REAGAN-UDALL FOUNDATION FOR THE FDA

Innovation in Medical Evidence and Development Surveillance (IMEDS)

THE RESEARCH RESOURCE

October 30, 2024 | 1:30-2:30 PM ET

IMEDS

Welcome

Carla Rodriguez-Watson, PhD, MPH
Director of Research
Reagan-Udall Foundation for the FDA

REAGAN-UDALL FOUNDATION FOR THE FDA

REAGAN-UDALL FOUNDATION FOR THE FDA

Virtual Meeting **Housekeeping**

Due to the size of the meeting, your cameras will be off and microphones muted.

If you'd like to ask a question, **enter it in the Zoom Q&A**.

This webinar is being **recorded**.

The recording, along with the slide deck and transcript, will be available at www.ReaganUdall.org early next week.

Agenda

1:30 PM ET	Welcome
1:33 PM ET	Keynote
1:40 PM ET	An Introduction to IMEDS
1:55 PM ET	Panel Discussion
2:25 PM ET	Closing Remarks
2:30 PM ET	Adjourn

REAGAN-UDALL FOUNDATION FOR THE FDA

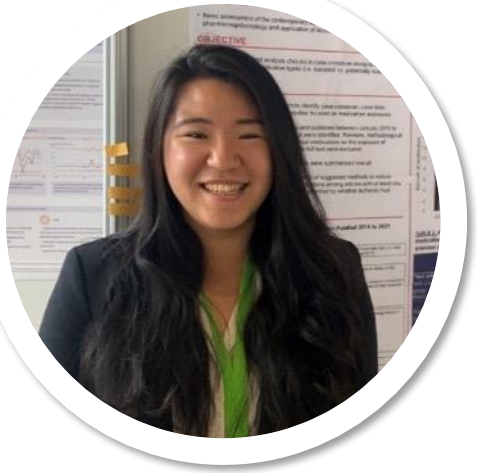
Keynote

Jacqueline Corrigan-Curay, J.D., M.D.

Principal Deputy Center Director

Center for Drug Evaluation and Research (CDER), FDA

Introduction to IMEDS



Claire (Hsiao-Ching) Huang, PhD, MPH
Research Scientist
Reagan-Udall Foundation for the FDA

Georgia Peeples, MPH
Program Coordinator
Reagan-Udall Foundation for the FDA

REAGAN-UDALL FOUNDATION FOR THE FDA

How **IMEDS** Began

2013

Innovation in Medical Evidence and Development Surveillance (IMEDS)

Launched in 2013 by Reagan-Udall Foundation for the FDA

FDA

REAGAN-UDALL
FOUNDATION
for the Food and Drug Administration

IMEDS Leverages Sentinel Capabilities

Innovation in Medical Evidence and Development Surveillance (IMEDS)

