MODIFICATION OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

Janssen Research & Development LLC
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
O'Neill House Office Building
WASHINGTON, DC 20201

CONCERNING

INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES

Modification No.: 0001

Date of Modification:

Effective Date of Modification:

Agreement No.: HHSO100201700018C
PR No.: N/A
Total Amount of the Agreement: $546,000,000 (INCLUDES RECIPIENT AND GOVERNMENT FUNDING)
Total Estimated Government Funding of the Agreement: $273,000,000
Total Estimated Recipient Funding of the Agreement: $273,000,000
Funds Obligated: $43,588,145
Effective Date of the Agreement: August 15, 2017

Authority: 10 USC 2371 and Sections 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417
Line of Accounting and Appropriation: unchanged

Description/Purpose of modification: The purpose of the modification is to add ARCTICLE XVIII: CONFIDENTIALITY to the other transaction. No other changes are agreed to at this time.

This bi lateral modification is entered into by mutual agreement of parties and pursuant to the terms of the OTA. All agreement terms and conditions are changed to be consistent with the description of modification listed above. All other terms and conditions remain the same.

1. ARTICLE I: SCOPE OF THE AGREEMENT, SECTION B Definitions - The following definitions shall be added to the OTAT Agreement in Article IB.

"**Business day:** A business day is any day that is not a Saturday or Sunday; a Federal holiday in the United States; a bank holiday or national public holiday in Belgium; or a bank holiday or national public holiday in The Netherlands.

Confidential Information: information or data of a personal nature about an individual, or proprietary information or data submitted to the Government by or on behalf of Recipient, its affiliates or other third parties or by the Government to the Recipient in connection with, or during performance of the OTAR Agreement, whether or not either party required or requested that such information be submitted."

2. ADD the following article after ARTICLE XVII: TRANSFERS & ASSIGNMENTS

"ARTICLE XVIII: CONFIDENTIALITY.

It is recognized by the parties that success of the OTAR is enhanced by sharing of Confidential Information to inform the Government and Recipient of developments outside of, but potentially relevant to, the scope of work being performed under the OTAR Agreement. The parties may use Confidential Information submitted hereunder for purposes of the OTAR, but for no other purpose.

Confidential Information shall be subject to the same prohibitions on disclosure as provided for under FAR Part 24.202 and shall not be disclosed by the Government or its representatives or Recipient without the prior written consent of the providing party except to the extent such disclosure is required by law. Further, any reproduction of Confidential Information or portions thereof that is disseminated within the Government or Recipient, shall be shared strictly on a need to know basis for the purposes of the OTAR, and is subject to the restrictions of this provision.

In addition to the above, Confidential Information is subject to the protections of the Trade Secrets Act as well as any other remedies available under this Agreement or the law.

In order to be subject to the provisions of this Article XVIII, the providing party shall identify Confidential Information as confidential or proprietary at the time of disclosure, either by separate written communication or by use of an appropriate stamp or legend; or shall provide written notice to the receiving party within thirty (30) days of disclosure of the information's confidential or proprietary nature. Any disclosure of Confidential Information by either party or its representatives prior to receipt of such notice of its confidential or proprietary nature shall not constitute a breach of this Article XVIII.

Recipient shall mark Confidential Information with the following legend or similar:

"*Confidential and Proprietary. This information is confidential and proprietary. The receiving party may not use, modify, reproduce, perform, display or disclose this information except within the receiving party's organization on a need to know basis for the purposes of Agreement HHSO100201700018C, and may not disclose to any party outside the receiving party's organization without prior agreement of the providing party. Any reproduction of this information or portions thereof must be marked with this legend.*"

Confidential Information shall also include the following information provided to the Government prior to the effective date of this modification, whether or not marked as confidential or proprietary, provided that any disclosure of such information by Government or its representatives prior to the effective date of this modification shall not constitute a breach of this Article XVIII:

- Powerpoint presentations sent on September 14, 2017 and related to Uniflu and Coronavirus
- Manuscript related to JNJ-445 and sent on October 12, 2017

- (b)(4) sent on December 1, 2017
- (b)(4) sent on September 28, 2017

The obligations of this Article XVIII shall survive expiration or termination of the OTAR."

FOR Janssen R&D LLC

(b)(6)

(Name, Title) (Date)

FOR THE UNITED STATES OF AMERICA
OFFICE OF ACQUISITION MANAGEMENT,
CONTRACTS & GRANTS
SECRETARY FOR PREPAREDNESS AND RESPONSE

(b)(6)

(Name, Title) (Date)

AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

JANSSEN RESEARCH & DEVELOPMENT LLC
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES

Amendment No. 0002
Effective Date of Amendment: Upon Last Signature in Section IV

Other Transaction Agreement No. HHSO100201700018C
Effective Date of Agreement: August 15, 2017

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

[*Remainder of this Page Intentionally Left Blank; See Next Page for Description*]

I. AMENDMENT PURPOSE

By the Parties' mutual agreement, this Amendment makes bilateral changes within the general scope of the existing Agreement to (i) (b)(4) (b)(4) ii) extend the Base Period's term until December 31, 2018 to conform the Agreement to the Recipient's accounting period, (iii) (b)(4) (b)(4) v) update the Recipient's Key Personnel and the Government's personnel working under the Agreement, and (v) make conforming changes to those ends.

II. AMENDMENTS TO AGREEMENT

A. Article II *Term* Section A *Term of this Agreement* is changed in the first paragraph by deleting the first sentence and replacing it with the following:

> The Agreement commences on the date of the last signature hereto and continues for a sixteen and one-half (16 ½) month period (the "Base Period") with an option to extend the term of the Agreement on three (3) occasions for an additional twelve months on each occasion and, additionally, on one (1) last occasion for an additional seven and one-half (7 ½) months (each of the four extensions hereinafter referred to as an "Option").

B. Pursuant to Article II *Term* Section C *Extending the Term*, and independently of any Option, the Base Period's expiration date is extended by four and one-half (4 ½) months from August 14, 2018 to December 31, 2018. As of this Amendment No. 0002, the Parties acknowledge that, during that extended Base Period, funds remain available and research opportunities exist.

C. For clarity, the Agreement's potential Period of Performance, including all Options, that is set forth on the Agreement's Signature Page remains unchanged at "August 15, 2017 – August 14, 2022."

D. Article IV *Management of the Project* is changed in Section A.3 *Organizational Chart* by

1. adding (b)(6) as a second Project Management Leader (PML) to the Joint oversight committee and the PMO steering committee; and
2. replacing (b)(6) with (b)(6) as the Co-Principal Investigator on the Joint oversight committee and the PMO steering committee.
3. replacing (b)(6) with (b)(6) as non-voting JOC member.
4. replacing (b)(6) with (b)(6) as voting JOC member

E. Article V *Agreement Administration* is changed by

1. revising the Paragraph entitled "Government Points of Contact" as follows:

a. Other Transaction Agreement Specialist (OTAS)'s phone number is +1 (b)(6)

2. revising the Paragraph entitled "Recipient Points of Contact" by

a. adding the following as the second Recipient Program Management Lead (PML):

(NAME) (b)(6)
(TITLE) (b)(6)
(PHONE
(EMAIL)

b. adding the following as the Recipient's Co-Principal Investigator (Co-PI):

(NAME) (b)(6)
(TITLE) (b)(6)
(b)(6)
(PHONE NUMBER) (b)(6)
(EMAIL) (b)(6)

F. Article VI *Cost Sharing* is changed in Section C *Global Cost Share* by

(b)(4)

G.

(b)(4)

H. Attachment 3 *Escalation Procedure Diagram* is changed by

1. deleting from the Janssen Escalation Procedure Diagram (b)(6) s a member of the first level of escalation resolution; and

2. indicating in the Janssen Escalation Procedure Diagram that (b)(6) is co-PI and voting member; and

3. adding (b)(6) o the Janssen Escalation Procedure Diagram as a member of the first level of escalation resolution and non-voting member of the JOC; and

4. replacing (b)(6) n the Janssen Escalation Procedure Diagram, as a member of the second level of escalation resolution; and

5. replacing (b)(6) n the Janssen Escalation Procedure Diagram, as third level of escalation resolution; and

6. revising in the BARDA Escalation Procedure Diagram Ruben Donis's title from "Acting Director" to "Deputy Director" in the first level of escalation resolution.

