U.S. FOOD & DRUG ADMINISTRATION

# OCS Innovation Forum at FDA/CDER

## Cultivating a Culture of Innovation and Looking to the Future

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***Disclaimer:*** *The information in this presentation represents the opinions of the speaker and does not necessarily represent FDA's position or policy.*

# The Origin of the OCS Innovation Forum

- The Office of Computational Science (OCS) promotes innovative ideas and forward-looking thinking.
- Under the leadership of Dr. Lilliam Rosario, OCS has a long history of innovations.
- OCS focuses on technology, modernization of CDER review process, site inspections, post-market information analysis, and research.
- OCS Innovation Forum grew in this nurturing environment.

# The OCS Innovation Forum:

- Is a dynamic, organic, and interactive platform that brings ideas and solutions to a diverse audience.
- Allows members of the FDA community to proactively explore, learn, collaborate, and innovate to advance personal and organizational growth and improvements.
- Is one of the programs in OCS that promotes innovation.
- Has a large impact in CDER and beyond.

# The OCS Innovation Forum Is a Visionary Program

- Actively understand and engage changes that are happening in the real world.
- Build innovation from the ground up, starting with individuals.
- Think of future concepts and technologies so that we can do our job effectively.

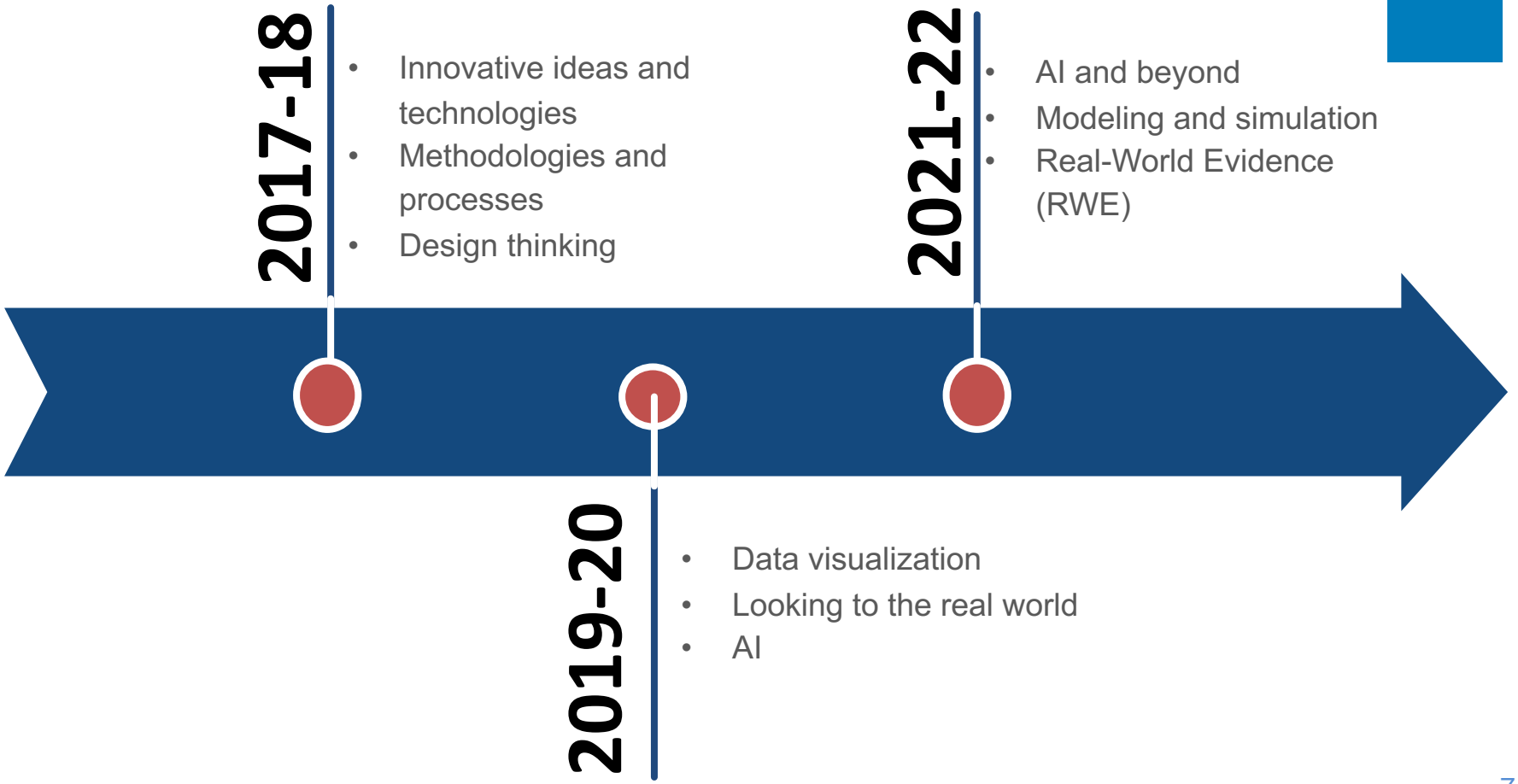
# The Focus of the OCS Innovation Forum

- Introducing Artificial Intelligence (AI) technologies, solutions, and practices that have been proven effective by industry.
- Sharing and developing innovative ideas and approaches that could trigger inspired thinking.
- Promoting a host of collaborations among FDA, industry, and academies.
- Saving time and money, bringing health products to people faster!

