Selection of the 2024-2025 Formula for COVID-19 Vaccines - Introduction

Vaccines and Related Biological Products Advisory Committee (6/5/2024)

Jerry P Weir, PhD, Director
Division of Viral Products/OVRR/CBER/FDA

Purpose of Today's VRBPAC Committee Discussion

- Review SARS-CoV-2 surveillance and epidemiology data, genetic and antigenic characteristics of recent virus isolates, serological responses to current vaccines, and the availability of candidate COVID-19 vaccines (2024-2025 Formula)

- Make recommendations for the composition of the 2024-2025 COVID-19 vaccine formula for use in the United States

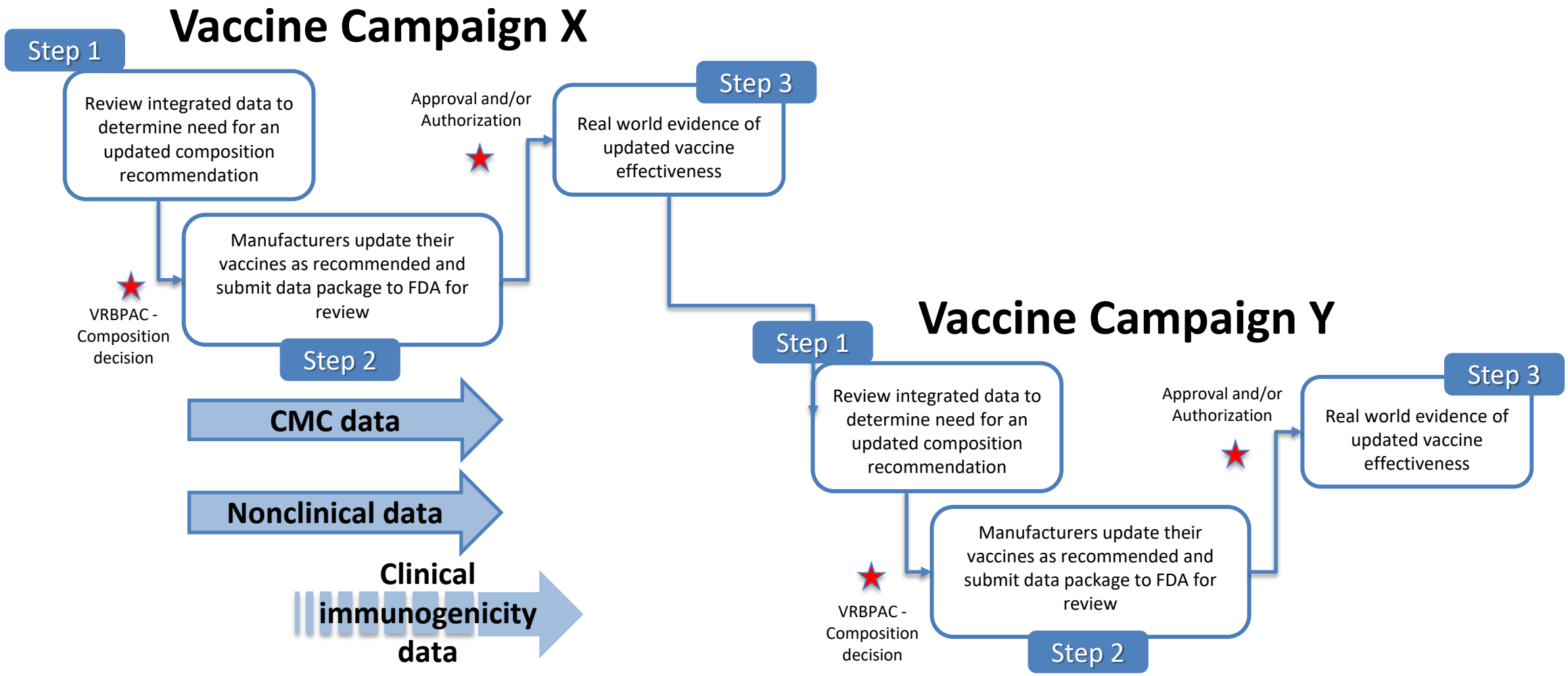
Agenda Outline

- Introduction
- Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants
  - Dr. Natalie Thornburg, CDC
- Update on COVID-19 Vaccine Effectiveness
  - Dr. Ruth Link-Gelles, CDC
- WHO TAG-CO-VAC April 2024 Recommendation on the Antigen Composition of COVID-19 Vaccines
  - Dr. David Wentworth, CDC – WHO Technical Advisory Group Chair
- Manufacturers Presentations
  - Moderna
  - Pfizer/BioNTech
  - Novavax
- FDA Considerations and Recommendations for Changes to COVID-19 Vaccine Formula Composition
  - Dr. Jerry Weir, FDA
- Open Public Hearing
- Additional Q & A
- Committee Discussion and Voting

Summary of the Process Used for the Vaccine Strain Composition Recommendation

- As proposed previously (January 2023 VRBPAC), the evidence used to determine the need for updating the strain composition of COVID-19 vaccines would ideally include multiple types and sources of data
- FDA reviews various types of data as listed below and engages with the key partners generating such data, including vaccine manufacturers and other government agencies
  - Virus surveillance and genomic analyses to identify emerging new virus variants
  - Antigenic characterization of viruses to identify antigenically distinct variant viruses
  - Post-vaccination human serology studies to evaluate antibody responses generated by the current vaccines against more recently circulating virus variants
  - Available post-infection human serology studies to evaluate antibody responses generated by recently circulating virus variants
  - Pre-clinical immunogenicity studies to evaluate immune responses generated by new candidate vaccines (e.g., expressing or containing updated variant spike components) against antigenically distinct circulating virus variants
- FDA reviews the discussions and recommendations put forth by other regulatory groups and public health agencies
- FDA discusses manufacturing timelines with each of the manufacturers of authorized/approved COVID-19 vaccines to understand the impact of a strain composition recommendation on vaccine availability

Approach to Updating Vaccine Composition – High Level Overview



Global Alignment of COVID-19 Strain Composition Recommendations

- There are many challenges for global coordination of the COVID-19 vaccine strain composition
- Nevertheless, global public health agencies and vaccine regulators meet throughout the year in an effort to align the criteria used and the vaccine strain composition recommendations when possible
  - The International Coalition of Medicines Regulatory Authorities (ICMRA), an informal group of international regulatory authorities, held a workshop on February 26-27, 2024 – "Global perspectives on COVID-19 vaccines strain update: Alignment on timing and data requirements"
    - Goal was to align, to the extent possible, the evidence required for and timing of recommendations on updated vaccine composition, to understand the time required by manufacturers to develop vaccines with an updated composition, and to understand the regulatory and timing requirements for regulatory approval
    - Meeting report released April 17, 2024 (https://icmra.info/drupal/en/covid-19)
  - The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) issued a statement on April 26, 2024, on the antigen composition of COVID-19 vaccines (update presented at this VRBPAC)
    - "As the virus is expected to continue to evolve from JN.1, the TAG-CO-VAC advises the use of a **monovalent JN.1 lineage** as the antigen in future formulations of COVID-19 vaccines"

Voting Question for the Committee

1. For the 2024-2025 Formula of COVID-19 vaccines in the U.S., does the committee recommend a monovalent JN.1-lineage vaccine composition?

Please vote “Yes” or “No” or “Abstain”

Discussion Topic for the Committee

- Based on the evidence presented, please discuss considerations for the selection of a specific JN.1 lineage strain (e.g., JN.1, KP.2, etc.) for COVID-19 vaccines (2024-2025 Formula) to be used in the U.S.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