Participant ID		
Initials of person entering data		
Staff email		

CONFIDENTIAL CASE REPORT FORM

Paediatric Medicinal Cannabinoids in Palliative Care Series No: 43

IMPACCT Trials Coordination Centre (ITCC)
UTS IMPACCT Rapid Program
The case report form (CRF) is to be completed in compliance with
ITCC Standard Operating Procedures (SOP)

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Medication Cessation (only complete if medication is ceased	62
during the 6-month study period. Otherwise leave blank).	
The Adhoc pages only need to be completed if an unexpected h	arm occurs outside of the
assessment timepoints.	
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Medicinal Cannabis - Baseline (T₀) Date of Assessment DD/MM/YYYY

Demographics (please tick)

Gende r ○ I	Male (○ Female	Other

Age (0 to <18yrs)		
	Years	
	Months	
	Weeks (only if < 3 months of age)	
	Days (only if < 1 month of age)	

Weight (kg)	
-------------	--

Tick ✓	Palliative Care Phase
	1. Stable Phase: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.
	2. Unstable Phase: The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment.
	3. Deteriorating Phase: The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.
	4. Terminal Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Tick ✓	Primary life limiting illness (please tick only one)
	Congenital condition
	Gastrointestinal condition
	Hepatic condition
	Advanced cancer
	Neurological disease
	Cardiac condition
	Respiratory condition
	End stage renal failure
	Metabolic conditions
	Other (e.g. extreme prematurity); please specify:

Tick ✓	Other secondary diagnosis - if any (please tick all that apply)	
	Congenital condition	
	Gastrointestinal condition	
	Hepatic condition	
	Advanced cancer	
	Neurological disease	
	Cardiac condition	
	Respiratory condition	
	End stage renal failure	
	Metabolic conditions	
	Other (e.g. extreme prematurity); 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.

		Lansky Scale (recipients age < 16yrs)	
Abl	e to carry on normal activity; no	Able to carry on normal activity; no	
	special care is needed		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 strenuous play
80	Normal activity with effort	80	Restricted in strenuous play, tires more easily, otherwise active
Unab	le to work, able to live at home cares		
fo	or most personal needs, a varying 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
	le to care for self, requires equivalent institutional or hospital care, disease may be progressing rapidly		Moderate to severe restriction
40	Disabled, requires special care and assistance	40	Able to initiate quiet activities
30	Severely disabled, hospitalisation indicated, although death not imminent	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

Reasons for Prescribing Cannabis. (Please answer 'yes' or 'no' to all symptoms. For each symptom you tick 'yes' please score severity of symptom and indicate whether medical cannabis is first line therapy or subsequent therapy).

Tick ✓		Reason/s for prescribing cannabis (tick yes or no)		
Yes	No	-	. , , ,	
		Pain:	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.	
		If prescribing medicinal cannabis for pain, is this:		
		○ 1 st line	○ add on therapy	

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 relaxed, 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 jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting				
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated 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	FLAC	C Score	here

					0	R					
		Scale – R dix for inst		_	_	for ch	<u>ildren</u>	aged 4	-10 yea	ars	
		osen face much pail					ng left to	right, s	o "0" =	"no pa	nin" and
O		2	(_4) 6		8	() 10	
					0	R					
Visual	Anal	ogue Sca	le– <u>us</u>	e this f	or child	ren a	ged 10)-18 yea	ars		
		the <i>pain i</i> Per in box t		_				ent?			
0 = no	pain	at all		5	= mode	rate p	ain	10	= wors	t possi	ble pain
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain	•			Мс	oderate pa	in			Worst	possible	pain
					0	R					
		score pa lease ans		_			-	scale, ti	ne FPS	-R sca	le or
From o		ians' pers t?	spectiv	e, wha	nt was p	atier	ıt's pai	n at tim	e of to	day's	
O Mild		○ Mode	erate	(○ Sever	e C	Ungrac	lable			
Tick Yes	√ No	Reason	/s for	presc	ribing	cann	abis (t	ick yes d	or no)		
		Naus	ea	Please	e score s	everit	y of nau	ısea beld	OW .		
		If presc					for na	usea, is	this:		
		1st line	9	○ ad	d on the	rapy					
Barf Nausea Rating Scale- please rate your patients' nausea using the pictures below and circling the appropriate score.											
(ē			((T	<u></u>		•)(() () () () () () () () () ()) (þ

Tick ✓		Reason/s for prescribing cannabis (tick yes or no)							
Yes No			, , ,						
		Vomiting	Please score severity of vomiting below						
Vomiti	ing Gra	ding 01 0	2 O 3 O 4 O 5 O ungradable O no symptom						
NCI Crit		g 0 <u> </u>							
		(separated by > 5 m							
		(separated by > 5 mi (separated by > 5 m	nutes) in 24 nours ninutes) in 24 hours; new tube feeding, nutritional support or						
hospitali			indees) in 24 hours, new case recaing, hadridonal support of						
4. Life th	nreatenir		gent intervention indicated						
5. Death		na madical can	nahia fay yamiting is this.						
	ine		nabis for vomiting, is this:						
\bigcirc 1	illie	○ add on tl	іегару						
Tick	< ✓	Reason/s for	prescribing cannabis (tick yes or no)						
Yes	No	Reason/s loi	prescribing cannabis (tick yes of no)						
	110	Poor Appetite	Please score severity of poor appetite below						
			, read control of poor appeals control						
	l .								
		e grade 🔘 1	○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom						
NCI Crit		na a dela cata alba de Cara	Serve Provident No.						
		te without alteration	in eating nabits ant weight loss or malnutrition; oral nutritional						
		indicated	and weight 1033 of manuaction, oral nacticional						
			loss or malnutrition (e.g., inadequate oral caloric						
		ntake); tube feeding							
5. Deat		ing consequences; ur	rgent intervention indicated						
		ng medical can	nabis for poor appetite, is this:						
○ 1 st		○ add on tl							
Tick	< ✓	Reason/s for	prescribing cannabis (tick yes or no)						
Yes	No								
		Anxiety	Please score severity of anxiety below						
Amadah									
	Anxiety grade 0 1 0 2 0 3 0 4 0 ungradable 0 no symptom								
NCI Criteria 1. Mild symptoms; intervention not indicated									
		nptoms; limiting instr							
3. Seve	re symp	toms; limiting self-ca	re ADL; hospitalisation indicated						
4. Life-threatening consequences; urgent intervention indicated If prescribing medical cannabis for anxiety, is this:									
	1st line add on therapy								

Ticl	∢ ✓								
Yes	No	Reason/s for p	rescribing cannabis (tick yes or no)						
		Insomnia	Please score severity of insomnia below						
Turanua		.d. 0							
	Insomnia grade 0 1 0 2 0 3 0 ungradable 0 no symptom NCI Criteria								
		falling asleep, staying a	asleep or waking up early						
			ying asleep or waking up early						
			ying asleep or waking up early						
	line	add on ther	bis for insomnia, is this:						
\bigcirc 1	IIIIC	o add on thei	ару						
Ticl	k ✓	Reason/s for n	rescribing cannabis (tick yes or no)						
Yes	No		(00.07,000)						
		Spasticity	Please score severity of spasticity below						
			2 02 04 05 0						
Spasti NCI Cri	city gra	ade 010	2 03 04 05 0 ungradable 0 no symptom						
		increase in muscle tone							
2. Mode	erate inc	rease in muscle tone and	d increase in resistance through range of motion						
			ncrease in resistance through range of motion						
5. Dear		ing consequences; unab	le to move active or passive range of motion						
		ng medical canna	bis for spasticity, is this:						
	line	add on ther	,						
Ticl	∢ ✓	Reason/s for p	rescribing cannabis (tick yes or no)						
Yes	No								
		Seizures	Please score severity of seizures below						
Seizur	es ara	de 01 0	2 03 04 05 0 ungradable 0 no symptom						
	Seizures grade 0 1 0 2 0 3 0 4 0 5 0 ungradable 0 no symptom								
		eizure and no loss of cor	nsciousness						
	2. Brief generalized seizure								
	 New onset seizures (partial or generalized); multiple seizures despite medical intervention Life-threatening consequences; prolonged repetitive seizures 								
5. Deat	h		·						
			bis for seizures, is this:						
\bigcirc 1 st	line	on ther	тару						

Tick ✓		Reason/s for prescribing cannabis (tick yes or no)							
Yes	No								
		Dystoni	а	Please score severity of dystonia below					
_	Dystonia grade 0 1 0 2 0 3 0 ungradable 0 no symptom								
	Grading Criteria 1. Mild - mild symptoms, no intervention necessary								
2. Mode	erate – h	aving trouble sitt	ing dowr	n, also limi	ting other instrumental activities of daily living. e.g.				
		j in chair, activitie			a a bathing and tailating tailating and and and				
	re - IIMII to sit up		lities of c	aaliy iiving,	e.g. bathing and toileting, toileting; confined to bed and				
			annab	is for dy	ystonia, is this:				
○ 1 st	line	o add o	n thera	ру					
			_						
Ticl	1	Reason/s	for pre	escribir	ng cannabis (tick yes or no)				
Yes	No	Moveme	nt	Plaaca d	score severity of dystonia helow				
		Disorde	_	Please score severity of dystonia below					
		21001010	-						
	•								
Movement Disorder grade 01 02 0				O 2	○ 3 ○ ungradable ○ no symptom				
	Criteria								
		ns, no interventio nptoms; limiting i			ies of daily living.				
					aily living, e.g. bathing and toileting.				
		_			ovement disorder, is this:				
$\bigcirc 1^{st}$	line	() add o	n thera	ру					
Ticl	k√	Peason/s	for nre	ecrihir	ng cannabis (tick yes or no)				
Yes	No	Reason/s	oi pie	ESCHIDII	ig Cailliabis (UCK yes Of 110)				
				If pre	escribing medical cannabis for general wellbeing,				
		General we	llbeing						
					it line \(\rightarrow \text{ add on therapy}				
Tick ✓									
Yes	No	Reason/S	or pre	escribir	ng cannabis (tick yes or no)				
	110				If prescribing medical cannabis for anti-cancer				
		Requested	by pati	ient	medication, is this:				
		and/or fam	ily as a	anti-	\bigcirc 1st line \bigcirc add on therapy				
		cancer med	icatior	1					

