



# OHDSI's Collaboration with the FDA Best Program

**OHDSI Community Call**  
**March 23, 2021 • 11 am ET**



# March/April OHDSI Community Calls

Date	Topic
March 23	Focus Topic: OHDSI Work with FDA Best program
March 30	OHDSI Challenge
April 6	Open Network Studies
April 13	10-Minute Tutorials
April 20	Community Presentations (Theme: Local Impacts of OHDSI)
April 27	OHDSI Networking Session



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# OHDSI Challenge



Albert Prats Uribe (Guest) 3/19 3:56 AM

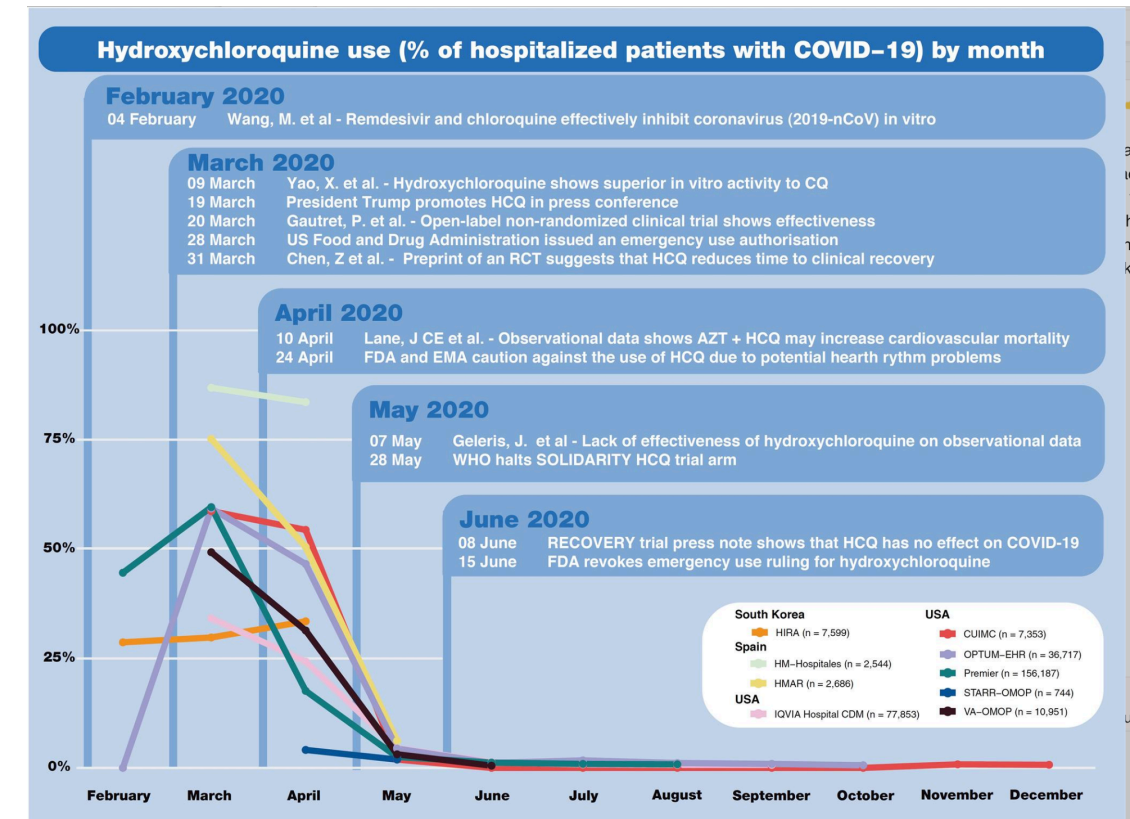
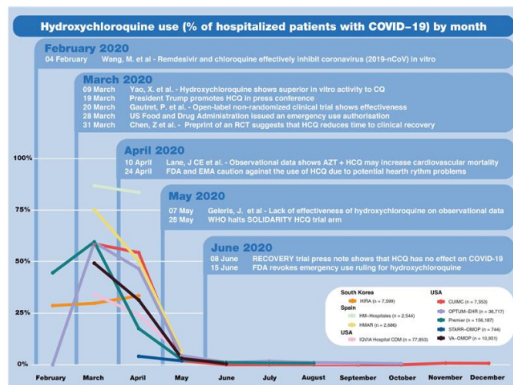
👍 1 ❤️ 10

