

FAQ: CURE ID Treatment of Long COVID (TLC)

Patient Case Report Form

CURE ID for Long COVID Basics:

Q: What is the goal of this project?

A: Our goal is to collect data on medications you are trying for your Long COVID symptoms and whether you feel any of these medications have improved your symptoms, have had no impact, or have made your symptoms worse. We hope that researchers will use this information to help choose medications to study in large randomized controlled trials (RCTs), given that there are no FDA-approved treatments for Long COVID.

Q: What are we asking Long COVID patients (you) to do?

A: Share your treatment experiences by completing the CURE ID Treatment of Long COVID (TLC) case report form. We estimate it will take you 30-45 minutes to complete the full form. You can submit for approval once your case(s) contains information of at least one medication, one symptom and treatment outcome. This quick submission can be done in a shorter amount of time. You then can go back and add in as much or as little detail as you would like, after you have saved throughout or completed the initial quick submission of just the required details.

Q: How do I participate?

A: You will complete the CURE ID TLC case report form by going to the CURE ID website (<https://cure.ncats.io>) or downloading the CURE ID mobile app from the Apple App store or the Google Play store. Once you register, you will be asked to share your treatment experience by completing a case report form, after providing your informed consent. You are asked to register with an email (and optionally a name) so that CURE ID staff can contact you if there are questions or clarifications about your case(s). Your email and name are not shared with anyone outside of the staff at NCATS/NIH who run the CURE ID platform.

CURE ID and CDRC Basics:

Q: What is CURE ID?

A: CURE ID is an internet-based repository (a treatment registry) that lets the clinical and patient communities report use of drugs for difficult-to-treat diseases through a website, a smartphone or other mobile device. The CURE ID platform enables the crowdsourcing of medical information from health care providers, patients, and care partners to identify existing drugs that may be effective treatments for diseases that lack incentives for the development of new therapies. CURE ID was developed through the collaboration of the U.S. Food and Drug Administration (FDA) and the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH). FDA and NIH are also collaborating with the World Health Organization and the Infectious Diseases Society of America to assess the global utility of CURE ID. CURE ID has received generous support from FDA, as well as the HHS Office of the Secretary's Patient-Centered Outcomes Research Trust Fund. With support from FDA's Oncology Center of Excellence (OCE), CURE ID is expanding beyond infectious diseases, to capture cases of drug repurposing for rare cancers and other rare diseases.

Q: What is the CURE Drug Repurposing Collaboratory ([CDRC](#))?

A: CDRC is a public-private partnership led by the Critical Path Institute ([C-Path](#)), a non-profit 501(c)3 organization dedicated to catalyzing the development of new approaches to advance medical innovation and regulatory science. Initiated in June 2020 by C-Path and the [FDA](#), in partnership with the [NCATS/NIH](#), the CDRC is designed to capture real-world clinical outcome data to advance drug repurposing and inform future clinical trials for diseases of high unmet medical need.

Q: What partners are engaged in CURE ID's Long COVID efforts?

A: FDA and NCATS/NIH host the CURE ID platform which will be used to gather cases of Long COVID treatment with repurposed medications. The CDRC is engaging with FDA, NIH, clinicians, patients/care partners, and other interested stakeholders to conduct outreach to patients with Long COVID and clinicians treating Long COVID, to analyze data contributed, and to help determine how best to ensure that promising treatments are studied in large randomized controlled trials.

Partners and Collaborators include:

- [Patient Led Research Collaborative](#)
 - [Dysautonomia International](#)
 - [#MEACTION](#)
 - [SOLVE M.E.](#)
 - [Discovery, The Critical Care Research Network, part of the Society for Critical Care Medicine](#)
 - [Stanford University School of Medicine's Long COVID Clinic](#)
 - [Emory University School of Medicine/Grady Long COVID Clinic](#)
 - [U.S. FDA](#)
 - [NCATS/NIH](#)
 - [CDRC](#)
 - [CDC Public Health Informatics Fellowship](#)
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Data Sharing and Use:

Q: How will my data be used?

A: Anyone who goes to the CURE ID website will be able to view data submitted by clinicians and patients/care partners. Overall study data can be viewed as well as your data in your individual case report with all the details you entered (Others will not be able to see that you were the person who entered your case, it is fully de-identified). Anyone can access this data via the Explore feature on CURE ID, by searching for Long COVID as a disease and selecting case reports. Users will also be able to filter the data to see cases of particular interest.

Q: Will people know the case I published is mine (i.e., am I identified as the author of the case)?

A: No, all patient and care partner case reports are fully de-identified, in accordance with the [Privacy Act](#), so your name will not be shown as the author of your case. A limited number of CURE ID staff at NCATS/NIH will be able to see your name, but this information will not be shared publicly. If you prefer not to have even the CURE ID staff know, you could choose not to include your name in the registration process, only an email is required.

Q: What information about me will be shared publicly, even if my case is de-identified (i.e., my name is not shown as the author)?

A: All information that you share on CURE ID in the case report form or on discussion posts is made openly accessible. This means all other users will be able to view your case reports and discussion posts. This is because the goal of the community is to promote open data-sharing.

However, to protect patient privacy, we do not publicly show your name or other personal identifiable information (as defined by the [Privacy Act](#)) with any cases you submit.

Q: What will my case look like to others? Where do people see this information?

A: In the Explore feature on CURE ID, this is what other users would see when looking at all cases.

Other

Race

- American Indian or Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Unknown

Ethnicity

- Hispanic/Latino
- Not Hispanic/Latino
- Unknown

Patient-Submitted Report

Last updated on October 4, 2023

Patient 51-60 years | Female

Symptom(s) Muscle weakness, Fatigue, Loss of smell, Loss of taste, + 1 more

Drug(s) Hydroxyurea, Rivastigmine

[Leave your comments](#)

Patient-Submitted Report

Last updated on September 30, 2023

Patient 61-70 years | Male

Symptom(s) Post-Exertional Malaise (PEM), Fatigue, Nausea, Vertigo, Dizziness, + 5 more

Drug(s) Alpha-GPC, Amitriptyline, Boswellia, Budesonide, Low Dose Naltrexone (LDN), + 6 more

[Leave your comments](#)

If a user clicks to open a case, here is what other users would see for the full case report.

