Flu vaccines (mRNA-1010/-20/-30/-11/-12)

Last updated: November 2nd, 2023

Modality	Program	ID #	Preclinical development	Phase 1	Phase 2	Phase 3	Commercial	Moderna rights
Adults	COVID-19 vaccine	Spikevax®						Worldwide
		mRNA-1283	Next generation (2-5 °C)					Worldwide
	Flu vaccine	**mRNA-1010**						Worldwide
		mRNA-1020						Worldwide
		mRNA-1030						Worldwide
		mRNA-1011						Worldwide
		mRNA-1012						Worldwide
Infectious disease vaccines	Older adults RSV vaccine	mRNA-1345						Worldwide
	Flu + COVID vaccine	mRNA-1083						Worldwide
	Flu + COVID + RSV vaccine	mRNA-1230						Worldwide
	Flu + RSV vaccine	mRNA-1045						Worldwide
	Endemic HCoV vaccine	mRNA-1287						Worldwide
	Pandemic Flu	mRNA-1018						Worldwide
	RSV + hMPV vaccine	mRNA-1365						Worldwide
Adolescents & Pediatrics	COVID-19 vaccine (adolescents)	mRNA-1273.815	TeenCOVE					Worldwide
	COVID-19 vaccine (pediatrics)	mRNA-1273.815	KidCOVE					Worldwide
	Pediatric RSV vaccine	mRNA-1345						Worldwide

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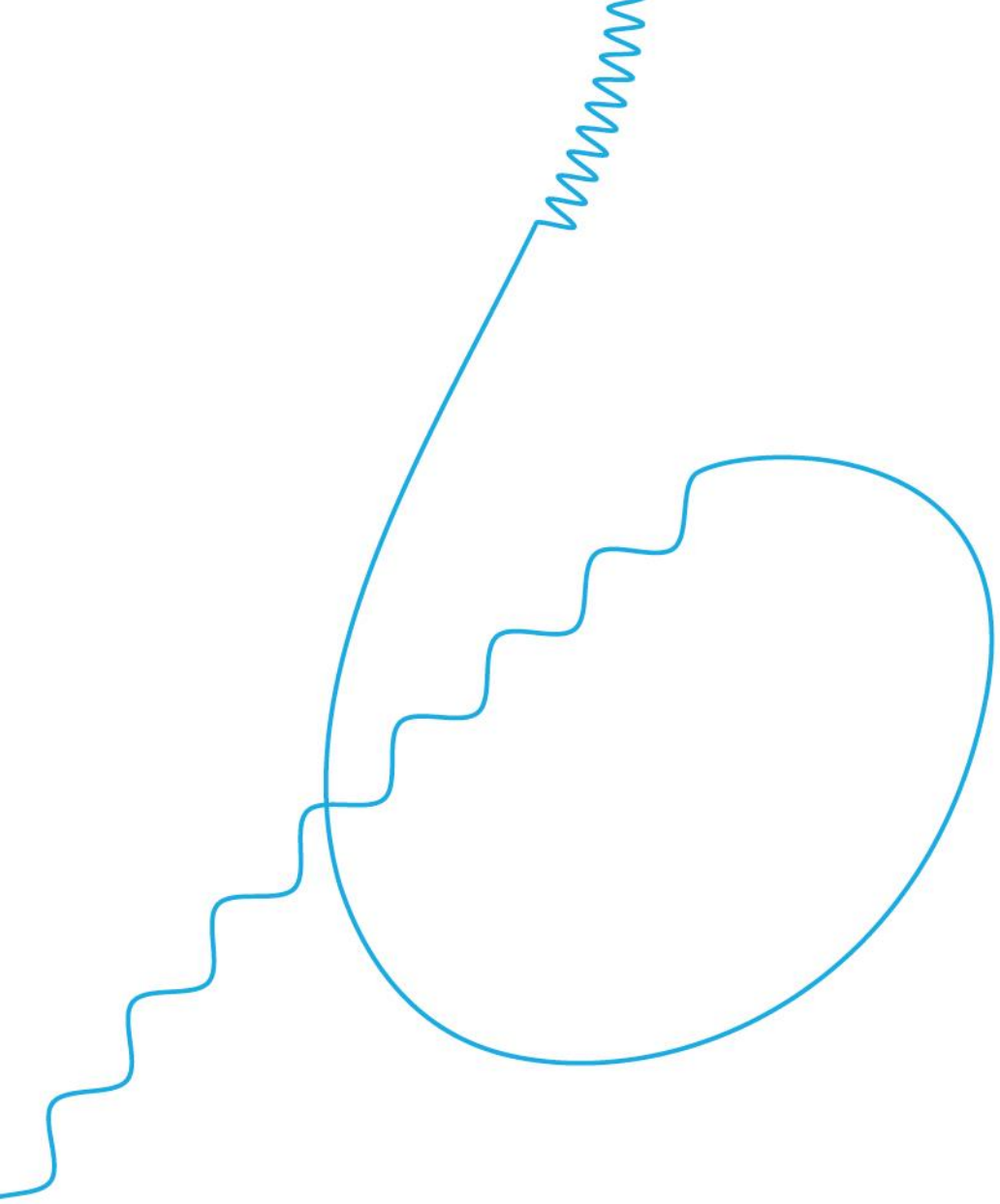

Ongoing Phase 3 Studies for mRNA-1010

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mRNA-1010 Phase 3 P303 study overview

P303 was designed to test the immunogenicity and safety of an optimized composition of mRNA-1010

Design
Randomized, observer-blind, active-controlled study

Number of participants
2,416 medically stable adults ≥ 18 years old

Vaccination schedule
Single dose of mRNA-1010 or Fluarix

Duration: 6 months
Enrollment period: April-May 2023

Study participants will be followed for 6 months after study injection

Site location
Northern Hemisphere (United States)

Total N = 2,416
Randomization Ratio = 1:1

mRNA-1010 (50 µg)
N=1227

Fluarix
N=1189

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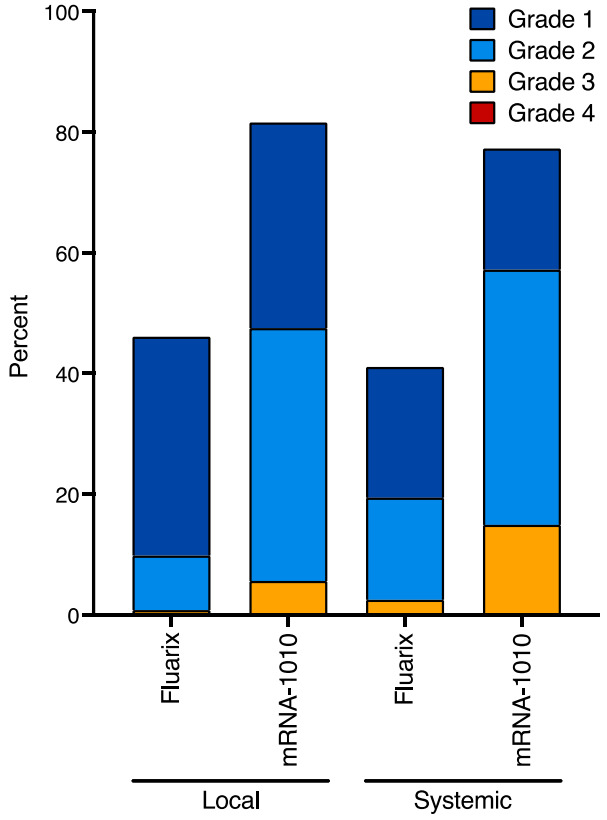
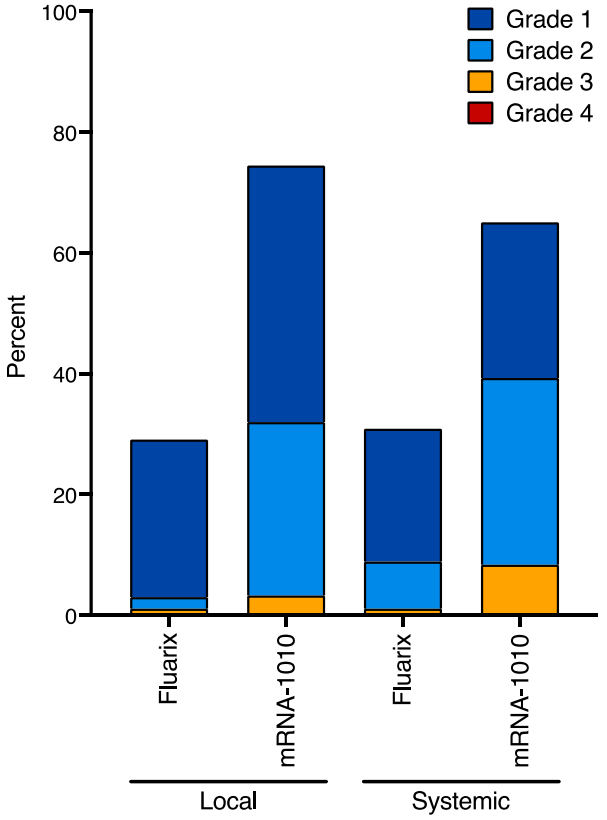
Reported rates of local and systemic reactogenicity after mRNA-1010 compared to standard dose influenza vaccine

- Safety profile was in line with prior clinical studies for mRNA-1010
- mRNA-1010 showed an acceptable reactogenicity profile, with the majority of solicited adverse reactions reported as grade 1 or 2 in severity
- Reactogenicity was higher in mRNA-1010 recipients compared to standard dose influenza vaccine recipients
- Reactogenicity in older adults was lower compared to younger age groups.

Adult 18 years and older



Adults 65 years and older



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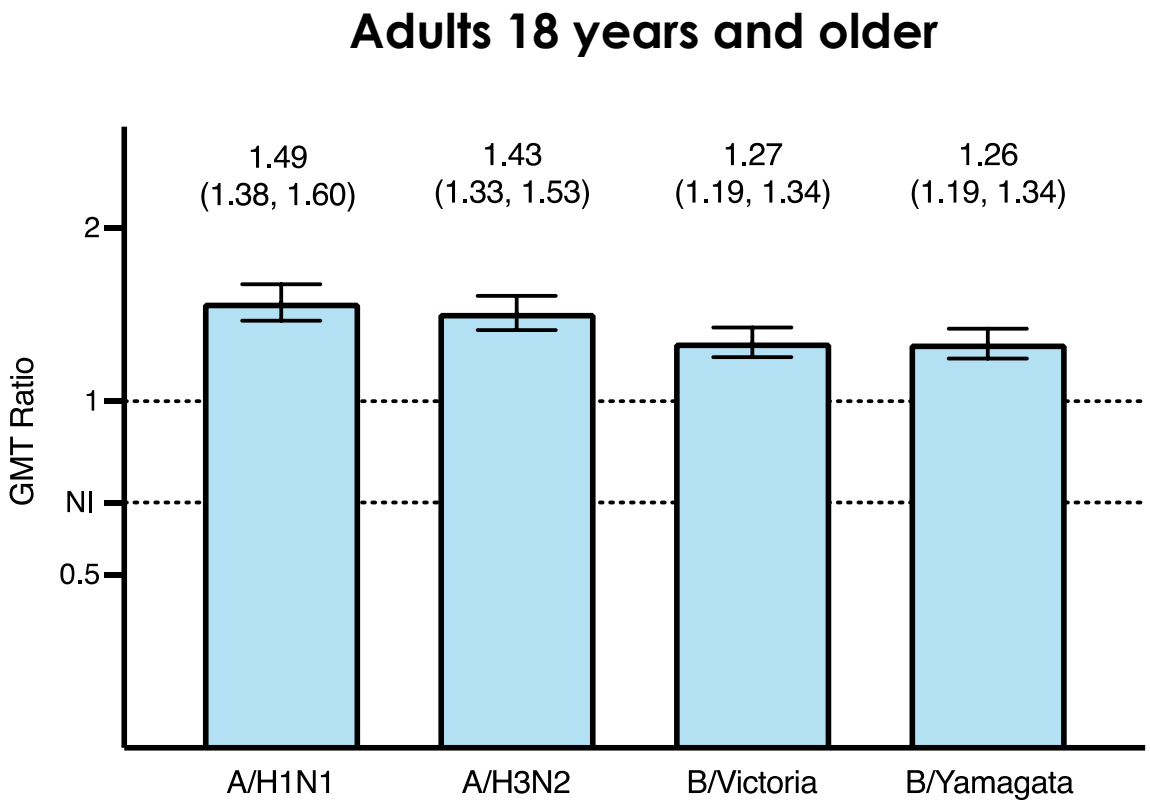
mRNA-1010 met all primary immunogenicity endpoints in P303

- Immunogenicity criteria for licensure according to regulatory guidance were met for all 8 co-primary endpoints
  - GMR
  - Seroconversion rates
- Higher GMTs and seroconversion rates were observed for mRNA-1010 for all four strains in P303 study
- Higher immunogenicity relative to standard dose influenza vaccine was consistently observed across age groups



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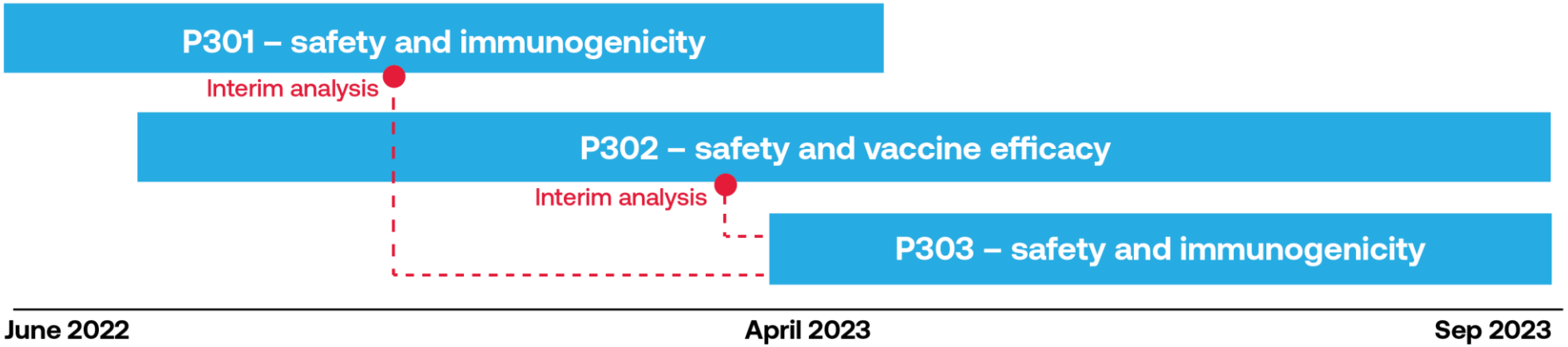
mRNA-1010 has made rapid progress in 15 months



P301
Southern Hemisphere

- Immunogenicity study met each of its endpoints for influenza A strains, including superiority for H3N2
- Did not meet non-inferiority for influenza B strains

P302
Northern Hemisphere

- End of season efficacy analysis did not accrue target number of cases (only 282 total cases; +48 since Vaccines Day update)
- Did not demonstrate protocol defined statistical non-inferiority

P303
Northern Hemisphere

- Made improvements to mRNA-1010 to increase immune responses in our P303 study
- mRNA-1010 met all 8 primary immunogenicity endpoints. GMT titers were higher compared to standard dose vaccine

