

FDA Drug Topics:

CURE ID:

Capturing Clinician's Experiences Repurposing Drugs
to Inform Future Studies in the Era of COVID-19

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Disclaimers

Heather Stone reports no financial disclaimers.

Discussion of Unapproved use

This presentation will contain significant discussion of the use of medical products for diseases and conditions that are not included in the FDA approved labeling. The discussion should not be construed as promoting unapproved uses of approved drugs, or that the data should be used for anything more than hypothesis-generation.

Intent and Limitations of Data

CURE ID is not intended to be used by pharmaceutical companies or manufacturers to advertise or promote unapproved uses of approved drugs

Individual case reports are insufficient to establish the safety or effectiveness of a new use of an approved product

Inclusion of data in the CURE ID repository also does not indicate that FDA, NIH, or other CURE ID partners endorse its validity, reliability, or usefulness in making individual patient treatment decisions

Learning Objectives

Discuss the intent behind CURE ID.

Demonstrate the mobile app and its features.

Explain the potential uses of CURE ID.

Summarize the limitations of CURE ID.

Outline

Overview and Context

- Diseases

- Drug Development

- Drug Repurposing

CURE ID Platform

- Background

- Demo

- Case Study: Nontuberculous Mycobacteria

- Data and FAQ

- Use for COVID-19

- CURE Drug Repurposing Collaboratory



Context of the Problem

What do these diseases have in common?

Parasites/protozoa

Sarcocystis

Anasikiasis

Dracunculiasis

Dirofilariasis

Fascioliasis

Paragonimiasis

Clonorchis

Babesiosis

Anaplasmosis

Balantidium

Sparganosis

Microsporidiosis

Loa loa

Plasmodium knowlesi

Enterophthoromycosis

Toxoplasmosis in pregnancy

Trichinellosis

Myiasis

Balamuthia mandrillaris

Acanthamoeba

Naegleria

Bacteria

Melioidosis

Nocardia

Whipples disease

Oroya fever

Atypical mycobacteria

Buruli ulcer

Fungi

Penicillium marneffii

Mycetoma

Xerophilum rostratus

Viruses

Dengue

Japanese encephalitis

Rabies

CCHF

Marburg/Lassa/Ebola

Zika/Chikungunya

West Nile

Western/Eastern encephalitis

Powassan

California encephalitis

Rift valley fever

Yellow fever

Creutzfeldt-Jacobs

MERS

SARS

COVID-19

What do these diseases have in common?

Parasites/protozoa

Sarcocystis

Anasikiasis

Dysentery

Trichinellosis

Myiasis

Balamuthia mandrillaris

Acanthamoeba

Viruses

Dengue

Japanese encephalitis

Babesiosis

They all lack sufficient approved treatments.

Balantidium

Sparganosis

Microsporidiosis

Loa loa

Plasmodium knowlesi

Enterophthoromycosis

Toxoplasmosis in pregnancy

Atypical mycobacteria

Buruli ulcer

Fungi

Penicillium marneffii

Mycetoma

Exerohilum rostratus

California encephalitis

Rift valley fever

Yellow fever

Creutzfeldt-Jacobs

MERS

SARS

COVID-19

Current State....

For FDA drug approval and marketing, a sponsor must submit a new drug application.

When there is no commercial incentive, diseases are often neglected, trials are not funded and drug discovery ceases.

A significant percentage of the world's population suffers from an infectious disease with no approved therapy; many others suffer from infectious diseases which have one or more approved therapies, but from which they are unable to benefit.

Current State, cont.

Upon approval, drugs are labeled for those indications or diseases sought by the drug sponsor for which there is substantial evidence of effectiveness.

Once a drug is approved, based on knowledge and professional judgement, physicians may take the responsibility for prescribing drugs for different populations, doses and diseases not listed in the approved label.

Q: So why aren't there any approved treatments for some infectious diseases or sufficient therapies for many others?

A: Because the commercial incentives for drug development may not work for all diseases and in all places...

Some of the challenges

Insufficient funding of research and development directed towards identifying effective therapies for diseases with high public health need, but low commercial value.

Even where there is anecdotal evidence of drug activity for a new indication, a commercial sponsor is unlikely to conduct formal clinical trials if the investment needed for a new indication will not be recouped through sales.

Academic or non-commercial institutions may perform studies demonstrating the value of a drug in a new indication, but they don't have the capacity to sponsor a drug application that can be reviewed by FDA.

Additional Challenges

Companies with an approved drug are unlikely to seek additional indications if market dynamics do not support the investment.

Companies are unlikely to pursue additional indications for older drugs that are no longer patent-protected, because a generic drug can be substituted.

For certain infectious diseases that are found in lower resource countries, the market incentives may not favor investment.

It may also prove very difficult to identify effective therapies for some infectious diseases.

For all of these reasons, there remain many tropical infectious diseases, parasitic diseases, drug-resistant infections and emerging infections that lack sufficient approved treatment.



What is Drug Repurposing?

Drug repurposing is the identification of potential novel uses of existing drugs.

What kinds of new information can be gleaned from looking at existing drugs?



Doctors may discover **new ways** of treating diseases.

Doctors may discover **new combinations** of drugs that are useful.

Doctors may discover **new dosing regimens and durations of therapy.**

Doctors may discover **new populations** that can benefit from existing treatments.

Doctors may discover that unapproved uses **do not work or are harming** patients.

What can be done for diseases lacking adequate approved treatments?

Clinical experience on how existing drugs are being used can be collected, so that promising candidates, drug combinations, and treatment regimens are quickly identified, and clinical trials are conducted to investigate these new uses.

