

Drug Science Project Twenty21

How to get started

For use by clinicians only – LIGHT VERSION FOR PUBLIC DOWNLOAD



Contents

- [About the project](#)
- [Project Protocol](#)
- [What you need to become a prescriber](#)
- [Data collection](#)
- [Patient consent](#)
- [Initial assessment](#)
- [Tracking patient progress](#)

About the project

Project Twenty21 is a registry aiming to **monitor the health outcomes of patients** using cannabis based medicinal products (CBMPs), creating the largest body of evidence in Europe for the safety and efficacy of CBMPs.

Drug Science hopes that the findings of Project Twenty21 will provide evidence for NHS funding where the benefits of treatment with medicinal cannabis is proven to outweigh the potential risks.

This real-world registry aims to target the following indications:

- **Anxiety Disorder** (from any cause, including anxiety from cancer or another debilitating condition)
- **Chronic Pain** (includes all sources of pain, eg. cancer pain, arthritic pain, nerve pain)
- **Multiple Sclerosis (MS)**
- **Post-Traumatic Stress Disorder (PTSD)**
- **Substance Use Disorder (as a harm reduction strategy)**
- **Tourette's Syndrome**
- **Epilepsy**
- **Attention Deficit Hyperactivity Disorder (ADHD)**

The project is currently operating within the private sector, as NHS funding for CBMPs for the above indications is not yet routinely available. This guide pertains to private independent clinicians and private clinics.

Protocol & Formulary



PROJECT PROTOCOL

Please familiarise yourself with our Project Twenty21 Protocol in order to understand fully the purpose and objectives of Project Twenty21.

FULL FORMULARY AVAILABLE ON REQUEST OF CLINICIAN

Clinicians prescribing through T21 must be with our medicine formulary and dispensing instructions. Expanded information for both clinicians and patients is available through the Sail system at the point of prescribing, and this is subject to ongoing change as products become available.

Our formulary consists of flower, oil and vape products from our T21 license producers. We ask that you prioritise prescribing product from our formulary, as only the products on our formulary are capped at £150 per month (in line with MCCA guidance). However, you are free to go off-formulary if you feel it is necessary and specify the reason at the point of prescribing.

What you need to become a prescriber

Please be aware that it can take longer than you might expect to setup as a prescriber of medical cannabis products, even if you are linking with an existing clinic, because they are controlled drugs. Make sure you have followed these steps as early in the process as possible to avoid delays getting started.

[DOWNLOAD FULL MCCS GUIDELINES HERE](#)



To prescribe medical cannabis, you must:

- ✓ Find suitable premises as an independent prescriber or link with an existing clinic
- ✓ Apply for your 'pink pad' (private controlled drug prescription pad)
- ✓ Familiarise yourself with the special prescribing system
- ✓ Review your indemnity insurance arrangements

Join the MCCS

We encourage you to become a member of the Medical Cannabis Clinicians Society. This is free for any clinician contributing to Project Twenty21 – simply include “Project Twenty21” in the field with your GMC number when registering.

As this is an observational study, Drug Science cannot give any advice or recommendations around the products on the T21 formulary. Instead, we encourage clinicians to connect with the Medical Cannabis Clinicians Society (MCCS) for educational materials and to share their experiences with other clinicians.



Becoming a member gives you access to a clinician Peer Support Group within which are some of the most experienced medical cannabis prescribers located all around the globe, and thus the opportunity to request a 1-2-1 mentor if needed.

In addition to their own educational materials, the MCCS provides links to various other learnings resources to help educate clinicians in medical cannabis and stay up to date with the latest industry news.

[REGISTER TO BECOME A MEMBER HERE](#)

Data Collection

We collect our patients' data for Project Twenty21 using software called Sail created by CB2 Insights.

You will receive live webinar training in how to use Sail from a member of the T21 team.

To access the Sail system, you will require a login for the Sail system – a user account with unique login credentials will be emailed to you from CB2 on completion of the training.



Any other clinic staff who will be involved in registry procedures will also be granted access via unique login credentials. At no point in time should login credentials be shared, even with individuals within the same clinic network. All users will only have access to patients at their assigned clinic.

In addition to your training, please download the Sail Patient Registry Manual - this provides step-by-step guidance on using the software.

[DOWNLOAD THE SAIL PATIENT REGISTRY MANUAL](#)

Patient consent

A Patient Informed Consent Form needs to be completed before the patient can be set up on the Sail system, and filed securely by the clinic (Drug Science does not store patient data).

If acting as an independent clinician, you can customise the T21 consent form for personal use prior to data collection. If operating from within a clinic structure, this should be customised for the clinic.

[DOWNLOAD THE PATIENT INFORMED
CONSENT FORM HERE](#)

Prior to patient registration, you must have:

- ✓ Confirmation of primary indication
- ✓ Confirmation of eligibility to be prescribed medical cannabis (at the discretion of the clinician)
- ✓ Provision of informed consent
- ✓ Confirmation as to whether the patient has previously been part of T21 at another clinic

If your patient has previously been part of T21 at another clinic, you will need to advise the patient's previous clinic that they have now moved (CC'ing in Drug Science). Then the new clinic must obtain the necessary patient consent and notify CB2 Insights directly to make the transfer.

