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Considerations for Simplification of Current COVID-19 Vaccine Use and Periodic Updates to COVID-19 Vaccine Composition

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Director, Office of Vaccines Research and Review
January 26, 2023

Need for *Simplification* of Current COVID-19 Vaccine Use

Current state

Different COVID-19 vaccine compositions and immunization schedules are authorized or approved in the U.S., leading to a complex context for use that complicates implementation and communication

Desired future state

For all current COVID-19 vaccines used in the U.S.:

- same COVID-19 vaccine strain composition for primary series and booster doses
- simplified immunization schedule (e.g., age- and risk-based) for use in periodic vaccination campaigns

Approach to *Periodic Updates* of Current COVID-19 vaccines

Current state

Continued rapid evolution of SARS-CoV-2 and waning of vaccine-induced immunity will likely require revaccination with periodically updated S protein sequence(s) contained or encoded in current COVID-19 vaccines

Desired future state

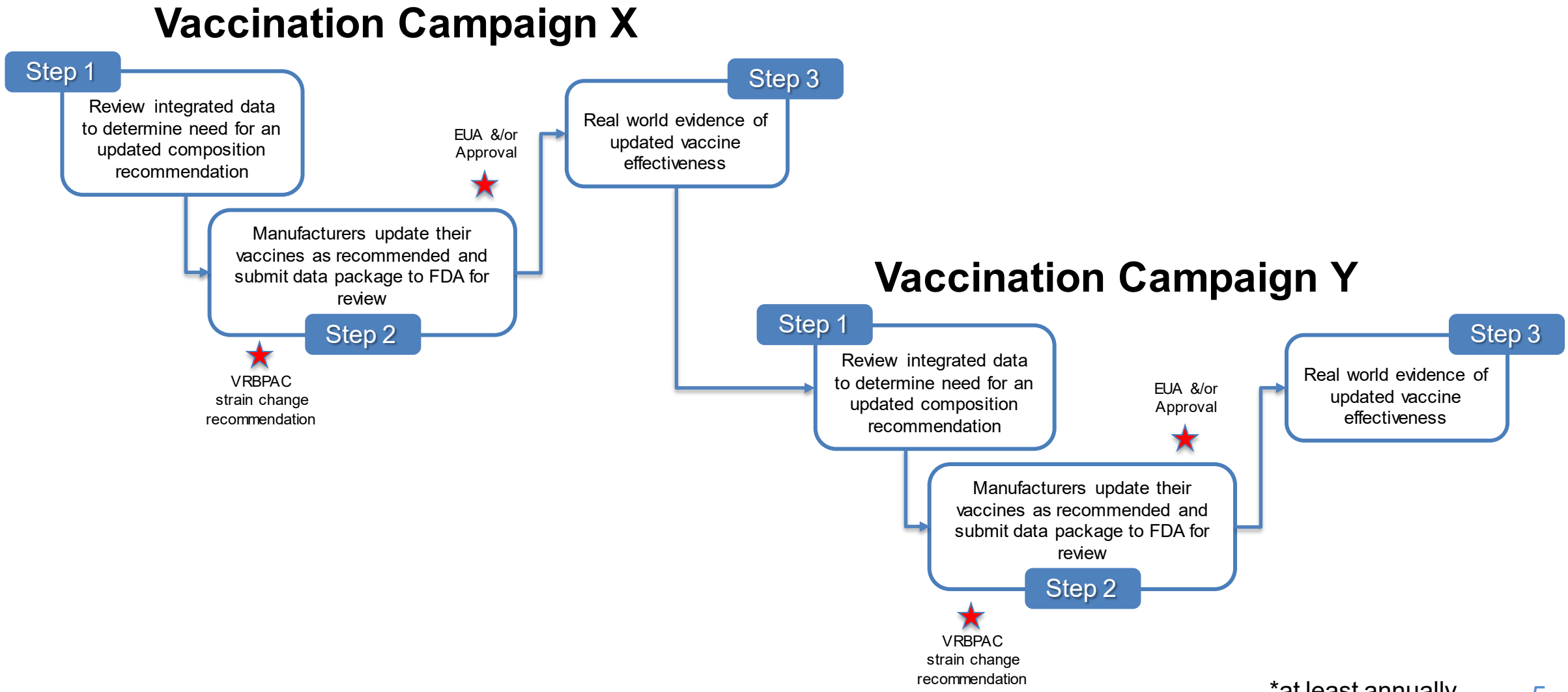
An evidence-driven approach, similar in many ways to the process used for influenza vaccines, to monitor and update, as needed, the composition used in all COVID-19 vaccines to induce or restore protective immunity through periodic vaccination campaigns