Case # f3c82d4e-d41b-42f9-96a0-6508f471c96a 📄 🔗

Submitted by Patient Mar 12 2024

Disease	Long COVID
Drug(s)	Low Dose Naltrexone (LDN) Valacyclovir

📄 *This drug is approved by the FDA for this disease/indication.

^ Collapse All

Case Characteristics ^

Age Group: 31-40 years
Sex assigned at birth: Female
Gender same as sex: No
Gender: Non-binary
Country Treated: United States
Race(s): White
Ethnicity: Not Hispanic/Latino

Other Conditions ^

Q: Where will my data be stored?

A: Data submitted to CURE ID is stored on an Amazon Web Service (AWS) server, hosted by NCATS/NIH. The information that is contributed as part of the CURE ID TLC study is then made publicly viewable (except names and email addresses, which are only visible to a limited number of NCATS/NIH staff, who monitor case submissions).

Q: Who owns the data?

A: You remain the owner of your data and have the right to remove it from the CURE ID platform at any time. However, if you choose to add your case to CURE ID, the platform has the right to make the data in that case report publicly accessible.

Q: Is my privacy/identity safe if I enter a case?

A: Yes! Your name (optional) and email address will not be shared publicly, and all other data entered as part of your case report will be de-identified to comply with the [Privacy Act](#). CURE ID staff at NCATS/NIH will be able to see that you are the author of the case, but your name (optional) and email will not be publicly visible to general users of CURE ID. You can be contacted through the CURE ID platform if other users comment on your case report. In this situation, you will receive an email and/or push notification that a comment has been made on your case (however, you can turn notifications off under your Account settings if you do not wish to receive these. If you respond, you will be shown as “Author of Report” but your name will not be visible.

Q: Will my name be shown anywhere else on the website/app?

A: If you submit a discussion post and choose not to anonymize yourself for that post or if you comment on another user’s case or discussion and choose not to anonymize your comment, then your name will be visible to other users.

Q: Why do I need to register with in order to submit a case report?

A: We ask all users who are submitting a case report or discussion post to register with an email address so they can be contacted by CURE ID staff if follow-up is needed, such as to ask a clarifying question about details in your case before it is approved.

Q: Will I be contacted by CURE ID staff?

A: Users who save cases but do not submit or who have errors in their case report may be emailed to ask: if they need assistance completing the form, can fix the incorrect information or clarify the error, or whether they wanted to submit their case but inadvertently hit save. This outreach will occur from the curesupport@nih.gov email address. Automated reminders are also sent for those cases that have been saved but not submitted.

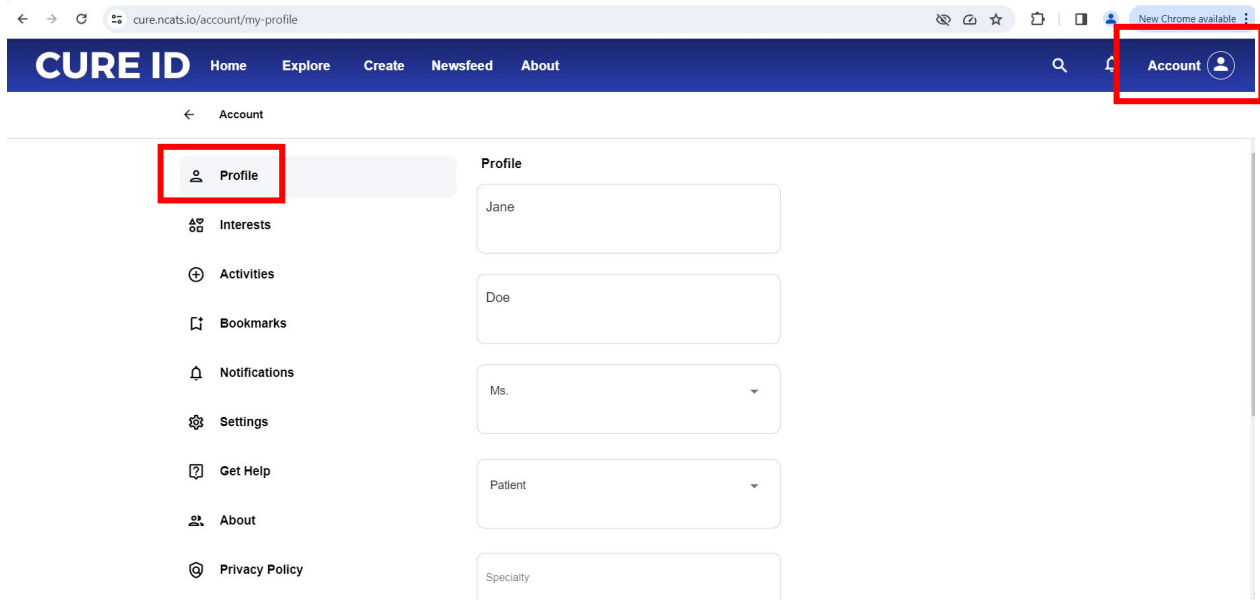
The only other follow-up that may occur is communication of summary results to participants who requested to be contacted in the future, or outreach to those individuals about opportunities to participate in future research by the same group.

Registered users of the CURE ID platform also receive an email newsletter once a month. However, users may choose to opt out of these newsletters in their notification settings under their Account.

Q: How can I see the information you collect about me?