III. Total funds obligated to this Agreement by the Government remain unchanged at $43,588,145. (b)(4)

(b)(4)

IV. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC	U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
	OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE
	BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY
BY: _____	BY: _____
NAME:	NAME:
ITS:	ITS:
DATE:	DATE:

member of the second level of escalation resolution; and

5. replacing (b)(6) in the Janssen Escalation Procedure Diagram, as third level of escalation resolution; and

6. revising in the BARDA Escalation Procedure Diagram Ruben Donis's title from "Acting Director" to "Deputy Director" in the first level of escalation resolution.

III. Total funds obligated to this Agreement by the Government remain unchanged at $43,588,145. (b)(4)

(b)(4)

IIII. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE

BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY

(b)(6)

(b)(6)

ME

TE:

EXHIBIT A

(b)(4)

AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

JANSSEN RESEARCH & DEVELOPMENT LLC
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES

Amendment No. 0003
Effective Date of Amendment: Upon Last Signature in Section III

Other Transaction Agreement No. HHSO100201700018C
Effective Date of Agreement: August 15, 2017

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

[*Remainder of this Page Intentionally Left Blank; See Next Page for Description*]

I. AMENDMENT PURPOSE

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0003 bilaterally (i) (b)(4) (b)(4) (iii) update the Recipient's Key Personnel and the Government's personnel working under the Agreement, and (iv) make administrative changes..

II. AMENDMENTS TO AGREEMENT

A. Exercise Option Period No. 1

1) Pursuant to Agreement Article II(A), Option Period No. 1 is hereby exercised, thereby extending the Agreement's expiry by one (1) year from December 31, 2018 to December 31, 2019.

2) Exhibit A Joint Oversight Committee – Decision Document (June 28, 2018), which evidences the agreement with the updated Option 1 budget, is incorporated and attached to this Amendment No. 0003.

3) For clarity, the Agreement's *potential* Period of Performance, including every Option, that is set forth on the Agreement's Signature Page remains unchanged at "August 15, 2017–August 14, 2022."

B. (b)(4) Under This Agreement

1) Pursuant to Agreement Amendment No. 0002 Section II(G)(2) (b)(4)

(b)(4)

2)

C. (b)(4)

1)

2)

D. (b)(4)

(b)(4)

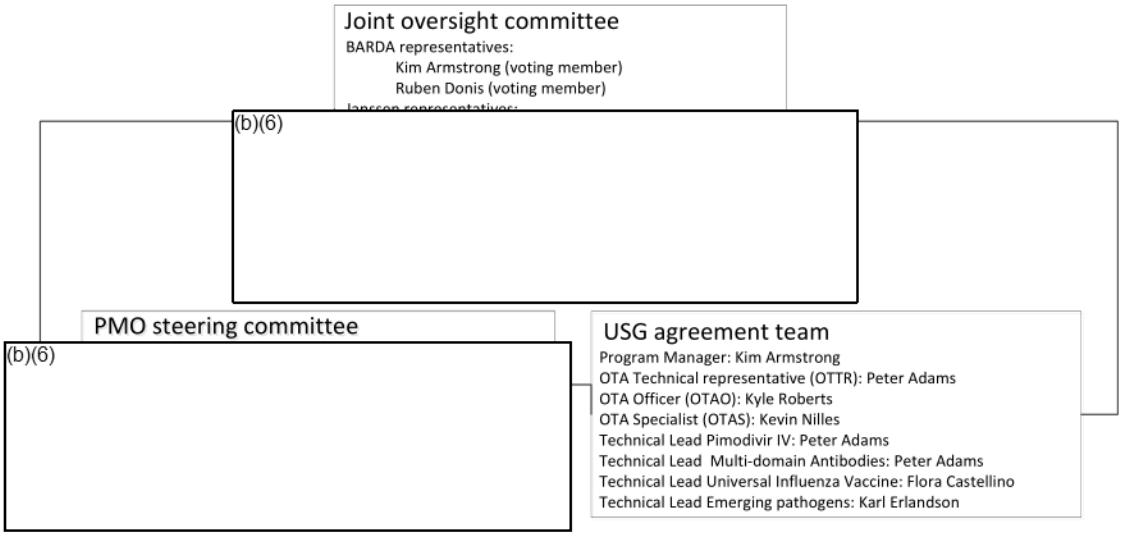
F. Government's Option Period No. 1 Accounting and Appropriation Data

Obligation Amount:	(b)(4)
Requisition No.:	OS233801
Object Class:	25103
Appropriation:	75X0140
CAN:	199TWSB: (b)(4)
CAN:	199TWRY: (b)(4)
FY Availability of Appropriation for Obligation:	
FY Funds Are Obligated:	FY2019

G. Total funds obligated to this Agreement by the Government increase (b)(4) (b)(4) 43,588,145 (b)(4) (b)(4)

H. Update on Recipient's Key Personnel and the Government's personnel working under the Agreement

1. Article IV *Management of the Project* Section A(3) *Organizational chart* is changed by deleting the chart and replacing it with the following:



2. Article V *Agreement Administration* is changed by

a. revising the Paragraph entitled "Government Points of Contact" as follows:

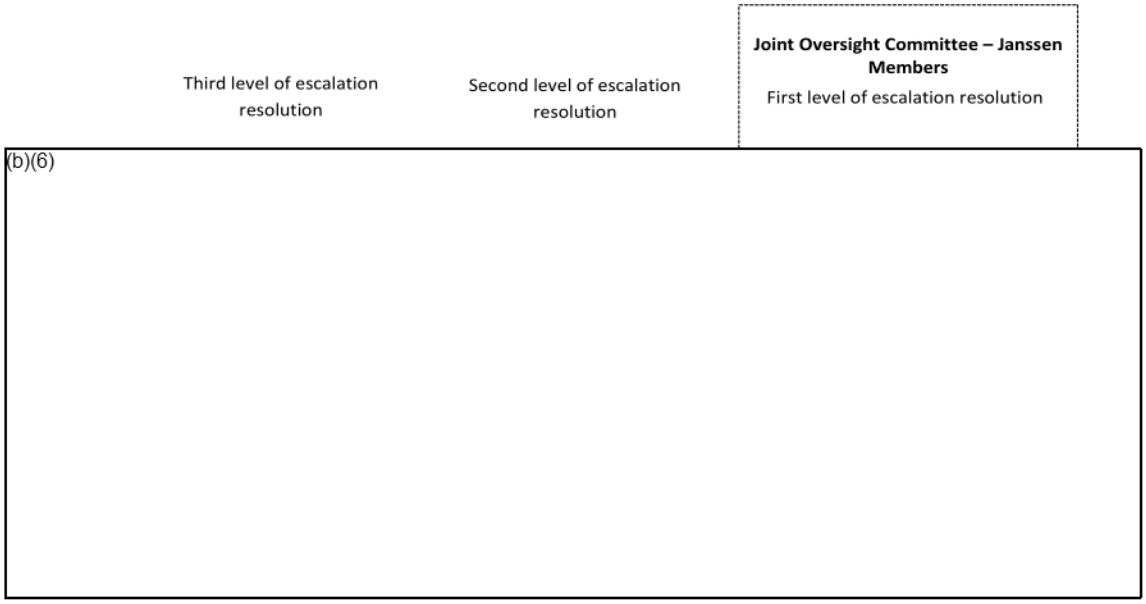
Other Transaction Agreement Technical Representative (OTTR) is

(NAME) (b)(6)
(TITLE) Health Scientist, Influenza and Emerging Diseases Division
(EMAIL) (b)(6)

b. adding the following as the Recipient's Co-Principal Investigator (Co-PI):

(NAME) (b)(6)
(TITLE) (b)(6)
(EMAIL)

3. Attachment 3 *Janssen Escalation Procedure Diagram* is changed by deleting the diagram and replacing it with the following:



Notes: (1) This chart reflects an example of the escalation points of contract within the Consortium for purposes of resolving a dispute with the Government.
(2) Consortium Voting members of the Joint Oversight Committee (JOC)
(3) Consortium Non-voting members of JOC

I. The following administrative updates to the existing agreement have been made in this Amendment No. 0003:

1. ARTICLE I: SCOPE OF THE AGREEMENT, SECTION B Definitions - The following definition shall be updated:
Recipient: Janssen Research & Development, LLC ("JRD" or "Janssen") acting on its own behalf and on behalf of the Consortium and each Consortium Member.

