



**MVC-COV1901**  
**Evidence of vaccine safety,  
developer's perspective**

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## DISCLAIMER:

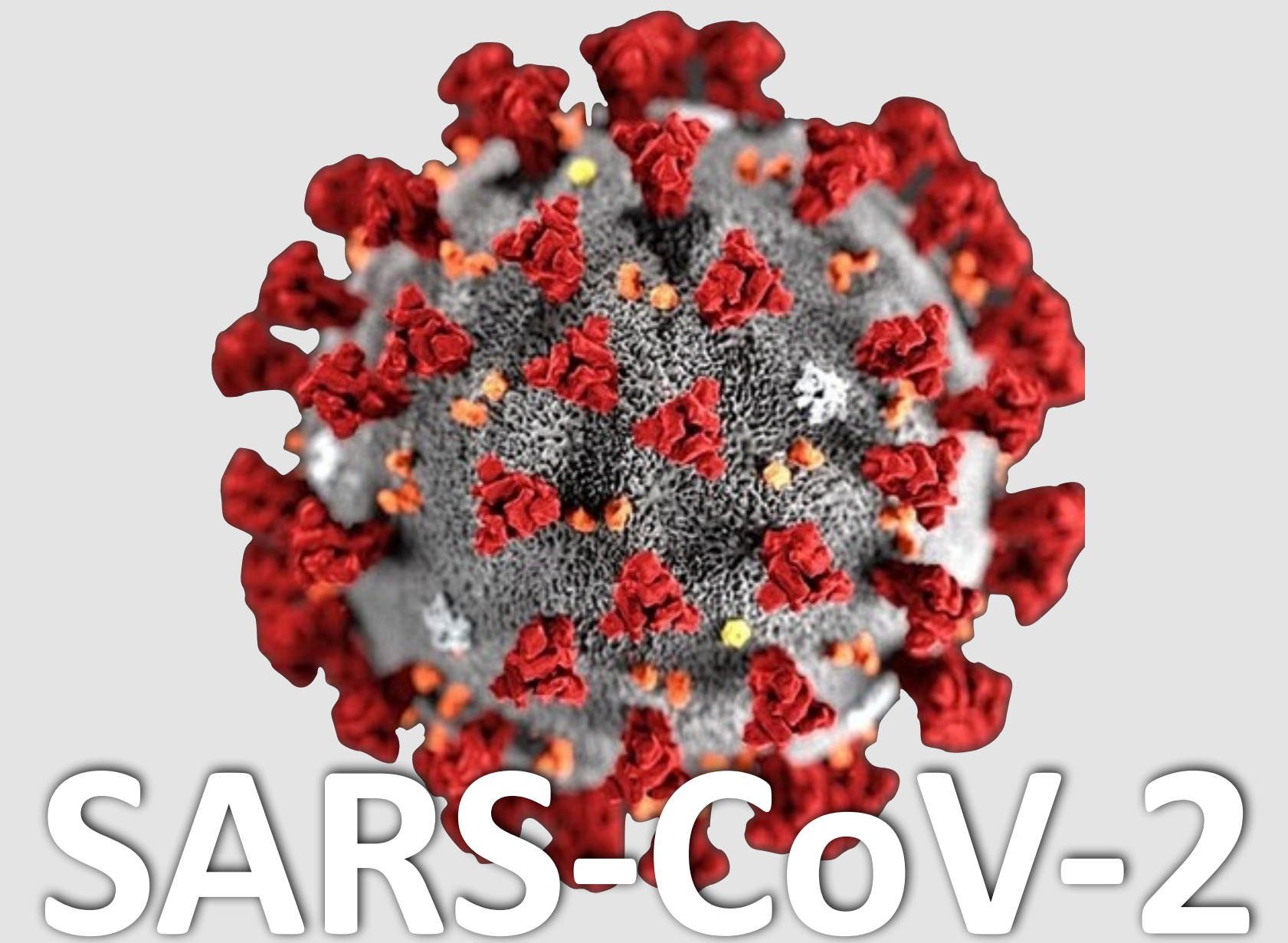
By their very nature, forward-looking statements for a development process involve inherent risks and uncertainties, both general and specific. Thus there is no assurance or guarantee that any predictions, forecasts, projections and other forward-looking statements will be achieved.

Given the unprecedented circumstances of the COVID-19 pandemic, regulatory uncertainty, funding and rapid production development schedule, all numbers and data presented as well as schedule must be subject to adaptations and change.



