IBM Clinical Development

This Service Description describes the Cloud Service IBM provides to Client. Client means the contracting party and its authorized users and recipients of the Cloud Service. The applicable Quotation and Proof of Entitlement (PoE) are provided as separate Transaction Documents.

1. Cloud Service

IBM Clinical Development ("Cloud Service") provides a flexible and scalable data management platform to help Client design and manage Clinical Trials by incorporating trial-specific features and services. Client can configure the Cloud Service to support Clinical Trials in any phase, capturing any type of data, from any source, over any modality. "Clinical Trial" is used in this Service Description to mean a research study that explores whether a medical strategy, treatment, or device is safe and effective.

Only study designers certified by IBM are authorized to set studies to live status within the Cloud Service and some modules require additional certification. If Client does not have a certified designer on staff, Client may contract with IBM or a third party under a separate agreement to build and/or set the study to live status on Client's behalf or Client may contract with IBM to train authorized users to build the trial and to obtain certified designer status.

Electronic Data Capture ("EDC") is the core component of the Cloud Service. It is a cloud-based data capture solution, designed to provide end-to-end visibility, and patient, site, and trial management capabilities. EDC centralizes and organizes trial details and provides Client with 24/7 access, via a single URL, to all study data, from any Web-enabled device.

Using the provided data visualization tool, Client can design and build standard and custom reports that can pull data from any field, or from related metadata.

When a Clinical Trial is moved to closed status, it is no longer accessible by Client or its authorized users in the Cloud Service. Client can use any of the provided reporting or export features of the Cloud Service to extract data. Custom data extraction services are available under a separate agreement.

The Cloud Service is designed to support compliance with Part 11 of Title 21 of the U.S. Code of Federal Regulations and EU GMP Annex 11.

The Cloud Service includes the following key modules that can be enabled for each Clinical Trial at no additional charge:

Data Imports/Application Programming Interface ("API")

This module enables automated communication, to push and pull data between a third-party solution and from the Cloud Service, without performing manual data entry.

Electronic Patient Reported Outcomes

The electronic Patient Reported Outcomes ("ePRO") module allows direct data entry by Clinical Trial participants, from their selected Internet-enabled device.

IBM My Clinical Diary Mobile is a separate mobile application that completes the ePRO module by providing an alternative way for Clinical Trial participants to enter and transfer their data into the Cloud Service.

Inventory Management and Dispensing

This module allows Client to: 1) define treatment options; 2) input and track inventory, shipments, and site inventory; and 3) dispense inventory to Client's subject database. Cohorts functionality enables grouping of subjects by specific criteria and allows control of population by users without Clinical Trial design modifications.

Languages/Translations

The Languages/Translations module enables translation of content in designer-defined areas to user-selected language(s). The Cloud Service native menus and interface are available in a variety of languages and dialects.

The Cloud Service also allows Clients to submit documents to an IBM-designated third party vendor for language translation. The translation service is provided under a separate agreement directly between Client and the third party vendor. Client is responsible for translation service charges. Once translation is performed, the translated document is made available to the Client within the Cloud Service.

Medical Coding

The Cloud Service provides access to Medical Dictionary for Regulatory Activities ("MedDRA") and WHO Drug Dictionary as provided by Uppsala Monitoring Centre ("UMC") to facilitate coding of events and medications within a Clinical Trial. Client is responsible for purchasing the appropriate licenses from MedDRA and/or UMC. IBM will verify which license the Client has obtained and grant access to the dictionaries accordingly.

Monitor Management

Monitor Management enables Client to create site visit templates used by the site monitors, define several site visit plans, track the site monitors' visit activities, and generate instant trip reports.

Monitoring Levels / Source Data Verification

Monitoring Levels is a tool designed to apply targeted source data verification ("SDV") strategies. A variety of SDV plans can be designed using criteria such as site performance, analyzed risk, or geography. Individual sites and subjects can be assigned to a monitoring level, thereby creating a customized, reduced SDV strategy for each Clinical Trial. Source Data Verification enables Client to designate any clinical data field as "Source Data Verified" when building a Clinical Trial.

Randomization

The Randomization module allows treatment assignment, based on a defined randomization scheme, while allowing more complex workflows such as double and replacement randomization.

Training/Tracking

This module tracks user trainings and compliance by assigning role-specific documents, quizzes or Web site visits, to be completed prior to accessing a Clinical Trial.

1.1 Optional Features and Services

1.1.1 IBM Clinical Development Endpoint Adjudication

Endpoint Adjudication uses a single dashboard to facilitate an automated approach to the adjudication workflow. A collaborative workspace that incorporates endpoint management and essential workflows into a single interconnected system is created. Such workflows may include paired consensus, parallel review, expert review and direct-to-committee needs. An electronic dossier of required endpoint details and source documents is automatically compiled and authorized users are provided with online access to trial documents and original materials.