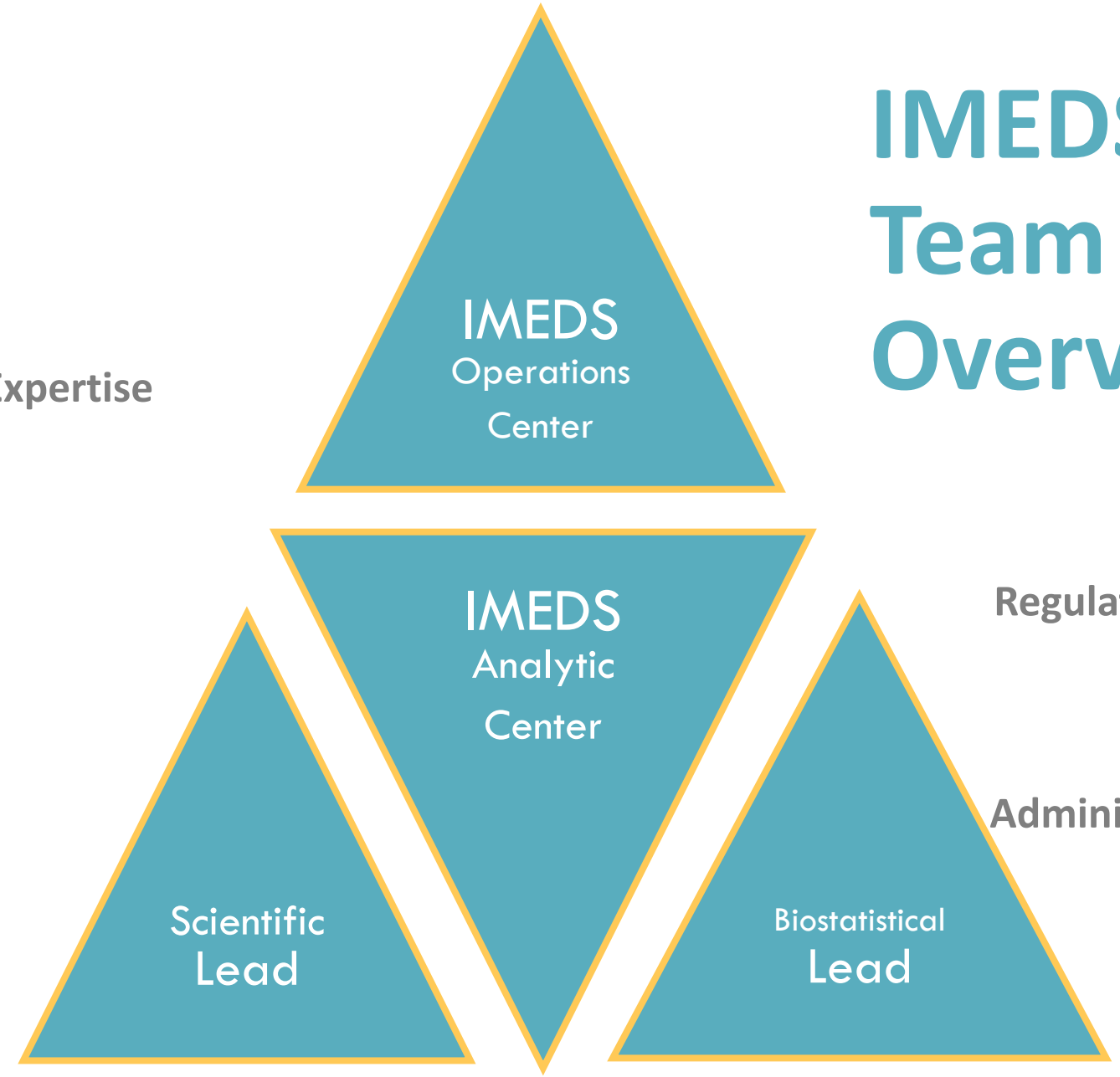
- Leverages Sentinel through IMEDS for evidence generation
- Utilize Sentinel Common Data Model and Sentinel Queries and Tools

Sentinel Initiative
FDA

IMEDS Team Overview

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

- Scientific and Epidemiologic Expertise
- Trustworthy Analytical Tool
- Relevant and Reliable Data