Meeting objectives

VRBPAC to consider the following topics:

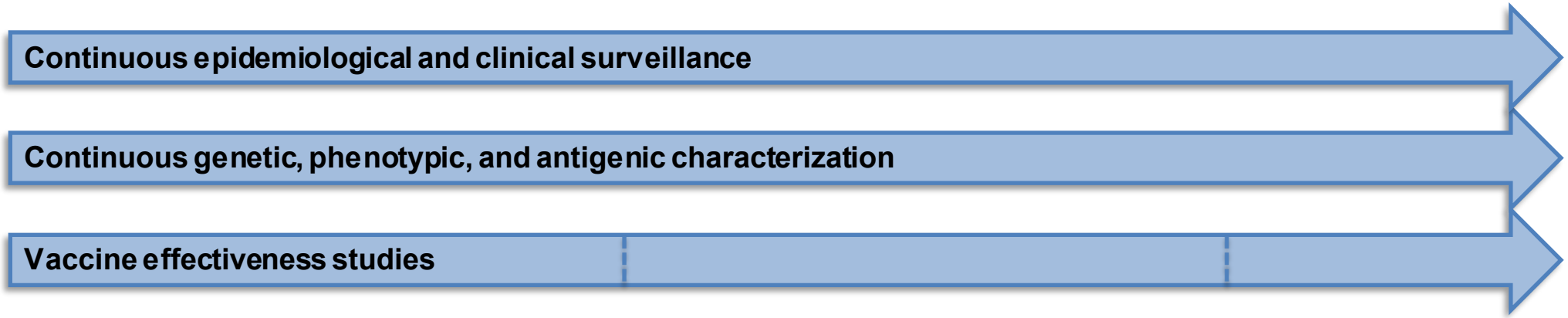
- Transitioning to the same vaccine strain composition for primary series and booster vaccination;
- Harmonizing the strain composition of all COVID-19 vaccines (e.g., mRNA, protein-based);
- Simplifying the immunization schedule for future vaccination campaigns to administer:
  - one dose for most adults, adolescents, and older children, and for young children who were previously immunized;
  - additional dose(s) for: i) high-risk older adults and persons with compromised immunity; and ii) young children who have not been previously immunized;
- Establishing a process for vaccine strain selection recommendations, similar in many ways to that used for seasonal influenza vaccines, based on prevailing and predicted variants that would take place by June to allow for vaccine production by September;
- Convening a strain selection meeting, at any time between routine periodic strain selections, to address a more pathogenic escape variant.

Approach to updating vaccine composition: High-level overview of a continuous* iterative 3-step process

