Sequential Administration of an mRNA-Based Seasonal Influenza Vaccine in Older Adults

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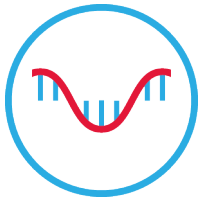

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Disclosures and Acknowledgements

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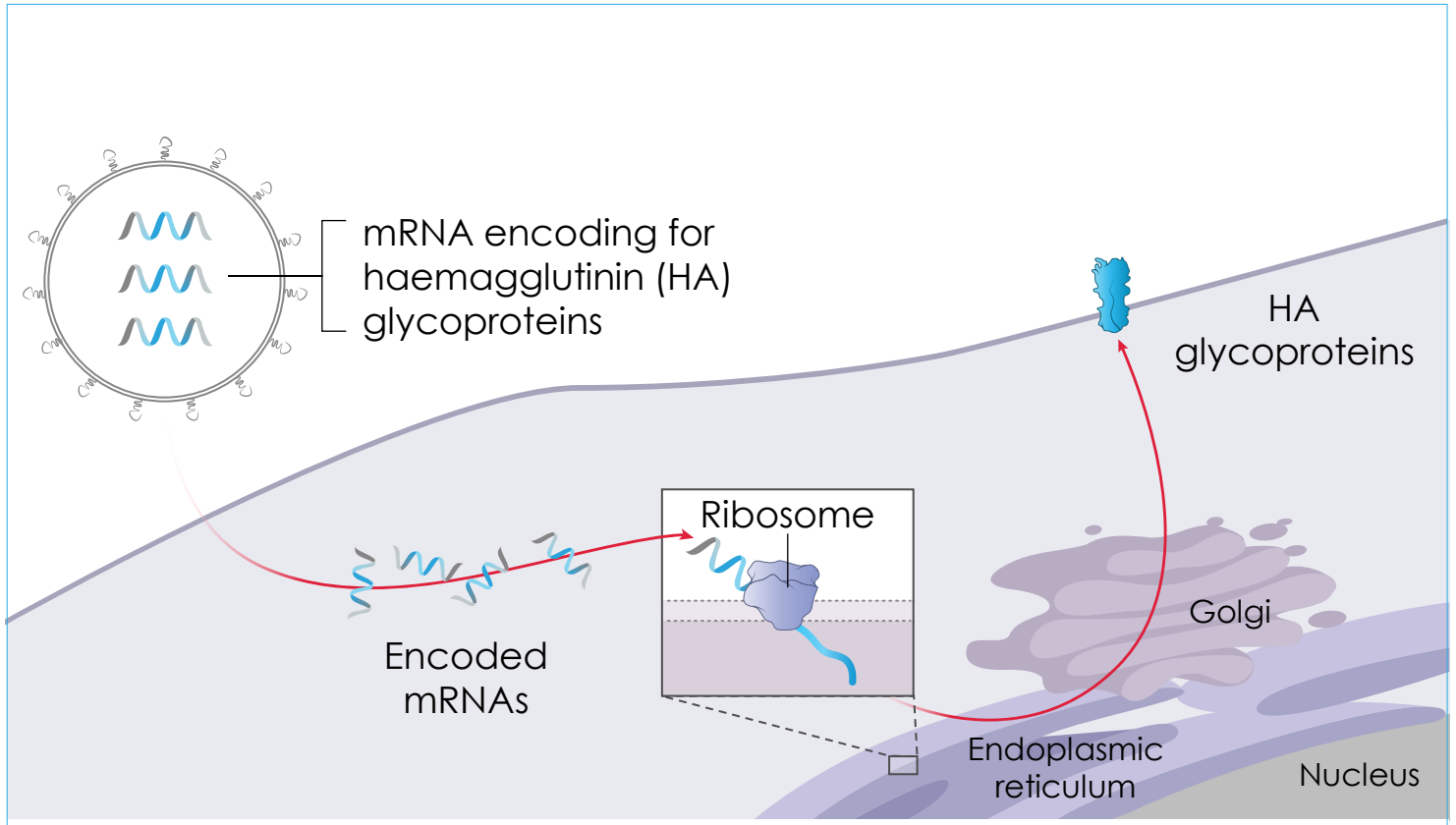
mRNA-1010: An mRNA-Based Seasonal Influenza Vaccine Candidate