# Innovation Takes a Village!

- FDA staff, drug manufacturers, the IT industry, academies, and PHUSE play key roles.
- OCS and PHUSE successfully implemented FDA/PHUSE Innovation Challenges twice in the middle of the pandemic.
- All parties that are involved in ideas, design, production, and regulatory reviews are integral to getting drugs on the market and post-market monitoring.

# Themes


2017-18
Innovative ideas and technologies
Methodologies and processes
Design thinking
2019-20
Data visualization
Looking to the real world
AI
2021-22
AI and beyond
Modeling and simulation
Real-World Evidence (RWE)

# Activities Hosted by the OCS Innovation Forum

**41** events from 2017 to present

**102** presenters and visitors

**2000+** attendees (estimated)

Presenters from the U.S. and abroad

# OCS Innovation Forum – Process

- OCS Innovation Forum is a platform for innovation
- Not for sales of any products
- Steps

  Step 1: Bring your presentation & demo ideas

  Step 2: Draft slides

  Step 3: Dry-run

  Step 4: Flyer and announcement

  Step 5: Host the session

# Challenge Questions for You (1) !

- What are the best approaches to follow up with the audience after an OCS Innovation Session?
- What are the best actions to follow up with the presenters and provide update to FDA staff?

Please contact Catherine.Li@fda.hhs.gov

# FDA/PHUSE Data Science Innovation Challenge 2020

Lilliam Rosario, Stephen Bamford & PHUSE Office

## OPIOID/SUBSTANCE USE DISORDER

Facilitate effective intervention for prevention and treatment of opioid/substance use disorder by harnessing social media data.

## APPROACH FOR PREDICTING DRUG INTERACTIONS

Overcome the limitations of traditional methods for mining post-market data sources or observational healthcare data to better predict drug interactions.

## DRUG SAFETY SURVEILLANCE

Define an ideal process for surveillance of multiple data sources that would be useful in the development of a pharmacovigilance tool.

# FDA/PHUSE Innovation Challenge 2022

## Lilliam Rosario, Chris Hurley & PHUSE Office

**Pillar 1**

Prototype solutions that prepare us to quickly identify signals in data from different sources to protect public health and promote health equity

Catherine Li, FDA
Mouly Satyavarapu, Takeda
Ojesh Upadhyay, GSK

**Pillar 2**

Develop use cases for development or implementation of standards and methods to integrate real-world data, improve clinical outcomes, increases efficiencies and accelerate equity in clinical research.

Sam Hume, CDISC
Patty Hegarty, Bayer
Rahul Madhaven, PointCross

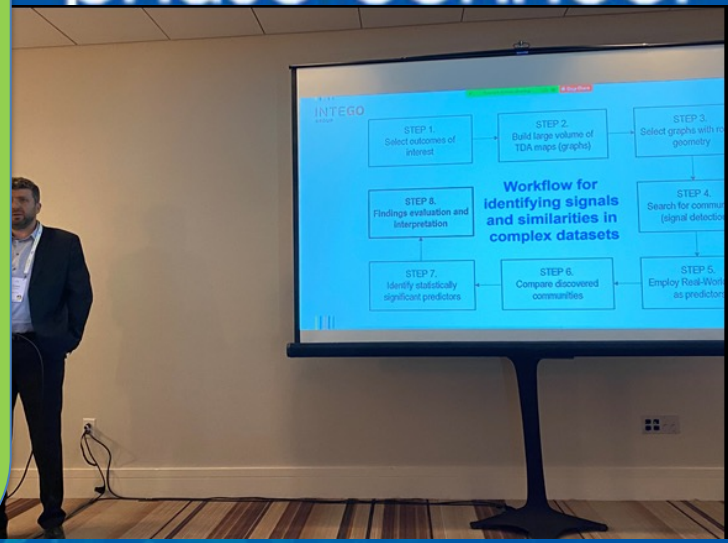
**Pillar 3**

Adapt the use of affordable and innovative technology approaches to the collection of clinical data that is fit for purpose, increases traceability, compliance and accelerates equity in clinical research and healthcare.

Bev Hayes, Janssen
Yogesh Pande, Merck
Nand Kishore Rawat, Lantheus

# FDA/PHUSE Innovation Challenge 2022

1. Excitement for in-person and redesigned conference
2. FDA engagement
3. Continued Innovation Challenge
4. Real World Events
5. AI
6. Modeling and simulations
7. R
8. Vaccines



# Challenge Questions for You (2) !

- How FDA should/can be more influential or impactful or helpful?
- What are the viable actions to implement FDA/PHUSE Innovation Challenge solutions?

Questions or presentation ideas? Contact Catherine.Li@fda.hhs.gov

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**5–8 March**
Renaissance Orlando
at SeaWorld Florida

# US 2023

## The Clinical Data Science Conference

PHUSE's US Connect 2023 will be held in Orlando next year from **5-8 March**

Call for Papers closes this week on **23 September**

For more information visit the PHUSE website – https://www.phuse-events.org/usconnect2023

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18-20 September
Silver Spring, MD

# CSS 2023

## The Computational Science Symposium

PHUSE's CSS 2023 will be held next year from **18-20 September**

Look out for registration details and the agenda next year

For more information visit the PHUSE website – https://www.phuse.global