## The Rise and Fall of Hydroxychloroquine

Here is my go at it! This is a depiction from our CHARYBDIS project of how the use of Hydroxychloroquine has changed over time over several settings around the world. I think it tells two great stories. The first on how bad science, bad politics, uncertainty and fear can sometimes make us take hasty decisions, but also, how good, well thought and performed science, acknowledgment of uncertainty, and good communication can also reverse them quickly. The second one on how, even in crazy times and with some bad actors trying to make profit of it, communities of involved citizens and scientists, such as OHDSI (and many more), in a collective thoughtful effort can quickly produce rigorous evidence that has great impact on worldwide policy and on people's lives.

P.D.: Thank you to the greater community and to all the people who have made CHARYDBIS possible!

[See less](#)







# OHDSI Challenge



OHDSI

General

OHDSI Challenge March2021

OHDSI coordinating center administration 

OHDSI Meme-a-thon

Teams Best Practices and Guidance

Technical support



OHDSI Challenge March2021

Posts Files Wiki +

Org-wide 1892 Guests



Craig Sachson 3/2 10:03 AM

## OHDSI Challenge - March 2021 - COVID Visualizations

The OHDSI community has generated a large array of evidence throughout the pandemic, including characterization (CHARYBDIS), estimation (SCYLLA, hydroxychloroquine studies), and prediction (COVER). We have other efforts in the works, including EUMAEUS and AESIncidenceCharacterization. We also have plenty more work across community or locally. And that's on top of work that someone could do de novo using OHDSI standardized tools, like ATLAS and HADES.

Sometimes though, even with all that evidence, it can be hard to tell a story. So, if a picture is worth a thousand words, what one visualization using OHDSI tools/data/results tells the most compelling story that touches on the COVID pandemic?

**The challenge:** We are asking community collaborators to submit a static image (something that could be scaled to print 8.5x11, landscape or portrait) or link to an interactive visualization that stands on its own, and then accompany it with a 1-paragraph summary of why you think the image tells a compelling story.

This image could be something that's already sitting in one of our papers or out on [data.ohdsi.org](https://data.ohdsi.org), which you could use as is, or perhaps you could augment it to help tell your story (if you do alter a graphic from another study, please add an attribution). Perhaps it could be a new graphic that you produce based on available results, or even something produced based on new analysis.

Whatever the graphic is, we want to know why it's meaningful to you — and perhaps why it should be meaningful to all of us.

All submissions should be posted in the OHDSI team in the channel 'OHDSI Challenge - March 2021' by Thursday, March 25, at 8 pm ET. On the March 30 community call, we will review the visualization gallery and recognize the contributions.

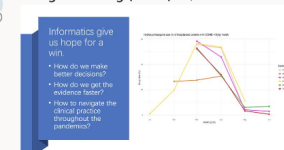
[See less](#)

