input type="radio"/>	Subcutaneous
<input type="radio"/>	Nebulised
<input type="radio"/>	IV
<input type="radio"/>	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; limiting instrumental ADL
3. Severe disorientation; limiting self care ADL
4. Life-threatening consequences; intervention 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; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

Dry Mouth

No Symptom 1 2 3 Ungradable

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately aliment orally; tube feeding or TPN indicated

Somnolence

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated

Urinary Retention

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Able to void with some residual; urinary, suprapubic or intermittent catheter placement not indicated
2. Medication indicated; placement of urinary, suprapubic or intermittent catheter placement indicated
3. Substantial loss of affected kidney function or mass; elective invasive intervention indicated
4. Life-threatening consequences; organ failure; urgent operative intervention indicated

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

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 medication*)

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

T₁ – 1-16 weeks after baseline survey

Date of Assessment

DD/MM/YYYY

Tick ✓	T ₁ : Assessed/Not assessed reason
<input type="radio"/>	Assessed today (<i>continue to complete T₁</i>) OR
<input type="radio"/>	Died (<i>record date of death below</i>)
<input type="radio"/>	Intervention ceased prior to assessment (<i>complete intervention cessation form</i>)
<input type="radio"/>	Not able to reach patient
<input type="radio"/>	Patient too unwell for reassessment of sialorrhea
<input type="radio"/>	Other

Date of Death*

DD/MM/YYYY

****End survey here***

Target Symptom Assessment (*Please grade all harms*)

Salivation

0 1 2 3 4 Ungradable

ALSFRS-R Criteria (modified)

0. Normal
1. Slight but definite excess of saliva in mouth; may have nighttime drooling
2. Moderately excessive saliva; may have minimal drooling
3. Marked excess of saliva with some drooling
4. Marked drooling; requires constant tissue or handkerchief

In your subjective assessment as a clinician, has sialorrhea improved or resolved?

No Improved/Partial resolution Complete resolution Not applicable

T₁ 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; limiting instrumental ADL
3. Severe disorientation; limiting self care ADL
4. Life-threatening consequences; intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

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; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Dry Mouth

No Symptom 1 2 3 Ungradable

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Somnolence

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Urinary Retention

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Able to void with some residual; urinary, suprapubic or intermittent catheter placement not indicated
2. Medication indicated; placement of urinary, suprapubic or intermittent catheter placement indicated
3. Substantial loss of affected kidney function or mass; elective invasive intervention indicated
4. Life-threatening consequences; organ failure; urgent operative intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

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

Please specify other symptom here _____

1 2 3 4 5 Ungradable

<p><i>NCI Criteria</i></p> <p>1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death</p>
<p>If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p>

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

Please specify additional other symptom here _____

1 2 3 4 5 Ungradable

<p><i>NCI Criteria</i></p> <p>1. Mild 2. Moderate 3. Severe 4. Life threatening 5. Death</p>
<p>If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p>

Tick ✓	Which symptom/harm is the <u>most</u> troublesome? (Tick one only)
<input type="radio"/>	Confusion
<input type="radio"/>	Constipation
<input type="radio"/>	Dry mouth
<input type="radio"/>	Somnolence
<input type="radio"/>	Urinary retention
<input type="radio"/>	Other
<input type="radio"/>	Additional Other
<input type="radio"/>	Not applicable

What is the intended plan based on today's assessment?	
Tick ✓	Intervention changes (Tick all that apply)
<input type="checkbox"/>	No change to intervention or treatment regimen/continue current dose(s)
<input type="checkbox"/>	<p>Dose decreased*</p> <p>Specify which intervention:</p> <p><input type="radio"/> Glycopyrrolate <input type="radio"/> Scopolamine <input type="radio"/> Atropine drops <input type="radio"/> Tricyclic antidepressants (e.g. amitriptyline) <input type="radio"/> Salivary gland botox <input type="radio"/> Other. Please specify:</p>
<input type="checkbox"/>	<p>Dose increased*</p> <p>Specify which intervention:</p>

	<input type="radio"/> Glycopyrrolate <input type="radio"/> Scopolamine <input type="radio"/> Atropine drops <input type="radio"/> Tricyclic antidepressants (e.g. amitriptyline) <input type="radio"/> Salivary gland botox <input type="radio"/> Other. Please specify:
<input type="checkbox"/>	Intervention ceased (<i>Complete intervention cessation form</i>)
<input type="checkbox"/>	New intervention*. Please specify here: _____

****If dose has decreased or increased, or new intervention is commenced/suggested, please complete the following table:***

New dosing plan at time of intervention adjustment or commencement of new treatment	
Please indicate which intervention	<input type="radio"/> Glycopyrrolate <input type="radio"/> Scopolamine <input type="radio"/> Atropine drops <input type="radio"/> Tricyclic antidepressants (e.g. amitriptyline) <input type="radio"/> Salivary gland botox <input type="radio"/> Other. Please specify:
Amount per dose (mg)	
Tick ✓	Frequency
<input type="radio"/>	Daily <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	BD/BID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	TDS/TID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	QID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Continuous <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Other; please specify: <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
Tick ✓	Route of administration
<input type="radio"/>	Oral/PEG tube
<input type="radio"/>	Subcutaneous
<input type="radio"/>	Topical
<input type="radio"/>	Nebulised
<input type="radio"/>	IV
<input type="radio"/>	Other; please specify:

