# Characterization of COVID-19 Vaccine Data in the Sentinel System

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## BACKGROUND

- COVID-19 vaccinations have been delivered in a range of settings, from healthcare visits to state-sponsored vaccination fairs.
- It is important to understand how and to what degree COVID-19 vaccination status is captured in real world data sources such as administrative claims data.

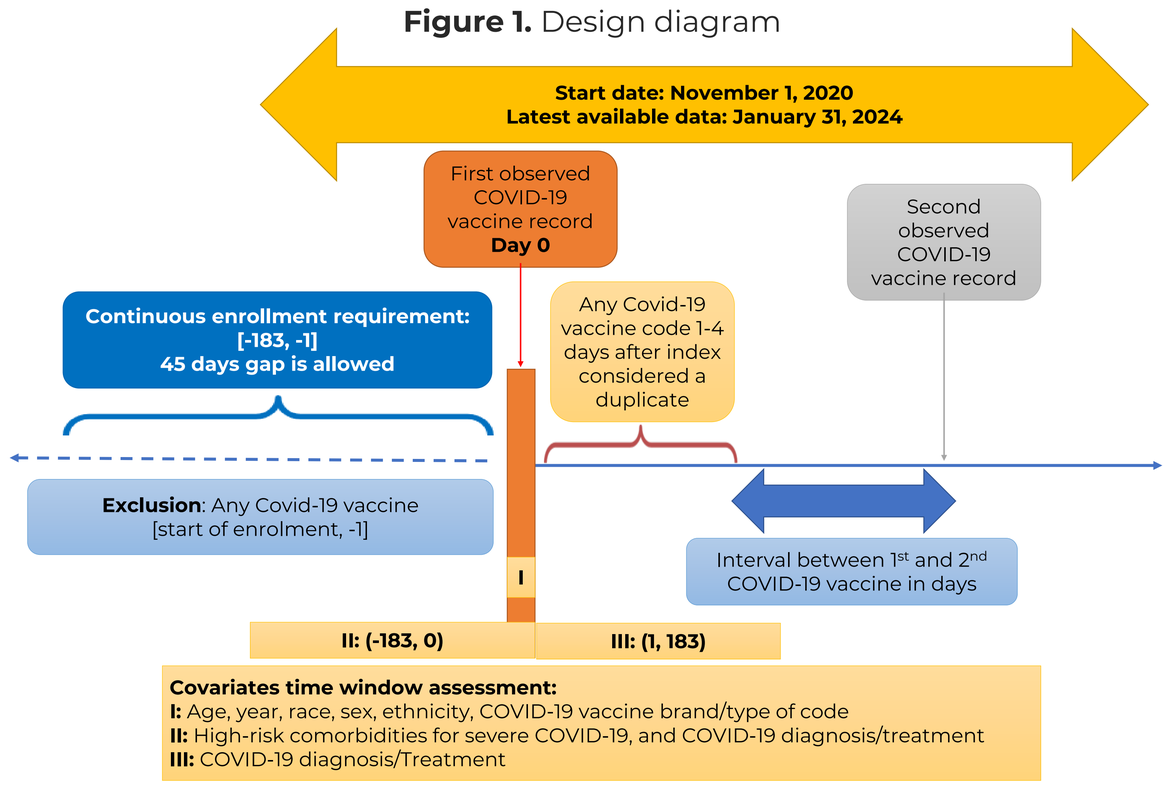
## OBJECTIVES

- To characterize the COVID-19 vaccine data in the FDA's Sentinel Distributed Database (SDD).

## METHODS

- Included Data Partners in the FDA's Sentinel Distributed Database (SDD): 12 commercial health plans, Medicaid, and Medicare
- Identified members with immunization procedure codes from traditional insurance claims and data from state-based Immunization Information Systems (IIS) if available; 5 of 14 Data Partners had IIS data
- Study period: November 1, 2020- January 31, 2024
- Index date was the date of first COVID-19 vaccine
- Identified all available brands and unspecified COVID-19 vaccines
- Inclusion: ≥ 183 days continuous medical and drug coverage before index date (45 days gap was allowed)
- Stratified by year-month*age group
- Demographic characteristics were assessed at index, clinical characteristics at index or 183 days prior, and COVID-19 identified by diagnosis codes at index or 183 days before and after index
- Identified potential duplicate/erroneous codes within 1-4 days of index
- Calculated time interval between 1st and 2nd doses when applicable

