



U.S. FOOD & DRUG
ADMINISTRATION

11th Annual Scientific Computing Days

Sharing and Collaboration in the Data Multiverse:
Scientific Computing for Public Health Solutions

September 12-13, 2023

EVENT PROGRAM





USE THE **FDA.GOV LINK BELOW** TO ACCESS
ALL EVENT INFORMATION: ZOOM WEBINAR LINK,
SPEAKERS, AND SESSION INFORMATION.

ACCESS **EVENT SITE ON FDA.GOV**



VIRTUAL + IN PERSON

DAY 1

TUESDAY, SEPTEMBER 12

9:00AM - 3:00PM ET

ACCESS ZOOM WEBINAR



9:00 AM - 9:05 AM EDT



DENNY SKILES
SCD CO-CHAIR
FDA/NCTR

DAY 1: WELCOME

9:05 AM - 9:25 AM EDT



RAM IYER
CHIEF DATA OFFICER
FDA/ODT

PUTTING OUR DATA TO WORK AT FDA

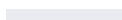
9:25 AM - 10:00 AM EDT



GREG SINGLETON
CHIEF ARTIFICIAL INTELLIGENCE OFFICER
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

SCIENTIFIC COMPUTING IN ACTION DURING COVID

10:00 AM - 10:15 AM EDT



BREAK

10:15 AM - 12:00 PM EDT



ARTIFICIAL INTELLIGENCE'S IMPACT ON FDA

ORGANIZER: DONNA MENDRICK, PHD (FDA/NCTR)

THIS BREAKOUT SESSION WILL DEAL WITH THREE DIFFERENT, EXCITING AI TOPICS. THE FIRST WILL BE A TALK ABOUT GENERATIVE AI AND PROVIDE USE CASES ON HOW GOVERNMENT AGENCIES ARE USING THIS APPROACH TO IMPROVE ON HOW INTERNAL WORK IS DONE. THE SECOND PRESENTATION WILL DISCUSS THE CONCEPT OF USING SENSOR-LESS (I.E. PUBLICLY AVAILABLE LOCATION AND METEOROLOGICAL DATA) TO MODEL THE CLIMATE INSIDE A CONTAINER TO IDENTIFY FOOD QUALITY DEGRADATION DURING TRANSPORT. THE THIRD SEMINAR WILL SHOW HOW ADVANCES IN MACHINE LEARNING AND AI WILL IMPACT THE 3RS AND TOXICOLOGY.

IMPACT OF GENERATIVE AI IN GOVERNMENT

WOLE MOSES (MICROSOFT AI)

**SENSOR-LESS CLIMATE MONITORING OF SHIPPING CONTAINERS:
A TECHNOLOGY TO IDENTIFY FOOD QUALITY DEGRADATION IN
TRANSPORT**

ARNAB CHAKRABARTI, PHD (HITACHI)

**APPLYING ADVANCES IN MACHINE LEARNING AND AI TO THE 3RS
AND TOXICOLOGY: THE VIRTUAL DOG CHALLENGE**

CATHERINE VICKERS, PHD (NC3RS)

Q&A (ALL SPEAKERS)



12:00 PM - 1:00 PM EDT

LUNCH

1:00 PM - 2:30 PM EDT



LARGE LANGUAGE MODELS IN PLAY

ORGANIZER: LIANG ZHAO, PHD (FDA/CDER)

JOIN US FOR AN EXTRAORDINARY SESSION THAT DELVES INTO THE TRANSFORMATIVE REALM OF LARGE LANGUAGE MODELS (LLMS) AND THEIR INVOLVEMENT IN CRITICAL CLINICAL DECISION-MAKINGS, REVIEW PROCESSES, AND RELEVANT COMPUTATIONAL TECHNOLOGIES. THIS SESSION BRINGS TOGETHER THREE DISTINGUISHED SPEAKERS TO EXPLORE CUTTING-EDGE ADVANCEMENTS AND APPLICATIONS IN THE FIELDS OF HEALTHCARE, REGULATORY REVIEW, AND BEYOND. IT WILL OFFER EXPERT INSIGHTS, REAL-WORLD SUCCESS STORIES, AND A GLIMPSE INTO THE LATEST TECHNOLOGIES PROPELLING LLMS TO NEW HEIGHTS.