A: You can visit the CURE ID platform to view the cases you have submitted. If you go to the “Account” section on the top right of the CURE ID platform and select “Activities” from the left menu bar, you can see any cases, discussions, etc. that you have saved or submitted. You can edit or delete your entries from this “Account” page, too.

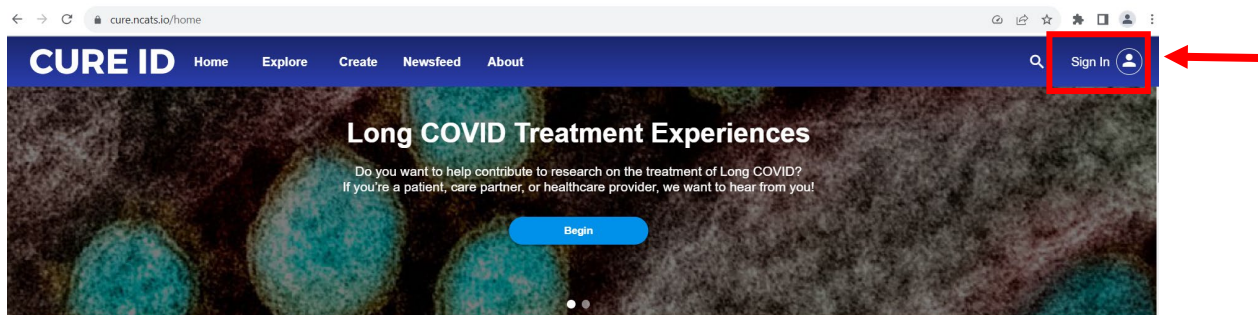
CURE ID collects details that you provide when registering. You are required to register with an email and password, and have the option to include your name, the type of participant you are (e.g., patient, care partner, healthcare professional), and any institutional affiliations or particular specialty areas of interest. This information can also be edited at any time by visiting your profile, under your Account. You can also add favorite diseases or medications to your profile to receive updates on those topics.



Navigating the Website and Mobile App/Where do I find...:

Q: How do I register on CURE ID?

A: To register on CURE ID (which you need to do to submit a case or discussion), click “Sign in” in the top right corner of the homepage or click “Account” on the bottom right corner of the mobile app.



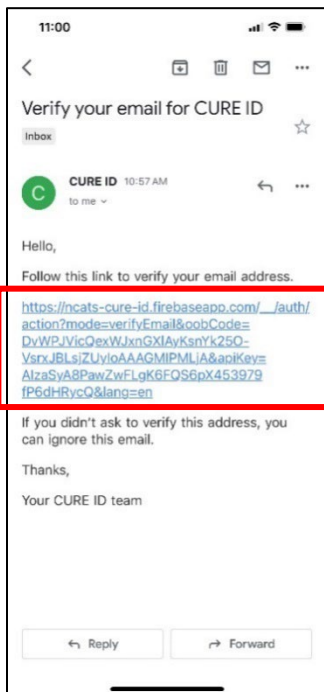
If you have an account already, you can sign in here. If you have not yet registered, click “Create One” at the bottom of the page.

You can also choose to sign up using a social sign-in, like Facebook or Google. If you choose to sign-in via a social sign-in, your name will still not be shown publicly if you enter a case. Only CURE ID staff at NCATS/NIH will be able to see these details.

To create your account, enter an email and password and select the checkboxes agreeing to the terms and conditions, then click “Sign up”.

★ Note: Your password needs to be at least 8 characters long and should include an upper-case letter, lower-case letter, and a number.

You will then be directed to go to your email account and click a link to verify your email.







In your email account, you will receive an email from noreply@ncats-cure-id.firebaseio.com. Click on the link in the email to verify your account.

You will then reach a screen that notes that your email has been verified.

You can now return to the CURE ID website to log-in.

Sign In

Sign in with your social network

Email sign in

Forgot password? [Reset](#)

Don't have an account?
[CREATE ONE](#)

By continuing, you are indicating that you accept our [Terms & Conditions](#) and [Privacy Policy](#).



Once you sign-in with the email and password you just created, or your social sign-in, you will be given the option to add additional information to your profile. This information is entirely optional, and you can skip this page if you don't want to share these details. You can always add them later by editing your Profile under "Account". Even if you share your name in the registration process, this information will not be shared on any submitted case reports. CURE ID staff at NCATS/NIH will be able to see your name (optional) and email, but no users will.. If you choose to submit a discussion post, you are given the option of whether you want your name to be shown as the author of the post or to be anonymized.

