

Participant ID	
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Initials of person entering data	
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Staff email	
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CONFIDENTIAL CASE REPORT FORM

MEDICINAL CANNABIS Series No: 19

IMPACCT Trials Coordination Centre (ITCC) n
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 (T₀)

Date of Assessment

DD/MM/YYYY

Demographics *(please tick)*

Gender Male Female Other

Age (yrs.)		Weight (kg)		Height (cm)	
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Tick ✓	Primary illness (please choose only one)		
	End stage renal failure		
	Hepatic failure		
	Neurodegenerative disease		
	Cardiac failure		
	Respiratory failure		
	AIDS		
	Other primary illness; Please specify:		
	Cancer – Please indicate stage: Stage 1-3 <input type="checkbox"/> or Stage 4 <input type="checkbox"/> Please specify cancer type below:		
Tick ✓		Tick ✓	
	GI Tract		Prostate
	Gynaecological		Haematological
	Lung		Other: Please specify below:
	Breast		

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.

Laboratory Tests (within last 14 days – only if available)	
Test	Value
Haemoglobin (Hb) g/dL	
White cell count	
Creatinine	
AST (units/L)	
ALT (units/L)	
Albumin (g/dL)	
Bilirubin (mg/dL)	

Tick ✓	Australian Modified Karnofsky Performance Scale (AKPS)
	100 - Normal; no complaints; no evidence of disease
	90 - Able to carry on normal activity; minor sign of symptoms of disease
	80 - Normal activity with effort; some signs or symptoms of disease
	70 - Cares for self; unable to carry on normal activity or to do active work
	60 - Requires occasional assistance but is able to care for most needs
	50 - Requires considerable assistance and frequent medical care
	40 - In bed more than 50% of the time
	30 - Almost completely bedfast
	20 - Totally bedfast and requiring extensive nursing care by professionals and/or family
	10 - Comatose or barely rousable
	0 - Dead
	Not able to determine

Charlson Comorbidity Index - Does the patient have any of the following? <i>Please tick all that apply.</i>			
Tick ✓		Tick ✓	
	Myocardial Infarction (history, not ECG changes only)		Hemiplegia
	Congestive Cardiac Failure		Moderate or Severe Renal Disease
	Peripheral Vascular Disease (includes aortic aneurysm \geq 6 cm)		Diabetes with End Organ Damage
	Cerebrovascular Disease (CVA with mild or no residual or TIA)		Any Tumour
	Dementia		Leukaemia (acute or chronic)
	Chronic Pulmonary Disease		Lymphoma
	Connective Tissue Disease		Moderate or Severe Liver Disease
	Peptic Ulcer Disease		Metastatic Solid Tumour
	Mild Liver Disease (without portal hypertension, includes chronic hepatitis)		AIDS (not just HIV positive)
	Diabetes (without organ damage) (excludes diet-controlled alone)		

Current cannabis intake

Is the patient currently using cannabis?

Yes **No** *If yes, please provide product formulation and product name, if known.*

Product Formulation

Product name

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

Dosing of Current Cannabis Use	Record dose here
Dose of CBD/Dosing in 24hr (if known)	
Dose of THC/Dosing in 24hr (if known)	
Other: Please describe. E.g. smokes 3 joints a day of home grown leaf	

Tick ✓	Is this current cannabis use
	Prescribed (Official)
	Unofficial

Tick ✓	Does the patient have a past history of using cannabis? <i>Tick whichever applies</i>
	<i>Yes: Provide further information if available. Include both prescribed and recreational.</i>
	No
	Unknown

If patient is currently using cannabis as above, will they continue to take this?

Yes **No**

Baseline T₀ - Medication Commencement

Indications of interest: *Please grade all symptoms. Indicate that each symptom has been assessed by ticking the square box next to each.*

Pain

Nil Mild Moderate Severe

If prescribing medical cannabis for pain, is this:

1st line 2nd or subsequent treatment not applicable

Nausea and Vomiting

Nil Mild Moderate Severe

If prescribing medical cannabis for nausea and vomiting, is this:

1st line 2nd or subsequent treatment not applicable

Appetite

Nil Mild Moderate Severe

If prescribing medical cannabis for appetite, is this:

1st line 2nd or subsequent treatment not applicable

Wellbeing

Nil Mild Moderate Severe

If prescribing medical cannabis for wellbeing, is this:

