

Session Title: Exploring Ethical, Equity, and Regulatory Implications for Pharmacogenomics

Implementation in Psychiatric Care Settings

Date and time: Friday April 5, 2024, 12-1 pm ET | 9-10 am PT

Presenters: Deepak Voora, M.D; Robert (Bob) Schuck, PharmD, PhD; Gary Proctor, M.D.

Sandra E. Yankah, PhD

Moderator: Rachele Hendricks Sturrup, DHSc, MSc, MA

Biographies:

Panelist: Deepak Voora, M.D.

Biography: https://medicine.duke.edu/profile/deepak-voora

Panelist: Robert (Bob) Schuck, PhD

Biography: https://www.linkedin.com/in/robert-schuck-93079659/

Panelist: Gary Proctor, M.D.

Biography: https://www.carelonhealth.com/perspectives/chronic-illness-mental-health

Moderator: Rachele Hendricks Sturrup, DHSc, MSc, MA

Biography: https://healthpolicy.duke.edu/people/rachele-hendricks-sturrup-dhsc-msc-ma

Speaker: Sandra Yankah, PhD

Biography: https://healthpolicy.duke.edu/people/sandra-e-yankah-phd

Resources from our speakers: Deepak Voora, M.D

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Link to VHA Sites of care:

 $\underline{https://phoenixmed.arizona.edu/sites/default/files/depts/medicine/clinical-data/voora-phaser-coll\ aboration.pdf}$

https://cpicpgx.org/wp-content/uploads/2023/01/VooraCPIC2023sharing.pdf

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Link to MVP cohort characteristics:

https://www.va.gov/RAC-GWVI/meetings/Jan2022/9_Muralidhar_RACGWVI_Briefing_REVIS_ED_SM_compl.pdf

[Slide 9]

Link to Prime CARE Trial Site: https://www.mirecc.va.gov/visn4/primecare/prime care.asp

Link to "Effect of Pharmacogenomic Testing for Drug-Gene Interactions on Medication Selection and Remission of Symptoms in Major Depressive Disorder, The PRIME Care Randomized Clinical Trial": https://jamanetwork.com/journals/jama/fullarticle/2794053

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Link to VA pharmacogenomics Implementation Map:

https://cpicpgx.org/wp-content/uploads/2023/01/VooraCPIC2023sharing.pdf

Resources from Robert Schuck, PhD

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Link to "Leveraging Genomic Factors to Improve Benefit–Risk": https://ascpt.onlinelibrary.wiley.com/doi/10.1111/cts.12439

Link to "Is This the Drug or Dose for You?: Impact and Consideration of Ethnic Factors in Global Drug Development, Regulatory Review, and Clinical Practice" https://ascpt.onlinelibrary.wiley.com/doi/abs/10.1038/clpt.2008.144

[Slide 3]

Link to "Evidence, in Context: A Regulatory Perspective on Pharmacogenetics" https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.2347

[Slide 4]

Link to Drug Products Labeling Information: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

Link to Table of Pharmacogenetic Associations:

https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations

Link to Table of Pharmacogenomic Biomarkers in Drug Labeling: https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling

Link to FDA Guidances: https://www.fda.gov/industry/fda-basics-industry/guidances

CERA/ELSIhub Resources

The upcoming April EFF will examine the visual representations of genetics in television and film and their significance for ELSI research. You may register here: https://us06web.zoom.us/webinar/register/7217103516694/WN_6vSbV_nuQxyJCsG_-YgaSA#/registration

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using #ELSIconversations

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A curated set of resources on ELSIhub for educators: https://elsihub.org/news/elsihub-resources-educators

Audience Contributions

Link to "What is CPIC":

https://cpicpgx.org/

Link to PharmGKB website:

https://www.pharmgkb.org/

Genotype Selection Interface tool on PharmGKB:

https://www.pharmgkb.org/genotype