**Figure 1.** Design diagram




## RESULTS

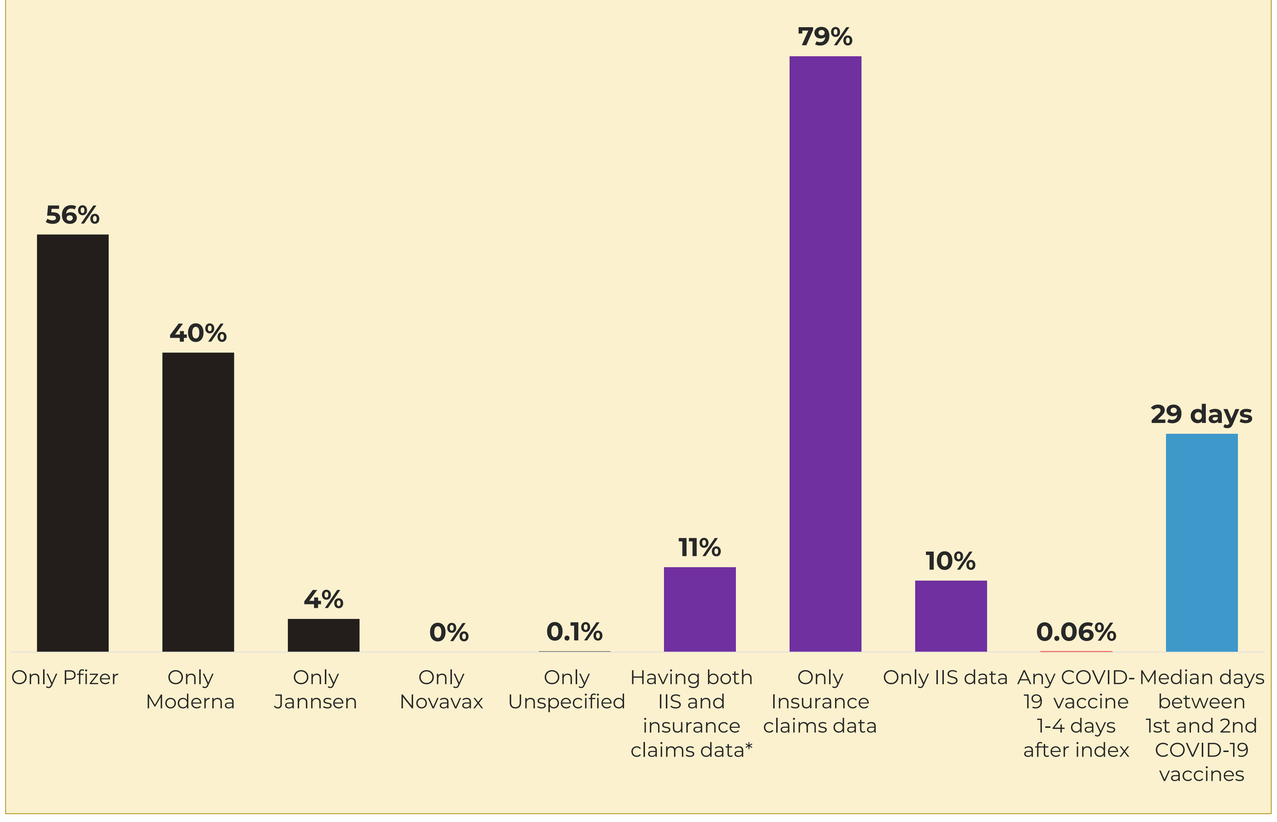
- Identified records for >38 million recipients (Table 1), with Pfizer (56%) and Moderna (40%) being the most common (Figure 2).
- Most vaccinations (79%) were identified through claim insurance data (Figure 2).
- About 27% of vaccinees had hypertension, 19% had obesity/overweight, and 13% had diabetes at the index date or 183 days prior (Table 1).
- Most adults (88%) received their first COVID-19 vaccination in 2021, while 10% were vaccinated in 2022 (Figure 3).