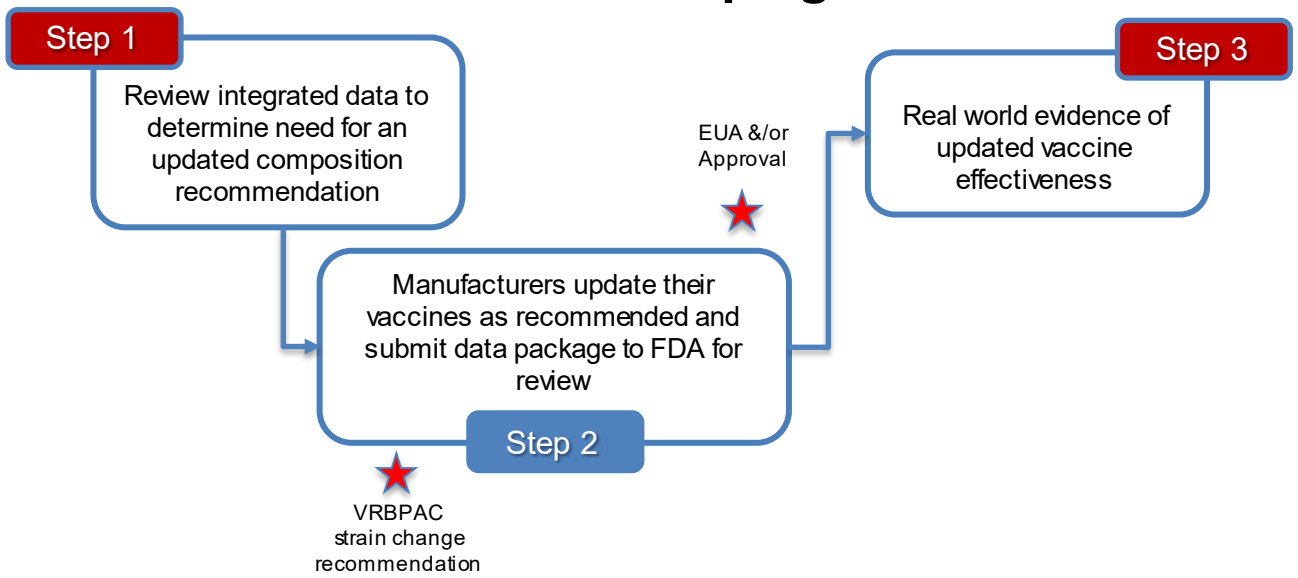


*at least annually

Approach to updating vaccine composition: High-level overview of a continuous* iterative 3-step process