Tick ✓		Reason/s for prescribir	ng cannabis (tick yes or no)
Yes	No	•	
		Other symptom Please specify symptom:	If prescribing medical cannabis for other symptom, is this: \bigcirc 1 st line \bigcirc add on therapy

'Other symptom' grade	\bigcirc 1	O 2	○ 3 ○ ungradable ○ no symptom
Grading Criteria 1. Mild			
2. Moderate3. Severe			

Tick ✓	Other Concurrent Medications (classes of drugs) that patient is currently taking (tick all that apply)								
	Opioids								
	Benzodiazepines								
	Anti-emetics								
	Laxatives/aperients								
	Tricyclic antidepressants								
	NMDA antagonists – Keta	mine, Dextromethorp	han						
	Alpha 2 agonists - Clonidi	ine							
	Paracetamol/NSAIDS								
	Baclofen								
	Anti-reflux medications								
	Anti-epileptics. Please circ	cle which one below.							
	Gabapentin/Pregabalin	levetiracetam	carbamazepine						
	valproic acid	clonazepam	Other anti-epileptic, please specify;						
	Antipsychotics	•							
	Steroids								
	Other cannabinoids- plea	se specify:							
	Other – please specify:								
	No other concurrent med	ications							

indicate that each harm has been assessed by ticking the square box next to each) ☐ Fatigue \bigcirc 1 ○ ungradable ○ no symptom ○ not reported \bigcirc 2 O no symptom \bigcirc 3 NCI Criteria 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; limiting instrumental ADL 3. Fatigue not relieved by rest, limiting self-care ADL □ Dizziness \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL □ Euphoria \bigcirc 1 \bigcirc 2 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1.Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania) ☐ Insomnia \bigcirc 1 \bigcirc 2 \bigcirc 3 ○ ungradable ○ no symptom ○ not reported NCI Critera 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early ☐ Loss of appetite/anorexia \bigcirc 3 \bigcirc 4 \bigcirc 5 ○ ungradable ○ no symptom ○ not reported \bigcirc 2 NCI Criteria 1. Loss of appetite without alteration in eating habits 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death ☐ Anxiety \bigcirc 2 \bigcirc 1 \bigcirc 3 \bigcirc 4 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1.Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL

Baseline Symptom/Harm/Toxicity Assessment (Please grade all symptoms/harms;

3. Severe symptoms; limiting self-care ADL; hospitalisation not indicated

4.Life-threatening consequences; urgent intervention indicated

□ Confusion
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
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
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria
1.Mild delusional symptoms 2.Moderate delusional symptoms 3.Severe delusional symptoms; hospitalisation not indicated 4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated 5.Death
□Hallucinations
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
 MCI Criteria Mild hallucinations (e.g., perceptual distortions) Moderate hallucinations Severe hallucinations; hospitalisation not indicated Life-threatening consequences, threats of harm to self or others; hospitalisation indicated Death
☐ Decreased level of consciousness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1.Decreased level of alertness 2.Sedation; slow response to stimuli; limiting instrumental ADL 3.Difficult to arouse 4.Life-threatening consequences 5.Death
□ Sedation
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
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
□ Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
○1 ○2 ○3 ○4 ○5 ○ Ungradable
☐ Additional other (if exists)
Please specify additional other symptom/harm here
Other toxicity grade here:
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable

Baseline To – Medicinal Cannabis Information

Current cannabis intake											
Is child	Is child currently using cannabis?										
○ Yes (Please answer questions below) ○ No											
76.77	If Yes: How long has the child been taking this cannabis? (days)										
If Yes:		How Ior	ng has the ci	niid been taking	this cannabis	? (<i>days)</i>					
Tick ✓ Who has prescribed the medicinal cannabis?											
		Palliat	ive care spe	cialist							
		1	tric Oncolog								
		Gener	al Practition	er							
		Gener	al Paediatric	ian							
		Specia	list Paediatr	ician; Please spe	ecify:						
		Other	Please spec	cify:							
_											
				n, please write (
Name o	f Produ	uct (if u	<u>ınknown, ple</u>	ease write ('not l	known')						
	6.54					•					
			Cannabis U		Record dos	se nere					
	•		4hr (if know								
Dose of	ТПС/ДО	ising inz	24hr (if know	/11)							
Tick ✓	Route	e of ad	ministratio	n (Tick all that	apply)						
	Topica	al									
	Bucca	l (oral r	nucosal spra	y)							
	Inhale	ed									
	Ingest	ted									
	Ingest	Ingested via PEG or NG tube.									
	Recta										
	1_										
Tick ✓			ild currentl <i>er applies)</i>	ly use recreati	onal cannab	is?					
	○ Yes		O No	0	Unknown						
				sed e.g., joints e and route?	s per day sm	oked or other					
Amoun	t										

T₀ - Commencement of Medicinal Cannabis

If child is being prescribed/commenced on medicinal cannabis today, please answer the following questions.

Date medicinal cannabis is being commenced	DD/MM/YYYY
Time of initial dose (in 24hr clock e.g., 2200)	HH:MM
Which product formulation is being commenced	○ CBD○ THC○ Both CBD & THC○ Other
Name of Product being commenced (if known)	

Tick ✓	Route of administration (Tick all that apply)
	Topical
	Buccal (oral mucosal spray)
	Inhaled
	Ingested
	Ingested via PEG or NG tube
	Rectal

Dosing of Cannabis	Starting dose	Frequency of dose (e.g., daily, BD TDS, nocte, PRN)
Dose of CBD		
Dose of THC		
Other dosing: Please specify		

T ₁ – 7 days post Baseline	
Date of Assessment	DD/MM/YYY
Time of Assessment (in 24hr clock e.g., 2200)	HH:MM

Tick ✓	T ₁ : Assessed/Not assessed reason						
	Assessed today (continue to complete T_1)						
	OR						
	Died – record date of death below						
	Not able to be contacted / located						
	Too unwell						
	Other						

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

*End survey here
Please provide reason if today's assessment is not 7 days after baseline.

Total dose of Cannabis taken/given in the last 24 hours	Record dose here
Total dose of CBD taken/given in last 24hrs	
Total dose of THC taken/given in last 24hrs	
Other dosing: Please specify.	
How long has the patient been on this dose (days)	

Symptoms of Interest. Please review all symptoms (*Please grade all symptoms of interest; indicate that each symptom has been assessed by ticking the square box next to each symptom*)

☐ Pain (Please score severity of pain at time of today's assessment using either 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> **Categories** 2 Face No particular Occasional grimace or Frequent to constant expression or smile frown, withdrawn, quivering chin, disinterested, sad, clenched jaw, appears worried distressed looking face, expression of fright/panic Normal position or Uneasy, restless, Kicking, or legs drawn Legs relaxed, usual tone tense, occasional up, marked increase in and motion to limbs tremors spasticity, constant tremors, jerking Arched. Rigid or Activity Lying quietly, normal Squirming, shifting back and forth, tense, position moves easily, jerking, severe regular, rhythmic tense. guarded agitation, head respirations movements, mildly banging, shivering, agitated, shallow breath holding, respirations, gasping, severe intermittent sighs splinting Cry No cry (awake or Moans or whimpers: Crying steadily, occasional complaint, screams, sobs, asleep) frequent complaints, occasional verbal outbursts, constant repeated outbursts, constant grunting grunting Consolability Content, relaxed Reassured by Difficult to console or occasional touching, comfort, pushing hugging, or being caregiver away, talked to: distractible 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.

Total Revised FLACC Score

Faces Pain Scale – Revised (FPS-R) - use for children aged 4-10 years						
Score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so "0" = "no pain" and						
"10" = "very much pain". Circle score below.						
0 2 4 6 8 10						

Pain Inten	sity – <u>use</u>	this fo	r child	ren ag	ed 10	-18 yea	ars			
What was			-				ent?			
(Circle numi	ber in box t	tnat bes	st descri	bes the	ır paın)				
0 = no pain	at all	_	5	= mode	erate p	ain	10	= wors	st possil	ble pain
0 1	L 2	3	4	5	6	7	8	9	10	Not reported
No pain		1	Мо	derate pa				Worst	possible	
If unable t	<u>-</u>		_			-	scale, th	ne FPS	-R sca	le or
From clinic	cians' pers						n at tim	e of to	oday's	
assessmen	it?									
	O 14			<u> </u>						
O Mild	O Mode	rate) Sever	<u>e</u>	Ungrad	lable			
☐ Nausea	1									
Barf Nause	ea Rating			ate you	r patie	nts' nau	ısea usir	ng the p	oictures	below
and circling	the approp	oriate sc	core.							
		7		5		5		. /		
(⊚ ⊙	b (50	্ট) ((TO	5) (6	5 b d	66	b (\<u \	b
			\bigcirc	/ '		/ `		'\	Par l	(0)
o	2		4		6		8		10	
☐ Vomiti	na									
O1 O2 NCI Criteria	<u> </u>)4 (<u> </u>	Ungrada	able (no syn	nptom			
0. Nil				241						
1. 1-2 episode 2. 3-5 episode		-	-							
3. >=6 episo	des (separate	•	•			v tube fee	eding, nutr	ritional sı	upport or	
hospitalisation 4. Life threate		uences: u	rgent inte	ervention	indicate	ed				
5. Death										
☐ Poor A	ppetite									
\bigcirc 1 \bigcirc 2	○3 ()4 () 5 ()	Ungrada	able C	no syn	nptom			
NCI Criteria 1.Loss of appe	tite without a	Iteration	in eating	habits						
2.Oral intake a	Itered withou				nalnutri	tion; oral	nutritiona	l		
supplements 3. Associated v		t weiaht	loss or m	alnutrition	n (e.a.	inadequa	te oral cal	oric		
and/or fluid	intake); tube	feeding o	r TPN inc	licated		-				
4. Life-threater 5. Death	ning conseque	ences; ur	gent inter	vention i	ndicated	1				