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Skip

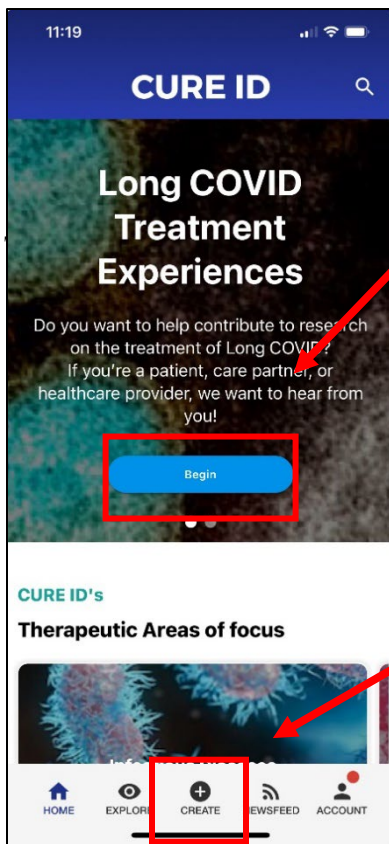
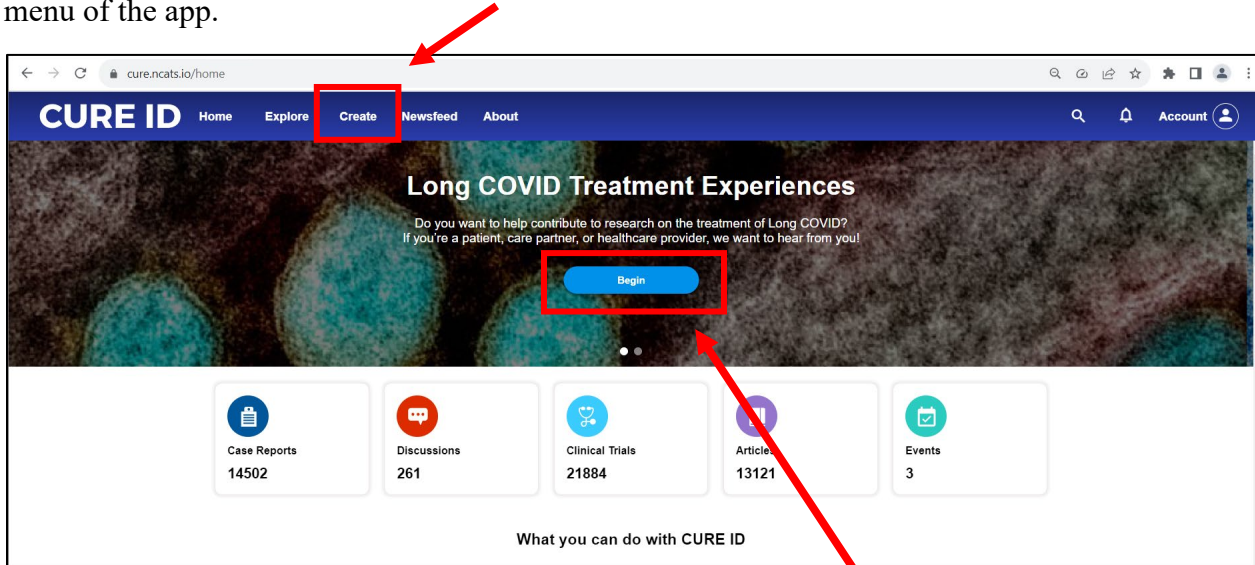
Tell us about yourself or skip to continue without sharing

Participant Type ▼

*You can always complete your profile on the 'Account' section.

Q: How do I add a case report?

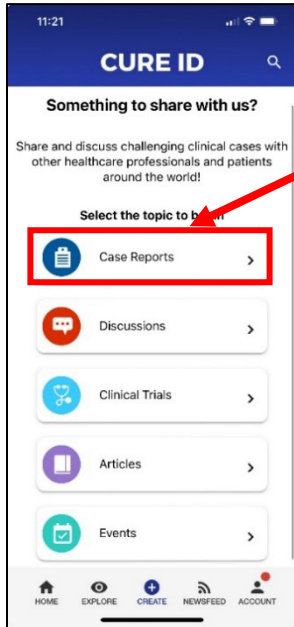
A: To add a case report, first click on “Create” from the top header of the website or the bottom menu of the app.



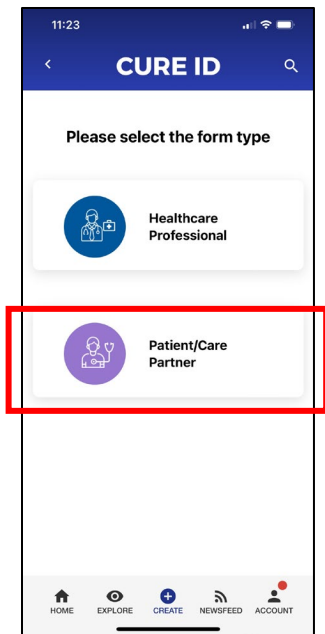
You can also add a case of Long COVID or MPOX through the banner on the homepage.

To enter a case for any disease, click on create from the menu.

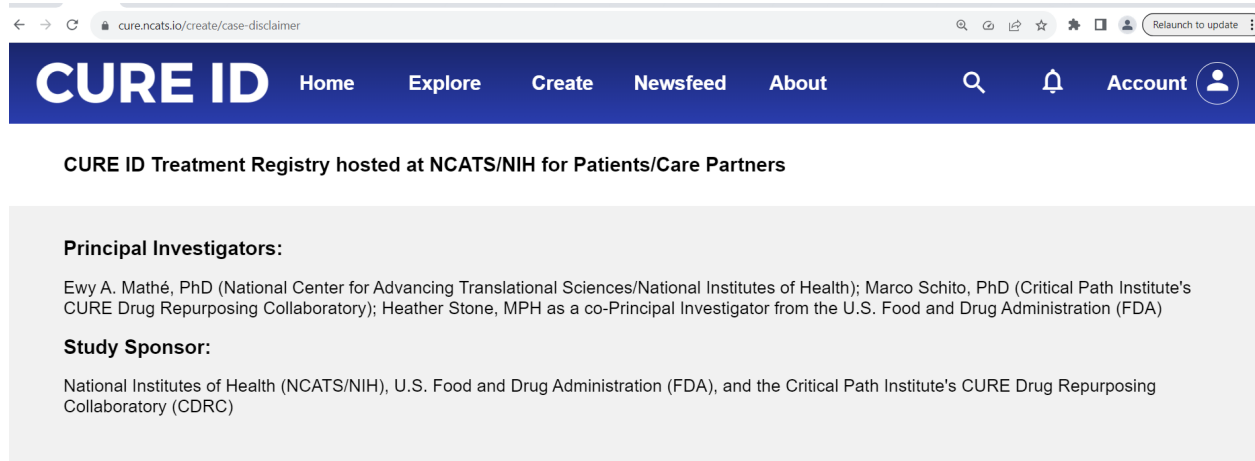
Select Case Reports from the menu to begin sharing your case.



You will then be asked which version of the case report you want to complete, the healthcare professional version (e.g., if you are a doctor submitting a case about a patient you treated), or the patient/care partner version (if you are submitting a case about yourself or a loved one).