2. Attachment 2: REPORT REQUIREMENTS (attached hereto as Exhibit D), is updated to:

   a. Correct the Item Description Numbering beginning at item 16, Final Report is renumbered 17 and subsequent report numbers are corrected accordingly

   b. Clarified the different Delivery date between the Monthly Technical report and the Business status report.

   c. Correction to Deliverables Table to adjust typos carried forward from previous contract reference

III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC		U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
		OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE
		BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY
(b)(6)		(b)(6)
		BY:
		NAM
		ITS:
		DAT

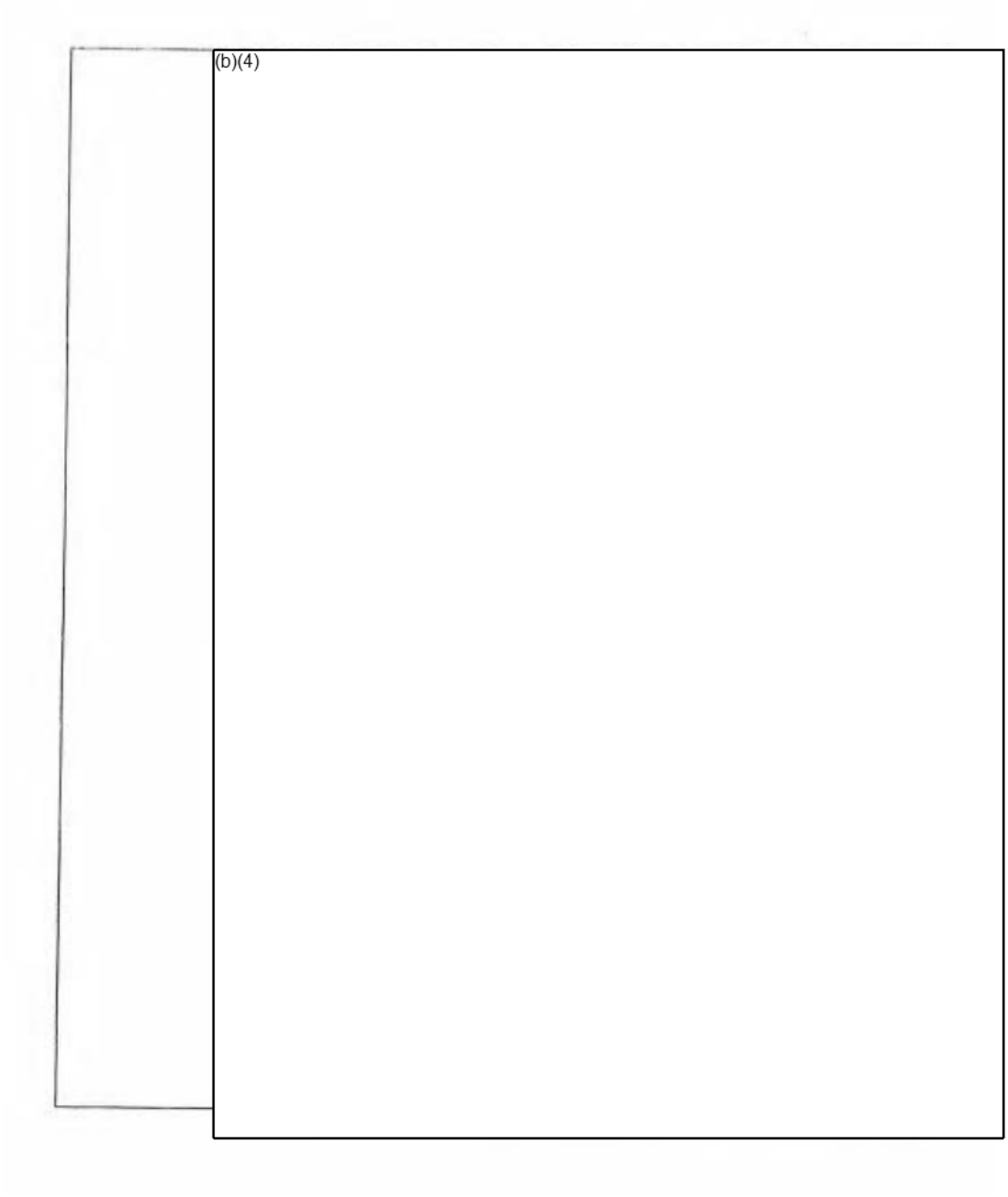
EXHIBIT A

Joint Oversight Committee – Decision Document

Dated June 28, 2018

BARDA/Janssen Research & Development LLC - Influenza and Emerging Pathogens OTA
Contract Number: HHSO100201700018C
Joint Oversight Committee – Decision Document

Date:	28 June 2018
JOC Meeting Number:	3 (off-line)
JOC Participants:	(b)(6) BARDA reps: - Melissa Willis (voting) - Ruben Donis (voting)
Invited participants:	[redacted] NAP (off-line) BARDA reps NAP (off-line)
Assets Reviewed:	(b)(4)
Decision Requested, Rationale and Budget Impact:	


(b)(4)

JOC Member Approvals:

(b)(6)

EXHIBIT B

Joint Oversight Committee – Decision Document

Dated August 9, 2018

BARDA/Janssen Research & Development LLC - Influenza and Emerging Pathogens OTA
Contract Number: HHSO100201700018C
Joint Oversight Committee – Decision Document

Date:	9 August 2018	
JOC Meeting Number:	4 (off-line)	
JOC Participants:	(b)(6)	BARDA reps: - Kimberly Armstrong (voting) - Rubes Donis (voting)
Invited participants:	NAP (off-line)	BARDA reps NAP (off-line)
Assets Reviewed:	(b)(4)	
Decision Requested, Rationale and Budget Impact:		

(b)(4)

(b)(6)

EXHIBIT C

(b)(4)

(b)(4)

WP 5.2 Clinical Studies

(b)(4)

WP 5.3 CMC

(b)(4)

WP 5.4 Regulatory

(b)(4)

PROJECT MANAGEMENT

Asset Project Management (one WP per asset)

These WPs include the Program Management activities associated with each of the assets. Each asset will have an (b)(4) who will oversee their specific (b)(4) (b)(4) requirements. This includes conducting frequent and regular (b)(4) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The (b)(4) of each asset will also include relevant functional Project Managers and a (b)(4) (b)(4) Each asset will also have an (b)(4) who will oversee their specific Technical requirements. This includes conducting frequent and regular (b)(4) (b)(4) meetings to define the overall development strategy. The (b)(4) of each asset will include Technical Lead, Preclinical Leader, Clinical Leader, the CMC Leader and the Regulatory Leader. Additional expertise required for executing asset-specific work possibly including subcontractors may be added as part of the (b)(4) & (b)(4)

WP 5.6 Joint Oversight Committee

The Joint Oversight Committee (JOC) is the larger decision making body that provides guidance, direction and control to the projects to ensure execution of the projects according to the SOW. The JOC will discuss and approve any changes to the SOW. To that extent, the JOC will meet at critical decision points in the program, but no less than two times per year, preferably face to face or alternatively by WebEx or telephone conference. Ad hoc meetings will be organized when urgent matters arise. The JOC will consist of voting and non-voting members from BARDA and Janssen.

Additional, non-voting members can be assigned or invited on an ad hoc basis. Decisions to reprioritize specific projects and resources as the need arises will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Janssen senior management member identified at the start of the project.

WP 5.6 PMO Steering Committee

The PMO (Program Management Organization) steering committee has dual responsibilities. One area of responsibility is the communication and coordination with BARDA regarding day to day management and execution of the project e.g. organizing meetings on a regular agreed basis. In addition, the PMO Steering Committee will coordinate all SOW activities and provide the technical and administrative infrastructure to ensure efficient planning, initiation, implementation, direction, management and completion of all tasks, including the establishment of the Compound Development Teams (CDT). These SOW activities will be coordinated by the Project Management Leader (PML). The Steering Committee will assess progress and where needed will work out strategic changes to be decided upon by the JOC. The Steering Committee consists of a group of dedicated and specialized Project Management experts, key personnel and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset area.