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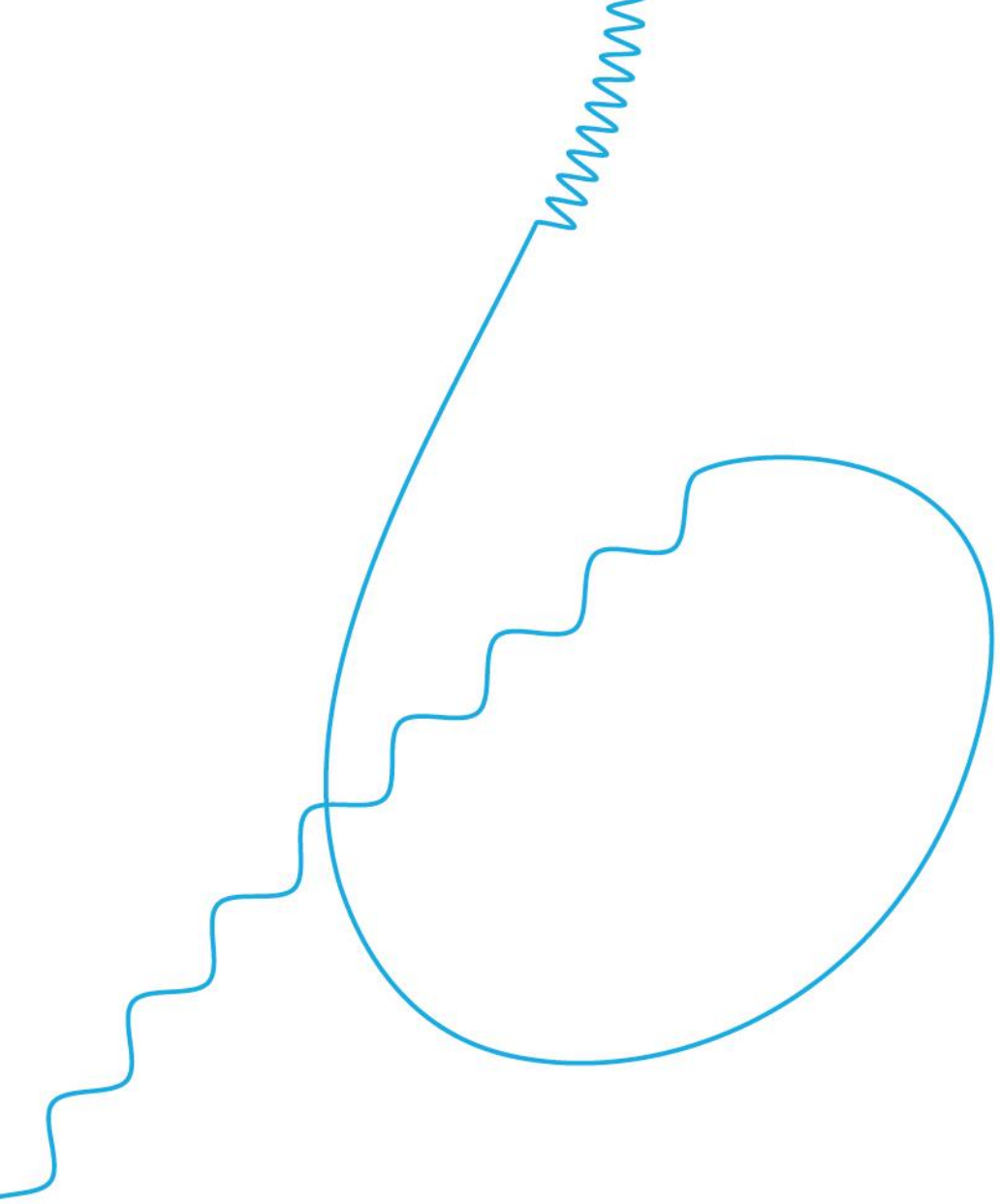

Seasonal influenza vaccine strategy

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Seasonal influenza (flu) overview

Seasonal influenza (influenza A and influenza B) occurs seasonally and varies in severity each year, causing respiratory illnesses and placing a substantial burden on healthcare systems

Disease burden:

- Worldwide, influenza leads to 3-5M severe cases of influenza and 290-650K influenza-related respiratory deaths annually[1]
- About 8% of the US population experiences symptoms from influenza each year, with 140-710K hospitalizations and 12-52K deaths per year[2]
- Peak influenza activity is seen in temperate climates during fall to winter and is reflected in increased outpatient visits, urgent care visits, and hospitalizations
- Influenza A viruses led to >95% of influenza-related hospitalizations in adults in the most recent season[3]

Influenza symptoms & complications	
Symptoms	Fever Cough Sore throat Nasal congestion Fatigue Vomiting/diarrhea (more common in children)
Complications	Pneumonia (viral and/or bacterial) Ear infections Sinus infections Exacerbation of chronic conditions (e.g. asthma, heart failure)

1. World Health Organization. Influenza (Seasonal). WHO. 2018. https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal)
2. Centers for Disease Control and Prevention. Disease burden of influenza. Available at: https://www.cdc.gov/flu/about/burden/index.html
3. https://www.cdc.gov/flu/weekly/influenza-hospitalization-surveillance.htm

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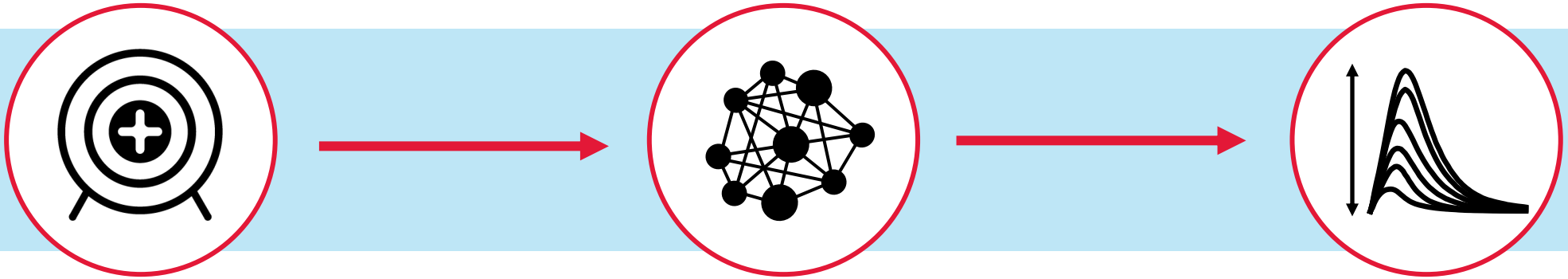
mRNA-1010 will be the foundation of a continuously improving influenza vaccine portfolio



Seasonal quadrivalent flu vaccine
(mRNA-1010)

- Using WHO recommended strains
- First generation vaccine using established licensure pathway

Broader antigen flu vaccines
(mRNA-1020/1030)

- Adding Neuraminidase (NA) antigens
- Improve immunity by targeting more conserved antigens

Beyond quadrivalent flu vaccines
(mRNA-1011/1012)

- Adding Hemagglutinin (HA) antigens (e.g. H3N2, H1N1) to expand strain matching
- Provide an enhanced antigen selection opportunity to public health authorities; potential for regional variation

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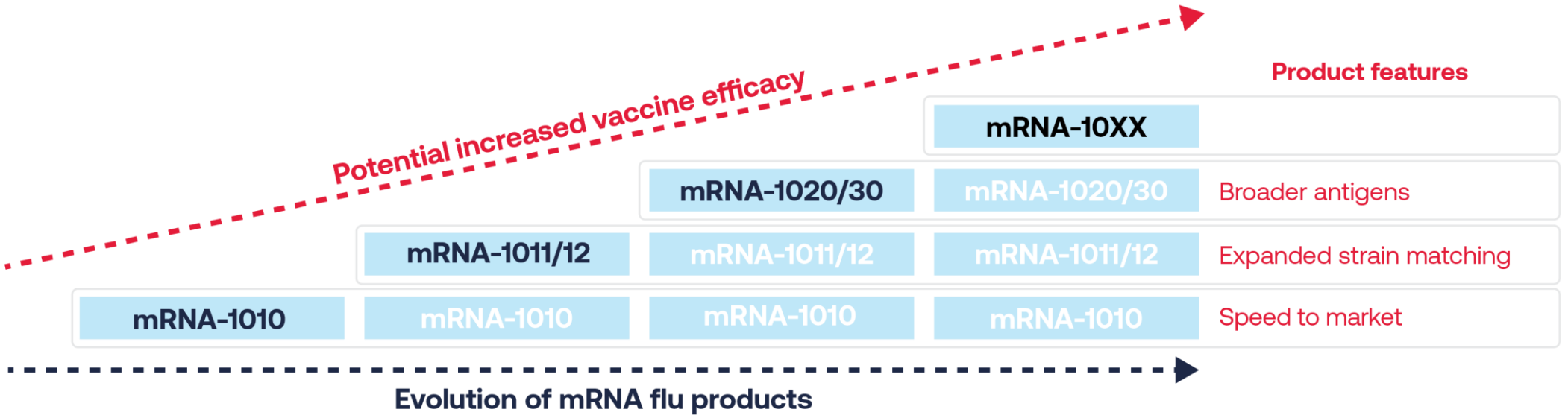
mRNA-1010 will be the foundation of a continuously improving influenza vaccine portfolio

mRNA-1020/1030 Phase 1/2 study initiated in April 2022 and generated proof-of-concept that mRNA vaccines can elicit immune responses against both hemagglutinin and neuraminidase

mRNA-1011/1012 Phase 1/2 study initiated in April 2023 and will generate data on the feasibility to include additional influenza A hemagglutinins to provide broader coverage against drifted strains and in mismatch seasons

mRNA-10XX could be a future vaccine candidate combining the features of the lead candidates identified in prior studies



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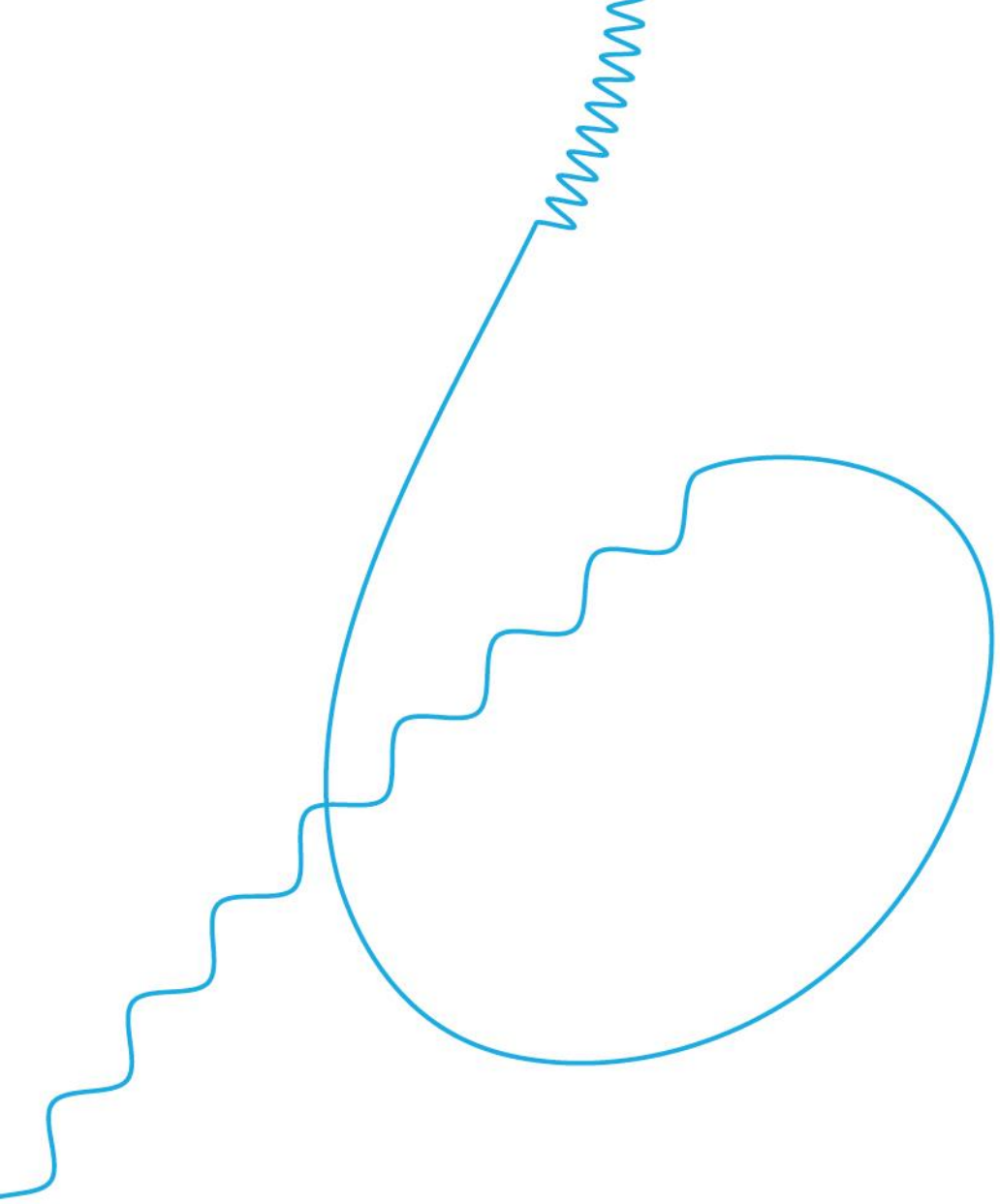

Review of mRNA-1010 Phase 1 interim analysis

Data presented December 10th, 2021

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mRNA-1010: Overview of Phase 1/2 study

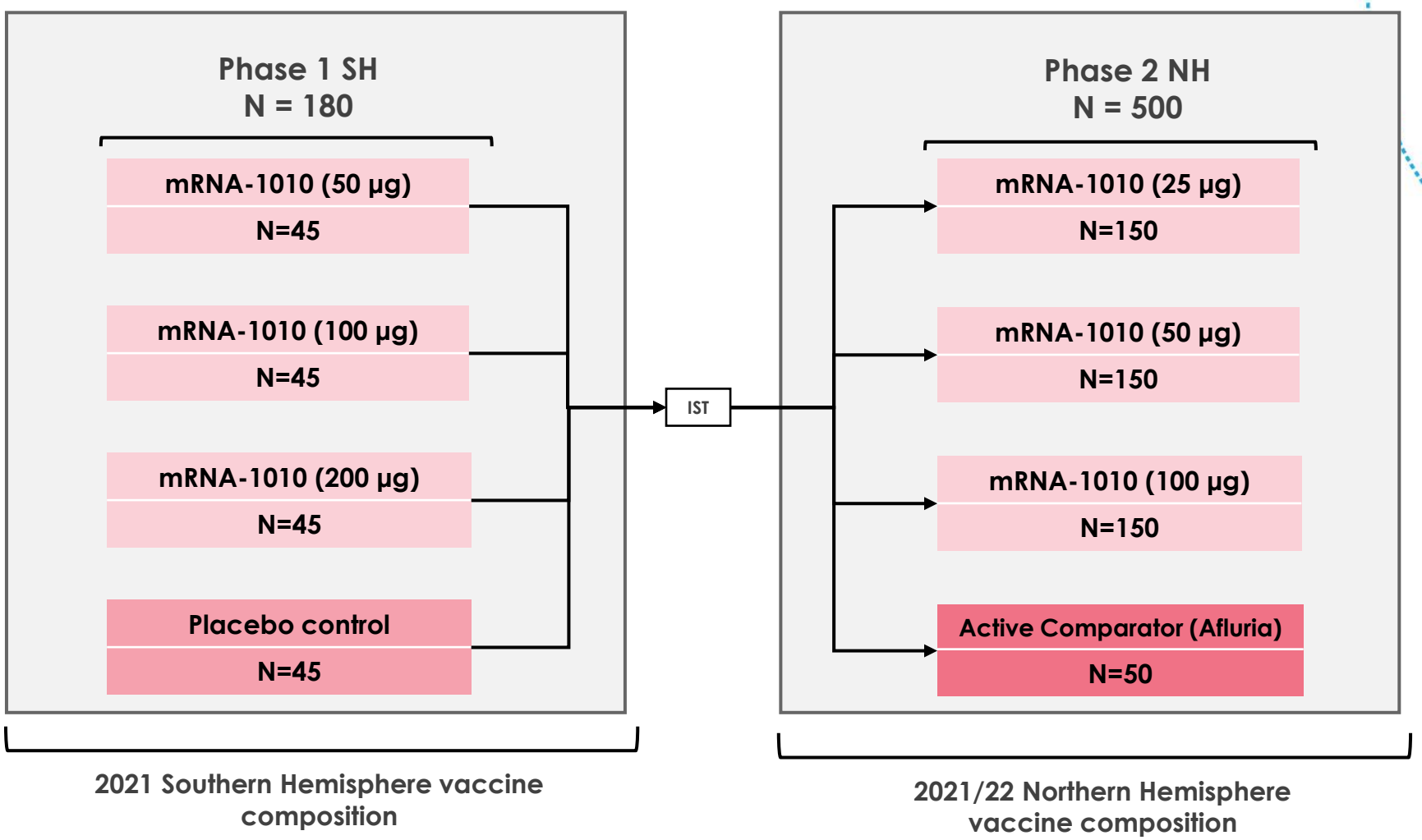
- Evaluating safety and immunogenicity of different dose levels of the mRNA influenza vaccine

