MEMORANDUM OF UNDERSTANDING
FOR DATA SHARING AND USE

This Data Sharing and Use Agreement ("**Agreement**") is made and entered into by and between Acumen, LLC, a California limited liability company located at 500 Airport Blvd., Suite 100, Burlingame, CA 94010 ("**Acumen**"), and the Virgin Islands Department of Health, Immunization Division (the "Participating IIS Jurisdiction"), an executive agency of the Government of the U.S. Virgin Islands of U.S. Virgin Islands (IIS Jurisdiction "**IISJ**"). Acumen and IISJ may be referred to herein collectively as the "**Parties**" or individually as a "**Party**" through the Virgin Islands Department of Property and Procurement. This Agreement shall be effective upon its execution by all signatories ("**Effective Date**") is made this 23rd day of October, 2022, in the Territory of the U.S. Virgin Islands.

WHEREAS, Participating IIS Jurisdiction is a governmental agency created under law and a public health authority under 45 CFR §164.501 of the regulations promulgated under the Health Insurance Portability and Accountability Act (**HIPAA**). Among its authorized public health activities is the receipt of information and reports concerning immunization, vaccination, disease, injury, and vital events for purposes including public health surveillance, investigations, and interventions;

WHEREAS, under the sponsorship of the Center for Biologics Evaluation and Research (**CBER**) of the Food and Drug Administration (**FDA**), Acumen serves as a Trusted Agent contractor of the FDA ("**FDA Agent**") in its surveillance programs monitoring the safety and effectiveness of vaccines distributed to the U.S. market; in this role, Acumen acts as a "public health authority" as defined in 45 CFR §164.501 of HIPAA;

NOW, THEREFORE, in consideration of the mutual covenants, terms, and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Background and Purpose

1.1 Background.

FDA launched the Biologics Effectiveness and Safety (BEST) Initiative in 2017 to enact an active post-market surveillance of the safety and effectiveness of biologic products, with BEST promulgated by the 21st Century Cures Act of 2016 (Cures Act). The Cures Act directed FDA to establish a regulatory framework incorporating use of real-world evidence to support expedited product development and conduct post-approval evaluations of product outcomes. A major component of BEST comprises rapid-cycle surveillance of the health outcomes related to immunizations, with its findings intended to inform FDA in its regulatory actions affecting the use and availability of different vaccines in U.S. healthcare markets.

Acumen serves as the primary FDA/CBER contractor providing the data analysis services necessary for the near real-time monitoring of the use of vaccines in the Medicare and Medicaid populations. Acumen's activities principally focus on establishing and building reliable capacities to conduct analyses of data from national electronic healthcare systems to follow the experiences of immunized individuals, assessing the extent to which these individuals experience various adverse (safety) and favorable (effectiveness) outcomes potentially attributable to vaccination. Acumen's data holdings include complete historical medical encounters and enrollment data for the entirety of Medicare and Medicaid (all states) populations, with records updated daily and weekly; these holdings further include comprehensive personally identifiable information (**PII**) and protected health information (**PHI**) for all beneficiaries in these populations. Acumen maintains official Federal government health data facilities, entitled the Acumen Data Center ("**ADC**"), where it

securely stores and analyzes the data used to monitor the safety and effectiveness of vaccines and other biological products regulated by the FDA.

Acumen conducts "signal detection" of adverse health events and initial empirical investigations of potential safety signals associated with immunizations. FDA heavily relies on these rapid-cycle findings to evaluate the post-market safety and efficacy of released vaccines, with processes in place to regulate their use and inform further studies of individual vaccines. Acumen's use of IIS vaccination data in its empirical analyses and reporting constitutes a public health surveillance activity, not independent research.

1.2 Purpose.

Acumen, as a Trusted Agent of FDA (**FDA Agent**), seeks to acquire IIS registry records with frequent updating for the universe of individuals ever enrolled in the Medicare and Medicaid programs. The request here is for individual-level immunization data to be made available to Acumen for linkage to Medicare and Medicaid beneficiaries enabling Acumen to perform statistical analyses and evaluations requested FDA, with descriptive findings and analytical results shared with FDA to inform its regulation, rule, and decision-making. FDA will not have direct access to immunization data, only access to data summaries and some de-identified records to validate the quality of clinical records.

