Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Presentation

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Post-Market Active Surveillance of COVID-19 Vaccines in the Pediatric Population in the FDA BEST System

Vaccines and Related Biological Products Advisory Committee
October 26, 2021

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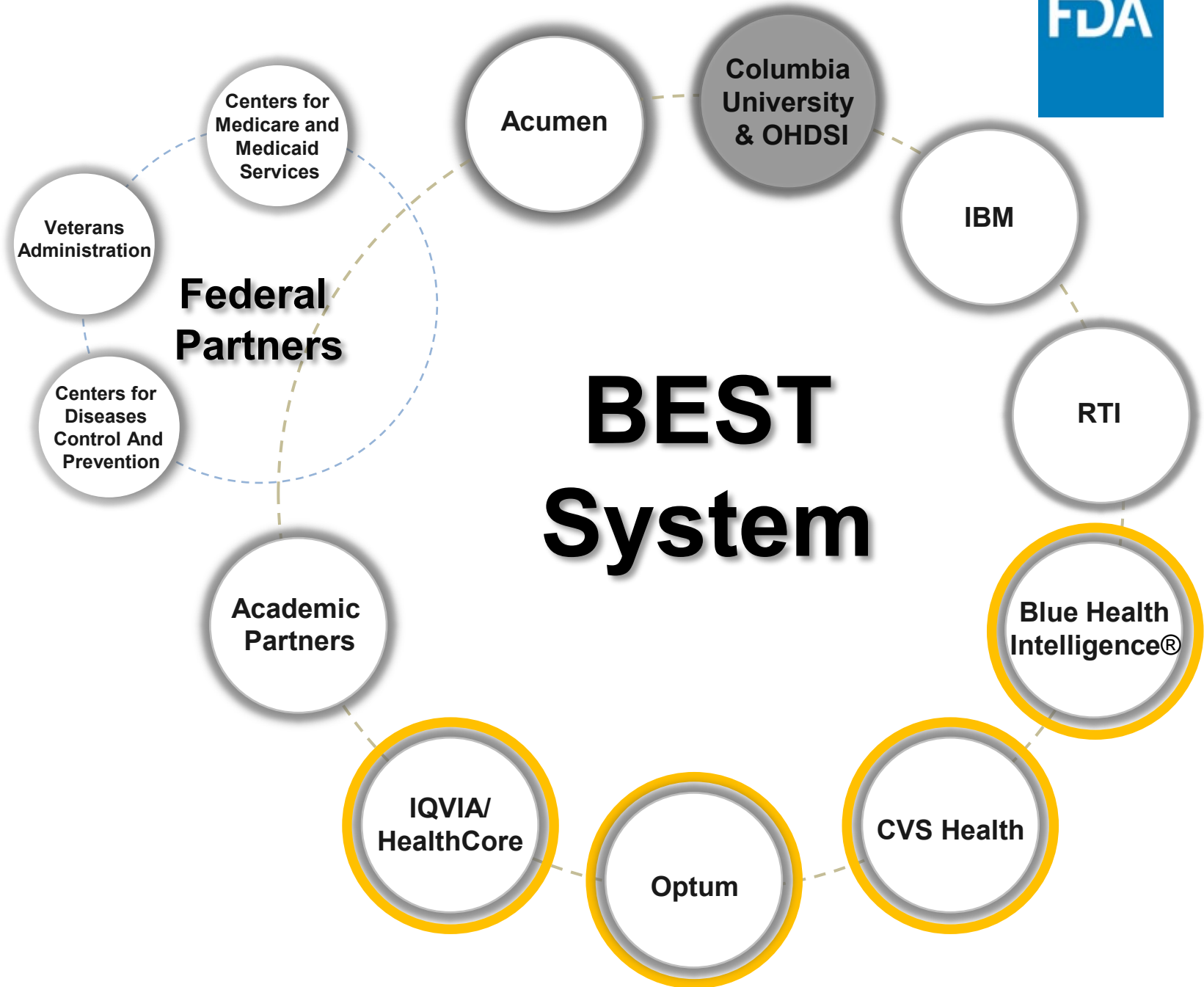US Food and Drug Administration

Outline

- Background: FDA Biologics and Effectiveness Safety (BEST) System

- Pediatric population in FDA BEST System

- Safety surveillance of children ages 12-15 years and 16-17 years after Pfizer-BioNTech vaccination

- Summary

FDA Biologics and Effectiveness Safety (BEST) System

FDA CBER Active Surveillance Program

BEST System

CBER: Center for Biologics Evaluation and Research
BEST: Biologics Effectiveness and Safety