Examples of approved drugs repurposed for infectious diseases

Drug	FDA approved indications	Uses documented in Literature/Guidelines
Imipenem	Lower respiratory tract, Urinary tract, Intraabdominal, Gynecologic, Bacterial septicemia, Bone and Joint, Skin and skin structure, Endocarditis, Polymicrobial infections	Nocardia
Azithromycin	Bacterial exacerbation of chronic bronchitis, Bacterial sinusitis, Pharyngitis/tonsillitis, Skin infections, urethritis/cervicitis, Genital ulcers, Pneumonia (CAP),	Trachoma
Levofloxacin	Pneumonia (CAP), Skin infections, Prostatitis, Plague, Anthrax, Urinary tract infections, Bacterial exacerbation of chronic bronchitis, Bacterial sinusitis	Tuberculosis, Oroya fever
Pentamidine	Pneumocystis Jirovecii	Trypanosomiasis
Ambisome	Aspergillus, candida, Cryptococcus, febrile neutropenia, visceral leishmaniasis,	Acanthamoeba
Ivermectin	Strongyloides, Onchocerciasis	Lymphatic filariasis, Scabies, Lice
Atovaquone	Pneumocystis	Babesiosis
Ceftriaxone	Lower Respiratory Tract Infections, Skin Infections, Urinary Tract Infections Pelvic Inflammatory Disease Bacterial Septicemia, Bone and Joint Infections, Intra-abdominal Infections, Meningitis, Surgical Prophylaxis	Whipple's disease Lyme disease
Rifampicin	Tuberculosis, Meningococcal prophylaxis	Brucellosis

Advantages of repurposing existing drugs

Time and cost to develop a new indication for an existing drug may be significantly less compared to developing a new drug from scratch because:

Most of the non-clinical drug development has already been done including chemistry, manufacturing and control, animal toxicology and clinical pharmacology

There is clinical data on safety in a population that may be relevant to the novel use

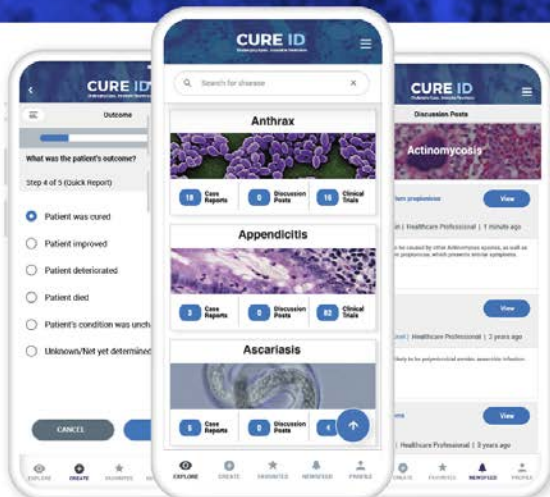
Drug Repurposing vs. De Novo Drug Development



A Platform to Capture Novel Uses of Existing Drugs



CURE ID
Challenging Cases... Innovative Treatments



Challenging Cases... Innovative Treatments

- +** **CONTRIBUTE**
Contribute your knowledge and expertise
- 👁️** **EXPLORE**
Explore experiences of clinicians globally
- 💬** **DISCUSS**
Discuss and share your most challenging clinical cases and treatment questions

What is CURE ID?

It is an internet-based data repository developed as a collaboration between the U.S. Food and Drug Administration (FDA) and the National Center for Advancing Translational Sciences, a part of the National Institutes of Health (NCATS/NIH).

It was developed with support from the Infectious Diseases Society of America (IDSA), the Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO).

It gives the global clinical community the opportunity to report novel uses of existing drugs for patients with difficult-to-treat infectious diseases through a website, a smartphone or other mobile device.

CURE ID Goals

To enhance the understanding of new uses of approved medical products.

To facilitate clinical trials and drug development.

To serve as a resource for physicians to share information where no FDA approved product (which has been proven to be safe and effective) exists for the new use.

Where can CURE ID be found?

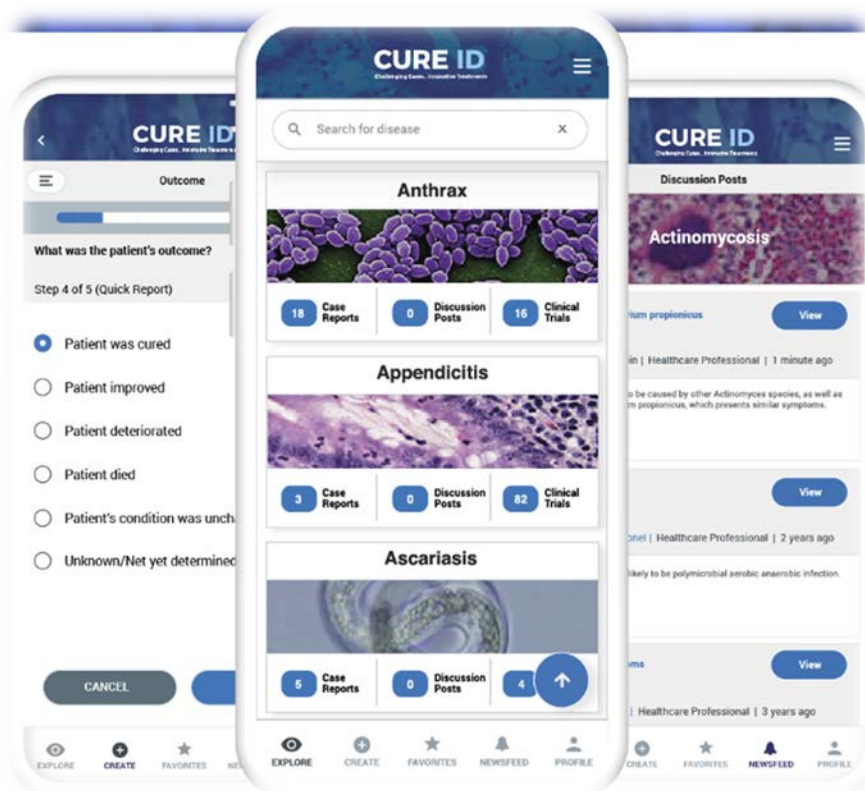
FDA

Visit:

<https://cure.ncats.io>

OR

Download from
the App or Play
store as “**CURE ID**”



CURE ID – A mobile app to help clinicians, regulators and drug developers

Share cases - report your own cases and read cases from other clinicians around the world of neglected infectious diseases with no sufficient approved therapies

Communicate – engage directly with communities of disease experts around the world

Access information – view information on approved therapies for each disease and on active clinical trials for each disease

Potential uses of CURE ID

Serve as a rapid communication platform for healthcare providers during an outbreak, providing for systematic case-sharing, discussions, and the latest literature.

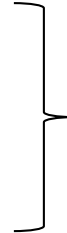
Facilitate the sharing of information on potential therapies for diseases which lack available, approved treatments and inform current and future clinical trials, serving as an important bridge between unstructured anecdotal reports and robust randomized trials ultimately required for drug approval.

Enable the exchange of opinions from global communities of experts.

Help to identify potential new uses for existing drugs, and limit unhelpful or harmful uses.

How can the global Infectious Disease community participate?

