MEMORANDUM OF UNDERSTANDING

between

FOOD AND DRUG ADMINISTRATION
UNITED STATES OF AMERICA

and

THE PAN AMERICAN HEALTH ORGANIZATION,
REGIONAL OFFICE OF THE WORLD HEALTH ORGANIZATION

for

REGULATORY EXCHANGE PLATFORM—SECURE

The Food and Drug Administration of the United States of America, duly represented by Howard R. Sklamberg (hereinafter "FDA"), and the Pan American Health Organization, Regional Office of the World Health Organization, duly represented by Carissa F. Etienne (hereinafter "PAHO" or "PAHO/WHO"), jointly referred to as the "Participants," hereby enter into the present Memorandum of Understanding ("MOU"):

WHEREAS PAHO is a public international organization with more than 100 years of experience working to improve health and living standards of the countries of the Americas. It serves as the specialized agency for health of the Inter-American System. As the Regional Office of the World Health Organization in the Americas, PAHO/WHO enjoys international recognition as a specialized agency of the United Nations. The fundamental purpose of PAHO is to promote and coordinate efforts of the countries of the Western Hemisphere to combat disease, lengthen life and promote the physical and mental health of the people.

WHEREAS strengthening regulatory capacities within national regulatory authorities ("NRAs") is a critical component of PAHO's technical cooperation program. The program is aimed at improving access to quality, safe and secure health technologies and strengthening health systems. Recognizing that sharing resources/information among Member States strengthens efforts to enhance regulatory functions, PAHO actively works to facilitate technical cooperation among NRAs.

WHEREAS PAHO's Regional Platform on Access and Innovation for Health Technologies (PRAIS) provides a network for regional and international stakeholders that promotes cooperation and communication among health technologies stakeholders.

WHEREAS NRAs in the Americas Region and globally that wish to share documents that include non-public information (NPI) do not have a dedicated tool to support a dynamic and secure exchange. Such a tool would permit the exchange of documents on regulatory processes and decisions related to all health technologies such as Good Manufacturing Practices ("GMP") reports, audit reports and other documents related to medicines, medical devices and other health technologies. Access to a secure exchange tool would support more efficient and timely

regulatory decisions and improve collaborative approaches and mutual reliance among NRAs in an increasingly global regulatory landscape.

WHEREAS the Participants intend to combine efforts toward developing of the Regulatory Exchange Platform—secure ("REPs"), a joint global IT portal solution to support the secure exchange of NPI between NRAs ("participating NRAs"). This should maximize the uses of a single platform to add efficiencies and tracking, and limit redundant efforts.

WHEREAS PAHO is in a unique position to act as the convening entity and facilitator for the development, deployment and administration of REPs , which is intended to facilitate the exchange of NPI and support the collaboration of regional and possibly global regulators in a secure IT environment.

NOW THEREFORE the Participants enter into this MOU for the development and implementation of REPs.

Section 1: Purpose of the MOU

The purpose of this MOU is to describe how the Participants intend to work together to develop and implement REPs, attached as Annex 1 and constitutes an integral part of this MOU.

Section 2: Objectives of the Cooperation

The overall goal of the cooperation is to develop and implement REPs, an IT portal to facilitate the secure exchange of NPI between NRAs, thereby enhancing cooperative efforts and joint work and contributing to improve national regulatory decisions on health technologies on an international scale, with direct impact to public health in the Americas and beyond.

Section 3: Intentions of PAHO

Pursuant to its rules, regulations, policies and procedures, and subject to the availability of funds, PAHO, intends to:

a. Be responsible for the development and the administration of REPs.
b. Contract a third party to design, develop, host, and service REPs.
c. Act as secretariat vis-à-vis participating NRAs to administer REPs.
d. Use its best efforts to safeguard the information and data on REPs and use its best efforts to maintain REPs operations. Best efforts are defined as utilization of security standards recommended by participating NRAs and agreed in advance by PAHO.
e. Adhere to a privacy policy safeguarding, to the extent possible, the confidentiality of the information furnished by the participating NRAs.
f. Refrain from reviewing or generally accessing the confidential or sensitive information contained on REPs. PAHO intends to only access this information, as necessary, to address issues that may arise and, when possible, with prior authorization of the participating NRAs.
g. Provide advance notice, when possible, to participating NRAs of any server maintenance

that may affect the availability of or access to REPs.

h. Carry out any modification that it considers necessary for maintaining/adjusting REPs system operation, and may do so without notifying users.

