The *Building UDI Into Longitudinal Data for Medical Device Evaluation* (BUILD) Consortium Charter

I. **Vision**

The BUILD Consortium provides leadership for a collaborative and coordinated effort to establish implantable device data capture and exchange using Unique Device Identification (UDI) as a best practice in U.S health care.

II. **Project Overview**

The BUILD initiative includes creation of a consortium of health care systems and manufacturers, hereafter called the BUILD Consortium. Members of the BUILD Consortium will support the BUILD initiative through their involvement with and collaborative focus on capture and exchange of implantable device data that includes UDI. The primary focus will be cardiac stents, pacemakers, cardioverter defibrillators, leads, and implant components/systems for hip and knee arthroplasty, with the intent to develop processes, procedures, and methods generalizable to all implantable medical devices. BUILD Consortium work will include an advisory role for the BUILD initiative which will be working in partnership with the U.S. Food and Drug Administration (FDA), MDEpiNet, and the Learning UDI Community, providing subject matter expertise regarding the current environment of implantable device data capture and exchange using UDI, the use and application of UDI, delineation of leading practices and barriers, deliberation on potential new technologies and processes to address barriers, and involvement in the development of future directions including pilot studies and initiatives based on project outcomes.

Public Health Impact – As key stakeholders for medical device data capture and exchange that includes UDI, health care systems and manufacturers play an important role in impacting patient safety and the Triple Aim goals of improved patient experience of care, improved health of populations, and lowered cost surrounding medical devices.

The project duration is expected to be 3 years, dependent on continued grant support by the funding agency.

III. Project Purpose

Medical device data capture and exchange using UDI is foundational to having robust device data for use in medical device evaluation, postmarket surveillance, and effectiveness research to support device innovation and to inform device safety and protect U.S. public health. As we move toward the creation of the National Medical Device Evaluation System (NMDES), it is necessary to facilitate more efficient implantable medical device data capture and exchange from manufacturer to clinical care via UDI. Understanding the roles, needs, and synergies of manufacturers and health care systems towards this goal, and supporting collaborative work for advancement is a key initiative. Whereas manufacturers have been mandated to label their marketed implantable devices with UDI and have

needed to ready their organizational systems for UDI labelling and input of required data to the Global UDI Database (GUDID), the number of health care systems that are successfully capturing and exchanging implantable device data using UDI is very limited. Additionally limited is collaborative work between health care systems and manufacturers to share knowledge and leading practices and to address barriers for advancement in this area. The interprofessional collaboration of the BUILD Consortium is expected to contribute significantly to the development of an ongoing Learning UDI Community, lead to new insights, provide leadership for the broader group of stakeholders and peers, and support advanvcement of medical device data capture and exchange using UDI as a best practice in U.S. health care.

IV. Goals

1. Promotion of collaboration and coordination to advance implantable device data capture and exchange using UDI
2. Provision of subject matter expertise and perspective for the BUILD Initiative
3. Delineation of the current environment for implantable device data capture and exchange using UDI including industry leaders, complementary initiatives, leading practices, barriers, and resources
4. Conceptualization of pilot projects and initiatives to study new process, technologic advancement, and address barriers, and methods for coordination with complementary efforts

V. Expectations

1. Attendance at quarterly BUILD Consortium Adobe Connect meetings throughout the duration of the project
2. Attendance at the in person BUILD Consortium meeting in Year 3 of the project
3. Exchange of meeting minutes, action items, and other materials as needed in-between regularly scheduled meetings. Communication management detailed in X4 below.
4. Availability for communication as needed in-between regularly scheduled meetings.
5. Participation in BUILD project workgroups as needed
6. Materials developed through the BUILD Consortium are intended for advancement of implantable device data capture and exchange using UDI

VI. Scope

Primary focus is on cardiac stents, pacemakers, cardioverter defibrillators, leads, and implant components/systems for hip and knee arthroplasty, but with the intent of developing systems and methods that are generalizable to all implantable medical devices. BUILD Consortium work is meant to be collaborative and coordinate with the Learning UDI Community but be specific to the advancement of implantable device data capture and exchange using UDI for public health and in support of the NMDES. While in development, draft documents are not intended to be publicly shared outside of the Consortium.

BUILD research team leadership has to approve new members or member substitutions in the BUILD Consortium. Work through the BUILD Consortium is not paid. The BUILD initiative is being carried out under the terms of a collaborative agreement with the FDA that includes involvement of FDA representatives in all aspects of the BUILD initiative.

VII. Timeline, Milestones, Deliverables

Timeline	
Project Begins	January 1, 2016
Quarterly Meeting	July 2016
Quarterly Meeting	October 2016
Quarterly Meeting	January 2016
Quarterly Meeting	April 2017
Quarterly Meeting	July 2017
Quarterly Meeting	October 2017
Quarterly Meeting	January 2017
In Person Meeting	April 2018
Quartley Meeting	July 2018
Project End	August 31, 2018

Major Milestones and Deliverables	
BUILD Consortium Charter	April 30, 2016
BUILD Consortium Member List	April 30, 2016
Initial BUILD Consortium Meeting	July 2016
Annual Summary of BUILD Consortium Progress	August 2016, 2017, 2018
White Paper	Year 3
Commentary for Peer-Review Journal and/or Webinar	Year 3
Manuscript for Peer-Review Journal	Year 3

VIII. Measurables/Metrics

1. Environmental scan of medical device data capture and exchange using UDI
2. Reference list of industry leaders for medical device data capture and exchange using UDI
3. Catalog of articles, white papers, and other resources for the BUILD UDI Link
4. Processes and leading practices document
5. Pilot projects and initiatives to test new process and technologic advancement, and address barriers

IX. Budget

The BUILD initiative is funded by the FDA. Funding is provided for investigators to conduct overall work of the project including creation and leadership of the BUILD Consortium.

