Participant ID		
Initials of person	entering data	
Staff email		

CONFIDENTIAL CASE REPORT FORM

Methadone for Pain in Paediatric Palliative Care

Series 51

RAPID Pharmacovigilance in Paediatric Chronic Pain The Case Report Form (CRF) is to be completed in compliance with University of Technology Sydney Standard Operating Procedures (SOP)

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occurs outside of the assessment timepoints.	
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T₀ - Baseline: Demographic Data Date of Assessment Gender ○ Non-Binary Other; Please specify Female Age (0 to <18yrs) Years Months Weeks (only if < 3 months of age) Days (only if < 1 month of age) Tick ✓ Ethnicity (as identified on health record) European NZ Maori **Pacific Peoples** Asian Middle Eastern Latin American/Hispanic Australian Aboriginal (Australian) Torres Strait Islander African Canadian first nations/Inuit American Classifications White American Black American Asian American American Indian/Alaskan Native Native Hawaiian/Pacific Islander American mixed ethnicity

Other group not listed above; Please specify;

Tick ✓	Primary life limiting illness (please choose only one)				
	Advanced Cancer – please specify.				
	Osteosarcoma				
	Neuroblastoma				
	Ewings Sarcoma				
	Other solid tumour: Please specify;				
	CNS tumour				
	Haematological malignancy.				
	Neurological disease – please specify.				
	Neuromuscular disorders				
	Static encephalopathy – GMFCS I-V				
	Progressive encephalopathy or Neurodegenerative disease				
	Other neurological disorder – please specify				
	Cardiac Condition				
	Respiratory Condition				
	Hepatic Condition				
	Renal condition				
	Congenital Condition				
	Metabolic Condition				
	Gastrointestinal Condition				
	Other – (e.g. extreme prematurity) please specify;				

Tick ✓	Place of Care	
	Acute hospital ward	
	Emergency department	
	Intensive Care Unit	
	Palliative Care Unit / Hospice	
	Long-term care/Skilled nursing facility	
	Patient's Home	
	Community	
	Other; please specify:	

Karnofsky/Lansky Performance Status Scale (please circle appropriate status)

The Karnofsky Scale is designed for recipients aged 16 years and older, and the Lansky Scale is designed for patients less than 16 years old. Use the table below to determine the score (10-100) that best represents the patient's activity status.

	(10-100) that best represents the patie					
Kar	nofsky Scale (patient's age >/= 16yrs)	Lansky Scale (recipients age < 16yrs				
Able to carry on normal activity; no special care is needed			Able to carry on normal activity; no special care is needed			
100	Normal, no complaints, no evidence of disease	100	Fully active			
90	Able to carry on normal activity	90	Minor restriction in physically stren- uous play			
80	Normal activity with effort	80	Restricted in strenuous play, tires more easily, otherwise active			
cares	ble to work, able to live at home of for most personal needs, a vary- g amount of assistance needed		Mild to moderate restriction			
70	Cares for self, unable to carry on normal activity or to do active work	70	Both greater restrictions of and less time spent in active play			
60	Requires occasional assistance but is able to care for most needs	60	Ambulatory up to 50% of the time, limited active play with assistance/supervision			
50	Requires considerable assistance and frequent medical care	50	Considerable assistance required for any active play, fully able to engage in quiet play			
alen	ole to care for self, requires equiv- t of institutional or hospital care, ease may be progressing rapidly	N	Moderate to severe restriction			
40	Disabled, requires special care and assistance	40	Able to initiate quiet activities			
30	Severely disabled, hospitalisation in- dicated, although death not immi- nent	30	Needs considerable assistance for quiet activity			
20	Very sick, hospitalisation necessary	20	Limited to very passive activity initiated by others (e.g., TV)			
10	Moribund, fatal process progressing rapidly	10	Completely disabled, not even passive play			

Was Q	Was QTc interval from ECG recorded prior to commencement of Methadone?				
(please	(please tick 'yes' or 'no')				
Yes	No	Tc interval			
		If yes, please record interval here;			

T₀ — Baseline: Pain Assessment - Please score severity of pain at time of today's assessment using <u>either</u> FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.

Pain Severity Score – (Revised FLACC Scale) <u>Use for children aged 0 -4/5 years</u>

Revised FLACC Scale SCORING					
Categories	0	1	2		
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, sad, appears worried	Frequent to constant quivering chin, clenched jaw, distressed looking face, expression of fright/panic		
Legs	Normal position or re- laxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked in- crease in spasticity, constant tremors, jerking		
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting		
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal out- bursts, constant grunting	Crying steadily, screams, sobs, fre- quent complaints, re- peated outbursts, constant grunting		
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures		

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

	Faces Pain Scale – Revised (FPS-R) <u>use for children aged 4-10 years</u> – see appendix for instructions on use				
	chosen face 0 ery much pain			left to right, so	"0" = "no pain" and
O 0	2	_4	6	○8	0 10

OR

Visual Analogue Scale— <u>use this for children aged 10-18 years</u>											
What was the <u>pain intensity at the time of assessment?</u> (Circle number in box that best describes their pain)											
0 = no p			iac see		= mode			10	= wors	st possil	ble pain
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain				Мо	derate pa	ain			Worst	possible	pain

<u>If unable</u> to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.					
From clinicians' perspective, what was patient's pain at time of today's assessment?					
O Mild	○ Moderate	○ Severe	○ Ungradable		

Tick ✓	Is Methadone being commenced as? (Please choose only one)			
	First line opioid agent			
	Rotating opioid agent			
	Adjuvant analgesic agent to existing opioids			
	Full conversion to Methadone			