Acquiring timely and comprehensive immunization data at the individual level is critical in growing FDA's capabilities to perform required, reliable surveillance investigations of vaccine outcomes. BEST monitoring requires reliable linkage of immunization data to medical service encounters to identify the incidence and timing of treatments and probable impacts on health outcomes. The IIS immunization registries accurately capture data about individuals' vaccine exposures not recorded in medical encounter events collected from health insurance entities, such as Medicare and Medicaid. Misclassifying individuals as unvaccinated when they are in fact vaccinated sharply diminishes statistical capabilities to ascertain elevated risks or may significantly underestimate rates of vaccine effectiveness. The required frequency of updating immunization information depends on the needs and priorities of FDA's rapid-cycle vaccination surveillance program, which can be as frequent as weekly updates during influenza vaccination seasons.

2. Legal Authorities

2.1 FDA Agent (Acumen)

2.1.1 Acumen serves as the prime contractor for the task order "Conduct Surveillance Activities for Safety and Effectiveness of Biologics" (contract HHSF-223-2018-10020I) under FDA's BEST IDIQ entitled Data, Tools, and Infrastructure for Surveillance of Biologics" (contract FDA-18-223-SOL-1196209). The primary objectives of this contract consist of expanding and enhancing CBER's available data sources, infrastructure, methods, and tools to conduct near real-time surveillance and rapid-cycle epidemiologic studies that promote CBER's Office of Biostatistics and Pharmacovigilance mission to assure the safety and effectiveness of biologic products including vaccines, blood and blood products, tissues, and advanced therapeutics.

2.1.2 The following statutory and regulatory provisions describe FDA's authorization by law to collect PHI/PII data (encompassing immunization records) and to delegate its "public health authority" for this activity to Acumen as its Trusted Agent. The

provisions below come from the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Part 164, Title 45 (Public Welfare), and the Food and Drug Administration Amendments Act of 2007 (FDAAA):

(a) Title 45 CFR § 164.512(b)(1)(i) of the HIPAA Privacy Rule permits a "covered entity" or part of a "hybrid entity" to disclose PHI to a public health authority that is authorized by law to collect or receive such information to carry out authorized public health activities. Such disclosures should be limited to the minimum data necessary to carry out the assigned public health activities (Title 45 CFR § 164.502(b)).

(b) Under Title 45 CFR § 164.501, a "public health authority" includes an agency of the United States responsible for public health matters as part of its official mandate. FDA is such an agency. Section 905 of FDAAA grants FDA authority to provide for active adverse event surveillance using data from healthcare programs, among other sources. The BEST Projects operate under this authority.

(c) As described in Title 45 § CFR 164.501 of the HIPAA Privacy Rule, the definition of "public health authority" also includes a "person or entity acting under a grant of authority from or contract" with a public agency that is responsible for public health matters as part of its official mandate. As such, when FDA's contractor (Acumen) reaches out to registries for individual immunization records for the surveillance work described above, it will be doing so as a public health authority.

(d) HIPAA-covered entities must verify that a person requesting PHI for public health purposes is a public health authority. For this purpose, HIPAA-covered entities are entitled to rely on a written statement on appropriate government letterhead that the person is acting under the government's authority (see 45 CFR § 164.514(h)(2)(ii)(C)). A copy of this letter, or content from this letter placed on FDA letterhead, should be provided by the FDA designated contractor to each PHI provider from whom immunization data will be sought under the BEST Projects. It will serve to provide the necessary written statement of authority to FDA contractors working on the project.

(e) The HIPAA Privacy Rule also requires covered entities to comply with the minimum necessary rule stated in Title 45 CFR § 164.502(b) but permits covered entities to rely on representations by a public health authority that it is requesting only the minimum amount of PHI necessary to carry out its public health mission (see 45CFR § 164.514(d)(3)(iii)(A)). The immunization records requested to conduct FDAs' safety and effectiveness surveillance are essential to producing reliable information for FDA to meet its statutory and regulatory requirements. In the judgment of FDA, these requests constitute the minimum necessary information required to carry out FDA's responsibilities under the BEST Program. Thus, IIS registries and HIPAA-covered entities may determine that data requests from FDA conveyed through its Trusted Agent Acumen meet the minimum necessary standards.

