DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Form Approved: OMB No. 0910-0396 Report Date: 03/31/2021

BLA

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical investigators (See attached)

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating dinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2 (a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

Clinical investigators (See attached)

~ As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

Clinical investigators (See attached)

NAME J.R Meloro	TITLE Global Data Dissemination, Publications and Transparency Lead
FIRM/ORGANIZATION Pfizer Inc.	
SIGNATURE J. R. Melaro	DATE 03/31/2021

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FDA-CBER-2021-5683-0013771

Product's Established Name:	BNT162b2
Protocol Number:	C4591001
Study Name:	A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS
Disclosure Start Date:	04/29/2020
Disclosure Cut-off Date:	03/25/2021

THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT **Protocol Number: C4591001** Center Number: 1001 Institution Name: Nyu Langone Health **List of Investigator Names** Dr. Mark Joseph Mulligan Elisabeth J. Cohen Tamia Davis Andrew B. Fleming Heather Givans Ramin Sedaghat Herati Angelica Cifuentes Kottkamp Dr. Alexander A. McMeeking Mary C. Olson Mila Brum Ortigoza Lalitha Parameswaran Purvi Parikh Rebecca Pellett Madan Kiana Piedrahita Vanessa Raabe Adam Jonathan Ratner Bo Shopsin Janine M. Sullivan Robert J. Ulrich Elizabeth Veneskey Mah ja Vucetovic Center Number: 1002 Institution Name: University Of Maryland, Center For Vaccine Development **And Global Health List of Investigator Names** Kathleen Maletic Neuzil Meagan Elise Deming Kirsten Elizabeth Lyke

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Protocol Number: C4591001

Center Number: 1005 Institution Name: Rochester Clinical Research, Inc.

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Zerina Zornic

Eleanor A Widdice

THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT	
Protocol Number: C4591001	
Center Number: 1006	Institution Name: J. Lewis Research, Inc. / Foothill Family Clinic
List of Investigator Names	
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Dr. Alexander Paul Clark	
Dr. Shana Kinsey Eborn	
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Center Number: 1007	Institution Name: Cincinnati Children's Hospital Medical Center
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THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT	
Protocol Number: C4591001	
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Center Number: 1009	Institution Name: J. Lewis Research, Inc. / Foothill Family Clinic South
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THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT Protocol Number: C4591001	
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THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT Protocol Number: C4591001 Center Number: 1013 Institution Name: Clinical Neuroscience Solutions, Inc List of Investigator Names Dr. med. Michael Edward Dever Chanel Keari Adams Dr. Patricia Ann W. Brown Joan Elizabeth Cutillo Ms. Letitia Mechelle Griffin Dr. Linda Sue Harper Rebecca Ann Klipper Geraldine Marino Dr. Robert Bond Molpus Priya Moorhouse

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Protocol Number: C4591001

Center Number: 1016 Institution Name: Kentucky Pediatric/ Adult Research

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Protocol Number: C4591001	
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Center Number: 1021	Institution Name: Pmg Research Of Raleigh, LLC
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Protocol Number: C4591001	
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Center Number: 1037	Institution Name: Clinical Neuroscience Solutions, Inc.
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Protocol Number: C4591001	
Center Number: 1042	Institution Name: Texas Health Family Care
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Protocol Number: C4591001	
Center Number: 1047	Institution Name: Medical Affiliated Research Center
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Center Number: 1048	Institution Name: Hope Research Institute
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THOSE LISTED BELOW HAVE DISCLOSE	D THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT
Protocol Number: C4591001	
Center Number: 1054	Institution Name: National Research Institute
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Center Number: 1055	Institution Name: Diablo Clinical Research, Inc.
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Center Number: 1056	Institution Name: Indago Research & Health Center, Inc.
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THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT		
Protocol Number: C4591001		
Center Number: 1066	Institution Name: Solaris Clinical Research	
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Center Number: 1068	Institution Name: Bozeman Health Deaconess Hospital Dba Bozeman Health	
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Institution Name: Pmg Research Of Charlotte LLC
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Protocol Number: C4591001		
Center Number: 1081	Institution Name: Sterling Research Group, Ltd.	
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BLA BNT162b2 Section 1.3.4 Financial Disclosure THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT Protocol Number: C4591001 Center Number: 1083 **Institution Name: Benchmark Research List of Investigator Names** Dr. Laurence Chu Ms. Jennifer Bacchi Maria Barrientes Taylor Bartlett Selena Bermudez Lamar Box Christian Casas Dr. Ruth Michelle Chouteau Lauren Christal Martha Clark Ms. Pamela B. Conley Katherine Marie Davis Ms. Tambra Layne Dora Cindy Janette Duran Pamela Fidler Ruth Fitch **Brooke Asheley Harris** Mr. Isaiah Knight Jennifer Leyva Michelle R. Listz Clara Loza Jennifer R. Montes Javier Perez Marisol P. Ramos