☐ Anxiety				
○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ no symptom				
 NCI Criteria 1. Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation indicated 4. Life-threatening consequences; urgent intervention indicated 				
□ Insomnia				
○ 1 ○ 2 ○ 3 ○ Ungradable ○ no symptom				
 NCI Criteria 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early 				
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom				
 NCI Criteria 1.Mild or slight increase in muscle tone 2. Moderate increase in muscle tone and increase in resistance through range of motion 3. Severe increase in muscle tone and increase in resistance through range of motion 4. Life-threatening consequences; unable to move active or passive range of motion 5. Death 				
□ Seizures				
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom				
 NCI Criteria 1.Brief partial seizure and no loss of consciousness 2. Brief generalized seizure 3. New onset seizures (partial or generalized); multiple seizures despite medical intervention 4. Life-threatening consequences; prolonged repetitive seizures 5. Death 				
☐ Dystonia				
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom				
Grading Criteria 1. Mild - mild symptoms, no intervention necessary 2. Moderate – having trouble sitting down, also limiting other instrumental activities of daily living. e.g. transfers, sitting in chair, activities of daily living 3. Severe - limiting self-care activities of daily living, e.g. bathing and toileting, toileting; confined to bed and unable to sit up				
☐ Movement Disorder				
○ 1 ○ 2 ○ 3 ○ No symptom ○ Ungradable				
Grading Criteria 1. Mild symptoms, no intervention necessary 2.Moderate symptoms; limiting instrumental activities of daily living. 3.Severe symptoms; limiting self-care activities of daily living, e.g. bathing and toileting.				
☐ 'Other' symptom				
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom				
Grading Criteria 1. Mild 2. Moderate – having trouble sitting down 3. Severe				

indicate that each harm has been assessed by ticking the square box next to each) ☐ Fatigue \bigcirc 1 ○ 3 ○ ungradable ○ No symptom \bigcirc 2 not reported NCI Criteria 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; limiting instrumental ADL 3. Fatigue not relieved by rest, limiting self-care ADL □ Dizziness ○ 3 ○ ungradable ○ No symptom ○ not reported \bigcirc 1 \bigcirc 2 NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL □ Euphoria \bigcirc 1 \bigcirc 2 \bigcirc 3 ○ ungradable ○ No symptom not reported NCI Criteria 1.Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania) ☐ Insomnia \bigcirc 1 \bigcirc 2 \bigcirc 3 ○ ungradable ○ No symptom ○ not reported NCI Critera 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early ☐ Loss of appetite/anorexia ○ 3 ○ 4 ○ 5 ○ ungradable ○ No symptom ○ not reported \bigcirc 2 NCI Criteria 1. Loss of appetite without alteration in eating habits 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death ☐ Anxiety \bigcirc 2 \bigcirc 1 \bigcirc 3 \bigcirc 4 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1.Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation not indicated 4. Life-threatening consequences; urgent intervention indicated

T₁ - Symptom/Harm/Toxicity Assessment (Please grade all symptoms/harms;

□ Confusion
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
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
□ Delucione
☐ Delusions ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria-Delusions
12.Moderate delusional symptoms3.Severe delusional symptoms; hospitalisation not indicated4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated5.Death
□Hallucinations
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria - Hallucinations
1. Mild hallucinations (e.g., perceptual distortions) 2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated5. Death
☐ Decreased level of consciousness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria
1.Decreased level of alertness 2.Sedation; slow response to stimuli; limiting instrumental ADL
3.Difficult to arouse
4.Life-threatening consequences 5.Death
Sedation○ 1○ 2○ 3○ 4○ 5○ ungradable○ no symptom○ not reported
1 0 2 0 3 0 4 0 5 0 ungradable 0 no symptom 0 not reported
1. Mild but more than usual drowsiness or sleepiness
Moderate sedation; limiting instrumental ADL Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death
Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable
☐ Additional other (if exists)
Please specify additional other symptom/harm here
Other toxicity grade here:
$\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc \text{Ungradable}$

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist (Tick 'yes', 'no', or 'don't know' for each question below)

	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 evidence?			

Efficacy index: Rate this on the basis of **drug effect only**.

Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.

(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

		Side effects				
		None	Do not significantly interfere with patients functioning	Significantly interfere with patients functioning	Outweighs therapeutic effect	
Therapeutic effect	Marked-Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04	
	Moderate-Decided improvement. Partial remission of symptoms	05	06	07	08	
	Minimal. Slight improvement which doesn't alter status of care of patient	09	10	11	12	
	Unchanged or worse	13	14	15	16	
	Not assessed = 00					

Tick ✓	Clinical Global Impression (CGI)
	Global improvement: (Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)
	0 = Not assessed
	1 = Very much improved
	2 = Much improved
	3 = Minimally improved
	4 = No change
	5 = Minimally worse
	6 = Much worse
	7 = Very much worse

Tick	✓	Are there any changes being made to medicinal cannabis product dosing at today's assessment? (Tick all that apply)				
		I am not the prescriber, so not aware of any dose change (please consider adding the dose change, if you are aware of this, even if you are not the prescriber)				
		No change to cannabis/continue current dose				
Cannabis ceased (complete cessation of medication page 62)						
	Cannabis dose reduced; please specify new dose below:					
		Cannabis dose increased; please specify new dose below:				
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:				

Based on the assessment today has the harm/toxicity resolved?			
○ Yes	O No	○ N/A	

New dose of Cannabis	Record dose here
Total dose of CBD to be taken in 24-hour period	
(Record '0' if not taking CBD)	
Total dose of THC to be taken in 24-hour period	
(Record '0' if not taking CBD)	
Other dosing: Please specify:	

T ₂ – 14 days post Baseline		
Date of Assessment	DD/MM/YYY	
Time of Assessment (in 24hr clock e.g., 2200)	HH:MM	

Tick ✓	T ₂ : Assessed/Not assessed reason
	Assessed today (continue to complete T ₂) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	DD/MM/YYYY
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*End survey here
Please provide reason if today's assessment is not 14 days after baseline.

Total dose of Cannabis taken/given in the last 24 hours	Record dose here
Dose of CBD/Total dose taken/given in last 24hrs	
Dose of THC/Total dose taken/given in last 24hrs	
Other dosing: Please specify.	
How long has the patient been on this dose (days)	

Symptoms of Interest. Please review all symptoms (Please grade all symptoms of interest; indicate that each symptom has been assessed by ticking the square box next to each symptom)						
☐ Pain (Please score severity of pain at time of today's assessment using either FLACC						
	le, Visual Analogue Scal					
Pain Severity Score	- (Revised FLACC Se	cale) <u>Use for childrer</u>	1 aged 0 -4/5 years			
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 relaxed, 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 jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting			
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated 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.

Total Revised FLACC Score

Faces Pain Scale – Revised (FPS-R) - use for children aged 4-10 years					
Score the chosen face 0 , 2 , 4 , 6 , 8 , or 10 , counting left to right, so "0" = "no pain" and "10" = "very much pain". Circle score below.					
0 2 4 6 8 10					

Pain Intensity – use this for children aged 10-18 years					
What was the pain intensity at the time of assessment? (Circle number in box that best describes their pain)					
0 = no pain at all $5 = moderate pain$ $10 = worst possible pain$					
0 1 2 3 4 5 6 7 8 9 10 Not reported					
No pain Moderate pain Worst possible pain OR					
If unable 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?					
○ Mild ○ Moderate ○ Severe ○ Ungradable					
□ Nausea					
Barf Nausea Rating Scale-please rate your patients' nausea using the pictures below and circling the appropriate score.					
□ Vomiting					
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No symptom ○ Ungradable					
 NCI Criteria 6. Nil 7. 1-2 episodes (separated by > 5 minutes) in 24 hours 8. 3-5 episodes (separated by > 5 minutes) in 24 hours 9. >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalisation indicated 10. Life threatening consequences: urgent intervention indicated 11. Death 					
☐ Poor Appetite					
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No symptom ○ Ungradable					
 NCI Criteria 1.Loss of appetite without alteration in eating habits 2.Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death 					

☐ Anxiety
○1 ○2 ○3 ○4 ○No symptom ○ Ungradable
 NCI Criteria 1. Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation indicated 4. Life-threatening consequences; urgent intervention indicated
☐ Insomnia
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc No symptom \bigcirc Ungradable
NCI Criteria
 Mild difficulty falling asleep, staying asleep or waking up early Moderate difficulty falling asleep, staying asleep or waking up early Severe difficulty in falling asleep, staying asleep or waking up early
3. Severe difficulty in railing asieep, staying asieep of waking up early
☐ Spasticity
○1 ○2 ○3 ○4 ○5 ○ No symptom ○ Ungradable
NCI Criteria 1.Mild or slight increase in muscle tone
Moderate increase in muscle tone Moderate increase in muscle tone and increase in resistance through range of motion
3. Severe increase in muscle tone and increase in resistance through range of motion
4. Life-threatening consequences; unable to move active or passive range of motion 5. Death
☐ Seizures
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc No symptom \bigcirc Ungradable
NCI Criteria
1.Brief partial seizure and no loss of consciousness
Serief generalized seizure New onset seizures (partial or generalized); multiple seizures despite medical intervention
4. Life-threatening consequences; prolonged repetitive seizures
5. Death
☐ Dystonia
○ 1 ○ 2 ○ 3 ○ No symptom ○ Ungradable
Grading Criteria
1. Mild - mild symptoms, no intervention necessary 2. Moderate – having trouble sitting down, also limiting other instrumental activities of daily living. e.g.
transfers, sitting in chair, activities of daily living
3. Severe - limiting self-care activities of daily living, e.g. bathing and toileting, toileting; confined to bed and
unable to sit up
☐ Movement Disorder
○ 1 ○ 2 ○ 3 ○ No symptom ○ Ungradable
Grading Criteria
Mild symptoms, no intervention necessary Moderate symptoms; limiting instrumental activities of daily living.
3.Severe symptoms; limiting instrumental activities of daily living, e.g. bathing and toileting.
☐ 'Other' symptom
○ 1 ○ 2 ○ 3 ○ No symptom ○ Ungradable
Grading Criteria
1. Mild 2. Moderate – having trouble sitting down
3. Severe

indicate that each harm has been assessed by ticking the square box next to each) ☐ Fatigue \bigcirc 1 ○ 3 ○ ungradable ○ No symptom \bigcirc 2 not reported NCI Criteria 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; limiting instrumental ADL 3. Fatigue not relieved by rest, limiting self-care ADL □ Dizziness \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL □ Euphoria \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1.Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania) ☐ Insomnia \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ No symptom ○ not reported NCI Critera 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early ☐ Loss of appetite/anorexia ○ 3 ○ 4 ○ 5 ○ ungradable ○ No symptom ○ not reported \bigcirc 2 NCI Criteria 1. Loss of appetite without alteration in eating habits 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death ☐ Anxiety \bigcirc 2 \bigcirc 1 \bigcirc 3 \bigcirc 4 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1.Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation not indicated 4.Life-threatening consequences; urgent intervention indicated