You will then be presented with some screening questions, details about submitting your case, and an informed consent document which you must agree to in order to continue.



Submitting Cases to CURE ID

CURE ID is a database for use by healthcare providers and public health officials to report disease case studies where existing drugs have been used in new ways. Patients and care partners/caregivers may also share case reports describing their treatment experiences on the platform.

What to Expect When Entering a Case Report:

- For many diseases, the case report form can be completed in 5-20 minutes.
- For diseases with many symptoms and treatments (e.g., Sarcomas, RASopathies, Long COVID), the case report form may take 30-45 minutes to complete.
- A case report form may be completed by either a healthcare provider, a person with the condition, or by a loved one or care partner on the patient's behalf, if the patient needs additional support or is under 18 years of age.

Case Report Criteria:

Case report submissions are expected to meet certain criteria and FDA and NIH maintain the right to remove submissions that do not meet the inclusion criteria listed below, which are flagged by users or CURE ID moderators (e.g., concern that a case report was made up, dangerous suggestion, etc.), or if the case report is considered otherwise inappropriate or offensive.

- At this time, CURE ID is limited to the collection of case reports regarding the treatment of patients with certain diseases (e.g., infectious diseases, Sarcomas, RASopathies, and Long COVID); cases of patients with other diseases will be excluded.

- CURE ID is limited to treatment of human diseases; reporting medications to treat animals will be excluded.
- Cases must contain treatment with a medication.

Minimum Information for Case Report Acceptance:

The minimum information required for a case report to be accepted and approved is:

- **Disease and/or Symptom or Presentation**
- **Medication**
- **Treatment Outcome (including Outcome Unknown/Not Yet Determined)**

Cases that are submitted without the minimum data will be rejected or returned to the user for further details to be added.

Informed Consent & Disclaimer

By submitting a case report form in CURE ID, you are invited to take part in a research study.

The purpose of the study is to learn whether healthcare providers, patients, or their care partners/caregivers feel that medications patients are taking have made their disease (or symptoms of their condition) better, have had no impact, or have made them worse.

Potential Risks:

- We believe there are minimal risks associated with this research study; however, a risk of breach of confidentiality always exists and we have taken steps to minimize this risk.
- While your name (optional) and email are collected, in addition to information about your demographics, symptoms, and treatments, this information will be secured and protected to comply with the Privacy Act of 1974, as amended (5 U.S.C. 552a).
- While the research is of minimal risk, there are also no direct benefits to you for your participation in the study. **Your contributions may, however, help to inform future research on potential treatments for conditions with unmet medical need.**

Protecting Patient Privacy:

- Individuals entering information in the case report form **should not include any personally identifiable information (PII) about the patient, in either text or uploaded images** (e.g., patient name, dates, medical records number, identifiable markings such as tattoos or birthmarks, etc. – these should be covered with a black box or otherwise removed from images/documents).

Images or documents that include PII will be denied. CURE ID moderators will review all case reports and may make minor modifications to the content to ensure patient privacy before approval.

Additional Details:

- Taking part in this research project is voluntary and there is no compensation for your participation. You do not have to participate, and you can stop at any time.
- **Clarifying questions may be asked of the author** by CURE ID moderators or other users.
- Cases can always be edited or deleted under the user's Account and Activities page.
- **If you have questions about this project or require assistance entering your case**, you may contact the CURE ID staff and researcher(s) at curesupport@mail.nih.gov. **CURE ID staff are available to assist users in entering their case by video call, phone call, or by email.**

By clicking "I agree" below you are indicating that you are at least 18 years old and have read this consent form and agree to participate in this research study. Please print a copy of this page for your records.

I agree to the terms and conditions and agree to participate in this research study.

CANCEL AGREE

Now you are ready to submit your case! Enter the disease and the form will adjust to the correct case report form for that disease (e.g., a cancer case report form if you enter sarcoma, or a Long COVID case report form if you enter Long COVID).

CURE ID Home Explore Create Newsfeed About

Step 1 of 21

Disease

Thank you for choosing to create a case report of your treatment experience.

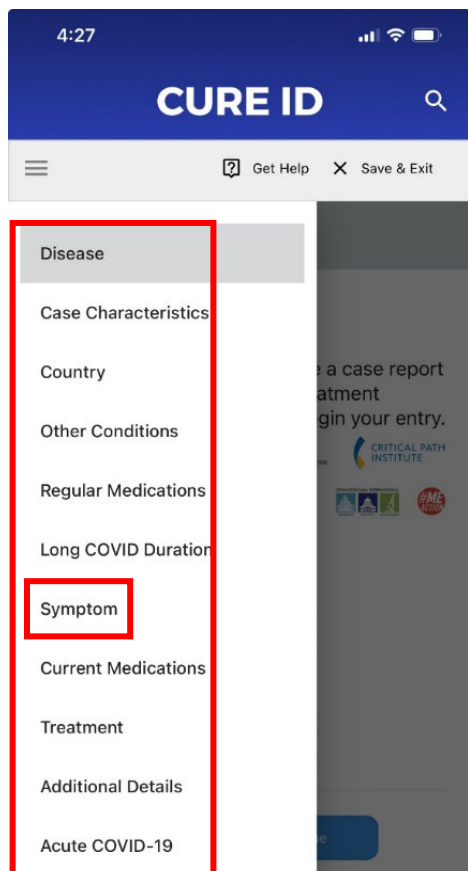
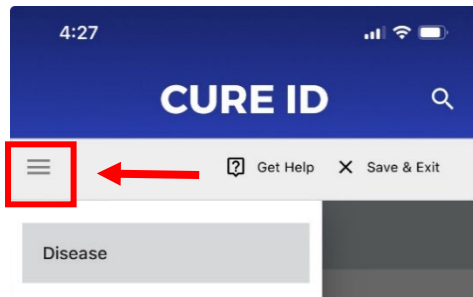
What is the disease that you are reporting that you received treatment for? *

Note: Users may add a term that is not currently in the list by typing the term and pressing enter.