# CURRENT VACCINE PROFILE

Attributes	Description
Technology	CHO cell derived spike protein (Subunit)
Route of administration	Intramuscular
Dosage schedule	2 doses 4 weeks apart
Target population	adults, >12 years of age, including the elderly. Upon success, further age-de-escalation to children, & escalate into special risk groups such as immunocompromised subjects.
Formulation	Liquid - Fully formulated, no mixing or dilution needed. Antigen: S-2P protein (15 mcg) Adjuvant 1: CpG 1018 (750 mcg) Adjuvant 2: Al(OH) <sub>3</sub> (375 mcg)
Volume	0.5 mL
Packaging	Pre-filled Syringe & Multi-dose Vials
Storage	Cold Chain, 2-8C (9 months and ongoing)



# ADVERSE REACTIONS LISTED ON TFDA APPROVED PACKAGE INSERT

MedDRA SOC	Frequency	Adverse reaction
Nervous system disorders	Very common	Headache
	Common	Dizziness
		Somnolence
	Rare	Facial paralysis*
Hypertension oculi		
Cardiac disorders	Uncommon	Palpitations
Gastrointestinal disorders	Very common	Diarrhea
	Common	Nausea/Vomiting
Musculoskeletal and connective tissue disorders	Common	Myalgia
Infections and infestations	Uncommon	Nasopharyngitis
Respiratory, thoracic and mediastinal disorders	Uncommon	Oropharyngeal pain
General disorders and administration site conditions	Very common	Injection site pain
		Malaise/Fatigue
		Injection site induration
	Common	Injection site erythema
	Uncommon	Pyrexia
		Injection site pruritus
		Chills
Rash		

As of 30th Sep 2021, the estimated cumulative number of clinical trial subjects was 4970; the cumulative number of distribution since the International Birth Date (IBD) to 30-Sep-2021 was 942,845 doses of MVC-COVID-19 Vaccine in total. **There were no new safety signals identified during the current reporting period.**

**Definitions:**

- Very common ( $\geq 1/10$ )
- Common ( $\geq 1/100$  to  $< 1/10$ )
- Uncommon ( $\geq 1/1000$  to  $< 1/100$ )
- Rare ( $\geq 1/10,000$  to  $< 1/1,000$ )
- Very Rare ( $< 1/10,000$ )
- Currently unknown (Cannot be estimated based on existing data)

\* MedDRA SOC: Medical Dictionary for Regulatory Activities (MedDRA) system organ classes (SOC)

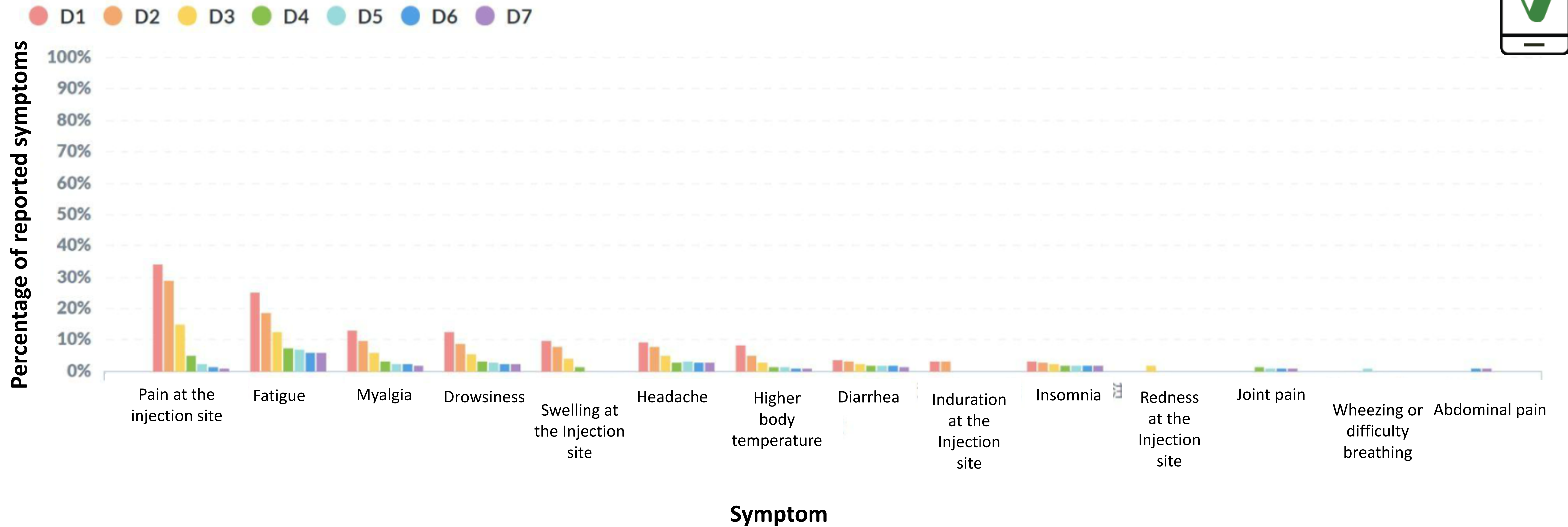
# CENTERS FOR DISEASE CONTROL - V-WATCH PROGRAM

- Established by the Taiwan CDC
- A self-reporting system for monitoring post-vaccination adverse events of approved COVID-19 vaccines in Taiwan.
- Tracking actively:
  - The **first 30,000** registered people from each brand of vaccine with the consent of the participating individual. Each participant will be reminded regularly to report health status after vaccination.
  - Individuals can still enroll if the number of registered people is more than 30,000 per brand.