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THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT Protocol Number: C4591001 Center Number: 1084 Institution Name: Clinical Trials Of Texas, Inc. **List of Investigator Names** Dr. Douglas Scott Denham Darlington Akahara Muhammad Omair Ahsan Ata Ayoade Oluwaseun Avworo Stephen E Brick Cathleen Chen Maristelle Co Graham Ellis Kimberly R. Evans Zachariah E Francois Dr. Parke Joseph Hedges Matthew Kenneth Korte Anshumaan Maharaj Mary Jo Perez-Jenkins Cynthia A. Ramos Clayton Alexander Stone Dr. Thomas Roderick Weiss Center Number: 1085 Institution Name: Ventavia Research Group, LLC **List of Investigator Names** Dr. Gregory Michael Fuller Pamela B. Martin Tracy Starnes Center Number: 1087 Institution Name: Pmg Research Of Wilmington, LLC **List of Investigator Names** Dr. Kevin Dougherty Cannon

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Protocol Number: C4591001	
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Center Number: 1092	Institution Name: Sterling Research Group, Ltd.
List of Investigator Names	
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Protocol Number: C4591001	
Center Number: 1093	Institution Name: Meridian Clinical Research, LLC
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Center Number: 1095	Institution Name: Tekton Research, Inc.
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Protocol Number: C4591001		
Center Number: 1097	Institution Name: Main Street Physician's Care	
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Center Number: 1098	Institution Name: Sms Clinical Research, LLC	
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List of Investigator Names		
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Protocol Number: C4591001

Center Number: 1109 Institution Name: Deland Clinical Research Unit

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THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT Protocol Number: C4591001 Ms. Amber Vasquez Erika Wierzbicki

Center Number: 1110 Institution Name: Alliance For Multispecialty Research, LLC-Miami

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Protocol Number: C4591001

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Protocol Number: C4591001

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Protocol Number: C4591001		
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List of Investigator Names	
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Protocol Number: C4591001	
Center Number: 1241	Institution Name: Hospital Santo Antonio/ Associacao Obras Sociais Irma
List of Investigator Names	Dulce
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Center Number: 1246	Institution Name: Jongaie Research
List of Investigator Names	
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Center Number: 1247	Institution Name: Tiervlei Trial Centre, Basement Level, Karl Bremer Hospita
List of Investigator Names	
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Dr. Matthys Michiel De Vries Basson	
Precious Nomcebo Garnett	
Dr. Rehana Loghdey	
Zarinah Mohamed	
Dr. Catharina Elizabeth Pretorius	
Dr. Maria Magdalena Pretorius	

Dr. Mirna Catharina Siebert

THOSE LISTED BELOW HAVE DISCLOS	ED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT
Protocol Number: C4591001	
Center Number: 1248	Institution Name: Pharmaron Cpc, Inc.
List of Investigator Names	
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Center Number: 1251	Institution Name: Birmingham Clinical Research Unit
List of Investigator Names	
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Dr. Gary Louis Boyd	
LaShondra Cade	
Aileen Cunningham	
Connie Moya	
Sita Patel	
Ms. Mitzi L. Roberts	
Center Number: 1252	Institution Name: Main Street Physician's Care
List of Investigator Names	
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Dr. Tom Allan Christensen	
Krystal S. Hill	
Dr. Steven O. Price	
Center Number: 1254	Institution Name: Bayview Research Group
List of Investigator Names	
Dr. Monica Lee	
Dr. Michael N. Pakdaman	

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Protocol Number: C4591001	
Center Number: 1258	Institution Name: Dayton Clinical Research
List of Investigator Names	
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Missy L. Chapman	
Amy A. Hitchler	
Tammy Jo Lilly	
Center Number: 1260	Institution Name: Umass Memorial Medical Center - University Campus
List of Investigator Names	
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Ms. Carol A. Ciccarelli	
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Dr. John P. Haran	
Danielle Kokoski	
Jaclyn Karen Longtine	
Ms. Karen Longtine	
Juan Perez Velazquez	
Bethany P. Trainor	
Jennifer Po-wen Wang	
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Center Number: 1261	Institution Name: Benaroya Research Institute At Virginia Mason
List of Investigator Names	
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Sandra Marian Lord	
Michael Richter	
Dana Elizabath VanDurakan	