ACCELERATING DECISION MAKING FOR CLINICAL DATA WITH LLMS AT HIVE

LUIS V. SANTANA-QUINTERO, PHD (FDA/CBER)

AN INTRODUCTION TO LARGE LANGUAGE MODELS AND THEIR POTENTIAL IN FDA REVIEW PROCESS

JAE HYUN KIM, PHD (FDA/NCTR)

ADVANCES IN FOUNDATION MODELS

PERCY LIANG, PHD (STANFORD UNIVERSITY)

PANEL (ALL SPEAKERS)

2:30PM - 2:40PM EDT



DENNY SKILES
SCD CO-CHAIR
FDA/NCTR

DAY 1: CLOSING



VIRTUAL + IN PERSON

DAY 2

WEDNESDAY, SEPTEMBER 13

9:00AM - 4:30PM ET

ACCESS ZOOM WEBINAR



9:00 AM - 9:10 AM EDT



MATT HARTOG, PHD
SCD CO-CHAIR
FDA/CTP

DAY 2 WELCOME & DAY 1 RECAP

9:10AM - 9:30 AM EDT



NELSON A. COLON, PHD
AI/ML LEAD
FDA/ODAR

THE FDA AI LANDSCAPE, TODAY AND INTO THE FUTURE

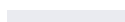
9:30 AM - 10:00 AM EDT



JAIME M. GUIDRY AUVIL, PHD
DIRECTOR OF OFFICE OF DATA SHARING
NATIONAL INSTITUTES OF HEALTH (NIH)
NATIONAL CENTER INSTITUTE (NCI)

***DATA DATA EVERYWHERE:
HOW TO HARNESS ITS POWER TO DRIVE CANCER CARE?***

10:00 AM - 10:30 AM EDT



BREAK



10:30 AM - 12:00 PM EDT

**OPEN LEDGER TECHNOLOGIES AND MACHINE READABILITY
IN REGULATORY SPACE****ORGANIZER:** [TOMAS DRGON, PHD](#) (FDA/ORA)

OPEN LEDGER (ALSO CALLED "DISTRIBUTED LEDGER" OR "SHARED LEDGER") IS A PEER-TO-PEER DIGITAL INFORMATION SHARING FRAMEWORK THAT ALLOWS DE-CENTRALIZED SHARING OF SYNCHRONIZED DIGITAL DATA IN GEOGRAPHICALLY AND/OR OTHERWISE DISTRIBUTED SITES, COUNTRIES, OR INSTITUTIONS. IN CONTRAST TO CENTRALIZED DATABASES, AN OPEN LEDGER DOES NOT REQUIRE A CENTRAL ADMINISTRATOR, AND CONSEQUENTLY DOES NOT HAVE A SINGLE POINT-OF-FAILURE. IN THIS SESSION WE WILL DISCUSS THE POTENTIAL, THE ADVANTAGES, AND THE DISADVANTAGES OF THE IMPLEMENTATION OF OPEN LEDGER TECHNOLOGIES IN FDA REGULATED INDUSTRIES AND AT THE FDA. WE WILL DISCUSS THE ROLE OF OPEN LEDGER TECHNOLOGIES VIA INFORMATION TRACEABILITY, DOCUMENT SHARING, MACHINE READABILITY, AND INFORMATION SECURITY.

