

<b>Participant ID</b>	
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<b>Initials of person entering data</b>	
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<b>Staff email</b>	
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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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## Medicinal Cannabis - Baseline (T<sub>0</sub>)

**Date of Assessment**

DD/MM/YYYY

### Demographics *(please tick)*

**Gender**  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 <i>(please tick only one)</i>
	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:

<b>Karnofsky/Lansky Performance Status Scale</b> <i>(please circle appropriate status)</i>			
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.			
<b>Karnofsky Scale (patient's age &gt; / = 16yrs)</b>		<b>Lansky Scale (recipients age &lt; 16yrs)</b>	
<b>Able to carry on normal activity; no special care is needed</b>		<b>Able to carry on normal activity; no special care is needed</b>	
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
<b>Unable to work, able to live at home cares for most personal needs, a varying amount of assistance needed</b>		<b>Mild to moderate restriction</b>	
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
<b>Unable to care for self, requires equivalent of institutional or hospital care, disease may be progressing rapidly</b>		<b>Moderate to severe restriction</b>	
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		
		<b>Pain:</b>	Please score severity of pain at time of today's assessment using <b>either</b> FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.
		<b>If prescribing medicinal cannabis for pain, is this:</b>	
		<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

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

Revised FLACC Scale SCORING			
Categories	0	1	2
<b>Face</b>	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
<b>Legs</b>	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
<b>Activity</b>	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
<b>Cry</b>	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
<b>Consolability</b>	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures

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

**Record Total Revised FLACC Score here**

**OR**

**Faces Pain Scale – Revised (FPS-R) use for children aged 4-10 years**

– see appendix for instructions on use

Score the chosen face **0, 2, 4, 6, 8, or 10**, counting left to right, so "0" = "no pain" and "10" = "very much pain". **Record score below.**

0       2       4       6       8       10

**OR**

**Visual Analogue Scale– 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**

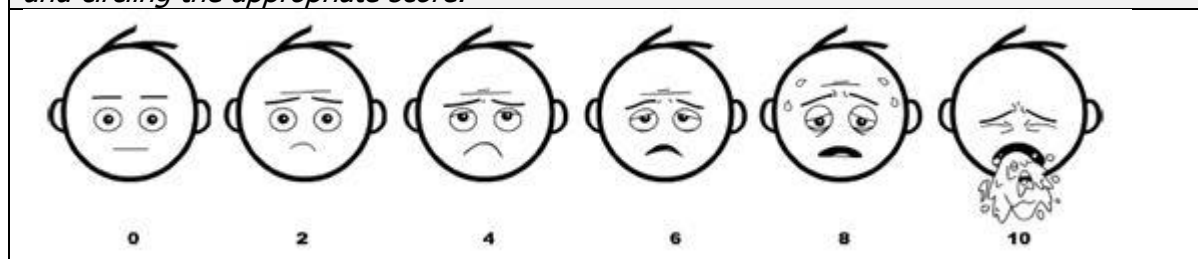
**If unable to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.**

**From clinicians' perspective, what was patient's pain at time of today's assessment?**

Mild       Moderate       Severe       Ungradable

Tick ✓		Reason/s for prescribing cannabis (tick yes or no)	
Yes	No		
		<b>Nausea</b>	<i>Please score severity of nausea below</i>
		<b>If prescribing medicinal cannabis for nausea, is this:</b>	
		<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

**Barf Nausea Rating Scale-** please rate your patients' nausea using the pictures below and circling the appropriate score.



<b>Tick ✓</b>		<b>Reason/s for prescribing cannabis</b> ( <i>tick yes or no</i> )	
<b>Yes</b>	<b>No</b>		
		<b>Vomiting</b>	<i>Please score severity of vomiting below</i>

<b>Vomiting Grading</b>	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>NCI Criteria</i>	
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	
<b>If prescribing medical cannabis for vomiting, is this:</b>	
<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

<b>Tick ✓</b>		<b>Reason/s for prescribing cannabis</b> ( <i>tick yes or no</i> )	
<b>Yes</b>	<b>No</b>		
		<b>Poor Appetite</b>	<i>Please score severity of poor appetite below</i>

<b>Poor appetite grade</b>	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>NCI Criteria</i>	
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	
<b>If prescribing medical cannabis for poor appetite, is this:</b>	
<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