T₂ - Symptom/Harm/Toxicity Assessment (Please grade all symptoms/harms;

□ Confusion
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
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
☐ Delusions
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria-Delusions 1 2.Moderate delusional symptoms 3.Severe delusional symptoms; hospitalisation not indicated 4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated 5.Death
□Hallucinations
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
 NCI Criteria - Hallucinations Mild hallucinations (e.g., perceptual distortions) Moderate hallucinations Severe hallucinations; hospitalisation not indicated Life-threatening consequences, threats of harm to self or others; hospitalisation indicated Death
□ Decreased level of consciousness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1.Decreased level of alertness 2.Sedation; slow response to stimuli; limiting instrumental ADL 3.Difficult to arouse 4.Life-threatening consequences 5.Death
□ Sedation
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
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
□ Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
○1 ○2 ○3 ○4 ○5 ○ Ungradable
☐ Additional other (if exists)
Please specify additional other symptom/harm here
Other toxicity grade here:
$\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc \square$

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist (Tick 'yes', 'no', or 'don't know' for each question below)

	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			
evidence?			

Efficacy index: Rate this on the basis of **drug effect only**.

Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.

(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

		Side effects					
		None	Do not significantly interfere with patients functioning	Significantly interfere with patients functioning	Outweighs therapeutic effect		
Therapeutic effect	Marked-Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04		
	Moderate-Decided improvement. Partial remission of symptoms	05	06	07	08		
	Minimal. Slight improvement which doesn't alter status of care of patient	09	10	11	12		
	Unchanged or worse	13	14	15	16		
	Not assessed = 00						

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Tick ✓	Clinical Global Impression (CGI)							
	Global improvement: (Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)							
	0 = Not assessed							
	1 = Very much improved							
	2 = Much improved							
	3 = Minimally improved							
	4 = No change							
	5 = Minimally worse							
	6 = Much worse							
	7 = Very much worse							

Tick	✓	What is the intended treatment based on today's assessment? (Tick all that apply)			
	I am not the prescriber, so not aware of any dose change (please consider adding the dose change, if you are aware of this, even if you are not the prescriber)				
		No change to cannabis/continue current dose			
		Cannabis ceased (complete cessation of medication page 62)			
	Cannabis dose reduced; please specify new dose below:				
		Cannabis dose increased; please specify new dose below:			
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:			

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in24hr	
Dose of THC/Total dose to be taken in24hr	
Other dosing: Please specify:	

Based on	Based on the assessment today has the toxicity resolved?				
○ Yes	O No	○ N/A			

T ₃ – 28 days post Baseline					
Date of Assessment	DD/MM/YYY				
Time of Assessment (in 24hr clock e.g., 2200)	HH:MM				

Tick ✓	T ₃ : Assessed/Not assessed reason
	Assessed today (continue to complete T ₂) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

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

*End survey here
Please provide reason if today's assessment is not 28 days after baseline.

Total dose of Cannabis taken/given in the last 24 hours	Record dose here
Dose of CBD/Total dose taken/given in last 24hrs	
Dose of THC/Total dose taken/given in last 24hrs	
Other dosing: Please specify.	
How long has the patient been on this dose (days)	

Symptoms of Interest. Please review all symptoms (*Please grade all symptoms of interest; indicate that each symptom has been assessed by ticking the square box next to each symptom*)

☐ Pain (Please score severity of pain at time of today's assessment using either 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> **Categories** 2 Face No particular Occasional grimace or Frequent to constant expression or smile frown, withdrawn, quivering chin, disinterested, sad, clenched jaw, appears worried distressed looking face, expression of fright/panic Normal position or Uneasy, restless, Kicking, or legs drawn Legs relaxed, usual tone tense, occasional up, marked increase in and motion to limbs tremors spasticity, constant tremors, jerking Arched. Rigid or Activity Lying quietly, normal Squirming, shifting back and forth, tense, position moves easily, jerking, severe regular, rhythmic tense. guarded agitation, head respirations movements, mildly banging, shivering, agitated, shallow breath holding, respirations, gasping, severe intermittent sighs splinting Cry No cry (awake or Moans or whimpers: Crying steadily, occasional complaint, screams, sobs, asleep) frequent complaints, occasional verbal outbursts, constant repeated outbursts, constant grunting grunting Consolability Content, relaxed Reassured by Difficult to console or occasional touching, comfort, pushing hugging, or being caregiver away, talked to: distractible 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.

Total Revised FLACC Score

Faces Pain Scale – Revised (FPS-R) - use for children aged 4-10 years							
Score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so "0" = "no pain" and							
"10" = "very r	"10" = "very much pain". Circle score below.						
0 2 4 6 8 10							

Pain Inte	nsity	/ – <u>use</u> †	this fo	or child	ren ag	ed 10	-18 yea	ars			
What wa		-						ent?			
(Circle nui	nber	in dox ti	nat bes	st aescri	bes the	ur pain)				
0 = no pai	n at a	all		5	= mode	erate p	ain	10	= wors	st possil	ble pain
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain				Мо	derate pa	nin R	•		Worst	possible	
If unable VAS scale		=		_			-	scale, th	ne FPS	-R sca	le or
From clin								n at tim	e of to	oday's	
assessme	ent?										
0		~			~ -						
O Mild	(O Moder	ate	() Sever	<u>е</u> О	Ungrad	lable			
	ea										
Barf Nau	sea R	_	•		ate you	r patie	ents' nau	ısea usir	ng the p	oictures	below
and circlin	g the	appropi	riate sc	core.							
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(⊚ ⊚	Þ	(୭ୂ	5) ((ভূ	5) (€	₹ Þ (66	pq.	≤">	Þ
0		2		4		6		8		10	
☐ Vomi	ting										
01 0	2 () 3 ()4 () 5 () Ungra	dable	○ No s	ymptom	ı		
NCI Criteria		<u> </u>	•	<u> </u>	, 011 <u>9</u> 10	<u> </u>	<u> </u>	<i>yp.</i> co	'		
12. Nil 13. 1-2 episo	odes (s	eparated l	oy > 5 r	ninutes) i	n 24 hou	rs					
14. 3-5 episo	•	•	•	,			+ba fa	بالمالية	اممانان		
15.>=6 epis hospitalisation			Dy > 5	minutes)	In 24 no	urs; nev	v tube ree	eaing, nuti	ritionai si	upport or	
16. Life threa	atening	g conseque	ences: u	irgent inte	ervention	indicate	ed				
17. Death											
Poor				<u> </u>							
NCI Criteria	2 () 3 (94 (\cup 5 \cup	Ungrad	able () No sy	mptom			
1.Loss of app								,			
2.Oral intake supplemer			significa	ant weigh	t loss or i	mainutri	tion; oral	nutritiona	I		
3. Associated	d with	significant				n (e.g.,	inadequa	te oral cal	oric		
and/or flui 4. Life-threa						ndicated	d				
5. Death		•	•								

☐ Anxiety
○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom
 NCI Criteria 1. Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation indicated 4. Life-threatening consequences; urgent intervention indicated
☐ Insomnia
☐ Insomnia ☐ 1 ☐ 2 ☐ 3 ☐ Ungradable ☐ No symptom
NCI Criteria
1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep or waking up early
☐ Spasticity
○1 ○2 ○3 ○4 ○5 ○ Ungradable ○ No symptom
NCI Criteria
1.Mild or slight increase in muscle tone 2. Moderate increase in muscle tone and increase in resistance through range of motion
3. Severe increase in muscle tone and increase in resistance through range of motion
4. Life-threatening consequences; unable to move active or passive range of motion
5. Death
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom
 NCI Criteria 1.Brief partial seizure and no loss of consciousness 2. Brief generalized seizure 3. New onset seizures (partial or generalized); multiple seizures despite medical intervention 4. Life-threatening consequences; prolonged repetitive seizures 5. Death
□ Dystonia
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom
Grading Criteria 1. Mild - mild symptoms, no intervention necessary 2. Moderate — having trouble sitting down, also limiting other instrumental activities of daily living. e.g. transfers, sitting in chair, activities of daily living 3. Severe - limiting self-care activities of daily living, e.g. bathing and toileting, toileting; confined to bed and unable to sit up
☐ Movement Disorder
○ 1 ○ 2 ○ 3 ○ No symptom ○ Ungradable
Grading Criteria
1. Mild symptoms, no intervention necessary
2.Moderate symptoms; limiting instrumental activities of daily living. 3.Severe symptoms; limiting self-care activities of daily living, e.g. bathing and toileting.
Other' symptom
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom
Grading Criteria
1. Mild
2. Moderate – having trouble sitting down
3. Severe

indicate that each harm has been assessed by ticking the square box next to each) ☐ Fatigue \bigcirc 1 ○ ungradable ○ No symptom \bigcirc 2 \bigcirc 3 not reported NCI Criteria 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; limiting instrumental ADL 3. Fatigue not relieved by rest, limiting self-care ADL □ Dizziness \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL □ Euphoria \bigcirc 1 \bigcirc 2 \bigcirc 3 ○ ungradable ○ No symptom not reported NCI Criteria 1.Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania) ☐ Insomnia \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ No symptom ○ not reported NCI Critera 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early ☐ Loss of appetite/anorexia \bigcirc 3 \bigcirc 4 \bigcirc 5 ○ ungradable ○ No symptom ○ not reported \bigcirc 2 NCI Criteria 1. Loss of appetite without alteration in eating habits 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death ☐ Anxiety \bigcirc 2 \bigcirc 1 \bigcirc 3 \bigcirc 4 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1.Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation not indicated 4.Life-threatening consequences; urgent intervention indicated