Neglected infectious diseases
Antimicrobial resistant organisms
Emerging threats



Insufficient or No
Approved
Therapies

Initial Pilot Priority Diseases:

COVID-19

Mycetoma

Atypical mycobacteria

Drug-Resistant Gonorrhea

Rare and Resistant Fungal Infections

Multi-drug resistant gram negatives (MDRGNB)

Platform Features



EXPLORE

View reported case reports (from individual clinicians and the published literature) individually and in aggregate, as well as discussions and clinical trials



CREATE

Create your own case report or discussion post using an easy electronic/mobile platform



COMMENT

Join the conversation by commenting on case reports and discussion posts from other users



NEWSFEED

Stay up to date on the latest infectious disease news, journal articles, events, and submissions to CURE ID

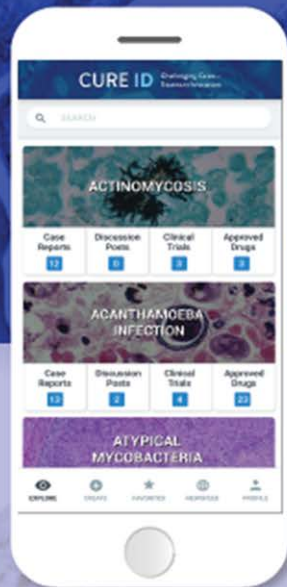
EXPLORE

Search by disease

View clinical trials

Look up published cases

Review user-submitted cases

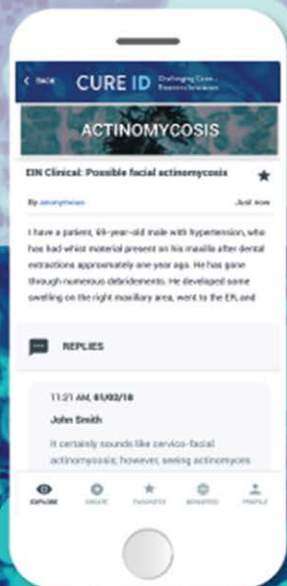
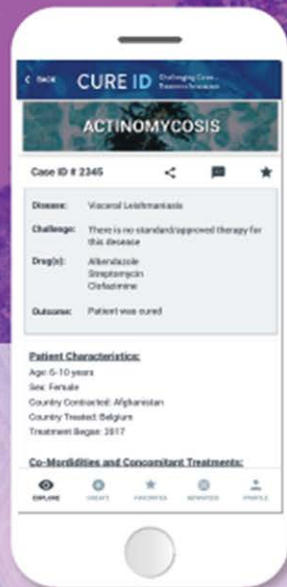


CONTRIBUTE

Enter or update a case

Participate as a curator

Get involved in the initiative



DISCUSS

Ask your questions and get replies

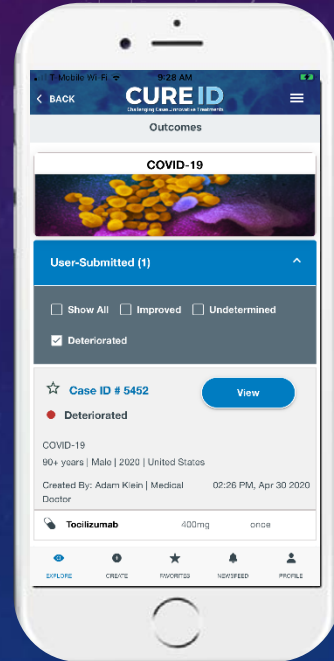
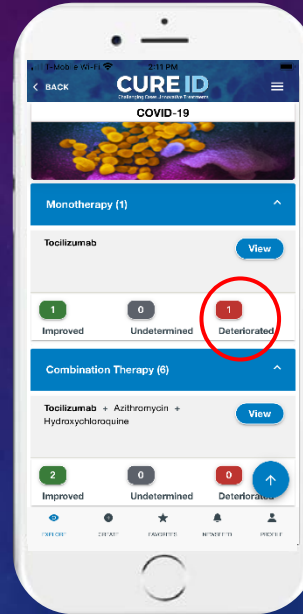
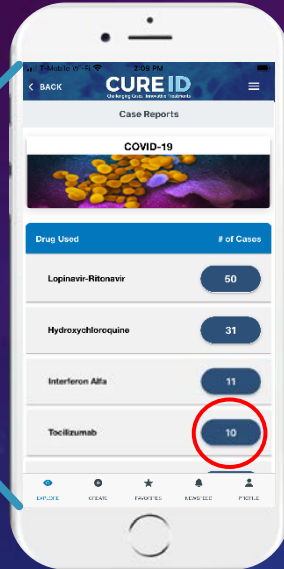
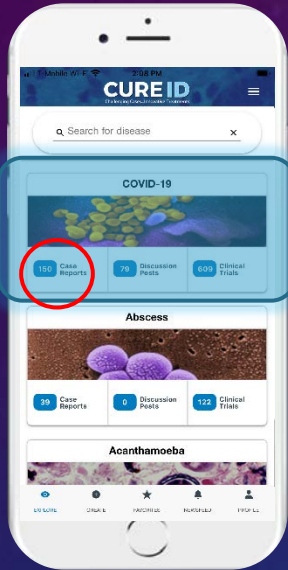
View others' discussion posts

Comment on others' cases

Consult with colleagues



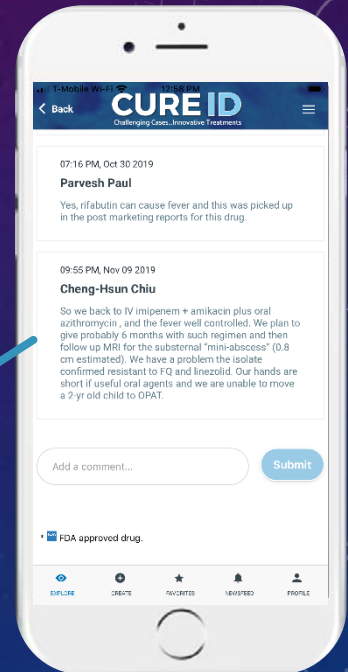
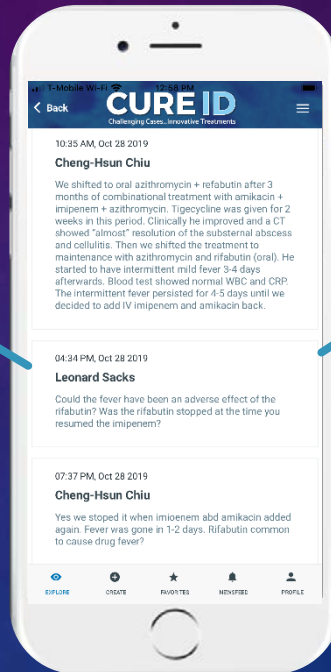
EXPLORE