Tick ✓	Primary reason for commencing methadone				
	(Please tick only one)				
	Poor neuropathic pain control				
	Poor non neuropathic pain control				
	Pharmacokinetic properties – long duration of action				
	Pharmacokinetic properties – poor renal function				
	Adverse reaction to current opioid(s)				
	Tolerance to current opioid(s)				
	Very high doses of other opioid(s)				
	Other – please specify:				

Dosing of methadone commenced	
Dose of methadone commenced (mg/kg/day)	
Time and date of first dose (please use 24hr time)	D:M:Y:H:M
Frequency of dose (e.g. 4th hourly, 6th hourly, 12 hourly	

Tick ✓	Route of administration
	Oral
	IV
	Sub cutaneous
	Other – please specify:

Is a PRN dose of Methadone being prescribed as well?				
(pleas	e tick ye	es or no)		
Yes	Yes No			
		If yes, please record PRN dosing details in table below.		

Dosing of PRN methadone	
Dose of PRN methadone commenced (mg/kg/dose)	
Frequency of dose <i>allowed</i> (e.g. 4 th hourly, 6 th hourly, 12 hourly	
Maximum PRN doses allowed in a 24hr period	

CURRENT OTHER OPIOIDS

Record below all opioids used within the last 24 hours prior to the commencement of methadone. If an opioid is being used as a regular dose but also PRN, please record on two separate lines. (e.g. Morphine sulphate 1mg regular q4h. Then on new line Morphine 0.5mg PRN q6h)

Opioid Name	Immediate Release	Sustained Release	Dose in mg/kg/dose	Route	Regular	PRN

Tick ✓	Concurrent Analgesic Agents		
	Name of Medication Dose (mg/day		
	Alpha 2 agonist e.g., Clonidine		
	Anti-epileptic (other than gabapentinoid) e.g., Carbamazepine, Sodium valproate		
	Baclofen		
	Bisphosphonate e.g., Pamidronate, Zoledronate		
	Capsaicin		
	Corticosteroids e.g., Dexamethasone		
	COX-II Inhibitor i.e., Celecoxib		
	Gabapentinoid i.e., Gabapentin, Pregabalin		
	NSAIDS e.g., Ibuprofen, Naproxen, Diclofenac, Ketorolac		
	Paracetamol (Acetaminophen)		
	Tricyclic anti-depressants i.e., Amitriptyline, Nortriptyline		
	NMDA antagonists – Ketamine, Dextromethorphan		
	Benzodiazepines e.g., Midazolam, Lorazepam, Diazepam,		
	Clonazepam		
	Other; Please specify		
	Other; Please specify		

Baseline Symptom/Harm/Toxicity Assessment Please grade all symptoms/harms. Indicate that each harm has been assessed by ticking the square box next to each.

□ Drowsiness			
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom			
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			
5.Death			
□ Nausea			
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom			
NCI Criteria			
1.Loss of appetite without alteration in eating habits			
2.Oral intake decreased without significant weight loss, dehydration, or malnutrition			
3.Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalisation indicated			
☐ Vomiting			
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc No Symptom			
NCI Criteria			
1.Intervention not indicated			
2. Outpatient IV hydration; medical intervention indicated			
3. Tube feeding, TPN, or hospitalisation indicated			
4. Life-threatening consequences 5. Death			

□ Confusion
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom
NCI Criteria 1.Mild disorientation 2.Moderate disorientation; limiting instrumental ADL 3.Severe disorientation; limiting self-care ADL 4.Life-threatening consequences; urgent intervention indicated 5.Death
□ Myoclonus
○1 ○2 ○3 ○4 ○5 ○ ungradable ○ no symptom
NCI Criteria
Mild; asymptomatic or mild symptoms Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death
☐ Respiratory Depression (RR<8/min)
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom
NCI Criteria- 1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of
existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated 5. Death
☐ Constipation ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ ungradable ☐ no symptom 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 5. Death
Pruritus
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenifi-
cation, oozing/crusts); oral intervention indicated; limiting instrumental ADL 3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive
therapy indicated
□ Other symptom (if exists)
Please specify other symptom:
Other symptom grade here:
$\bigcirc 1$ $\bigcirc 2$ $\bigcirc 3$ $\bigcirc 4$ $\bigcirc 5$ \bigcirc Ungradable
☐ Additional other symptom (if exists)
Please specify additional other symptom:
Other additional symptom grade here:
$\bigcirc 1$ $\bigcirc 2$ $\bigcirc 3$ $\bigcirc 4$ $\bigcirc 5$ $\bigcirc $ Upgradable

T₁ – 2 days post commencing Methadone (Please complete as close to 48 hours as possible) Date of Assessment DD/MM/YYYY

HH:MM

Tick ✓	T ₁ : Assessed/Not assessed reason		
	Assessed today (continue to complete T ₁) OR		
	Not assessed		
	Participant Withdrew – Complete Medication Cessation		
	Participant Died – Please record Date of Death, below		
	Other; Please specify		

Time of Assessment (24hr clock)

Date of Death*	DD/MM/YYYY
----------------	------------

If not assessed at 2 days, please complete:	
Time since Methadone (in hours) commenced	
Reason for variance	

Tick ✓	Current place of Care
	Acute hospital ward
	Emergency department
	Intensive Care Unit
	Palliative Care Unit / Hospice
	Long-term care/Skilled nursing facility
	Patient's Home
	Community
	Other; please specify:

Has Q	Has QTc interval from ECG been remeasured since commencement of						
metha	methadone? (please tick yes or no)						
Yes	No	Tc interval					
		If yes, please record interval here;					

Current Methadone Dose (mg/kg/ <u>day</u>)	
Total dose of Methadone given in last 24hrs (mgs)	

Has dose of any <u>Concurrent Opioid</u> changed since baseline? (please tick yes or no)						
(pieas	No	es or m	10)			
res	NO	TC			C	atd days below
		It ye	s, piease reco	ora change of the	Concurrent Opi	oid dose below.
Opioid	l Name		Dose Chan	ge		New dose of concurrent opioid (mg/kg/dose)
			Dose Increased	Dose Decreased	Medication Ceased	
1.						
2.						
3.						
				ent Analgesi	<u>c</u> agent(s) ch	anged since baseline?
Yes	e tick ye N	lo				
			If yes, please	e record chang	ges below.	
Medic Name			Dose Chan	ge		New dose of concurrent analgesic medication (mg/day)
			Dose Increased	Dose Decreased	Medication Ceased	
1.						
2.						
3.						
4.						
Have any <u>new concurrent analgesic</u> agents commenced since baseline. Y/N (Please record details below)						

Have any <u>new concurrent analgesic</u> agents commenced since baseline. Y/N						
(Please record details below)						
1. Medication name:	Dose (mg/day)					
2. Medication name:	Dose (mg/day)					

T₁ — Pain Assessment - Please score severity of pain at time of today's assessment using <u>either</u> FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.

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Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerk- ing, severe agitation, head banging, shiver- ing, breath holding, gasping, severe splint- ing			
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal out- bursts, constant grunt- ing	Crying steadily, screams, sobs, fre- quent complaints, re- peated outbursts, con- stant grunting			
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing care- giver away, resisting care or comfort measures			

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

	Faces Pain Scale – Revised (FPS-R) <u>use for children aged 4-10 years</u> – see appendix for instructions on use						
	chosen face 0 ery much pain'		,	left to right, so	"0" = "no pain" and		
O	2	_4	6	○8	O 10		

Visual A	Analog	ue Scal	e– <u>use</u>	this f	or child	iren a	ged 10	-18 yea	<u>rs</u>		
		pain in in box th		_				ent?			
0 = no ¡	oain at a	all		5	= mode	erate pa	ain	10	= wors	st possi	ble pain
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain				Мо	derate pa	iin			Worst	possible	pain
						R					
		core pai ase ans		_			-	cale, th	e FPS	-R sca	le or
								at tim	e of to	day's	assess-
○ Mild	() Moder	ate	(○ Sever	e O	Ungrad	able			
they ar	e attrib		to the i	medica	ation of	intere	est or n	cities reg ot; indic ach)			
	siness		4	-	\	ا مامادا)				
	ia more thate se sedation ation or st	•	rowsines instrume	s or slee ental AD	piness L) no syr	прсот			
□ Naus	_										
2.Oral inta	<i>ia</i> appetite v ake decre		eration ir	n eating icant we	habits ight loss,	dehydra		malnutritio ation indic			
	2 0	3 0	4 0	5 C) ungrad	lable (No Sy	mptom	○ not	recorde	ed
3. Tube fe	ntion not i ent IV hy eeding, TF	indicated dration; m PN, or hos consequei	pitalisatio			ed					

□ Confusion
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent intervention indicated
5.Death
□ Myoclonus
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom
NCI Criteria
Mild; asymptomatic or mild symptoms Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death
☐ Respiratory Depression (RR<8/min)
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom
NCI Criteria- 1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of
existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated 5. Death
☐ Constipation ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ ungradable ☐ no symptom
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 5. Death
□ Pruritus
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded
NCI Criteria 1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenifi-
cation, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated
Other symptom (if exists)
Please specify other symptom:
Other symptom/toxicity grade here: 0 1 0 2 0 3 0 4 0 5 0 Ungradable
☐ Additional other symptom (if exists)
Please specify additional other symptom:
Other symptom/toxicity grade here:
$\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc \text{Ungradable}$

		Yes	No	Don't know
1. Did the adv drug was gi	erse reaction appear after the suspected ven?			
	erse reaction improve when the drug was d, or a specific antagonist was given?			
	ternative causes (other than the drug) that eir own have caused the reaction?			
	ent have a similar reaction to the same or in any previous exposure?			
5. Was the addidence?	verse event confirmed by any objective ev-			

Tick	✓	What is the intended treatment based on today's assessment? (Tick all that apply)
		No change to Methadone/continue current dose
		Methadone dose decreased. Please record the new mg/kg/day dose here:
		Methadone dose increased. Please record the new mg/kg/day dose here:
		Methadone ceased (complete Medication Cessation page 33)
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please
		specify medication to treat specific harm:

T ₂ – 5 days post commencement of Methadone				
Date of Assessment	DD/MM/YYYY			
Time of Assessment (24hr clock)	HH:MM			

Tick ✓	T ₂ : Assessed/Not assessed reason
	Assessed today (continue to complete T ₂) OR
	Not assessed
	Participant Withdrew – Complete Medical Cessation
	Patient Died – Record date of death below
	Other; please specify

If not assessed at 5 days, please complete:					
Time since Methadone commenced (days)					
Reason for variance					

Tick ✓	Current place of Care		
	Acute hospital ward		
	Emergency department		
	Intensive Care Unit		
	Palliative Care Unit / Hospice		
	Long-term care/Skilled nursing facility		
	Patient's Home		
	Community		
	Other; please specify:		