Primary outcome measures

- Safety and immunogenicity at Day 29

Trial progress

- All cohorts fully enrolled
- First interim analysis presented December 10th



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mRNA-1010 Phase 1 interim analysis: Solicited local adverse reactions

	≥18 to <50 years old				≥50 years old			
Solicited Adverse Reaction Category Grade	Placebo (N=20) n (%)	50 µg (N=23) n (%)	100 µg (N=21) n (%)	200 µg (N=23) n (%)	Placebo (N=24) n (%)	50 µg (N=22) n (%)	100 µg (N=25) n (%)	200 µg (N=21) n (%)
Solicited Local Adverse Reactions - N1	20	23	21	23	24	22	25	21
Any	4 (20.0)	19 (82.6)	18 (85.7)	21 (91.3)	5 (20.8)	14 (63.6)	23 (92.0)	19 (90.5)
95% CI	5.7, 43.7	61.2, 95.0	63.7, 97.0	72.0, 98.9	7.1, 42.2	40.7, 82.8	74.0, 99.0	69.6, 98.8
Grade 1	4 (20.0)	16 (69.6)	8 (38.1)	6 (26.1)	4 (16.7)	10 (45.5)	16 (64.0)	7 (33.3)
Grade 2	0	3 (13.0)	6 (28.6)	10 (43.5)	0	3 (13.6)	5 (20.0)	11 (52.4)
Grade 3	0	0	4 (19.0)	5 (21.7)	1 (4.2)	1 (4.5)	2 (8.0)	1 (4.8)
Grade 4	0	0	0	0	0	0	0	0

- No serious adverse events or pause rules were observed through Day 29
- The most common solicited local ARs were pain and axillary swelling/tenderness

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mRNA-1010 Phase 1 interim analysis: Solicited systemic adverse reactions

	≥18 to <50 years old				≥50 years old			
Solicited Adverse Reaction Category Grade	Placebo (N=20) n (%)	50 µg (N=23) n (%)	100 µg (N=21) n (%)	200 µg (N=23) n (%)	Placebo (N=24) n (%)	50 µg (N=22) n (%)	100 µg (N=25) n (%)	200 µg (N=21) n (%)
Solicited Local Adverse Reactions - N1	20	23	21	23	24	22	25	21
Any	6 (30.0)	18 (78.3)	19 (90.5)	21 (91.3)	8 (33.3)	12 (54.5)	23 (92.0)	20 (95.2)
95% CI	11.9, 54.3	56.3, 92.5	69.6, 98.8	72.0, 98.9	15.6, 55.3	32.2, 75.6	74.0, 99.0	76.2, 99.9
Grade 1	3 (15.0)	8 (34.8)	3 (14.3)	4 (17.4)	5 (20.8)	5 (22.7)	7 (28.0)	2 (9.5)
Grade 2	3 (15.0)	7 (30.4)	7 (33.3)	6 (26.1)	2 (8.3)	5 (22.7)	13 (52.0)	13 (61.9)
Grade 3	0	3 (13.0)	9 (42.9)	11 (47.8)	1 (4.2)	2 (9.1)	3 (12.0)	5 (23.8)
Grade 4	0	0	0	0	0	0	0	0

- No serious adverse events or pause rules were observed through Day 29
- The most common solicited systemic ARs were fatigue, myalgia, arthralgia, and headache

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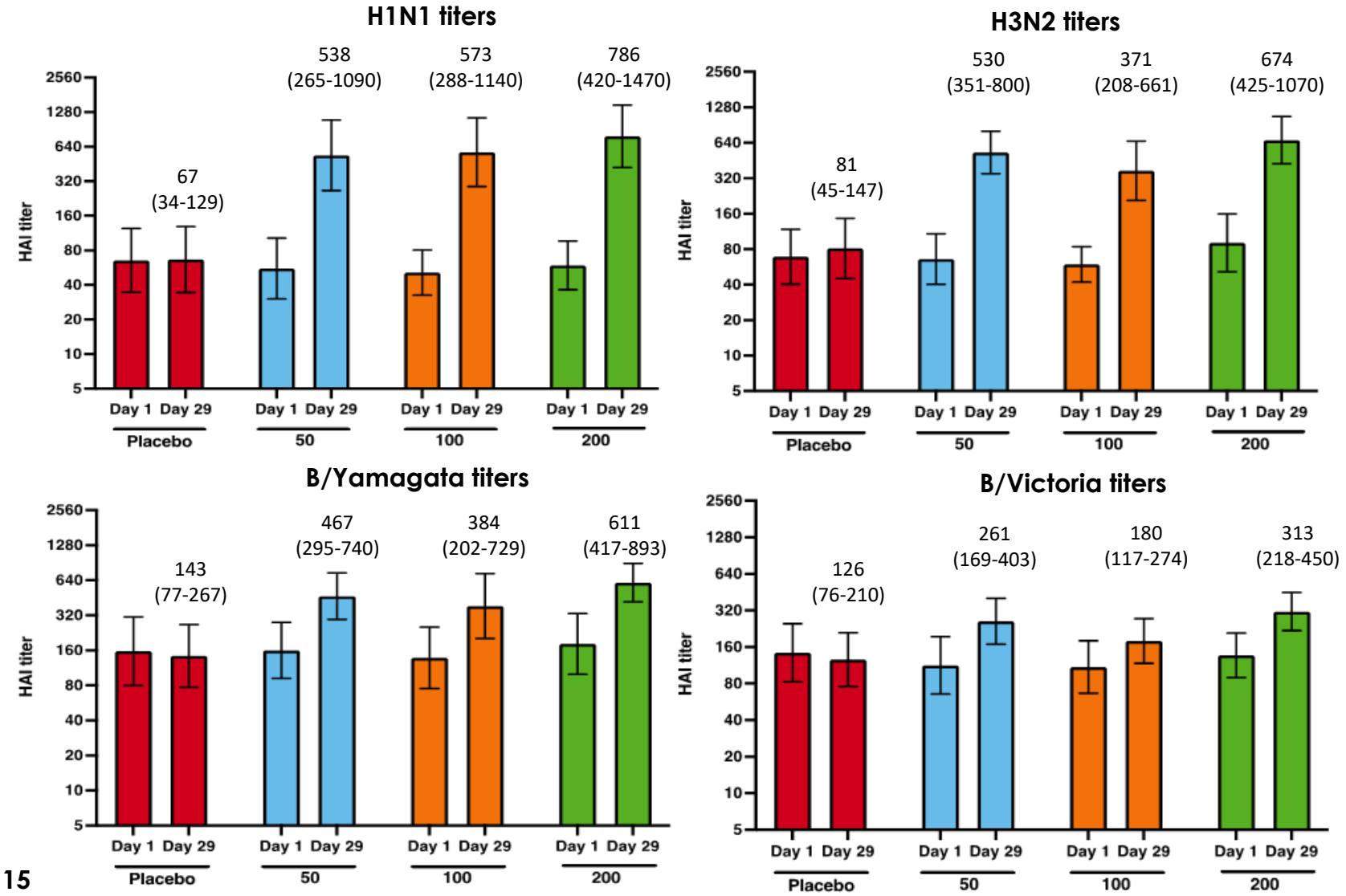
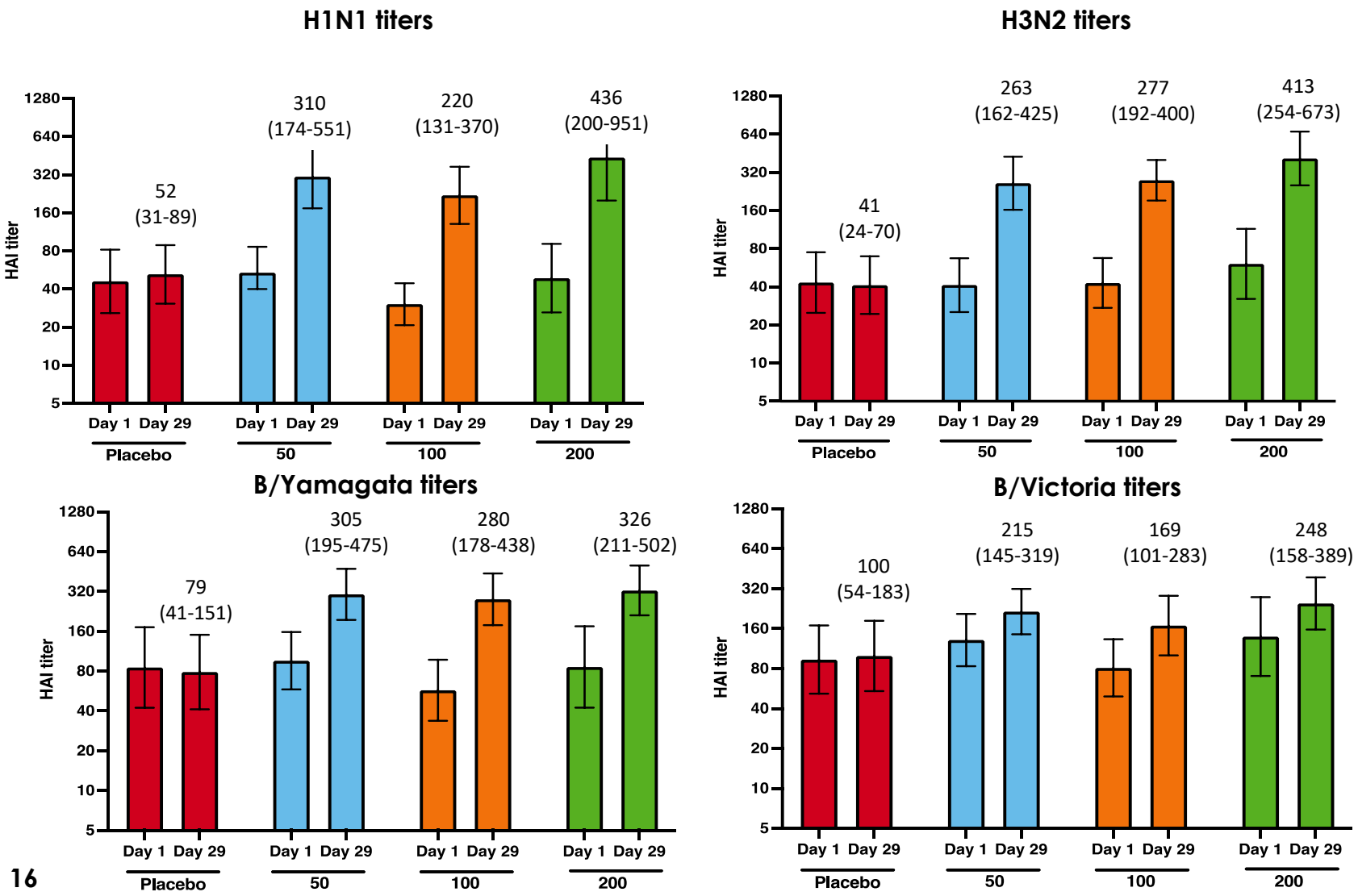
Phase 1 immunogenicity data: Pre- and post-vaccination GMTs in younger adults (18-49 yrs old)



- Minimal dose response was observed; exploring lower dose levels
- At the lowest dose level (50 µg), Day 29 geometric mean titers (GMT) against influenza A strains were 530 (H1N1) and 538 (H3N2); GMT against influenza B strains were 467 (B/Yamagata) and 261 (B/Victoria)

Phase 1 immunogenicity data: Pre- and post-vaccination GMTs in older adults (≥50 yrs old)



- Minimal dose response was observed; exploring lower dose levels
- At the lowest dose level (50 µg), Day 29 GMT against influenza A strains were 310 (H1N1) and 263 (H3N2); titers against influenza B strains were 305 (B/Yamagata) and 215 (B/Victoria)