Pediatric Population by Age in Administrative Claims, FDA BEST System

FDA BEST Partners	Age 0-4 years	Age 5-11 years	Age 12-15 years	Age 16-17 years
Blue Health Intelligence®	2,534,214	2,521,796	1,719,844	892,165
CVS Health	1,065,238	1,507,802	969,471	507,637
HealthCore	1,242,325	1,832,048	1,219,367	641,236
Optum	1,020,020	1,362,267	891,228	461,513
Total	**5,861,797**	**7,223,913**	**4,799,910**	**2,502,551**

Pediatric population: Number of enrollees ever enrolled since 12/11/2020 to date of data cutoff (Blue Health Intelligence®: 6/30/2021, CVS Health: 7/31/2021, HealthCore: 8/5/2021, Optum: 9/18/2021)

Estimated Percent Coverage of US Population by Age in Administrative Claims, FDA BEST System

	Age 0-4 years	Age 5-11 years	Age 12-15 years	Age 16-17 years
Total Across Data Partners*	5,861,797	7,223,913	4,799,910	2,502,551
Census Estimate of US Population (2020)	19,301,292	28,384,878	16,783,176	8,352,767
Estimated Percent Coverage of US Population	**30.4%**	**25.5%**	**28.6%**	**30.0%**

*Number of enrollees ever enrolled since 12/11/2020 to date of data cutoff (Blue Health Intelligence®: 6/30/2021, CVS Health: 7/31/2021, HealthCore: 8/5/2021, Optum: 9/18/2021)

Pediatric Population in Pediatric Electronic Health Records, FDA BEST System

PEDSnet

- Electronic Health Records
- 8 Children's Hospital Health Systems
- Covers over 7 million children; ~ 1-2 million annually
  - Jan 1, 2020 - Dec 31, 2020:
    - 1.6 million patients with at least 1 encounter, aged 0-17 years

Boston Children's Hospital

St. Louis Children's Hospital

Children's Hospital of Philadelphia

Children's Hospital Colorado

Seattle Children's

Cincinnati Children's

Nemours Children's Health

Nationwide Children's

Pfizer-BioNTech COVID-19 Vaccine Doses in Ages 12-17 Years, FDA BEST System

FDA BEST Partners	Total*	
	Age 12-15 years	Age 16-17 years
Optum	405,534	209,091
HealthCore	406,107	233,677
Total	**811,641**	**442,768**

*First, Second and Third or Unknown /unspecified doses
Data through 8/5/2021 (HealthCore), 9/18/2021 (Optum)

Near Real-Time Safety Surveillance of COVID-19 Vaccines, FDA BEST System

These potential adverse events of special interest <u>have not been associated </u>with COVID-19 vaccines based on pre-authorization evidence

Acute myocardial infarction	Bell's Palsy	Narcolepsy
Anaphylaxis	Encephalomyelitis	Non-hemorrhagic Stroke
Appendicitis	Guillain-Barré syndrome	Pulmonary Embolism
Disseminated intravascular coagulation	Hemorrhagic Stroke	Transverse Myelitis
Deep Vein Thrombosis	Myocarditis/Pericarditis	Immune thrombocytopenia
	Thrombosis with Thrombocytopenia	

Near Real-Time Surveillance of Pfizer-BioNTech COVID-19 Vaccines in 12-64 years, FDA BEST System

Adverse Events of Special Interest	Risk Window (days)	Safety Signal During Testing	
		Optum	HealthCore
Acute Myocardial Infarction	1-28	No	No***
Anaphylaxis	0-1	Yes	Yes
Appendicitis	1-42	No	No
Bell's Palsy	1-42	No	No
Common Thromboses* with Thrombocytopenia	1-28	No	No
Unusual Site Thromboses** with Thrombocytopenia Syndrome	1-28	No	No
Deep Vein Thrombosis	1-28	No	No
Disseminated Intravascular Coagulation	1-28	No	No
Encephalomyelitis	1-42	No	No
Guillain-Barré Syndrome	1-42	No	No***
Hemorrhagic Stroke	1-28	No	No
Immune Thrombocytopenia	1-42	No	No
Multisystem Inflammatory Syndrome	1-42	No	No
Myocarditis/Pericarditis	1-42	No	No
Narcolepsy	1-42	No	No
Non-Hemorrhagic Stroke	1-28	No	No
Pulmonary Embolism	1-28	No	No
Transverse Myelitis	1-42	No	No***

Data through 8/5 (HCI), 9/18 (Optum)
*acute myocardial infraction, deep vein thrombosis, pulmonary embolism, hemorrhagic stroke, non-hemorrhagic stroke; ** cerebral and abdominal
***RCA excludes pediatric population (12-17) due to lack of estimable background rates

10

Summary of Active Surveillance of Post-Market Safety Data in Pediatric Population in FDA BEST System

- FDA BEST is monitoring the safety of COVID-19 vaccines in near-real time surveillance

- Observed versus Expected Analyses for pediatric population will be conducted when events sufficiently accrue

Acknowledgements

FDA BEST Partners

Acumen

CVS Health

Optum

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12