Has QTc interval from ECG been remeasured since T ₁ ? (please tick yes or no)					
Yes	No	QTc interval			
		If yes, please record interval here;			

Current Methadone Dose (mg/kg/ <u>day</u>)	
Total dose of Methadone given in last 24hrs (mgs)	

Has dose of any <u>Concurrent Opioid</u> changed since T ₁ ? (please tick yes or no)									
Yes	No No	25 OF 1	10)						
		If ye	s, please reco	ord change of	Concu	rrent Opi	oid dose below.		
Opioid Name		Dose Chan		New dose of concurrent opioid (mg/kg/dose)					
			Dose Increased	Dose Decreased	Med Ceas	ication sed			
1.									
2.									
3.									
				ent Analgesi	<u>c</u> age	nt(s) ch	anged since T ₁ ?		
(Pleas Yes	e tick ye	es or r lo	10)						
res	ľ	10	If yes nless	If yes, please record changes below.					
Medication Name		Dose Chan		New dose of concurrent analgesic medication (mg/day)					
			Dose Increased	Dose Decreased	Med Ceas	ication sed			
1.									
2.									
3.									
4.									
Uac co	31/ PO:	6026	urront anala	ocic agent/s	1	1mores	d since T V/N		
			<u>urrent anaig</u> Is below)	<u>jesic</u> agent(s) con	ппепсе	d since T ₁ . Y/N		
_ •	dication				[Dose (r	ng/day)		
						Dose (mg/day)			

T₂ — Pain Assessment - Please score severity of pain at time of today's assessment using <u>either</u> FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.

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Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal out- bursts, constant grunt- ing	Crying steadily, screams, sobs, fre- quent complaints, re- peated outbursts, con- stant grunting			
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing care-giver away, resisting care or comfort measures			

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

			OIX		
	ain Scale – Re pendix for instru	-		dren aged 4-1	<u>10 years</u>
	e chosen face 0 , very much pain'			left to right, so	"0" = "no pain" and
\bigcirc 0	○ 2	_4	6	○8	○ 10

Visual	Analog	ue Scal	e– use	this f		dren a	aed 10)-18 yea	rs		
What w		pain in in box tl	_					ent?			
Circic i	idilibei	III DOX LI	iai besi	ucscr	ibes tric	ii pairi,	,				
0 = no ¡	oain at a	all		5	= mode	erate p	ain	10	= wors	t possi	ble pain
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain			l l	Мс	derate p	ain			Worst	possible	
					C	R					
If unab	<u>le</u> to so	core pa	in usin	g eith	er the	FLACC	pains	scale, th	e FPS	-R sca	le or
VAS sca						•					
From c ment?	linician	s' pers	pective	, wha	it was	patien	t's pai	n at tim	e of to	day's	assess-
ment											
O Mild	() Moder	ate	(○ Seve	re O	Ungrac	dable			
T2 _	Harm	Λεει	acem	ont	(Dloos)	arada	all har	ms/toxici	itios ro	aardlaa	c of
											ach harm
has bee	-								iuicace	ulat C	acii iiaiiii
TIUS DCC	ir asses.	ocu by u	cking tr	ic squ	are box	TICKL L	Cucity				
□ Drow	siness										
\bigcirc 1	2	3 🔾	4 (5 C) unara	dable (no sy	mntom			
NCI Criter		<u> </u>	1	<u> </u>	z urigiai	Jabic (<u> </u>	прст			
1.Mild but											
2.Moderat 3.Obtunda			instrume	ental AD)L						
4.Life-thre			ices; urge	nt inter	vention i	ndicated					
5.Death		•									
□ Naus	ea										
\bigcirc 1 \bigcirc	2 0	3 🔾	ungrada	able C	no syr	nptom					
NCI Criter											
1.Loss of						ما مام، بطبیر	ation or		_		
								malnutritio sation indic			
_				o,		,	oopicao				
∐ Vomi											
$\bigcirc 1$ \bigcirc	2 0	3 🔾	4 ()	5 C	ungra	dable () No Sy	mptom	\bigcirc not	recorde	ed
NCI Criter 1.Interver		ndicated									
2. Outpat			nedical int	erventi	on indicat	ted					
3. Tube fe	eding, TF	N, or hos	pitalisatio								
4. Life-thr 5. Death	eatening	conseque	nces								
5. Death											

$□$ Confusion $○$ 1 $○$ 2 $○$ 3 $○$ 4 $○$ 5 $○$ ungradable \bigcirc no symptom
NCI Criteria 1.Mild disorientation 2.Moderate disorientation; limiting instrumental ADL 3.Severe disorientation; limiting self-care ADL 4.Life-threatening consequences; urgent intervention indicated 5.Death
☐ Myoclonus ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ ungradable ☐ no symptom
 NCI Criteria 1. Mild; asymptomatic or mild symptoms 2. Moderate; minimal; local or non-invasive intervention indicated 3. Severe or medically significant but not immediately life threatening 4. Life threatening consequences; urgent intervention indicated 5. Death
□ Respiratory Depression (RR<8/min)○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom
NCI Criteria- 1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL 3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL 4. Life-threatening consequences; urgent intervention indicated 5. Death
☐ Constipation○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom
 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 5. Death
☐ Pruritus ○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded
NCI Criteria 1. Mild or localized; topical intervention indicated 2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL 3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated
☐ Other symptom (if exists) Please specify other symptom:
Other symptom/toxicity grade here: 1 0 2 0 3 0 4 0 5 0 Ungradable
☐ Additional other symptom (if exists)
Please specify additional other symptom: Other symptom/toxicity grade here:
○1 ○2 ○3 ○4 ○5 ○ Ungradable

	Yes	No	Don't know
1. Did the adverse reaction appear after the suspected			
drug was given?			
2. Did the adverse reaction improve when the drug was			
discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that			
could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or			
similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evi-			
dence?			