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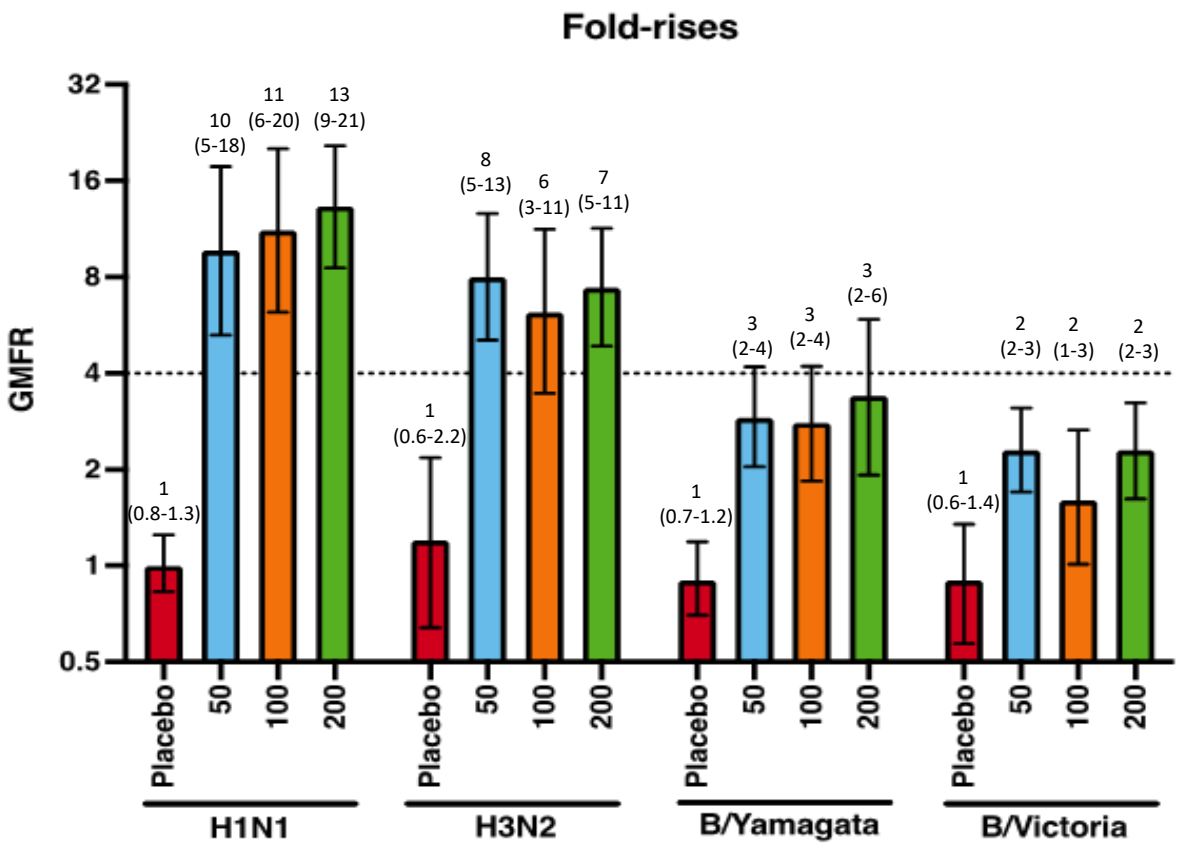
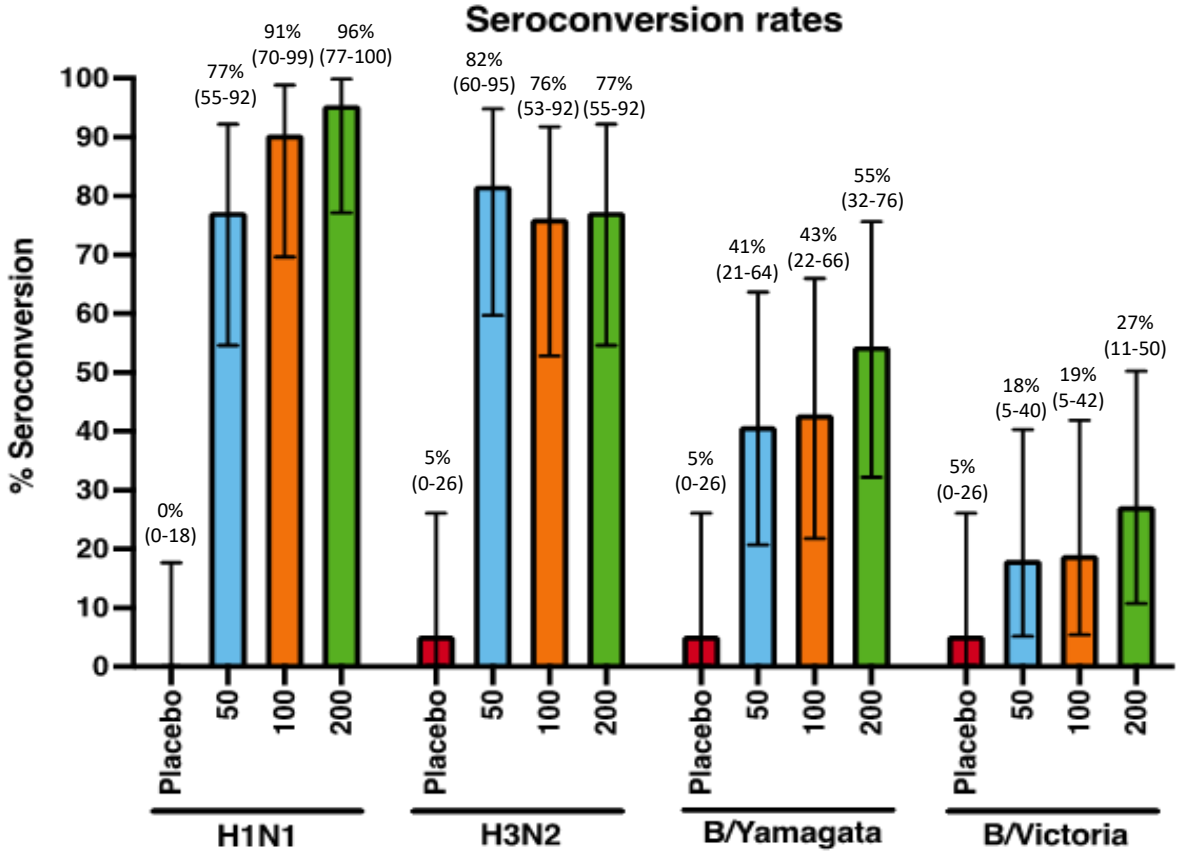
Phase 1 immunogenicity data: Fold-rises and seroconversion rates for younger adults

Younger Adults

(18-49 yrs old)





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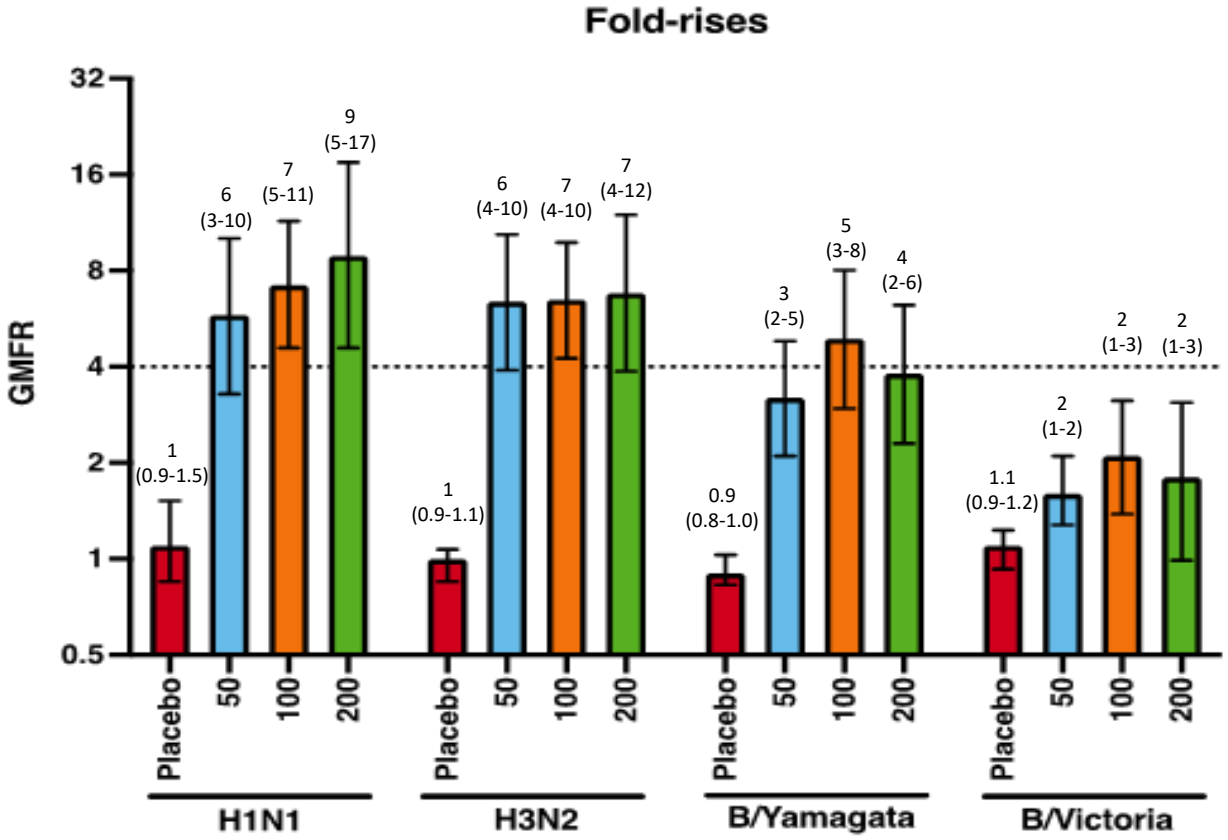
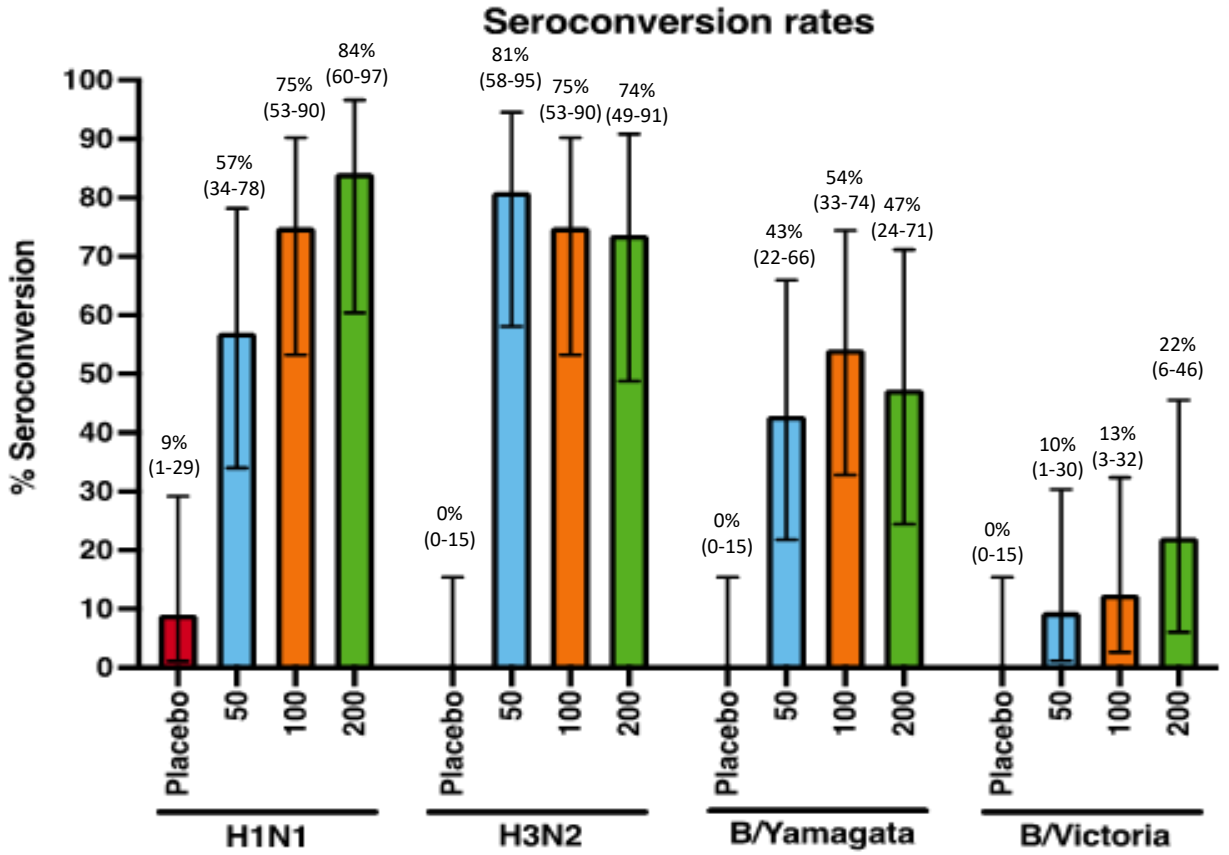
Phase 1 immunogenicity data: Fold-rises and seroconversion rates for older adults

Older Adults

(≥50 yrs old)





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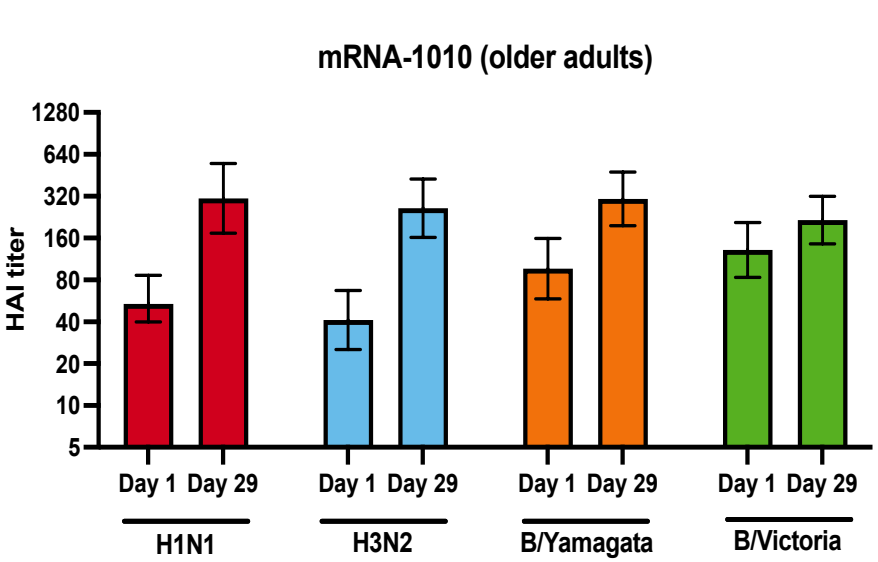
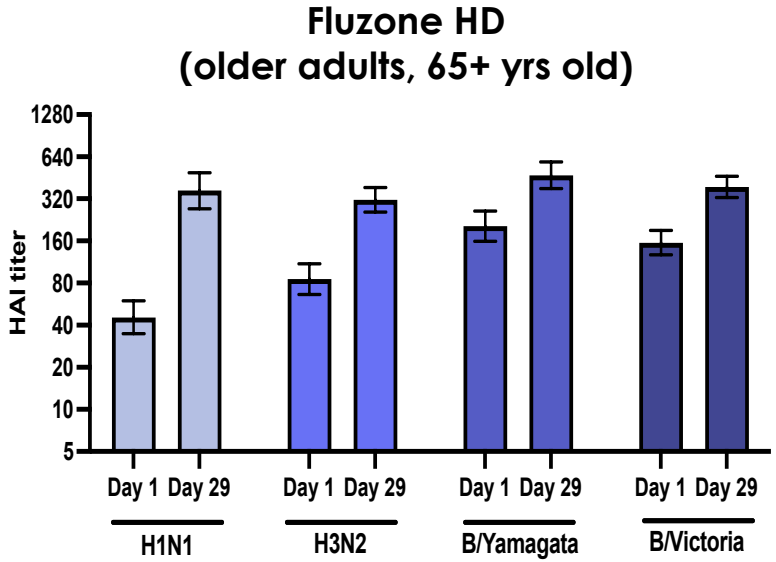
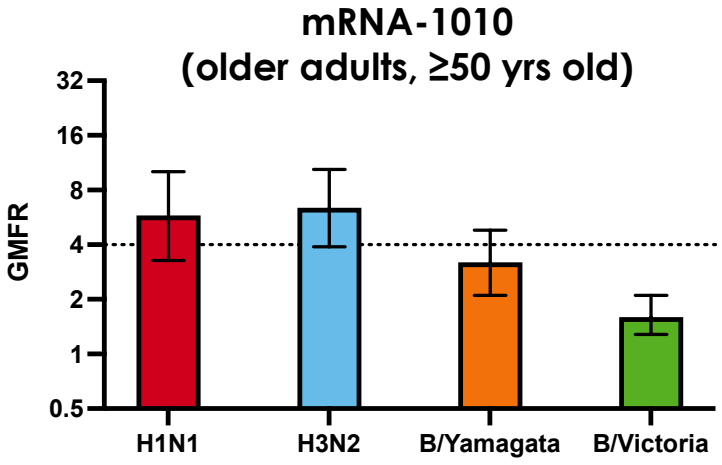
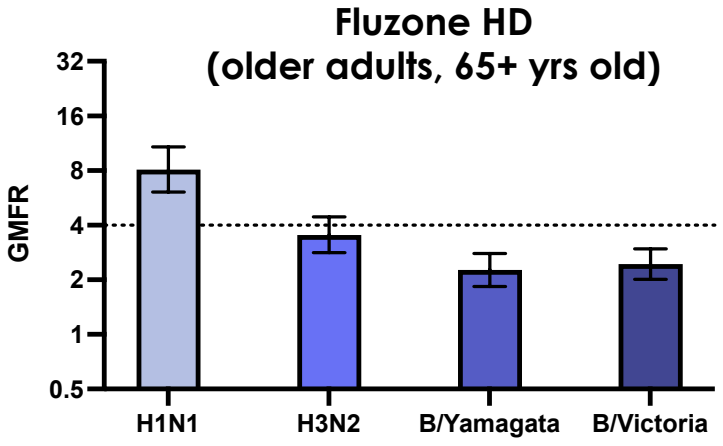
Immunogenicity comparison vs. Fluzone HD in older adults (data from Sanofi/Moderna co-admin study)