EXHIBIT D

REPORT REQUIREMENTS

Item Description	Delivery Date	Deliver To
1. Monthly Technical Progress Report describing project progress over the previous month.	The 15th of each month	OTAO/OTAS and OTTR via e-mail. Additionally, email invoices to PSC_Invoices@psc.hhs.gov
2. Quarterly Invoices and Business status update	Invoice: within 60 calendar days of the end of each quarter Business status update: within 15 calendar days of the invoice	
3. Bi-Weekly Conference Call Minutes	Proposed agenda 2 business days prior to call. Minutes within 7 business days following each conference call	
4. Quarterly PMO Steering Committee / Site Visit Minutes	Within 10 business days following each PMO Steering Committee /site visit	
5. Bi-annually Joint Oversight Committee minutes	Within 10 business days following each Joint Oversight Committee	
6. Portfolio Progress Milestone Presentation. Annual or event driven review of program	No later than 10 business days before Milestone Review at Joint Oversight Committee	
7. Study Protocols for each relevant non-clinical study and clinical trials	No later than 10 business days before submission to the FDA	OTAO/OTAS and OTTR via e-mail and, if requested, CD-ROM
8. Study Reports for each relevant non-clinical study and clinical trials	No later than 15 business days before submission to the FDA	
9. Manufacturing Campaign Reports for contract funded clinical trial material and registration lots	No later than 15 business days before submission to the FDA	

10. Technical Documents from contract funded activities such as Process Development Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis	Within 10 business days upon request by CO/COR or 15 business days prior to submission to FDA	
11. QA Audit Reports including findings, results and next steps. BARDA reserves the right to participate in the audits.	Within 5 business days of report completion	
12. Formal FDA Submissions of any kind pertaining to the scope of the project as necessary during Contract performance	No later than 10 business days before submission to the FDA BARDA will coordinate with Contractor for reviewing NDA sections	
13. Memo with Date and Time of Scheduled Meetings with FDA. BARDA reserves the right to attend FDA meetings relevant to contract funded activities	As soon as possible after scheduling	
14. Communications from FDA related to contract funded activities	Within 2 business days of receipt from FDA	
15. Minutes for Formal Meetings with FDA	Within 2 business days of receipt from FDA	
16. Draft Final Report	No later than 45 business days prior to contract expiration	OTAO/OTAS and OTTR via e-mail.
17. Final Report	No later than 45 Business Days prior to contract expiration	
18. Incident Report for any critical programmatic concerns, risks or potential risks	Within 96 hours of incident	OTAO/OTAS and OTTR via e-mail or telephone
19. Raw Data and Analysis Pertaining to Scope of the Project Generated Using USG Funds	Within a reasonable time after request within industry standards	OTAO/OTAS via e-mail
20. Weekly Clinical Report during Active Enrollment Periods	The Monday following the week being reported	OTTR via email

21. Clinical Site Enrollment Reporting and Updates to support the BARDA Clinical Trial Database	Submitted monthly as part of technical report	
22. Quality Agreements with Subcontractors	Within 10 business days upon request by OTAO/OTTR	OTAO/OTAS and OTTR via e-mail
22. Publications/Presentations	No later than 30 calendar days before submission for publications and 15 calendar days for presentations	OTAO/OTAS and OTTR via email

A. Monthly Technical Progress Report

On or before ninety (90) calendar days after the effective date of the Agreement and monthly thereafter throughout the term of the Agreement, Recipient shall submit or otherwise provide a monthly technical progress report. Two (2) copies shall be submitted or otherwise provided to the HHS Program Manager (or OTTR), one (1) copy shall be submitted or otherwise provided to the ASPR OTAO.

The report will detail technical progress to date and report on all problems, technical issues, major developments, and the status of external collaborations during the reporting period.

B. Business Status Report

The Business Status Report will be provided on a quarterly basis consistent with the invoice cycle, within fifteen (15) calendar days after invoice submission. The business status report shall provide summarized details of the resource status of this Agreement, including the status of Recipient contributions. This report will include a quarterly accounting of current expenditures as outlined in the Annual Program Plan. Any major deviations, over plus or minus 10%, shall be explained along with discussions of the adjustment actions proposed. The report will also include an accounting of any interest earned on Government funds. Recipient is reminded that interest in amounts greater than $250 per year is not expected to accrue under this Agreement. In the event that this interest does accrue on Government funds, Recipient is required to provide an explanation for the accrual in the business report. Depending on the circumstances, the Payable Milestones may require adjustment

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
0004	See Block 16C		

6. ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

7. ADMINISTERED BY *(If other than Item 6)* CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 638-G
Washington DC 20201

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

JANSSEN RESEARCH AND DEVELOPMENT LLC 1418051
Attn: (b)(6)
JANSSEN RESEARCH & DEVELOPMENT, LLC
920 US HWY 202
RARITAN NJ 088691420

CODE 1418051 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201700018C

10B. DATED *(SEE ITEM 13)* 08/15/2017

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER If by virtue of this amendment you desire to change an offer already submitted , such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* Other Transaction (Not subject to the FAR): Unilateral Administrative Amendment to Correct a Mistake

E. IMPORTANT: Contractor ☒ is not. ☐ is required to sign this document and return 0 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 51-0524195
DUNS Number: 119237597
The Other Transaction Recipient's name and administrative information are changed in BARDA's information systems to correct a mistake in recording the Recipient in those BARDA information systems from "Janssen Pharmaceuticals Inc (TIN: 232085699, DUNS: 079494318)" to "Janssen Research & Development LLC (TIN:510524195, DUNS:119237597)," which correction records the actual Recipient set forth in the Agreement.
Period of Performance: 08/15/2017 to 12/31/2019

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* (b)(6)	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	16C. DATE SIGNED

AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

JANSSEN RESEARCH & DEVELOPMENT LLC
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES

Amendment No. 0005
Effective Date of Amendment: Upon Last Signature in Section III

Other Transaction Agreement No. HHSO100201700018C
Effective Date of Agreement: August 15, 2017

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

[*Remainder of this Page Intentionally Left Blank; See Next Page for Description*]

I. AMENDMENT PURPOSE

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0005 bilaterally (i) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (ii) (b)(4) ii) Modifies the Joint Oversight Committee (JOC) purpose to align with the restructured budget, (iv) Replaces language in Article VII (B) to clarify the calculation of the exchange rate, (v) updates the Statement of Work to reflect JOC decisions and new asset structure, (vi) updates the Recipient's Key Personnel and the Government's personnel working under the Agreement, and (vii) Other administrative updates

II. AMENDMENTS TO AGREEMENT

A. Incorporate new budget and workplan structure to reflect two assets remaining in the portfolio.

1) Pursuant to Agreement Article VI(C), the budget allocation summary of assets is hereby replaced to incorporate the following.

(b)(4)

(b)(4)

(b)(4)

C. JOC Update

1) Agreement Article IV (B) (1) *Joint Oversight Committee (JOC)*, is deleted in its entirety and restated with the following:

The JOC will meet at critical decision points in the program, preferably face to face or alternatively by telephone conference. For agenda items strictly related to funding, a JOC will be held. The JOC will be requested to endorse the potential funding of activities which will commence upon a bona fide need being identified through programmatic, data-driven decisions for proposed work packages in the respective fiscal year the need is determined. Those funded work packages will continue until full completion. Based on some program circumstances, data and other information brought to the JOC for funding decisions may be limited. This period of performance will not be bound to fiscal years (e.g. an endorsed funded activity could last multiple years after receiving funding and commencing). Ad hoc meetings will be organized when urgent matters arise or prior to the exercising of an Option. The JOC will consist of two (2) voting members each from the Consortium and BARDA and non-voting members from the Consortium and BARDA, or other additional Consortium or U.S. Government Members (non-voting) as may be required. Additional, non-voting members may be assigned or invited by Recipient on an ad-hoc basis. Decisions to reprioritize specific projects and resources within the scope of this Agreement will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Consortium senior management member identified at the start of the project.