**INTRODUCTION TO OPEN LEDGER TECHNOLOGIES
AND THE ROLE OF ISPE GAMP**[JAMES C. CANTERBURY](#) (ISPE-GAMP, ERNST & YOUNG LLP)**MAINSTREAMING OF DECENTRALIZED TECHNOLOGIES**[DANIEL BURNETT, PHD](#) (ENTERPRISE ETHEREUM ALLIANCE)**PRODUCT TOKENIZATION AND THE BENEFITS OF INVENTORY VISIBILITY
ACROSS AN ECOSYSTEM OF BUSINESS PARTNERS**[SUJATHA GURUSWAMY, MS](#) (MERCK)**PANEL DISCUSSION**[TOMAS DRGON, PHD](#) (FDA/ORA)[JAMES C. CANTERBURY](#) (ISPE-GAMP, E&Y LLP)[JAMES GANNON](#) (PHARMALEDGER)[DANIEL BURNETT, PHD](#) (ENTERPRISE ETHEREUM ALLIANCE)[SUJATHA GURUSWAMY, MS](#) (MERCK)[SENECA TOMS, MS](#) (FDA/ORA)[MARK WALDERHAUG, PHD](#) (FDA/CBER)

12:00PM - 1:00PM EDT

LUNCH

1:00PM - 2:00PM EDT

**POSTER SESSION**FEATURING **TOP 5** SCIENTIFIC COMPUTING POSTERS

2:00PM - 2:15PM EDT

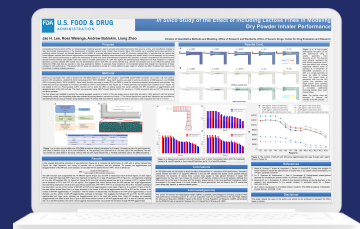
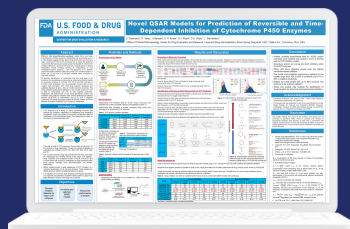
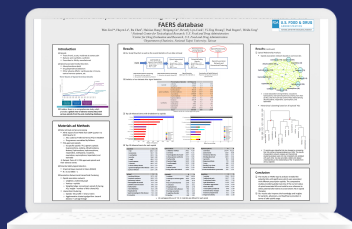
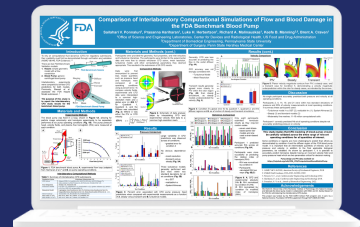
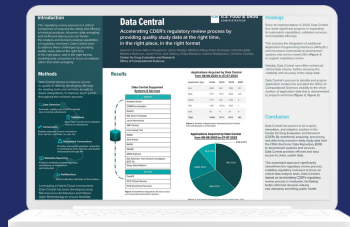
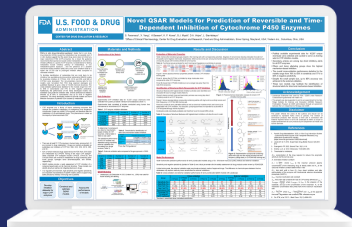
BREAK

DAY 2
WEDNESDAY, SEPTEMBER 13
1:00PM - 2:00PM ET



JOIN POSTER SESSION

FEATURING **TOP 5** POSTERS



VIEW POSTER GALLERY

FEATURING **33** POSTERS



2:15 PM - 4:15 PM EDT



UNDERSTANDING THE LANDSCAPE OF DATA MANAGEMENT AND SHARING AT FDA AND NCI

CO-ORGANIZERS:

ALEXIS NORRIS, PHD (FDA/CVM) & EMILY BOJA, PHD (NIH/NCI)