Additional new dosing plan at time of intervention adjustment or commencement of new treatment	
Please indicate which intervention	<input type="radio"/> Glycopyrrolate <input type="radio"/> Scopolamine <input type="radio"/> Atropine drops <input type="radio"/> Tricyclic antidepressants (e.g. amitriptyline) <input type="radio"/> Salivary gland botox <input type="radio"/> Other. Please specify:
Amount per dose (mg)	
Tick ✓	Frequency
<input type="radio"/>	Daily <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	BD/BID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	TDS/TID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	QID <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Continuous <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
<input type="radio"/>	Other; please specify: <input type="radio"/> Regular/scheduled <input type="radio"/> As needed
Tick ✓	Route of administration
<input type="radio"/>	Oral/PEG tube
<input type="radio"/>	Subcutaneous
<input type="radio"/>	Topical
<input type="radio"/>	Nebulised
<input type="radio"/>	IV
<input type="radio"/>	Other; please specify:

Intervention Cessation (complete this page if intervention was ceased at any point during the study period)

Date of Assessment (Medication Cessation)	DD/MM/YYYY
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Tick ✓	Which intervention(s) ceased? (Tick all that apply)
<input type="checkbox"/>	Glycopyrrolate
<input type="checkbox"/>	Scopolamine
<input type="checkbox"/>	Atropine drops
<input type="checkbox"/>	Tricyclic antidepressants (e.g. amitriptyline)
<input type="checkbox"/>	Salivary gland botox
<input type="checkbox"/>	Other. Please specify:

Tick ✓	Reason intervention was ceased. If more than one ceased, specify intervention: _____
<input type="radio"/>	Sialorrhea resolved - Please indicate date symptom resolved: DD/MM/YYYY
<input type="radio"/>	Due to toxicity - Please record NCI grade below*
<input type="radio"/>	Lack of efficacy
<input type="radio"/>	Burden of treatment
<input type="radio"/>	Cost
<input type="radio"/>	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 intervention was ceased. If more than one ceased, specify intervention: _____
<input type="radio"/>	Sialorrhea resolved - Please indicate date symptom resolved: DD/MM/YYYY
<input type="radio"/>	Due to toxicity - Please record NCI grade below*
<input type="radio"/>	Lack of efficacy
<input type="radio"/>	Burden of treatment
<input type="radio"/>	Cost
<input type="radio"/>	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✓	Interventions
<input type="checkbox"/>	Glycopyrrolate
<input type="checkbox"/>	Scopolamine
<input type="checkbox"/>	Atropine drops
<input type="checkbox"/>	Tricyclic antidepressants (e.g. amitriptyline)
<input type="checkbox"/>	Salivary gland botox
<input type="checkbox"/>	Other. Please specify:

Ad hoc A - Unscheduled Harm/Toxicity Assessment

Date of Assessment

dd/mm/yyyy

Unscheduled harm/toxicity due to which intervention? (Please tick)

<input type="radio"/>	Glycopyrrolate
<input type="radio"/>	Scopolamine
<input type="radio"/>	Atropine drops
<input type="radio"/>	Tricyclic antidepressants (e.g. amitriptyline)
<input type="radio"/>	Salivary gland botox
<input type="radio"/>	Other. Please specify:

Confusion

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self care ADL
4. Life-threatening consequences; intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

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; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Dry Mouth

No Symptom 1 2 3 Ungradable

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Somnolence

No Symptom 1 2 3 4 Ungradable

NCI Criteria

- 1. Mild but more than usual drowsiness or sleepiness
- 2. Moderate sedation; limiting instrumental ADL
- 3. Obtundation or stupor
- 4. Life-threatening consequences; urgent intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Urinary Retention

No Symptom 1 2 3 4 Ungradable

NCI Criteria

- 1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
- 2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
- 3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
- 4. Life-threatening consequences; organ failure; urgent operative intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

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

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 intervention commenced for sialorrhea?

Yes No

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

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 intervention commenced for sialorrhea?

Yes No

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment

dd/mm/yyyy

Unscheduled harm/toxicity due to which intervention? (Please tick)

<input type="radio"/>	Glycopyrrolate
<input type="radio"/>	Scopolamine
<input type="radio"/>	Atropine drops
<input type="radio"/>	Tricyclic antidepressants (e.g. amitriptyline)
<input type="radio"/>	Salivary gland botox
<input type="radio"/>	Other. Please specify:

Confusion

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self care ADL
4. Life-threatening consequences; intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

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; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Dry Mouth

No Symptom 1 2 3 Ungradable

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration

2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)

3: Inability to adequately ailment orally; tube feeding or TPN indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Somnolence

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Urinary Retention

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

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

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 intervention commenced for sialorrhea?

Yes No

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

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 intervention commenced for sialorrhea?

Yes No

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment

dd/mm/yyyy

Unscheduled harm/toxicity due to which intervention? (Please tick)

<input type="radio"/>	Glycopyrrolate
<input type="radio"/>	Scopolamine
<input type="radio"/>	Atropine drops
<input type="radio"/>	Tricyclic antidepressants (e.g. amitriptyline)
<input type="radio"/>	Salivary gland botox
<input type="radio"/>	Other. Please specify:

Confusion

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self care ADL
4. Life-threatening consequences; intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

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; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Dry Mouth

No Symptom 1 2 3 Ungradable

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately aliment orally; tube feeding or TPN indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Somnolence

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

Urinary Retention

No Symptom 1 2 3 4 Ungradable

NCI Criteria

1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated

If grading 1 or more, do you think this is attributable to intervention commenced for sialorrhea?

Yes No

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

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 intervention commenced for sialorrhea?

Yes No

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

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 intervention commenced for sialorrhea?

Yes No