Tick	✓	What is the intended treatment based on today's assessment? (Tick all that apply)
		No change to Methadone/continue current dose
		Methadone dose decreased. Please record the new mg/kg/day dose here:
		Methadone dose increased. Please record the new mg/kg/day dose here:
		Methadone ceased (complete Medication Cessation page 33)
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

T ₃ – 10 days post commencement of Methadone						
Date of Assessment DD/MM/YYYY						
Time of Assessment (24hr clock) HH:MM						

Tick ✓	T ₃ : Assessed/Not assessed reason
	Assessed today (continue to complete T ₃) OR
	Not assessed
	Participant Withdrew – Complete Medical Cessation
	Patient Died – Record date of death below
	Other; please specify

Date of Death*	DD/MM/YYYY
----------------	------------

If not assessed at 10 days, please comp	plete:
Time since Methadone commenced (days)	
Reason for variance	

Tick ✓	Current place of Care					
	Acute hospital ward					
	Emergency department					
	Intensive Care Unit					
	Palliative Care Unit / Hospice					
	Long-term care/Skilled nursing facility					
	Patient's Home					
	Community					
	Other; please specify:					

Has Q	Has QTc interval from ECG been remeasured since T₂? (please tick yes or no)							
Yes	No	QTc interval						
		If yes, please record interval here;						

Current Methadone Dose (mg/kg/ <u>day</u>)	
Total dose of Methadone given in last 24hrs (mgs)	

				pioid change	ed sind	ce T₂?	
Yes	se tick ye No	es or r	10)				
		If ye	s, please reco	ord change of	Concu	rrent Op	ioid dose below.
Opioid	pioid Name Dose Change						New dose of concurrent opioid (mg/kg/dose)
			Dose Increased	Dose Decreased	Med Ceas	ication sed	
1.							
2.							
3.							
(Pleas	se tick ye	es or r lo		re record chan	nes he	low	
Medic Name			If yes, pleas Dose Chan	e record chang ge	ges be	low.	New dose of concurrent analgesic medication
			Dose Increased	Dose Decreased	Med Ceas	ication sed	(mg/day)
1.							
2.							
3.							
4.							
			urrent analg	gesic agent(s	s) con	ımence	d since T ₂ . Y/N
1. Me	dicatior	n nam	ie:				mg/day)
2. Me	2. Medication name: Dose (mg/day)						

T₃ — **Pain Assessment** - *Please score severity of pain at time of today's assessment using <u>either</u> FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.*

Pain Severity Score – (Revised FLACC Scale) <u>Use for children aged 0 -4/5 years</u>

Revised FLACC Scale SCORING							
Categories	0	1	2				
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, dis- interested, sad, ap- pears worried	Frequent to constant quivering chin, clenched jaw, dis- tressed looking face, expression of fright/panic				
Legs	Normal position or re- laxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking				
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerk- ing, severe agitation, head banging, shiver- ing, breath holding, gasping, severe splint- ing				
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal out- bursts, constant grunt- ing	Crying steadily, screams, sobs, fre- quent complaints, re- peated outbursts, con- stant grunting				
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing care-giver away, resisting care or comfort measures				

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

			OIX			
Faces Pain Scale – Revised (FPS-R) <u>use for children aged 4-10 years</u> – see appendix for instructions on use						
	chosen face 0 , ery much pain'			left to right, so	"0" = "no pain" and	
\bigcirc 0	2	_4	6	○8	0 10	

Visual	Analog	ue Scal	e– use	this f		dren a	aed 10)-18 yea	rs		
What v		pain in in box tl	_					ent?			
Circic i	idiliber	III DOX LI	iai besi	ucscr	ibes tric	ii pairi,	,				
0 = no	oain at a	all		5	= mode	erate p	ain	10	= wors	t possi	ble pain
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain			l l	Мс	derate p	ain			Worst	possible	
					C	R					
If unab	<u>le</u> to so	core pa	in usin	g eith	er the	FLACC	pains	scale, th	e FPS	-R sca	le or
VAS sc						•					
From c ment?	linician	s' pers	pective	, wha	it was	patien	t's pail	n at tim	e of to	day's	assess-
ment											
O Mild	() Moder	ate	(○ Seve	re O	Ungrad	lable			
T2 _	Harm	Λεει	acem	ont	(Dloos)	arada	all har	ms/toxici	itios ro	aardlaa	c of
											ach harm
has bee								-	luicace	ulat C	acii iiaiiii
TIUS DCC	11 43363.	ocu by u	cking tr	ic squ	are box	TICKL L	Cacriy				
□ Drow	siness										
\bigcirc 1	2	3 🔾	4 (5 C) unara	dable (no sy	mntom			
NCI Crite		<u> </u>	1 0	<u> </u>	z urigi u	Judic C	> 110 3y	прст			
1.Mild but											
2.Modera 3.Obtund			instrume	ental AD)L						
4.Life-thre			ices; urge	nt inter	vention i	ndicated					
5.Death		•									
□ Naus	ea										
\bigcirc 1 \bigcirc	2 0	3 🔾	ungrada	able C	no syr	nptom					
NCI Crite											
1.Loss of						ما مام، بطبیر	ation or i		_		
								malnutritio sation indic			
				o,		,	оорисано				
∐ Vomi									\sim		
$\bigcirc 1$	2 0	3 🔾	4 ()	5 C	ungra	dable () No Sy	mptom	○ not	recorde	ed
NCI Criter 1.Interver		ndicated									
2. Outpat			nedical int	erventi	on indicat	ted					
3. Tube fe	eding, TF	N, or hos	pitalisatio								
4. Life-thr 5. Death	eatening	conseque	nces								
5. Death											

