Drug Science Project Twenty21

How to get started

For use by clinicians only

Drug Science

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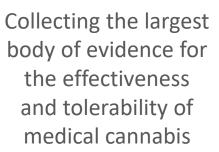
Why be part of Project Twenty21?





We're the UKs biggest national medical cannabis real-world registry / observational study

Multi-stakeholder partnership with academia, industry, clinicians and patients



Publication of data, regardless of whether favourable or not



Aiming to help patients access medical cannabis through clear, competitive pricing

The project is currently operating within the **private sector**, as NHS funding for CBMPs for the above indications is not yet routinely available. Drug Science hopes that this will result in enough **evidence for NHS funding** where the benefits of treatment with medicinal cannabis is proven to outweigh the potential risks.



Patient eligibility

To join the study, the patient must have a diagnosed condition that can be treated with medical cannabis at one of our participating clinics and then meet their chosen clinic's eligibility criteria.

Some clinics may ask that the patient has tried two other forms of treatment or therapies for their condition which have proven ineffective before considering medical cannabis. Conditions treated at our registered clinics include (but are not exclusive to):

- 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

Patient process & costs

- Patient chooses a clinic to from our <u>Clinic</u> <u>Directory</u> based on factors such as their condition, the clinic's specialisms and appointment availability
- Patient contacts the clinic directly to arrange their initial consultation – Drug Science is not involved with this process, as this is an observational study

- Clinics set their own consultation costs
- T21 product/prescription pricing updated March 2022 – <u>see website for details</u>
- Non-T21 products still available at the discretion of the prescribing doctor, but non-T21 price points will apply
- Dispensing and delivery costs absorbed into the prescription cost for T21 products



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 ONLY AFTER SIGNING OUR MEMORANDUM OF UNDERSTANDING. 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 set at T21 prices. 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 Clinicians Cannabis 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

WATCH THE SAIL DEMO TRAINING VIDEO



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. Drug Science Project Twenty21



Project Twenty21: Resources & Dosage Guidance

For use by clinicians only



Prescribing medical cannabis as a Psychiatrist

Dr Rebecca Moore is a Consultant Psychiatrist at one of our registered Project Twenty21 clinics, The Medical Cannabis Clinics.

In this video she talks about how she became interested in medical cannabis, as well as why and how she came to be part of the study.

WATCH ON YOUTUBE



Drug Science

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



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 a founding member and vice-chair of the UK Medical Cannabis Clinicians Society (MCCS). 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.

WATCH DANI'S BITESIZE EDUCATIONAL VIDEOS

ACCESS HER ARTICLES, TALKS AND PODCAST APPEARANCES





Sativa Learning

The newest training course, launched January 2022, is the Medical Cannabis module from Sativa Learning. It is a fantastic CPD-accredited resource for medical professionals wishing to learn how to become a medical cannabis prescriber, and includes over 2 hours of video content and first-hand accounts from Project Twenty21 prescribers and patients. The course has been developed by industry experts and takes a deep dive into 10 conditions for which cannabis has been shown to be effective.

Sativalearning



ACCESS COURSE 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





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).



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.



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).



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. For use by clinicians only



Drug Science resources

FURTHER INFORMATION FOR PATIENTS, PRESCRIBERS & LATEST UPDATES

CLINIC DIRECTORY

SCIENTIFIC OVERSIGHT BOARD

DOWNLOAD OUR T21 ZERO TOLERANCE POLICY

MEDICAL CANNABIS EDUCATIONAL SLIDES

(Aimed at medical students)

YOUTUBE CHANNEL FEATURING PATIENT CASE STUDIES



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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