- Fluzone HD is the:
  - Enhanced vaccine targeting older adults
  - Highest dose vaccine
  - Market leader in older adults

Evaluate Pharma, CMS

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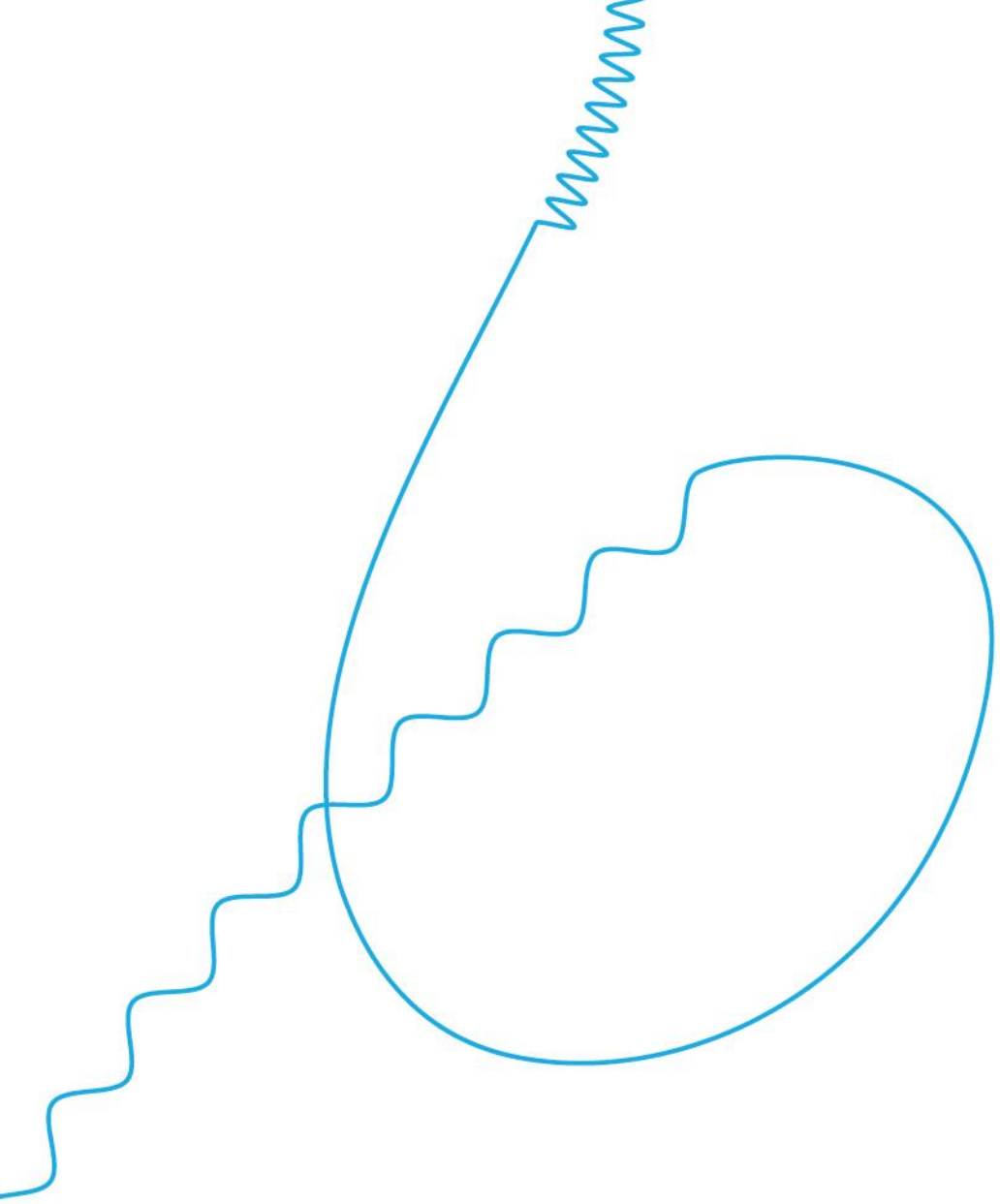

Review of mRNA-1010 Phase 2 interim analysis

Data presented March 24th, 2022

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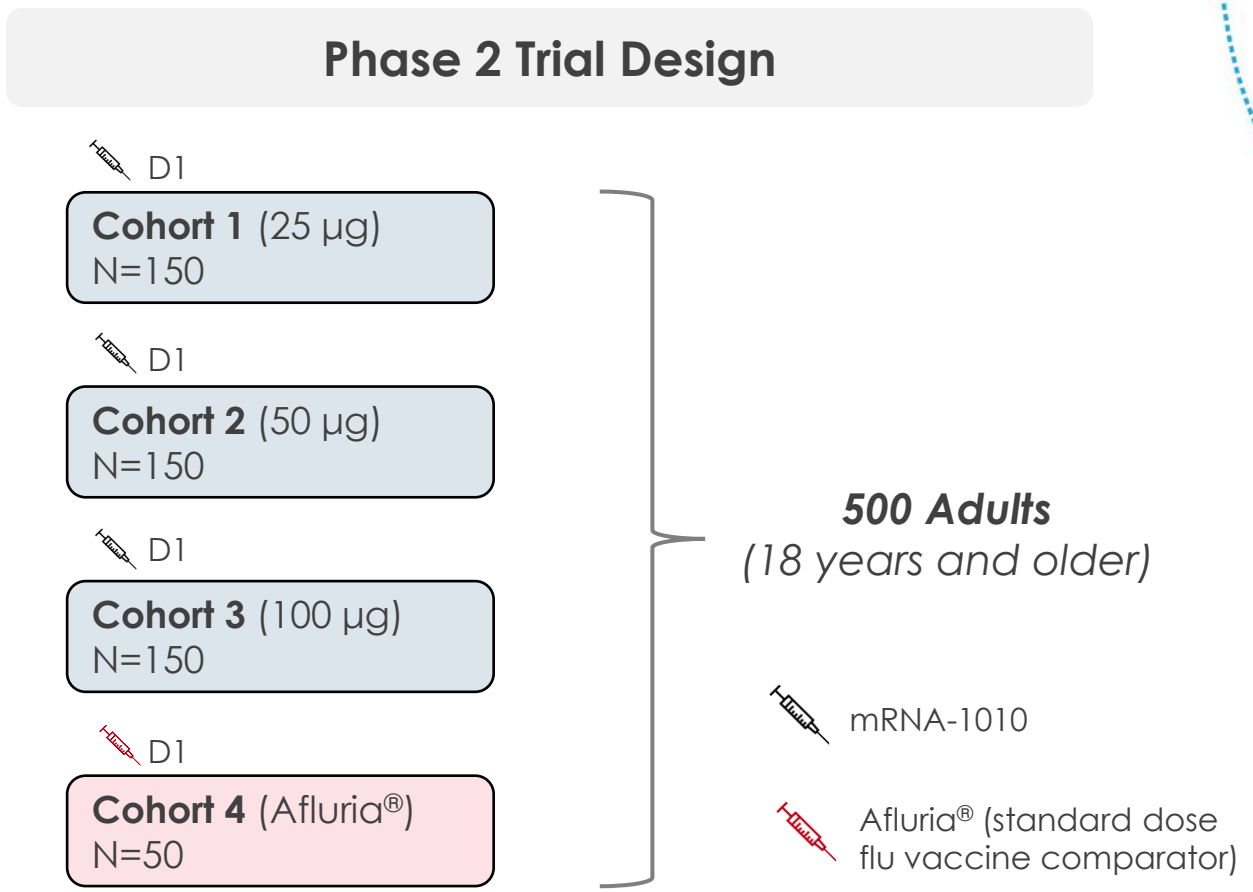
Influenza vaccine (mRNA-1010) Phase 2 trial overview

Trial Overview

- Evaluating safety and immunogenicity of different dose levels of the mRNA influenza vaccine
- Testing the Northern Hemisphere strains for the 2021/22 NH influenza season

Primary Outcome Measures

- Safety and immunogenicity at Day 29



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mRNA-1010 Phase 2 demographics

	18 to 49 years old				50 to 64 years old				65+ years old			
Group	Afluria	mRNA-1010 25 µg	mRNA-1010 50 µg	mRNA-1010 100 µg	Afluria	mRNA-1010 25 µg	mRNA-1010 50 µg	mRNA-1010 100 µg	Afluria	mRNA-1010 25 µg	mRNA-1010 50 µg	mRNA-1010 100 µg
N	21	60	58	59	20	60	57	57	12	31	32	31
Age (Mean, Min, Max)	35.9 (20, 49)	34.3 (18, 49)	34.5 (19, 49)	32.4 (18, 47)	56.0 (50, 64)	56.0 (50, 64)	54.9 (50, 64)	56.3 (50, 64)	73.8 (66, 86)	70.5 (65, 86)	71.1 (65, 81)	71.7 (65, 82)
% Female	57.1	55.0	56.9	55.9	45	58.3	49.1	64.9	66.7	67.7	59.4	51.6
% Male	42.9	45.0	43.1	44.1	55	41.7	50.9	35.1	33.3	32.3	40.6	48.4
% White	71.4	76.7	77.6	81.4	80	85	75.4	78.9	100	90.3	87.5	83.9
% Black or African American	14.3	13.3	19	11.9	15	8.3	8.8	14.0	0	9.7	6.3	9.7
% Asian	0	3.3	1.7	1.7	0	0	1.8	1.8	0	0	3.1	0
% Other	14.3	6.7	1.7	5	5	6.7	14	5.3	0	0	3.1	6.4

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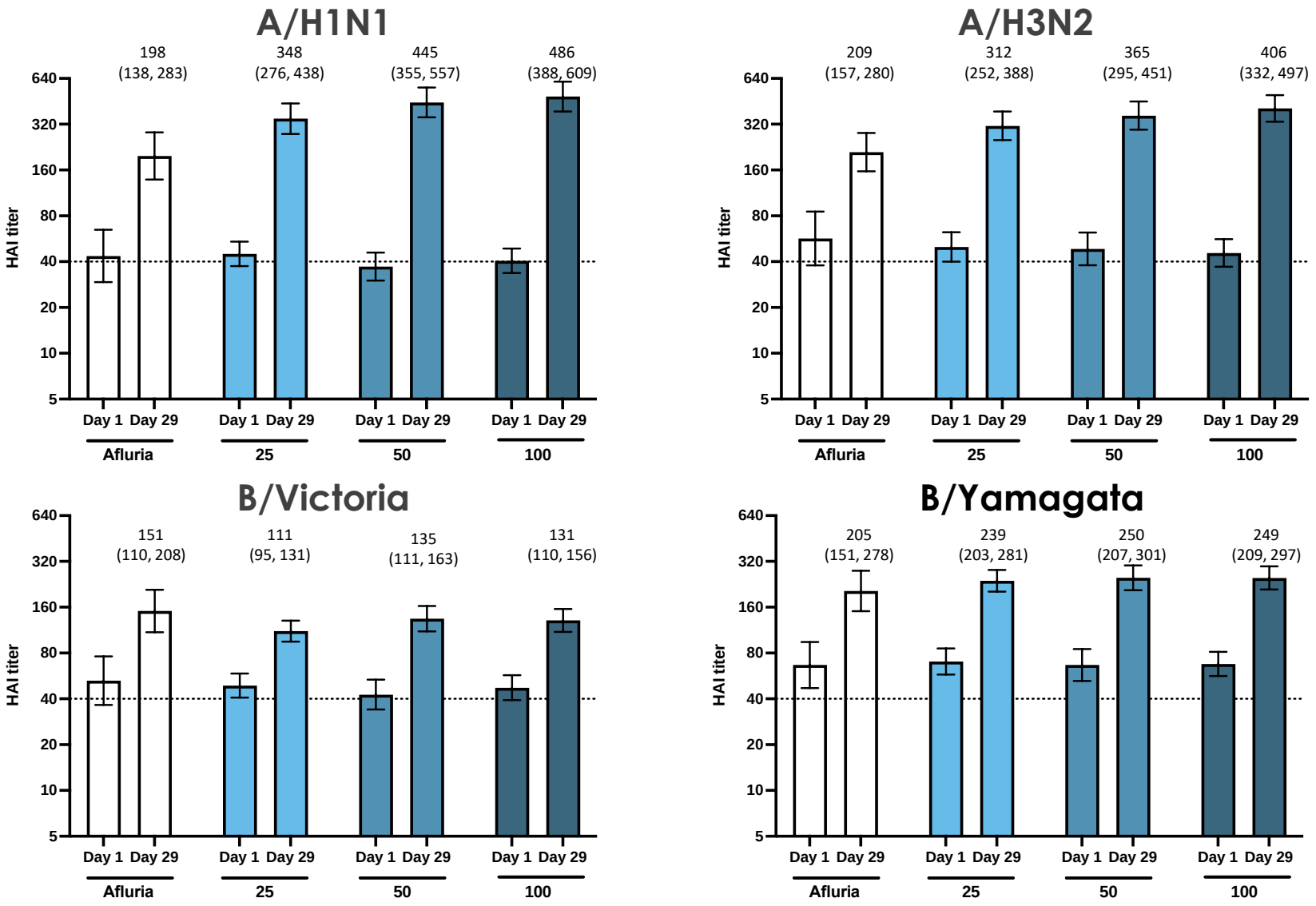
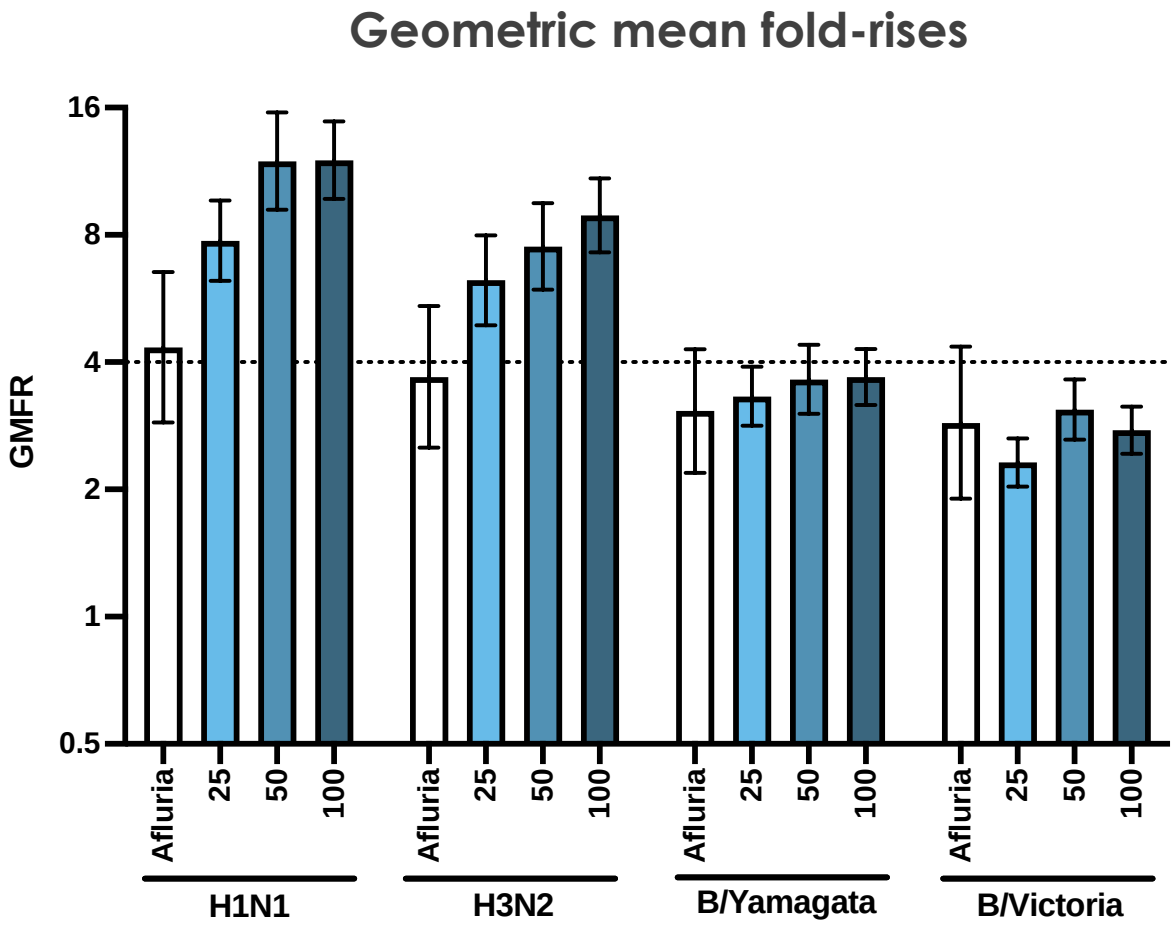
Geometric mean titers (GMTs) across all ages

