Assessing High-Dose Versus Standard Dose Influenza Vaccine Protection Against Cardiovascular and Respiratory Hospitalizations





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STUDY OVERVIEW

Cardiovascular Burden of Influenza

Influenza infection is associated with increased risk of acute cardiovascular events



Older adults are particularly vulnerable to the cardiovascular effects of influenza infection^{1,2}



HD-IIV

Contains four-times the antigen of SD-IIV⁵

Was developed to provide increased protection in older adults⁵

Has demonstrated superior efficacy against LCI in a pivotal RCT⁶

FLUNITY-HD Study Design

Pre-specified pooled analysis of methodologically harmonized, individually randomized DANFLU-2 and GALFLU trials⁶⁻⁸



The SD-IIV used are the standard of care in the populations and geography under study and are licensed by the EMA6-8



Pragmatic design using real-world healthcare registry data for all baseline data collection and follow-up

Cardiovascular Hospitalizations⁹

Additional benefit of HD-IIV compared to SD-IIV

Consistent benefit regardless of

baseline cardiovascular disease status

Overall population (aged 65+)

+6.3% (95% CI: 2.5-10.0%)

+6.6% (95% CI: 1.6-11.5%)

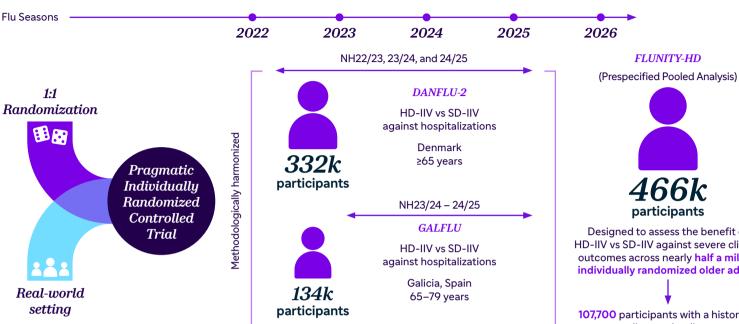
+6.5% (95% CI: 0.7-11.9%)

rVE (%)



Conducted across three influenza seasons (2022/23-2024/25) with follow-up 14 days postvaccination through May 31st of the following year 9,10

Largest ever individually randomized influenza vaccine effectiveness study⁶⁻⁸



Designed to assess the benefit of HD-IIV vs SD-IIV against severe clinical outcomes across nearly half a million individually randomized older adults

107,700 participants with a history of cardiovascular disease

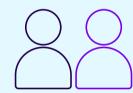
SUMMARY OF RESULTS

HD-IIV demonstrated *superior protection* compared

to SD-IIV against cardio-respiratory hospitalizations.

This reduction was driven by both cardiovascular and

respiratory hospitalizations.9



aVE:

Outcomes in a vaccinated cohort compared to those in an unvaccinated or placebo cohort¹¹



Additional benefit of highdose vaccine compared to standard-dose vaccine, not absolute protection rates¹¹

rVE in FLUNITY-HD shows how much additional protection older adults gain by choosing HD-IIV over SD-IIV7

ENDPOINTS FROM SECONDARY ANALYSES Heart Failure9

Consistent benefit regardless of baseline HF status, including both incident and recurrent HF hospitalizations

> +21.3% rVE for HF hospitalizations

ASCVD Subgroup Analysis¹⁰

Consistent protection in patients with and without **ASCVD**

ASCVD Subgroup Analysis

+9.2% (95% CI: 0.81-16.80%)

+8.8% (95% CI: -5.91 to 21.55%)

rVE (%)

8

10

HF hospitalization risk reduced by approximately 21% with HD-IIV versus SD-IIV9



Benefits of HD-IIV over SD-IIV remained consistent across patients with and without ASCVD, with a trend in favor of HD-IIV in higher-risk groups.10

Abbreviations:

ACC: American College of Cardiology; AHA: American Heart Association; ASCVD: atherosclerotic cardiovascular disease; aVE: absolute vaccine effectiveness; HD-IIV: high-dose inactivated influenza vaccine; HF: heart failure; LCI: laboratory-confirmed influenza; rVE: relative vaccine effectiveness; SD-IIV: standard-dose inactivated influenza vaccine; vs: versus.

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Cardiorespiratory hospitalizations

Cardiovascular disease hospitalization

Respiratory disease hospitalization

- Smith SC et al. Circulation. 2006;113(19):2363-72.
- Virani SS et al. Circulation. 2023;148(9):e9-119.

HF hospitalizations

- DiazGranados CA et al. N Engl J Med. 2014;371(7):635-45.
- 6. Johansen ND et al. JAMA Cardiol. 2025;DOI:10.1001/ jamacardio.2025.3460.

+21.3% (95% CI: 7.4-33.2%)

20

25

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- 8. Tor Biering-Sørensen. NCT06506812. https://clinicaltrials.gov/ study/NCT06506812.
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Pneumonia or influenza

hospitalization (patients

without ASCVD)

Pneumonia or influenza hospitalization (patients

with ASCVD)

LEARN MORE

POOLED ANALYSIS OF HOSPITALIZATION **OUTCOMES IN OLDER ADULTS**

US-MAT-2506846 V1.0 P EXP DATE 10/11/2026 Disclaimer: The comparator standard-dose vaccine used in the trial is not licensed in the U.S.