1st line 2nd or subsequent treatment not applicable

Anxiety

Nil Mild Moderate Severe

If prescribing medical cannabis for anxiety, is this:

1st line 2nd or subsequent treatment not applicable

Sleep

Nil Mild Moderate Severe

If prescribing medical cannabis for sleep, is this:

1st line 2nd or subsequent treatment not applicable

Seizures

Nil Mild Moderate Severe

If prescribing medical cannabis for seizures, is this:

1st line 2nd or subsequent treatment not applicable

Other

Nil Mild Moderate Severe

If prescribing medical cannabis for 'other' symptom, is this:

1st line 2nd or subsequent treatment not applicable

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 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 no symptom ungradable 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 no symptom ungradable not reported

NCI Criteria

1. Mild mood elevation
2. Moderate mood elevation
3. Severe mood elevation (e.g., hypomania)

Insomnia

1 2 3 no symptom ungradable 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 no symptom ungradable 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 5 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; hospitalisation indicated
5. Death

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/Hallucinations

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria-Delusions

1. No grading
2. Moderate delusional symptoms
3. Severe delusional symptoms; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

Hypotension

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria

1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalisation indicated
4. Life-threatening and urgent intervention indicated
5. Death

Palpitations

1 2 ungradable no Symptom not reported

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Intervention indicated

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

Other (if exists)

Please specify other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Date medical cannabis commenced	DD/MM/YYYY
Time of initial dose (<i>in 24hr clock e.g., 22:00</i>)	HH:MM

Product formulation	
Product name if known	

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

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

T₁ – 7 days post Baseline

Date of Assessment

DD/MM/YYYY

Time of Assessment (in 24hr clock e.g., 22:00)

HH:MM

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

Date of Death*

DD/MM/YYYY

****End survey here***

Please provide reason if today's assessment is not 7 days after baseline.

--

Indications of interest: (Please grade all symptoms; indicate that each symptom has been assessed by ticking the square box next to each)

Pain

Nil Mild Moderate Severe

If prescribing medical cannabis for pain, is this:

1st line 2nd or subsequent treatment not applicable

Nausea and Vomiting

Nil Mild Moderate Severe

If prescribing medical cannabis for nausea and vomiting, is this:

1st line 2nd or subsequent treatment not applicable

Appetite

Nil Mild Moderate Severe

If prescribing medical cannabis for appetite, is this:

1st line 2nd or subsequent treatment not applicable

Wellbeing

Nil Mild Moderate Severe

If prescribing medical cannabis for wellbeing, is this:

1st line 2nd or subsequent treatment not applicable

Anxiety

Nil Mild Moderate Severe

If prescribing medical cannabis for anxiety, is this:

1st line 2nd or subsequent treatment not applicable

<input type="checkbox"/> Sleep
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for sleep, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Seizures
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for seizures, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Other
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for 'other' symptom, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable

T₁ – 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.

<input type="checkbox"/> Fatigue
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
1.Fatigue relieved by rest
2.Fatigue not relieved by rest; limiting instrumental ADL
3.Fatigue not relieved by rest, limiting self-care ADL

<input type="checkbox"/> Dizziness
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
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

<input type="checkbox"/> Euphoria
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
1.Mild mood elevation
2.Moderate mood elevation
3.Severe mood elevation (e.g., hypomania)

<input type="checkbox"/> Insomnia
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<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

Loss of appetite/anorexia

1 2 3 4 5 no symptom ungradable 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 5 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; hospitalisation indicated
5. Death

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/Hallucinations

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria-Delusions

1. No grading
2. Moderate delusional symptoms
3. Severe delusional symptoms; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

Hypotension

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria

1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalisation indicated
4. Life-threatening and urgent intervention indicated
5. Death

Palpitations

1 2 ungradable no Symptom not reported

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Intervention indicated

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

Other (if exists)

Please specify other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Tick ✓	Which symptom/harm is the most troublesome? <i>Tick one only</i>
	Fatigue
	Dizziness
	Euphoria
	Insomnia
	Loss of appetite/anorexia
	Anxiety
	Confusion
	Delusions/Hallucinations
	Hypotension
	Decreased level of consciousness
	Palpitations
	Other
	Additional other
	Not applicable

Total dose of Cannabis given in the last 24 hours	Record dose here
Dose of CBD/Total dose taken in 24hr	
Dose of THC/Total dose taken in 24hr	
Other dosing: Please specify.	