- **Potential to address several limitations associated with currently licensed influenza vaccines**[1-4]
  - Encodes specific antigen protein (precise match)
  - No requirement for egg-based or other complex culture systems
  - Reduced production time allowing for strain selection closer to start of influenza season and decreasing risk for mismatch
- **Elicited superior immunogenicity compared with licensed standard-dose (in adults aged 18-64 years) and high-dose (in adults aged ≥65 years) licensed influenza vaccine comparators**[5]
- **Demonstrated superior prevention of RT-PCR–confirmed protocol-defined ILI in adults ≥50 years, without evident safety concerns**[6]



mRNA-1010 encodes membrane-bound HA of WHO-recommended seasonal influenza strains

HA, haemagglutinin; ILI, influenza-like illness; RT-PCR, reverse transcription polymerase chain reaction; WHO, World Health Organization.

1. World Health Organization. *Wkly Epidemiol Rec*. 2022;19:185-208. 2. Barr IG, et al. *NPJ Vaccines*. 2018;3:44. 3. Dolgin E. *Nat Rev Drug Discov*. 2021;20:801-803. 4.Okoli GN, et al. *Vaccine*. 2021;39:1225-1240. 5. Soens M, et al. *Vaccine*. 2025;50:126874. 6. Malkin E, et al. Presented at: IDWeek 2025; October 19-22, 2025; Atlanta, GA.

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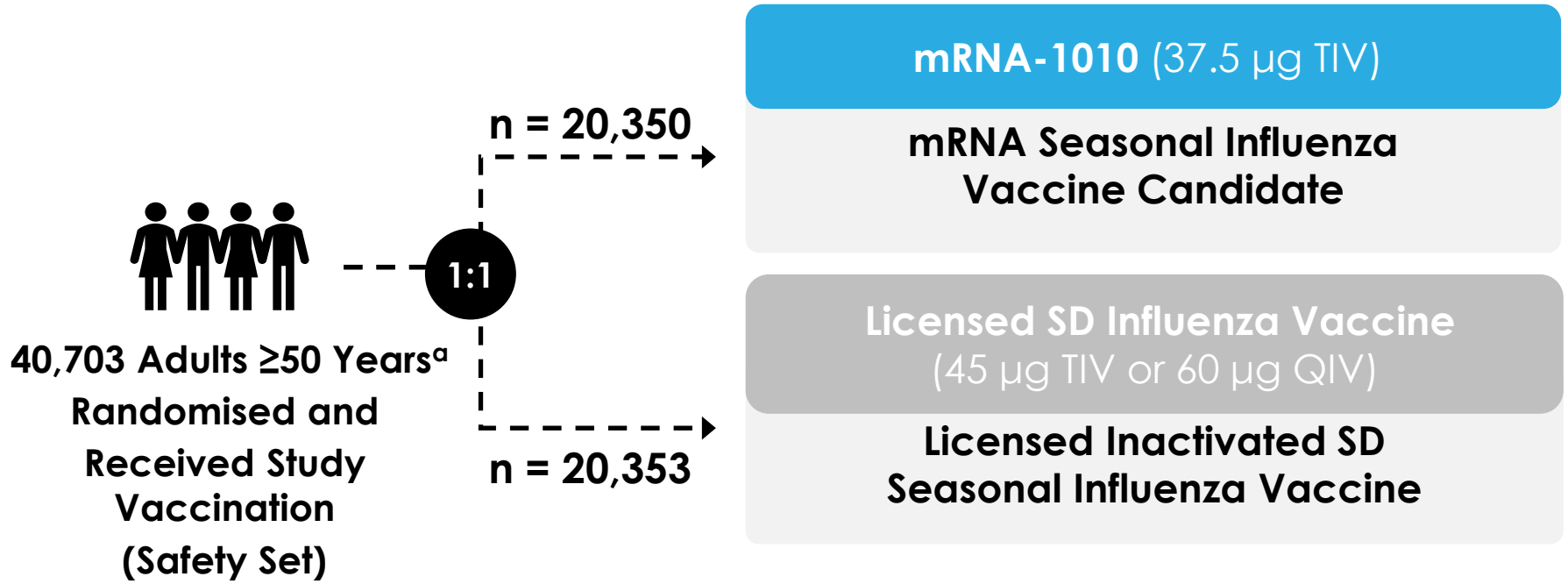
mRNA-1010 P304 Study Design