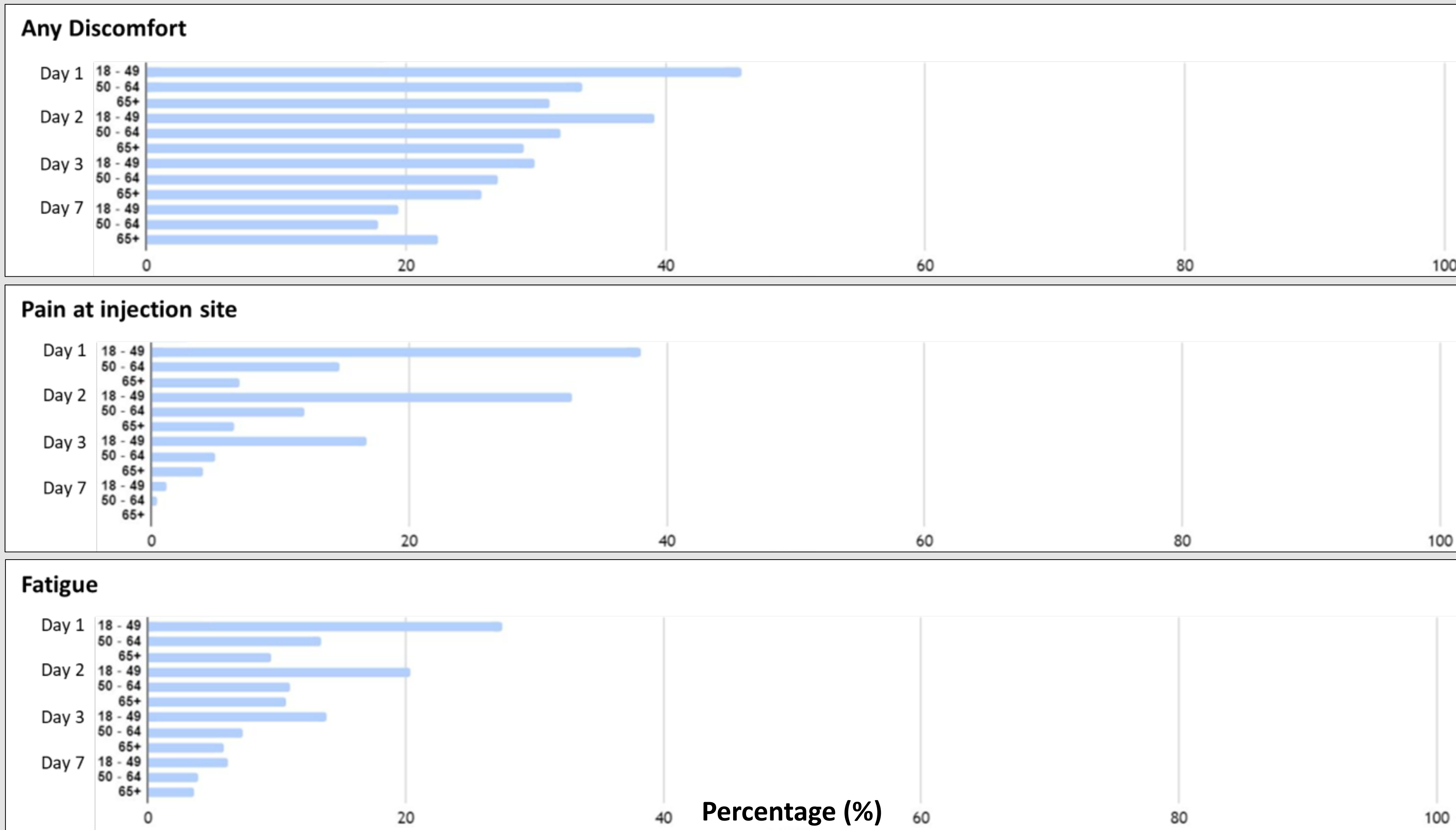
# COMMON SYMPTOMS WITHIN 7 DAYS AFTER FIRST DOSE OF MVC VACCINE

Ratio of top 10 reported symptoms per day (MVC first dose)