How long has the patient been on this dose (days)	
--	--

Tick ✓	Clinical Global Impression (CGI) Global improvement: <i>Clinician to rate total improvement compared to patient's condition at admission to the project - how much has the patient 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

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

Select the terms below which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect e.g. If therapeutic effect is rated as 'moderate' and side effects are judged 'do not significantly interfere with patients functioning' the score = 6)

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

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. Tick 'yes', 'no', or 'don't know' for each question below. If the symptom was present at baseline and grading remains unchanged, there is no need to answer the Naranjo questions.

	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?			

Post toxicity assessment

Tick ✓	What is the intended treatment based on today's assessment? Tick all that apply)
	No change to cannabis/continue current dose
	Cannabis ceased
	Cannabis dose reduced; please specify new dose below:
	Cannabis dose increased; please specify new dose below:
Yes	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
No	

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in 24hr	
Dose of THC/Total dose to be taken in 24hr	
Other dosing: Please specify:	

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

T₂ – 14 days post Baseline

Date of Assessment

DD/MM/YYYY

Time of Assessment (in 24hr clock e.g., 22:00)

HH:MM

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

Date of Death*

DD/MM/YYYY

****End survey here***

Please provide reason if today's assessment is not 14 days after baseline.

--

Indications of interest: *Please grade all symptoms. Indicate that each symptom has been assessed by ticking the square box next to each.*

Pain

Nil Mild Moderate Severe

If prescribing medical cannabis for pain, is this:

1st line 2nd or subsequent treatment not applicable

Nausea and Vomiting

Nil Mild Moderate Severe

If prescribing medical cannabis for nausea and vomiting, is this:

1st line 2nd or subsequent treatment not applicable

Appetite

Nil Mild Moderate Severe

If prescribing medical cannabis for appetite, is this:

1st line 2nd or subsequent treatment not applicable

Wellbeing

Nil Mild Moderate Severe

If prescribing medical cannabis for wellbeing, is this:

1st line 2nd or subsequent treatment not applicable

Anxiety

Nil Mild Moderate Severe

If prescribing medical cannabis for anxiety, is this:

1st line 2nd or subsequent treatment not applicable

<input type="checkbox"/> Sleep
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for sleep, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Seizures
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for seizures, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Other
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for 'other' symptom, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable

T₂– 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.

<input type="checkbox"/> Fatigue
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i> 1.Fatigue relieved by rest 2.Fatigue not relieved by rest; limiting instrumental ADL 3.Fatigue not relieved by rest, limiting self-care ADL
<input type="checkbox"/> Dizziness
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i> 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
<input type="checkbox"/> Euphoria
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i> 1.Mild mood elevation 2.Moderate mood elevation 3.Severe mood elevation (e.g., hypomania)
<input type="checkbox"/> Insomnia
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<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

Loss of appetite/anorexia

1 2 3 4 5 no symptom ungradable 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 5 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; hospitalisation indicated
5. Death

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/Hallucinations

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria-Delusions

1. No grading
2. Moderate delusional symptoms
3. Severe delusional symptoms; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

Hypotension

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria

1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalisation indicated
4. Life-threatening and urgent intervention indicated
5. Death

Palpitations

1 2 ungradable no Symptom not reported

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Intervention indicated

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

Other (if exists)

Please specify other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Tick ✓	Which symptom/harm is the most troublesome? <i>Tick one only.</i>
	Fatigue
	Dizziness
	Euphoria
	Insomnia
	Loss of appetite/anorexia
	Anxiety
	Confusion
	Delusions/Hallucinations
	Hypotension
	Decreased level of consciousness
	Palpitations
	Other
	Additional other
	Not applicable

Total dose of Cannabis given in the last 24 hours	Record dose here
Dose of CBD/Total dose taken in last 24hrs	
Dose of THC/Total dose taken in last 24hrs	
Other dosing: Please specify:	

How long has the patient been on this dose (<i>days</i>)	

Tick ✓	Clinical Global Impression (CGI) Global improvement: <i>Clinician to rate total improvement compared to patient's condition at admission to the project - how much has the patient 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

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

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

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

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

Post toxicity assessment

Tick ✓		What is the intended treatment based on today's assessment? Tick all that apply.
		No change to cannabis/continue current dose
		Cannabis ceased
		Cannabis dose reduced; please specify new dose below:
		Cannabis dose increased; please specify new dose below:
Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in 24hrs	
Dose of THC/Total dose to be taken in 24hrs	
Other dosing: Please specify:	

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. Tick 'yes', 'no', or 'don't know' for each question below. If the symptom was present at baseline and grading remains unchanged, there is no need to answer the Naranjo.