T₃ - Symptom/Harm/Toxicity Assessment (Please grade all symptoms/harms;

□ Confusion
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
 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
□ Delucione
☐ Delusions ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ ungradable ☐ no symptom ☐ not reported
NCI Criteria-Delusions
12.Moderate delusional symptoms3.Severe delusional symptoms; hospitalisation not indicated4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated5.Death
□ Hallucinations
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria - Hallucinations 1. Mild hallucinations (e.g., perceptual distortions)
Moderate hallucinations Severe hallucinations; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death
☐ Decreased level of consciousness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1.Decreased level of alertness 2.Sedation; slow response to stimuli; limiting instrumental ADL
3.Difficult to arouse
4.Life-threatening consequences 5.Death
□Sedation
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria1. Mild but more than usual drowsiness or sleepiness2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated 5. Death
☐ Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable
☐ Additional other (if exists)
Please specify additional other symptom/harm here
Other toxicity grade here:

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist (Tick 'yes', 'no', or 'don't know' for each question below)

	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			
evidence?			

Efficacy index: Rate this on the basis of **drug effect only**.

Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.

(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

		Side effects				
		None	Do not significantly interfere with patients functioning	Significantly interfere with patients functioning	Outweighs therapeutic effect	
Therapeutic effect	Marked-Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04	
	Moderate-Decided improvement. Partial remission of symptoms	05	06	07	08	
	Minimal. Slight improvement which doesn't alter status of care of patient	09	10	11	12	
	Unchanged or worse	13	14	15	16	
	Not assessed = 00					

Tick ✓	Clinical Global Impression (CGI)
	Global improvement: (Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)
	0 = Not assessed
	1 = Very much improved
	2 = Much improved
	3 = Minimally improved
	4 = No change
	5 = Minimally worse
	6 = Much worse
	7 = Very much worse

Tick	✓	Are there any changes being made to medicinal cannabis product dosing at today's assessment? (Tick all that apply)
		I am not the prescriber, so not aware of any dose change (please consider adding the dose change, if you are aware of this, even if you are not the prescriber)
		No change to cannabis/continue current dose
		Cannabis ceased (complete cessation of medication page 62)
		Cannabis dose reduced; please specify new dose below:
		Cannabis dose increased; please specify new dose below:
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in24hr	
Dose of THC/Total dose to be taken in24hr	
Other dosing: Please specify:	

Based on	the assessm	ent today has the toxicity resolved?
○ Yes	O No	○ N/A

T ₄ – 2 months post Baseline	
Date of Assessment	DD/MM/YYY
Time of Assessment (in 24hr clock e.g., 2200)	HH:MM

Tick ✓	T ₄ : Assessed/Not assessed reason
	Assessed today (continue to complete T ₂) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

*End survey here
Please provide reason if today's assessment is not 2 months after baseline.

Total dose of Cannabis taken/given in the last 24 hours	Record dose here
Dose of CBD/Total dose taken/given in last 24hrs	
Dose of THC/Total dose taken/given in last 24hrs	
Other dosing: Please specify.	
How long has the patient been on this dose (days)	

Symptoms of Interest. Please review all symptoms (*Please grade all symptoms of interest; indicate that each symptom has been assessed by ticking the square box next to each symptom*)

☐ Pain (Please score severity of pain at time of today's assessment using either 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> Categories 2 Face No particular Occasional grimace or Frequent to constant expression or smile frown, withdrawn, quivering chin, disinterested, sad, clenched jaw, appears worried distressed looking face, expression of fright/panic Normal position or Uneasy, restless, Kicking, or legs drawn Legs relaxed, usual tone tense, occasional up, marked increase in and motion to limbs tremors spasticity, constant tremors, jerking Arched. Rigid or Activity Lying quietly, normal Squirming, shifting back and forth, tense, position moves easily, jerking, severe regular, rhythmic tense. guarded agitation, head respirations movements, mildly banging, shivering, agitated, shallow breath holding, respirations, gasping, severe intermittent sighs splinting Cry No cry (awake or Moans or whimpers: Crying steadily, occasional complaint, screams, sobs, asleep) frequent complaints, occasional verbal outbursts, constant repeated outbursts, grunting constant grunting Consolability Content, relaxed Reassured by Difficult to console or occasional touching, comfort, pushing hugging, or being caregiver away, talked to: distractible 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.

Total Revised FLACC Score

Faces Pain Scale – Revised (FPS-R) - <u>use for children aged 4-10 years</u>					
	sen face 0, 2, 4 much pain". Cir		_	right, so "0" = "	no pain" and
0	2	4	6	8	10

Pain Inte	ensity	y – <u>use</u> '	this fo	r child	ren ag	ed 10	-18 yea	ars			
What wa				_				ent?			
(Circle nui	ilibei	ווו טטג נו	iat Des	st uestri	bes the	и раш)				
0 = no pa	in at	all		5	= mode	erate p	ain	10	= wors	st possil	ole pain
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain				Мо	derate pa	in R			Worst	possible	
If unable		-		_			-	scale, th	ne FPS	-R scal	le or
From clin	iciar							n at tim	e of to	day's	
assessme	ent?										
○ Mild	(Moder	nto.	(Cover	(Ungrad	lablo			
O Mild		○ Moder	ale) Sever	e O	Ungrad	lable			
☐ Nause	ea										
Barf Nau		Rating S	cale-	please r	ate you	r patie	ents' nau	ısea usir	ng the p	oictures	below
and circlin	g the	appropi	riate sc	core.							
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5233				50				126	į		
0		2		4		6	8	8		10	
☐ Vomi	ting										
01 0	2 (3 C)4 (O 5 O	Ungrada	able (O No sy	mptom			
NCI Criteria								I			
18. Nil 19. 1-2 episo	odes (s	separated	by > 5 r	ninutes) i	n 24 hou	rs					
20. 3-5 episo	•	•	•	,							
21. >=6 epi			by > 5	minutes)	in 24 ho	urs; nev	v tube fee	eding, nuti	itional si	apport or	
22. Life thre			ences: u	rgent inte	ervention	indicate	ed				
23. Death											
☐ Poor	Appe	etite									
	2 (\bigcirc 3 \bigcirc) 4 (\bigcirc 5 \bigcirc	Ungrad	lable (No sy	mptom			
NCI Criteria 1.Loss of ap											
2.Oral intake supplemer	altere	ed without				malnutri	tion; oral	nutritiona	I		
3. Associated	d with	significant				n (e.g.,	inadequa	te oral cal	oric		
and/or flui 4. Life-threa						ndicato	4				
5. Death	ceriiiig	conseque	ices, ur	gent intel	veriuori I	inuicate					

☐ Anxiety
○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom
 NCI Criteria 1. Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation indicated 4. Life-threatening consequences; urgent intervention indicated
☐ Insomnia
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom
NCI Criteria 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early
☐ Spasticity
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom
 NCI Criteria 1.Mild or slight increase in muscle tone 2. Moderate increase in muscle tone and increase in resistance through range of motion 3. Severe increase in muscle tone and increase in resistance through range of motion 4. Life-threatening consequences; unable to move active or passive range of motion 5. Death
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable \bigcirc No symptom
 NCI Criteria 1.Brief partial seizure and no loss of consciousness 2. Brief generalized seizure 3. New onset seizures (partial or generalized); multiple seizures despite medical intervention 4. Life-threatening consequences; prolonged repetitive seizures 5. Death
☐ Dystonia
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom
Grading Criteria 1. Mild - mild symptoms, no intervention necessary 2. Moderate – having trouble sitting down, also limiting other instrumental activities of daily living. e.g. transfers, sitting in chair, activities of daily living 3. Severe - limiting self-care activities of daily living, e.g. bathing and toileting, toileting; confined to bed and unable to sit up
☐ Movement Disorder
○ 1 ○ 2 ○ 3 ○ No symptom ○ Ungradable
Grading Criteria 1. Mild symptoms, no intervention necessary 2.Moderate symptoms; limiting instrumental activities of daily living. 3.Severe symptoms; limiting self-care activities of daily living, e.g. bathing and toileting.
☐ 'Other' symptom
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom
Grading Criteria 1. Mild 2. Moderate – having trouble sitting down 3. Severe

indicate that each harm has been assessed by ticking the square box next to each) ☐ Fatigue \bigcirc 1 ○ 3 ○ ungradable ○ No symptom \bigcirc 2 not reported NCI Criteria 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; limiting instrumental ADL 3. Fatigue not relieved by rest, limiting self-care ADL □ Dizziness \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ No symptom not reported NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL □ Euphoria \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1.Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania) ☐ Insomnia \bigcirc 1 \bigcirc 2 ○ 3 ○ ungradable ○ No symptom ○ not reported NCI Critera 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early ☐ Loss of appetite/anorexia \bigcirc 3 \bigcirc 4 \bigcirc 5 ○ ungradable ○ No symptom ○ not reported \bigcirc 2 NCI Criteria 1. Loss of appetite without alteration in eating habits 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death ☐ Anxiety \bigcirc 2 \bigcirc 1 \bigcirc 3 \bigcirc 4 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1.Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation not indicated 4.Life-threatening consequences; urgent intervention indicated

T₄ - Symptom/Harm/Toxicity Assessment (Please grade all symptoms/harms;

□ Confusion
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
 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
□ Delusions
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria-Delusions
12.Moderate delusional symptoms3.Severe delusional symptoms; hospitalisation not indicated4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated5.Death
□ Hallucinations
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
 NCI Criteria - Hallucinations 1. Mild hallucinations (e.g., perceptual distortions) 2. Moderate hallucinations 3. Severe hallucinations; hospitalisation not indicated 4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated 5. Death
Description of consciousness
☐ Decreased level of consciousness☐ 1☐ 2☐ 3☐ 4☐ 5☐ ungradable☐ no symptom☐ not reported
NCI Criteria 1. Decreased level of alertness 2. Sedation; slow response to stimuli; limiting instrumental ADL 3. Difficult to arouse 4. Life-threatening consequences 5. Death
□ Sedation
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
 NCI Criteria Mild but more than usual drowsiness or sleepiness Moderate sedation; limiting instrumental ADL Obtundation or stupor Life-threatening consequences; urgent intervention indicated Death
☐ Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable
☐ Additional other (if exists) Please specify additional other symptom/harm here
Other toxicity grade here:

	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			
evidence?			

