COVID-19 Vaccines for Children

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National Institute of Allergy and Infectious Diseases

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US Effort in Trials for Special Populations

- Goal: “SARS CoV2 vaccine for whole of US population”
- USG will provide resources for vaccine trials in pregnant women and pediatrics
- Company can elect to be the sponsor
- Protocols must be approved by USG partners with NIAID, BARDA, engaged on protocol team
- Protocol chairs will include NIAID-funded investigators
- USG partners and company will jointly oversee operationalization of the studies
- Joint oversight team (BARDA, NIAID, Company) will resolve conflicts

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Rationale for Pediatric SARS CoV2 Vaccine Trials

- Pediatric burden of disease is significant
- Disproportionate burden among children in minority communities
- Indirect effects to the child and society (school, development, etc)
- Continued burden if we wait for natural "herd" effects
- Data suggests that vaccination prevents asymptomatic carriage, thus reversing pandemic more rapidly
- Safety data are best collected in clinical trials

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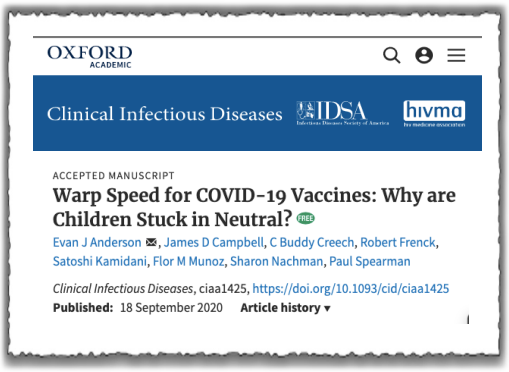

OXFORD ACADEMIC

Clinical Infectious Diseases IDSA hivma

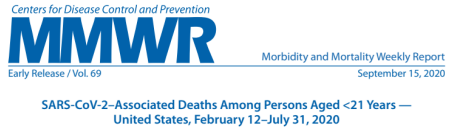
ACCEPTED MANUSCRIPT

Warp Speed for COVID-19 Vaccines: Why are Children Stuck in Neutral?

Evan J Anderson, James D Campbell, C Buddy Creech, Robert Frenck, Satoshi Kamidani, Flor M Munoz, Sharon Nachman, Paul Spearman

Clinical Infectious Diseases, ciaa1425, https://doi.org/10.1093/cid/ciaa1425

Published: 18 September 2020 **Article history**


Centers for Disease Control and Prevention

MMWR Morbidity and Mortality Weekly Report

Early Release / Vol. 69 September 15, 2020

SARS-CoV-2–Associated Deaths Among Persons Aged <21 Years — United States, February 12–July 31, 2020

Table 1. Numbers of hospitalizations and deaths for COVID-19 in comparison to varicella, rubella, hepatitis A, and rotavirus in pre-vaccine era*

Virus	Hospitalizations/year	Deaths
COVID-19	19.4 per 100,000 age 0-4 yrs 11.4 per 100,000 age 5-17 yrs Through 10/10/2020	185 children Age ≤ 18 yrs Through 12/16/2020
Varicella	4-13 per 100,000 Age < 20 yrs Years 1988 – 1995	50 children per year Age< 15 yrs Years 1970-1994
Rubella	Not available	17 children per year All ages Years 1966 – 1968
Hepatitis A	107 hospitalized children Age < 15 yrs Year 2005	3 children per year Age < 20 yrs Years 1990 – 1995
Rotavirus	55,000 - 70,000 children Age < 5 yrs Years 1993 – 2002	20 – 60 children per year Age < 5 yrs Years 1999 - 2007
Influenza	34-92 per 100,000 age 0– 4yrs 20-41 per 100,000 age 5–17yrs for 2016 – 2020 season	110-192 children per year Years 2016 – 2020