CASE REPORTS

EXPLORE

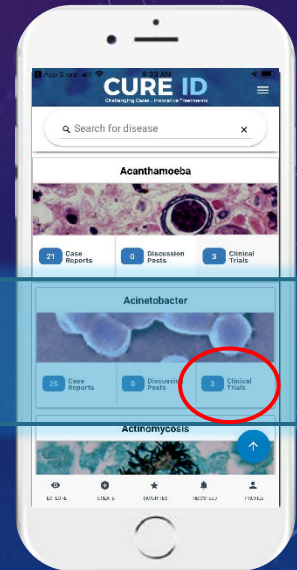
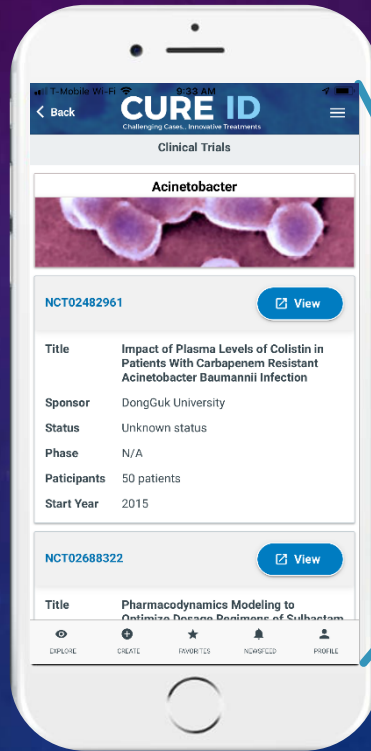
DISCUSSIONS





EXPLORE

CLINICAL TRIALS





CREATE



CASE REPORTS

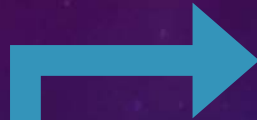
Share your experience with an infection that was difficult to treat



Create Case Report



Create Discussion Post



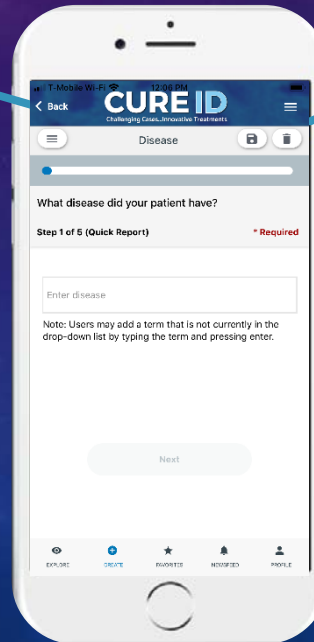
EXPLORE

CREATE

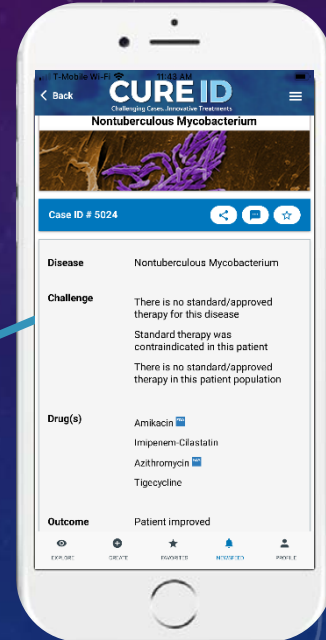
FAVORITES

NEWSFEED

PROFILE



T-Mobile Wi-Fi 12:00 PM
Back CURE ID
Challenging Cases. Innovative Treatments
Disease
What disease did your patient have?
Step 1 of 6 (Quick Report) * Required
Enter disease
Note: Users may add a term that is not currently in the drop-down list by typing the term and pressing enter.



T-Mobile Wi-Fi 11:43 AM
Back CURE ID
Challenging Cases. Innovative Treatments
Nontuberculous Mycobacterium
Case ID # 5024
Disease Nontuberculous Mycobacterium
Challenge There is no standard/approved therapy for this disease
Standard therapy was contraindicated in this patient
There is no standard/approved therapy in this patient population
Drug(s) Amikacin
Impenem-Cloastatin
Azithromycin
Tigecycline
Outcome Patient improved

CREATE

CASE REPORTS

CURE ID
Challenging Cases... Innovative Treatments

Case ID # 5452

Disease	COVID-19
Diagnosis	Clinical assessment PCR Imaging
Challenge	There is no standard/approved therapy for this disease
Drug(s)	Tocilizumab
Outcome	Patient deteriorated
Adverse Events	stroke

EXPLORE CREATE FAVORITES NEWSFEED PROFILE

CURE ID
Challenging Cases... Innovative Treatments

Patient Characteristics	Age: 90+ years Sex: Male Country Contracted: United States Country Treated: United States Treatment Began: 2020
Co-Morbidities	Co-Morbidities: atrial fibrillation, hypertension
Diagnosis	Organism: Sars-cov-2
Treatment Details	Tocilizumab 400mg once IV X 1 day How new way: To treat a disease other than the one for which the drug is approved Treatment setting: ICU/Critical Care Surgery: No

EXPLORE CREATE FAVORITES NEWSFEED PROFILE

CURE ID
Challenging Cases... Innovative Treatments

Outcome	Method(s) of outcome determination are: Clinical assessment Imaging Outcome assessed: At the time the treatment was completed Relapse: No
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Comments

09:38 PM, Apr 26 2020
Rita Abbud (Medical Doctor)
Had similar experience in my practice

09:31 AM, Apr 27 2020
CURE ID Admin (Medical Doctor)
Dr. Abbud, please consider sharing your experiences as case reports as well. Thanks for adding your comment!

Add a comment...

Post anonymously

EXPLORE CREATE FAVORITES NEWSFEED PROFILE

EXPLORE CREATE FAVORITES NEWSFEED PROFILE



CREATE

DISCUSSIONS



Share your experience with an infection that was difficult to treat

Create Case Report

Create Discussion Post

CURE ID
Challenging Cases, Innovative Treatments

Create Discussion Post

Disease Search

Note: discussions that are not disease specific or the diagnosis is unknown should go under "Disease Not Specified" as disease Name.