2 replies



Mengchun Gong (Guest) 3/3 5:10 AM

1





# Three Stages of The Journey

**Where Have We Been?**

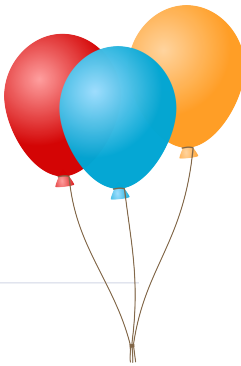
**Where Are We Now?**

**Where Are We Going?**





# OHDSI Shoutouts!



Congratulations to Eng Hooi Tan, Anthony Sena, Albert Prats-Urbe, Seng Chan You, Waheed-Ul-Rahman Ahmed, Kristin Kostka, Christian Reich, Scott Duvall, Kristine Lynch, Michael Matheny, Talita Duarte-Salles, Sergio Fernandez Bertolin, George Hripcsak, Karthik Natarajan, Thomas Falconer, Matthew Spotnitz, Anna Ostropolets, Clair Blacketer, Thamir Alshammari, Heba Alghoul, Osaid Alser, Jennifer Lane, Dalia Dawoud, Karishma Shah, Yue Yang, Lin Zhang, Carlos Areia, Asieh Golozar, Martina Recalde, Paula Casajust, Jitendra Jonnagaddala, Vignesh Subbian, David Vizcaya, Lana Lai, Fredrik Nyberg, Daniel Morales, Jose Posada, Nigam Shah, Mengchun Gong, Arani Vivekanantham, Aaron Abend, Evan Minty, Marc Suchard, Peter Rijnbeek, Patrick Ryan, Daniel Prieto-Alhambra on this study published in Rheumatology: [COVID-19 in patients with autoimmune diseases: characteristics and outcomes in a multinational network of cohorts across three countries.](#)

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## RHEUMATOLOGY

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### Article Contents

Abstract

Supplementary data

Comments (0)

ACCEPTED MANUSCRIPT

### COVID-19 in patients with autoimmune diseases: characteristics and outcomes in a multinational network of cohorts across three countries

Eng Hooi Tan, Anthony G Sena, Albert Prats-Urbe, Seng Chan You, Waheed-Ul-Rahman Ahmed, Kristin Kostka, Christian Reich, Scott L Duvall, Kristine E Lynch, Michael E Matheny ... Show more

Rheumatology, keab250, <https://doi.org/10.1093/rheumatology/keab250>

Published: 16 March 2021 Article history ▼

PDF Split View Cite Permissions Share ▼

### Abstract

#### Objective

Patients with autoimmune diseases were advised to shield to avoid COVID-19, but information on their prognosis is lacking. We characterised 30-day outcomes and mortality after hospitalisation with COVID-19 among patients with prevalent autoimmune diseases, and compared outcomes after hospital admissions among similar patients with seasonal influenza.





# OHDSI Shoutouts!



Congratulations to **Torunn Elise Sivesind, Taylor Runion, Megan Branda, Lisa Schilling, and Robert Dellavalle** on this study published in **Dermatology: Dermatologic Research Potential of the Observational Health Data Sciences and Informatics (OHDSI) Network.**

The screenshot shows the Karger journal website interface. At the top is a dark green navigation bar with the Karger logo and links for JOURNALS, BOOKS, COLLECTIONS, and SUBJECT GUIDE. Below this is a lighter green bar with links for Journal Home, About This Journal, Guidelines, Journal Contact, and Subscription. The main content area is white and displays the journal title 'Dermatology' and the article title 'Dermatologic Research Potential of the Observational Health Data Sciences and Informatics (OHDSI) Network'. The article is marked as 'Free Access' and is a 'Review Article'. The authors listed are Sivesind T.E.<sup>a</sup>, Runion T.<sup>b</sup>, Branda M.<sup>c</sup>, Schilling L.M.<sup>d</sup>, and Dellavalle R.P.<sup>a</sup>. There are links for 'Author affiliations' and 'Corresponding Author'. Keywords include Data standardization, Analytics, Networks, Observational research, Treatment guidelines, and Electronic health records. The article is categorized under 'Dermatology' and has a DOI link: <https://doi.org/10.1159/000514536>.





# OHDSI Shoutouts!



**Any shoutouts from the community? Please share and help promote and celebrate OHDSI work!**

Have a study published? Please send to [sachson@ohdsi.org](mailto:sachson@ohdsi.org) so we can share during this call and on our social channels.  
Let's work together to promote the collaborative work happening in OHDSI!





# Three Stages of The Journey

**Where Have We Been?**

**Where Are We Now?**

**Where Are We Going?**





# Upcoming Workgroup Calls



Date	Time (ET)	Meeting
Wednesday	12 pm	Data Quality Dashboard Development
Thursday	10 am	Medical Devices
Thursday	11 am	Latin America
Thursday	1 pm	OMOP CDM Oncology – CDM/Vocabulary Subgroup
Monday	11:30 am	Pharmacovigilance Evidence Investigation (PEI)
Tuesday	9 am	OMOP CDM Oncology – Genomic Subgroup

[www.ohdsi.org/upcoming-working-group-calls](http://www.ohdsi.org/upcoming-working-group-calls)





# Next APAC Community Call

The next **APAC Community Call** will be this Wednesday/Thursday, and will focus on OHDSI APAC Network research. Presenters will be **Yuan Lu** and **Lei Feng**. Calls are hosted within the OHDSI APAC Team environment.