Study 304: Randomised, Double-Blind, Active-Controlled Phase 3 Trial (NCT06602024)



- Followed through 6 months (Day 181) or end of influenza season, whichever occurred later
- 11 countries and 301 global sites

QIV, quadrivalent; SD, standard dose; TIV, trivalent.
Active comparators include Fluarix (TIV), Fluarix Tetra, Influsplit® Tetra, Alpharix® Tetra.
[a]47.8% of participants were ≥65 years old; 11.6% of participants were ≥75 years old.

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Study Objectives

Exploratory Post Hoc Objectives

- **To assess the safety and immunogenicity of repeated mRNA-1010 vaccination**
- **To compare repeated mRNA-1010 vaccination with mixed egg-based influenza vaccination regimens**
  - P304 was the pivotal phase 3 mRNA-1010 efficacy study evaluating mRNA-1010 against SD influenza vaccine
  - P302 and P303 were phase 3 mRNA-1010 studies conducted in adults aged ≥18 years and preceded P304

Group	Prior study (P302/P303)	Current study (P304)
Group 1	mRNA-1010	mRNA-1010
Group 2	Active comparator	mRNA-1010
Group 3	mRNA-1010	Active comparator
Group 4	Active comparator	Active comparator

SD, standard-dose.
Active comparator was a licensed, egg-based influenza vaccine.

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Demographics and Baseline Characteristics

Safety Set

		Group 1 mRNA-1010 in current and prior studies (N = 522)	Group 2 mRNA-1010 in current study, AC in prior study (N = 521)	Group 3 AC in current study, mRNA-1010 in prior study (N = 524)	Group 4 AC in current and prior studies (N = 535)
Median age, years		67	67	67	67
Female, n (%)		319 (61.1)	303 (58.2)	322 (61.5)	309 (57.8)
Age group, n (%)	**≥50 to <65 years**	211 (40.4)	214 (41.1)	209 (39.9)	259 (48.4)
	≥65 to <75 years	229 (43.9)	232 (44.5)	239 (45.6)	200 (37.4)
	≥65 years	311 (59.6)	307 (58.9)	321 (61.1)	276 (51.6)
	≥ 75 years	2 (15.7)	75 (14.4)	76 (14.5)	76 (14.2)
Race/ethnicity, n (%)	**White**	465 (89.1)	453 (86.9)	465 (88.7)	456 (85.2)
	Black or African American	48 (9.2)	57 (10.9)	50 (9.5)	65 (12.1)
	Hispanic/Latino ethnicity	37 (7.1)	38 (7.3)	32 (6.1)	22 (4.1)
	Asian	6 (1.1)	6 (1.2)	4 (0.8)	6 (1.1)
Baseline high-risk factors, n (%)					
	High-risk	320 (61.3)	338 (64.9)	318 (60.7)	338 (63.2)
Median time between doses, months (range, 9.5 – 26.4)		23.7	23.7	23.9	23.7

AC, active comparator.
AC was a licensed, egg-based influenza vaccine.