2.1.3 Exhibit B presents a copy of FDA's Letter of Support, citing Acumen as its Trusted Agent for the work covered by the Purpose of this Agreement and officially delegating its public health authority. Accordingly, when Acumen reaches out to IIS registries for individual immunization records for FDA's vaccination surveillance work, it does so as a public health authority.

2.2 IISJ

2.2.1 The Virgin Islands Department of Health is responsible for ensuring health care to the residents of the Territory pursuant to Title 3, Section 23 and Title 19, Section 1 of the Virgin Islands Code.

2.2.1 By entering into this Agreement, the IISJ agrees that it is authorized to transmit or allow the transmission of its IISJ Response File data to the Acumen Data Center (ADC).

2.2.2 As applicable, the Parties acknowledge that the IISJ is a "covered entity" or part of a "hybrid entity," as those terms are defined under the HIPAA Privacy Rule, 45 CFR § 160.103 and § 164.103, respectively.

3. Description of Data Files and Exchanges

3.1 Data Files Covered by this Agreement

3.1.1 **Finder File** – FDA Agent (Acumen) will periodically send Finder Files to IISJ identifying the Medicare and Medicaid beneficiaries in the IISJ's jurisdiction and a time frame for acquiring immunization data.

(a) The FDA Agent Finder Files will contain PII and PHI data, including records depicting some or all the following data elements: beneficiary name, date of birth, gender, Social Security Number, mailing address, Medicare Beneficiary Identifier, and Medicaid Beneficiary Identifier.

(b) The data elements in the Finder File will be limited to the minimum necessary data elements for the IISJ or its authorized representatives to perform a complete and accurate query identifying those Medicare and Medicaid beneficiaries residing in the IIS's jurisdiction.

(c) Each Finder Files will include the dates of service defining the time horizon requested for records.

3.1.2 **IISJ Response File** – In response to receiving a Finder File, the IISJ will return to FDA Agent an IISJ Response File disclosing vaccine events and administration records for those Medicare and Medicaid beneficiaries identified by the Finder File for whom the IISJ has immunization records. The IISJ Response File will contain:

(a) The same PII data elements provided in the Finder File to confirm the identified individuals for whom data are being exchanged.

(b) The PHI and administration data records describing all immunizations received by each identified individual for the period of time specified in the FDA Agent Finder File.

(c) In cases of multiple or nearly complete matches of PII data to individuals in immunization registries, including IIS records for all these "matched"

individuals will allow FDA Agent to identify the proper match using its extensive supplementary data sources.

3.1.3 **IISJ Data** – The accumulation of the immunization data obtained by FDA Agent from integrating the records and data elements contained in the union of IISJ Response Files.

3.2 Exhibit A provides the list of the data elements to be included for each IIS immunization record in the IISJ Response File. The data elements in the IISJ Response File will be limited to the minimum necessary data elements for Acumen to undertake the Purpose of this Agreement.

3.3 Operational Time Span for Response File Records

3.3.1 FDA Agent will transmit the IISJ a Finder File weekly or monthly, depending on the priorities and needs of the FDA safety surveillance program.

4. Description of Data Uses

4.1 FDA Agent (Acumen)

4.1.1 FDA Agent will link IISJ immunization records to the universe of medical records in the Medicare and Medicaid databases collected and maintained by the Centers for Medicare & Medicaid Services (CMS), with linkage performed at the individual level. This linkage and all data analyses will be performed within the Acumen Data Center (ADC) and will not directly involve CMS. FDA Agent will use this integrated dataset to construct detailed health and medical service histories for individual Medicare and Medicaid beneficiaries, enabling tracking the incidence and timing of vaccination events and various classifications of health outcomes.