	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?			

Medication Cessation (complete this page if the intervention/medication of interest is ceased at any point during the study period)

Date of Assessment (medication cessation) DD/MM/YYYY

Tick ✓	Medication was ceased (related to indication of interest)
	Symptom resolved; please indicate date symptom resolved: DD/MM/YYYY
	Symptom continued unchanged
	Symptom/s worsened; please record NCI grade here:

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

What treatment did you subsequently initiate following the cessation of the medication of interest?

--

Ad hoc A - Unscheduled Harm/Toxicity Assessment

Date of Assessment

DD/MM/YYYY

Was there any benefit?

Yes

No

Tick ✓	What is the intended treatment based on today's assessment? Tick all that apply.
	No change to cannabis/continue current dose
	Cannabis ceased
	Cannabis dose reduced; please specify new dose below:
	Cannabis dose increased; please specify new dose below:
Yes	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
No	

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in 24hrs	
Dose of THC/ Total dose to be taken in 24hrs	
Other dosing: Please specify:	

Indications of interest: Please grade all symptoms. Indicate that each symptom has been assessed by ticking the square box next to each.

<input type="checkbox"/> Pain
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for pain, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Nausea and Vomiting
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for nausea and vomiting, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Appetite
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for appetite, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Wellbeing
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for wellbeing, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable

<input type="checkbox"/> Anxiety
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for anxiety, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Sleep
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for sleep, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Seizures
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for seizures, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Other
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for 'other' symptom, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable

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.

<input type="checkbox"/> Fatigue
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
1.Fatigue relieved by rest 2.Fatigue not relieved by rest; limiting instrumental ADL 3.Fatigue not relieved by rest, limiting self-care ADL
<input type="checkbox"/> Dizziness
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
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
<input type="checkbox"/> Euphoria
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
1.Mild mood elevation 2.Moderate mood elevation 3.Severe mood elevation (e.g., hypomania)
<input type="checkbox"/> Insomnia
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<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

Loss of appetite/anorexia

1 2 3 4 5 no symptom ungradable 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 5 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; hospitalisation indicated
5. Death

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/Hallucinations

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria-Delusions

1. No grading
2. Moderate delusional symptoms
3. Severe delusional symptoms; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

Hypotension

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria

1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalisation indicated
4. Life-threatening and urgent intervention indicated
5. Death

Palpitations

1 2 ungradable no Symptom not reported

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Intervention indicated

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

Other (if exists)

Please specify other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Tick ✓	Which symptom/harm is the most troublesome? <i>Tick one only.</i>
	Fatigue
	Dizziness
	Euphoria
	Insomnia
	Loss of appetite/anorexia
	Anxiety
	Confusion
	Delusions/Hallucinations
	Hypotension
	Decreased level of consciousness
	Palpitations
	Other
	Additional other
	Not applicable

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment

DD/MM/YYYY

Was there any benefit?

Yes **No**

Tick ✓	What is the intended treatment based on today's assessment? <i>Tick all that apply.</i>
	No change to cannabis/continue current dose
	Cannabis ceased
	Cannabis dose reduced; please specify new dose below:
	Cannabis dose increased; please specify new dose below:
Yes	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
No	

New dose of Cannabis	Record dose here
Dose of CBD/ Total dose to be taken in 24hrs	
Dose of THC/ Total dose to be taken in 24hrs	
Other dosing: Please specify:	

Indications of interest: *Please grade all symptoms. Indicate that each symptom has been assessed by ticking the square box next to each.*

<input type="checkbox"/> Pain
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for pain, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Nausea and Vomiting
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for nausea and vomiting, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Appetite
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for appetite, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Wellbeing
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for wellbeing, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable

<input type="checkbox"/> Anxiety
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for anxiety, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Sleep
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for sleep, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Seizures
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for seizures, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Other
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for 'other' symptom, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable

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)