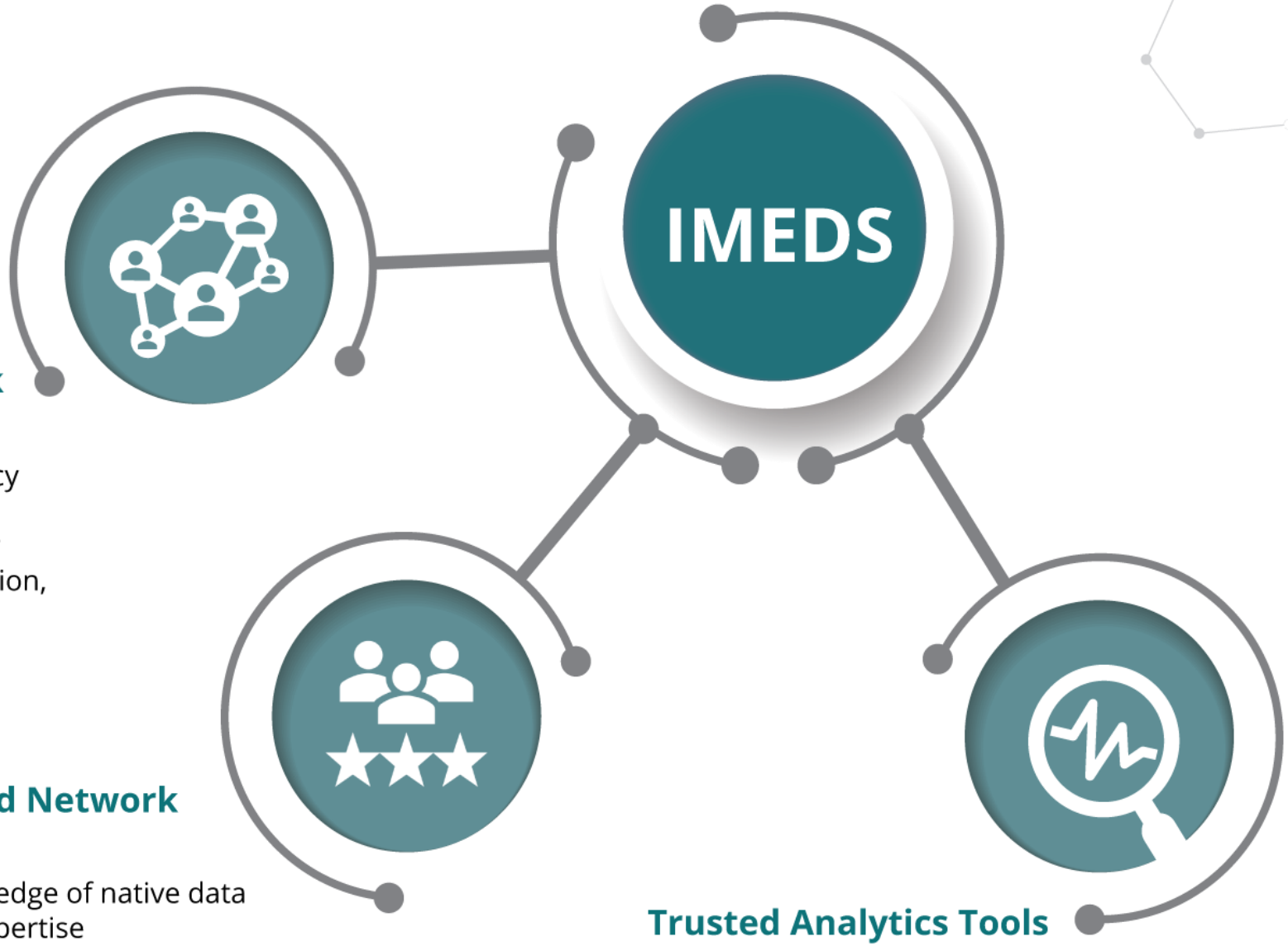
- Experience with Regulatory Science and Submissions
- Administrative Services

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

The IMEDS Network

- CVS Healthspire Life Sciences Solutions
- Harvard Pilgrim Health Care
- Carelon Research, Inc.
- Health Partners Institute
- Humana Healthcare Research
- Kaiser Permanente Washington Health Research Institute
- Marshfield Clinic Health Systems
- Vanderbilt University Medical Center
- University of Massachusetts Chan Medical School Division of Health Systems Science

REAGAN-UDALL FOUNDATION for the Food and Drug Administration



Distributed Network Framework

- Data protection & privacy
- Partner autonomy
- Central coordination for contracting, administration, and analysis

