Walking the Talk: Harnessing COVID-19 EHR Data to Inform Clinical Trial Design Using CURE ID

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Abstract

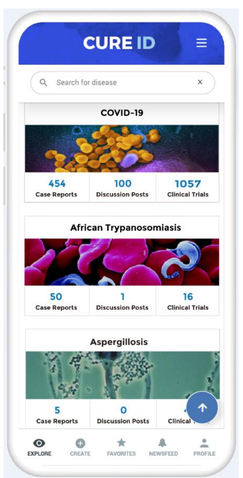
The COVID-19 pandemic has brought great attention to both the opportunity presented by drug repurposing as well as the challenges of harnessing real-world data to generate clinical evidence.

The CURE ID platform developed collaboratively by the FDA and NCATS/NIH is an open-access mobile application and website that allows clinicians globally to share their clinical experience with repurposed drugs.

Currently CURE ID relies on manual data extraction, which is time-consuming and unsustainable (Fig.1)

Electronic Health Records (EHR) and registries provide a larger source of available data without requiring additional effort by healthcare providers, serving as a powerful resource to identify potential treatments for COVID-19, pending the development of new drugs.

Introduction



As of April 2021, CURE ID has:

- 7966 registered users globally
- 180 user submitted clinical case reports
- 239 repurposed drugs identified for COVID-19
- 2123 clinical trials
- 116 discussion threads

CURE ID EHR Automated Data Extraction Strategy

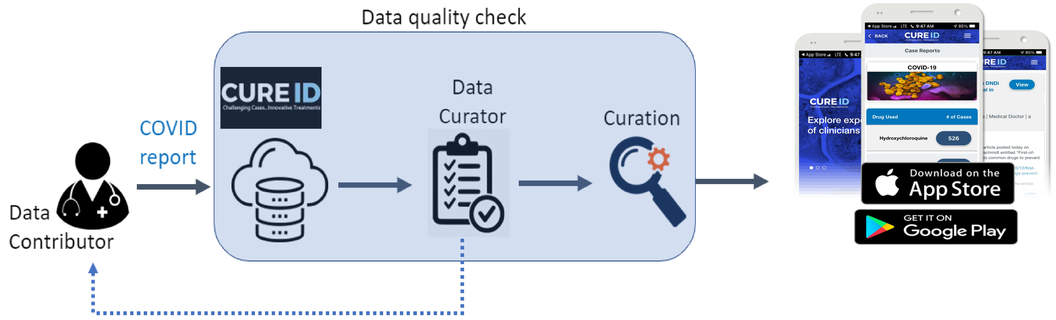


Figure 1. Current CURE ID data acquisition model from global data contributors.

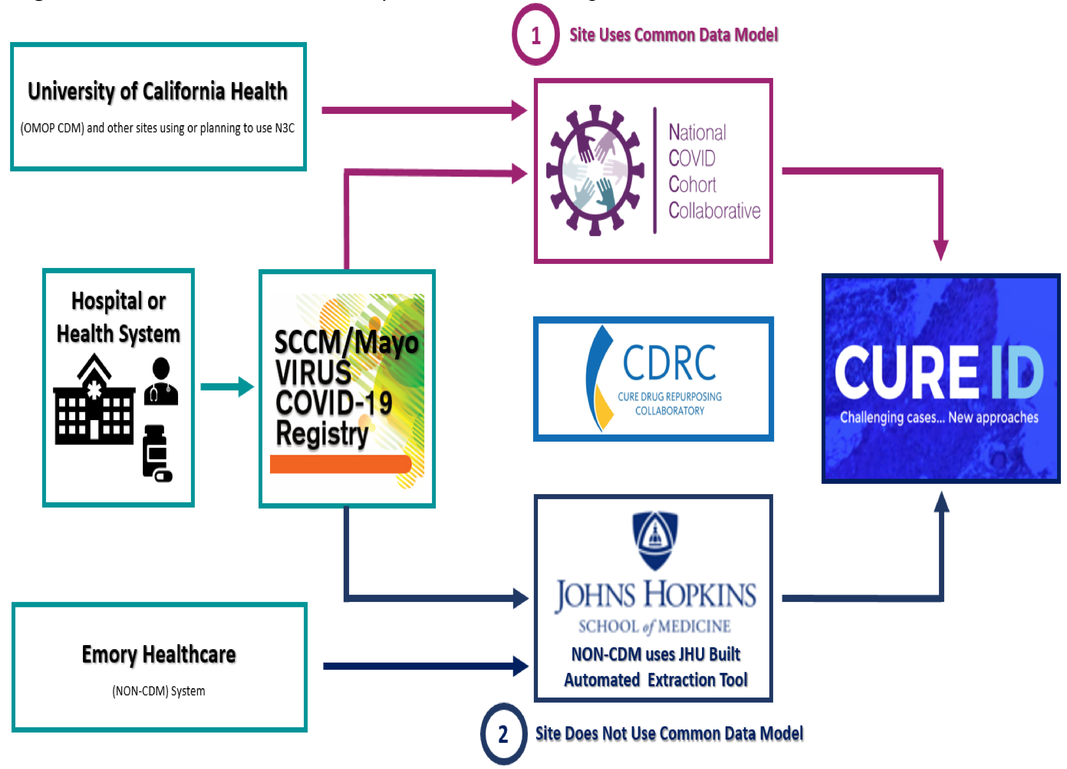


Figure 2. Complimentary approach for data extraction strategy via SCCM- (1) Common Data Model mapped to CURE ID or (2) JHU Extraction Tool for sites not using Common Data Model.

Results and Discussion

CURE ID in collaboration with the Society of Critical Care Medicine (SCCM)/Mayo Clinic's VIRUS Registry and the Johns Hopkins School of Medicine is developing an **automated extraction tool** to enable data from different EHR and registry systems to be extracted and converted into the CURE ID format (Fig.2)

Data are to be extracted from more than **250 participating sites**.

The expanded CURE ID platform will provide **open access** to case reports on patients, including treatment outcomes.

Expected to include over **100,000 new cases** within the next year.

Researchers and regulatory communities will be able to identify signals of potentially safe and effective COVID-19 treatments from existing FDA approved therapeutics that could then be **studied further in randomized controlled trials.**

Conclusion

In the wake of the COVID-19 pandemic, it has become increasingly important to harness the power of real-world data to inform clinical trial design.

Expansion to EHR and registry data will enable the generation of robust clinical hypotheses and by doing so, may accelerate the identification and development of effective treatments.

Inclusive partnerships with all stakeholders – public and private sectors partners, academia, policy makers and, most importantly, patients – will leverage our comparative strengths and respective voices toward collective solutions to identify safe and effective treatments.