Efficacy index: Rate this on the basis of **drug effect only**.

Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.

(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

		Side effects				
		None	Do not significantly interfere with patients functioning	Significantly interfere with patients functioning	Outweighs therapeutic effect	
	Marked-Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04	
effect	Moderate-Decided improvement. Partial remission of symptoms	05	06	07	08	
Therapeutic effect	Minimal. Slight improvement which doesn't alter status of care of patient	09	10	11	12	
	Unchanged or worse	13	14	15	16	
	Not assessed = 00					

Tick ✓	Clinical Global Impression (CGI)
	Global improvement: (Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)
	0 = Not assessed
	1 = Very much improved
	2 = Much improved
	3 = Minimally improved
	4 = No change
	5 = Minimally worse
	6 = Much worse
	7 = Very much worse

Tick	✓	Are there any changes being made to medicinal cannabis product dosing at today's assessment? (Tick all that apply)
		I am not the prescriber, so not aware of any dose change (please consider adding the dose change, if you are aware of this, even if you are not the prescriber)
		No change to cannabis/continue current dose
		Cannabis ceased (complete cessation of medication page 62)
		Cannabis dose reduced; please specify new dose below:
		Cannabis dose increased; please specify new dose below:
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in24hr	
Dose of THC/Total dose to be taken in24hr	
Other dosing: Please specify:	

Based on	the assessm	ent today has the toxicity resolved?
○ Yes	O No	○ N/A

T ₅ – 3 months post Baseline						
Date of Assessment	DD/MM/YYY					
Time of Assessment (in 24hr clock e.g., 2200)	HH:MM					

Tick ✓	T ₅ : Assessed/Not assessed reason								
	Assessed today (continue to complete T ₅)								
	OR								
	Died – record date of death below								
	Not able to be contacted / located								
	Too unwell								
	Other								

*End survey here
Please provide reason if today's assessment is not 3 months after baseline.

Total dose of Cannabis taken/given in the last 24 hours	Record dose here
Dose of CBD/Total dose taken/given in last 24hrs	
Dose of THC/Total dose taken/given in last 24hrs	
Other dosing: Please specify.	
How long has the patient been on this dose (days)	

Symptoms of Interest. Please review all symptoms (*Please grade all symptoms of interest; indicate that each symptom has been assessed by ticking the square box next to each symptom*)

☐ Pain (Please score severity of pain at time of today's assessment using either 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> Categories 2 Face No particular Occasional grimace or Frequent to constant expression or smile frown, withdrawn, quivering chin, disinterested, sad, clenched jaw, appears worried distressed looking face, expression of fright/panic Normal position or Uneasy, restless, Kicking, or legs drawn Legs relaxed, usual tone tense, occasional up, marked increase in and motion to limbs tremors spasticity, constant tremors, jerking Arched. Rigid or Activity Lying quietly, normal Squirming, shifting position moves easily, back and forth, tense, jerking, severe regular, rhythmic tense. guarded agitation, head respirations movements, mildly banging, shivering, agitated, shallow breath holding, respirations, gasping, severe intermittent sighs splinting Cry No cry (awake or Moans or whimpers: Crying steadily, asleep) occasional complaint, screams, sobs, occasional verbal frequent complaints, outbursts, constant repeated outbursts, constant grunting grunting Consolability Content, relaxed Reassured by Difficult to console or occasional touching, comfort, pushing hugging, or being caregiver away, talked to: distractible 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.

Total Revised FLACC Score

Faces Pain Scale – Revised (FPS-R) - use for children aged 4-10 years										
Score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so "0" = "no pain" and										
"10" = "very r	"10" = "very much pain". Circle score below.									
	, ,									
0 2 4 6 8 10										

Pain Intensity – <u>use this for children aged 10-18 years</u>										
What was							ent?			
(Circle num	iber in box	that bes	st descri	bes the	ir pain)				
0 = no pair	0 = no pain at all 5 = moderate pain 10 = worst possible pain									
0	1 2	3	4	5	6	7	8	9	10	Not reported
No pain			Мо	derate pa	in R			Worst	possible	pain
If unable to VAS scale	_		_			-	scale, th	ne FPS	-R sca	le or
From clini							n at tim	e of to	oday's	
assessmei	nt?									
0	<u> </u>			~ -						
O Mild	∪ Mod	erate	() Sever	<u>e</u>	Ungrad	lable			
☐ Nause	a									
Barf Naus	-	Scale-	please r	ate you	r patie	ents' nau	ısea usir	ng the p	pictures	below
and circling	the appro	priate so	core.		- 12					
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		3			-			1	4759	
0 2 4 6 8 10										
☐ Vomiti	ng									
\bigcirc 1 \bigcirc 2	○ 3	04) 5 ()	Ungrac	lable (○ No sv	mptom			
NCI Criteria										
24. Nil 25. 1-2 episod	les (separate	ed by > 5 r	ninutes) i	n 24 houi	rs					
26. 3-5 episod 27. >=6 episod	• •	•	•			v tubo foc	odina nuti	ritional cu	innort or	
hospitalisation		eu by > 5	minutes)	111 24 1101	urs, nev	v tube ree	ang, nuu	ilionai Si	иррогт ог	
28. Life threatening consequences: urgent intervention indicated 29. Death										
_	ppetite	<u> </u>	<u> </u>							
○ 1 ○ 2 NCI Criteria	○ 3	<u> </u>	<u> </u>	ungrada	able () No sy	mptom			
1.Loss of appe							and about the co			
2.Oral intake a supplement		ut significa	ant weigh	t ioss or r	nainutri	นon; oral	nutritiona	I		
3. Associated	with significa				n (e.g.,	inadequa	te oral cal	oric		
4. Life-threate	intake); tube ning consequ				ndicated	d				
5. Death										

☐ Anxiety
○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom
 NCI Criteria 1. Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation indicated 4. Life-threatening consequences; urgent intervention indicated
Insomnia
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom
NCI Criteria
1. Mild difficulty falling asleep, staying asleep or waking up early
Moderate difficulty falling asleep, staying asleep or waking up early Severe difficulty in falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asiecp, staying asiecp of waking up early
☐ Spasticity
○1 ○2 ○3 ○4 ○5 ○ Ungradable ○ No symptom
NCI Criteria 1.Mild or slight increase in muscle tone
2. Moderate increase in muscle tone and increase in resistance through range of motion
3. Severe increase in muscle tone and increase in resistance through range of motion
4. Life-threatening consequences; unable to move active or passive range of motion
5. Death
☐ Seizures
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom
 NCI Criteria 1.Brief partial seizure and no loss of consciousness 2. Brief generalized seizure 3. New onset seizures (partial or generalized); multiple seizures despite medical intervention 4. Life-threatening consequences; prolonged repetitive seizures 5. Death
☐ Dystonia
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom
Grading Criteria 1. Mild - mild symptoms, no intervention necessary 2. Moderate – having trouble sitting down, also limiting other instrumental activities of daily living. e.g. transfers, sitting in chair, activities of daily living 3. Severe - limiting self-care activities of daily living, e.g. bathing and toileting, toileting; confined to bed and unable to sit up
☐ Movement Disorder
○ 1 ○ 2 ○ 3 ○ No symptom ○ Ungradable
Grading Criteria
Mild symptoms, no intervention necessary Moderate symptoms; limiting instrumental activities of daily living.
3.Severe symptoms; limiting institutional activities of daily living.
☐ 'Other' symptom
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom
Grading Criteria
1. Mild 2. Moderate – having trouble sitting down
Severe

indicate that each harm has been assessed by ticking the square box next to each) ☐ Fatigue \bigcirc 1 ○ ungradable ○ No symptom ○ not reported \bigcirc 2 \bigcirc 3 NCI Criteria 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; limiting instrumental ADL 3. Fatigue not relieved by rest, limiting self-care ADL □ Dizziness \bigcirc 1 \bigcirc 2 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1.Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL □ Euphoria \bigcirc 1 \bigcirc 2 \bigcirc 3 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1.Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania) ☐ Insomnia \bigcirc 1 \bigcirc 2 \bigcirc 3 ○ ungradable ○ No symptom ○ not reported NCI Critera 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early ☐ Loss of appetite/anorexia \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc 2 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1. Loss of appetite without alteration in eating habits 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death ☐ Anxiety \bigcirc 2 \bigcirc 1 \bigcirc 3 \bigcirc 4 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1.Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation not indicated 4.Life-threatening consequences; urgent intervention indicated

T₅ - Symptom/Harm/Toxicity Assessment (Please grade all symptoms/harms;

□ Confusion
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
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
S.Beddi
□ Delusions
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria-Delusions 1
2.Moderate delusional symptoms
3. Severe delusional symptoms; hospitalisation not indicated 4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5.Death
☐ Hallucinations ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ ungradable ☐ no symptom ☐ not reported
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported **NCI Criteria - Hallucinations**
1. Mild hallucinations (e.g., perceptual distortions)
Moderate hallucinations Severe hallucinations; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death
☐ Decreased level of consciousness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1.Decreased level of alertness
2.Sedation; slow response to stimuli; limiting instrumental ADL
3.Difficult to arouse
4.Life-threatening consequences 5.Death
Sedation○ 1○ 2○ 3○ 4○ 5○ ungradable○ no symptom○ not reported
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported NCI Criteria
Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
Obtundation or stupor Life-threatening consequences; urgent intervention indicated
5. Death
□ Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable
□ Additional other (if exists)
Please specify additional other symptom/harm here
Other 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			
evidence?			