Initial assessment

The patient will already have been setup on the Sail system and filled in their patient questionnaire(s), so this data will be pre-populated in Sail for the clinician to check through ahead of the initial assessment. This should speed up patient appointment time, enabling you to get to the point of prescribing more quickly.

10 weeks after the date that the patient's initial data is submitted in Sail (2 weeks prior to ideal follow-up dates), an automated email will be sent to the patient asking them to complete their questionnaires ahead of their next appointment.

- ✓ We ask that you make sure your patient is provided with adequate product information and any how-to guides that may be applicable to the product being prescribed – this should all be available within the Sail system.
- ✓ Please mark the prescription with 'T21'.
- ✓ Please read NHS guidance on potential drug interactions.

[NHS GUIDANCE ON POTENTIAL DRUG INTERACTIONS](#)

Tracking patient progress

All patient data collection for T21 is managed through the Sail system. To adhere to our project Protocol, you will be expected to conduct a minimum of 3-month assessments with each T21 patient over a 24 month period (or as long as the patient is part of T21).

As a support tool, patients can track their medication and symptoms in real time using the [Eva mobile app](#) by Alta Flora, a Twenty21 founding industry partner. This data cannot be accessed by T21 and is not linked to our own data collection.

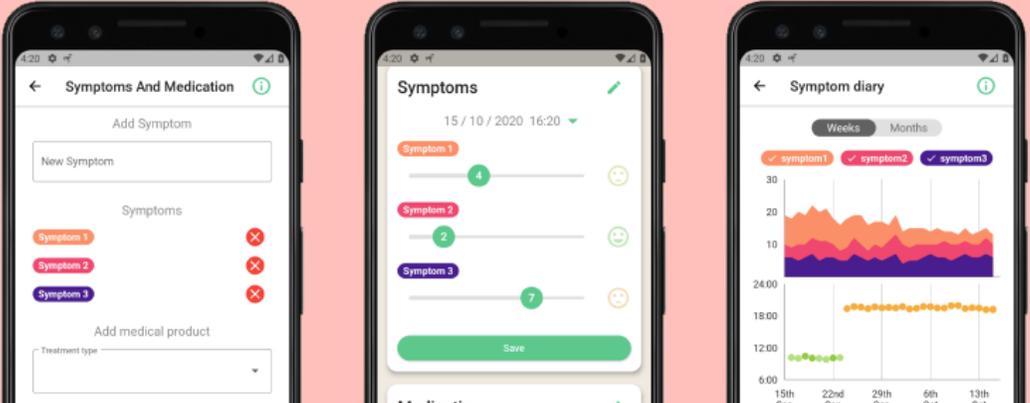
We ask that clinicians tell their patients about Eva at the first consultation, and encourage patients to download and start using the app as soon as they receive their prescription.



Add
your symptoms
and medication

Track
symptom
severity and
medication use

Explore
your data for
trends and
patterns



[Download
on Apple](#)



[Download
on Android](#)

Project Twenty21: Resources & Dosage Guidance

Medical Cannabis Explained: live training sessions

Drug Science has partnered with MCCS to offer exclusive online training for Project Twenty21 medical professionals. This training is intended to give you an in-depth, fully up-to-date knowledge of the medical cannabis products available to prescribe in the UK, together with the confidence to know what to prescribe according to a patient's indication.

Training duration is 3 hours, and takes place every 1-2 months over Zoom video conference. It is fully interactive and provides an opportunity for meeting other like-minded medical professionals across the UK.



[REGISTER HERE](#)

Drug Science resources

[FURTHER INFORMATION FOR PATIENTS, PRESCRIBERS & LATEST UPDATES](#)

[CLINIC DIRECTORY](#)

[SCIENTIFIC OVERSIGHT BOARD](#)

[DOWNLOAD OUR T21 ZERO TOLERANCE POLICY](#)

[DRUG SCIENCE MEDICAL CANNABIS EDUCATIONAL SLIDES](#)

(Aimed at medical students)

[PODCAST EPISODE 'MEDICAL CANNABIS, MUM AND ME':](#)

Prof. David Nutt interviews Lucy Stafford (t21 patient and director at patient led engagement for access, plea)



Practical Prescribing with Prof. Mike Barnes

Watch our 'Practical Prescribing' training video hosted by Prof. Mike Barnes (MCCS) on how to prescribe medical cannabis.

In the description below the video you will find a list of timecodes referring to the different sections in the video, so you can skip to the point of interest rather than having to trawl through the whole hour.

[PRACTICAL PRESCRIBING' TRAINING VIDEO](#)



Dr. Dani Gordon

Dr Dani Gordon is Vice-Chair of the Medical Cannabis Clinicians Society. She is a double board-certified medical doctor and international leading expert in both CBD and clinical cannabis medicine, after treating thousands of patients in Canada in a referral complex chronic disease practice. Dr Gordon trained the UK's first cannabis medicine specialist physicians and is a founding member and vice-chair of the UK Medical Cannabis Clinicians Society (MCCS).