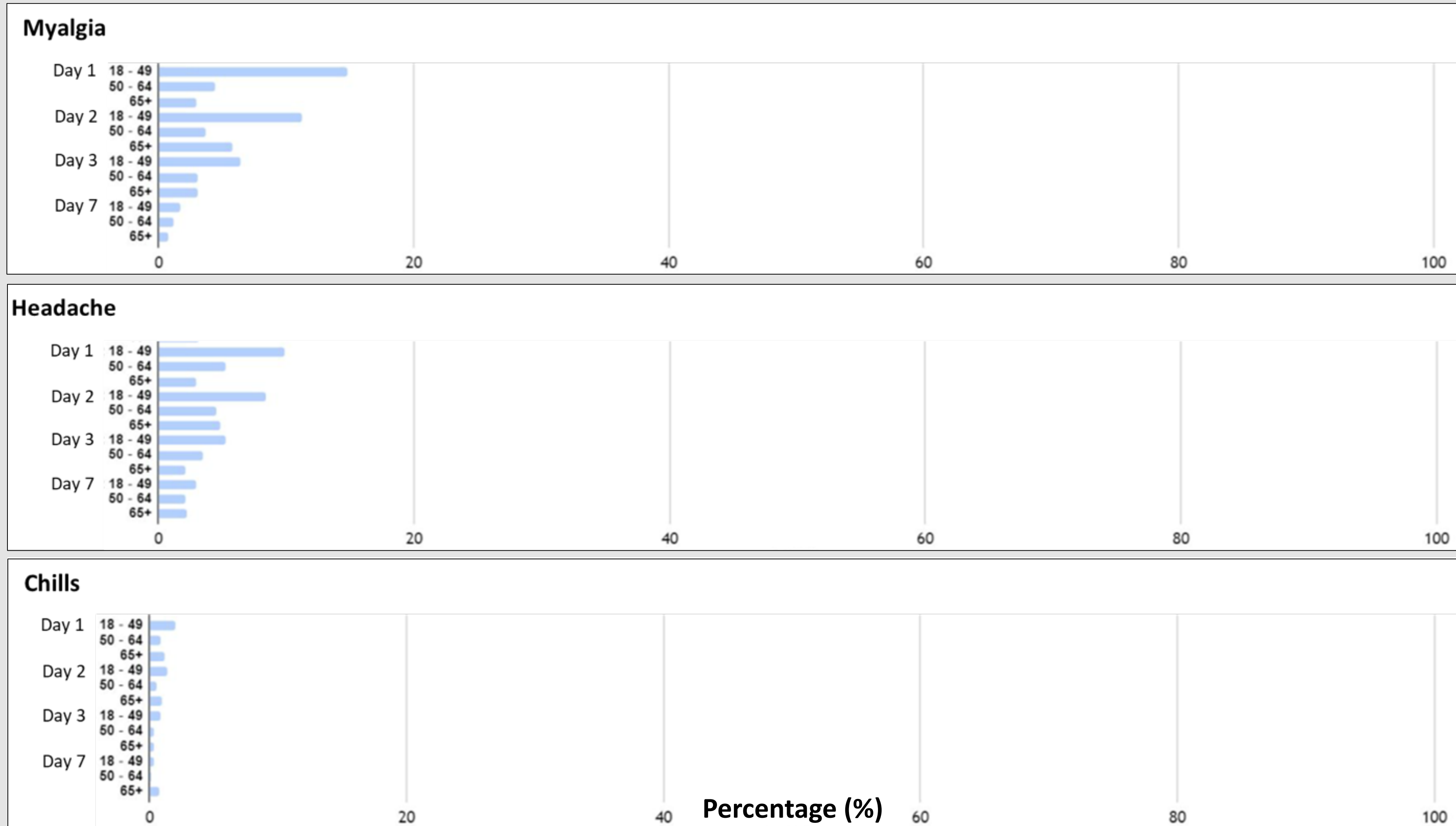
# COMMON SYMPTOMS WITHIN 7 DAYS AFTER FIRST DOSE OF MVC VACCINE (BY AGE)