D. Exchange Rate Clarification (to be effective with the first full quarter after the mod has been signed)

1) Article VII (B) *Payments* language regarding exchange rates is updated to: "The Recipient will convert any foreign currency amount(s) in the invoice to U.S. dollars each

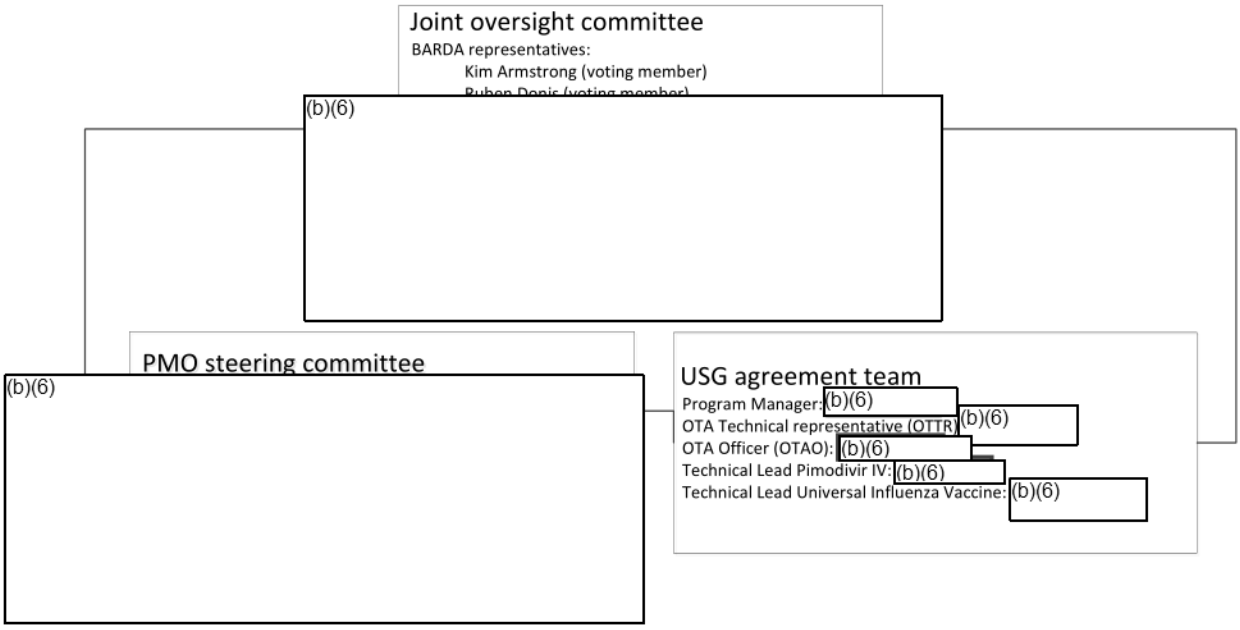
month, using the 1st of each month's foreign exchange rate index published on www.federalreserve.gov"

E. Updated the Statement of Work

1) The Statement of Work shall be updated to reflect JOC decisions and the new asset structure. The updated SOW for incorporation in the OTA is included in Exhibit D.

F. Update of Recipient's Key Personnel and the Government's personnel working under the Agreement

1) Article IV *Management of the Project* Section A (3) *Organizational Chart* is deleted and replaced with the following:



2) Article V *Agreement Administration* is changed by revising the Paragraph entitled "Government Points of Contact" as follows:

Other Transaction Agreement Officer (OTAO/OTAS) is

(NAME) (b)(6)
(TITLE) Lead Contracting Officer & Other Transaction Agreement Officer (OTAO)
(EMAIL (b)(6)

G. Other Administrative Changes

1) Related to the budget update, Article II (A) *Term of this Agreement* is deleted in its entirety and restated with the following: "The Agreement commences on the date of the last signature hereto and continues for all work packages funded via the most recent JOC decision and modification. Further, optional work packages may be exercised in accordance with the JOC structure articulated in the amended Article IV (B) (1) *Joint Oversight Committee (JOC)* as amended by Section II C of Modification 0005 to this Agreement. The Recipient may decline "options" and such declination will be treated as a termination and Recipient shall act in accordance with the terms in Section B. The Parties may also agree mutually to extend the term of this agreement and its options by written agreement on or before the expiration of the Agreement."

Note: The current end of performance as of this modification, is April 30, 2023. This is subject to change as the agreement continues in accordance with program and JOC decisions (per the updated language above).

III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

(b)(6)

DATE: December 19, 2019

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR
PREPAREDNESS & RESPONSE
BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT

(b)(6)

ITS: OTAO

DATE: DECEMBER 19, 2019

M0005 Exhibit A - Budget Allocation (b)(4)

(b)(4)

M0005 Exhibit A - Budget Allocatio(b)(4)

(b)(4)

M0005 Exhibit A - Budget

(b)(4)

(b)(4)

M0005 Exhibit A - Budget

(b)(4)

(b)(4)

M0005 Exhibit A - Total Yearly Budget Details

(b)(4)

M0005 Exhibit A - Total Yearly Budget Summary

(b)(4)

Summary Allocation

(b)(4)

M0005 Exhibit B

(b)(4)

(b)(4)

M0005 Exhibit C

(b)(4)

ATTACHMENT 1: TASK DESCRIPTION DOCUMENT (SOW)

Overall Objectives and Scope

Seasonal and pandemic influenza remains one of the most important public health threats despite current vaccine and therapeutic options. The Consortium is developing a broad portfolio of innovative and novel countermeasures against influenza and other emerging infectious diseases comprising small molecules, biologics and vaccines. The portfolio employs (b)(4) modes of action complementary to current Standard of Care treatments to develop single or combination therapies that have the potential to increase therapeutic benefit and preclude the rapid emergence of drug resistance. The (b)(4) aims to (b)(4) the influenza vaccine field by providing broad protection for both seasonal and pandemic influenza.

Specifically, this Agreement includes: an influenza (b)(4) that is now ready for (b)(4) (b)(4) a (b)(4) influenza A or B viruses; a (b)(4) (b)(4) a (b)(4)

In addition, Recipient may propose to augment the portfolio by replacing molecules listed in this SOW with backup molecules from their ongoing research programs. With support from the JOC, the Consortium may also consider in-licensing drug or vaccine candidates to supplement the Program's portfolio of emerging infectious disease medical countermeasures in the Field. Recipient may also add Consortium Members as may be appropriate or complimentary to the performance and goals of this Agreement.

(b)(4)

M0005 Exhibit D

(b)(4)

(b)(4)

6 Project Management

Coordinating project management has been brought under WP 5.6 as per JOC memo 4 (initially in 1.6)

6.1 Joint Oversight Committee – check updated language from more recent MOD

The Joint Oversight Committee (JOC) is the larger decision-making body that provides guidance, direction and control to the projects to ensure execution of the projects according to the SOW. The JOC will discuss and approve any changes to the SOW. To that extent, the JOC will meet at critical decision points in the program, but no less than two times per year, preferably face to face or alternatively by WebEx or telephone conference. Ad hoc meetings will be organized when urgent matters arise. The JOC will consist of voting and non-voting members from BARDA and Janssen. Additional, non-voting members can be assigned or invited on an ad hoc basis. Decisions to reprioritize specific projects and resources as the need arises will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Janssen senior management member identified at the start of the project.

6.2 PMO Steering Committee

The PMO (Program Management Organization) steering committee has dual responsibilities. One area of responsibility is the communication and coordination with BARDA regarding day to day management and execution of the project e.g. organizing meetings on a regular agreed basis. In addition, the PMO Steering Committee will coordinate all SOW activities and provide the technical and administrative infrastructure to ensure efficient planning, initiation, implementation, direction, management and completion of all tasks. This will be coordinated by the Project Manager Leader (PML). The Steering Committee will assess progress and where needed will work out strategic changes to be decided upon by the JOC. The Steering Committee consists of a group of dedicated and specialized Project Management experts, key personnel and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset area.

6.3 Asset Project Management

These WPs include the Program Management activities associated with each of the assets. Each asset will have an (b)(4) ho will oversee their specific (b)(4) requirements. This includes conducting frequent and regular (b)(4) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The (b)(4) (b)(4) team of each asset will also include Technical Lead, Preclinical Leader, Clinical Leader, the CMC Leader, the Regulatory Project Management Leader and Finance representatives. Additional expertise required for executing asset-specific work

possibly including subcontractors may be added as part of the Project Management Team.