Dana Elizabeth VanBuecken

Protocol Number: C4591001	
Center Number: 1264	Institution Name: Uc Davis Medical Center
List of Investigator Names	
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Dr. Roblee Peter Allen	
Dr. Stuart Harvey Cohen	
Angela Haczku	
Richart Harper	
Dr. Nicholas James Kenyon	
Brian Michael Morrissey	
Dr. Susan (Nmi) Murin	
Justin Michael Oldham	
Dr. Christian Erik Sandrock	
Dr. Namita Sood	
Dr. Ken Y. Yoneda	
Center Number: 1265	Institution Name: Kaiser Permanente Los Angeles Medical Center
List of Investigator Names	
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Jennifer J. Chang	
Celia M. Garza-Halstead	
V kas K. Jayadeva	
Dr. Marc Joseph La Riviere	
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Center Number: 1269	Institution Name: Providence Clinical Research
List of Investigator Names	
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Dr. Parul M. Desai	

Scott Preston Sligh

THOSE LISTED BELOW HAVE DISCLOSED THAT THEY HAVE NO FINANCIAL INTERESTS IN THIS PRODUCT

Protocol Number: C4591001

Center Number: 1270 Institution Name: Kaiser Permanente Santa Clara

List of Investigator Names

Rebecca B. Alexander

Janelle M. Baires

Jessica Margaux Barraza

Latisha Marie Burun

Christine Cash

Gail Larie Cook

David Cooper

Jolynne Gerardo Encarnacion

Douglas Ernst

Lauren Blair Fontenot

LaVonne Freed

Jeremy Giese

Sarah Kang

Lisa Kennedy

Roma Kaur Kullar

Ludy Pasaoa Lemus

Ms. Eva S. Lowe

Lorrie Aileen Lowe

Nicole D. Makram

Ms. Shannon Mullen

Courtney Ann Oxandale

Ken Purdy

Sally Ann Upadhyaya

Dana Maria Weisshaar

Amy Wiesner

DUE DILIGENCE WAS PERFORMED TO OBTAIN DISCLOSURES FROM THESE INVESTIGATORS**	
Protocol Number: C4591001	
Center Number: 1042	Institution Name: Texas Health Family Care
List of Investigator Names	
Katherine Hollie	
Center Number: 1116	Institution Name: Medpharmics, Limited Liability Company
List of Investigator Names	
Wendy Shaw	
Jessica Stahl	
Center Number: 1247	Institution Name: Tiervlei Trial Centre, Basement Level, Karl Bremer
List of Investigator Names	Hospital
Dr Corli Marx	

^{**}Pfizer was unable to obtain a completed Financial Disclosure Form for the Clinical Investigator(s) listed above, despite acting with Due Diligence to obtain the required financial information. If no response was received from the initial request to the clinical investigator(s), additional attempts were performed (via mail, phone, fax, and/ or e-mail) in order to meet the recommendations mentioned within the FDA's Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators for certifying Due Diligence (B.7.Q&A). For those investigators no longer at the institution where the study was conducted - Pfizer made reasonable attempts to research and request the clinical investigator's new contact information. By declaring Due Diligence Pfizer is certifying that it has conducted reasonable efforts to contact the Clinical Investigator(s) above to obtain disclosable financial information.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Form Approved: OMB No. 0910-0396

Report Date: 03/30/2021

BLA

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

(1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical investigators (See attached)

As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2 (a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

Clinical investigators (See attached)

As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

Clinical investigators (See attached)	
NAME Dr. Christopher Marshallsay	TITLE
r. Christopher Marshallsay	Head of Scientific/Medical Writing & Trial Transparency
FIRM/ORGANIZATION	
BioNTech SE	
SIGNATURE Charadlsay	DATE 03/30/2021 2021
(0	

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in: 29-Apr-2021 19:08 (GMT)

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Product's Established Name:	BNT162b2
Protocol Number:	BNT162-01
Study Name:	A MULTI-SITE, PHASE I/II, 2-PART, DOSE-ESCALATION TRIAL INVESTIGATING THE SAFETY AND IMMUNOGENICITY OF FOUR PROPHYLACTIC SARS-COV-2 RNA VACCINES AGAINST COVID19 USING DIFFERENT DOSING REGIMENS IN HEALTHY AND IMMUNOCOMPROMISED ADULTS
Disclosure Start Date:	04/22/2020
Disclosure Cut-off Date:	10/23/2020

Protocol Number: BNT162-01	
Center Number: 276-01	Institution Name: CRS Clinical Research Services Mannheim GmbH
List of Investigator Names	
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Helen Basse	
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Ewald Schrader	
Brigitte Schneiderheinze	
Marina Streckebein	
Thomas Stolte	
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Volker Urban	
Jolanta Wierdak	
Center Number: 276-02	Institution Name: CRS Clinical Research Services Berlin GmbH
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Luca E bach	
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Protocol Number: BNT162-01	
Center Number: 276-03	Institution Name: CRS Clinical Research Services Kiel GmbH
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Center Number: 276-04	Institution Name: Medizinische Universitätsklinik Heidelberg
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Amin Muhareb	
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Evelyn Krohmer	
Center Number: 276-05	Institution Name: Universitätsklinikum Frankfurt
List of Investigator Names	
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