Updated table courtesy of Evan Anderson

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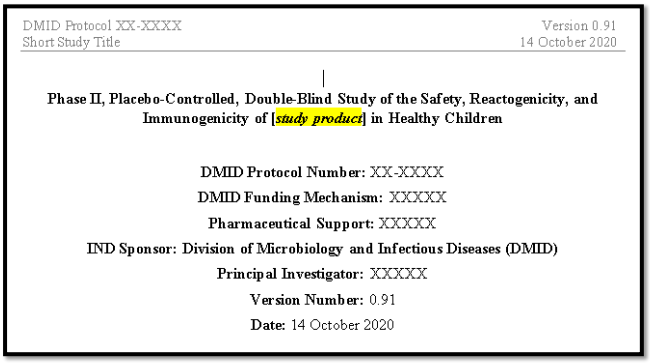
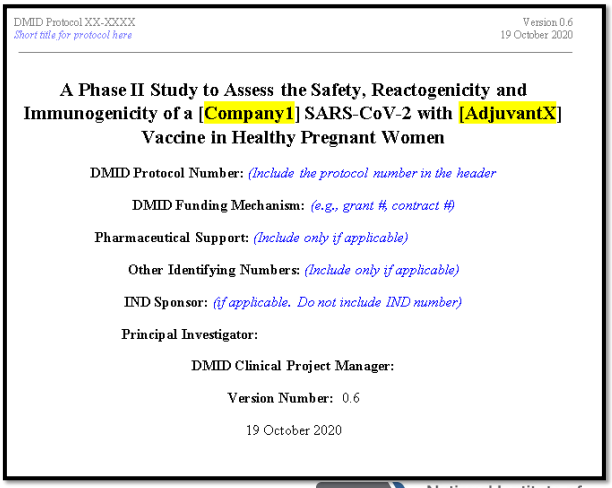
Shell Protocols developed by Pediatric and Maternal Working Groups, IDCRC, and shared with manufacturers



DMID Protocol XX-XXXX
Short Study Title
Version 0.91
14 October 2020

Phase II, Placebo-Controlled, Double-Blind Study of the Safety, Reactogenicity, and Immunogenicity of [*study product*] in Healthy Children

DMID Protocol Number: XX-XXXX
DMID Funding Mechanism: XXXXX
Pharmaceutical Support: XXXXX
IND Sponsor: Division of Microbiology and Infectious Diseases (DMID)
Principal Investigator: XXXXX
Version Number: 0.91
Date: 14 October 2020



DMID Protocol XX-XXXX
Short title for protocol here
Version 0.6
19 October 2020

A Phase II Study to Assess the Safety, Reactogenicity and Immunogenicity of a [Company1] SARS-CoV-2 with [AdjuvantX] Vaccine in Healthy Pregnant Women

DMID Protocol Number: *(Include the protocol number in the header*
DMID Funding Mechanism: *(e.g., grant #, contract #)*
Pharmaceutical Support: *(Include only if applicable)*
Other Identifying Numbers: *(Include only if applicable)*
IND Sponsor: *(if applicable. Do not include IND number)*
Principal Investigator:
DMID Clinical Project Manager:
Version Number: 0.6
19 October 2020

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Vaccine clinical development: Children

	BIONTECH Pfizer	moderna	janssen	OXFORD AstraZeneca
Platform/ Design	mRNA: encodes stabilized spike; lipid NP	mRNA: encodes 2P-stabilized spike; lipid NP	Replication incompetent Ad26; stabilized spike	Replication incompetent ChAdOx1 chimp Ad; wild type spike
Dose/ Schedule Adults	IM 2 doses X 30 µg 21 days apart	IM 2 doses 100 µg 28 days apart	IM 1 dose at 5 x 10^{10} vp (also testing 2 doses (0, 56 days)	IM 2 doses at 5 × 10^{10} vp, (0, 28 days)
Current Status	EUA ages 16 and up	EUA ages 18 and up	Phase 3 adults	Phase 3 adults
Adolescents	Fully enrolled	TeenCOVE	Start 4-6wks after results from adult trials	Begin Early 2021
Younger Children	Planning early 2021	Planning early 2021	Planning early 2021	Planning early 2021
Comments			Platform used widely in teens, infants, children	

