

**Protocol:**

**[NAME]**

**[Posting Date:]**

**Biologics Effectiveness and Safety (BEST) Initiative**

**Center for Biologics Evaluation and Research**

**Office of Biostatistics and Pharmacovigilance**

# Study Team

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# Version Control

|  |  |  |
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| **Version** | **Description** | **Posting Date** |
|  |  |  |
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# List of Abbreviations

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# Data Sources

**Table 1. Description and Characteristics of Administrative Claims Data Sources**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Data Source** | **Claims Type** | **Update Frequency** | **Data Lag\*** | **Population Enrolled** |
|  |  |  |  |  |

# Study Population

# Study Period

# Study Variables

## Care Settings Definitions

## Exposures

## Outcomes

**Table 3. Outcomes, Care Settings, Clean Windows, and Risk Intervals for the Study Population Monitored During Surveillance**

| **Health Outcome** | **Care Settings** | **Clean Window\*** | **Risk Interval\*\*** | **Control Interval\*\*\*** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |

## Covariates

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## Vaccine Product Code List

**Appendix Table 1. Product Descriptions, Dosage Forms, Product Compositions, Dose Strengths, Authorization Dates, and Relevant Codes for Included Vaccines. 6, 7, 9**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scientific Name** | **Proprietary Name**  **and Manufacturer** | **Description and Composition** | **Vaccine Authorization Date** | **CVX Code** | **NDC 11 Labeler Product ID** | **HCPCS / CPT Code** |
|  |  |  |  |  |  |  |

## Concomitant Vaccination Code List

Concomitant vaccines will be captured using HCPCS/CPT and NDCs. Table A2 outlines the vaccine products and administration codes that will be used to identify persons with concomitant vaccinations.

**Appendix Table 2. Concomitant Vaccine Products and Administration Code List**

| **Concomitant Vaccination** | **CPT/HCPCS** | **CVX Code** | **Vaccine Administration Code** | **NDC** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

## Descriptive Analysis Table Shells