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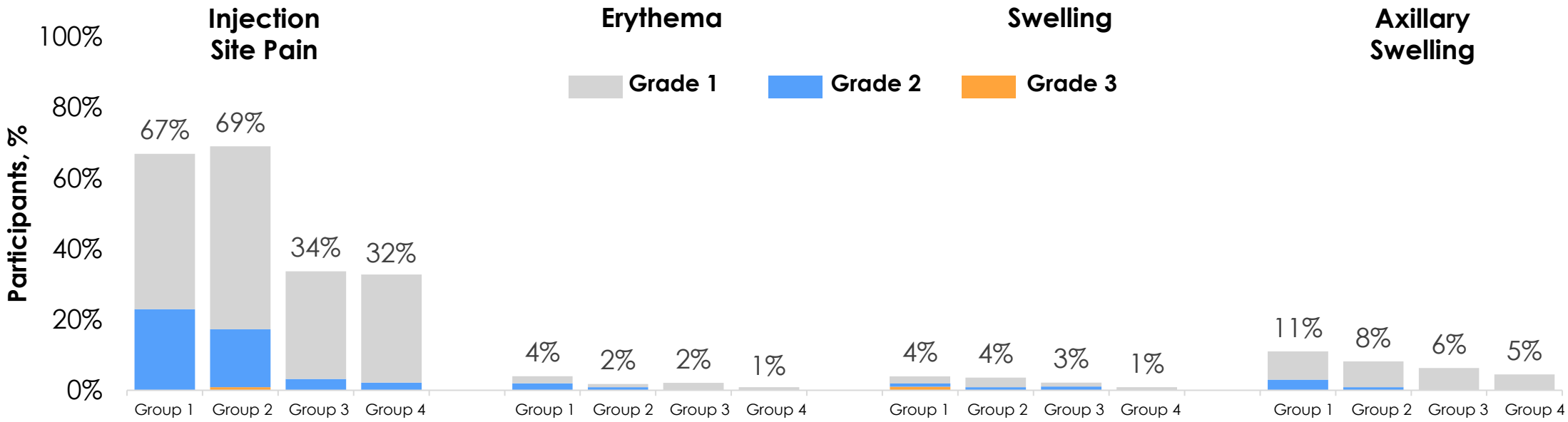
Safety

Solicited Local Adverse Reactions Within 7 Days of Injection Were Mild to Moderate and of Short Duration

Solicited Safety Set



Group 1 – mRNA-1010 prior study, mRNA-1010 repeat vaccination

Group 2 – Active comparator prior study, mRNA-1010 vaccination

Group 3 – mRNA-1010 prior study, Active comparator vaccination

Group 4 – Active comparator prior study, Active comparator repeat vaccination

- Rates of solicited local adverse reactions were higher in those who received mRNA-1010 most recently, regardless of prior study vaccination
- The majority of reactions were mild to moderate with a low frequency of grade 3 reactions
- The most frequently reported local reaction in all groups was injection site pain

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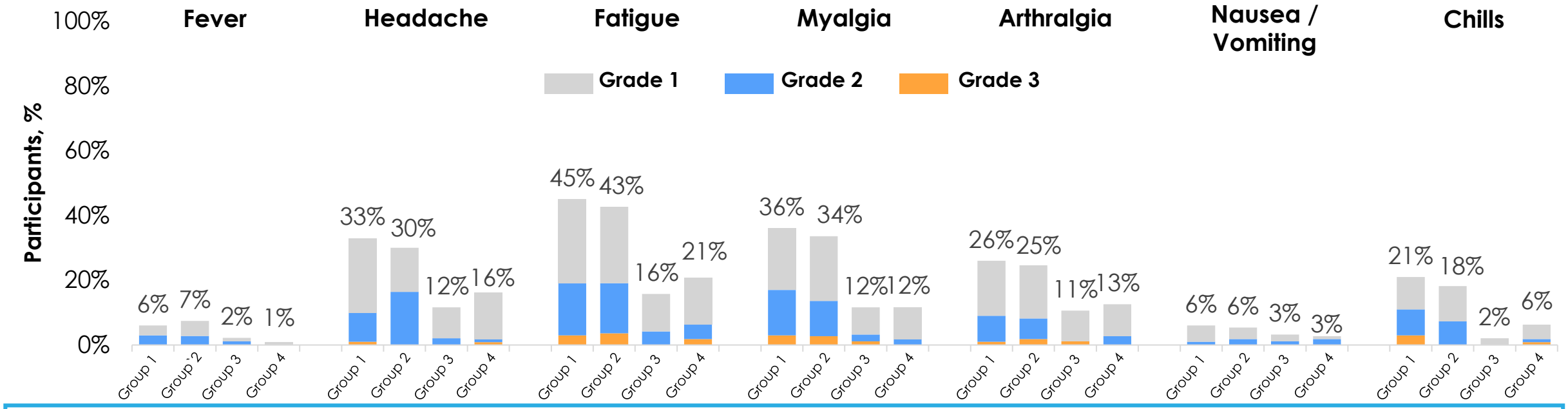
Solicited Systemic Adverse Reactions Within 7 Days of Injection Were Mostly Mild to Moderate and of Short Duration