Others supported by USG: Novavax (Ph3 enrolling), Sanofi

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Approaches to label indication for vaccination in age 12-17 yr old cohort

- Expand age eligibility in adult efficacy trials (Pfizer/BioNTech)
- Stand-alone trial for safety (Moderna TeenCOVE)
- Expand age eligibility in Phase 2 trials for immunogenicity/safety

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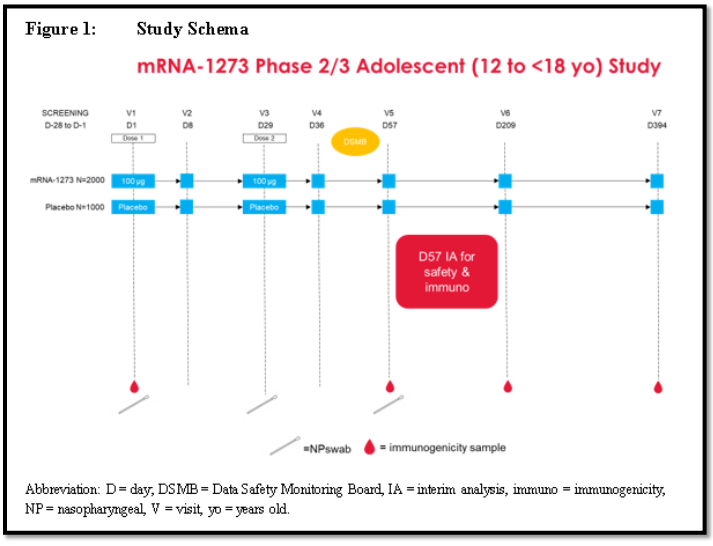
TeenCOVE Study

Figure 1: Study Schema



Abbreviation: D = day, DSMB = Data Safety Monitoring Board, IA = interim analysis, immuno = immunogenicity, NP = nasopharyngeal, V = visit, yo = years old.

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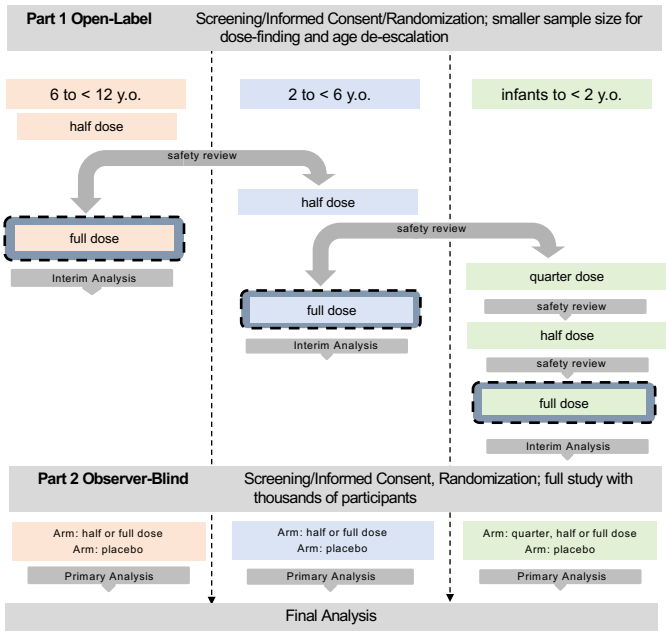
Example: dose-ranging study in children, infants to <12 years

- Protocols in development
- 3 age groups:
  - 6 to <12 years
  - 2 to < 6 years
  - Infants to < 2 years
- May relatively large N for safety if novel platform
- May test multiple dose levels
  - Full, half, and quarter doses considered by age group



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Thank You

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