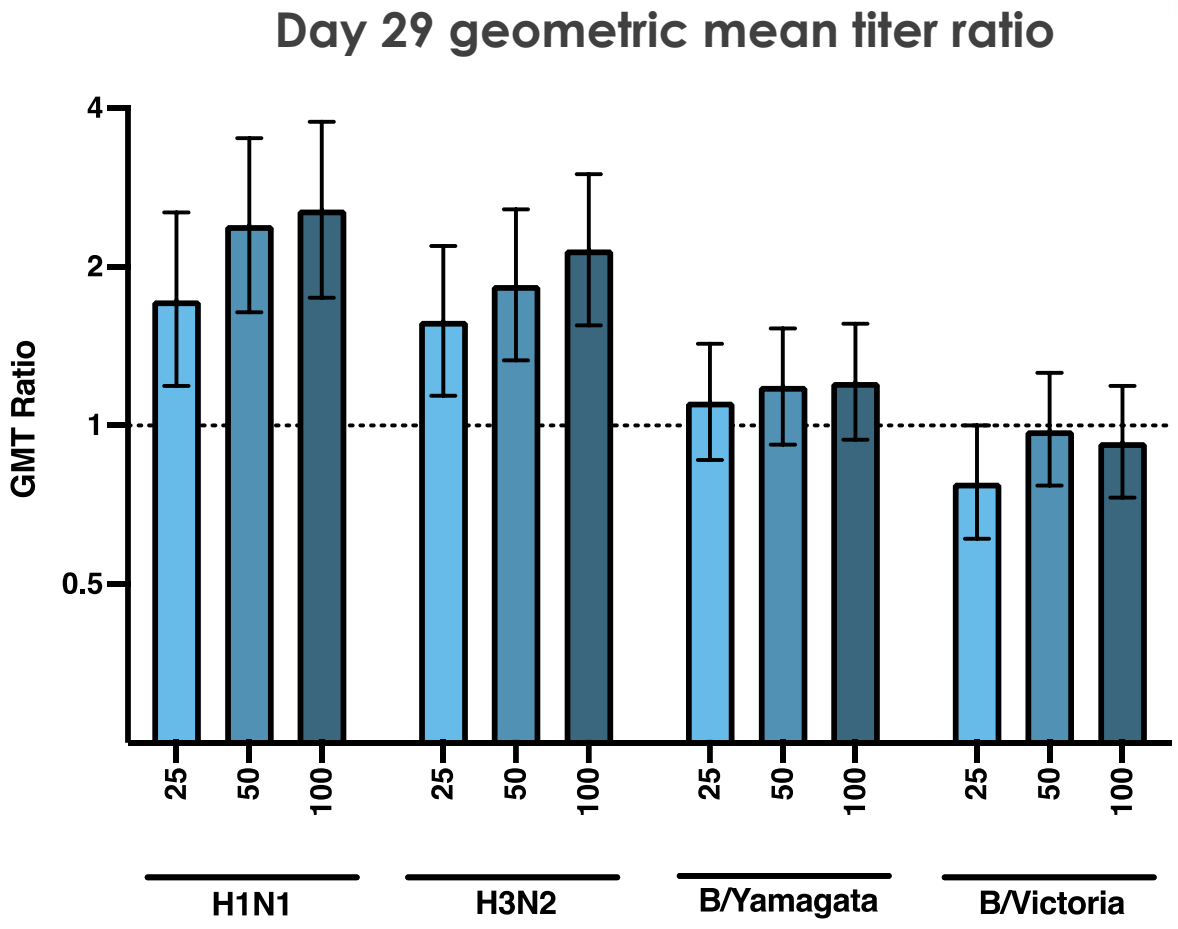


- mRNA-1010 elicits high HAI antibody titers, substantially exceeding 1:40 threshold associated with a 50% reduction in risk of infection
- Day 29 antibody levels are comparable to Afluria for influenza B and higher than Afluria for influenza A strains

H1N1, B/Yamagata, B/Victoria HAI used cell-grown virus; H3N2 HAI used egg-grown virus (in-line with cell-based assays)

Geometric mean fold-rises (GMFRs) and geometric mean titer ratios (GMTrs) across all ages





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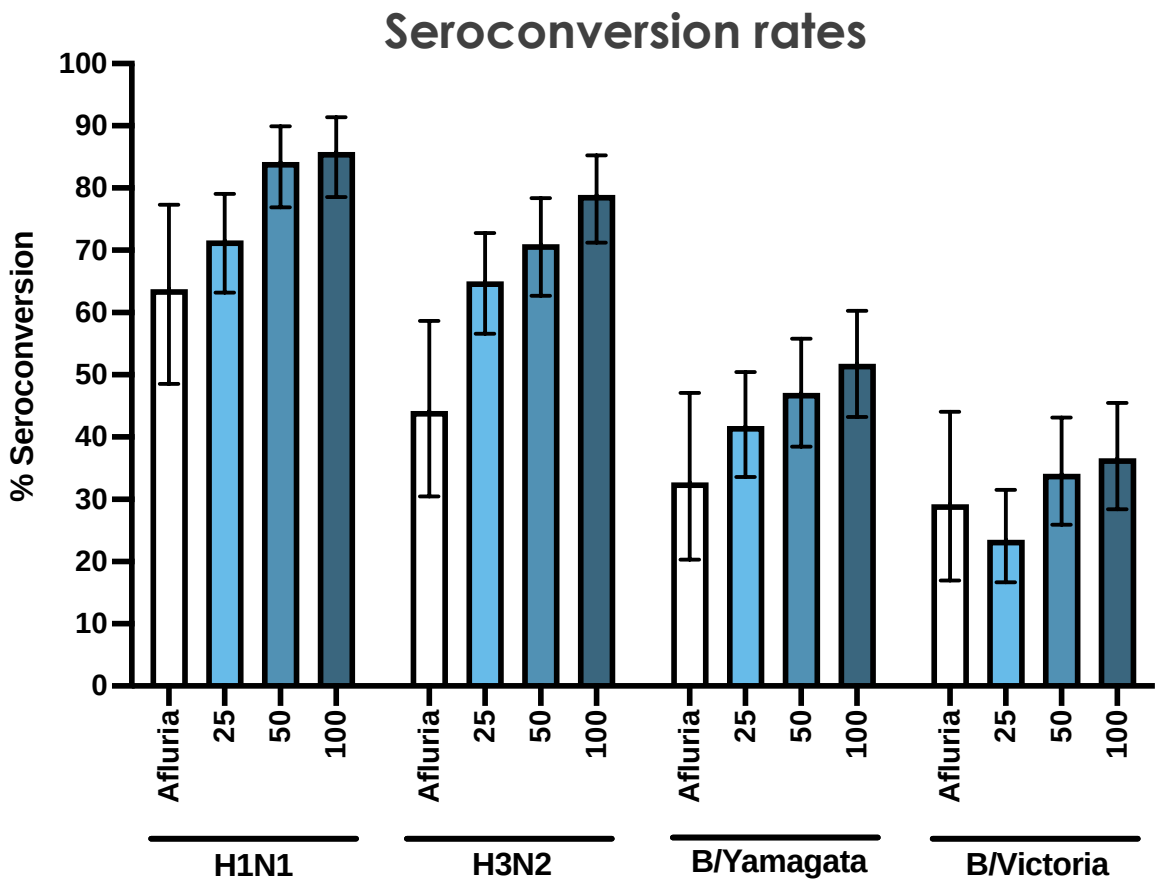
Seroconversion rates across all ages



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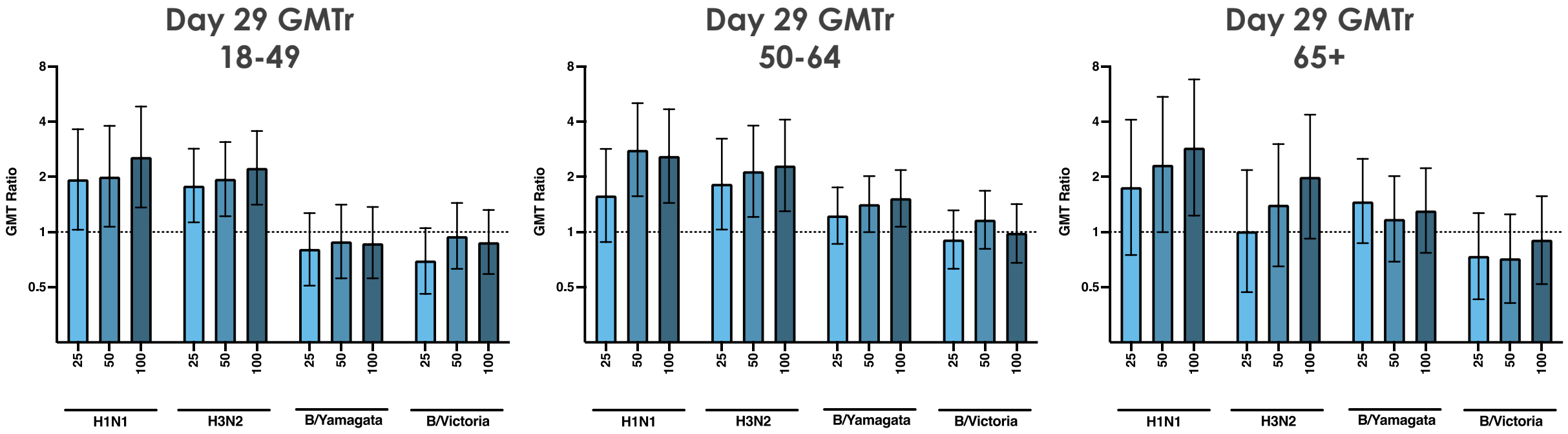
mRNA-1010 responses were generally consistent across all ages: GMTrs by age group



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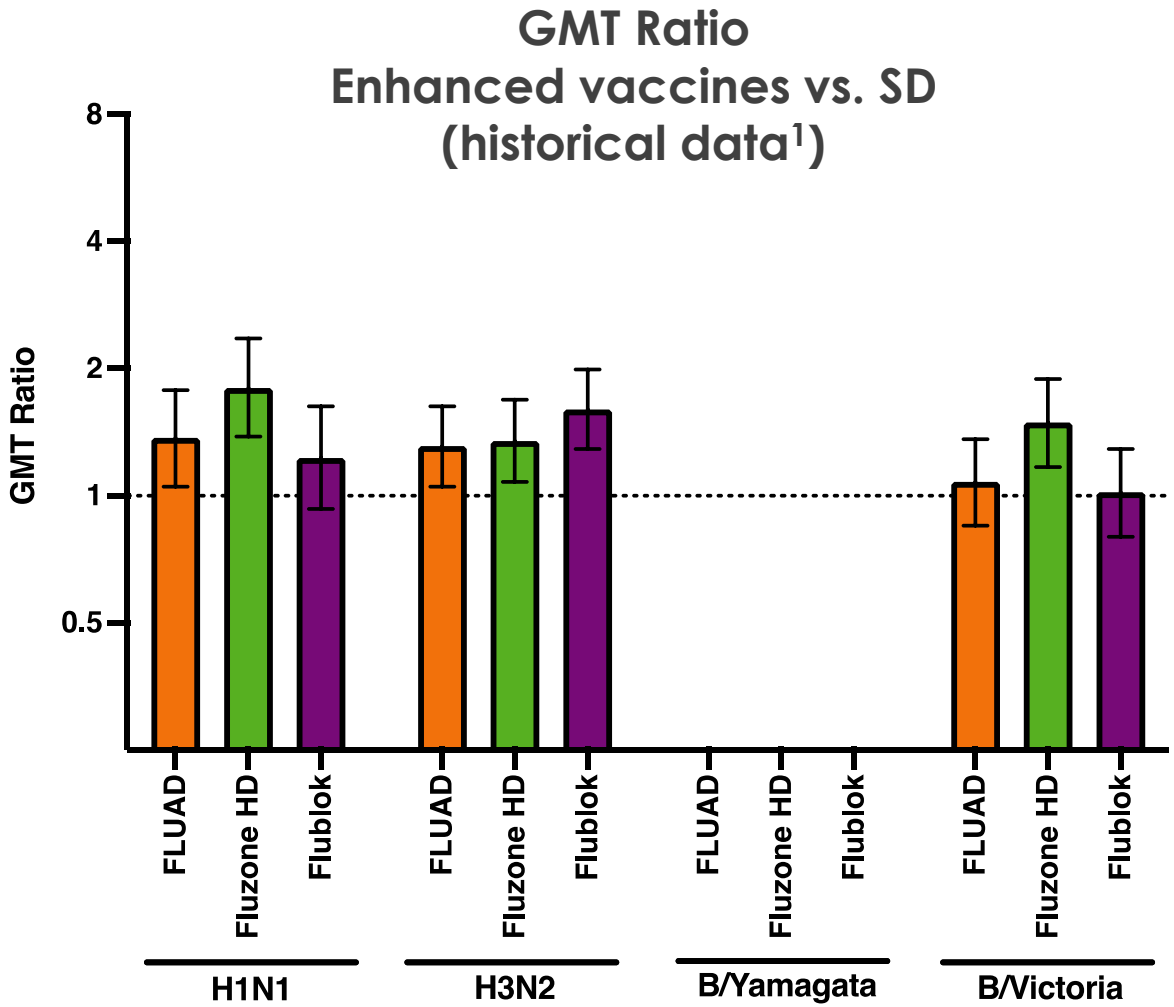
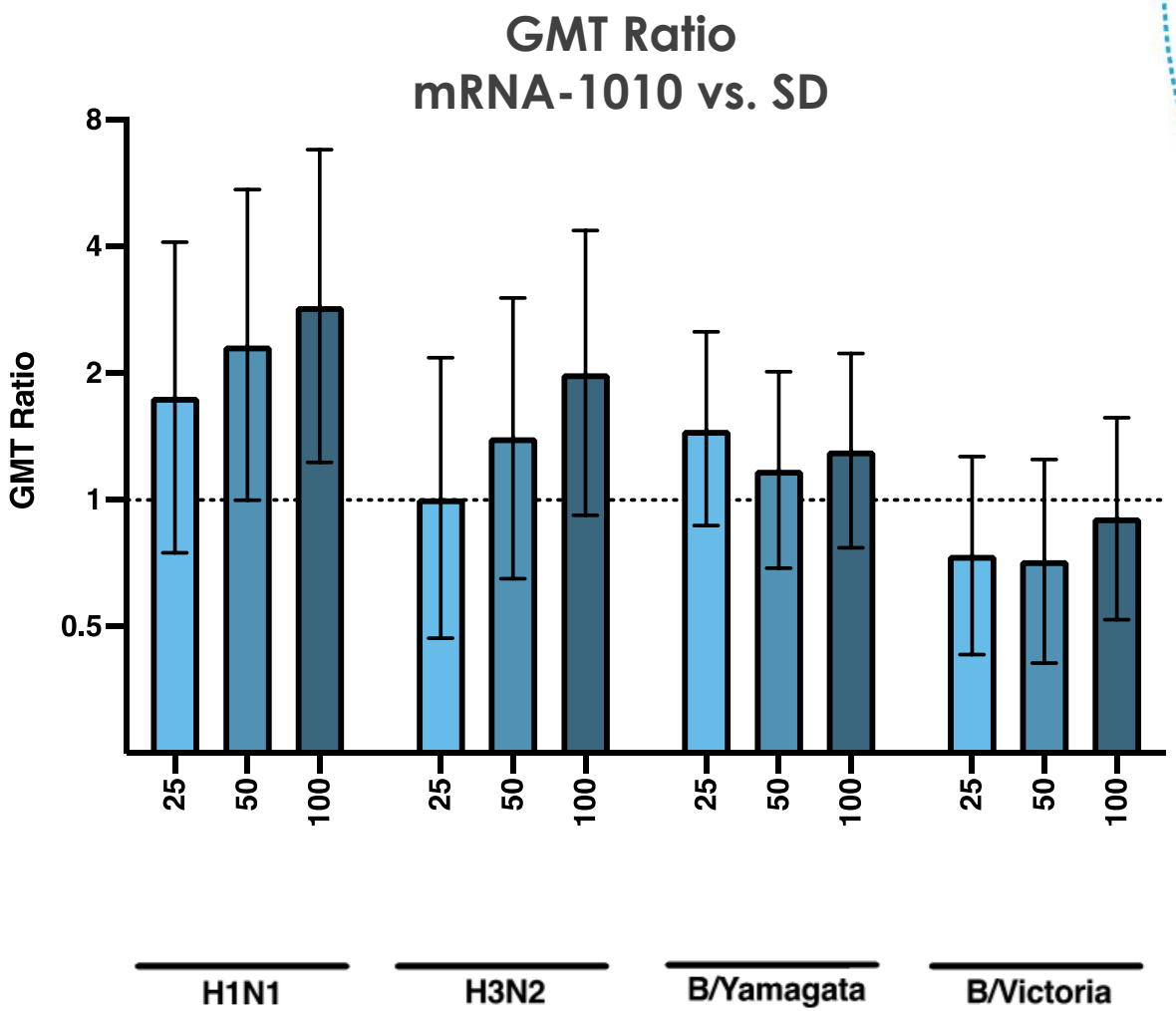
GMT ratio of enhanced vaccines vs. SD vaccine (historical data) compared to mRNA-1010 vs. SD vaccine in older adults





