Potential public health advantages of COVID-19 and influenza combination vaccines for older adults

Background

COVID-19 and influenza pose significant threats, especially to older adults, leading to substantial hospitalization and mortality rates[1,2]

Sanofi combination vaccine candidates aims at preventing both influenza and COVID-19 infections with a single shot

Combination vaccines are anticipated to improve vaccine coverage rate and adherence, requiring fewer injections to protect against several diseases while minimizing syringe and vial disposal[3]

Impact of COVID-19 and Influenza

Preliminary 2024-2025 U.S COVID-19 Burden Estimates[4]

CDC estimates that from 01 OCT 2024 through 15 MAR 2025, there have been:

7.6 million - 13.1 million	1.8 million - 3.1 million	210,000 - 360,000	25,000 - 42,000
COVID-19 Illnesses	COVID-19 Outpatient Visits	COVID-19 Hospitalizations	COVID-19 Deaths

Preliminary 2024-2025 U.S Influenza Burden Estimates[5]

CDC estimates that from 01 OCT 2024 through 15 March 2025, there have been:

43 million - 75 million	19 million - 34 million	560,000 - 1.2 million	24,000 - 120,000
Flu Illnesses	Flu Medical Visits	Flu Hospitalizations	Flu Deaths

COVID-19 and Influenza Vaccine Recommendations

A Timely Approach

The *CDC advised* that is *safe to receive COVID-19* and *influenza vaccines at the same healthcare visit*[6].

Combination vaccines targeting both COVID-19 and influenza may be *highly valuable* when vaccination recommendations cover the same population simultaneously.

Impact on Vaccine Coverage in the Elderly

Vaccination is particularly *crucial for older adults*, as they may have compromised immunity, and face a higher risk of hospitalization following infection.

However, older adults *hesitate to receive multiple vaccine injections at a single visit* and may be unlikely to repeat visits, placing them at increased risk of infection[7].

Sanofi Clinical Trials of COVID-19 and Influenza Combination Vaccines

Two separate clinical studies have been initiated to evaluate the safety and efficacy of *two combination vaccine candidates*

- **NCT06695117** → Recombinant *COVID-19* and high-dose inactivated *influenza vaccine*
- **NCT06695130** → Recombinant *COVID-19* and recombinant *influenza vaccine*

The combination vaccines in development contain recombinant COVID-19 vaccine and influenza vaccine, both of which are already licensed and authorized

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Study design:

Phase 1/2, randomized, modified double-blind, multi-center studies

Participants:

Approximately 980 participants aged ≥50 years

Groups/Arms:

COVID-19 vaccine; influenza vaccine; COVID-19 and influenza vaccines co-administered; COVID-19 and influenza combination vaccines

Intervention:

Single IM injection on D01

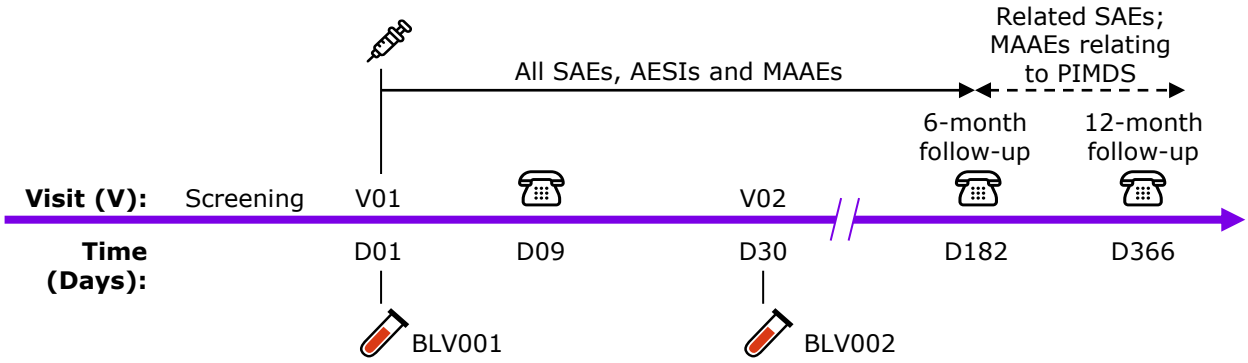
Visits:

D01, D09 (phone call), D30, D182* (phone call), and D366 (phone call)

**NCT06695117 only*

Study outcomes:

Solicited and unsolicited reactogenicity and safety; and immunogenicity



Overview

- Sanofi believes in developing medically-appropriate, low-reactogenicity *combination vaccines which may offer protection against both COVID-19 and influenza*
- Sanofi is conducting clinical trials including *two influenza vaccines* with individually-randomized *evidence of improved protection* compared to standard dose flu vaccines: *the high-dose and recombinant influenza vaccines*
- The aim is to provide the *protection* without compromising on patient experience, and thereby *boosting vaccination coverage rates* and *improving public health*

ABBREVIATIONS:

AESI, Adverse event of special interest; BLV, blood sample/visit identifier; D, day; IM, intramuscular; MAAE, medically attended adverse event; PIMD, potential immune mediated disease; SAE, serious adverse event; US FDA, United States Food and Drug Administration; V, visit

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1. Mueller AL, et al. Why does COVID-19 disproportionately affect older people? Aging (Albany NY). 2020;12(10):9959-9981. doi: 10.18632/aging.103344; **2.** Langer J, et al. High Clinical Burden of Influenza Disease in Adults Aged ≥ 65 Years: Can We Do Better? A Systematic Literature Review. Adv Ther. 2023;40(4):1601-1627. doi: 10.1007/s12325-023-02432-1; **3.** Press Release: Two combination vaccine candidates for prevention of influenza and COVID-19 granted Fast Track designation in the US. Accessed from https://www.sanofi.com/en/media-room/press-releases/2024/2024-12-11-06-00-00-2995072 on February 05, 2025; **4.** Preliminary Estimates of COVID-19 Burden for 2024-2025. Preliminary Estimates of COVID-19 Burden for 2024-2025 | COVID-19 | CDC Accessed 28 MAR 2025; **5.** Preliminary Estimated Flu Disease Burden 2024-2025 Flu Season. Preliminary Estimated Flu Disease Burden 2024-2025 Flu Season | Flu Burden | CDC Accessed 28 MAR 2025; **6.**CDC Recommends Updated 2024-2025 COVID-19 and Flu Vaccines for Fall/Winter Virus Season. Accessed from https://beta.cdc.gov/media/releases/2024/s-t0627-vaccine-recommendations.html#print on February 12, 2025; **7.** Harris DA, et al. COVID-19 and Influenza Vaccine Coadministration Among Older U.S. Adults. Am J Prev Med. 2024;67(1):67-78. doi: 10.1016/j.amepre.2024.02.013.