AGE:  
18-49  
50-64  
65+



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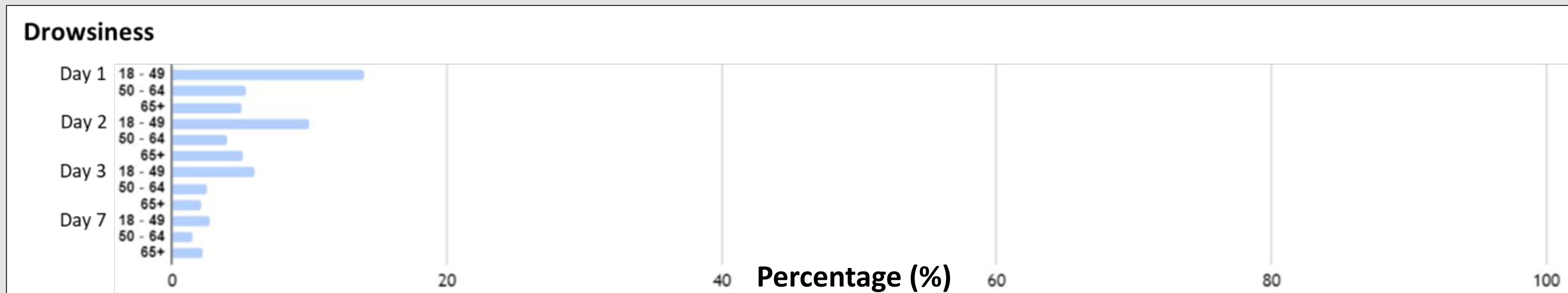
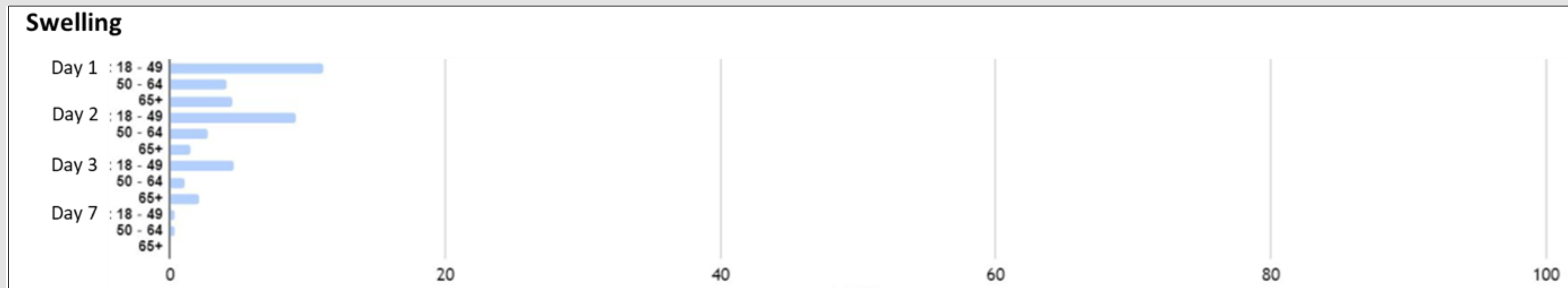
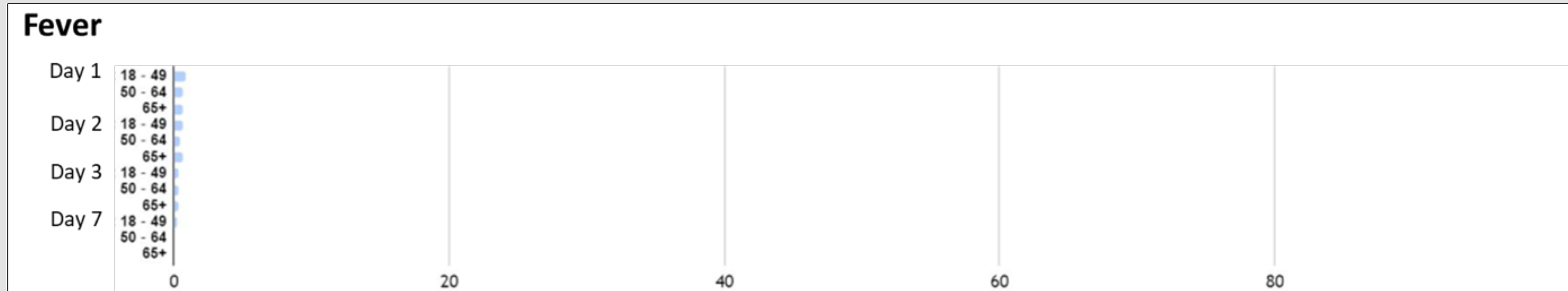
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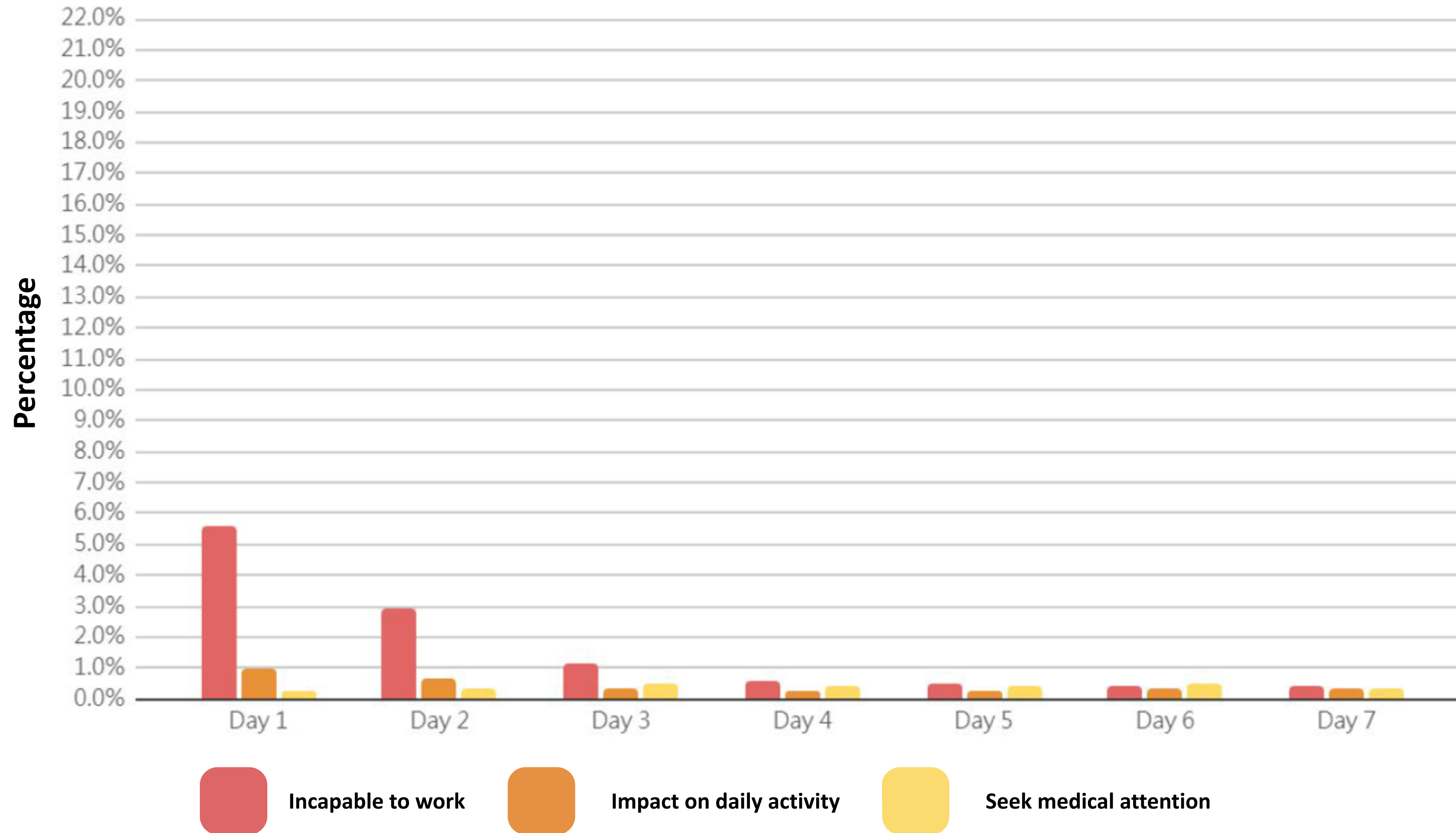