Efficacy index: Rate this on the basis of **drug effect only**.

Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.

(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

		Side effects			
		None	Do not significantly interfere with patients functioning	Significantly interfere with patients functioning	Outweighs therapeutic effect
	Marked-Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04
effect	Moderate-Decided improvement. Partial remission of symptoms	05	06	07	08
Therapeutic effect	Minimal. Slight improvement which doesn't alter status of care of patient	09	10	11	12
	Unchanged or worse	13	14	15	16
	Not assessed = 00				

Tick ✓	Clinical Global Impression (CGI)		
	Global improvement: (Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)		
	0 = Not assessed		
	1 = Very much improved		
	2 = Much improved		
	3 = Minimally improved		
	4 = No change		
	5 = Minimally worse		
	6 = Much worse		
	7 = Very much worse		

Tick	✓	Are there any changes being made to medicinal cannabis product dosing at today's assessment? (Tick all that apply)		
, , , , , , , , , , , , , , , , , , , ,		I am not the prescriber, so not aware of any dose change (please consider adding the dose change, if you are aware of this, even if you are not the prescriber)		
	No change to cannabis/continue current dose			
	Cannabis ceased (complete cessation of medication pg)			
	Cannabis dose reduced; please specify new dose below:			
	Cannabis dose increased; please specify new dose below:			
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:		

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in24hr	
Dose of THC/Total dose to be taken in24hr	
Other dosing: Please specify:	

Based on the assessment today has the toxicity resolved?			
○ Yes	O No	○ N/A	

T ₆ – 6 months post Baseline	
Date of Assessment	DD/MM/YYY
Time of Assessment (in 24hr clock e.g., 2200)	HH:MM

Tick ✓	T ₆ : Assessed/Not assessed reason			
	Assessed today (continue to complete T ₂) OR			
	Died – record date of death below			
	Not able to be contacted / located			
	Too unwell			
	Other			

*End survey here
Please provide reason if today's assessment is not 6 months after baseline.

Total dose of Cannabis taken/given in the last 24 hours	Record dose here
Dose of CBD/Total dose taken/given in last 24hrs	
Dose of THC/Total dose taken/given in last 24hrs	
Other dosing: Please specify.	
How long has the patient been on this dose (days)	

Symptoms of Interest. Please review all symptoms (*Please grade all symptoms of interest; indicate that each symptom has been assessed by ticking the square box next to each symptom*)

Scale, Faces Pain Scale, Visual Analogue Scale or clinician question) Pain Severity Score – (Revised FLACC Scale) Use for children aged 0 -3 years						
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 relaxed, 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 jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting			
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated 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.

Total Revised FLACC Score

Faces Pain Scale – Revised (FPS-R) - use for children aged 3-7/8 years						
Score the chosen face 0 , 2 , 4 , 6 , 8 , or 10 , counting left to right, so "0" = "no pain" and "10" = "very much pain". Circle score below.						
0 2 4 6 8 10						

Pain In	tensity	/ – <u>use</u> †	this fo	r child	ren ag	ed 8+	years				
		pain in		_				ent?			
(Circle i	number	in box ti	nat bes	st descri	ibes the	eir pain)				
0 = no pain at all 5 = moderate pain 10 = worst possible pain											
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain		•		Мо	derate pa	nin R		1	Worst	possible	
If unab	<u>le</u> to s	core pa	in usii	ng eith			pain s	scale, th	ne FPS	-R scal	e or
		ase ans is' persi						n at tim	o of to	day's	
assessi		is pers	Jectiv	e, wiia	t was j	patien	ics pair	ıı at tiili	e or to	uay s	
O Mild	(○ Moder	ate	() Sever	re O	Ungrad	lable			
☐ Nau	ısea										
		Rating S			ate you	ır patie	nts' nau	isea usiri	ng the p	oictures	below
(<u>•</u>											
□ Vomiting											
\bigcirc 1		3 C)4 () 5 ()	Ungrad	able 🤇	No sy	mptom			
NCI Criteria 1. 1-2 episodes (separated by > 5 minutes) in 24 hours 2. 3-5 episodes (separated by > 5 minutes) in 24 hours 3.>=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalisation indicated 4.Life threatening consequences: urgent intervention indicated 5.Death											
☐ Poor Appetite											
01		\bigcirc 3 \bigcirc) 4 (\bigcirc 5 \bigcirc	Ungrad	able 🤇	No sy	mptom			
2.Oral into supplen	appetite vake alterenents indi	without alt ed without icated significant	significa	ant weigh	t loss or r						
and/or	fluid intak	conseque	eeding o	or TPN inc	dicated						

☐ Anxiety					
○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No symptom					
NCI Criteria					
1. Mild symptoms; intervention not indicated					
2. Moderate symptoms; limiting instrumental ADL					
3. Severe symptoms; limiting self-care ADL; hospitalisation indicated					
4. Life-threatening consequences; urgent intervention indicated					
☐ Insomnia					
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom					
NCI Criteria					
1. Mild difficulty falling asleep, staying asleep or waking up early					
2. Moderate difficulty falling asleep, staying asleep or waking up early					
3. Severe difficulty in falling asleep, staying asleep or waking up early					
○1 ○2 ○3 ○4 ○5 ○ Ungradable ○ No symptom					
NCI Criteria					
1.Mild or slight increase in muscle tone					
2. Moderate increase in muscle tone and increase in resistance through range of motion					
3. Severe increase in muscle tone and increase in resistance through range of motion					
4. Life-threatening consequences; unable to move active or passive range of motion 5. Death					
5. Death					
☐ Seizures					
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No symptom					
NCI Criteria					
1.Brief partial seizure and no loss of consciousness					
2. Brief generalized seizure					
3. New onset seizures (partial or generalized); multiple seizures despite medical intervention					
4. Life-threatening consequences; prolonged repetitive seizures 5. Death					
_					
☐ Dystonia					
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom					
Grading Criteria					
1. Mild - mild symptoms, no intervention necessary					
2. Moderate – having trouble sitting down, also limiting other instrumental activities of daily living. e.g.					
transfers, sitting in chair, activities of daily living					
3. Severe - limiting self-care activities of daily living, e.g. bathing and toileting, toileting; confined to bed and					
unable to sit up					
☐ Movement Disorder					
○ 1 ○ 2 ○ 3 ○ No symptom ○ Ungradable					
Grading Criteria					
1. Mild symptoms, no intervention necessary					
2.Moderate symptoms; limiting instrumental activities of daily living.					
3.Severe symptoms; limiting self-care activities of daily living, e.g. bathing and toileting.					
☐ 'Other' symptom					
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom					
Grading Criteria					
1. Mild					
2. Moderate – having trouble sitting down					
3 Severe					

indicate that each harm has been assessed by ticking the square box next to each) ☐ Fatigue \bigcirc 1 ○ 3 ○ ungradable ○ No symptom \bigcirc 2 not reported NCI Criteria 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; limiting instrumental ADL 3. Fatigue not relieved by rest, limiting self-care ADL □ Dizziness \bigcirc 1 \bigcirc 2 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1.Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL □ Euphoria \bigcirc 1 \bigcirc 2 \bigcirc 3 ○ ungradable ○ No symptom ○ not reported NCI Criteria 1.Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania) ☐ Insomnia \bigcirc 1 \bigcirc 2 \bigcirc 3 ○ ungradable ○ No symptom ○ not reported NCI Critera 1. Mild difficulty falling asleep, staying asleep or waking up early 2. Moderate difficulty falling asleep, staying asleep or waking up early 3. Severe difficulty in falling asleep, staying asleep or waking up early ☐ Loss of appetite/anorexia ○ 3 ○ 4 ○ 5 ○ ungradable ○ No symptom ○ not reported \bigcirc 2 NCI Criteria 1. Loss of appetite without alteration in eating habits 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death ☐ Anxiety \bigcirc 2 \bigcirc 1 \bigcirc 3 \bigcirc 4 ○ ungradable ○ no symptom ○ not reported NCI Criteria 1.Mild symptoms; intervention not indicated 2. Moderate symptoms; limiting instrumental ADL 3. Severe symptoms; limiting self-care ADL; hospitalisation not indicated

T₆ - Symptom/Harm/Toxicity Assessment (Please grade all symptoms/harms;

4.Life-threatening consequences; urgent intervention indicated

□ Confusion						
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported						
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						
□ Delusions						
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported						
NCI Criteria-Delusions 1 2.Moderate delusional symptoms 3.Severe delusional symptoms; hospitalisation not indicated 4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated 5.Death						
□Hallucinations						
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported						
 NCI Criteria - Hallucinations 1. Mild hallucinations (e.g., perceptual distortions) 2. Moderate hallucinations 3. Severe hallucinations; hospitalisation not indicated 4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated 5. Death 						
☐ Decreased level of consciousness						
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported						
NCI Criteria 1.Decreased level of alertness 2.Sedation; slow response to stimuli; limiting instrumental ADL 3.Difficult to arouse 4.Life-threatening consequences 5.Death						
□ Sedation						
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported						
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						
□ Other (if exists)						
Please specify other symptom/harm here						
Other toxicity grade here:						
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable						
☐ Additional other (if exists)						
Please specify additional other symptom/harm here						
Other toxicity grade here:						
$\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc \text{Ungradable}$						

	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			
evidence?			

Efficacy index: Rate this on the basis of **drug effect only**.

Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.