Solicited Safety Set



Group 1 – mRNA-1010 prior study, mRNA-1010 repeat vaccination

Group 2 – Active comparator prior study, mRNA-1010 vaccination

Group 3 – mRNA-1010 prior study, Active comparator vaccination

Group 4 – Active comparator prior study, Active comparator repeat vaccination

- Rates and severity of solicited systemic adverse reactions were similar in those who received mRNA-1010 most recently, regardless of prior study vaccination
- The majority of reactions were mild to moderate, with a low frequency of grade 3 reactions
- Most frequently reported systemic reactions were fatigue, myalgia, and headache in Groups 1 and 2

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Unsolicited AEs Through 28 Days After Injection, Regardless of Relationship, Were Similar Between Groups

Safety Set

	Group 1 mRNA-1010 in current and prior studies (N = 522)	**Group 2** mRNA-1010 in current study, AC in prior study (N = 521)	**Group 3** AC in current study, mRNA-1010 in prior study (N = 524)	**Group 4** AC in current and prior studies (N = 535)
All unsolicited AEs, n (%)	34 (6.6)	32 (6.2)	29 (5.6)	42 (7.9)
Serious	3 (0.6)	2 (0.4)	0	2 (0.4)
Fatal	0	0	0	0
Medically attended	25 (4.9)	28 (5.4)	19 (3.7)	29 (5.5)
Leading to study discontinuation	0	0	0	0
Severe (grade ≥3)	3 (0.6)	1 (0.2)	0	2 (0.4)
Any AE of special interest	1 (0.2)	0	0	0

- The frequency of unsolicited adverse events was similar across groups
- No safety concerns observed

AC, active comparator; AE, adverse event.

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Immunogenicity and Relative Vaccine Efficacy

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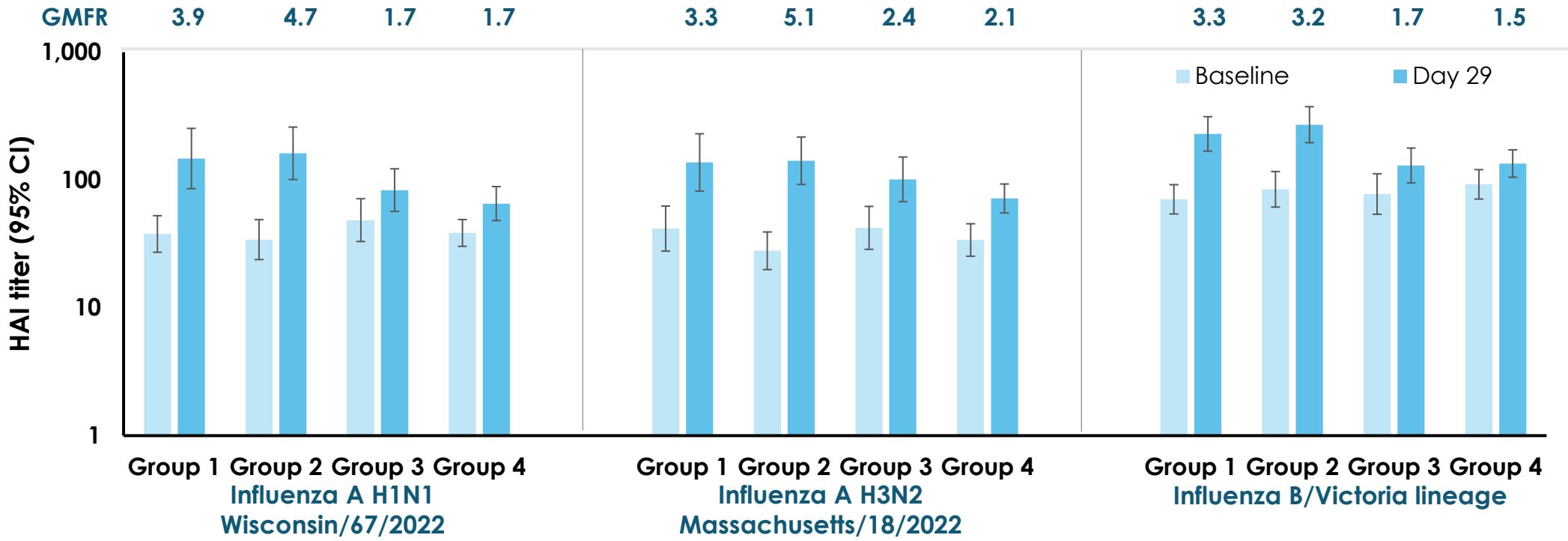
HAI Geometric Mean Fold Rises for All 3 Strains Were Similar in Groups 1 and 2