<b>Tick ✓</b>		<b>Reason/s for prescribing cannabis</b> ( <i>tick yes or no</i> )	
<b>Yes</b>	<b>No</b>		
		<b>Anxiety</b>	<i>Please score severity of anxiety below</i>

<b>Anxiety grade</b>	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>NCI Criteria</i>	
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	
<b>If prescribing medical cannabis for anxiety, is this:</b>	
<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

<b>Tick ✓</b>		<b>Reason/s for prescribing cannabis</b> ( <i>tick yes or no</i> )	
<b>Yes</b>	<b>No</b>		
		<b>Insomnia</b>	<i>Please score severity of insomnia below</i>

Insomnia grade	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>NCI Criteria</i>	
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	
<b>If prescribing medical cannabis for insomnia, is this:</b>	
<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

<b>Tick ✓</b>		<b>Reason/s for prescribing cannabis</b> ( <i>tick yes or no</i> )	
<b>Yes</b>	<b>No</b>		
		<b>Spasticity</b>	<i>Please score severity of spasticity below</i>

Spasticity grade	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>NCI Criteria</i>	
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	
<b>If prescribing medical cannabis for spasticity, is this:</b>	
<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

<b>Tick ✓</b>		<b>Reason/s for prescribing cannabis</b> ( <i>tick yes or no</i> )	
<b>Yes</b>	<b>No</b>		
		<b>Seizures</b>	<i>Please score severity of seizures below</i>

Seizures grade	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>NCI Criteria</i>	
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	
<b>If prescribing medical cannabis for seizures, is this:</b>	
<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

Tick ✓		Reason/s for prescribing cannabis (tick yes or no)	
Yes	No		
		<b>Dystonia</b>	Please score severity of dystonia below

Dystonia grade	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>Grading Criteria</i>	
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	
<b>If prescribing medical cannabis for dystonia, is this:</b>	
<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

Tick ✓		Reason/s for prescribing cannabis (tick yes or no)	
Yes	No		
		<b>Movement Disorder</b>	Please score severity of dystonia below

Movement Disorder grade	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>Grading Criteria</i>	
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.	
<b>If prescribing medical cannabis for movement disorder, is this:</b>	
<input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy	

Tick ✓		Reason/s for prescribing cannabis (tick yes or no)	
Yes	No		
		<b>General wellbeing</b>	If prescribing medical cannabis for general wellbeing, is this: <input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy

Tick ✓		Reason/s for prescribing cannabis (tick yes or no)	
Yes	No		
		<b>Requested by patient and/or family as anti-cancer medication</b>	If prescribing medical cannabis for anti-cancer medication, is this: <input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy



Tick ✓		Reason/s for prescribing cannabis ( <i>tick yes or no</i> )	
Yes	No		
		<b>Other symptom</b> Please specify symptom: _____	If prescribing medical cannabis for other symptom, is this: <input type="radio"/> 1 <sup>st</sup> line <input type="radio"/> add on therapy

'Other symptom' grade	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> ungradable <input type="radio"/> no symptom
<i>Grading Criteria</i> 1. Mild 2. Moderate 3. Severe	

Tick ✓	Other Concurrent Medications (classes of drugs) that patient is currently taking ( <i>tick all that apply</i> )		
	Opioids		
	Benzodiazepines		
	Anti-emetics		
	Laxatives/aperients		
	Tricyclic antidepressants		
	NMDA antagonists – Ketamine, Dextromethorphan		
	Alpha 2 agonists - Clonidine		
	Paracetamol/NSAIDS		
	Baclofen		
	Anti-reflux medications		
	Anti-epileptics. Please circle which one below.		
	Gabapentin/Pregabalin	levetiracetam	carbamazepine
	valproic acid	clonazepam	Other anti-epileptic, please specify; _____
	Antipsychotics		
	Steroids		
	Other cannabinoids– please specify:		
	Other – please specify:		
	No other concurrent medications		

**Baseline Symptom/Harm/Toxicity Assessment** (Please grade all symptoms/harms; indicate that each harm has been assessed by ticking the square box next to each)

**Fatigue**

1  2  3  no symptom  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 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

**Loss of appetite/anorexia**

1  2  3  4  5  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**

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**

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*

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

*NCI Criteria*

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:

1    2    3    4    5    Ungradable

## Baseline T<sub>0</sub> – Medicinal Cannabis Information

### Current cannabis intake

#### Is child currently using cannabis?

**Yes** (Please answer questions below)  **No**

**If Yes:** How long has the child been taking this cannabis? (*days*)

Tick ✓	Who has prescribed the medicinal cannabis?
	Palliative care specialist
	Paediatric Oncologist
	General Practitioner
	General Paediatrician
	Specialist Paediatrician; Please specify: _____
	Other; Please specify: _____

**Product Formulation** (*if unknown, please write ('not known')*)

**Name of Product** (*if unknown, please write ('not known')*)

Dosing of Medicinal Cannabis Use	Record dose here
Dose of CBD/Dosing in 24hr (if known)	
Dose of THC/Dosing in 24hr (if known)	

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

**Tick ✓ Does the child currently use recreational cannabis?**  
(*tick whichever applies*)

**Yes**  **No**  **Unknown**

**If Yes; What amount is being used e.g., joints per day smoked or other cannabis product including dose and route?**

**Amount**

## T<sub>0</sub> - Commencement of Medicinal Cannabis

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

<b>Date medicinal cannabis is being commenced</b>	DD/MM/YYYY
<b>Time of initial dose</b> ( <i>in 24hr clock e.g., 2200</i> )	HH:MM
<b>Which product formulation is being commenced</b>	<input type="radio"/> CBD <input type="radio"/> THC <input type="radio"/> Both CBD & THC <input type="radio"/> Other
<b>Name of Product being commenced</b> ( <i>if known</i> )	

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

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

**T<sub>1</sub> – 7 days post Baseline****Date of Assessment**

DD/MM/YYYY

**Time of Assessment** (*in 24hr clock e.g., 2200*)

HH:MM

Tick ✓	T <sub>1</sub> : Assessed/Not assessed reason
	Assessed today (continue to complete T <sub>1</sub> ) 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.	
<b>How long has the patient been on this dose</b> ( <i>days</i> )	

**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) Use for children aged 0 -4/5 years**

Categories	0	1	2
<b>Face</b>	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
<b>Legs</b>	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
<b>Activity</b>	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
<b>Cry</b>	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
<b>Consolability</b>	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**

**OR**

**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.**

<b>0</b>	<b>2</b>	<b>4</b>	<b>6</b>	<b>8</b>	<b>10</b>
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**OR**

**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**

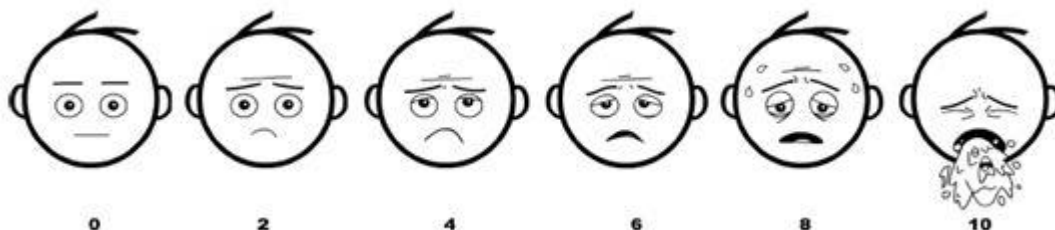
**If unable to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.**

**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     Ungradable     no symptom

*NCI Criteria*

0. Nil

- 1-2 episodes (separated by > 5 minutes) in 24 hours
- 3-5 episodes (separated by > 5 minutes) in 24 hours
- >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalisation indicated
- Life threatening consequences: urgent intervention indicated
- Death

**Poor Appetite**

1     2     3     4     5     Ungradable     no symptom

*NCI Criteria*

- Loss of appetite without alteration in eating habits
- Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- Life-threatening consequences; urgent intervention indicated
- Death



<input type="checkbox"/> <b>Anxiety</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Ungradable <input type="radio"/> no symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Insomnia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> no symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Spasticity</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Seizures</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Dystonia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 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
<input type="checkbox"/> <b>Movement Disorder</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>Grading Criteria</i> 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.
<input type="checkbox"/> <b>'Other' symptom</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 1. Mild 2. Moderate – having trouble sitting down 3. Severe

**T<sub>1</sub> - Symptom/Harm/Toxicity Assessment** (Please grade all symptoms/harms; 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 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

**Loss of appetite/anorexia**

1  2  3  4  5  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**

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**

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**

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:

1    2    3    4    5    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
<b>Therapeutic effect</b>	<b>Marked-Vast improvement. Complete or nearly complete remission of all symptoms</b>	<b>01</b>	<b>02</b>	<b>03</b>	<b>04</b>
	<b>Moderate-Decided improvement. Partial remission of symptoms</b>	<b>05</b>	<b>06</b>	<b>07</b>	<b>08</b>
	<b>Minimal. Slight improvement which doesn't alter status of care of patient</b>	<b>09</b>	<b>10</b>	<b>11</b>	<b>12</b>
	<b>Unchanged or worse</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>
	<b>Not assessed = 00</b>				
<b>Record Efficacy Index Score here</b>					

<b>Tick ✓</b>	<b>Clinical Global Impression (CGI)</b> <b>Global improvement:</b> <i>(Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)</i>
	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

<b>Tick ✓</b>	<b>Are there any changes being made to medicinal cannabis product dosing at today's assessment?</b> <i>(Tick all that apply)</i>
	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:
<b>Yes</b>	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
<b>No</b>	

<b>Based on the assessment today has the harm/toxicity resolved?</b>
<input type="radio"/> <b>Yes</b> <input type="radio"/> <b>No</b> <input type="radio"/> <b>N/A</b>

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

**T<sub>2</sub> – 14 days post Baseline****Date of Assessment**

DD/MM/YYYY

**Time of Assessment** (*in 24hr clock e.g., 2200*)

HH:MM

Tick ✓	T <sub>2</sub> : Assessed/Not assessed reason
	Assessed today (continue to complete T <sub>2</sub> ) 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 14 days after baseline.

--

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

**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) Use for children aged 0 -4/5 years**

Categories	0	1	2
<b>Face</b>	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
<b>Legs</b>	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
<b>Activity</b>	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting
<b>Cry</b>	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
<b>Consolability</b>	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**

**OR**

**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.**

<b>0</b>	<b>2</b>	<b>4</b>	<b>6</b>	<b>8</b>	<b>10</b>
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**OR**

**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**

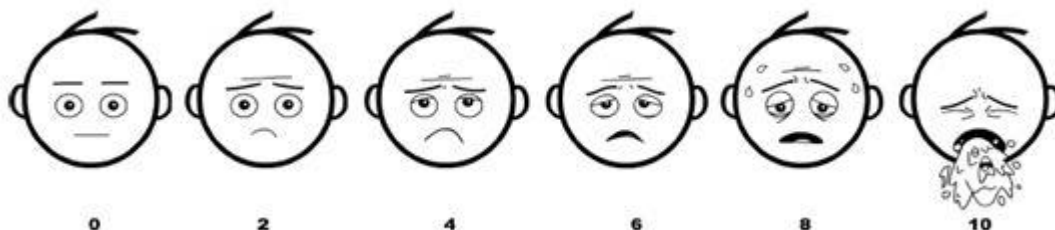
**If unable to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.**

**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



<input type="checkbox"/> <b>Anxiety</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Insomnia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Spasticity</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Seizures</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Dystonia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>Grading Criteria</i> 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
<input type="checkbox"/> <b>Movement Disorder</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>Grading Criteria</i> 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.
<input type="checkbox"/> <b>'Other' symptom</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>Grading Criteria</i> 1. Mild 2. Moderate – having trouble sitting down 3. Severe

**T<sub>2</sub> - Symptom/Harm/Toxicity Assessment** (Please grade all symptoms/harms; 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 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

**Loss of appetite/anorexia**

1    2    3    4    5    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**

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**

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**

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:

1    2    3    4    5    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
<b>Therapeutic effect</b>	<b>Marked-Vast improvement. Complete or nearly complete remission of all symptoms</b>	<b>01</b>	<b>02</b>	<b>03</b>	<b>04</b>
	<b>Moderate-Decided improvement. Partial remission of symptoms</b>	<b>05</b>	<b>06</b>	<b>07</b>	<b>08</b>
	<b>Minimal. Slight improvement which doesn't alter status of care of patient</b>	<b>09</b>	<b>10</b>	<b>11</b>	<b>12</b>
	<b>Unchanged or worse</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>
	<b>Not assessed = 00</b>				
<b>Record Efficacy Index Score here</b>					

<b>Tick ✓</b>	<b>Clinical Global Impression (CGI)</b> <b>Global improvement:</b> <i>(Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)</i>
	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