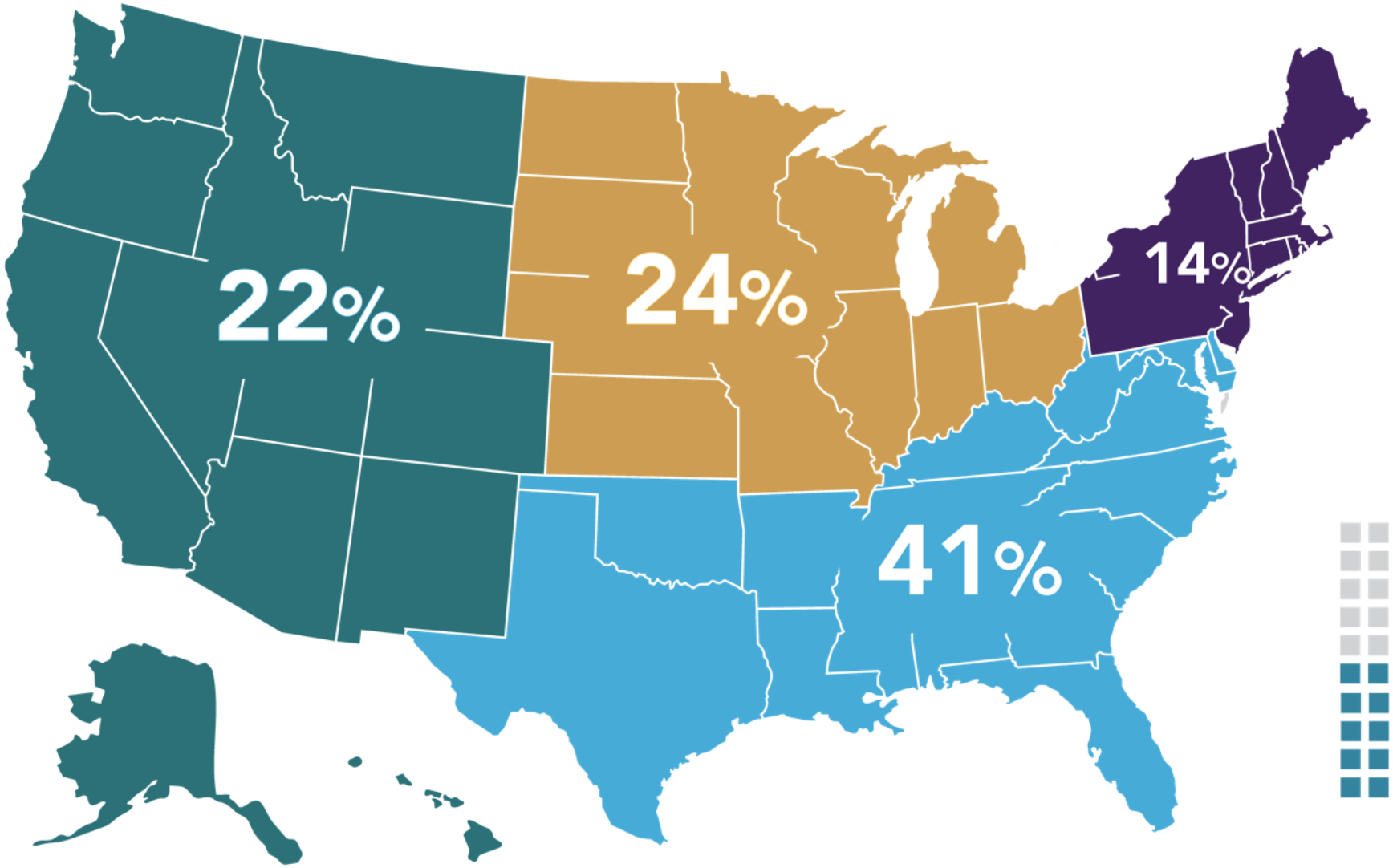
Experienced Network Partners

- Deep knowledge of native data
- Scientific expertise
- Geographically representative of all US states and territories

Trusted Analytics Tools

- Developed by FDA Sentinel
- Ensures relevance & reliability of results

IMEDS Population Data



HISTORICAL DATA

Timespan = 2000 - 2023
Number of Patients = 125M patients with at least one day of medical coverage