Enter disease

Q: How do I navigate throughout the Case Report Form on the mobile app, without repeatedly clicking Continue?

A: On the mobile app, if you click the three horizontal lines in the top left corner of the screen, a menu will open and you can select the section you wish to navigate to. Keep in mind at a minimum a disease/symptom, medication and treatment outcome must be entered for submission of a case report.



Select any of the sub-headings from the menu to navigate to that section of the case report form.

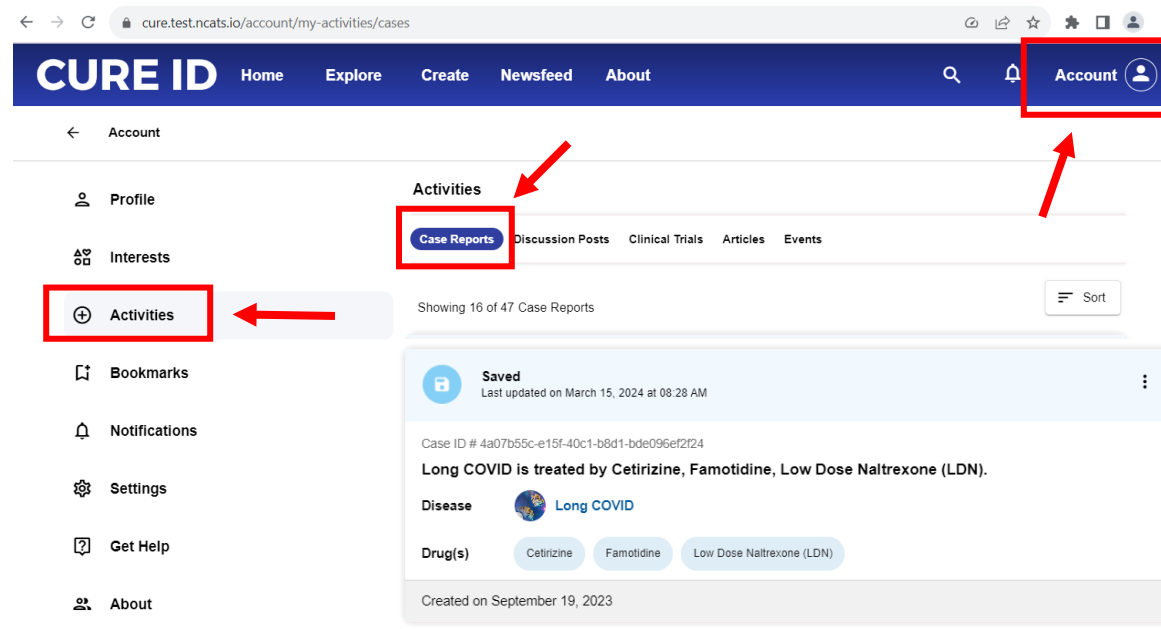
Q: Can I save my case part way through if I need a break?

A: Yes, absolutely! Your case automatically saves, every time you hit the continue button, but to make sure you don't lose any information if you leave the form, be sure to select the "Save and Exit" button on the top right of the screen in the case report form. You may then return to the case at a later time to make edits or add any details to your case report.



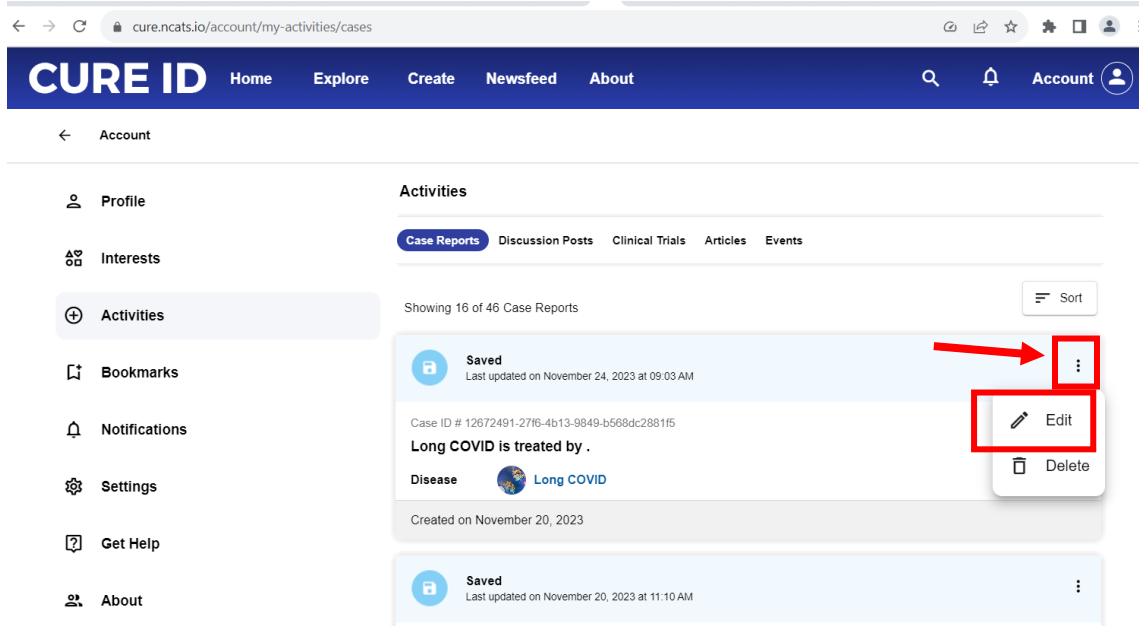
Q: Where can I find my saved case reports?

A: You can find your saved and submitted content (case reports, discussions, etc.) under your "Account", within the "Activities" section.