BARDA/Janssen Research & Development LLC - Influenza and Emerging Pathogens OTA

Contract Number: HHSO100201700018C

Joint Oversight Committee – Decision Document

Date:	2 Dec 2019	
JOC Meeting Number:	8	
JOC Participants:	Janssen reps: (b)(6)	BARDA reps: - (b)(6) - - -
Assets Reviewed:	(b)(4)	
Decision Requested, Rationale and Budget Impact:		

M0005 Exhibit E

(b)(4)

M0005 Exhibit E

(b)(4)

M0005 Exhibit E

JOC Member Approvals:

(b)(6)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00009	See Block 16C		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	ASPR-BARDA	ASPR-BARDA
200 Independence Ave., S.W. Room 640-G Washington DC 20201		200 Independence Ave., S.W. Room 638-G Washington DC 20201	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

JANSSEN RESEARCH AND DEVELOPMENT LLC 1418051
Attn: (b)(6)
JANSSEN RESEARCH & DEVELOPMENT, LLC
920 US HWY 202
RARITAN NJ 088691420

CODE 1418051 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201700018C

10B. DATED *(SEE ITEM 13)* 08/15/2017

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* Section 319L(C)(5) of the Public Health Service Act, 42 USC 247d-7e(C)(5)

E. IMPORTANT: Contractor ☒ is not ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 51-0524195
DUNS Number: 119237597
This Amendment 9 to the Agreement accomplishes the following:

Amendment No. 0009

Administrative modification to align data within PRISM system to be consistent with obligated funding amounts only for external data reporting consistency.

Except as provided in this Amendment, all terms and conditions of the Agreement, as
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		(b)(6)	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		*(Signature of Contracting Officer)*	

NAME OF OFFEROR OR CONTRACTOR
JANSSEN RESEARCH AND DEVELOPMENT LLC 1418051

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	heretofore changed, remain unchanged and in full force and effect. FOB: Destination Period of Performance: 08/15/2017 to 12/31/2024 Cancel Item 5 in its entirety. Cancel Item 6 in its entirety. Cancel Item 7 in its entirety. Cancel Item 8 in its entirety.				

AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

Agreement Number HHSO100201700018C
Effective Date of Agreement: August 15, 2017

BETWEEN

JANSSEN RESEARCH & DEVELOPMENT LLC
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES

Amendment No. 0010

Amendment No. 0010 to the agreement updates the budget information and scope of work for various work packages that are related to COVID-19 vaccine research and development efforts. Because Amendment No. 0009 served primarily as a tool for administrative internal alignment, the new information provided in this document relate most closely to Amendment No. 0008. As such, the financial data provided in this amendment effectively serves as a budget update to Amendment No. 0008 of the agreement. All increases noted below reflect updates to Amendment No. 0008.

Effective Date of Modification: Upon Last Signature in Section III

Total Amount of the Agreement increased by (b)(4) or additional studies and activities in pre-clinical, Phase I & Phase II related to the COVID-19 vaccine (including government and

recipient funding). The total amount of the agreement for all assets in the OTA is raised from (b)(4) to (b)(4)

Government Share of Total Amount of the Agreement is increased by (b)(4) from (b)(4) to (b)(4)

Recipient Share of Total Amount of the Agreement is increased by (b)(4) from (b)(4) to (b)(4)

Current Government commitment: With additional studies (i.e. Work Package [WP] 6.2 and WP 6.17) and other adjustments to WP 6.1 - 6.10 and 6.13 - 6.17, the total, obligated governmental funds obligated is increased by (b)(4) from (b)(4) to (b)(4)

Current Recipient commitment: The obligated recipient funds provided in Mod 0008 is decreased by (b)(4) With additional studies (WPs 6.2 and 6.17) and other adjustments to WP 6.1 - 6.10 and 6.13 - 6.17, the total, obligated recipient funds is increased by (b)(4) from (b)(4) to (b)(4)

Period of Performance: The Period of Performance of this agreement is extended from December 31, 2024 to December 31, 2025.

Authority: Section 319L(C)(5) of the Public Health Service Act, 42 USC 247d-7e(C)(5).

Line of Accounting and Appropriation:

Work Packages	Title	Requisition (OS)	CAN	Obj.Class	Amt. (Govt Share)	Changed
(b)(4)						
WP 6.1 – 6.10, and 6.13 – 6.17	COVID-19 - Vaccines discovery thru Phase 3 Trial, excluding WPs 6.11 and 6.12.	OS256464 OS262675	199COV1 199C014	25103 25103	(b)(4)	Adjusted with this modification
(b)(4)						
Total					(b)(4)	**Changed**

I. AMENDMENT PURPOSE

This Amendment, based on Joint Oversight Committee (JOC) recommendation, documented in Memo #12 dated 16 June 2020, and in accordance with Article IV of the OTA, adds (i) a non-human primate (NHP) within Work Package (WP) 6.2, (ii) adds a Randomized, Double-blind, Placebo-controlled Phase 2 study (WP 6.17), and (iii) revises work packages (prior to Phase 3).For the purposes of this SOW update, the work packages associated with the Phase 3 Study (WPs 6.10 – 6.13) have been marked as RESERVED as they are in the process of being updated , and these changes will be reflected in a forthcoming Amendment. All changes to cost are captured in

This Amendment also clarifies the terminology used to describe the subcontractor notification process described in Article XIII "Subcontracting". The process in which notification is provided to BARDA shall be referred to as the "Contracting Officer Notification (CON)" process.

By the Parties' mutual agreement and within the existing Agreement's general scope, to include specific terms and conditions applicable to COVID related activities as described in Amendments 0007 and 0008, this Amendment No. 0010 bilaterally:

i. Incorporates the updated budget;
ii. incorporates the updated Statement of Work (Exhibit A);
iii. Adds language to Article XIII Subcontracting, to clarify Contracting Officer Notification terminology;
iv. In Article XIII Subcontracting, replace "calendar day" with "business day";
v. In Article XIII Subcontracting, replace references to Amendments 0007 & 0008 with "COVID-19 Antiviral and Vaccines efforts"
vi. Adds language defining a "Publications" and "Presentations;"
vii. Adds language requiring acknowledgement of federal funding; and
viii. Closes out the "redirect" of funding from NOI JOC #12, dated June 18, 2020

II. AMENDMENTS TO AGREEMENT

A. Incorporate new Cost Share Estimates/Budget Summary in accordance with the updated budget.

1) Pursuant to Agreement Article VI(C), the budget allocation summary of assets is hereby replaced to incorporate **Table 1 – Cost Share Estimates Budget Summary***.

(b)(4)

Updated the Statement of Work - The Statement of Work shall be replaced to reflect the changes in WPs 6.1-6.10 and 6.14-6.17. For purposes of this updated SOW, work packages associated with the Phase 3 Study (WPs 6.10 – 6.13) have been marked as RESERVED as they are in the process of being updated and will be restated in a forthcoming Amendment. The updated SOW (other than Phase 3) for incorporation in the OTA is included in **Exhibit A**. The corresponding WP budget **Table 2 - Budget Allocation Summary)**, with shaded options in gray, replaces all previous budget work package tables.

C. Article XIII: Add the following language to the end of the first paragraph of the Article: "For clarity and consistency, the review period for subcontracts planned within the scope of the OTA shall be referred to as the Contracting Officer Notification (CON) or Other Transaction Agreement Officer Notification (OTAON) process."

ARTICLE XIII SUBCONTRACTING, incorporating changes iii-v from Amendment Purpose, shall now be replaced with the following:

For any subcontracts in excess of (b)(4) that will be reimbursed under this Agreement, Recipient will provide BARDA the opportunity to review the subject subcontracting agreement seven (7) business days before execution. The subcontract agreement shall include the nature of the work that the subcontractor is going to perform, an estimated period of performance and the proposed costs for the work. Recipient will provide OTTR, OTAO, OTAS and OTTS with an electronic copy of the subcontracting document. For avoidance of doubt, the Recipient is not required to wait for the Government's comments before executing an Agreement with a subcontractor once the 7-business day review period has expired. For clarity and consistency, the review period for subcontracts planned within the scope of the OTA shall be referred to as the Contracting Officer Notification (CON) or Other Transaction Agreement Officer Notification (OTAON) process."

