Work Order # 1

This Work Order # 1 ("Work Order") is made and entered into on 1 December 2015 ("Work Order Effective Date") by and between **Sandoz International GmbH**, located at Industriestraße 25, 83607 Holzkirchen, Germany ("**Sandoz**") and **Trustees of Boston University**, located at 25 Buick Street, Boston, MA 02215, USA ("**Service Provider**"), hereinafter jointly referred to as the "**Parties.**"

WHEREAS, Sandoz and Service Provider have entered into a Master Services Agreement dated 20 November 2015 (the "**Master Agreement**");

WHEREAS, pursuant to the Master Agreement, Service Provider has agreed to perform certain Services in accordance with Work Orders from time to time entered into by the Parties, and Sandoz and Service Provider now desire to enter into such a Work Order; and

WHEREAS, Sandoz and Service Provider desire that Service Provider provide certain services with respect to Sandoz's project entitled Novartis Access Programme ("**Project**").

NOW THEREFORE, in consideration of the mutual covenants and promises contained herein, the parties agree as follows:

1. Project Specifications. Service Provider agrees to perform the services described in Appendix A, which is attached hereto and incorporated herein by reference ("Services").

2. Compensation.

2.1 In consideration of the Services performed by Service Provider, Sandoz agrees to pay to Service Provider the amounts set forth in the Budget, which is attached hereto and incorporated herein by reference as Appendix B. Except as otherwise pre-approved by Sandoz in writing, the total payments for Services under this Work Order shall not exceed US [redacted] Dollars), exclusive of any applicable taxes.

2.2 In addition, Sandoz will pay the pass-through expenses identified in the Budget set forth in Appendix B, or as reasonably required to be incurred by Service Provider in connection with the Services (such as for travel following Sandoz travel policy and international courier charges), subject to production of receipts or other evidence of payment, all as preapproved in writing by Sandoz. Reimbursement of travel expenses shall be subject to the following:

(a) Travel expenses shall, however, be reimbursable only subject to production of receipts or other evidence of payment.
(b) Service Provider should use the most cost-effective and safe means of getting to final destination / place of performance, including public transport, where reasonable.
(c) Train: Travelers are entitled to first class rail travel.
(d) Flight: For the selection of the flight class the following rules apply: For domestic flights to destinations and where reasonably acceptable (up to four (4) hours flight time) economy class tickets have to be booked. For international flights to all other destinations business class tickets are permitted. For cost reasons

air travel should not be used for short distances unless this substantially reduces the absence from the place of performance and/or if high accommodation costs can be avoided.

(e) Private Car: Business trips by private car will be reimbursed at the rate of EUR 0.30 per kilometer.

(f) Accommodation: Reasonable accommodation to be agreed with Sandoz in advance.
Hotels where Novartis has special price arrangements have to be chosen whenever possible.

Except as otherwise pre-approved by Sandoz in writing, the total payments for pass-through expenses under this Work Order shall not exceed 0 US Dollars, exclusive of any applicable taxes.

2.3 Service Provider acknowledges and agrees that: (i) the compensation paid for the Services is consistent with the fair market value in arm's length transactions and has not been determined in a manner that takes into account any referrals or other business generated between Service Provider and Sandoz; (ii) all amounts received are only for legitimate expenses, reimbursement of such expenses or compensation for the performance of the Services and that nothing in this Agreement shall require, induce or in any way influence Service Provider to promote, recommend, require the use of or list on any formulary, any pharmaceutical or biopharmaceutical product(s) manufactured, produced or distributed by Sandoz; and (iii) receipt of such amounts is in full accordance with all applicable laws, regulations and policies.

3. Key Personnel. The following persons are responsible for performing the Services and/or overseeing the Project hereunder:

Service Provider: Dr. Richard Laing
Title: Professor, Global Health Department
Address: Boston University, Center for Global Health and Development, 801 Massachusetts Avenue, 3rd Floor Boston, MA 02118, USA
Phone: [redacted]
Fax: [redacted]
Email: [redacted]

Sandoz: [redacted]
Title: Global Head, Novartis Access
Address: Sandoz International GmbH, Industriestr. 25, D-83607 Holzkirchen, GERMANY
Phone [redacted]
Fax
Mobile
Email:

4. Term. This Agreement shall become effective on the Work Order Effective Date and shall remain in force until completion of the Services under this Work Order, unless earlier terminated under the terms of the Master Agreement.

5. Incorporation by Reference; Conflict. The provisions of the Master Agreement are expressly incorporated by reference into and made a part of this Work Order. By signing this Work Order, the Parties hereto (if not Parties to the Master Agreement) agree to adhere to the terms and conditions of the Master Agreement. In the event of a conflict between the terms and

conditions of this Work Order and the Master Agreement, the terms and conditions of the Master Agreement will take precedence and control.