\Box Confusion \bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom
NCI Criteria 1.Mild disorientation 2.Moderate disorientation; limiting instrumental ADL 3.Severe disorientation; limiting self-care ADL 4.Life-threatening consequences; urgent intervention indicated 5.Death
 ☐ Myoclonus ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom NCI Criteria
1. Mild; asymptomatic or mild symptoms 2. Moderate; minimal; local or non-invasive intervention indicated 3. Severe or medically significant but not immediately life threatening 4. Life threatening consequences; urgent intervention indicated 5. Death
☐ Respiratory Depression (RR<8/min)
1 2 3 4 5 ungradable ono symptom NCI Criteria- 1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL 3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL 4. Life-threatening consequences; urgent intervention indicated 5. Death
\Box Constipation \bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom
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 5. Death
□ Pruritus
 ○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded NCI Criteria 1. Mild or localized; topical intervention indicated 2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL 3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated
☐ Other symptom (if exists) Please specify other symptom:
Other symptom/toxicity grade here: 1 2 3 4 5 Ungradable
□ Additional other symptom (if exists)
Please specify additional other symptom: Other symptom/toxicity grade here:
Other symptomy toxicity grade field: O 1 O 2 O 3 O 4 O 5 O Ungradable

	Yes	No	Don't know
1. Did the adverse reaction appear after the suspected			
drug was given?			
2. Did the adverse reaction improve when the drug was			
discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that			
could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or			
similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evi-			
dence?			

Tick	✓	What is the intended treatment based on today's assessment? (Tick all that apply)	
		No change to Methadone/continue current dose	
Methadone dose decreased. Please record the new mg/kg/day dose here			
		Methadone dose increased. Please record the new mg/kg/day dose here:	
		Methadone ceased (complete Medication Cessation page 33	
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please	
		specify medication to treat specific harm:	

T ₄ – 30 days post commencement of Methadone				
Date of Assessment DD/MM/YYYY				
Time of Assessment (24hr clock) HH:MM				

Tick ✓	T ₄ : Assessed/Not assessed reason			
	Assessed today (continue to complete T ₄) OR			
Not assessed				
	Participant Withdrew – Complete Medical Cessation			
	Patient Died – Record date of death below			
	Other; please specify			

Date of Death*	DD/MM/YYYY
----------------	------------

If not assessed at 30 days, please complete:				
Time since Methadone commenced (days)				
Reason for variance				

Tick ✓	Current place of Care
	Acute hospital ward
	Emergency department
	Intensive Care Unit
	Palliative Care Unit / Hospice
	Long-term care/Skilled nursing facility
	Patient's Home
	Community
	Other; please specify:

Has QTc interval from ECG been remeasured since T₃? (please tick yes or no)				
Yes	No	QTc interval		
		If yes, please record interval here;		

Current Methadone Dose (mg/kg/ <u>day</u>)	
Total dose of Methadone given in last 24hrs (mgs)	

Has dose of any Concurrent Opioid changed since T ₃ ? (please tick yes or no)							
Yes	No No	5 01 1	10)				
		If ye	s, please reco	ord change of	Concur	rent Opi	oid dose below.
Opioid	Name		Dose Change				New dose of concurrent opioid (mg/kg/dose)
			Dose Increased	Dose Decreased	Medi Ceas	cation ed	
1.							
2.							
3.							
Has th	ne dose	of ot	her Concurr	ent Analgesi	ic ageı	nt(s) ch	anged since T₃?
	e tick ye					. ,	
Yes	N	lo					
			If yes, please	e record chang	ges bel	low.	
Medica Name			Dose Chan	ge			New dose of concurrent analgesic medication (mg/day)
			Dose Increased	Dose Decreased	Medi Ceas	cation ed	
1.							
2.							
3.							
4.							
Has any <u>new</u> concurrent analgesic agent(s) commenced since T ₃ . Y/N (Please record details below)							
1. Med	dication	nam	ie:			Dose (r	ng/day)
2. Med	2. Medication name: Dose (mg/day)					ng/day)	

T4 — Pain Assessment - Please score severity of pain at time of today's assessment using <u>either</u> FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.