For this COVID-19 Antiviral and Vaccines efforts only, for any subcontracts in excess of (b)(4) that will be reimbursed under the OTA, Recipient will provide BARDA the opportunity to review the subject subcontracting agreement three (3) business days before execution. The subcontract agreement shall include the nature of the work that the subcontractor is going to perform, an estimated period of performance and the proposed costs of the work. Recipient will provide OTTR, OTAO and OTTS with an electronic copy of the subcontracting document. For avoidance of doubt, the Recipient is not required to wait for the Government's comments before executing an Agreement with a subcontractor once the 3-business day review period has expired.

D. The following Articles and language are added to the agreement:

ARTICLE XVII: PUBLICATIONS AND PRESENTATIONS

Publications
Publications shall mean written scientific meeting abstract(s), scientific journal article(s) or other articles authored or co-authored by Recipient's personnel or Recipient's subcontractor personnel containing data generated under this OTA.

Any scientific meeting abstract, scientific journal article, or other articles, authored or co-authored by any Recipient personnel or Recipient's subcontractor personnel, which contains data generated under Biomedical Advanced Research and Development Authority ("BARDA"), OTA No. HHSO100201700018C must be submitted to the OTAR for review no less than 30 calendar days prior to submission for publication. However, the Parties may agree to negotiate abbreviated timeframes, as needed.

Presentations
Any Presentation materials containing data generated under this OTA, authored/co-authored or to be delivered by or on behalf of, any Recipient or Recipient's vendor's personnel, must be submitted to the OTAR for review no less than 15 calendar days prior to the presentation. However, the Parties may agree to negotiate abbreviated timeframes, as needed.

Presentations shall mean any materials containing data generated under this OTA, authored, co-authored, or to be delivered by or on behalf of, any Recipient or Recipient's vendor's personnel.

ARTICLE XVIII: ACKNOWLEDGEMENT OF FEDERAL FUNDING in MEDIA and PRESS RELEASES

The Recipient shall accurately and factually represent the work conducted or to be conducted under the OTA. The Recipient shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this OTA in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under OTA No. HHSO100201700018C."

REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK

Except as provided in this Amendment, all terms and conditions of the Agreement, unless previously changed, remain unchanged and in full force and effect.

III. SIGNATURES

Acknowledged, accepted, and agreed for

Janssen Research & Development, LLC

(b)(6)

U.S. Department of Health & Human Services
Office of the Assistant Secretary for
Preparedness & Response
Biomedical Advanced Research &
Development Authority

(b)(6)

DATE: 8.21.2020

Table 1 – Cost Share Estimates Budget Summary

M0010 Cost Share Estimates/Budget Summary									
Summary	Invoiced 8/15/2017 Through 12/31/2018	1/1/2019 Through 12/31/2019	1/1/2020 Through 12/31/2020	1/1/2021 Through 12/31/2021	1/1/2022 Through 12/31/2022	1/1/2023 Through 12/31/2023	1/1/2024 Through 12/31/2024	1/1/2025 Through 12/31/2025	Total
(b)(4) (BARDA:Janssen) Cost Share		Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	
(b)(4)									

Table 2 - Budget Allocation Summary

M0010 Exhibit B - Budget Allocation Summary									
		1/1/2019 through 12/31/2019	1/1/2020 through 12/31/2020	1/1/2021 through 12/31/2021	1/1/2022 through 12/31/2022	1/1/2023 through 12/31/2023	1/1/2024 through 12/31/2024	1/1/2025 through 12/31/2025	Cost Estimate 100%
Work Package Number	Work Package Name	PERIOD 1	PERIOD 2	PERIOD 3	PERIOD 4	PERIOD 5	PERIOD 6	PERIOD 7	TOTAL
(b)(4)									
2019-nCoV Vaccines - Amendment 0010									
(b)(4)									
(b)(4)									

July 1, 2020

COVID-19 Vaccine SoW

In response to the COVID-19 outbreak, Janssen has mobilized many resources to develop a vaccine based on its AdVac® and PER.C6® platform within an unprecedented short time frame. Vectors based on Adenovirus serotype 26 (Ad26) with different designs of the SARS-CoV-2 spike (S) protein have been tested for their suitability as a vaccine candidate in terms of manufacturability and immunogenicity in different animal species. A lead vaccine candidate has been selected, and the first steps of GMP manufacturing have started. Drug Product will be available for assessment of safety, tolerability and immunogenicity in humans in a Phase 1/2a clinical study in July 2020.

Given the emergency with the current COVID-19 outbreak, several activities have started in parallel to minimize white space between the activities and different phases of the project. With the exception of WPs 6.11 to 6.13, activities in all WPs have started. WP6.17, which defines a dose- and regimen-finding study, has been added in this version of the SoW.

Janssen is working closely together with the FDA and regulatory agencies in several other countries to discuss the plans both from a manufacturing and control strategy perspective as well as non-clinical safety and immunogenicity perspective.

Similar to the earlier versions of the SoW, the information provided herein reflects our best estimates based on the facts and circumstances as we know them today but could change as performance proceeds and more information becomes available. Additionally, due to the uncertainty of the spread, duration, and impact of the current COVID-19 outbreak, it is difficult to provide more precise estimates for the duration or cost for all of the activities contained in this proposal. As such, all activities, deliverables, milestones, and decision points described below may be subject to change in accordance with the governance process outlined in the OTA and relevant Amendments. In addition, associated timelines assume that business continuity at J&J and third parties will be sufficient to support the described activities.

WP6.1 Antigen design, manufacturability testing and preMVS manufacturing

Activities

- DNA encoding for several designs of the SARS-CoV-2 spike protein will be (b)(4) at multiple CROs
- Research batches of Ad26 vectors (b)(4) (b)(4) spike protein (b)(4)
- (b)(4)

(b)(4)

(b)(4)

- Several critical reagents such as expression plasmids, soluble proteins, peptide pools and detection antibodies will be generated or ordered

(b)(4)

WP6.2 Pre-Clinical Immunology (Performed at Janssen (b)(4)

Activities

- Mice, (b)(4) and non-human primates (NHP) will be immunized with DNA constructs of candidate vaccine inserts to set up immunogenicity assays and to get a first idea of immunogenicity.
- Ad26 based candidate vaccines will be tested for immunogenicity (b)(4) mouse (b)(4) Syrian hamster, rabbits, (b)(4) nd NHP.

(b)(4)

- Mice, Syrian hamster, rabbits, (b)(4) and NHP will be considered for viral challenge studies. If challenge models can be developed, animals from immunogenicity studies with Ad26-based vaccine candidates may be rolled over to a challenge study to determine preclinical vaccine efficacy.
    - **June 2020 update:** Additional viral challenge studies in (b)(4) NHP are planned to determine vaccine efficacy of lead candidate Ad26COVS1. The aim of these studies is to evaluate vaccine efficacy after different dose levels, compare one to two doses, evaluate durability of immune response and vaccine efficacy in older animals.

(b)(4)

Milestones

- Initial PoC based on immunogenicity of DNA vaccine constructs
- PoC based on immunogenicity of Ad26-based vaccine candidates
- PoC based on protective efficacy of Ad26-based vaccine candidate in NHP

Deliverables

- Study reports of in vivo studies

Go/No go decisions

- Proof of immunogenicity triggers go for preMVS manufacturing
-

WP6.3 CMC Development until First in Human ("FIH")

Activities:

(b)(4)

(b)(4) method development will occur to make insert specific assays fit for purpose.