THIS SESSION, CO-ORGANIZED WITH THE NATIONAL CANCER INSTITUTE (NCI) OFFICE OF DATA SHARING, WILL EXPLORE COMMONALITIES AND UNIQUE DIFFERENCES OF DATA MANAGEMENT AND SHARING (DMS) ALONG THE SCIENTIFIC DATA LIFE CYCLE AT THE FDA AND NCI. WITH DIFFERENT MISSIONS OF BOTH AGENCIES, FDA AND NCI HAVE DISTINCT AND OVERLAPPING PRIORITIES AND CONSIDERATIONS WHEN IT COMES TO THE DATA SHARING AND PUBLIC ACCESS; THIS SESSION WILL HELP STAKEHOLDERS BETTER UNDERSTAND THE LANDSCAPE AND TERMINOLOGIES FROM DATA GENERATION, SUBMISSION AND SHARING, TO DATA ACCESS AND FACTORS TO CONSIDER ASSOCIATED WITH THESE STEPS. THE FIRST TWO PRESENTATIONS WILL PRESENT AN OVERVIEW AND INTRODUCE THE OSTP OPEN ACCESS POLICY FOR ALL FEDERAL AGENCIES. THEN, THERE WILL BE A MORE IN-DEPTH LOOK AT WHAT THE CHALLENGES AND PRIORITIES FOR DATA SUBMISSION AND ACCESS ARE AT NCI. NEXT, A SERIES OF PRESENTERS WILL HIGHLIGHT DIFFERENT ASPECTS AT THE FDA - FROM RECEIVING, TO INTERNAL SHARING, TO EXTERNAL SHARING OF BOTH REGULATORY AND RESEARCH DATA. FINALLY, WE WILL SHARE A SUCCESS STORY OF DATA ACCESS AND SHARING THROUGH PRECISIONFDA CHALLENGES.

UNDERSTANDING THE POLICIES AND PROCESSES FOR NCI'S RESEARCH DATA

EMILY BOJA, PHD (NIH/NCI)

RECEIVING AND SHARING DATA AT THE FDA

ALEXIS NORRIS, PHD (FDA/CVM)

NCI'S CANCER RESEARCH DATA COMMONS TO FACILITATE DATA SHARING

TANJA DAVIDSEN, PHD (NIH/NCI)

RECEIVING AND SHARING DATA WITH THE WORLD ON PRECISIONFDA

TYLER PERVEA (FDA/ODT)

MULTI-CENTER COLLABORATION WITH REGULATED INDUSTRY TO PILOT APPROACHES TO RECEIVING AND ANALYZING LARGE DATASETS

QIAN CAO, PHD (FDA/CDRH), THIBAUD COROLLER, PHD (NOVARTIS)

FDA'S INTELLIGENT DATA LIFECYCLE ECOSYSTEM (FIDLE) FOR CROSS-CENTER DATA MANAGEMENT, AND ADVANCING DATA SCIENCE

SWATI KULKARNI (FDA/ODT)

FDA CYBERSECURITY, COUNTERINTELLIGENCE, AND INSIDER THREAT PROGRAM

SEAN HANLON (FDA/ODT)

OPEN SCIENCE AT THE FDA

BEN HOPE, MLIS (FDA/ODT)

PUBLISHING YOUR RESEARCH DATA ON OPENFDA

LONNIE SMITH (FDA/ODT)

LEVERAGING PARTNERSHIPS TO SOLVE PUBLIC HEALTH PROBLEMS

ELAINE JOHANSON (FDA/ODT)



4:15 PM - 4:30 PM EDT



CLOSING PLENARY & AWARD CEREMONY

SCIENTIFIC COMPUTING INNOVATOR AWARDS

PRESENTED BY ODT LEADERSHIP

SCD POSTER CONTEST AWARDS

PRESENTED BY

MATT HARTOG, PHD (FDA/CTP)

DENNY SKILES (FDA/NCTR)

SCD CO-CHAIRS

SCB LEADERSHIP AWARDS

PRESENTED BY

JAMIE PETTENGILL, PHD (FDA/CFSAN)

RAJU RAYAVARAPU, PHD (FDA/ODT)

SCB CO-CHAIRS



THANK YOU

FDA SCIENTIFIC COMPUTING BOARD

FDASCB@FDA.HHS.GOV