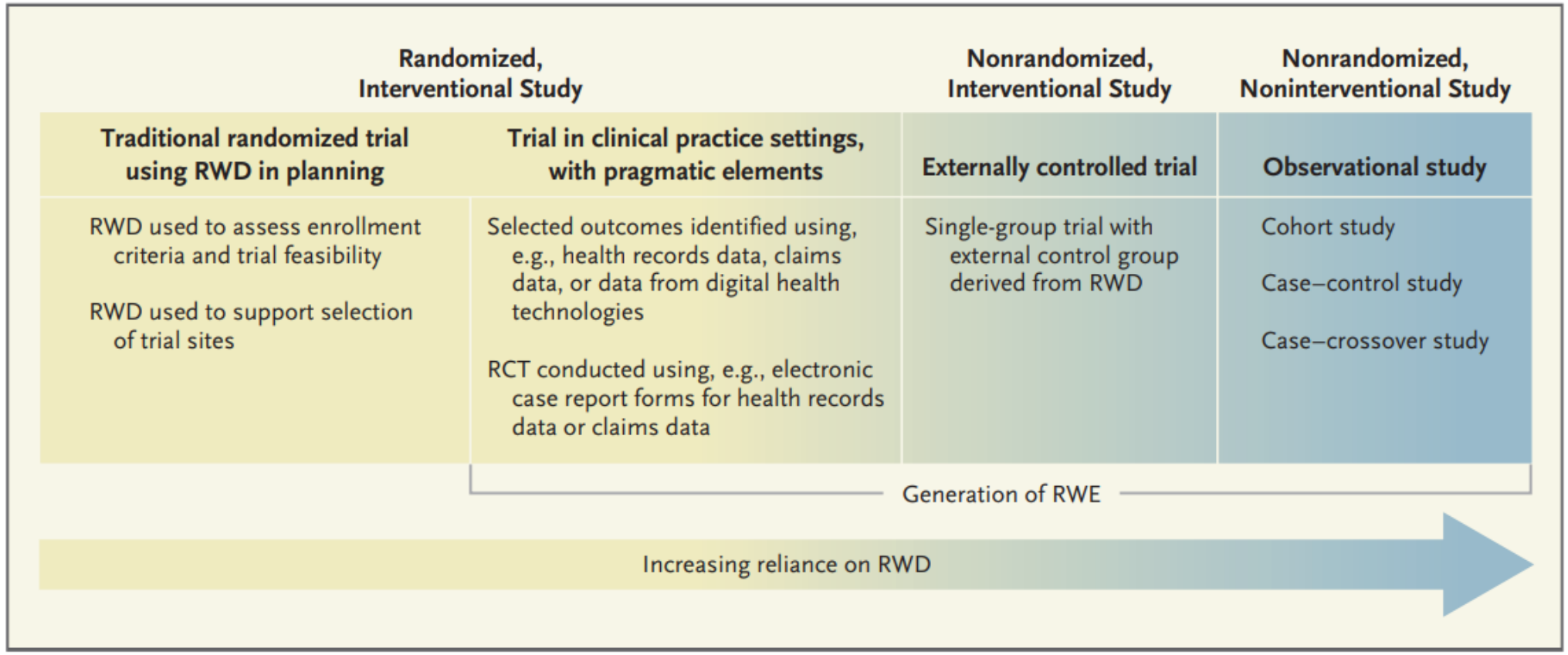
MALE
49%
61,219,933

FEMALE
51%
63,442,129

What Can IMEDS Do?

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

The Role of Real-World Data (RWD) in Research



Reliance on RWD in Representative Types of Study Design.

RCT denotes randomized, controlled trial; RWD real-world data; and RWE real-world evidence.

Concato & Corrigan-Curay 2022

IMEDS Post Market Requirement Studies

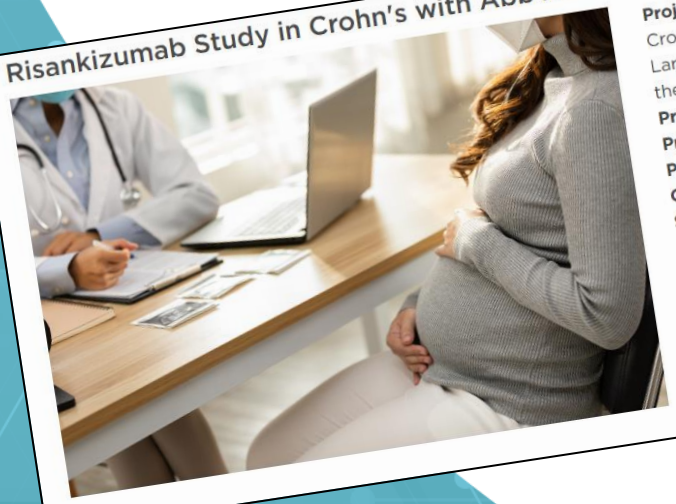
REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Ertugliflozin Study with Merck

