



**U.S. FOOD & DRUG  
ADMINISTRATION**

## Memorandum

**DATE:** April 29, 2021

**TO:** Ramchandra Naik, PhD, Chair  
Susan Wollersheim, MD, Clinical reviewer

**FROM:** Bhanu Kannan, MS, BIMO Reviewer, Bioresearch Monitoring Branch  
Division of Inspections and Surveillance  
Office of Compliance and Biologics Quality

**THROUGH:** Dennis Cato, Chief, Bioresearch Monitoring Branch

**THROUGH:** Carrie M. Mampilly, MPH, Director, Division of Inspections and Surveillance

**THROUGH:** Mary A. Malarkey, Director, Office of Compliance and Biologics Quality

**SUBJECT:** Bioresearch Monitoring Review Memo  
EUA 27034, amendment 132  
PRODUCT: Pfizer-BioNTech COVID-19 Vaccine  
SPONSOR: BioNTech RNA Pharmaceuticals GmbH

Dennis Cato -S

Digitally signed by Dennis Cato -S  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,  
ou=People, cn=Dennis Cato -S,  
0.9.2342.19200300.100.1.1=2000356248  
Date: 2021.04.29 11:16:39 -0400

Carrie M.  
Mampilly -S

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ou=FDA, ou=People,  
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cn=Carrie M. Mampilly -S  
Date: 2021.04.29 11:52:31 -0400

Mary A.  
Malarkey -S

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0.9.2342.19200300.100.1.1=1300054353,  
cn=Mary A. Malarkey -S  
Date: 2021.04.29 12:17:38 -0400

Bioresearch Monitoring (BIMO) inspections were conducted at three domestic clinical investigator sites participating in the conduct of a study entitled *A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals- Protocol C4591001*, that included pediatric subjects 12 through 15 years of age. Based on the review of the inspection reports, the inspections did not reveal problems impacting the data submitted in support of this Emergency Use Authorization (EUA) amendment.

**Inspected Clinical Trial Sites**

Site ID	Location	IND#: 19736, Protocol ID: c4590001 Subjects (n)	Inspection Dates (most recent)	Final Classification*
1007	Cincinnati Children's Hospital Medical Center, Cincinnati, OH	Screened: 582 Randomized: 567	3/15/2021- 3/19/2021	NAI
1009	J. Lewis Research, Inc. Salt Lake City, UT	Screened: 414 Randomized: 398	3/29/2021- 4/07/2021	NAI
1044	Virginia Research Center, LLC Midlothian, VA	Screened: 384 Randomized: 379	3/15/2021 – 3/17/2021	NAI

\*NAI (No Action Indicated) = No objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further regulatory action)

Should you have any questions or comments about the contents of this memo or any aspect of bioresearch monitoring, please contact me at (240) 402-8979.

**Bhanumathi Kannan -S**  
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DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People,  
0.9.2342.19200300.100.1.1=1300073493,  
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Bhanu Kannan, M.S.  
Consumer Safety Officer

## DISTRIBUTION

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