Discussion Title *

Please provide relevant details *

Post anonymously

CURE ID
Challenging Cases, Innovative Treatments

Hematocrit 20.9, platelets 126, creatinine 2, bilirubin 3, SCOT 4636, SGPT 2325, alk phos nl CXR - bilateral interstitial infiltrates improved from prior week 2/n

0

☆ Empiric Rx Of Immunocompromised Patient With Sepsis, Shock Liver 3/N [View](#)

By Judy Stone | Medical Doctor | 2 years ago

issues: 1) empiric Rx of profoundly immunocompromised patient with sepsis picture and 2) shock liver type enzymes 3) what, if anything to do w + CMV PCR (not acute)? I have a white female in her 60s with Waldenstrom macroglobulinem. PMH incl diabetes and COPD, remove Hep B and TB, arial f/a On Canceplon for at least 1 week pre PE. Washed out appearing and lethargic, but easily arousable. Afebrile. BP was 100 systolic. IP flush (on digoxin) R=16 PE, no x fine crackles at bases. 2e pitting edema, a pri and jugular cath for her pretransfusion fr lung bx. Labs: Lactic acid: 5.3 pulse oximetry was 79 on room air wbc 3.6, ~75% polys. Hematocrit 20.5, platelets 105, creatinine 2, bilirubin 3, SGOT 4636, SGPT 2325, alk phos nl CXR - bilateral interstitial infiltrates improved from prior week 2/n. Curious what your differential would include, and what antibiotics you would give her empirically, given the liver failure and med renal insufficiency?

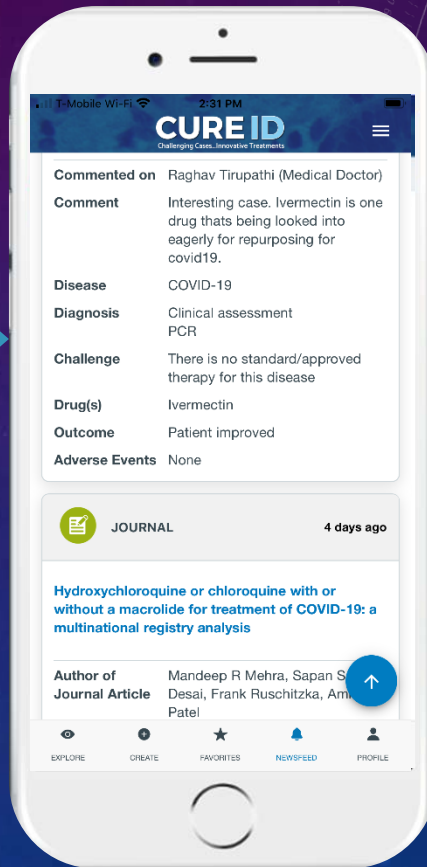
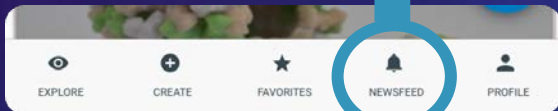
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[Submit a new discussion](#)

EXPLORE **CREATE** FAVORITES NEWSFEED PROFILE



NEWSFEED



THOUGHTS OF FDA AND NIH LEADERSHIP...

“The CURE ID application focuses on drugs for infectious diseases lacking adequate treatments, including neglected tropical diseases, emerging infectious threats and infections caused by antimicrobial-resistant organisms. When health care professionals directly input their clinical cases into the app, **CURE ID allows these real-world experiences to be organized and analyzed much faster, making it easier to spot promising new uses for existing drugs,**” said Amy Abernethy, M.D., Ph.D., FDA Principal Deputy Commissioner. “Our hope is that this app will serve as a connector among major treatment centers, academics, private practitioners, government facilities and other health care professionals from around the world and ultimately get treatments to patients faster.”

- **Amy Abernethy, M.D., Ph.D., FDA Principal Deputy Commissioner**

“The potential importance of new therapeutic opportunities from repurposing drugs can’t be understated,” said NCATS Director Christopher P. Austin, M.D. “The CURE ID platform exemplifies how collaborative efforts can spark innovations that benefit patients. **This new platform harnesses the power of crowdsourcing to help gather medical observations in the field and help identify potentially effective treatments for diseases.**”

- **Christopher Austin, M.D., NCATS/NIH Director**

Case Study:

Repurposing for Nontuberculous Mycobacteria

Examples from the Published Literature:

[Intern Med.](#) 2018 Dec 15;57(24):3625-3629. doi: 10.2169/internalmedicine.1195-18. Epub 2018 Aug 10.

Improvement of *Mycobacterium abscessus* Pulmonary Disease after Nivolumab Administration in a Patient with Advanced Non-small Cell Lung Cancer.

Ishii S¹, Tamiya A¹, Taniguchi Y¹, Tanaka T¹, Abe Y¹, Isa S¹, Tsuyuguchi K³, Suzuki K¹, Atagi S².

[Future Microbiol.](#) 2017 May; 12(6): 473–480.

Published online 2017 Feb 16. doi: [10.2217/fmb-2016-0234](https://doi.org/10.2217/fmb-2016-0234)

PMCID: PMC5618940

PMID: [28326811](https://pubmed.ncbi.nlm.nih.gov/28326811/)

Combinations of avibactam and carbapenems exhibit enhanced potencies against drug-resistant *Mycobacterium abscessus*

Amit Kaushik,¹ Chhavi Gupta,¹ Stefanie Fisher,² Elizabeth Story-Roller,¹ Christos Galanis,¹ Nicole Parrish,^{2,3} and Gyanu Lamichhane^{*1,3}

[Chest.](#) 2015 Aug;148(2):499-506. doi: 10.1378/chest.14-2764.

Preliminary Results of Bedaquiline as Salvage Therapy for Patients With Nontuberculous Mycobacterial Lung Disease.

Phillely JV¹, Wallace RJ Jr², Benwill JL³, Taskar V⁴, Brown-Elliott BA⁵, Thakkar F⁴, Aksamit TR⁶, Griffith DE⁴.