X. BUILD Consortium

1. Research Team members
    i. Natalia Wilson, MD MPH, Principal Investigator of Medical Device Capture and Exchange: Leading Practices and Future Directions, Arizona State University
    ii. Joseph Drozda, MD, Principal Investigator of the BUILD Initiative, Mercy
    iii. James Tcheng, MD, Co-Principal Investigator of the BUILD Initiative, Duke University Medical Center
    iv. Mike Schiller, Project Consultant for Medical Device Capture and Exchange: Leading Practices and Future Directions, Association of Healthcare Resource and Materials Management
    v. Alexzandra Douglass, Graduate Research Assistant, Arizona State University
    vi. Anticipated additional research team members in Years 2 & 3: Dave Kaufman, PhD, Co-investigator, ASU, Davide Sottara, PhD, Co-investigator, ASU, David Slotwiner, MD, Principal Investigator of ePulse, NY Presbyterian Hospital
2. Health Care system & Manufacturer Members – List in development
3. Government Respresentatives
    i. Terrie Reed, Senior Advisor for UDI Adoption, US FDA
4. Communication Management
    i. Prior to the first BUILD Consortium meeting, each member will receive a copy of the Charter, list of members with biographies, summary of the BUILD Project, and list of BUILD project investigators with biographies
    ii. Communication to members will be accomplished via email by the ASU graduate research assistant
    iii. Members will need access to email and Adobe Connect for quarterly Consortium meetings
    iv. Members will receive via email the meeting agenda and associated materials prior to quarterly meetings and the meeting minutes after quarterly meetings

XI. Appendix

1. References
    i. Gross TP, Crowley J. Unique Device Identification in the Service of Public Health. *N Engl J Med*. 2012;367(17):1583-1585
    ii. Wilson NA, Drozda J. Value of Unique Device Identification in the Digital Health Infrastructure. *JAMA*. 2013;309(20):2107-2108

iii. Unique Device Identification System. 78 Fed.Reg. 58785 (September 24, 2013)
iv. Campion TR, Johnson SB, Paxton EW, Mushlin AI, Sedrakyan A. Implementing Unique Device Identification in Electronic Health Record Systems. Organizational, Workflow, and Technologic Challenges. *Med Care*. 2014;52(1):26-31
v. Wilson NA, Jehn M, York S, et al. Revision Total Hip and Knee Arthroplasty Implant Identification: Implications for Use of Unique Device Identification 2012 AAHKS Member Survey Results. *J Arthroplasty*. 2014;29:251-255
vi. Tcheng JE, Crowley J, Tomes M, et al. Unique device identifiers for coronary stent postmarket surveillance and research: A report from the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier Demonstration. *Am Heart J*. 2014;168(4):405-413
vii. Daniel G, McClellan M, Gardina S, Deak D, Bryan J, Streit C. *Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation*. The Brookings Institution. Washington, D.C.; December 2014
viii. Daniel G, McClellan M, Colvin H, Aurora P, Khaterzai S. *Strengthening Patient Care: Building an Effective National Medical Device Surveillance System*. The Brookings Institution. Washington, D.C.; February 2015.
ix. Drozda JP, Dudley C, Helmering P, Roach J, Hutchison L. The mercy unique device identifier demonstration project: Implementing point of use product identification in the cardiac catheterization laboratories of a regional health system. *Healthcare*. doi:10.1016/j.hjdsi.2015.07.002 (in press)
x. Wilson N, Broatch J, Jehn M, Davis C. National projections of time, cost and failure in implantable device identification: Consideration of unique device identification use. *Healthcare*. 2015;3(4):196-201.
xi. NMDES Planning Board. *Better Evidence on Medical Devices: A Coordinating Center for a 21st Century National Medical Device Evaluation System*; Duke-Margolis Center for Health Policy; April 2016.

2. Key terms
   i. Global Unique Device Identification Database (GUDID): A database created the U.S. FDA and administered by the National Library of Medicine that will serve as a reference catalog for every device with a UDI.
   ii. Implantable device: A medical device that is placed inside or on the surface of the body and may be permanent or removable.
   iii. Learning UDI Community: A privately led multi-stakeholder group with the goal of creating a repeatable and generalizable framework for coordinating with expert workgroups to

produce tools, resources, best practices, and implementation guidelines for community-identified UDI adoption issues

iv. Medical Device Epidemiology Network (MDEpiNet): A public-private partnership focused on innovative data source development and analytic methodologies to enhance regulatory science applied to medical device research and surveillance.

v. National Medical Device Evaluation System (NMDES): A proposed coordinated network of voluntary partnerships that include patient communities, government agencies, device manufacturers, institutional data partners, and methods partners, all working together to generate higher quality post-market device data and evidence at lower costs to inform and improve patient care.

vi. Unique device identification (UDI): A unique identifier for medical devices that is required on the label, packaging, and/or actual medical device in both human and machine readable forms.