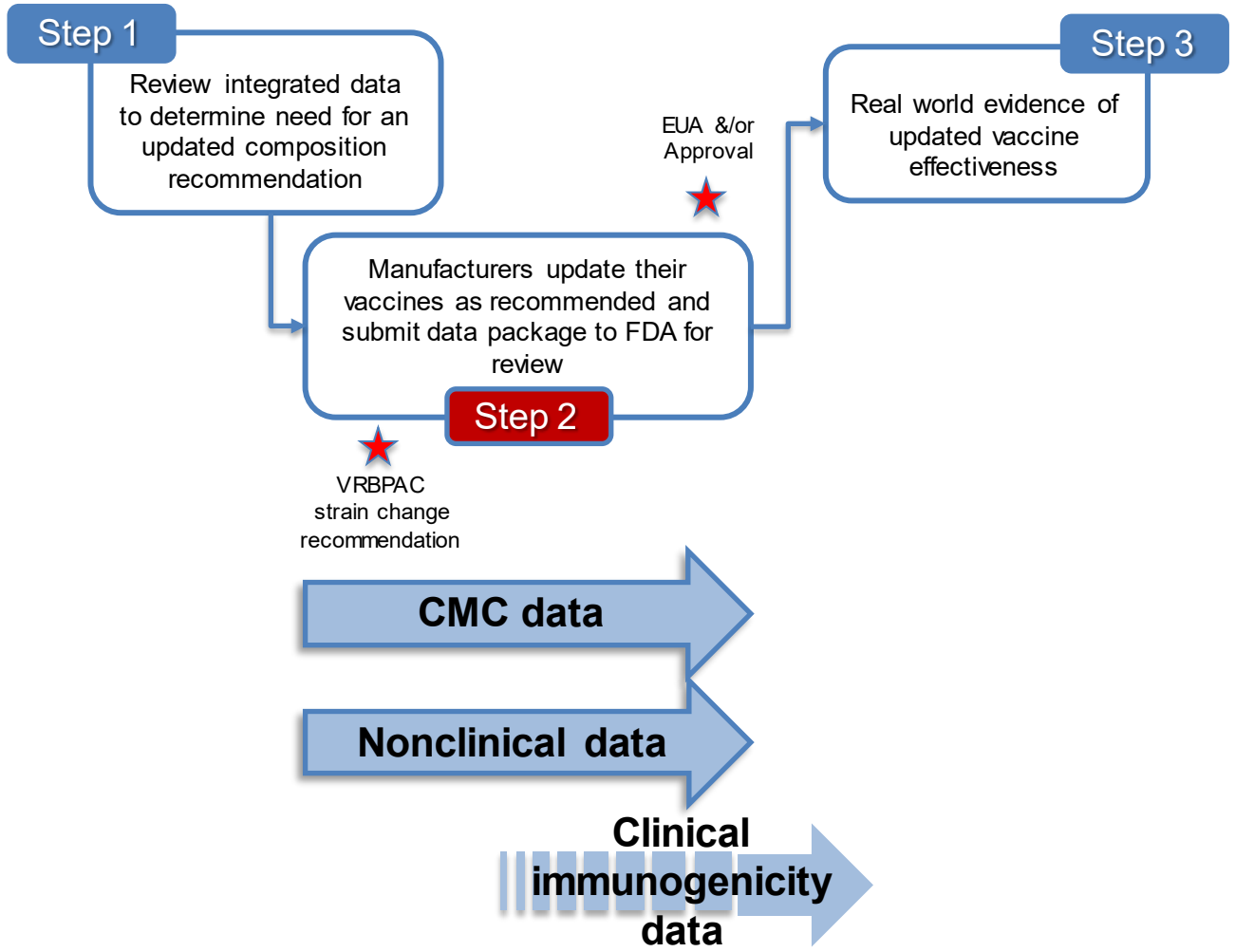
Vaccination Campaign X



*at least annually

Approach to updating vaccine composition: High-level overview of a continuous* iterative 3-step process

Vaccination Campaign X



*at least annually

An Age- and Risk-Based Immunization Schedule
A Proposed *Potential* Simplified Approach for Future Periodic Vaccination Campaigns

General Population (age-based; one dose)*	Risk-based adjustments (dose(s) and schedule to be determined) **
Most adults	**High-risk older adults**
Adolescents and Older children	**Persons with compromised immunity**
Young children *who were previously immunized*	**Young children** *who have not been previously immunized*

*Presumed to have had sufficient S protein exposures such that a single dose of COVID-19 vaccine induces or restores vaccine effectiveness
**Presumed to have insufficient preexisting immunity based on age and other risks (e.g., young children who have not been previously immunized, older adults who have higher-level risk for severe COVID-19 and death, and persons with compromised immunity); may require more than one dose of vaccine in each COVID-19 vaccination campaign; the number of doses and schedule to be determined

Overview of Today's Agenda

EST Time	Presentation/Presenter
8:30 a.m.	**Opening Remarks: Call to Order and Welcome (5 Min)** Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus Professor of Public Health and Epidemiology University of Michigan **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (15 Min)** Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division Of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA
8:50 a.m.	**FDA Introduction (20 Min)** **Welcome (5 Min)** • Peter Marks, M.D. Ph.D. Center Director, CBER, FDA **Considerations for Updating Boosters and Whether and How Primary COVID-19 Vaccine Strain Composition Should be Modified (10 Min)** • David Kaslow, M.D. Director Office of Vaccines Research and Review (OVRR), CBER, FDA Q/A – 5 Min
9:10 a.m.	**CDC Presentation (30 Min total including Q/A)** **Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants (25 Min)** • CDR Heather Scobie, Ph.D., MPH Surveillance and Analytics Team Lead (Acting) National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention (CDC)
	Q/A – 5 Min
9:40 a.m.	**CDC Presentations (45 Min total including Q/A)** **Update on Original COVID-19 Vaccine and COVID-19 Vaccine Bivalent Effectiveness and Safety (40 Min)** • Ruth Link-Gelles, PH.D., M.PH. (20 min) LCDR, U.S. Public Health Service COVID-19 Vaccine Effectiveness Program Lead National Center for Immunization and Respiratory Diseases, CDC • Tom Shimabukuro, M.D., M.PH., M.B.A. (5 min) Captain, U.S. Public Health Service Director Immunization Safety Office, CDC • Nicola Klein, M.D., Ph.D. (15 min) Director, Kaiser Permanente Vaccine Study Center Professor, Department of Health Systems Science Kaiser Permanente Bernard J. Tyson School of Medicine Q/A – 5 Min
10:25 a.m.	**FDA Presentation (30 Min Total including Q/A)** **Update on Original COVID-19 Vaccine and COVID-19 Vaccine, Bivalent Effectiveness and Safety (25 min)** • Richard Forshee, Ph.D. Deputy Director Office of Biostatistics and Pharmacovigilance, CBER, FDA Q/A – 5 Min
10:55 a.m.	**NIH Presentation (25 Min Total including Q/A)** **Evaluation of Improved Generation COVID-19 Vaccines (20 min)** • John Beigel, M.D. Associate Director for Clinical Research Division of Microbiology and Infectious Diseases