[WATCH DANI'S BITESIZE EDUCATIONAL VIDEOS](#)

[ACCESS HER ARTICLES, TALKS AND PODCAST APPEARANCES](#)



Learning modules

The Academy of Medical Cannabis (TAOMC) provides an expansive and deep education in cannabis-based medicinal products and their related therapies. By working through this series of modules, you will be preparing yourself to actively consult with patients around these medicines, and where appropriate write prescriptions with the necessary grounding of knowledge and understanding.

You will need to continually refresh and update this training, in line with the requirements for medical practitioners of every school of medicine. Emerging research and continued developments will also allow TAOMC to proactively grow their content in real time.



[ACCESS LEARNING MODULES HERE](#)

KhironAcademy training

A highly regarded non-promotional educational tool for medical cannabis, provided by one of our licensed partners.

Project Twenty21 clinicians receive free access to this product- neutral CPD-certified Continuing Medical Education program, “KhironAcademy”. Clinicians receive practical guidance on the therapeutic use of medical cannabis acquired by KhironMed doctors from their experience treating over 21,000 patients at their clinics in Latin America.

[REGISTER HERE](#)

Although it does include company branding, this training resource does not promote the producer’s products.



MedCan Hub

Launched in Autumn 2020, the MedCan Hub is a free platform developed by NHS consultants to support doctors prescribing medical cannabis. It includes a large range of tools and tips for doctors to offer better care to patients.

[REGISTER HERE](#)

Although it does include company branding, this training resource does not promote the producer's products.

Cellen
Therapeutics
—
MedCanHub

MDT webinar series

CPASS has launched a new multi-disciplinary team (MDT) webinar series that will run until late 2021 and feature leaders on medical cannabis for UK nurses and healthcare professionals.

Each event is presented in two parts: the theory of a particular area of medical cannabis treatment (pain, mental health, neurology, oncology, women's health and palliative care) followed by a real-world case study. The series involves collaborations across medical sectors, clinics, private practice and organisations, with every MDT comprising of a Specialist Nurse, Specialist Consultant and Pharmacist.

The CPASS team are launching a resource platform where recordings of the webinar series will be made available for download.



[REGISTER TO ATTEND EVENTS HERE](#)

Start low, go slow



The following information is taken from the MCCS Prescribing Guidelines as Drug Science cannot give specific advice or recommendations around dosage:

[ACCESS THE MCCS PRESCRIBING GUIDELINES](#)



Generally, patients should be started on a low dose – about 10mgs of CBD and build up slowly to the average dose of CBD of 60-100mgs daily (usually in 2/3 divided doses).



It is unusual for people to need more than 150 mgs CBD or 20mgs THC daily in oil form or 1-2grams per day in dried flower form (for vaping).



Children with epilepsy can need to go higher – up to about 10-12mgs/kg. If you as the clinician feel it necessary to add in THC then again it starts low (even as low as 1mg THC) and builds up slowly.



Patients who insist on needing a very high amount - e.g. 4 to 5 grams of flower per day or more for their medical cannabis prescription based on their current usage should raise flags for problematic use. Although not always the case, these large amounts for the base of therapy, especially if using a high THC flower, should be discouraged, although there may be exceptions to this rule.

Dried flower dosage

More than 1g/day is available through Project Twenty21, although this would require a further payment as it is 30g that is capped at £150, so higher dosages would require additional payment.

International and national guidance states that flower, due to its mode of action and length of duration, should predominantly be used for breakthrough pain. Oils or other variations of CBPMs should be used as the main treatment.

Administration of flower through vaping has an onset of 10 minutes and lasts for approximately 1 hour, which is why it is used for breakthrough pain, as it is fast-acting with a shorter duration.

As Project Twenty21 is a medical study, we recommend patients have cannabis according to medical guidance. Prescribed doses in excess of the specified maximum risk encouraging addiction and/or diversion and are not recommended by T21.

Government advice

[LATEST GOVERNMENT ADVICE ON MEDICINAL CANNABIS](#)

[LATEST GOVERNMENT ADVICE ON SUPPLY OF UNLICENCED MEDICINAL PRODUCTS](#)

THE ACMD CBPMS ASSESSMENT REPORT INCLUDES THE FOLLOWING CONCLUSION WHICH RELATES DIRECTLY TO PROJECT TWENTY21:

The availability of a CBPM patient registry should be recognised as crucial for future assessments of the impact of the rescheduling of CBPMs in November 2018. The Government should continue to support the development of an official CBPM patient registry. Depending on whether the official CBPM patient registry is developed to be able to collect all necessary CBPM private prescription data, the Government may wish to consider how the official registry can interact with those in development outside of Government.

[ACCESS ACMD CBPMS ASSESSMENT REPORT](#)

For further support,
please contact:

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