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(1) Cowling, Benjamin et al., *Clin Infect Dis* (2020), https://doi.org/10.1093/cid/ciz1034

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mRNA-1010 Phase 2 interim analysis: Solicited local adverse reactions

	18 to 49 years old				50 to 64 years old				65+ years old			
Solicited Adverse Reaction	Afluria % (N=21)	25 µg % (N=60)	50 µg % (N=57)	100 µg % (N=58)	Afluria % (N=19)	25 µg % (N=58)	50 µg % (N=58)	100 µg % (N=57)	Afluria % (N=13)	25 µg % (N=31)	50 µg % (N=31)	100 µg % (N=30)
Any	42.9%	83.3%	84.2%	93.1%	36.8%	72.4%	84.5%	80.7%	30.8%	67.7%	83.9%	80.0%
95% CI	21.8, 66.0	71.5, 91.7	72.1, 92.5	83.3, 98.1	16.3, 61.6	59.1, 83.3	72.6, 92.7	68.1, 90.0	9.1, 61.4	48.6, 83.3	66.3, 94.5	61.4, 92.3
Grade 1	38.1%	70%	56.1%	39.7%	31.6%	51.7%	55.2%	50.9%	23.1%	58.1%	74.2%	53.3%
Grade 2	4.8%	13.3%	21.2%	37.9%	--	19%	24.1%	21.1%	7.7%	3.2%	9.7%	53.3%
Grade 3	--	--	7%	15.5%	5.3%	1.7%	5.2%	8.8%	--	6.5%	--	6.7%
Grade 4	--	--	--	--	--	--	--	--	--	--	--	--

- No serious adverse events related to the study vaccine or pause rules were observed through Day 29
- The most common solicited local ARs were pain and axillary swelling/tenderness

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mRNA-1010 Phase 2 interim analysis: Solicited systemic adverse reactions

	18 to 49 years old				50 to 64 years old				65+ years old			
Solicited Adverse Reaction	Afluria % (N=21)	25 µg % (N=60)	50 µg % (N=57)	100 µg % (N=58)	Afluria % (N=19)	25 µg % (N=58)	50 µg % (N=58)	100 µg % (N=57)	Afluria % (N=13)	25 µg % (N=31)	50 µg % (N=31)	100 µg % (N=30)
Any	42.9%	85.0%	73.7%	91.4%	31.6%	68.4%	75.9%	75.4%	38.5%	48.4%	77.4%	76.7%
95% CI	21.8, 66.0	73.4, 92.9	60.3, 84.5	81.0, 97.1	12.6, 56.6	54.8, 80,1	62.8, 86.1	62.2, 85.9	13.9, 68.4	30.2, 66.9	58.9, 90.4	57.7, 90.1
Grade 1	19%	31.7%	24.6%	12.1%	10.5%	33.3%	27.6%	19.3%	38.5%	22.6%	32.3%	30%
Grade 2	23.8%	43.3%	33.3%	56.9%	10.5%	29.8%	37.9%	42.1%	--	25.8%	29%	36.7%
Grade 3	--	10%	15.8%	22.4%	10.5%	5.3%	10.3%	14%	--	--	16.1%	10%
Grade 4	--	--	--	--	--	--	--	--	--	--	--	--

- No serious adverse events related to the study vaccine or pause rules were observed through Day 29
- The most common solicited systemic ARs were myalgia, headache and fatigue

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Influenza vaccine (mRNA-1010) Phase 2 safety summary

- **The solicited adverse reactions were higher in the mRNA-1010 groups than in the Afluria group**
  - Most common local solicited adverse reactions were pain and axillary swelling/tenderness
  - Most common systemic solicited adverse reactions were myalgia, headache and fatigue
  - Local and systemic solicited adverse reactions were mostly mild to moderate in severity without any Grade 4 adverse reactions
- **No significant safety concerns were identified at the time of interim analysis**; no AESIs or AEs leading to study pauses; No SAEs that were assessed as related to the study vaccine

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mRNA-1010 Phase 2 interim analysis summary

- The immunogenicity data at D29 were consistent with a potential for superiority to standard dose vaccine for influenza A strains (which drive majority of disease in adults)
- The data were consistent with potential for non-inferiority to standard dose vaccine in influenza B strains (primarily a concern in pediatrics)
- Consistent profile across ages; GMTrs for influenza A strains in 65+ appear higher than published GMTrs for enhanced vaccines
- No major safety concerns/issues; overall reactogenicity is 2-3x standard dose vaccine (appears to mirror immunogenicity)

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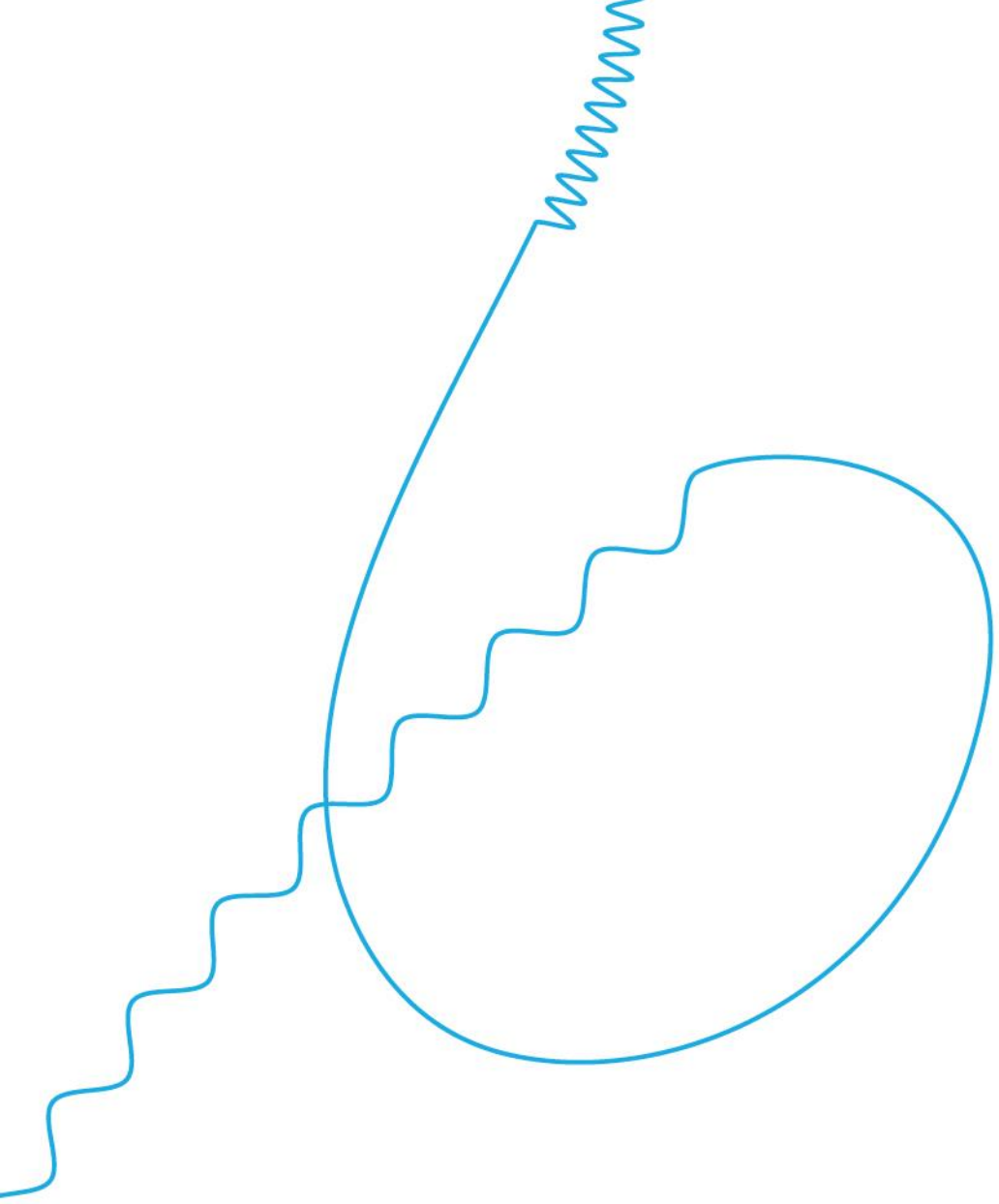

Broader antigen flu vaccines

mRNA-1020 & mRNA-1030

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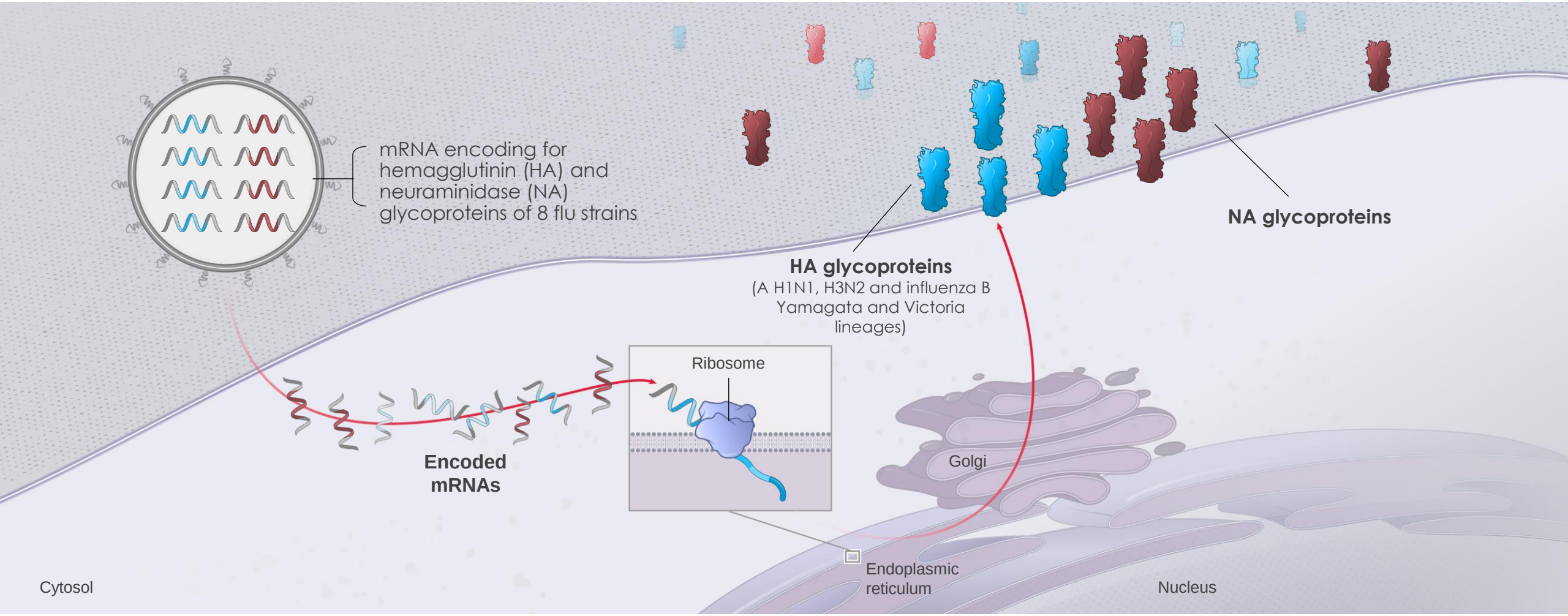
Broader antigen flu vaccines (mRNA-1020 and mRNA-1030)



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mRNA-1020 and mRNA-1030 are fully enrolled in a Phase 1/2 clinical study