Project Title: Post-authorization safety study to assess the risk of diabetic ketoacidosis among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents (AHA)
Project Sponsor: Merck
Project Status: Current
Product: Ertugliflozin
Conditions: Diabetic ketoacidosis, Type 2 diabetes mellitus
Summary: The Reagan-Udall Foundation for the FDA (FDA Foundation PI: Carla Rodriguez-Watson) was recently awarded a contract to leverage data from the Innovation in Medical Evidence Development and Surveillance (IMEDS) Network to continue implementation of a study titled: "Post-authorization safety study to assess the risk of diabetic ketoacidosis among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents (AHA)" (EU PAS Register number: EUPAS31378). This work is being conducted to fulfill a requirement from the European Medicines Agency (EMA). The research activities are a collaborative effort between the Merck research team, the IMEDS Operations Center at FDA Foundation, the IMEDS Analytic Center at the Harvard Pilgrim Health Care Institute, and participating IMEDS Network Partners.

- Click to view the European Union electronic Register of Post-Authorisation Studies (EU PAS) register number (EUPAS31718)

Risankizumab Study in Crohn's with AbbVie



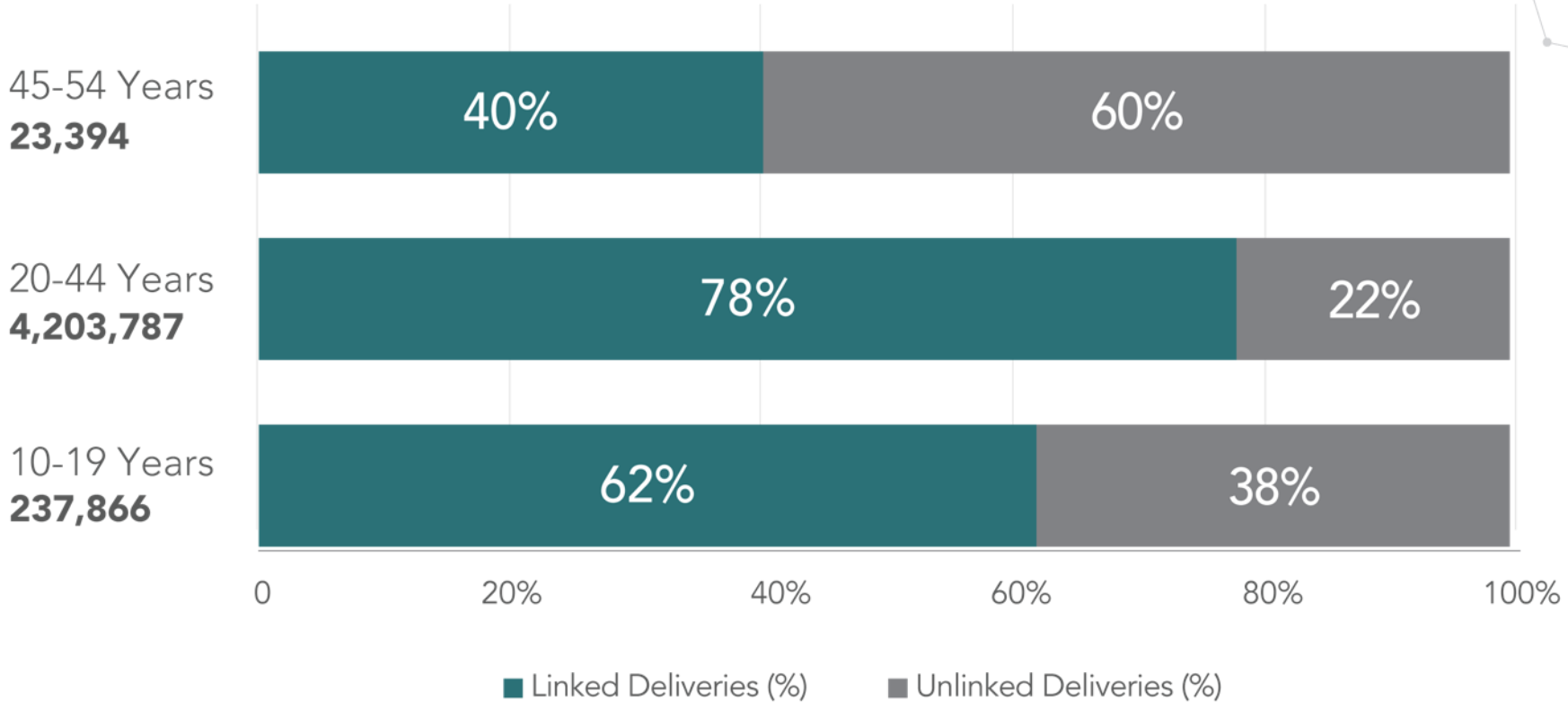
Project Title: Pregnancy Exposures and Outcomes in Women with Crohn's Disease Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States
Project Sponsor: AbbVie
Project Status: Current
Product: Risankizumab
Conditions: Crohn's Disease
Summary: To help fulfill a requirement from the European Medicines Agency (EMA), IMEDS was contracted to help design and execute a study to assess the safety of Risankizumab among women with Crohn's Disease during pregnancy. The risk of pre-specified pregnancy and outcomes will be estimated in pregnant women with Crohn's Disease and are exposed to Risankizumab, as well as in those exposed to comparator biologics (anti-tumor necrosis factor (TNF), integrin receptor antagonist biologics or their biosimilars [comparator biologic-exposed group]).