Comprehensive comparative effectiveness and safety of second-line antihypertensive agents:  
Utilizing the LEGEND principles to mobilize collaboration across the OHDSI APAC network

Yuan Lu, ScD  
Assistant Professor  
Yale School of Medicine  
#OHDSIAPAC  
OHDSI Asia Pacific Study Group

Treatment Patterns and Risk of Switch to Mania in Bipolar Depressive Patients Treated with Antidepressants:

**A real world study using the OHDSI Network**

Lei Feng\*, Weiwei Wang\*, Xialin Wang, Xinwei Zhang, Panpan Miao, Yuji Feng, Mui Van Zandt, Sarah Seager, Kristin Kostka, Christian Reich, Gang Wang





# Next APAC Community Call

Our new OHDSI APAC web page ([ohdsi.org/apac](https://ohdsi.org/apac)) is now live and will host the recordings of previous OHDSI APAC calls, as well as more information from the regional chapters.

## OHDSI APAC - Our Asia-Pacific Community

OHDSI is a global, multi-stakeholder, interdisciplinary and open-science network that collaborates to bring out the value of health data through large-scale analytics. Our Asia-Pacific (APAC) community comprises six regional chapters (Australia, China, Japan, Singapore, South Korea, Taiwan) and has led important OHDSI initiatives around the world.

The [first OHDSI APAC Symposium](#) was held virtually Dec. 5-6, 2020, and it provided an opportunity for our Asia-Pacific collaborators (along with others around the world) to share research, provide community updates, collaborate in regional breakouts or network discussions, and have some OHDSI fun.

The APAC community has its own group in the OHDSI MS Teams environment to promote greater collaboration on our collaborative efforts. It will also be the home of our bi-weekly APAC Community Calls, where we will provide updates, share research presentations, collaborate on topics of shared interest, and plenty more. How can you get involved? First, [request access to our MS Teams Environment](#), then request access to [our OHDSI APAC workgroup](#). You can also join the meetings [by using this direct link](#).

Our calls, which are scheduled on a bi-weekly basis, take place Thursday at 10 am CST/SGT, 11 am KST/JST, 12:30 pm ACDT, as well as Wednesday at 10 pm EST and 7 pm PST.

All calls are recorded, so if you miss one or want to share with a collaborator,



### Upcoming APAC Community Calls

Date	Topic
March 25	Network Research
April 8	OMOP Projects
April 22	Regional Updates
May 6	15-Minute Tutorials
May 20	Collaborator Showcase Presentations
June 3	Network Research
June 17	Welcome to OHDSI
July 1	OMOP Projects

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+ Mar. 25, 2021 - OHDSI APAC Network Research (Presentations by Yua

- Mar. 11, 2021 - Collaborator Showcase (Presentations by Ty Stanford

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### Theme - Collaborator Showcase

Meeting contents included the following OHDSI presentations:

- Ty Stanford - Mapping to standardized vocabularies: a process for medicine codes in Australia
- Jason Hsu and Alex Aguyen - Introduction of Taipei Medical University Clinical Research Database; TMUCDR - OHDSI CDM Mapping Progress

### Slides

[Stanford | Hsu/Aguyen](#)

### Recordings

Ty Stanford

0 OHDSI APAC Community Call 20210311 Ty Stanford

## BACKGROUND

Conversion of your clinical data to the OMOP common data model (CDM) has two main steps:

1. Convert your data source into the CDM pre-specified tables
2. Convert native vocabularies ('source' codes) to be translated to their respective OHDSI 'standardized vocabularies'



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[www.ohdsi.org](https://www.ohdsi.org)

#JoinTheJourney



[linkedin.com/company/ohdsi](https://linkedin.com/company/ohdsi)