FDA Approved Drugs with any Nontuberculous Mycobacteria Indication

Amikacin

Azithromycin

Clarithromycin

Minocycline

Rifabutin

< BACK

Nontuberculous Mycobacterium > Case Reports

Nontuberculous Mycobacterium



Case Reports

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Discussion Posts

0

Clinical Trials

82

Drug Used

of Cases

Clarithromycin 

38

Ethambutol

36

Rifampicin


20

Moxifloxacin

19

Amikacin 

14

Rifabutin 

13

Ciprofloxacin

7

Levofloxacin

4



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Nontuberculous Mycobacterium > Case Reports > Drug Therapies

Nontuberculous Mycobacterium



Case Reports

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Discussion Posts

0

Clinical Trials

82

Monotherapy (0)

Combination Therapy (4)

Levofloxacin + Amikacin ^{FDA}

View

1

Improved

0

Undetermined

0

Deteriorated

Levofloxacin + Azithromycin ^{FDA} + Clarithromycin ^{FDA} + Ethambutol

View

1

Improved

0

Undetermined

0

Deteriorated

Levofloxacin + Rifabutin ^{FDA}

View

0

Improved

1

Undetermined

0

Deteriorated

* ^{FDA} This drug is approved by the FDA for this disease/indication.

Case ID # 5060



Disease	Nontuberculous Mycobacterium
Challenge	Other - Patient refused IV of PICC lines Patient failed previous therapy
Drug(s)	Levofloxacin Rifabutin
Outcome	Patient's condition was unchanged

Patient Characteristics:	Age: 51-60 years Sex: Male Country Contracted: United States Country Treated: United States
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Co-Morbidities and Concomitant Treatments:	Co-Morbidities: COPD
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Presentation:	Site(s) of disease: Cavitory Clinical syndrome: MAC
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Diagnosis:	Diagnosis made by: Smear PCR Culture Clinical assessment Etiology: Mycobacterium avium complex (mac)
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www.fda.gov

Previous drugs:
Azithromycin
Ethambutol
Rifampicin

Treatment Details:

Levofloxacin

750 mg QD Oral X 12 months

How new way:

In a novel combination with another drug

To treat a disease other than the one for which the drug is approved

Rifabutin

300 mg QD Oral X 12 months

How new way:

In a novel combination with another drug

To treat a disease other than the one for which the drug is approved

Method(s) of outcome determination are:

Serology
Smear
Culture
Clinical assessment

Surgery: No

Outcome assessed: While the patient was still on treatment

Relapse: No

Other: My case was a middle aged male smoker with cavitory MAC to which received 18-months of standard MAC therapy (azithromycin, rifampin and ethambutol) per ATS guidelines; however, the patient did not improve despite therapy. His monthly respiratory samples continued to demonstrate growth of MAC. Multiple sensitivities revealed no resistance. Serum levels demonstrated adequate absorption and antimicrobial levels too. As a salvage method I tried oral rifabutin and levofloxacin (the patient refused IV and PICC) but still no resolution. He was referred to CT surgery but due to his COPD classification he is unable to have a surgical resection.

Comments

Add a comment...

Submit

App Development Process

The group has focused on an agile, user-centered design approach to ensure that the CURE ID platform will be useful for healthcare providers.

This has involved extensive user-testing of the platform (including internationally – India, Peru, and South Africa), as well as continuous improvements based on this user feedback.

How does the data platform work?

A healthcare provider submits a case report form via the app or website with completely de-identified data and largely standardized terminology.

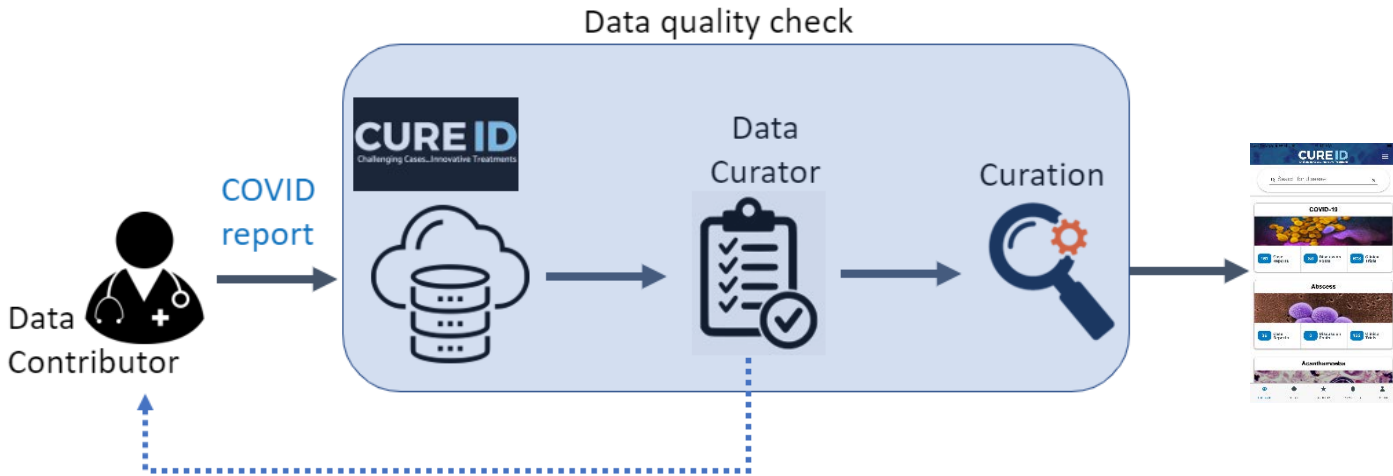
Once a case is posted, it is rapidly reviewed (typically within 12 hours) by CURE ID moderators to ensure quality. The moderators may contact the user for additional details or clarification.

The data from the case reports is then aggregated to show the total number of cases using each drug as either monotherapy or specific combination therapies.

It is then further broken down by treatment outcome.

Users can also download the entire de-identified dataset to conduct their own research.

Data Curation



Who can participate?

CURE ID is open to licensed healthcare professionals to report their clinical experience.