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# COMMON SYMPTOMS WITHIN 7 DAYS AFTER FIRST DOSE OF MVC VACCINE (BY AGE)




# PHASE II INTERIM STUDY RESULT

THE LANCET  
Respiratory Medicine

ARTICLES | [ONLINE FIRST](#)

## Safety and immunogenicity of CpG 1018 and aluminium hydroxide-adjuvanted SARS-CoV-2 S-2P protein vaccine MVC-COV1901: interim results of a large-scale, double-blind, randomised, placebo-controlled phase 2 trial in Taiwan

[Szu-Min Hsieh, MD](#) • [Ming-Che Liu, MD](#) • [Prof Yen-Hsu Chen, MD](#) • [Wen-Sen Lee, MD](#) • [Prof Shinn-Jang Hwang, MD](#) • [Shu-Hsing Cheng, MD](#) • et al. [Show all authors](#) • [Show footnotes](#)

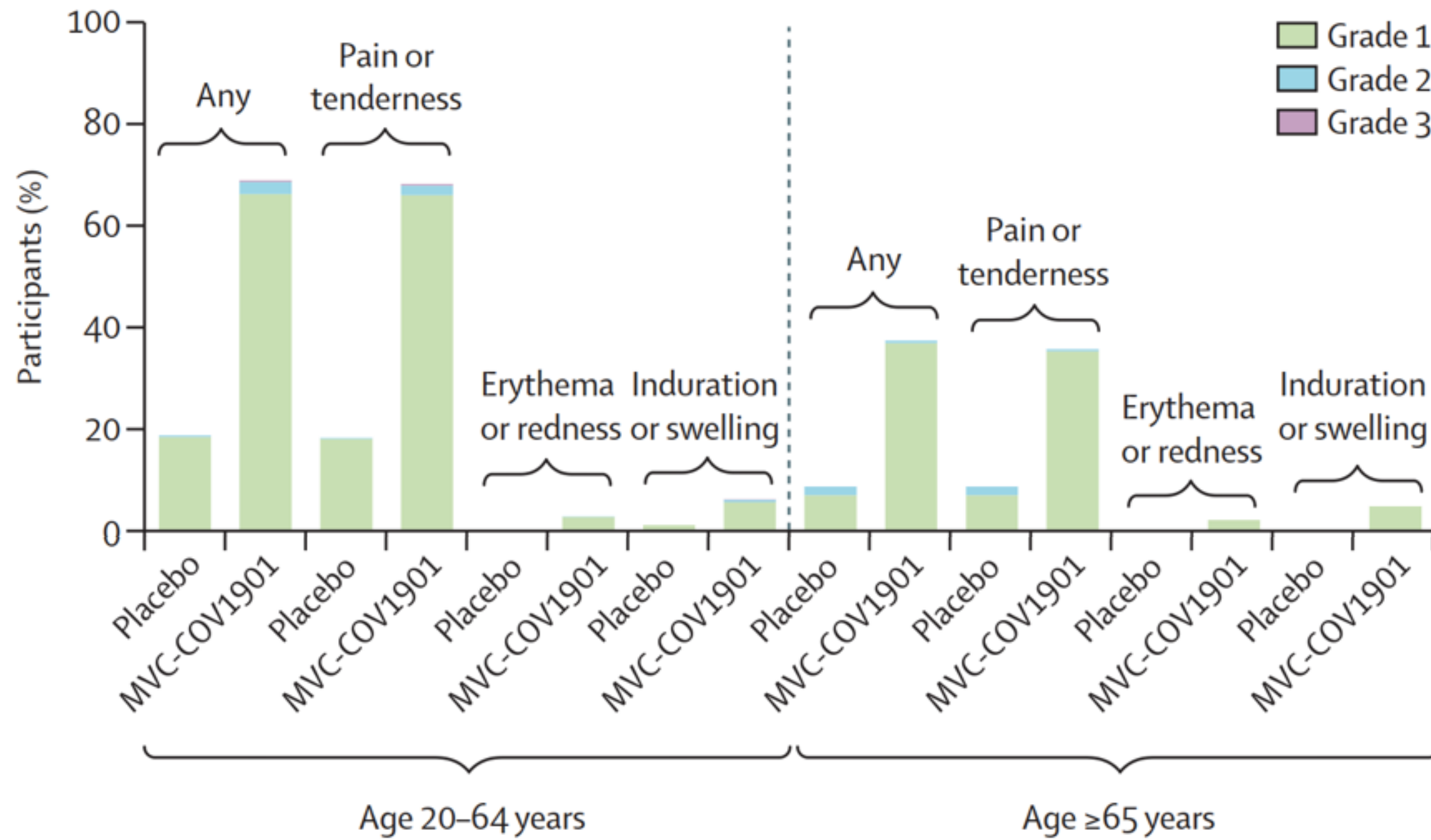
Published: October 13, 2021 • DOI: [https://doi.org/10.1016/S2213-2600\(21\)00402-1](https://doi.org/10.1016/S2213-2600(21)00402-1) • 



