FLUCELVAX QUADRIVALENT (ccIIV4) a Phase III Randomized Controlled Trial

Immunogenicity & Safety Results in Young Children

(6 through 47 months of age)

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AGENDA

- Background
- Study Objectives
  - Immunogenicity
  - Safety
- Study Design
- Inclusion & Exclusion Criteria
- Demographics
- Results
- Summary

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BACKGROUND

- **Flucelvax® Quadrivalent is the only cell-based quadrivalent influenza vaccine (ccIIV4) in the United States**
- **A cell based influenza vaccine avoids egg adaptation, thus potentially resulting in a closer match to the FDA-selected strains for each season[1,2]**
- **Flucelvax Quadrivalent is approved for use in persons 2 years of age and older in the United States**

1. Centers for Disease Control and Prevention. https://www.cdc.gov/flu/prevent/cell-based.htm (accessed March 15, 2021)
2. Rajaram S. et al. *Ther Adv Vaccines Immunother*. 2020 Feb 22: 8:2515135520908121

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STUDY OBJECTIVES (ccIIV4) IN CHILDREN 6 - 47 MONTHS

Immunogenicity Objectives (8 endpoints measured)

- Geometric Mean Titer (GMT) ratio (IIV4/ccIIV4)/Vaccine Strain (4 endpoints)
  - Upper Bound of the 2 sided 95% Confidence Interval ≤1.5
- Seroconversion Rates (SCR) difference (IIV4-ccIIV4)/Vaccine Strain (4 endpoints)
  - Upper Bound of the 2 sided 95% CI does not exceed 10 percentage points

Safety Objectives

- Safety and Tolerability

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STUDY DESIGN

- **Phase 3 Randomized Controlled Trial**
  - **ccIIV4 (Flucelvax Quadrivalent) versus a US-licensed IIV4 (Afluria Quadrivalent)**
  - **2019–2020 Northern Hemisphere Flu Season**
  - **47 centers in the United States**
  - **Immunogenicity assessed using hemagglutination inhibition assays for A/H1N1, B/Yamagata, and B/Victoria strains and microneutralization assay for A/H3N2 strain**
  - **Participants randomized 2:1 (ccIIV4:IIV4)**

EudraCT number 2020-002785-13; NCT04074928.
QIV, US-licensed quadrivalent influenza vaccine; QIVc, cell-based quadrivalent influenza vaccine

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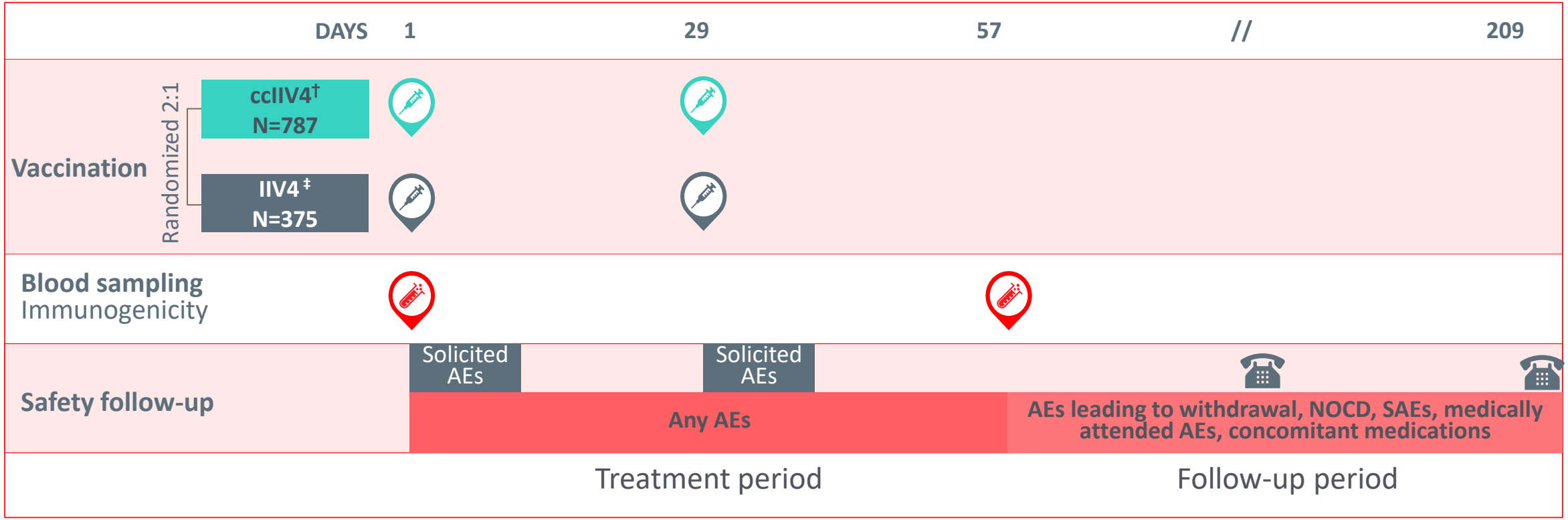
STUDY GROUP
NOT PREVIOUSLY VACCINATED