IN WITNESS WHEREOF, the Parties have signed this Work Order effective as of the Work Order Effective Date.

Sandoz International GmbH

By: [redacted]

Name: [redacted]

Title: Global Head Novartis Access

Date: 23.12.2015

By: [redacted]

Name: [redacted]

Title: Head Legal Novartis Access

Date: 22 Dec 2015

Trustees of Boston University

By: [redacted]

Name: [redacted]

Title: Associate Director
Industry Contracts & Agreements

Date: 12/23/2015.

By: _____

Name: _____

Title: _____

Date: _____

Read and Acknowledged:

R O Laing

Dr. Richard Laing

Date: 23 Dec. 2015

List of Appendices:

Appendix A: Project Specifications
Appendix B: Budget

Appendix A
Project Specifications

NOVARTIS ACCESS

CENTER FOR GLOBAL HEALTH & DEVELOPMENT (CGHD)

OBJECTIVES & RATIONALE FOR COLLABORATION

The Center for Global Health & Development (CGHD) at Boston University (BU) is a multidisciplinary research center that engages faculty from across the University to help solve the critical global health and social development challenges of our time. The mission of the center is to conduct high-quality applied research to improve the health of underserved populations. Through our collaborative work with scientists worldwide, we seek to strengthen individual and institutional capacity to conduct and utilize research.

CGHD has capabilities and experience relevant to the Novartis NCD Medicines Access Initiative (called *Novartis Access*) in the following areas:

1. Monitoring and Evaluation, including experience monitoring medicines prices and availability
2. Non-Communicable Disease (NCD) research and program experience
3. Country-level experience in Kenya, Zambia, Vietnam, Latin America, and other countries
4. Health Systems Strengthening initiatives
5. Evaluation of Corporate Social Responsibility (CSR) activities and Public-Private Partnerships
6. Skilled faculty and staff experienced in design and conduct of evaluations and in the field of essential medicines and NCDs, and institutional capacity to administer grants, communicate with and supervise field-based research teams, and systems to ensure compliance with ethical procedures when working with research subjects and confidential data.
7. Publications of reports and peer-reviewed papers in high impact journals (see Annex 1)

The *Novartis Access* aims to improve access to NCD medicines for low income household in a number of low and middle income countries over the next three to five years. The funders of *Novartis Access* –Novartis/Sandoz- decided to invest in the Initiative over the next five years from September 2015 to 2020.

The goal of *Novartis Access* is to contribute to improving population health through the provision of high quality medicines for the prevention and treatment of NCDs. The initiative will, increase availability and affordability as well as promoting appropriate use of NCD medicines. Several specialized resource partners such as faith-based organizations providing NCD care have joined *Novartis Access* as implementing partners. Boston

University will be a specialized resource partner responsible for the monitoring and evaluation of the initiative.

The objective of the collaboration between Novartis/Sandoz and BU from December 2015 to April 2016 is to twofold: a) to provide technical advice to Novartis in the design of *Novartis Access*; b) to develop a monitoring and evaluation plan measuring the impact of the *Novartis Access*.

During the first four months of the collaboration the BU team will carry out the following technical assistance activities and tasks:

- Provide technical advice to Novartis/Sandoz on the development of the *Novartis Access* and its implementation plan in the initial pilot phase. This would include advice to Kenya based staff how to undertake an initial assessment of availability and prices of a core set of essential NCD and other medicines.
- Assist *Novartis Access* in the development of a proposal to monitor and evaluate the project implementation and outcomes.
- Develop data collection and analysis instruments for baseline, interim and final country studies as well as for the sentinel surveillance monitoring system.
- Develop manuals to train field workers to collect data during the different phases and activities of the evaluation
- Obtain ethical approval by the BU Institutional Review Board (IRB) and the Kenyan local IRB to conduct the evaluation in Kenya
- Prepare a report that presents the proposal for the evaluation including all necessary data collection instruments and manuals

Note that the location of the baseline, interim and final evaluation of the *Novartis Access* may be determined based on the experience during the launch in late 2015 in Kenya.

SOW for Program Year 1, first five months (December 2015 to April 2016) Activities:

Specifically for the period December 2015 to April 2016, BU will complete the following tasks:

Activity 1 Consultancy to advise Novartis/Sandoz

Background statement:

The technical assistance will consist of providing verbal or written feedback to queries directed to Drs. Laing and Wirtz by the Novartis/Sandoz team with respect to the implementation of *Novartis Access* in Kenya and any other country where the intervention will be implemented between December 2015 and April 2016.

Specific tasks to be performed:

Regular conference calls will be conducted in which the Novartis team can discuss technical aspects of the project implementation. Advice includes, among other issues, choice of local implementing partners, locations of project operation, and advice on portfolio of medicines and initial indicators to be collected by Novartis/Sandoz field staff. In addition, assistance with analysis of this early data may be provided. In addition advice will be provided to Kenya field staff to assist them in undertaking an assessment of availability and prices of NCD and other medicines in different areas of Kenya.