Overview of Today's Agenda Continued

	National Institute of Allergy and Infectious Diseases National Institutes of Health Q/A – 5 min
11:20 a.m.	**Break (10 min)**
11:30 a.m.	**Moderna Presentation (30 Min Total including Q/A)** **Introduction: Moderna COVID-19 Bivalent Vaccines Primary Series and Booster** Antonella Lozito, PharmD Executive Director, Regulatory Affairs - Infectious Disease Moderna, Inc. **Clinical Data with Omicron-Containing mRNA-1273 Bivalent Vaccines** Rituparna Das, M.D., Ph.D. Vice President, Clinical Development, COVID-19 Vaccines Moderna, Inc. **Real-World Effectiveness Data** Rituparna Das, M.D., Ph.D. Vice President, Clinical Development, COVID-19 Vaccines Moderna, Inc. **Preclinical Results from Authorized and Investigational Multivalent Vaccines** Darin Edwards, Ph.D. Senior Director of Immunology Infectious Disease Group Moderna, Inc. **Summary and Conclusions** Rituparna Das, M.D., Ph.D. Vice President, Clinical Development, COVID-19 Vaccines Moderna, Inc. Q/A –5 Min

12:00 p.m.	**Pfizer presentation (30 Min Total including Q/A)** **Pfizer/BioNTech COVID-19 Variant Vaccines (25 Min)** Kena A. Swanson, Ph.D. Vice President, Viral Vaccines, Vaccine Research and Development, Pfizer Inc. Q/A – 5 Min
12:30 p.m.	**Novavax presentation (30 Min Total including Q/A)** **Novavax Vaccine Regimens Addressing COVID-19 (25 Min)** Dr. Filip Dubovsky, M.D. Executive Vice President and Novavax Chief Medical Officer - Novavax Q/A – 5 Min
1:00 p.m.	**Lunch (30 Min)**
1:30 p.m.	**Open Public Hearing (60 Min)**
2:30 p.m.	**FDA Presentation (30 Min Total including Q/A)** **FDA Considerations for Potential Changes to COVID-19 Vaccine Strain Composition (25 Min)** • Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review, CBER, FDA Q/A - 5 Min
3:00 p.m.	**Break (10 Min)**
3:10 p.m.	**Additional Q & A for CDC, FDA and Sponsor Presenters (20 Min)**
3:30 p.m.	**Committee Discussion and Voting (120 Min)**
5:30 p.m.	**Meeting Adjourned - DFO**

VRBPAC VOTING QUESTION

***Simplification* of current COVID-19 vaccine use:**

- *Vaccine composition:* Does the committee recommend harmonizing the vaccine strain composition of primary series and booster doses used in the U.S. to a single composition, e.g., the composition for all vaccines administered currently would be a bivalent vaccine (Original plus Omicron BA.4/BA.5)?

VRBPAC DISCUSSION TOPICS

Future periodic vaccination campaigns

Periodic update to COVID-19 vaccines:

- *Vaccine composition:* Please discuss and provide input on the consideration of periodic updates to COVID-19 vaccine strain composition, including to the currently authorized or approved vaccines to be available for use in the U.S. in the fall of 2023.

VRBPAC DISCUSSION TOPICS CONTINUED

Future periodic vaccination campaigns

Simplification of COVID-19 vaccine use*:*

- *Immunization schedule:* Please discuss and provide input on simplifying the immunization schedule to authorize or approve:
  - A) one dose for most adults, adolescents, and older children, and for young children who were previously immunized;
  - B) additional dose(s) for:
    - i) high-risk older adults and persons with compromised immunity;
    - ii) young children who have not been previously immunized.


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