Objective

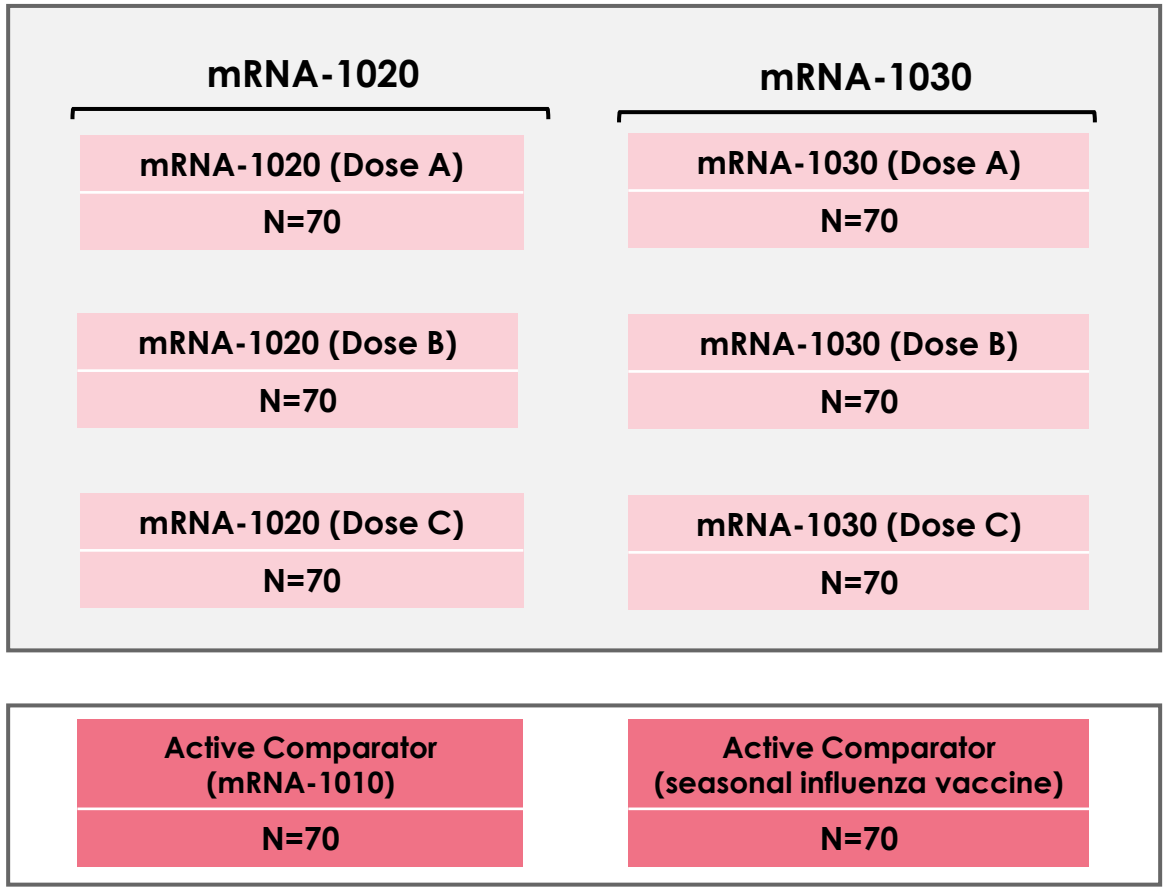
- Evaluating safety and immunogenicity of different dose levels of mRNA influenza vaccines (mRNA-1010/-20/-30) in healthy adults (ages 18-75)

Primary outcome measures

- Safety and immunogenicity at Day 29

Trial progress

- Trial is fully enrolled



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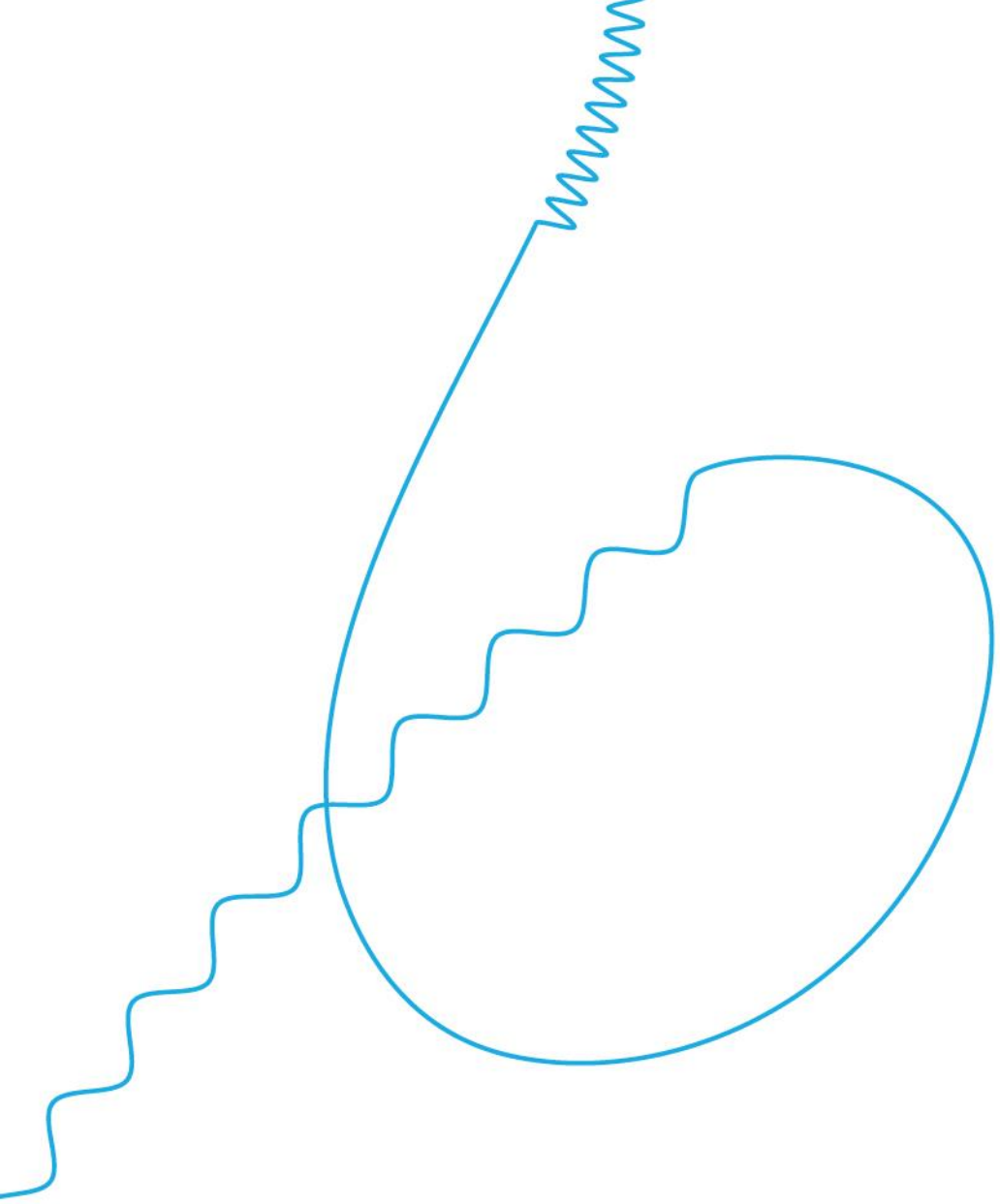

Early look at mRNA-1020/-1030 from Vaccines Day

mRNA-1020 & mRNA-1030

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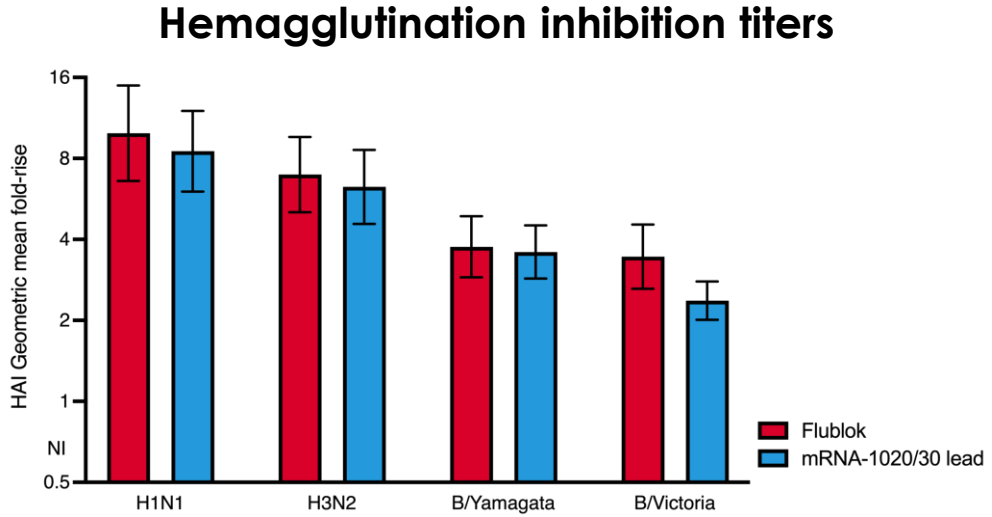
mRNA-1020/1030 P101 study results demonstrate that mRNA vaccines can elicit responses against neuraminidase

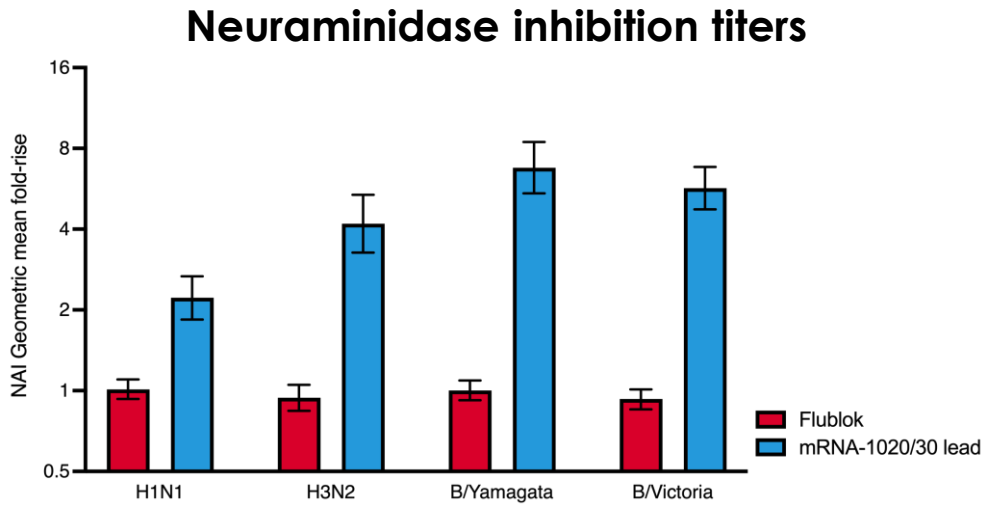
Flublok® is an enhanced vaccine that demonstrated **30% rVE** against a standard dose vaccine in its pivotal efficacy trial, **despite not including any neuraminidase** antigens

Inclusion and standardization of neuraminidase content into vaccines has posed a challenge for traditional manufacturing platforms, but is **not a limitation for mRNA vaccines**

A **2-fold increase in neuraminidase inhibition** titers (NAI) has been associated with an approximately **30% reduced** risk of infection[1,2]

The **mRNA-1020/1030 lead candidate elicits functional NAI titers** in addition to inducing hemagglutination inhibition (HAI) titers in a similar range to Flublok®





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[1] https://doi.org/10.1093/cid/ciz1198
[2] https://doi.org/10.1093/infdis/jiv195

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mRNA-1020/1030 P101 study results demonstrate that mRNA vaccines can elicit responses against neuraminidase

Flublok® is an enhanced vaccine that demonstrated **30% rVE** against a standard dose vaccine in its pivotal efficacy trial, **despite not including any neuraminidase** antigens

Inclusion and standardization of neuraminidase content into vaccines has posed a challenge for traditional manufacturing platforms, but is **not a limitation for mRNA vaccines**

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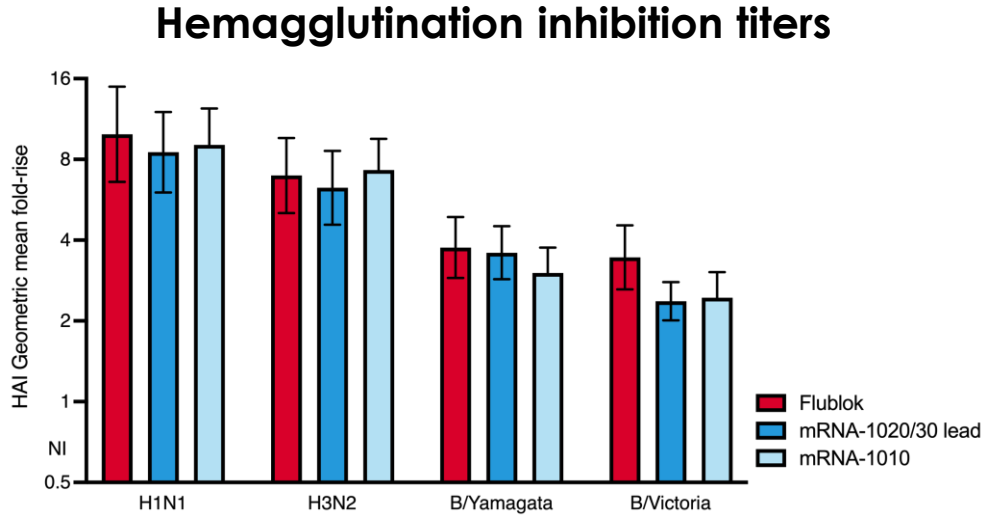

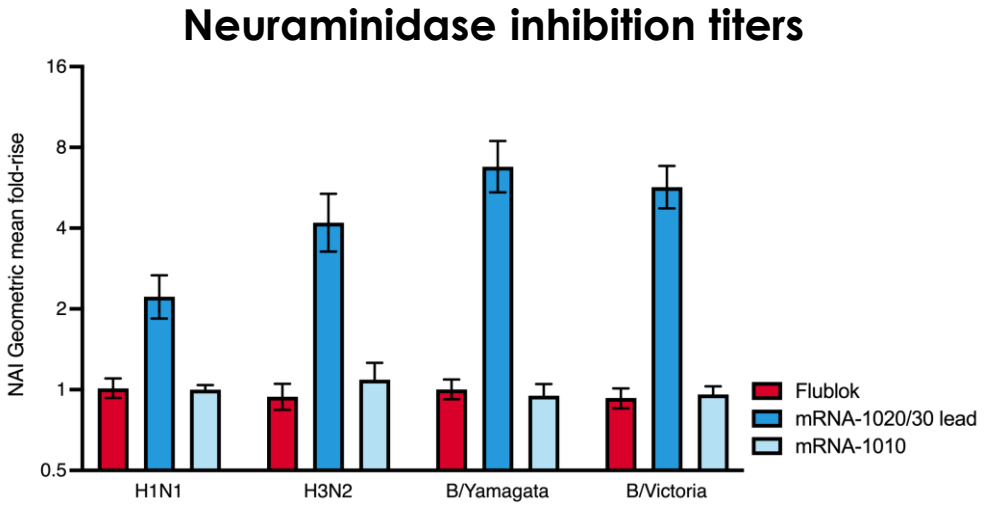

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[1] https://doi.org/10.1093/cid/ciz1198
[2] https://doi.org/10.1093/infdis/jiv195

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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: potential market size; Moderna's seasonal influenza vaccine strategy; Moderna's clinical trials; the potential for superiority of mRNA-1010 to standard dose vaccine for influenza A strains and non-inferiority to standard dose vaccine for influenza B strains; the potential for an updated formulation of mRNA-1010 to lead to improved immune responses against influenza B strains and enable licensure through accelerated approval; Moderna's expectations for a continuously improving influenza vaccine portfolio; and the potential for eliciting immune responses against HA and NA . 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.

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