Activity 2 Develop proposal to monitor and evaluate *Novartis Access*

Background statement:

BU will be responsible for developing a monitoring and evaluation plan for *Novartis Access* between December 2015 and April 2016. This will include the development of a study proposal, data collection and analysis instruments, data transfer, analysis procedures and platforms. In addition, BU will be tasked to produce training manuals for field staff and submit the proposal for ethical review to local review boards in Kenya as well as the BU's Medical Campus Institutional Review Board.

Specific tasks to be performed:

1. Develop a detailed technical proposal for baseline data collection and sentinel surveillance of key indicators for *Novartis Access*, including both qualitative and quantitative data collection (e.g. availability and price at facility level);
2. Incorporate feedback by Novartis about the technical proposal;
3. Develop data collection and analysis instruments and tools;
4. Produce a manual for trainers to train supervisors and data collectors;
5. Produce a manual for data collectors and field supervisors for conducting field work;

6. Submit study protocol to BUMC IRB and the appropriate local or national IRB for approval by the end of December. Incorporate comments received;
7. Work with other implementation partners of Novartis Access to identify training needs for the baseline study, and align on quantitative data collection and analysis, qualitative data collection and analysis, and sentinel surveillance system for monitoring.
8. Based on Phase I products, develop SOW and budget for Phase II

Deliverables or products to be developed

- Written and verbal comments on the consultation queries by Novartis
- Summary document of the proposal
- Data collection instrument(s) at facility level
- Data collection instrument(s) at household level
- Training manual for trainers of field workers
- Manual for data collector/field workers
- Supervisors manual
- Proposal for pilot test of instruments, manuals and analysis tools.
- Phase II SOW, timeline, and budget

Core Personnel Bios

Richard Laing, Principal Investigator, MB, ChB, MSc, MD. Originally trained as a medical doctor, Dr. Laing worked for the Ministry of Health in Zimbabwe for over 18 years, during which time he undertook postgraduate Masters and Doctoral studies on Community Health for Developing Countries and on Comparative Health Systems & Policy Analysis. After receiving his degrees, he spent six years working for Management Sciences for Health (MSH) and establishing the International Network for the Rational Use of Drugs. Following his work with MSH, Dr. Laing taught international public health at the Boston University School of Public Health (BUSPH) before joining WHO as a medical officer. At WHO, he led the team responsible for Medicines Evidence and Information for Policy, and was editor of the Essential Drugs Monitor. He was one of the authors of the Priority Medicines for Europe and the World report 2004 (and the update in 2013), and of the report From Access to Adherence: The Challenges of Antiretroviral Treatment. He has been engaged in measurement of medicines pricing and availability as part of the joint WHO/HAI project on medicine prices. Working with IMS Health, he has reported on the impact of the global recession on the pharmaceutical sector. Recently he has published research on the availability and price of chronic disease medicines. He was also the editor for the third edition of the World Medicines Situation Report. Dr. Laing has rejoined the faculty at BUSPH and teaches on pharmaceutical topics within the Pharmaceuticals Program including a course on Analyzing Pharmaceutical Systems. Dr Laing has extensive experience in developing pharmaceutical country profiles, investigating medicine use in developing countries and advising on National Medicine Policies.

Veronika Wirtz, Co-Investigator, MSc, PhD. Dr. Wirtz is Associate Professor of Global Health at Boston University School of Public Health (BUSPH) where she teaches courses in health systems, pharmaceuticals in public health, and non-communicable diseases. She is a Visiting Professor of the National Institute of Public Health (INSP) in Mexico and coordinator of a student exchange program between the institutions of her affiliation. Trained as a pharmacist, Dr. Wirtz's interests and areas of expertise include medicines price analysis, generic medicines policies, access to medicines for non-communicable diseases and the role of the private sector to promote equitable access and efficient use of medicines in low and middle income countries. As an INSP researcher and lecturer from 2004 to 2012, she carried out pharmaceutical policy analysis in Mexico and Latin America. She has also worked with the Ministry of Health in Mexico on several program evaluations and capacity building initiatives. Dr. Wirtz has worked as a technical advisor for various international organizations, including WHO, the Pan American Health Organization, the Global Fund to fight AIDS, Tuberculosis and Malaria, the Bill and Melinda Gates Foundation, Alliance for Health Systems and Policy Research, Health Action International, and the Ford Foundation. Recently she became the Co-Chair of The Lancet Commission on Essential Medicine Policies. She received her training as a pharmacist from Albert-Ludwigs-University in Freiburg, Germany and her Master in Clinical Pharmacy and PhD from the University of London in the UK.