Pain Severity Score – (Revised FLACC Scale) <u>Use for children aged 0 -4/5 years</u>

Revised FLACC Scale SCORING						
Categories	0	1	2			
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, dis- interested, sad, ap- pears worried	Frequent to constant quivering chin, clenched jaw, dis- tressed looking face, expression of fright/panic			
Legs	Normal position or re- laxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking			
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerk- ing, severe agitation, head banging, shiver- ing, breath holding, gasping, severe splint- ing			
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal out- bursts, constant grunt- ing	Crying steadily, screams, sobs, fre- quent complaints, re- peated outbursts, con- stant grunting			
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing care-giver away, resisting care or comfort measures			

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

			OIX		
Faces Pain Scale – Revised (FPS-R) <u>use for children aged 4-10 years</u> – see appendix for instructions on use					
	chosen face 0 , ery much pain'			left to right, so	"0" = "no pain" and
\bigcirc 0	2	_4	6	○8	0 10

Visual A	Analog	ue Scal	e– <u>use</u>	e this f	or child	dren a	ged 10)-18 yea	ars		
What w		_						ent?			
0 = no pain at all $5 = moderate pain$ $10 = worst possible parameters$					ole pain						
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain				Мо	derate pa	in		I.	Worst	possible	
					0	R					
If unab								scale, tl	ne FPS	-R scal	e or
From cl ment?								n at tim	e of to	oday's a	assess-
○ Mild	(⊃ Moder	ate	(⊃ Sevei	e C	Ungrad	lable			
Drow 1 O NCI Criter 1.Mild but 2.Moderat 3.Obtunda 4.Life-thre 5.Death	siness 2 ia more that e sedation or satening of	3 0 an usual d in; limiting	4 Crowsines	5 C ss or slee	ungrade piness	<i>next t</i>	no sy	,	nuicate	- triat ea	ach harm
 Nausea 1 ○ 2 ○ 3 ○ ungradable ○ no symptom NCI Criteria 1.Loss of appetite without alteration in eating habits 2.Oral intake decreased without significant weight loss, dehydration, or malnutrition 3.Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalisation indicated 											
	2 C	3 0	<u>4 C</u>) 5 C	ungrac	dable (⊃ No Sy	mptom	○ not	recorde	ed
NCI Critera 1.Interven 2. Outpatio 3. Tube fe 4. Life-thro 5. Death	tion not ent IV hy eding, T	dration; m PN, or hos	pitalisati			ed					

□ Confusion
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL 4.Life-threatening consequences; urgent
intervention indicated
5.Death
Myoclonus
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom NCI Criteria
1. Mild; asymptomatic or mild symptoms
Moderate; minimal; local or non-invasive intervention indicated Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death
Respiratory Depression (RR<8/min)
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom NCI Criteria-
1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death
☐ Constipation○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom 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 5. Death
Pruritus
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive
therapy indicated
☐ Other symptom (if exists)
Please specify other symptom:
Other symptom/toxicity grade here:
Additional other symptom (if exists)
Please specify additional other symptom: Other symptom/toxicity grade here:
other symptomy toxicity grade here.
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

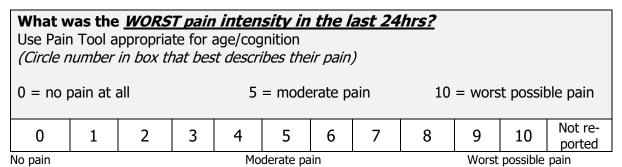
	Yes	No	Don't know
1. Did the adverse reaction appear after the suspected			
drug was given?			
2. Did the adverse reaction improve when the drug was			
discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that			
could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or			
similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evi-			
dence?			

Tick	✓	What is the intended treatment based on today's assessment? (Tick all that apply)
		No change to Methadone/continue current dose
		Methadone dose decreased. Please record the new mg/kg/day dose here:
		Methadone dose increased. Please record the new mg/kg/day dose here:
		Methadone ceased (complete Medication Cessation page 34
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

Medication Cessation (Complete this page if Methad point during the study period)	done is ceased at any
Date and Time of last dose of methadone	DD:MM:YYYY

Tick ✓	Methadone was ceased for following reason:
	Effective for pain and no longer required
	Effective for pain but intolerable adverse effects
	Ineffective with escalating pain; Please grade pain below
	Ineffective for pain and intolerable adverse effects
	Tolerance
	Other: Please specify

PAIN SEVERITY SCORE



What treatment (if any) was initiated after cessation of Methadone? (If none respond 'none')					
Medication	Dose	Frequency	Route		

Ad hoc A - Unscheduled Harm/Toxicity Assessment **Date of Assessment** Harm Assessment (Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each) □ Drowsiness \bigcirc 1 \bigcirc 2 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc 3 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 5.Death □ Nausea $\bigcirc 1 \bigcirc 2$ ○ 3 ○ ungradable ○ no symptom NCI Criteria 1.Loss of appetite without alteration in eating habits 2.Oral intake decreased without significant weight loss, dehydration or malnutrition 3. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated □ Vomiting \bigcirc 1 \bigcirc 2 ○ ungradable ○ No Symptom ○ not recorded \bigcirc 5 NCI Criteria 1.Intervention not indicated 2. Outpatient IV hydration; medical intervention indicated 3. Tube feeding, TPN, or hospitalisation indicated 4. Life-threatening consequences 5. Death □ Confusion \bigcirc 1 \bigcirc 2 ○ 5 ○ ungradable ○ no symptom NCI Criteria 1.Mild disorientation 2. Moderate disorientation; limiting instrumental ADL 3. Severe disorientation; limiting self-care ADL 4.Life-threatening consequences; urgent intervention indicated 5.Death ☐ Myoclonus \bigcirc 1 \bigcirc 2 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom NCI Criteria 1. Mild; asymptomatic or mild symptoms

5. Death

Moderate; minimal; local or non-invasive intervention indicated
 Severe or medically significant but not immediately life threatening
 Life threatening consequences; urgent intervention indicated