Section 4: Intentions of the FDA

Pursuant to its rules, regulations, policies and procedures, FDA intends to:

a. Maintain existing legal rights and/or secure the necessary rights to place or exchange information through REPs, either directly or through PAHO.
b. Maintain existing and/or secure the necessary bi-lateral or multi-lateral agreements in place to share information through REPs with its intended recipients.
c. Ensure that confidential or sensitive information is made available only to its employees or personnel on a "need to know" basis. FDA intends that no information will be made available to third parties without written authorization from the relevant NRA or PAHO, as applicable and that all information, reports and documents placed and contained on REPs will be considered non-public.
d. Monitor the use of REPs by the registered users within its institution, safeguarding the user names and passwords issued for access.
e. As part of the MDSAP Consortium requirements for auditing organizations, include a requirement that the auditing organization's legally enforceable arrangements with manufacturers contains a provision allowing for sharing of documents and records related to medical devices to other Regulatory Authorities through REPs, which is administered by PAHO, and said manufacturers should further agree to indemnify PAHO for any and all claims, demands, and/or liabilities arising out of or related to its documents and records on REPs.

Section 5: Coordinators

The Participants designate the following individuals to serve as the coordinators or focal points for the implementation of this MOU, until notification to the contrary:

By PAHO: Analia Porras, Unit Chief of Medicines and Health Technologies - Department of Health Systems and Services - HSS/MT

By the FDA: Neil A. Mafnas, LCDR, USPHS, Senior Regulatory Operations Officer, CDRH/OC/DICO

Section 6: Reporting

PAHO intends to prepare an annual technical progress report on REPs.

Section 7: Personnel

Personnel assigned to work on REPs by each Participant are intended to remain employees of the Participant.

Section 8: Intellectual Property

All rights, including title, copyright, patent or related rights resulting from the design, development, implementation, and administration of REPs, are intended to be vested in PAHO, which will be entitled to make changes, if necessary. It is intended that PAHO will retain custody of and have primary rights to the data and software. There is no intention for this clause to modify or supersede the rights and obligation of the Participants with respect to existing agreement(s) that relate to funding of REPs.

Section 9: Privileges and Immunities

Nothing contained in this MOU is intended to be deemed a waiver, express or implied, of any immunity from suit, judicial process, confiscation, taxation or other immunity or privilege which the Participants may enjoy, whether pursuant to treaty, international convention, law, order or decree of an international or national character or otherwise, including but not limited to the International Organizations Immunity Act (22 U.S.C.A. Section 288 et. seq.).

Section 10: Disclaimer

PAHO intends to use best efforts to ensure that the REPs will, under normal use, perform substantially in accordance with the standards set forth the Statement of Work (Annex 2). This is conditioned on users' observance of all operating, security and data control procedures set forth in the Statement of Work. Accordingly, it is PAHO's intention:

a. Not to provide any warranties, or assume any legal liability or responsibility for the accuracy, completeness or usefulness of any of the information published or transmitted through REPs; and unless expressed herein, not to grant or imply any condition, warranty or representation in relation to REPs, includes any related to failure of performance, error, omission, interruption, deletion, defect, delay in operation or transmission, computer virus, communication line failure, breach or destruction.
b. Not to be responsible for any damages, claims or costs whatsoever, or any consequential indirect or incidental damages or any loss related to or derived from the use of REPS, even if a PAHO representative has been advised of the possibility of such loss, damages, claims or costs; and not to be responsible for any claim arising out of use or inability to use the REPs.
c. Not to be responsible for information published on REPs, whether by PAHO or Participants; and not to have any obligation to monitor or control the content stored by REPs users, and therefore not be held responsible for any information or statement by

REPs users, including any of an illegal, immoral, or unethical nature.

d. Not to be liable in the event that confidential or sensitive information provided by a participating NRA and/or users is disclosed or accessed without authorization.
e. To use its best efforts to safeguard the information provided, but in no case to be liable for any harm, consequence, or effect, direct or indirect, occurring.

Section 11: Conflict Resolution

PAHO and the FDA intend that any dispute arising under this Memorandum of Understanding be solved amicably through consultations, discussions and negotiations between the Participants.

Section 12: Effective Date, Modification, and Termination

a. This MOU takes effect on the date of last signature by both Participants and remain in effect until terminated by the Participants.

b. This MOU may be modified in writing by the Participants. In addition, either of the Participants may terminate this MOU by giving 60 days advance notice in writing.

IN WITNESS WHEREOF, the duly authorized representatives sign this MOU in two (2) copies of equal content and validity, on the dates and in the places indicated below.

FOR THE FOOD AND DRUG ADMINISTRATION
UNITED STATES OF AMERICA

---/s/---

Howard R. Sklamberg, J.D.
Deputy Commissioner for Global Regulatory Operations and Policy

Place: Silver Spring, Maryland
Date: April 25, 2016

FOR THE PAN AMERICAN HEALTH ORGANIZAITON,
REGIONAL OFFICE OF THE WORLD HEALTH ORGANIZATION

---/s/---

Dr. Carissa F. Etienne
Director

Place: Washington, D.C.
Date: MAY 05 2016