# APAC Home Page



## OHDSI

OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Who We Are ▾ OHDSI Updates & News ▾ Standards ▾ Software Tools ▾ OHDSI Studies ▾ Book of OHDSI ▾ Resources ▾ New To OHDSI? ▾

EHDEN Academy ▾ This Week In OHDSI ▾ Events & Collaborations ▾ Collaborate with OHDSI in MTeams ▾ Social Media/Newsletter ▾

OHDSI Community Calls  
OHDSI APAC Community Calls  
Upcoming Working Group Calls

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#### Slides

[Stanford](#) | [Hsu/Aguyen](#)

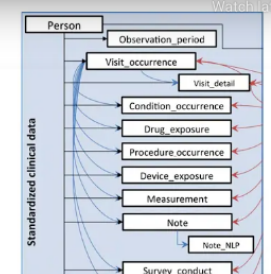
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# CBER Best Seminar – Tomorrow!



The first session of the CBER BEST Initiative Seminar Series will be held tomorrow at 11 am ET.

**Dr. Daniel Salmon**, a member of the Johns Hopkins Bloomberg School of Public Health, will present “Vaccine Safety Surveillance Systems for Routine and Pandemic Immunization Programs.”

Registration is free:

[https://northeastern.zoom.us/webinar/register/WN\\_Sa3\\_Um\\_ISrm-lamtSUWfLA](https://northeastern.zoom.us/webinar/register/WN_Sa3_Um_ISrm-lamtSUWfLA)

## CBER BEST Initiative Seminar Series



**Date:**  
March 24, 2021

**Time:**  
11:00 -12:00 PM EDT

**Topic:**  
Vaccine Safety Surveillance Systems for Routine and Pandemic Immunization Programs

**Background:**  
The [CBER BEST Initiative](#) Seminar Series is designed to share and discuss recent research of relevance to ongoing and future surveillance activities of CBER regulated products, namely biologics. The series focuses on safety and effectiveness of biologics including vaccines, blood components, blood-derived products, tissues and advanced therapies. The seminars will provide information on characteristics of biologics, required infrastructure, study designs, and analytic methods utilized for pharmacovigilance and pharmacoepidemiologic studies of biologics. They will also cover information regarding potential data sources, informatics challenges and requirements, utilization of real-world data and evidence, and risk-benefit analysis for biologic products. The length of each session may vary, and the presenters will be invited from outside FDA. Please see the details below for our upcoming seminar. [Anyone can register and join for free.](#) Stay tuned for more details and additional webinars during the course of the year.

**Description:** Post-authorization safety surveillance is critically important to fully define the safety profile of vaccines, including uncommon adverse reactions and those that have delay in onset or among subpopulation that cannot be adequately studied through clinical trials. Safety surveillance is particularly important for mass vaccination programs where large numbers of people will be quickly vaccinated and coincidental adverse events following immunization can derail the vaccine program. Rigorous, rapid and credible safety surveillance and risk assessment are essential. Healthcare databases can enhance both rigor and speed of evaluations. However, well validated methods are essential, size of populations under surveillance greatly impacts speed, and often chart review using standardized case definitions are necessary. Credibility of risk assessment can be enhanced through careful planning, separation of risk assessment from risk management, and transparency. 2009-10 H1N1 vaccine safety monitoring provides a model for safety monitoring during use of pandemic vaccines.

**Presenter:**  
Dr. Daniel Salmon, PhD, MPH



Dr. Salmon's primary research and practice interest is optimizing the prevention of childhood infectious diseases through the use of vaccines. He is broadly trained in vaccinology, with an emphasis in epidemiology, behavioral epidemiology, and health policy. Dr. Salmon's focus has been on post-licensure vaccine safety, determining the individual and community risks of vaccine refusal, understanding factors that impact vaccine acceptance, evaluating and improving state laws providing exemptions to school immunization requirements, developing systems and science in vaccine safety, and effective vaccine risk communication. Dr. Salmon has considerable experience developing surveillance systems, using surveillance data for epidemiological studies, and measuring immunization coverage through a variety of approaches. Dr. Salmon has worked with state and federal and global public health authorities to strengthen immunization programs and pandemic planning.

