moderna

Respiratory vaccines

Program Pack

Combo COVID-Flu (mRNA-1083)

mRNA-1083-P301 Phase 3 study

Study was designed to test the immunogenicity and safety of mRNA-1083

Design
Randomized, observer-blind, active control study

Participants
~8,000 adults ≥ 50 years of age

Vaccination schedule
2 injections on Day 1 (mRNA-1083 + placebo or licensed influenza vaccine + COVID-19 vaccine)

Duration: 6 months
Participants followed up for 6 months

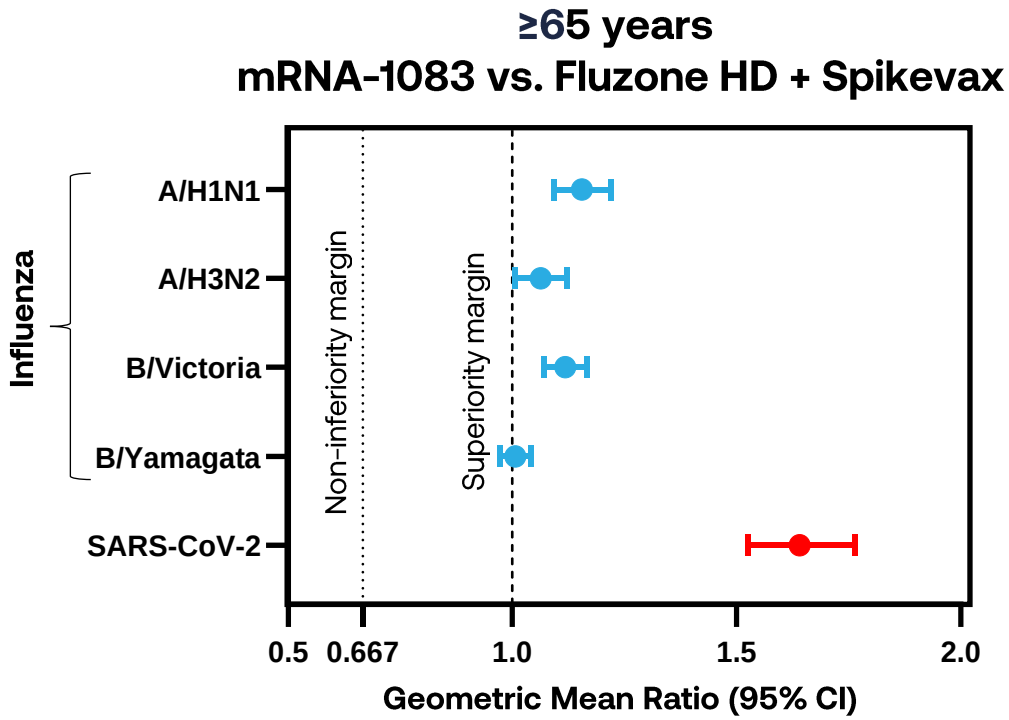
Site locations
Northern hemisphere (United States)

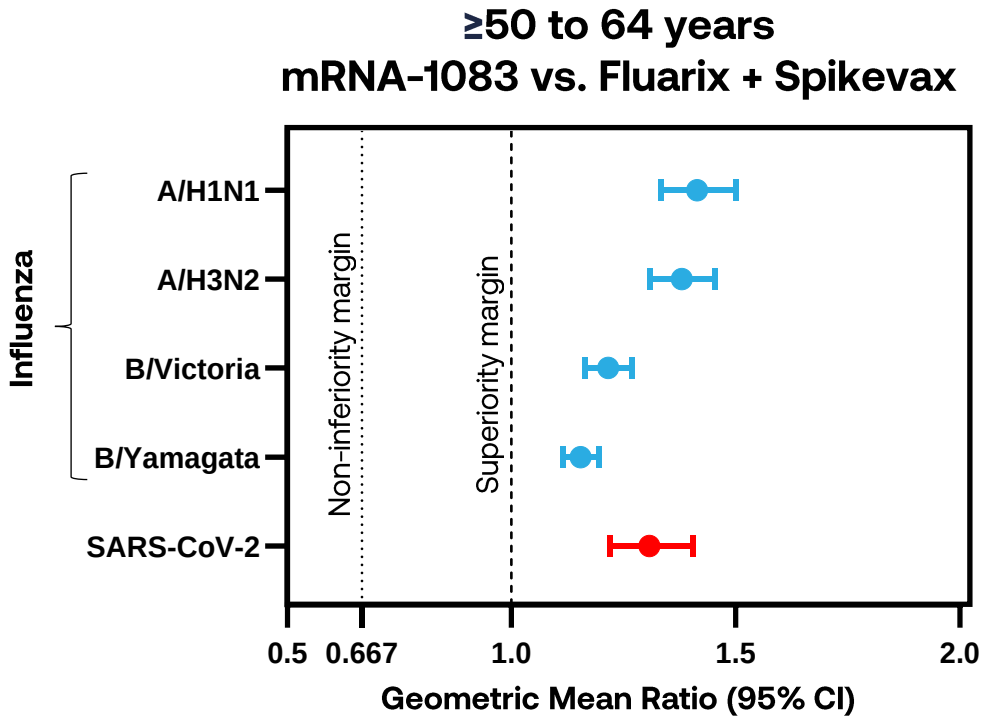
Phase 3 clinical study

Cohort A: Ages ≥ 65 years	Cohort B: Ages ≥ 50 to 64 years
mRNA-1083 + placebo N~2000	**mRNA-1083 + placebo** N~2000
Fluzone HD + Spikevax N~2000	**Fluarix + Spikevax** N~2000