4.1.2 FDA Agent will use these integrated datasets to conduct data analyses informing FDA's post-market surveillance of the safety and effectiveness of vaccines. These data analyses serve as the primary source of information for FDA in their near real-time monitoring of health outcomes related to immunizations, including both "signal detection" of adverse health events and initial empirical investigations of potential safety signals. FDA heavily relies on these rapid-cycle findings to evaluate the post-market safety and efficacy of released vaccines, with processes in place to regulate their use and inform further studies of individual vaccines.

4.1.3 The IISJ Data governed by this Agreement will only be used for FDA monitoring vaccines' safety and effectiveness. Data uniquely obtained through Response Files will not be used in any manner other than to support the Purpose of this Agreement.

4.2 IISJ

4.2.1 The IISJ may have access to FDA Agent's Finder Files in the querying of its immunization registries, which will contain PII data for Medicare and Medicaid beneficiaries. Data from the Finder Files obtained under this Agreement may be used only for that purpose and only as indicated in this Agreement; other uses and disclosures by the IISJ are not permitted.

4.3 FDA and other agencies

4.3.1 The FDA receives statistical surveillance findings from aggregated and de-identified empirical results. FDA does not have access to any PII or individually-identifiable PHI data.

4.3.2 No government agency, including FDA, will have access to any personally identifiable IISJ immunization data or findings.

4.4 IISJ and Acumen exchange of personally-identifying information

4.4.1 By mutual written agreement, IISJ and Acumen may coordinate exchanging PII data to improve the accuracy of the PII information in their respective databases related to vaccinated persons.

5. Roles and Responsibilities of FDA Agent (Acumen)

5.1 Following the execution of this Agreement, FDA Agent will transmit Finder Files to the IIJS periodically in a manner through secured and encrypted communication mechanisms. Procedures for the linkage and extraction of matched immunization data and the structure/format of the Response File will be determined by IISJ and Acumen in a manner with the least burden incurred by the IISJ. The frequency of the acquisition of IISJ Response Files will depend on FDA priorities and as mutually determined by IISJ and Acumen.

5.2 Data and System Security

5.2.1 FDA Agent will use commercially reasonable efforts to maintain the confidentiality of IISJ data within an IT/data infrastructure with an Authority to Operate (ATO) accredited as a moderate-level Federal Information Security Modernization Act (FISMA) or Federal Risk and Authorization Management Program (FedRAMP) system.

(a) FISMA/FedRAMP security provisions provide a level and scope of security consistent with the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A–130, Appendix III—Security of Federal Automated Information Systems, which sets forth guidelines for security plans for automated information systems in Federal agencies. Federal data centers with an ATO under FISMA/FedRAMP are authorized to store and transmit confidential health data and make it available for analysis.

(b) FDA Agent will use protocols consistent with FISMA/FedRAMP provisions in executing any transmissions of IISJ's data to authorized entities and will not perform such transmissions unless approved by IISJ.

(c) FISMA/FedRAMP provisions mandate that all FDA Agent employees with any access or interaction with IISJ Data must adhere to stringent behavioral and training security protocols consistent with this Section 5.2 (Data and System Security). These provisions fully extend to all FDA Agent's agents, subcontractors, and their associated employees with any access to IISJ Data or the findings derived from it.

5.2.2 FDA Agent will designate a custodian of the Response Files received from IISJ, with this custodian responsible for ensuring the protection of IISF immunization

datasets and derivate files. Upon agreement execution, FDA Agent will provide the designated custodian's name and contact information to IISJ.

5.3 Data Protection and Disclosures

5.3.1 FDA Agent will under no circumstances use, share, copy, duplicate, or otherwise reproduce any immunization data obtained from IISJ Response Files or any portion thereof in any manner other than to support the Purpose.

5.3.2 FDA Agent will not disclose to any third parties, nor permit any third parties to access or use, any immunization data uniquely obtained through IISJ Response linked to PII data without prior written consent from IISJ.

5.3.3 FDA Agent will share no findings revealing personally-identifiable immunization data received through IISJ registries with the FDA or any other agency without prior written consent from IISJ. FDA conducts its surveillance duties through reviews of aggregated data analysis and statistical findings received from its FDA Agent.