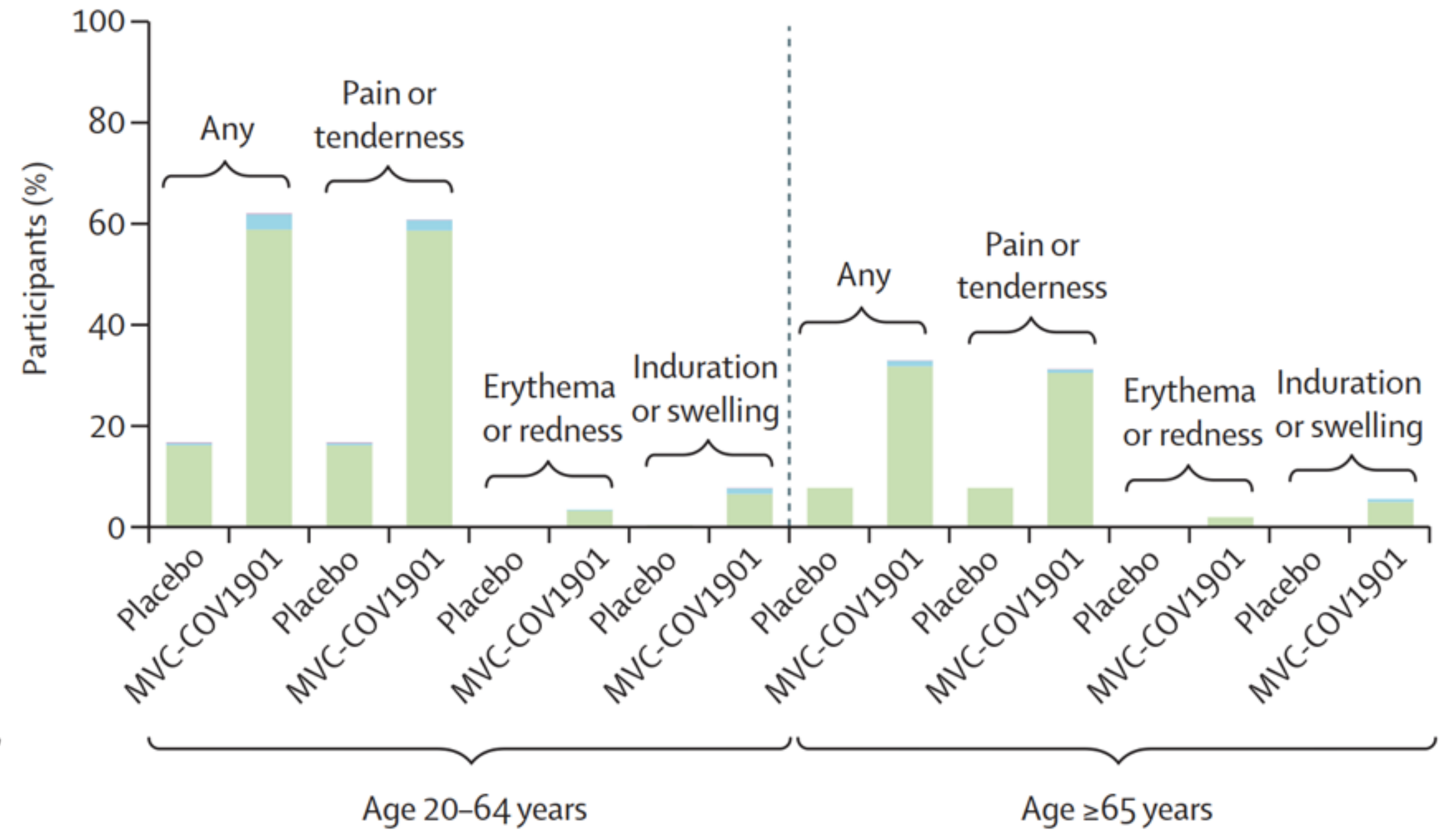
# SOLICITED LOCAL ADVERSE EVENTS OCCURRING WITHIN 7 DAYS AFTER FIRST & SECOND DOSES OF MVC-COV1901