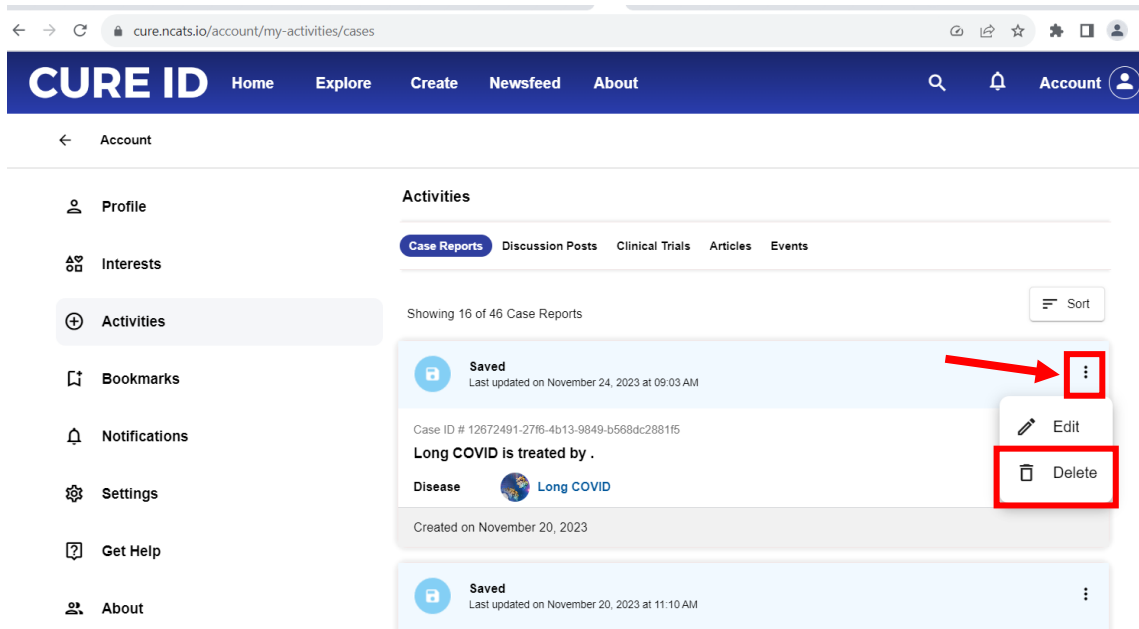
Q: How do I edit a previously saved or submitted case report?

A: To edit a case report or other entry, select the three vertical dots and click “Edit”



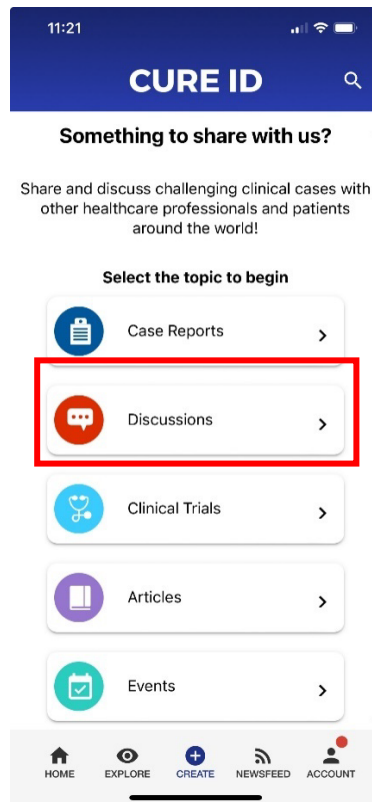
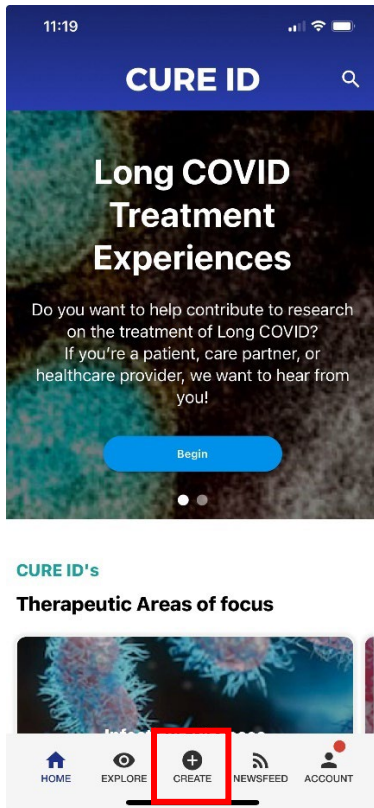
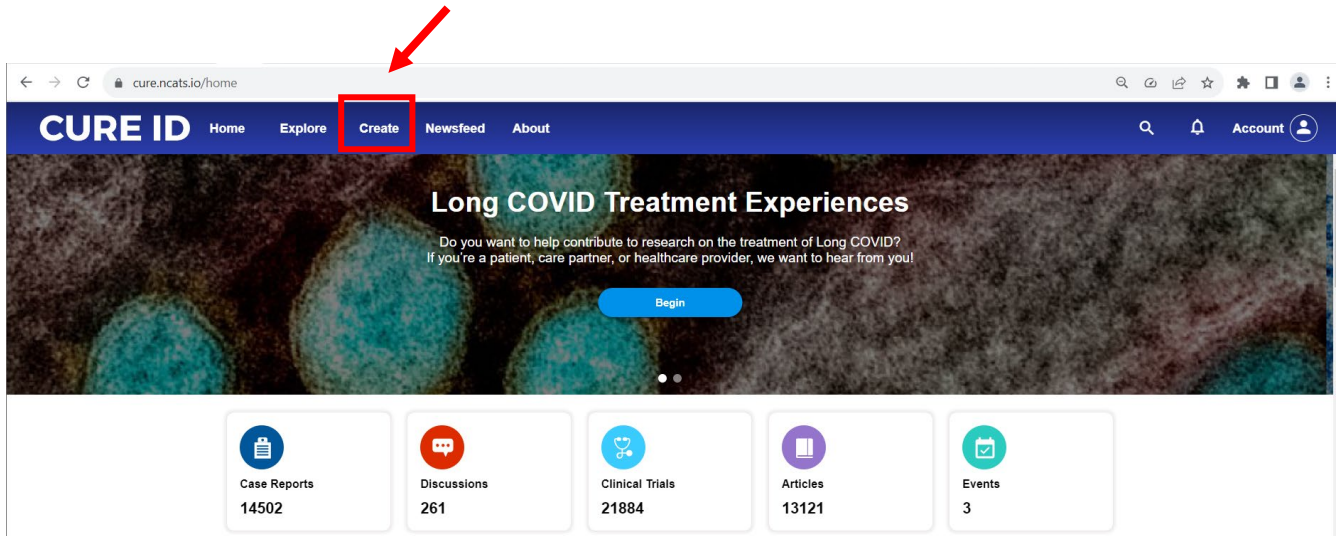
Q: How do I delete a case report I previously saved or submitted?