†ccIIV4 administed as a 0.5 mL dose; ‡IIV4 (Afluria®) administered as a 0.25 mL dose for children 6–35 months of age and a 0.5 mL dose for children 36–47 months of age.

AE, adverse event; NOCD, new onset of chronic disease; SAE, serious adverse event

IIV4, egg-based quadrivalent influenza vaccine; ccIIV4, cell-based quadrivalent influenza vaccine

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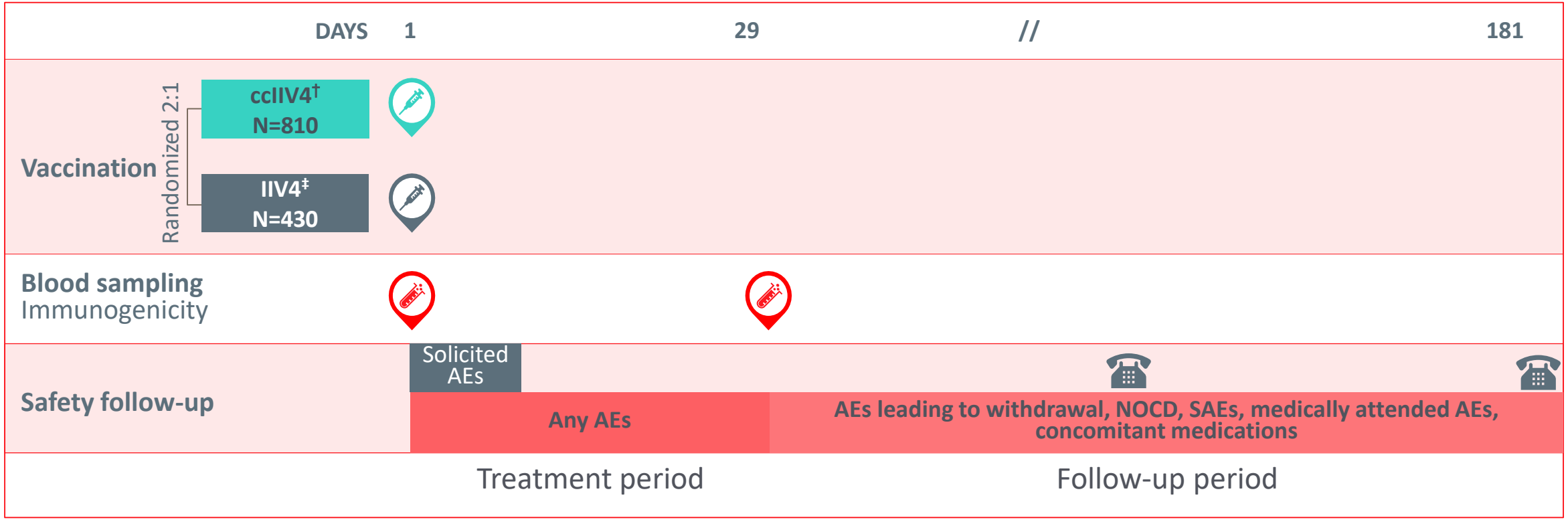
STUDY DESIGN
PREVIOUSLY VACCINATED