5.3.4 FDA Agent will not use data acquired through IISJ Response Files for any purpose that knowingly and willfully:

(a) infringes on IISJ's or any third party's copyright, patent, trademark, or other proprietary rights or rights of publicity or privacy; or

(b) violates any applicable law.

5.3.5 If disclosure of the IISJ Data other than that necessary to conduct the Purpose is required by law, it shall take place only after prior notification of IISJ.

5.4 Reporting and Treatment of Data Breaches

5.4.1 FDA Agent will notify IIJS without unreasonable delay, but in any event, no later than within twenty-four (24) hours of the discovery of any acquisition, access, use, or disclosure of privacy information that is not in compliance with the terms of this Agreement.

5.4.2 FDA Agent will make every effort to cure any privacy violation as soon as possible and regularly update IISJ on the status and progress of such cures.

6. Roles and Responsibilities of IISJ

6.1 Following the execution of this Agreement, the IISJ will establish and maintain procedures and protocols for using the Finder Files to query the IISJ registry for vaccine records and administration data to create the IISJ Response Files.

6.2 The IISJ will establish mechanisms and procedures to create and transmit IISJ Response Files to FDA Agent promptly and securely. The IISF Response Files will be sent electronically via encrypted transmission, as determined by IISJ and Acumen.

6.3 Data Protection, Disclosures, and Retention

6.3.1 The IISJ attests that it will maintain, use, and disclose the Finder File data only as permitted by this Agreement and in accordance with applicable law, including HIPAA and any applicable state laws.

6.3.2 The IISJ may have access to FDA Agent's Finder File in querying its immunization registries, including PII data for Medicare and Medicaid beneficiaries. Data from the Finder File obtained under this Agreement may be used only for that purpose and only as indicated in this Agreement; other uses and disclosures by the IISJ are not permitted.

6.3.3 IISJ acknowledges that FDA Agent is disclosing PII data to the IISJ, and the IISJ is not disclosing any PII data beyond that already revealed by FDA Agent.

6.3.4 The Parties acknowledge that IISJ retains no form of ownership rights to the Finder File data for which it gains access under the terms of this Agreement, and that the IISJ does not obtain any right, title, or interest in any of the data furnished in these Finder Files.

6.3.5 The IISJ will retain the Finder File data and any derivative only for the period of time required to process or for purposes related to the approved uses for which the data were received. Upon the end of this retention period, IISJ will securely destroy any Finder File information in its possession. These retention provisions survive the conclusion or termination of the Agreement.

7. Term and Termination

7.1 Term. The term of this Agreement will commence on the Effective Date and, unless terminated earlier in accordance with Section 7.2 (Termination), will continue thereafter in full force and effect until IISJ Data is no longer needed to fulfill the Purpose specified in this Agreement.

7.2 Termination. In addition to any other express termination right set forth in this Agreement:

7.2.1 Either Party may terminate this Agreement without cause upon sixty (60) calendar days' prior written Notice to the other Party.

7.2.2 Either Party may terminate this Agreement for cause, effective on written Notice to the other Party, if the other Party materially breaches this Agreement and such breach: (i) is incapable of cure; or (ii) being capable of cure, remains uncured thirty (30) calendar days after the non-breaching Party provides the breaching Party with written Notice of such breach.

7.3 Effect of Termination. Upon any termination or expiration of this Agreement for any reason, FDA Agent will cease using IISJ's Data and return or destroy any datasets derived from IISJ Response Files in connection with this Agreement, unless otherwise directed by IISJ in written communication. If FDA Agent cannot perform either of the aforementioned actions, FDA Agent will continue to protect any such information from unauthorized access or disclosure pursuant to Section 5 so long as such information remains in its possession and control.

7.4 Survival. FDA Agent 's obligations of non-disclosure with regard to privacy information will survive the termination or expiration of this Agreement for as long as such privacy information remains subject to protection under applicable law.

8. Representations, Warranties, and Limitation of Liability

8.1 IISJ Data supplied to FDA Agent pursuant to this Agreement are provided "as is." IISJ makes no warranty of any kind, express or implied, concerning the Data, including any warranties of merchantability or fitness for a particular purpose. IISJ assumes no responsibility or legal liability concerning IISJ Data's accuracy, reliability, completeness, or timeliness.