**Table 1.** Characteristics of patients with ≥1 COVID-19 vaccination, Nov 2020-Jan 2024*

| | |
|---|---|
| **Number of patients** | 38,575,376 |
| **Age in years - mean (SD)** | 57 (16) |
| **Female (%)** | 55 |
| **Known race (%)** | 71 |
| White among known race | 83 |
| **Known ethnicity (%)** | 64 |
| Hispanic origin among known ethnicity | 4 |
| **Year (%)** | |
| 2020 | <1 |
| 2021 | 88 |
| 2022 | 10 |
| 2023 | 1 |
| 2024 | <1 |
| **Hypertension (%)** | 27 |
| **Obesity/overweight (%)** | 19 |
| **Diabetes types 1 or 2** | 13 |
| **COVID-19 diagnosis at index or 183 days prior (%)** | 5 |
| **COVID-19 diagnosis in 183 days post index (%)** | 3 |

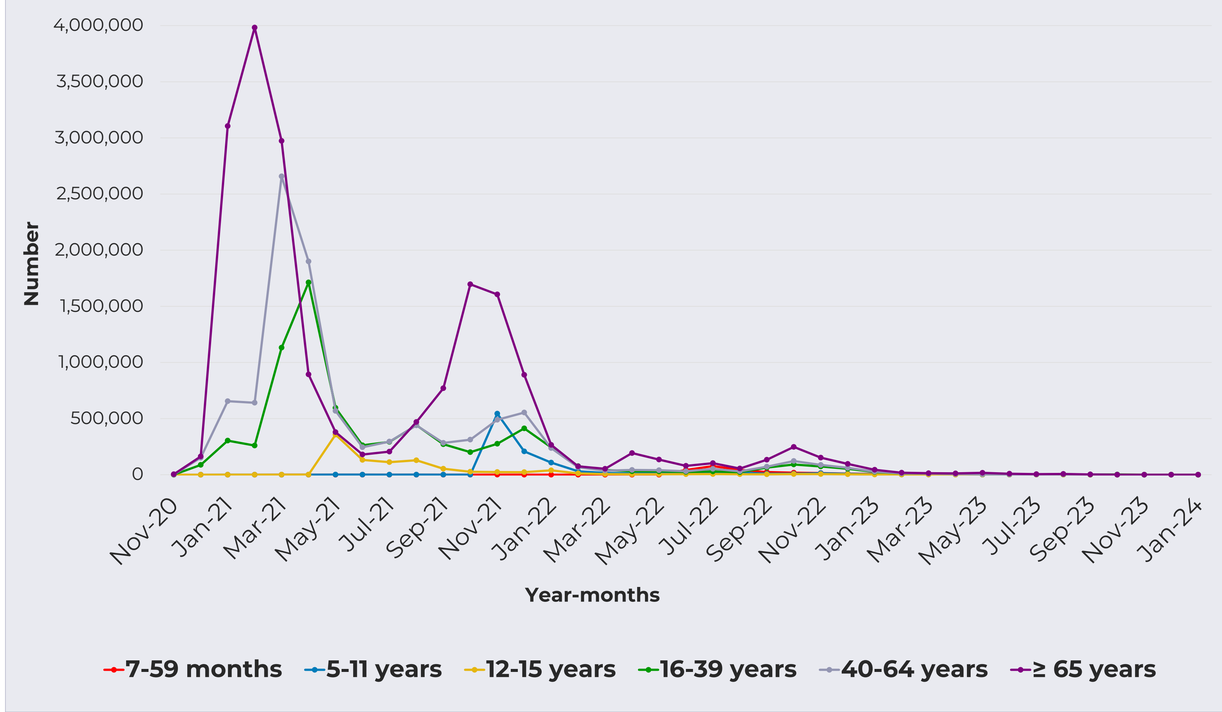
** Most covariates are assessed at the index date or 183 days prior to it, unless stated otherwise*

**Figure 2.** Characteristics of COVID-19 vaccinations, Nov 2020- Jan 2024




** Not all but 5 of 14 Data Partners had state-based Immunization Information Systems (IIS) linkage data*

**Figure 3.** Number of patients with 1st COVID-19 vaccine, Nov 2020-Feb 2024, by Age and Month-Year




## CONCLUSIONS

- Data on >38 million people with COVID-19 vaccination are available for analysis in Sentinel through January 2024.
- Data quality:
  - Low proportion (<1%) with duplicate codes
  - Median time from 1st to 2nd doses (29 days) aligns with recommendations
- Most adults (88%) received their first COVID-19 vaccine in 2021; however, vaccine uptake varied across age groups and by month and year.
- The Sentinel Data Partners continue to link to state-based IIS, and IIS data availability expected to increase with more linkages by commercial health plans.

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- B. Rasouli, G. Brisbane, J. Burk, JG. Connolly and N. Cocoros are employees at Harvard Pilgrim Health Care Institute, which conducts work for government and private organizations, including pharmaceutical companies.