Healthcare Professionals Include:

Physicians

Nurse Practitioners

Physician Assistants

Nurses

Pharmacists

Other Key Features - Platform

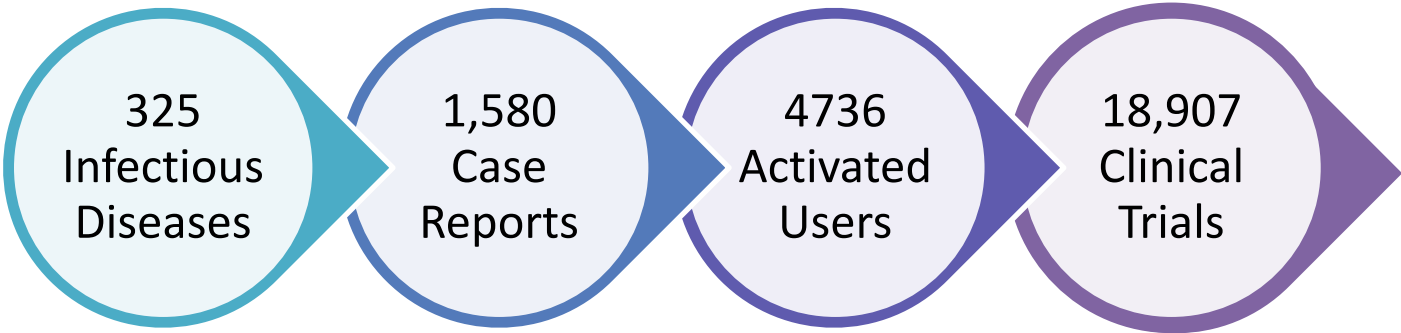
Free, Open-source, Globally-accessible Platform (including offline capabilities for access in resource-limited settings)

De-identified case information; Curation; Ability to anonymize individual submissions

Emphasis on both successful and unsuccessful treatments (what doesn't work is as important as what does), as well as adverse events

Ability to connect clinicians from around the world and provide a “one-stop shop” of information

Total Numbers To Date:



CURE ID Updates for COVID-19

Facilitates clinicians reporting their real-world experiences treating COVID-19 patients, when patients are unable to be enrolled in a clinical trial.

Includes an updated case report form tailored to COVID-19 and data fields that have been harmonized with other RWD and clinical trial platforms.

Enables data to be entered and adverse events to be automatically shared with the [FDA's Medwatch Adverse Reporting System](#).

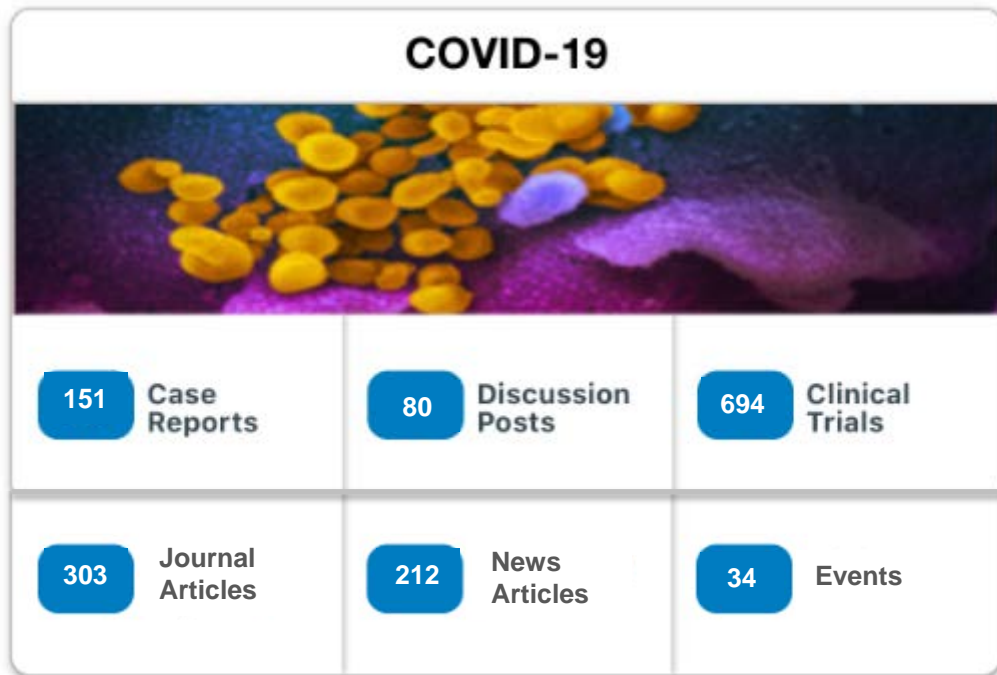
Voluntary submission of cases to CURE ID is not a substitute for filing information with regulatory and public health authorities, where required.

Includes almost all clinical trials for COVID-19 treatments submitted to [clinicaltrials.gov](#); updated nearly daily.

Includes relevant COVID-19 journal articles, news articles, and events; updated nearly daily.

Includes more than 150 case reports of COVID-19 treatments that have been extracted from the published literature or entered by clinician users, with the data displayed in an aggregated format.

COVID-19 Data in CURE ID



Drug Used	# of Cases
Lopinavir-Ritonavir	50
Hydroxychloroquine	31
Azithromycin	27
Arbidol	22
Interferon alfa-2B	18
Moxifloxacin	17
Methylprednisolone	16
Ivermectin	12
Lopinavir	12
Oseltamivir	12
Danoprevir-Ritonavir	11
Immunoglobulins, IV	11
Interferon	11
Interferon alfa	11
Tocilizumab	10

COVID-19 Cases

150+ cases reported

65 repurposed drugs identified

15 drugs with 10 or more cases

Current CURE ID Goals

Get cases submitted to CURE ID from as many clinicians as possible, if they choose to use approved drugs for unapproved uses.

Provide a platform for discussion amongst healthcare providers globally.

Responsibly share the limited data that is available.

Use anecdotal reports (captured systematically and then aggregated) to inform randomized clinical trials, as rapidly as possible.

Use of CURE ID for COVID-19 Case Collection



FDA, NIH (NIAID and NCATS), CDC, C-Path, and IDSA are now collaborating to promote the use of CURE ID as a tool to collect cases on the treatment of patients with COVID-19, in conjunction with ongoing clinical trial efforts.

Activities are also being coordinated with WHO through the existing FDA-WHO CURE ID partnership.

Healthcare providers around the world are encouraged to share their COVID-19 treatment experiences via the CURE ID platform.

Voluntary submission of cases to CURE ID is not a substitute for filing information with regulatory and public health authorities, where required.

Do you have COVID-19 cases to share?

FDA encourages patients to be enrolled in clinical trials of potential COVID-19 treatments.

If that is not possible:

Have you used an existing drug approved for another indication to treat a patient infected with SARS-CoV-2?

Did you use a combination of approved products?

Did you find any safety concerns with the approved products being used in a new way?

Please share these cases on CURE ID!

Utility Now and in the Future

By utilizing the CURE ID platform now for COVID-19 case collection - in conjunction with data gathered from other registries, EHR systems, and clinical trials - data collected during an outbreak can be improved and coordinated.