Risankizumab Study in Psoriasis with AbbVie

Project Title: Pregnancy Exposures and Outcomes in Women with Psoriasis Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States
Project Sponsor: AbbVie
Project Status: Current
Product: Risankizumab
Conditions: Psoriasis, Pregnancy
Summary: To help fulfill a requirement from the European Medicines Agency (EMA), IMEDS was contracted to help design and execute a study to assess the safety of Risankizumab among pregnant women with psoriasis. The risk of pregnancy, birth and infant outcomes will be estimated in pregnant women exposed to Risankizumab, as well as in those exposed to comparator biologics including anti-tumor necrosis factor (TNF), interleukin (IL)-17 biologics or their biosimilars (comparator biologic-exposed group).

IMEDS and Pregnancy Data

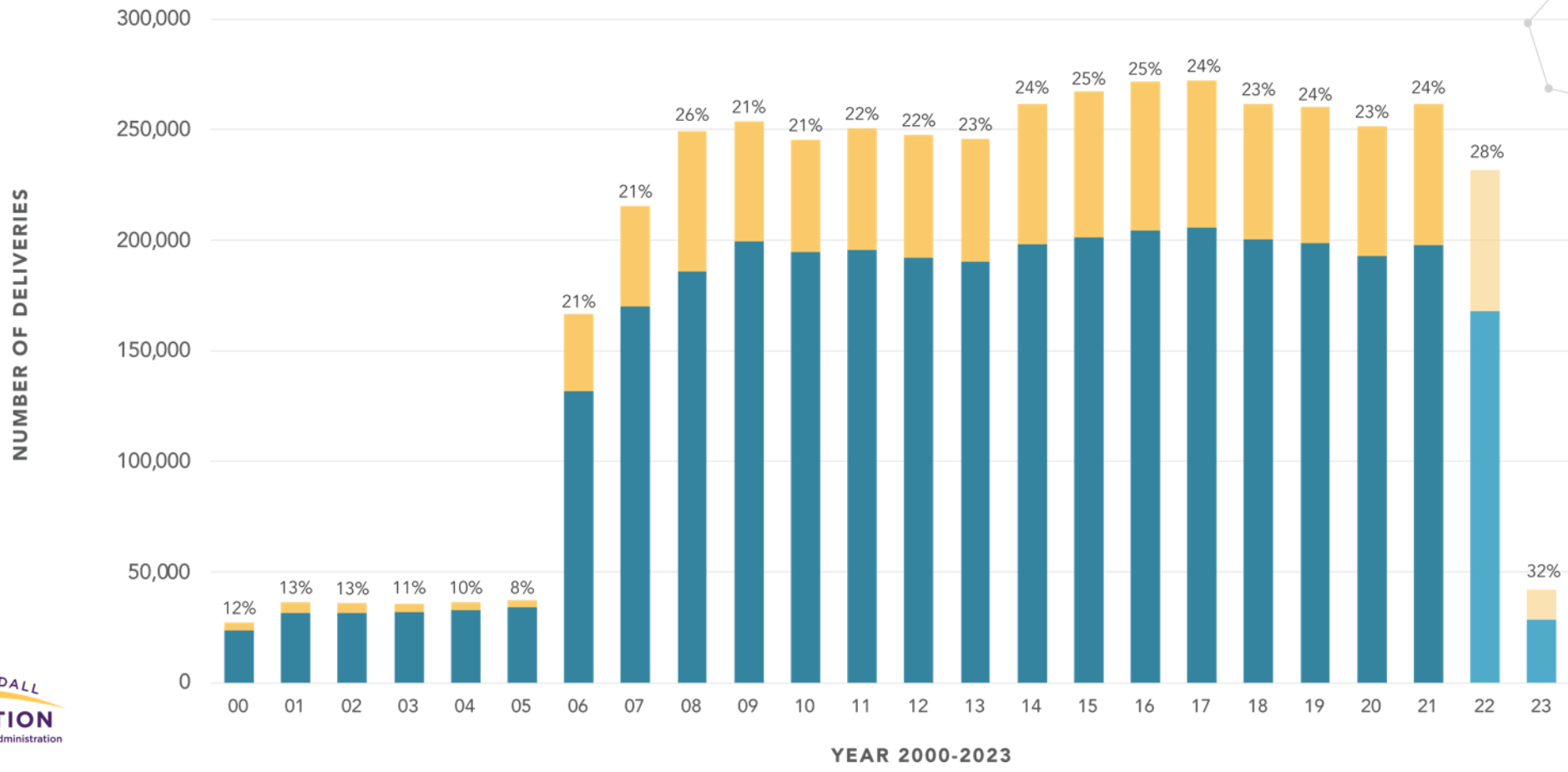
Linked and Unlinked Deliveries in IMEDS Network, by Mother's Age



REAGAN-UDALL FOUNDATION for the Food and Drug Administration

IMEDS and Pregnancy Data

Numbers of Deliveries in IMEDS Network, by Year and Linkage Status



REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Beyond the Post Market Research Studies

Real- World Evidence Generation

- Descriptive studies
- Utilization studies
- Hypothesis generation
- Safety and effectiveness studies

Regulatory Tool Project

- Pregnancy ACE-IT
- Reliability and Relevance of database (QCARD)