- (b)(4)

(b)(4)

WP6.4 Clinical Development and Regulatory Activities to Start First in Human Study

Activities

- Setup of immunological assays at CROs or at Janssen:

(b)(4)

- Writing of protocol elements document (PED)
- Protocol writing
- Writing and submission of preIND document
- Writing and submission of IND documents
- Contracting with vendors
- Contracting with clinical sites

Milestones

(b)(4)

Activities

- A GLP Toxicity study will be performed (b)(4)

(b)(4)

WP6.6 GMP Manufacturing to Enable FIH Clinical Trial

- Master Virus Seed manufacturing and release

(b)(4)

(b)(4)

WP6.7 Phase 1/2a Clinical Trial

Activities

- A Randomized, Double-blind, Placebo-controlled Phase 1/2a Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26COVS1 in Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older.
- Primary objective will be assessment of safety and reactogenicity. Secondary and exploratory endpoints will evaluate vaccine-induced immune responses to SARS-CoV-2.
- Two dose levels (high dose and low dose) given intramuscularly, will be evaluated, either as a single immunization, or as two immunization regimens, and compared to placebo
- Study cohorts:
    - Cohort 1:
        - Cohort 1a: (b)(4) participants (b)(4) participants per group) aged ≥18 to ≤55 years who will be randomized in parallel in a 1:1:1:1:1 ratio to 1 of 5 vaccination groups.
        - Cohort 1b: (b)(4) participants (b)(4) participants per group) aged ≥18 to ≤55 years who (b)(4) and randomized in parallel in a 1:1:1:1:1 ratio to 1 of 5 vaccination groups. Additional exploratory immunogenicity evaluations (eg, epitope mapping, passive transfer, and certain analyses of functional and molecular antibody characteristics) will be performed for Cohort 1b.
    - Cohort 2: (b)(4) participants aged ≥18 to ≤55 years will be randomized to receive Ad26COVS1 ((b)(4) participants) or a placebo (b)(4) participants) in the regimens scheduled for the Phase 3 ie single immunization with (b)(4) or two immunizations of (b)(4) spaced 56 days apart. Cohort 2 will include an evaluation of a single booster vaccination given either at 6,12 or 24 months for each of the two regimens
    - Cohort 3: (b)(4) participants ((b)(4) participants per group) aged ≥65 years who will be randomized in parallel in a 1:1:1:1:1 ratio to 1 of 5 vaccination groups.
- Total study size is targeted at (b)(4) subjects
- Th1/Th2 determination to characterize immune response; this is relevant in light of the unproven, yet, theoretical possibility of enhanced respiratory disease (ERD) will be measured in approximately half of the subjects in cohorts 1 and 3.

- Serum and PBMC (PBMC in Cohorts 1 and 3, and a subset of Cohort 2) will be collected at day(s) of immunization, and at days 7, 14 and 28 after each immunization. Durability of immune responses will be measured at 6 months and after one year after last dose.
- Five subjects/group within Cohort 1 (b)(4) samples will be subject to exploratory immune studies.
- Immuno sample analysis and long-term storage.

Milestones

- Safety analysis of solicited and unsolicited AEs after the 1st (b)(4) subjects in Cohort 1
- Interim analysis Cohort 1 after first dose for Safety and Immunogenicity
- Interim analysis Cohort 3 after 1 dose
- Primary Analysis Cohort 1 after 2nd dose for Safety and Immunogenicity
- Final analysis top line results.

Deliverables

- TLR reports
- Clinical study report

Go/No go decisions

- Safety analysis of solicited and unsolicited AEs after the 1st (b)(4) subjects in Cohort 1 in order to proceed to Cohort 3 and to proceed to Study COV2001.
- Interim analysis Cohort 1 after first dose for Safety and Immunogenicity to decide whether to proceed to a Phase 3 efficacy study in adults ≥18 to ≤59 years of age, and Cohort 2 in this study. This decision is based on adequate 28-day safety, immunologic responses including Neutralizing antibody and a TH1-like response indicating it will be safe and that the vaccine should induce protective responses. This in combination with appropriate preclinical studies.
- Interim analysis Cohort 3 after 1 dose as a Go/No go proceed to Phase 3 efficacy trial in participants aged ≥60 years.
- Primary analysis Cohort 1 after 2 doses for Safety and Immunogenicity to demonstrate the expected increased response in antibodies to justify the 2nd immunization in the 2-dose regimen in Phase 3.

WP6.8 CMC Development and GMP Manufacturing Process to Enable late phase clinical studies, Large Scale Manufacturing and Launch to Support the Regulatory Filing

(b)(4)

(b)(4)

- PPQ for both DS and DP will be executed. (b)(4)

(b)(4)

(b)(4)

- Studies to enable launch and support licensure will be assessed and executed as appropriate.

(b)(4)

(b)(4)

WP6.9 Toxicology Studies

A Phase 1 enabling GLP toxicology study is described under WP6.5. (b)(4)

(b)(4)

Activities

- Conduct developmental and reproductive toxicity (DART) study

(b)(4)

(b)(4)

WP6.14 Regulatory Support

Activities to establish an IND for an Ad26-based COVID-19 vaccine will involve an arrangement of a pre-IND meeting with CBER before the intended IND submission (b)(4) Prior to the pre-IND, (b)(4)

(b)(4)

(b)(4)

(b)(4)

The pre-IND and IND preparation to enable Phase 1 will be led by RA. Further regulatory activities beyond Phase I are interactions with FDA to support the development of the vaccine up to regulatory submission (to be discussed: pre-EUA and/or BLA submission, or other pathways as per Agency's guidance). This involves an end-of-Phase 2 meeting and a pre-BLA meeting. Type C meetings will be scheduled on an as-needed basis. Pediatric requirements will be discussed as per Agency's requirements.

Annual reports will be prepared and submitted to CBER according to the foreseen timelines after the IND comes into effect. Development of regulatory intelligence with respect to development and licensing of a COVID-19 vaccine will carefully be monitored.

Discussions with other regulatory Agencies as required by the program and in particular to allow for a harmonized approach from a CMC, non-clinical and clinical development perspective, and facilitate multi-country trials as required per discussion with the Agencies, may also have to be conducted and will then be covered under WP6.14.

WP6.15 Project Management Support

This WP includes the Program Management activities associated with development of an Ad26-based COVID-19 vaccine. The program will have an (b)(4) (b)(4) who will oversee their specific (b)(4) requirements. This includes conducting frequent and regular (b)(4) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The (b)(4) team of each asset will also include relevant functional Project Managers and a (b)(4) (b)(4) The Program will also have an (b)(4) who will oversee their specific Technical requirements. This includes conducting frequent and regular (b)(4) (b)(4) meetings to define the overall development strategy. The (b)(4) of each asset will include, but is not limited to, the Technical Lead, Preclinical Leader, Clinical Leader, the

CMC Leader and, the Regulatory Leader. Clinical Team (CT) and Trial teams will oversee clinical program and trial execution. These teams include operational staff, Operational Leader and representatives of operational departments such as data management; GCO; medical writing, programming, stats. Additional expertise required for executing asset-specific work possibly including subcontractors may be added as part of (b)(4) and (b)(4)

WP6.16 Dissecting the Evolution of SARS-CoV-2 and Specific Humoral and Cellular Immunity Following Infection

Activities

- The understanding of the roles that (b)(4) esponses to SARS-CoV-2 are thought to play in protection, disease resolution, or enhancement of disease are evolving with the assessment of patients with varying disease outcomes. (b)(4) (b)(4)
- Identification of antigen-specific biomarkers of disease trajectory (survival, disease, death) and SARS-CoV-2 specific immune responses against the virus by (b)(4) approaches (b)(4) using samples from previously and prospectively collected, longitudinal cohorts at the (b)(4) (b)(4)

(b)(4)

WP6.17 Phase 2 study - NEW

(b)(4)

This is a Randomized, Double-blind, Placebo-controlled Phase 2a Study to Evaluate a Range of Dose Levels and Vaccination Intervals of Ad26COVS1 in Healthy Adults Aged 18 to 55 Years Inclusive

In this study, safety and immunogenicity responses following 2-dose (b)(4) (b)(4) and single-dose (b)(4) primary vaccination regimens will be assessed. (b)(4) (b)(4) Safety and immunogenicity of 0,28-, 0,56-, and 0,84-day vaccination intervals for the 2-dose regimen (b)(4) will also be assessed.

A target of approximately (b)(4) adult male and female participants will be enrolled in this study and will be randomly assigned to 1 of 10 groups.

Participants will receive Ad26COVS1 or a placebo intramuscularly (b)(4) ose levels of Ad26COVS1 will be administered (b)(4)

Milestones

- An interim analysis of safety and immunogenicity will be performed, including 28-day immunogenicity (if applicable) and 28-day safety data post vaccination 1 of all groups
- The primary analysis of safety and immunogenicity post-vaccination 2 will be performed when all participants have completed the visit that takes place 28 days after the last study vaccination in all groups, or discontinued earlier
- A second interim analysis of safety and immunogenicity will be performed, including 28-day immunogenicity and 28-day safety data post antigen presentation of all groups
- The final analysis will be performed when all included participants have completed the last visit, or discontinued earlier

Deliverables

- TLR reports
- Clinical study report

Go/No go decisions

- Go-No go for inclusion of shorter regimen for emergency use
- Go-No Go for consideration of lower dose for Emergency use

(b)(4)

(b)(4)