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KEY INCLUSION AND EXCLUSION CRITERIA

Inclusion

- Healthy children ≥6 to ≤47 months old
- Ability to comply with study procedures
- Informed consent/ assent provided†

Exclusion

- Fever
- History of Hypersensitivity to any of the vaccine components
- History of Guillain–Barré syndrome/demyelinating diseases
- History of immunodeficiency or impaired immune function
- Received an influenza vaccination or documented influenza in the 6 months prior to informed consent
- Received blood products or immunoglobulins within 180 days prior to informed consent
- Received an investigational medical product within 30 days prior to informed consent

†By the parent/legal guardian

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DEMOGRAPHICS AND BASELINE CHARACTERISTICS

		ccIIV4 N=1597 (%)	IIV4 N=805 (%)	Total N=2402 (%)
Age (months)	Mean (SD)	28.1 (11.5)	28.2 (11.6)	28.1 (11.7)
Age group	6 months thru 23 months	595 (37.3)	299 (37.1)	894 (37.2)
	24 months thru 47 months	1002 (62.7)	506 (62.9)	1508 (62.8)
Sex	Male	803 (50.3)	406 (50.4)	1209 (50.3)
	Female	794 (49.7)	399 (49.6)	1193 (49.7)
Race*	White	1039 (65.1)	539 (67.0)	1578 (65.7)
	Black or African American	455 (28.5)	209 (26.0)	664 (27.6)
Ethnicity	Hispanic or Latino	434 (27.2)	226 (28.1)	660 (27.5)
	Not Hispanic or Latino	1160 (72.6)	575 (71.4)	1735 (72.2)
Vaccination History	Not Previously Vaccinated	787 (49.3)	375 (46.6)	1162 (48.4)
	Previously Vaccinated	810 (50.7)	430 (53.4)	1240 (51.6)

Abbreviations: IIV4 = quadrivalent influenza vaccine; ccIIV4 = cell-based quadrivalent subunit influenza virus vaccine; SD = standard deviation; US = United States

***Other groups represented at 1% or less: Asian, Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native; Race Group "Other" was 4.3%**

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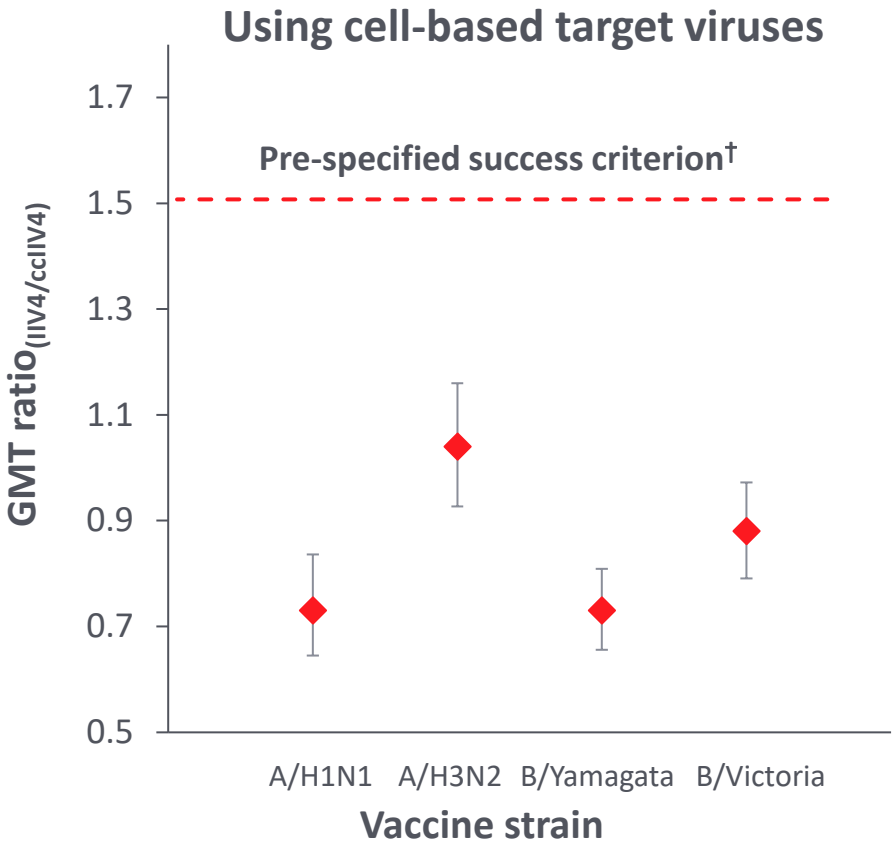
IMMUNOGENICITY RESULTS:
GEOMETRIC MEAN TITER RATIOS