Taryn Vian, Co-Investigator, MSc, PhD. Dr. Vian is Associate Professor of Global Health. She was the Project Director for the Pfizer Global Health Fellows Evaluation (2007-2010), and the Lesotho PPP Endline Evaluation (2013), overseeing the study design, technical implementation, data analysis, and reporting. From 2007 to 2009, Dr. Vian served as a Management Advisor to the Transforming District Hospitals initiative in Lesotho where she helped design improved tools for financial management, budgeting, and planning in district hospitals. Since 2013, Dr. Vian has been part of the evaluation team for the Merck for Mothers Maternity Access Project in Zambia, guiding analyses of willingness to pay, governance and sustainability. Prior to joining Boston University in 1999, Dr. Vian worked as a Senior Health Financing Advisor for Management Sciences for Health (MSH), and as a Health Economist for Abt Associates, Inc., advising governments in many countries on health financing policy and management. Dr. Vian has worked in 35 countries on policy studies related to health systems strengthening and management. She participates on the WHO Technical Working Group for Good Governance in Medicines, the Steering Committee for the Evaluation of the global Medicines Transparency Alliance (MeTA), and the USAID Technical Advisory Group for Supply Chain Sustainability. A former Peace Corps volunteer in Cameroon, she holds a PhD in Public Policy and Global Health from Boston University and an MSc degree in Health Policy and Management from the Harvard School of Public Health.

Peter Rockers, Co-Investigator, MPH, ScD. Dr. Rockers is an Assistant Professor at the Center for Global Health & Development and in the Department of Global Health. He is Director of the Monitoring & Evaluation Certificate Program at the Boston University School of Public Health. Dr. Rockers has several ongoing evaluation studies testing the impacts of health system strengthening interventions in developing country settings. In South Africa, he is Principal Investigator for three projects, variously testing: the impact

of improved financial management at primary care facilities on service delivery and population health outcomes; the effects of mHealth supervision and support on the productivity and effectiveness of community health workers; and the impact and sustainability of a home-based early childhood development program delivered by community health workers. Dr. Rockers is also Co-Principal Investigator for two ongoing cluster-randomized trials in Zambia to test the effects of household interventions that aim to improve child physical and cognitive development through better health and nutrition. Finally, Dr. Rockers is a Co-Investigator on a large cluster-randomized trial in Zambia that aims to test the impact of maternity homes on women's access to and use of facility-based delivery services. Dr. Rockers received a Master of Public Health degree from the University of Michigan and a Doctor of Science degree from the Harvard School of Public Health.

Paul Ashigbie, Research Fellow, B.Pharm, MPH, DrPH student. Paul Ashigbie is a Research Fellow at the Department of Global Health at the Boston University School of Public Health (BUSPH). He is a Pharmacist from Ghana with over six years' work experience in various fields of pharmacy practice including regulation, community and clinical pharmacy practice and as a Medical Representative. Mr. Ashigbie has extensive experience in health policy and systems analysis, quantitative and qualitative data collection, analysis and reporting. Before joining the Department of Global Health, he had worked as a Research Assistant at the Department of Family Medicine at Boston University, gathering and analyzing market information on donor funded HIV, malaria and tuberculosis medicines and diagnostics in low and middle income countries. Since 2012, Mr. Ashigbie has taken part in the annual evaluation of the work of Pfizer Global Health Fellows in strengthening health systems in resource constrained countries. He has worked with the WHO on the 2010 Pharmaceutical Country Profile Pilot Survey, and contributed a chapter and background paper on the treatment of post-partum hemorrhage in the 2013 edition of the Priority Medicines for Europe and the World report. He is also one of the authors of *Medicines in Health Systems* the 2014 Flagship report of the Alliance for Health Policy and Systems Research. Mr. Ashigbie is enrolled in the Doctor of Public Health Program at BUSPH. His research and professional interests include pharmaceutical regulation and access to medicines in developing countries.

References:

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Gantt chart: Timeline BU Novartis Access collaboration Initial Activity

	Phase I: December 2015 – April 2016																				Phase II: May 2016 onwards*											
	Dec 2015				Jan 2016				Feb 2016				March 2016				April 2016				May				June				July			
Activities/week	1	2	3	4	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	1	2	3	4	5	6	7	8	9	10	11	12
Proposal development																																
Facility data collection instruments																																
Household data collection instruments																																
Data analysis instrument																																
Field worker manual																																
Supervisor manual																																
Training manual																																
BU Institutional Review Board (IRB) submission																																
Revision of BU IRB submission																																
Local, in-country IRB submission																																
Revision of local in-country IRB submission																																
Submission of final proposal report																																
Development of phase II																																
Pilot test proposal																																
Conduction of pilot																																
Analysis of pilot and adaptation of instruments																																
Start of baseline assessment																																

*Note: Phase II activities are illustrative only; they are not included in the Phase I budget or Scope of Work