Per-Protocol Immunogenicity Set



Group 1 – mRNA-1010 prior study, mRNA-1010 repeat vaccination

Group 2 – Active comparator prior study, mRNA-1010 vaccination

Group 3 – mRNA-1010 prior study, Active comparator vaccination

Group 4 – Active comparator prior study, Active comparator repeat vaccination

- As was shown in previous phase 3 studies, mRNA-1010 elicited a higher/more robust immune response than active comparator
- There was no evidence of attenuation in those who received repeated mRNA-1010 vaccination

CI, confidence interval; GMFR, geometric mean fold rise; HAI, haemagglutination inhibition assay.
Group 1, n = 25; Group 2, n = 31; Group 3, n = 25; Group 4, n = 38.

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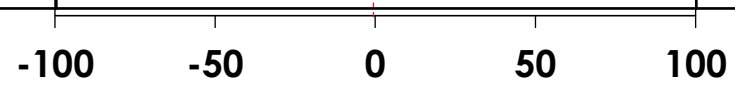
Relative Vaccine Efficacy Is Favorable After Recent mRNA-1010 Vaccination vs Licensed Influenza Vaccine

Per-Protocol Set

Received mRNA-1010 in at least 1 study	Number of ILI events/N1 (%)		Relative vaccine efficacy, % (95% CI)
	Group 1, 2 or 3	Group 4 (AC in current & prior)	
Group 1 mRNA-1010 in current & prior study	9/513 **(1.75%)**	19/529 **(3.59%)**	**49.8** (−11.1, 77.3)
Group 2 mRNA-1010 in current study, AC in prior study	10/516 **(1.94%)**	19/529 **(3.59%)**	**43.6** (−21.5, 73.8)
Group 3 AC in current study, mRNA-1010 in prior study	14/518 **(2.70%)**	19/529 **(3.59%)**	**22.1** (−55.6, 61.0)



Group 1 – mRNA-1010 prior study, mRNA-1010 repeat vaccination

Group 2 – Active comparator prior study, mRNA-1010 vaccination

Group 3 – mRNA-1010 prior study, Active comparator vaccination

Group 4 – Active comparator prior study, Active comparator repeat vaccination

- Relative vaccine efficacy was highest in participants who were vaccinated most recently with mRNA-1010

AC, active comparator; CI, confidence interval; ILI, influenza-like illness; N1, number of participants in the group; % = 100 × (n/N1).

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Conclusions

Immunogenicity	• Robust immune responses were seen with recent mRNA-1010 vaccination (regardless of prior vaccine) compared with active comparator
Safety	• Reactogenicity was higher in groups with recent mRNA-1010 vaccination vs active comparator • Most solicited adverse reactions were grade 1 or 2, and transient • No new safety concerns observed with repeated mRNA-1010 vaccination
Efficacy	• Though numbers were small, there is no evidence that repeated mRNA-1010 vaccination blunts efficacy

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Thank you

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