Regulatory Tool Example:

The Algorithm CErtainty Tool (ACE IT)

OBJECTIVE:

To inform the user's judgement to determine the fitness of an algorithm for use as an endpoint in a target safety study of the user's design

CLINICAL AREAS OF INTEREST:

- MACE
- Pregnancy outcome
- Acute/Severe Liver Injury
- Cancer
- Kidney Injury
- Serious Infections resulting in medical intervention
- Depression/Suicide

Panel Discussion

IMEDS Webinar

MODERATOR

Carla Rodriguez-Watson, PhD, MPH
Director of Research,
Reagan-Udall Foundation for the FDA

Cheryl N. McMahill-Walraven, PhD, MSW
Executive Director
CVS Healthspire Life Science Solutions

Darren Toh, ScD
DPM Endowed Professor,
Harvard Medical School,
Harvard Pilgrim Health Care Institute

Kristin K. Palmsten, ScD
Senior Research Investigator
HealthPartners Institute

Ryan D. Kilpatrick, PhD
Vice President and Head of Global Epidemiology
AbbVie, Inc.

PANEL DISCUSSION

Closing Remarks

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the FDA

REAGAN-UDALL FOUNDATION FOR THE FDA

Summary

- Relevant and Reliable Data
- Experience with Regulatory Science and Submissions
- Scientific and Epidemiologic Expertise
- Administrative Services
- Exciting Research Opportunities
- Large, geographically representative database

Thank you

for attending the IMEDS Webinar!

Contact us: imeds@reaganudall.org

REAGAN-UDALL FOUNDATION FOR THE FDA