<input type="checkbox"/> Fatigue
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
1.Fatigue relieved by rest 2.Fatigue not relieved by rest; limiting instrumental ADL 3.Fatigue not relieved by rest, limiting self-care ADL
<input type="checkbox"/> Dizziness
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
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
<input type="checkbox"/> Euphoria
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i>
1.Mild mood elevation 2.Moderate mood elevation 3.Severe mood elevation (e.g., hypomania)
<input type="checkbox"/> Insomnia
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<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

Loss of appetite/anorexia

1 2 3 4 5 no symptom ungradable 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 5 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; hospitalisation indicated
5. Death

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/Hallucinations

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria-Delusions

1. No grading
2. Moderate delusional symptoms
3. Severe delusional symptoms; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

Hypotension

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria

1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalisation indicated
4. Life-threatening and urgent intervention indicated
5. Death

Palpitations

1 2 ungradable no Symptom not reported

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Intervention indicated

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

Other (if exists)

Please specify other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Tick ✓	Which symptom/harm is the most troublesome? <i>(Tick one only)</i>
	Fatigue
	Dizziness
	Euphoria
	Insomnia
	Loss of appetite/anorexia
	Anxiety
	Confusion
	Delusions/Hallucinations
	Hypotension
	Decreased level of consciousness
	Palpitations
	Other
	Additional other
	Not applicable

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment

DD/MM/YYYY

Was there any benefit?

Yes

No

Tick ✓	What is the intended treatment based on today's assessment? <i>Tick all that apply.</i>
<input type="checkbox"/>	No change to cannabis/continue current dose
<input type="checkbox"/>	Cannabis ceased
<input type="checkbox"/>	Cannabis dose reduced; please specify new dose below:
<input type="checkbox"/>	Cannabis dose increased; please specify new dose below:
Yes	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:
No	

New dose of Cannabis	Record dose here
Dose of CBD/Total dose to be taken in 24hr	
Dose of THC/ Total dose to be taken in 24hr	
Other dosing: Please specify:	

Indications of interest: *Please grade all symptoms. Indicate that each symptom has been assessed by ticking the square box next to each.*

<input type="checkbox"/> Pain
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for pain, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Nausea and Vomiting
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for nausea and vomiting, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Appetite
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for appetite, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Wellbeing
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for wellbeing, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable

<input type="checkbox"/> Anxiety
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for anxiety, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Sleep
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for sleep, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Seizures
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for seizures, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable
<input type="checkbox"/> Other
<input type="radio"/> Nil <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
If prescribing medical cannabis for 'other' symptom, is this:
<input type="radio"/> 1st line <input type="radio"/> 2nd or subsequent treatment <input type="radio"/> not applicable

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.

<input type="checkbox"/> Fatigue
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i> 1.Fatigue relieved by rest 2.Fatigue not relieved by rest; limiting instrumental ADL 3.Fatigue not relieved by rest, limiting self-care ADL
<input type="checkbox"/> Dizziness
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i> 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
<input type="checkbox"/> Euphoria
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<i>NCI Criteria</i> 1.Mild mood elevation 2.Moderate mood elevation 3.Severe mood elevation (e.g., hypomania)
<input type="checkbox"/> Insomnia
<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> no symptom <input type="radio"/> ungradable <input type="radio"/> not reported
<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

Loss of appetite/anorexia

1 2 3 4 5 no symptom ungradable 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 5 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; hospitalisation indicated
5. Death

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/Hallucinations

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria-Delusions

1. No grading
2. Moderate delusional symptoms
3. Severe delusional symptoms; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

Hypotension

1 2 3 4 5 ungradable no symptom not reported

NCI Criteria

1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalisation indicated
4. Life-threatening and urgent intervention indicated
5. Death

Palpitations

1 2 ungradable no Symptom not reported

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Intervention indicated

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

Other (if exists)

Please specify other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other symptom/harm:

Other toxicity grade here:

1 2 3 4 5 Ungradable

Tick ✓	Which symptom/harm is the most troublesome? <i>Tick one only.</i>
	Fatigue
	Dizziness
	Euphoria
	Insomnia
	Loss of appetite/anorexia
	Anxiety
	Confusion
	Delusions/Hallucinations
	Hypotension
	Decreased level of consciousness
	Palpitations
	Other
	Additional other
	Not applicable