**Registration:**  
[https://northeastern.zoom.us/meeting/register/tJAKdeGuqDopGN2Tw7e9crwjb\\_O4i5xIYhkj](https://northeastern.zoom.us/meeting/register/tJAKdeGuqDopGN2Tw7e9crwjb_O4i5xIYhkj)



# CDM Brainstorm Session March 30



The CDM workgroup has scheduled a special two-hour planning session for CDM 5.4 next Tuesday, March 30, at 1 pm in the CDM Teams environment.

**Clair Blacketer** has shared a proposed list of changes.

Please join for some or all of the meeting if you are interested in helping shape the next update of the OMOP CDM.

## KR1: List of Changes

Tuesday, March 16, 2021 10:25 AM

Start with v5.3 -> v5.4?

### Easy Additions

- PROCEDURE\_OCCURRENCE
  - PROCEDURE\_STATUS\_CONCEPT\_ID
    - Similar to CONDITION\_STATUS\_CONCEPT\_ID [#376](#) - maybe
- LOCATION\_CONCEPT\_ID
  - Make the location table international [#365](#)
  - Do we also need REGION\_CONCEPT\_ID and COUNTRY\_CONCEPT\_ID or is that subsumed by [LOCATION\\_CONCEPT\\_ID](#)?
- UDI field in DEVICE\_EXPOSURE
  - Make 250 characters to allow all permutations of UDI - technically just a DDL change
- UNIT\_CONCEPT\_ID in DEVICE\_EXPOSURE [#264](#)
- UNIT\_SOURCE\_CONCEPT\_ID in MEASUREMENT [#259](#)
- Representation of infusion rates - is this solved with DOSE\_UNIT\_SOURCE\_VALUE? [#224](#)
- Add METADATA\_ID and VALUE\_AS\_NUMBER to METADATA [#202](#)
- Add VALUE\_SOURCE\_VALUE to OBSERVATION [#193](#)
- Change CDM\_VERSION in CDM\_SOURCE to numeric and use a concept\_id [#306](#)
  - Also \*technically\* breaking but really a DDL change
- Add DEATH\_DATE alongside the DEATH table?
  - Add DEATH\_TYPE\_CONCEPT\_ID to PERSON
- EPISODE and EPISODE\_EVENT

### Potentials

- Rename VISIT\_DETAIL\_PARENT\_ID to PARENT\_VISIT\_DETAIL\_ID [#329](#)
  - This is \*technically\* breaking but I don't believe any standard processes currently reference it
- GENDER\_CONCEPT\_ID
  - Changing this to SEX\_CONCEPT\_ID would be a breaking change. Should we add it instead and keep both fields?
- PROCEDURE\_END\_DATETIME [#286](#)
  - Agree, convention that if no end\_datetime then set to start\_datetime
  - This would necessitate the addition of procedure\_start\_datetime or renaming of procedure\_date
  - Instead, add length of procedure to get around the breaking change

MBLACKE@ITS.JNJ.COM





# 2021 OHDSI Symposium



## Save The Dates



**The 2021 OHDSI Symposium  
will be held Sept. 12-15.**

**More details will be announced when  
available, but please save those  
dates for the highlight event of the  
OHDSI year! #JoinTheJourney**



# Where Are We Going?

**Any other announcements  
of upcoming work, events,  
deadlines, etc?**





# Three Stages of The Journey

**Where Have We Been?**

**Where Are We Now?**

**Where Are We Going?**





# March 23 Community Call Topic

## OHDSI Collaboration with FDA Best Program



### **FDA BEST Overview; Research Methods Development – Incidence Rates for Vaccine Safety**

George Hripcsak, Chair and Vivian Beaumont Allen Professor of Biomedical Informatics, Columbia University



### **Research Methods Development – Small Sample Meta-Analysis, EUMAEUS**

Marc Suchard, Professor in the Departments of Biomathematics and of Human Genetics in the David Geffen School of Medicine at UCLA



### **FDA Workshops and Seminar Series**

David Madigan, Provost and Senior Vice-President for Academic Affairs, Northeastern University



### **Training and Engagement**

Rita Kukafka, Professor of Biomedical Informatics and Sociomedical Sciences, Columbia University