	GMT		GMT ratio
	ccIIV4 (95% CI)	IIV4 (95% CI)	IIV4/ccIIV4 (95% CI)
A/H1N1	78.0 (70.8, 86.0)	57.3 (50.8, 64.6)	0.73 (0.65, **0.84**)
A/H3N2‡	23.1 (21.2, 25.1)	23.9 (21.6, 26.6)	1.04 (0.93, **1.16**)
B/Yamagata	35.6 (32.9, 38.6)	26.0 (23.5, 28.6)	0.73 (0.66, **0.81**)
B/Victoria	22.4 (20.7, 24.2)	19.6 (17.8, 21.6)	0.88 (0.79, **0.97**)

Noninferiority criteria were met for all four strains

†The pre-specified success criterion was that the upper bound of the 2-sided 95% CI for GMT ratios did not exceed 1.5;
‡Using MN assay. CI, confidence interval; GMT, geometric mean titer; HAI, hemagglutination inhibition assay; MN, microneutralization assay;

PPS, per-protocol set; IIV4, egg-based quadrivalent influenza vaccine; ccIIV4, cell-based quadrivalent influenza vaccine

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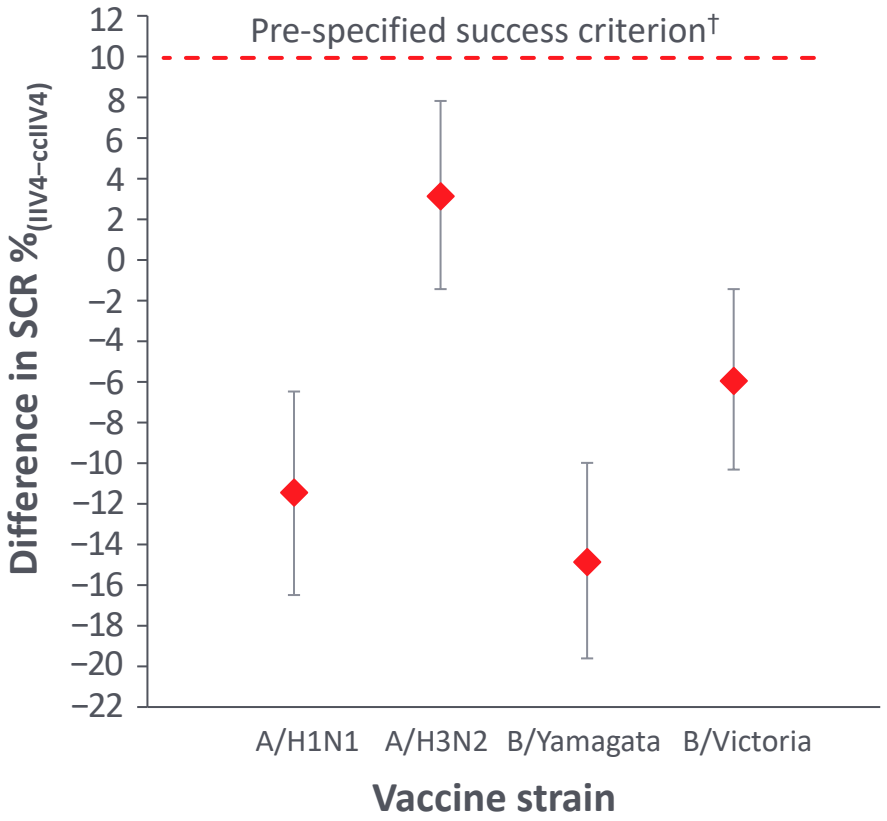
IMMUNOGENICITY RESULTS:
SEROCONVERSION RATE DIFFERENCE