(E.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

		Side effects				
		None	Do not significantly interfere with patients functioning	Significantly interfere with patients functioning	Outweighs therapeutic effect	
	Marked-Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04	
effect	Moderate-Decided improvement. Partial remission of symptoms	05	06	07	08	
Therapeutic effect	Minimal. Slight improvement which doesn't alter status of care of patient	09	10	11	12	
	Unchanged or worse	13	14	15	16	
	Not assessed = 00					

Tick ✓	Clinical Global Impression (CGI)				
	Global improvement: (Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)				
	0 = Not assessed				
	1 = Very much improved				
	2 = Much improved				
	3 = Minimally improved				
	4 = No change				
	5 = Minimally worse				
	6 = Much worse				
	7 = Very much worse				

Tick	✓	Are there any changes being made to medicinal cannabis product dosing at today's assessment? (Tick all that apply)		
		I am not the prescriber, so not aware of any dose change (please consider adding the dose change, if you are aware of this, even if you are not the prescriber)		
		No change to cannabis/continue current dose		
		Cannabis ceased (complete cessation of medication page 62)		
		Cannabis dose reduced; please specify new dose below:		
		Cannabis dose increased; please specify new dose below:		
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please		
		specify:		

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in24hr	
Dose of THC/Total dose to be taken in24hr	
Other dosing: Please specify:	

Based on	Based on the assessment today has the toxicity resolved?			
○ Yes	O No	○ N/A		

Medication Cessation (complete this page ceased at any point during the study period)	e if the medicinal cannabis is
Date of Assessment (medication cessation)	DD/MM/YYYY

Tick ✓	Medicinal Cannabis was ceased (related to indication/symptoms of interest)
	Symptom resolved; please indicate date symptom resolved: DD/MM/YYYY
	Symptom continued unchanged
	Symptom/s worsened

Tick ✓	Medicinal Cannabis was ceased (related to other reasons)		
	Harm/toxicity		
	Patient unable to take medication due to swallowing difficulty		
	Other: please specify:		

Tick ✓	When you ceased the cannabis, did you;
	Cease dose completely all at once
	Wean patient off slowly; If patient was weaned, please describe weaning schedule here.

What treatment did you subsequently initiate following the cessar medicinal cannabis?	tion of the

Ad hoc A - Unscheduled Harm/Toxicity Assessment Date of Assessment DD/MM/YYYY

Harm/Toxicity Assessment

(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)

square box next to each)
☐ Fatigue
○ 1 ○ 2 ○ 3 ○ ungradable ○ No symptom ○ not reported
NCI Criteria
1.Fatigue relieved by rest 2.Fatigue not relieved by rest; limiting instrumental ADL
3.Fatigue not relieved by rest, limiting instrumental ADL
Dizziness
○ 1 ○ 2 ○ 3 ○ ungradable ○ No symptom ○ not reported NCI Criteria
1.Mild unsteadiness or sensation of movement
2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3.Severe unsteadiness or sensation of movement; limiting self-care ADL
□ Euphoria
○ 1 ○ 2 ○ 3 ○ ungradable ○ No symptom ○ not reported
NCI Criteria
1.Mild mood elevation
2.Moderate mood elevation 3.Severe mood elevation (e.g., hypomania)
Control of the state of the sta
☐ Insomnia
○ 1 ○ 2 ○ 3 ○ ungradable ○ No symptom ○ not reported
NCI Critera
1.Mild difficulty falling asleep, staying asleep or waking up early 2.Moderate difficulty falling asleep, staying asleep or waking up early
3.Severe difficulty in falling asleep, staying asleep or waking up early
Loss of appetite/anorexia
1 02 03 04 05 0 ungradable 0 No symptom 0 not reported
NCI Criteria 1. Loss of appetite without alteration in eating habits
2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake);
tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated
5. Death
☐ Anxiety
○1 ○2 ○3 ○4 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1.Mild symptoms; intervention not indicated
2.Moderate symptoms; limiting instrumental ADL
3.Severe symptoms; limiting self-care ADL; hospitalisation not indicated
4.Life-threatening consequences; urgent intervention indicated

□ Confusion
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
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
5.Death
☐ Delusions
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria-Delusions 1 2.Moderate delusional symptoms 3.Severe delusional symptoms; hospitalisation not indicated 4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated 5.Death
□Hallucinations
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria - Hallucinations 1. Mild hallucinations (e.g., perceptual distortions) 2. Moderate hallucinations 3. Severe hallucinations; hospitalisation not indicated 4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated 5. Death
□ Decreased level of consciousness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1. Decreased level of alertness 2. Sedation; slow response to stimuli; limiting instrumental ADL 3. Difficult to arouse 4. Life-threatening consequences 5. Death
□ Sedation
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
 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
□ Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable
☐ Additional other (if exists)
Please specify additional other symptom/harm here
Other toxicity grade here:
$\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc $ 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			
evidence?			

Ad hoc B - Unscheduled Harm/Toxicity Assessment
Date of Assessment DD/MM/YYYY
Harm/Toxicity Assessment (Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)
☐ Fatigue ○ 1 ○ 2 ○ 3 ○ ungradable ○ No symptom ○ not reported
NCI Criteria 1.Fatigue relieved by rest 2.Fatigue not relieved by rest; limiting instrumental ADL 3.Fatigue not relieved by rest, limiting self-care ADL
☐ Dizziness ○ 1 ○ 2 ○ 3 ○ ungradable ○ No symptom ○ not reported
NCI Criteria 1.Mild unsteadiness or sensation of movement 2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3.Severe unsteadiness or sensation of movement; limiting self-care ADL
□ Euphoria ○ 1 ○ 2 ○ 3 ○ ungradable ○ No symptom ○ not reported
NCI Criteria 1.Mild mood elevation 2.Moderate mood elevation 3.Severe mood elevation (e.g., hypomania)
☐ Insomnia ○ 1 ○ 2 ○ 3 ○ ungradable ○ No symptom ○ not reported
NCI Critera 1.Mild difficulty falling asleep, staying asleep or waking up early 2.Moderate difficulty falling asleep, staying asleep or waking up early 3.Severe difficulty in falling asleep, staying asleep or waking up early
\Box Loss of appetite/anorexia \bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc No symptom \bigcirc not reported
 NCI Criteria 1. Loss of appetite without alteration in eating habits 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death
☐ Anxiety○ 1 ○ 2 ○ 3 ○ 4 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1.Mild symptoms; intervention not indicated 2.Moderate symptoms; limiting instrumental ADL 3.Severe symptoms; limiting self-care ADL; hospitalisation not indicated 4.Life-threatening consequences; urgent intervention indicated

□ Confusion
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
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
□ Delusions
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria-Delusions 1 2.Moderate delusional symptoms 3.Severe delusional symptoms; hospitalisation not indicated 4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated 5.Death
□Hallucinations
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria - Hallucinations 1. Mild hallucinations (e.g., perceptual distortions) 2. Moderate hallucinations 3. Severe hallucinations; hospitalisation not indicated 4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated 5. Death
☐ Decreased level of consciousness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1. Decreased level of alertness 2. Sedation; slow response to stimuli; limiting instrumental ADL 3. Difficult to arouse 4. Life-threatening consequences 5. Death
□ Sedation
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
 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
□ Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable
☐ Additional other (if exists)
Please specify additional other symptom/harm here
Other toxicity grade here:
$\bigcirc 1$ $\bigcirc 2$ $\bigcirc 3$ $\bigcirc 4$ $\bigcirc 5$ $\bigcirc $ 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			
evidence?			

Ad hoc C - Unsched	uled Harm/Toxicity Assessment
Date of Assessment	DD/MM/YYYY
	es regardless of whether they are attributable to the dicate that each harm has been assessed by ticking the
	le ○ No symptom ○ not reported
NCI Criteria 1.Fatigue relieved by rest 2.Fatigue not relieved by rest; limiting i 3.Fatigue not relieved by rest, limiting s	
☐ Dizziness ○ 1 ○ 2 ○ 3 ○ ungrada NCI Criteria	ble ○ No symptom ○ not reported
1.Mild unsteadiness or sensation of mo	of movement; limiting instrumental ADL
	le ○ No symptom ○ not reported
NCI Criteria 1.Mild mood elevation 2.Moderate mood elevation 3.Severe mood elevation (e.g., hypoma	nnia)
☐ Insomnia ○ 1 ○ 2 ○ 3 ○ ungradable	e ○ No symptom ○ not reported
NCI Critera 1.Mild difficulty falling asleep, staying a 2.Moderate difficulty falling asleep, stay 3.Severe difficulty in falling asleep, stay	ring asleep or waking up early
☐ Loss of appetite/anorexia	o S ○ ungradable ○ No symptom ○ not reported
NCI Criteria 1. Loss of appetite without alteration in 2. Oral intake altered without significan	eating habits It weight loss or malnutrition; oral nutritional supplements indicated ss or malnutrition (e.g., inadequate oral caloric and/or fluid intake);
□ Anxiety ○ 1 ○ 2 ○ 3 ○ 4 ○ un	ngradable O no symptom O not reported
NCI Criteria 1.Mild symptoms; intervention not indic 2.Moderate symptoms; limiting instrum 3.Severe symptoms; limiting self-care A 4.Life-threatening consequences; urger	ental ADL ADL; hospitalisation not indicated

☐ Confusion
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
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
Delusions
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported NCI Criteria-Delusions
1
2.Moderate delusional symptoms 3.Severe delusional symptoms; hospitalisation not indicated
4.Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5.Death
□ Hallucinations
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc ungradable \bigcirc no symptom \bigcirc not reported
NCI Criteria - Hallucinations
Mild hallucinations (e.g., perceptual distortions) Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated 5. Death
J. Death
Decreased level of consciousness
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported
NCI Criteria 1.Decreased level of alertness
2.Sedation; slow response to stimuli; limiting instrumental ADL
3.Difficult to arouse 4.Life-threatening consequences
5.Death
□ Sedation
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not reported NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
Moderate sedation; limiting instrumental ADL Obtundation or stupor
Use-threatening consequences; urgent intervention indicated
5. Death
□ Other (if exists)
Please specify other symptom/harm here
Other toxicity grade here:
○1 ○2 ○3 ○4 ○5 ○ Ungradable
□ Additional other (if exists)
Please specify additional other symptom/harm here
Other 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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5. Was the adverse event confirmed by any objective			
evidence?			