<b>Tick ✓</b>	<b>What is the intended treatment based on today's assessment?</b> <i>(Tick all that apply)</i>
	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:
<b>Yes</b>	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
<b>No</b>	

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

<b>Based on the assessment today has the toxicity resolved?</b>
<input type="radio"/> <b>Yes</b> <input type="radio"/> <b>No</b> <input type="radio"/> <b>N/A</b>

**T<sub>3</sub> – 28 days post Baseline****Date of Assessment**

DD/MM/YYYY

**Time of Assessment** (*in 24hr clock e.g., 2200*)

HH:MM

Tick ✓	T <sub>3</sub> : Assessed/Not assessed reason
	Assessed today (continue to complete T <sub>2</sub> ) 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.

--

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

**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) Use for children aged 0 -4/5 years**

Categories	0	1	2
<b>Face</b>	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
<b>Legs</b>	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
<b>Activity</b>	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
<b>Cry</b>	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
<b>Consolability</b>	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**

**OR**

**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.**

<b>0</b>	<b>2</b>	<b>4</b>	<b>6</b>	<b>8</b>	<b>10</b>
----------	----------	----------	----------	----------	-----------

**OR**

**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**

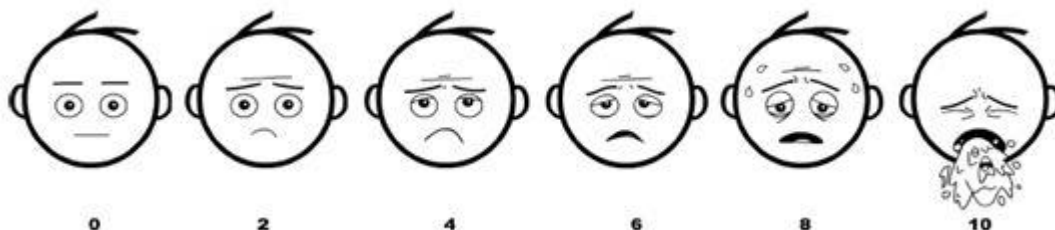
**If unable to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.**

**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     Ungradable     No symptom

*NCI Criteria*

12. Nil

13. 1-2 episodes (separated by > 5 minutes) in 24 hours

14. 3-5 episodes (separated by > 5 minutes) in 24 hours

15. >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalisation indicated

16. Life threatening consequences: urgent intervention indicated

17. Death

**Poor Appetite**

1     2     3     4     5     Ungradable     No symptom

*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



<input type="checkbox"/> <b>Anxiety</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Insomnia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Spasticity</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Seizures</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Dystonia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 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
<input type="checkbox"/> <b>Movement Disorder</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>Grading Criteria</i> 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.
<input type="checkbox"/> <b>'Other' symptom</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 1. Mild 2. Moderate – having trouble sitting down 3. Severe

**T<sub>3</sub> - Symptom/Harm/Toxicity Assessment** (Please grade all symptoms/harms; 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 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

**Loss of appetite/anorexia**

1    2    3    4    5    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**

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**

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**

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:

1    2    3    4    5    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
<b>Therapeutic effect</b>	<b>Marked-Vast improvement. Complete or nearly complete remission of all symptoms</b>	<b>01</b>	<b>02</b>	<b>03</b>	<b>04</b>
	<b>Moderate-Decided improvement. Partial remission of symptoms</b>	<b>05</b>	<b>06</b>	<b>07</b>	<b>08</b>
	<b>Minimal. Slight improvement which doesn't alter status of care of patient</b>	<b>09</b>	<b>10</b>	<b>11</b>	<b>12</b>
	<b>Unchanged or worse</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>
	<b>Not assessed = 00</b>				
<b>Record Efficacy Index Score here</b>					

<b>Tick ✓</b>	<b>Clinical Global Impression (CGI)</b> <b>Global improvement:</b> <i>(Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)</i>
	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

<b>Tick ✓</b>	<b>Are there any changes being made to medicinal cannabis product dosing at today's assessment?</b> <i>(Tick all that apply)</i>
	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:
<b>Yes</b>	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
<b>No</b>	

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

<b>Based on the assessment today has the toxicity resolved?</b>
<input type="radio"/> <b>Yes</b> <input type="radio"/> <b>No</b> <input type="radio"/> <b>N/A</b>

**T<sub>4</sub> – 2 months post Baseline****Date of Assessment**

DD/MM/YYYY

**Time of Assessment** (*in 24hr clock e.g., 2200*)

HH:MM

Tick ✓	T <sub>4</sub> : Assessed/Not assessed reason
	Assessed today (continue to complete T <sub>2</sub> ) 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 2 months after baseline.