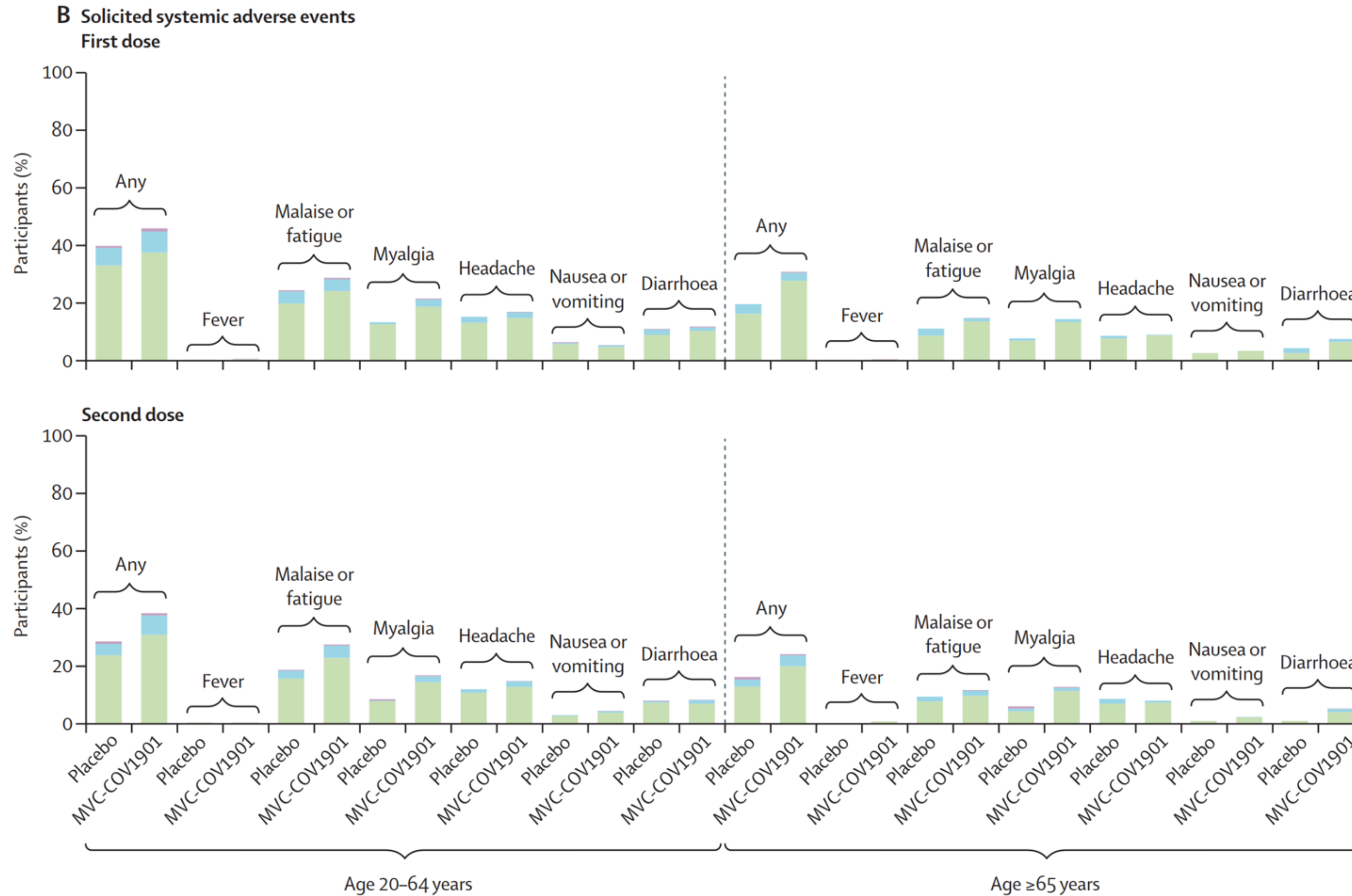
**A Solicited local adverse events**  
First dose



Second dose



# SOLICITED SYSTEMIC ADVERSE EVENTS OCCURRING WITHIN 7 DAYS AFTER FIRST & SECOND DOSES OF MVC-COV1901



# ADDITIONAL COVID-19 VACCINE SAFETY INFORMATION

1. COVID-19 vaccine adverse event notification abstract

<https://www.fda.gov.tw/TC//siteList.aspx?pn=3&sid=1571>

2. COVID-19 vaccine statistics

<https://www.cdc.gov.tw/Category/Page/9jFXNbCe-sFK9ElmRRi2Og>

3. Notification of adverse events after COVID-19 vaccination

<https://www.cdc.gov.tw/Category/MPage/Q8n9n-Q4aBpRrGnKVGfKng>

4. Taiwan V-Watch COVID-19 vaccine inoculation - health reporting

[https://www.cdc.gov.tw/Category/MPage/ucz02Kh3\\_q28Jena2Z3AoA](https://www.cdc.gov.tw/Category/MPage/ucz02Kh3_q28Jena2Z3AoA)



## CONCLUSION

- Most common reported events within 7 days after the first dose of Medigen vaccine:
  - Systemic: fatigue, myalgia and headache
  - Local: pain and swelling at injection site
- Individuals aged between 18 to 49 reported events more frequently than those between 50 to 64 or above 65.
- Safety data of 6 months post-vaccination (Phase II, N>3,000) by Nov 2021.
- As of 22 Oct, 1,362,524 doses administered. Ongoing efforts to capture safety signals to inform large scale pharmacovigilance studies.



# THANK YOU

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