mRNA-1083 met all primary immunogenicity endpoints in Phase 3

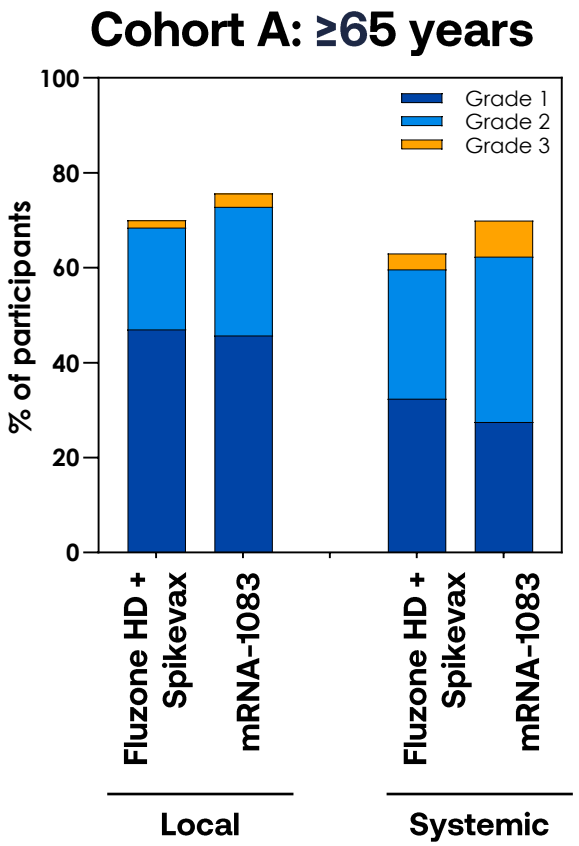
- **Noninferiority criteria were met for all immunogenicity endpoints** (GMT ratios; seroconversion and seroresponse rates)
- **mRNA-1083 induced a higher antibody response compared to licensed influenza/COVID-19 vaccines**, including Fluzone HD, for 3 clinically relevant influenza strains (A/H1N1, A/H3N2, B/Victoria) and SARS-CoV-2

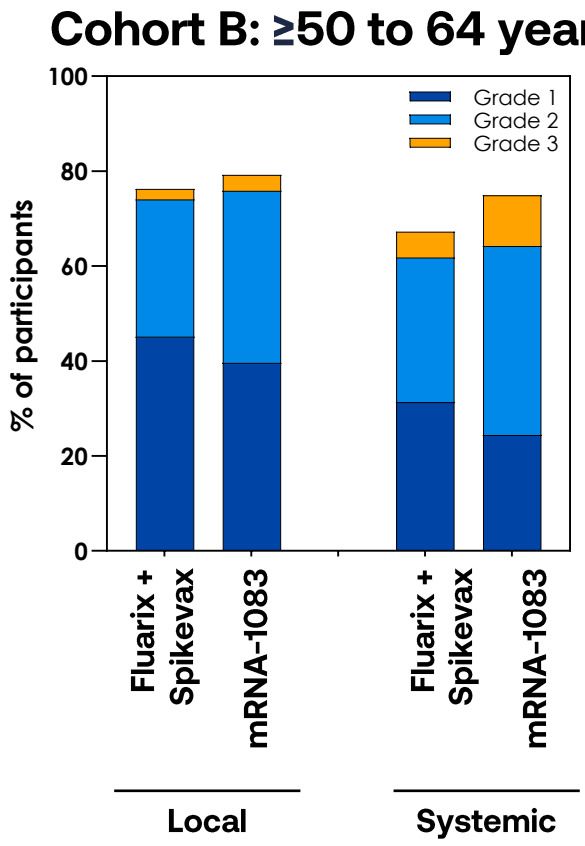




mRNA-1083 showed an acceptable reactogenicity profile compared to co-administered influenza and COVID-19 vaccines

- **Majority of solicited adverse reactions reported as grade 1 or 2 in severity and of short duration**
- **Reactogenicity was lower in 65+ cohort than in the ≥50 to 64 years of age cohort**





mRNA-1083 safety

The rates of unsolicited AEs were similar across groups

No deaths, SAEs or adverse events leading to study discontinuation were considered related to mRNA-1083

No events of myocarditis or pericarditis were reported that were considered related to mRNA-1083

Overall, no safety concerns were identified for mRNA-1083

An acceptable tolerability and safety profile was observed

Flu + COVID combo (mRNA-1083) summary and next steps

Immunogenicity

- mRNA-1083 met all 10 co-primary immunogenicity endpoints in Phase 3 study
- mRNA-1083 elicited a higher immune response against SARS-CoV-2 and clinically relevant influenza strains in both 50–64-year-old and 65 + year old cohorts
- Antibodies are established surrogates of protection against influenza and COVID-19

Reactogenicity / Safety

- mRNA-1083 showed an acceptable safety and reactogenicity profile compared to co-administered influenza and COVID-19 vaccines
- No safety risks were identified

Next steps

- Pending results from standalone flu (mRNA-1010) vaccine efficacy study in summer 2025, planning to file BLA in 2025

Sources: (1) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8453618/

Medical and scientific presentations

ECSMID 2025 (6-month persistence & safety)

https://s29.q4cdn.com/435878511/files/doc_presentations/2025/Apr/14/Flu-poster-Durability-of-mRNA-Platform.pdf

Options 2024

https://s29.q4cdn.com/435878511/files/doc_presentations/2024/Sep/29/Sunday_M4_12h16_Callendret_v1-15.pdf

Forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: clinical trials and Moderna's ability to produce combination vaccines; expected benefits of combination vaccines; and anticipated timing of results from Moderna's standalone Phase 3 flu study and expectations to file a BLA in 2025 for its combination vaccine. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward -looking statements contain these words. The forward-looking statements in this presentation are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include those described in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements in this presentation in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date referenced on the first page.