--

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

**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) Use for children aged 0 -4/5 years**

Categories	0	1	2
<b>Face</b>	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
<b>Legs</b>	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
<b>Activity</b>	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
<b>Cry</b>	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
<b>Consolability</b>	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**

**OR**

**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.**

<b>0</b>	<b>2</b>	<b>4</b>	<b>6</b>	<b>8</b>	<b>10</b>
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**OR**

**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**

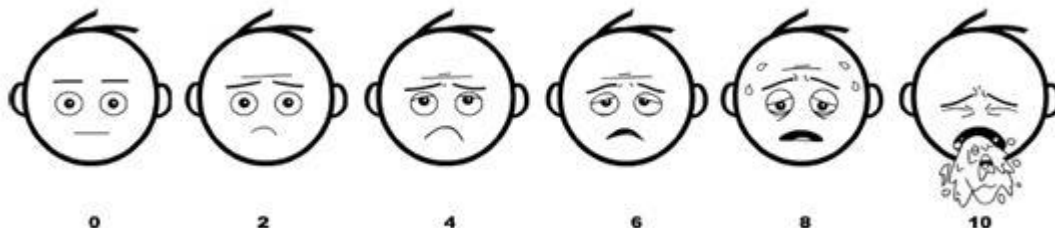
**If unable to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.**

**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     Ungradable     No symptom

*NCI Criteria*

18. Nil

19. 1-2 episodes (separated by > 5 minutes) in 24 hours

20. 3-5 episodes (separated by > 5 minutes) in 24 hours

21. >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalisation indicated

22. Life threatening consequences: urgent intervention indicated

23. Death

**Poor Appetite**

1     2     3     4     5     Ungradable     No symptom

*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



<input type="checkbox"/> <b>Anxiety</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Insomnia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Spasticity</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Seizures</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Dystonia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 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
<input type="checkbox"/> <b>Movement Disorder</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>Grading Criteria</i> 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.
<input type="checkbox"/> <b>'Other' symptom</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 1. Mild 2. Moderate – having trouble sitting down 3. Severe

**T<sub>4</sub> - Symptom/Harm/Toxicity Assessment** (Please grade all symptoms/harms; 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 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

**Loss of appetite/anorexia**

1    2    3    4    5    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**

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**

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**

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:

1    2    3    4    5    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
<b>Therapeutic effect</b>	<b>Marked-Vast improvement. Complete or nearly complete remission of all symptoms</b>	<b>01</b>	<b>02</b>	<b>03</b>	<b>04</b>
	<b>Moderate-Decided improvement. Partial remission of symptoms</b>	<b>05</b>	<b>06</b>	<b>07</b>	<b>08</b>
	<b>Minimal. Slight improvement which doesn't alter status of care of patient</b>	<b>09</b>	<b>10</b>	<b>11</b>	<b>12</b>
	<b>Unchanged or worse</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>
	<b>Not assessed = 00</b>				
<b>Record Efficacy Index Score here</b>					

<b>Tick ✓</b>	<b>Clinical Global Impression (CGI)</b> <b>Global improvement:</b> <i>(Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)</i>
	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

<b>Tick ✓</b>	<b>Are there any changes being made to medicinal cannabis product dosing at today's assessment?</b> <i>(Tick all that apply)</i>
	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:
<b>Yes</b>	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
<b>No</b>	

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

<b>Based on the assessment today has the toxicity resolved?</b>
<input type="radio"/> <b>Yes</b> <input type="radio"/> <b>No</b> <input type="radio"/> <b>N/A</b>

**T<sub>5</sub> – 3 months post Baseline****Date of Assessment**

DD/MM/YYYY

**Time of Assessment** (*in 24hr clock e.g., 2200*)

HH:MM

Tick ✓	T <sub>5</sub> : Assessed/Not assessed reason
	Assessed today (continue to complete T <sub>5</sub> ) 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 3 months after baseline.