Using cell-based target viruses



	SCR		SCR difference
	ccIIV4 % (95% CI)	IIV4 % (95% CI)	IIV4−ccIIV4 % (95% CI)
A/H1N1	58.2 (55.3, 61.2)	46.8 (42.6, 51.0)	−11.46 (−16.44, **−6.42**)
A/H3N2‡	27.6 (25.0, 30.4)	30.8 (27.0, 34.7)	3.13 (−1.44, **7.81**)
B/Yamagata	46.5 (43.5, 49.5)	31.7 (27.9, 35.6)	−14.87 (−19.61, **−9.98**)
B/Victoria	30.3 (27.6, 33.1)	24.4 (20.9, 28.1)	−5.96 (−10.33, **−1.44**)

Noninferiority criteria were met for all four strains

†The pre-specified success criterion was that the upper bound of the 2-sided 95% CI for SCR differences did not exceed 10%;
‡Using MN assay

CI, confidence interval; HAI, hemagglutination inhibition assay; MN, microneutralization assay; PPS, per-protocol set; IIV4, egg-based quadrivalent influenza vaccine; ccIIV4, cell-based quadrivalent influenza vaccine; SCR, seroconversion rate.

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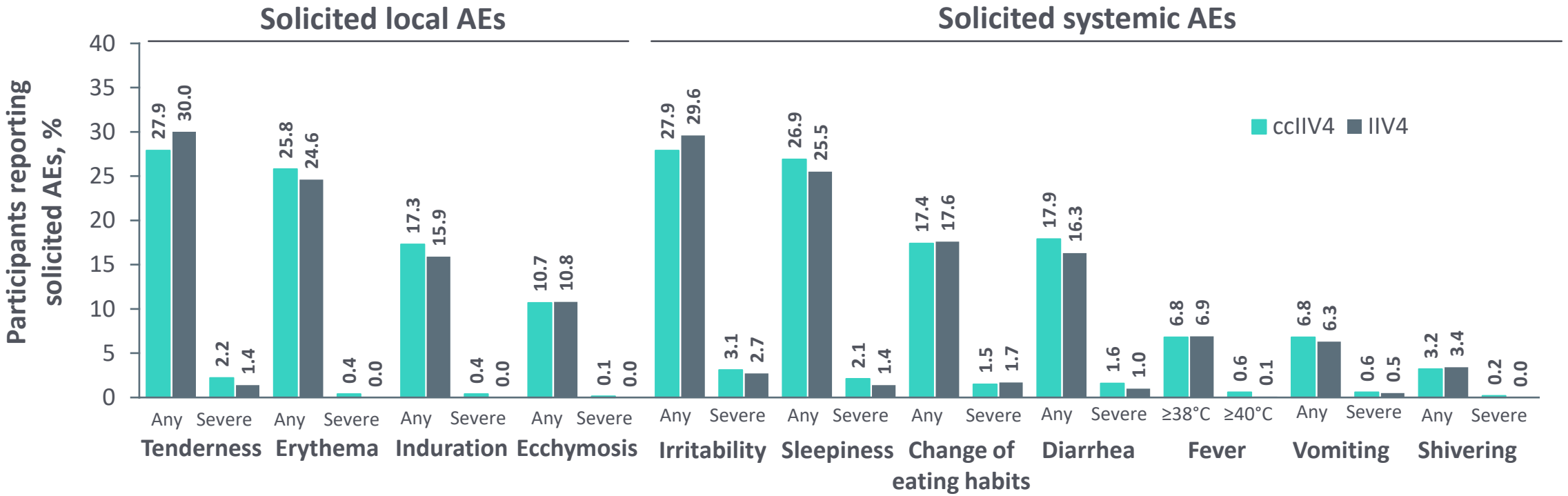
SAFETY AND TOLERABILITY SUMMARY
SOLICITED LOCAL AND SYSTEMIC ADVERSE EVENTS