8.2 IISJ will not be liable to FDA Agent for any loss, claim, or demand made by FDA Agent or made against FDA Agent by any other party arising from the use of IISJ's Data, except to the extent permitted by law or when caused by the negligence or willful misconduct by IISJ.

8.3 No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement.

8.4 Each Party will be responsible for its own acts or omissions and those acts or omissions of its officers, direct employees, contractors and agents in the performance of this Agreement. Neither Party to this Agreement will be responsible for the acts and omissions of those entities or individuals not a party to this Agreement.

8.5 Each Party represents its execution and performance of this Agreement will not violate any applicable law or other agreement.

9. General Provisions

9.1 Governing law. Each party shall be governed by the laws of its own jurisdiction and any applicable federal laws.

9.2 Notices. All notices, requests, consents, claims, demands, waivers, and other communications hereunder (each, a "**Notice**") must be in writing, and the sending Party must have written acknowledgment of receipt from the receiving Party. All Notices must be delivered by email (with confirmation of transmission), or personal delivery, nationally recognized overnight courier (with all fees pre-paid), or certified or registered mail (in each case, return receipt requested, postage pre-paid). If acknowledgment of receipt is not forthcoming without unreasonable delay, the sending Party must transmit this Notice by certified or registered mail addressed to the Party at the addresses that may be designated by the Party receiving Notice from time to time in accordance with this Section. Except as otherwise provided in this Agreement, a Notice is effective only: (a) upon receipt by the receiving Party; and (b) if the Party giving the Notice has complied with the requirements of this Section.

9.3 Electronic Signatures. Duly authorized representatives may use electronic and digital signatures to execute this Agreement and any of its amendments, unless prohibited by any applicable law.

9.4 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signed documents, including this Agreement and any amendment hereto, transmitted via electronic means shall be afforded the same weight as documents with signatures and will be sufficient to show execution and delivery thereof.

9.5 Severability. The terms and provisions of this Agreement are severable, and if any term or provision of this Agreement shall be held to be invalid, illegal, or otherwise unenforceable, in whole or in part, the remainder of the terms and provisions, or enforceable parts thereof, shall not be affected thereby and shall be enforced to the fullest extent permitted by law. Upon a determination that any term or provision is invalid, illegal, or otherwise unenforceable, the Parties hereto shall negotiate in good faith to modify this Agreement to effect the original intent of the Parties as closely as possible in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

9.6 Amendment and Modification. No amendment or modification to this Agreement is effective unless it is in writing, identified as an amendment to this Agreement, and signed by an authorized representative of each Party to this Agreement.

9.7 Assignment. This Agreement may not be assigned or transferred for any reason whatsoever without the other party's prior written consent and any action or conduct in violation of the foregoing will be void and without effect.

9.8 Entire Agreement. This Agreement, together with any other documents incorporated herein by reference and all related Exhibits, constitutes the sole and entire agreement of the Parties with respect to the subject matter of this Agreement and supersedes all prior and contemporaneous understandings, agreements, and representations and warranties, both written and oral, with respect to such subject matter.

9.9 Exhibit A and B attached hereto are a part of this Agreement and are incorporated herein by reference.

[*SIGNATURE PAGE FOLLOWS.*]

[*REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK.*]

Each Party has caused this Agreement to be executed by its duly authorized representative as of the Effective Date.

Acumen, LLC

By: Bonnie Johnson
(Signature)

Bonnie Johnson
(Print Name)

Contracts Director
(Print Title)

9/16/2022
(Date)

WITNESSES: **GOVERNMENT OF THE U. S. VIRGIN ISLANDS**

Derese A Dunlop-Harley

Justa E. Encarnacion, Commissioner
Department of Health

10/12/2022
Date

Magdalene A. Moraine

Anthony D. Thomas, Commissioner
Department of Property and Procurement

10/23/2022
Date

APPROVED AS TO LEGAL SUFFICIENCY
DEPARTMENT OF JUSTICE BY: Carol E. McDonald Date 10/21/2022
Assistant Attorney General