--

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

**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) Use for children aged 0 -4/5 years**

Categories	0	1	2
<b>Face</b>	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
<b>Legs</b>	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
<b>Activity</b>	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
<b>Cry</b>	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
<b>Consolability</b>	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**

**OR**

**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.**

<b>0</b>	<b>2</b>	<b>4</b>	<b>6</b>	<b>8</b>	<b>10</b>
----------	----------	----------	----------	----------	-----------

**OR**

**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**

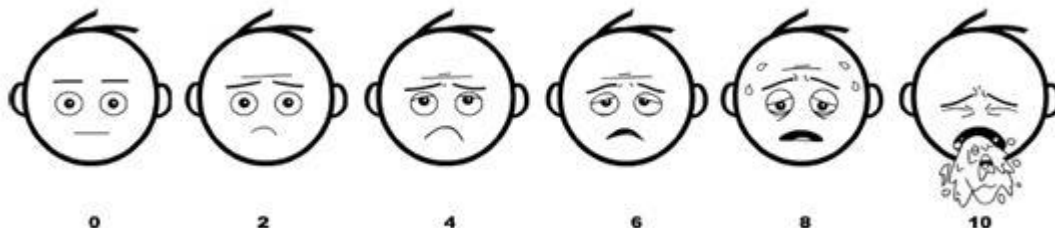
**If unable to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.**

**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     Ungradable     No symptom

*NCI Criteria*

- 24. Nil
- 25. 1-2 episodes (separated by > 5 minutes) in 24 hours
- 26. 3-5 episodes (separated by > 5 minutes) in 24 hours
- 27. >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalisation indicated
- 28. Life threatening consequences: urgent intervention indicated
- 29. Death

**Poor Appetite**

1     2     3     4     5     Ungradable     No symptom

*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



<input type="checkbox"/> <b>Anxiety</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Insomnia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Spasticity</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Seizures</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Dystonia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 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
<input type="checkbox"/> <b>Movement Disorder</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>Grading Criteria</i> 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.
<input type="checkbox"/> <b>'Other' symptom</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 1. Mild 2. Moderate – having trouble sitting down 3. Severe

**T<sub>5</sub> - Symptom/Harm/Toxicity Assessment** (Please grade all symptoms/harms; 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 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

**Loss of appetite/anorexia**

1    2    3    4    5    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**

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**

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**

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:

1    2    3    4    5    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
<b>Therapeutic effect</b>	<b>Marked-Vast improvement. Complete or nearly complete remission of all symptoms</b>	<b>01</b>	<b>02</b>	<b>03</b>	<b>04</b>
	<b>Moderate-Decided improvement. Partial remission of symptoms</b>	<b>05</b>	<b>06</b>	<b>07</b>	<b>08</b>
	<b>Minimal. Slight improvement which doesn't alter status of care of patient</b>	<b>09</b>	<b>10</b>	<b>11</b>	<b>12</b>
	<b>Unchanged or worse</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>
	<b>Not assessed = 00</b>				
<b>Record Efficacy Index Score here</b>					

<b>Tick ✓</b>	<b>Clinical Global Impression (CGI)</b> <b>Global improvement:</b> <i>(Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)</i>
	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

<b>Tick ✓</b>	<b>Are there any changes being made to medicinal cannabis product dosing at today's assessment?</b> <i>(Tick all that apply)</i>
	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:
<b>Yes</b>	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
<b>No</b>	

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

<b>Based on the assessment today has the toxicity resolved?</b>
<input type="radio"/> <b>Yes</b> <input type="radio"/> <b>No</b> <input type="radio"/> <b>N/A</b>

**T<sub>6</sub> – 6 months post Baseline****Date of Assessment**

DD/MM/YYYY

**Time of Assessment** (*in 24hr clock e.g., 2200*)

HH:MM

Tick ✓	T <sub>6</sub> : Assessed/Not assessed reason
	Assessed today (continue to complete T <sub>2</sub> ) 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 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.	
<b>How long has the patient been on this dose</b> ( <i>days</i> )	

**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) Use for children aged 0 -3 years**

Categories	0	1	2
<b>Face</b>	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
<b>Legs</b>	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
<b>Activity</b>	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
<b>Cry</b>	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
<b>Consolability</b>	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**

**OR**

**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.**

<b>0</b>	<b>2</b>	<b>4</b>	<b>6</b>	<b>8</b>	<b>10</b>
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**OR**