- Erythema and tenderness were the most common solicited local AEs
- Sleepiness and irritability were the most common solicited systemic AEs
- Most AEs were mild or moderate in severity
- Safety and tolerability were similar between the two vaccine groups

AE, adverse event; IIV4, egg-based quadrivalent influenza vaccine; ccIIV4, cell-based quadrivalent influenza vaccine

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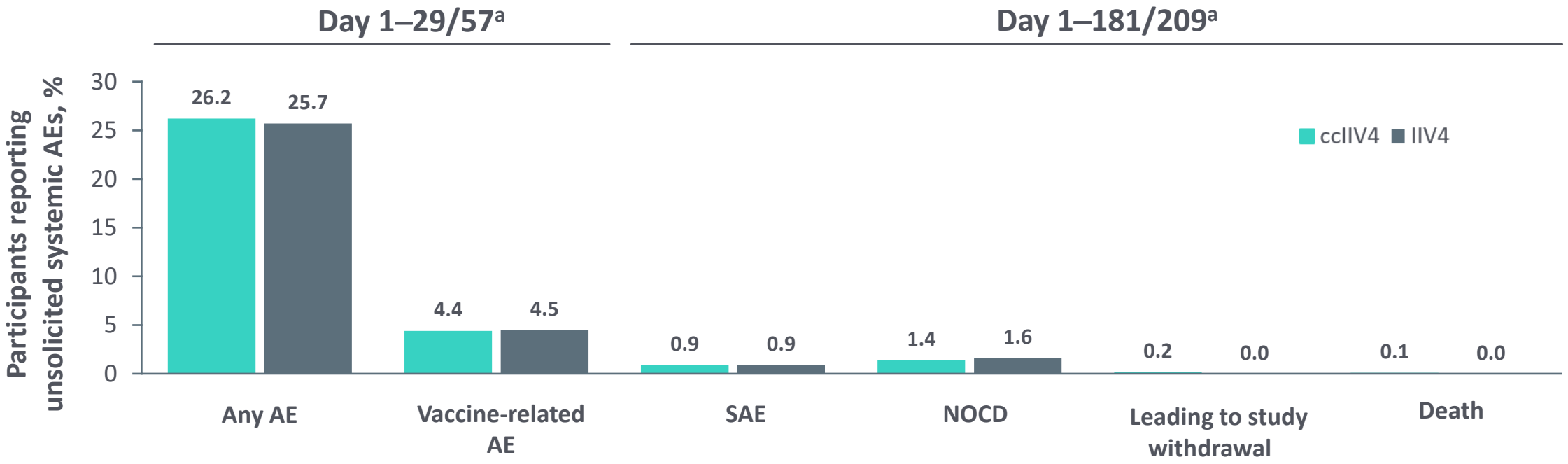
SAFETY AND TOLERABILITY SUMMARY
UNSOLICITED ADVERSE EVENTS



- Similar proportions of participants in the ccIIV4 and IIV4 groups reported at least one unsolicited AE
- Adverse events leading to withdrawal were reported by three participants in the ccIIV4 group

[a]Day 57 and Day 209 in participants not previously vaccinated

AE, adverse event; NOCD, new onset of chronic disease; IIV4, egg-based quadrivalent influenza vaccine; ccIIV4, cell-based quadrivalent influenza vaccine; SAE, serious adverse event.

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FLUCELVAX QUADRIVALENT (ccIIV4) Phase III
Immunogenicity & Safety in 6 through 47 months

- **SUMMARY**
  - **ccIIV4 met all of the predefined non-inferiority criteria for immunogenicity as compared to IIV4**
  - **Immunogenicity data consistent against all four strains**
  - **ccIIV4 was well tolerated, with similar rates of solicited and unsolicited adverse events between the two vaccination groups, consistent with previously reported data in older children**

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