This may allow us to find possible treatments to help ease this pandemic, and prepare us better to fight the next one.

How can the scientific community move from the collection of anecdotal reports to informing clinical trials, and potentially drug labeling?

The CURE ID Partners believe it is important to establish a consortium, made up of all of the relevant stakeholders.

Next, the partners hope to identify a clear pathway forward, both for generating adequate evidence from RCTs, and submitting that evidence to the FDA for review.

Announcing the Launch of the CURE Drug Repurposing Collaboratory



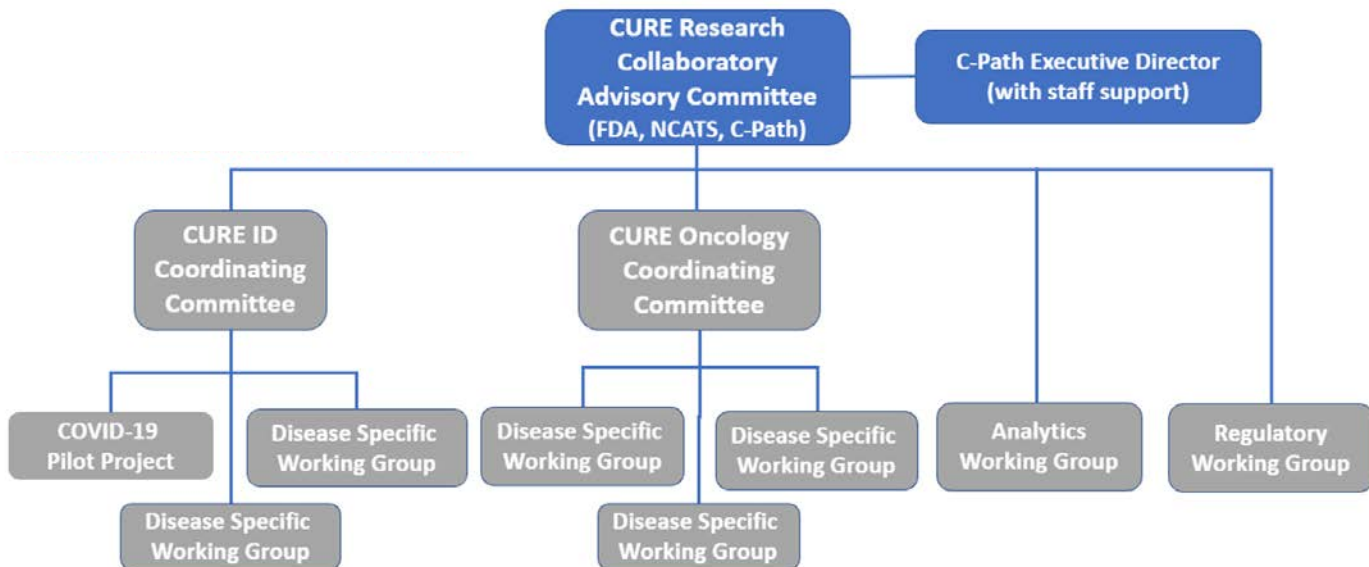
CURE ID was initiated in 2013 by FDA and NCATS/NIH with support from WHO, IDSA, CDC, and NIAID, and promises to be a long-term initiative.

To this end, the [Critical Path Institute](#) (C-Path) has announced that it is convening a public-private partnership in collaboration with FDA and NCATS/NIH called the [CURE Drug Repurposing Collaboratory](#).

It will begin with a pilot focused on furthering drug development for COVID-19 through use of the CURE ID platform.

The Collaboratory will demonstrate how data shared from clinicians in real-time can be used to inform ongoing and future clinical trials, and potentially drug labeling.

Structure





CURE Drug Repurposing Collaboratory

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.

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OVERVIEW

[Introduction](#) [CDRC Team](#) [Collaborators](#)

The CURE Drug Repurposing Collaboratory (CDRC) is a public-private partnership initiated in June 2020 by C-Path and the U.S. Food and Drug Administration (FDA) in partnership with the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH).

CDRC, in partnership with the FDA-NCATS CURE ID* platform, is a dedicated initiative designed to capture real-world clinical outcome data to advance drug repurposing and inform future clinical trials for diseases of high unmet medical need. The initiative includes emerging/reemerging diseases, anti-microbial drug resistant infections, neglected infectious diseases as well as rare oncology diseases where there are limited treatment options. The Collaboratory is strongly interested in capturing data from diverse populations including pediatric and pregnant women. C-Path leads CDRC, with participation from a diverse set of global stakeholders including, but not limited to, clinicians, scientists, U.S. Health and Human Services (HHS) agencies, non-government organizations, foundations and societies in order to:

- Promote the CURE ID platform to enable the global health community to openly share patient treatment outcomes
- Evaluate drug leads through advanced analytics to identify candidates for repurposing as new treatments in a transparent open forum
- Inform the design of clinical trials of existing marketed drugs for new indications
- Generate real-world evidence for expanding drug labels
- Provide a regulatory roadmap to advance drug repurposing and expedite the availability of safe and efficacious treatments for diseases with limited or no treatment options

Get involved with the CDRC

Join as an Institutional Partner

Serve on the Advisory or Coordinating Committees

Become a CURE ID Curator

Contribute your dataset to the CURE ID database

Participate as a CURE ID Clinical Champion

Visit the Consortium's Website:

<https://c-path.org/programs/cdrc/>

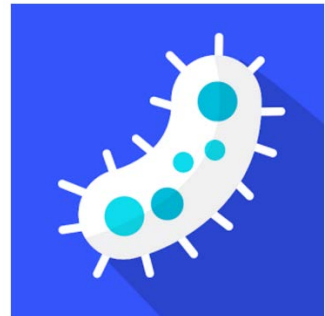
Or email:

cdrc@c-path.org

Participate and Get in Touch!

The app is available for free as “CURE ID” in the Google Play store and iTunes App Store.

Visit us at: <https://cure.ncats.io/>



If you have comments or suggestions or are interested in other ways to be involved, please email us at cureadmin@mail.nih.gov.

CURE ID Partners



Thanks to the CURE ID Team!



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Volunteers:	Advisors:	Advisors:	Funders/In Kind Support:
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	Bob Bollinger	Soumya Swaminathan	FDA Medical Countermeasures Initiative
	Carlos Seas	David Aronoff	HHS IDEA LAB
			NCATS/NIH

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