**Pain Intensity – use this for children aged 8+ 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**

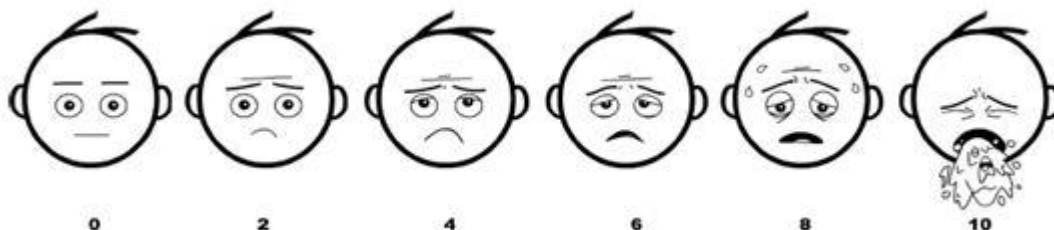
**If unable to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.**

**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     Ungradable     No symptom

*NCI Criteria*

- 1-2 episodes (separated by > 5 minutes) in 24 hours
- 3-5 episodes (separated by > 5 minutes) in 24 hours
- >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalisation indicated
- Life threatening consequences: urgent intervention indicated
- Death

**Poor Appetite**

1     2     3     4     5     Ungradable     No symptom

*NCI Criteria*

- Loss of appetite without alteration in eating habits
- Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- Life-threatening consequences; urgent intervention indicated
- Death



<input type="checkbox"/> <b>Anxiety</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Insomnia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Spasticity</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Seizures</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>NCI Criteria</i> 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
<input type="checkbox"/> <b>Dystonia</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 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
<input type="checkbox"/> <b>Movement Disorder</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> No symptom <input type="radio"/> Ungradable
<i>Grading Criteria</i> 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.
<input type="checkbox"/> <b>'Other' symptom</b>
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Ungradable <input type="radio"/> No symptom
<i>Grading Criteria</i> 1. Mild 2. Moderate – having trouble sitting down 3. Severe

**T<sub>6</sub> - Symptom/Harm/Toxicity Assessment** (Please grade all symptoms/harms; 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 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

**Loss of appetite/anorexia**

1    2    3    4    5    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**

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**

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**

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:

1    2    3    4    5    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
<b>Therapeutic effect</b>	<b>Marked-Vast improvement. Complete or nearly complete remission of all symptoms</b>	<b>01</b>	<b>02</b>	<b>03</b>	<b>04</b>
	<b>Moderate-Decided improvement. Partial remission of symptoms</b>	<b>05</b>	<b>06</b>	<b>07</b>	<b>08</b>
	<b>Minimal. Slight improvement which doesn't alter status of care of patient</b>	<b>09</b>	<b>10</b>	<b>11</b>	<b>12</b>
	<b>Unchanged or worse</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>
	<b>Not assessed = 00</b>				
<b>Record Efficacy Index Score here</b>					

<b>Tick ✓</b>	<b>Clinical Global Impression (CGI)</b> <b>Global improvement:</b> <i>(Clinician to rate total improvement compared to child's condition at admission to the project, how much have they changed?)</i>
	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

<b>Tick ✓</b>	<b>Are there any changes being made to medicinal cannabis product dosing at today's assessment?</b> <i>(Tick all that apply)</i>
	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:
<b>Yes</b>	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
<b>No</b>	

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

<b>Based on the assessment today has the toxicity resolved?</b>
<input type="radio"/> <b>Yes</b> <input type="radio"/> <b>No</b> <input type="radio"/> <b>N/A</b>

**Medication Cessation** (complete this page if the medicinal cannabis is ceased at any point during the study period)

**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 cessation of the medicinal cannabis?**

--

## 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)*

**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 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

**Loss of appetite/anorexia**

1    2    3    4    5    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**

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**

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**

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:

1    2    3    4    5    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)**

	<b>Yes</b>	<b>No</b>	<b>Don't know</b>
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 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

**Loss of appetite/anorexia**

1    2    3    4    5    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**

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**

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**

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:

1    2    3    4    5    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*)

	<b>Yes</b>	<b>No</b>	<b>Don't know</b>
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 - 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 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

**Loss of appetite/anorexia**

1    2    3    4    5    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**

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**

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**

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:

1    2    3    4    5    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*)

	<b>Yes</b>	<b>No</b>	<b>Don't know</b>
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?			