☐ Respiratory Depression (RR<8/min)
○1 ○2 ○3 ○4 ○5 ○ ungradable ○ no symptom
 NCI Criteria- Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL Life-threatening consequences; urgent intervention indicated Death
□ Constipation
○1 ○2 ○3 ○4 ○5 ○ ungradable ○ no symptom
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 5. Death
□ Pruritus
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded
NCI Criteria 1. Mild or localized; topical intervention indicated 2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL 3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated
 NCI Criteria 1. Mild or localized; topical intervention indicated 2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL 3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive
 NCI Criteria Mild or localized; topical intervention indicated Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated Other symptom (if exists)
 NCI Criteria Mild or localized; topical intervention indicated Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated Other symptom (if exists) Please specify other symptom:
 NCI Criteria Mild or localized; topical intervention indicated Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated Other symptom (if exists) Please specify other symptom: Other symptom/toxicity grade here:
 NCI Criteria Mild or localized; topical intervention indicated Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated Other symptom (if exists) Please specify other symptom: Other symptom/toxicity grade here: Ungradable
 NCI Criteria Mild or localized; topical intervention indicated Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated Other symptom (if exists) Please specify other symptom: Other symptom/toxicity grade here: 1 2 3 4 5 Ungradable Additional other symptom (if exists)

	Yes	No	Don't know
1. Did the adverse reaction appear after the suspected			
drug was given?			
2. Did the adverse reaction improve when the drug was			
discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that			
could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or			
similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evi-			
dence?			

Ad hoc B - Unscheduled Harm/Toxicity Assessment

	_	_	
Date	Λf	Assessment	

DD:MM:YYYY

assessed by ticking the square box next to each)
□ Drowsiness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom
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 5.Death
□ Nausea
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom
 NCI Criteria 1.Loss of appetite without alteration in eating habits 2.Oral intake decreased without significant weight loss, dehydration or malnutrition 3.Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated
□ Confusion
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom
NCI Criteria 1.Mild disorientation 2.Moderate disorientation; limiting instrumental ADL 3.Severe disorientation; limiting self-care ADL 4.Life-threatening consequences; urgent intervention indicated 5.Death
☐ Myoclonus○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom
 NCI Criteria 1. Mild; asymptomatic or mild symptoms 2. Moderate; minimal; local or non-invasive intervention indicated 3. Severe or medically significant but not immediately life threatening 4. Life threatening consequences; urgent intervention indicated 5. Death
☐ Anxiety ☐ 1
 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom NCI Criteria 1.Mild symptoms; intervention not indicated 2.Moderate symptoms; limiting instrumental ADL 3.Severe symptoms; limiting self-care ADL; hospitalization not indicated 4.Life-threatening; hospitalization indicated 5.Death Restlessness
1 0 2 0 3 ungradable ono symptom NCI Criteria- 1.Mild symptoms; intervention not indicated 2.Moderate symptoms; limiting instrumental ADL
3 Severe symptoms: limiting self-care ADI

☐ Respiratory Depression (RR<8/min)
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom
 NCI Criteria- 1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL 3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL 4. Life-threatening consequences; urgent intervention indicated 5. Death
☐ Other symptom (if exists)
Please specify other symptom:
Othersymptom/toxicity grade here:
O1 O2 O3 O4 O5 O Ungradable
☐ Additional other symptom (if exists)
Please specify additional other symptom:
Other symptom/toxicity grade here:
O 1 O 2 O 3 O 4 O 5 O Ungradable

	Yes	No	Don't know
1. Did the adverse reaction appear after the suspected			
drug was given?			
2. Did the adverse reaction improve when the drug was			
discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that			
could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or			
similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evi-			
dence?			

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment DD:MM:	YYYY
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Harm Assessment (Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)
□ Drowsiness
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom
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 5.Death
□ Nausea ○1 ○2 ○3 ○ ungradable ○ no gymptom
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom NCI Criteria
1.Loss of appetite without alteration in eating habits 2.Oral intake decreased without significant weight loss, dehydration or malnutrition 3.Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated
□ Confusion
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom NCI Criteria
1.Mild disorientation 2.Moderate disorientation; limiting instrumental ADL 3.Severe disorientation; limiting self-care ADL 4.Life-threatening consequences; urgent intervention indicated 5.Death
☐ Myoclonus
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom NCI Criteria
1. Mild; asymptomatic or mild symptoms 2. Moderate; minimal; local or non-invasive intervention indicated 3. Severe or medically significant but not immediately life threatening 4. Life threatening consequences; urgent intervention indicated 5. Death
□ Anxiety
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom
NCI Criteria 1.Mild symptoms; intervention not indicated 2.Moderate symptoms; limiting instrumental ADL 3.Severe symptoms; limiting self-care ADL; hospitalization not indicated 4.Life-threatening; hospitalization indicated 5.Death
☐ Restlessness
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom NCI Criteria- 1.Mild symptoms; intervention not indicated 2.Moderate symptoms; limiting instrumental ADL 3. Severe symptoms: limiting self-care ADI

☐ Respiratory Depression (RR<8/min)							
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom							
NCI Criteria-							
1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL							
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of							
existing hospitalisation indicated; disabling; limiting self-care ADL 4. Life-threatening consequences; urgent intervention indicated							
5. Death							
☐ Other symptom (if exists)							
Please specify other symptom:							
Other symptom/toxicity grade here:							
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable							
☐ Additional other symptom (if exists)							
Please specify additional other symptom:							
Other symptom/toxicity grade here:							
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable							

	Yes	No	Don't know
1. Did the adverse reaction appear after the suspected			
drug was given?			
2. Did the adverse reaction improve when the drug was			
discontinued, or a specific antagonist was given?			
3.Are there alternative causes (other than the drug) that			
could on their own have caused the reaction?			
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similar drug in any previous exposure?			
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dence?			