A: Select the three vertical dots next to the case and then select “Delete”.

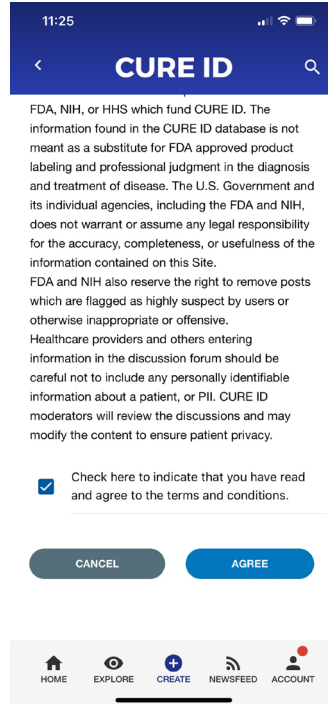
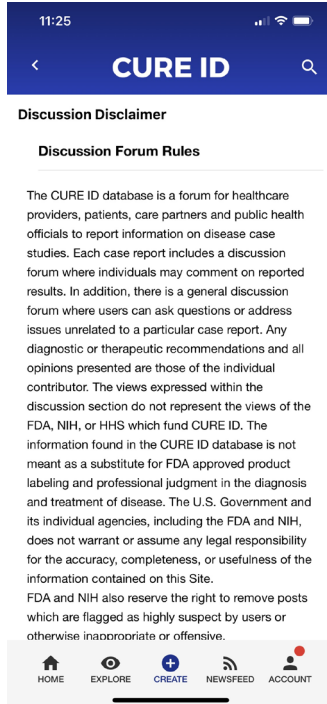


Q: How do I add a discussion post?

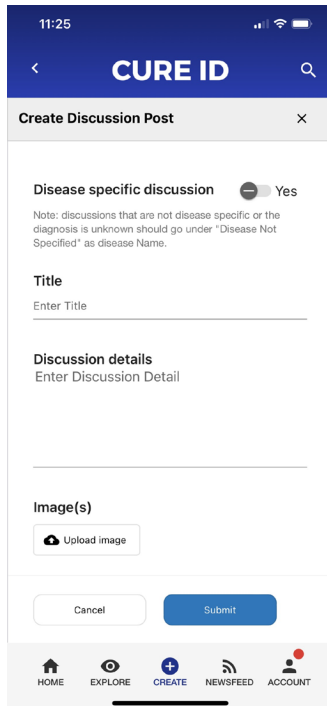
A: To add a discussion post, go to “Create”, and then select “Discussions”.



You'll then see a Discussion Disclaimer which you will need to agree to.



Now you're ready to enter your discussion!



Drug Repurposing:

Q: What is Drug Repurposing (also known as off-label use)?

A: Drug repurposing involves identifying existing drugs that may be effective for diseases that the drugs were not initially developed for. Drug repurposing includes drugs or medications that are being used in a new way, such as to treat a different disease from the one it was originally studied and approved to treat; in a very novel dose, route, or duration; in a new combination with other drugs, or in a new population (e.g., pregnant patients, pediatrics, neonates, etc.).

Q: How do I know if the drug I am taking is repurposed?

A: All existing, FDA-approved drugs that are being used to treat Long COVID are repurposed drugs, as there is currently no approved treatment that has been demonstrated to be safe and effective for Long COVID. An example is: Low-dose naltrexone for Long COVID is an example of a repurposed drug.

You can determine if a drug is repurposed by looking at the FDA approved drug label (drugs@FDA). If the condition you are taking it for is listed in the section entitled “Indications and Usage”, then the drug has been determined by FDA to be safe and effective for your condition and has been approved for use and marketing for that indication and population. If, however, the reason you are taking the drug is not listed in the “Indications and Usage” section on the label, then it means the drug is being used “off-label” and is an example of a repurposed drug. Repurposed drugs may also describe drugs that are being used for the same disease, but in a very different way such as a novel dose, duration, population, or combination.

Miscellaneous:

Q: Will I be compensated for participating?

A: No, participation is voluntarily and there is no compensation available for participation.

Q: Will my doctor(s) be contacted?

A: No.

Q: What if I live outside the United States?

A: CURE ID is accessible worldwide and is open to data/case reports from around the world. If you live outside of the U.S., we encourage you to submit your cases as well.

Q: Where can I learn more, ask additional questions, or ask for help if I'm having trouble entering my case?

A: If you have questions about this project or require assistance entering your case, you may contact the CURE ID staff and study researcher(s) at: curesupport@mail.nih.gov. CURE ID staff are available to assist users in entering their case by video call, phone call, or by email.

If you would like to be involved in the CDRC public-private partnership that supports CURE ID, email: CDRC@c-path.org.