1.1.2 IBM Clinical Development DICOM Imaging

DICOM Imaging module enables image upload, redaction, pixel de-identification, and review within the Cloud Service, without the need for a separate imaging database. The images are stored like other data points relative to a CRF, and reviewers are provided with a zero footprint iConnect® Access viewer.

Because this module is integrated directly into the Cloud Service, all DICOM images in a Clinical Trial can be incorporated into any workflow. The module facilitates compliance with privacy standards by allowing de-identification of DICOM headers and pixel de-identification inside the workflow.

1.1.3 IBM Clinical Development Consulting

IBM will provide hourly consulting as requested by Client and agreed to by IBM ("Consulting"). Consulting may be used by Client for activities where the resolution to Client's request requires knowledge of the industry, specific trial needs, or falls outside of standard Technical and Customer Support for the Cloud Service. Consulting does not include Cloud Service

implementation activities, trial design or modification, the creation of deliverables for Client, or Client training, which are available under a separate agreement with IBM. Consulting is intended to provide proposals or guided direction to resolve a request utilizing IBM's expertise, domain knowledge, input, and, if agreed, partial supervision. Consulting is intended for protocol or situation specific needs and does not replace Client training. Consulting normally requires a larger understanding of the industry, the Cloud Service, common practices, and experience with the situation.

Client may request Consulting by contacting IBM. Upon receipt of a request, IBM will confirm that the request is within the scope of Consulting, provide an estimated number of Hour entitlements required to complete the requested Consulting activity, and provide an estimated start date based on availability of personnel. Client will be billed based on the actual Hours used.

2. Security Description

This Cloud Service follows IBM's Data Security and Privacy Principles for IBM Cloud Services which are available at http://www.ibm.com/cloud/data-security and any additional terms provided in this section. Any change to IBM's data security and privacy principals will not degrade the security of the Cloud Service.

This Cloud Service may be used to process content that contains personal data and the sensitive personal data described below if Client, as the data controller, determines that the technical and organizational security measures are appropriate to the risks presented by the processing and the nature of the data to be protected. The Cloud Service is not designed to process data to which additional regulatory requirements apply.

The sensitive personal data that can be processed by the Cloud Service is information regarding an individual's physical and mental health (for example, medical procedure codes, medical diagnostic information, and medical prescriptions).

2.1 Security Features and Responsibilities

This Cloud Service is included in the Privacy Shield certification of Merge eClinical, an IBM company, when Client chooses to have the Cloud Service hosted in a data center located in the United States, and is subject to the Privacy Shield Privacy Policy available at https://pages.eclinicalos.com/data-privacy.

3. Technical Support

Technical and Customer Support for the Cloud Service is provided. Support is offered with the Cloud Service and is not available as a separate offering. Current details regarding contact methods and hours of operation can be found on the Web at: http://www.ibm.com/software/support/watsonhealth/eClinicalecos_support.html.

4. Entitlement and Billing Information

4.1 Charge Metrics

The Cloud Service is available under the charge metric specified in the Transaction Document:

a. Clinical Trial Subject is a unit of measure by which the Cloud Service can be obtained. A Clinical Trial is a research study that explores whether a medical strategy, treatment, or device is safe and effective. A Clinical Trial Subject is any individual or thing that is tracked as per the study design of the Clinical Trial. Sufficient entitlements must be obtained to cover all Clinical Trial Subjects managed or tracked by the Cloud Service during the measurement period specified in Client's PoE or Transaction Document.

b. Concurrent Clinical Trial is a unit of measure by which the Cloud Service can be obtained. A Clinical Trial is a research study that explores whether a medical strategy, treatment, or device is safe and effective. Sufficient entitlements must be obtained to cover the maximum number of Concurrent Clinical Trials simultaneously managed or tracked by the Cloud Service during the measurement period specified in Client's PoE or Transaction Document.

   For the purpose of this Cloud Service, Concurrent Clinical Trials refer to Clinical Trials that are active, meaning that they are in live or locked status.

c. Event is a unit of measure by which the Cloud Service can be obtained. Event entitlements are based on the number of occurrences of a specific event related to the use of the Cloud Service. Event entitlements are specific to the Cloud Service and the type of event may not be exchanged, interchanged, or aggregated with other Event entitlements of another Cloud Service or type of event. Sufficient entitlements must be obtained to cover every event that occurs during the measurement period specified in Client's PoE or Transaction Document.

d. Hour is a unit of measure by which the Cloud Service can be obtained. Sufficient Hour entitlements must be obtained to cover the total number of whole or partial Hours of the Cloud Service used during the measurement period specified in Client's PoE or Transaction Document.

4.2 Overage Charges

If actual usage of the Cloud Service during the measurement period exceeds the entitlement specified in the PoE, an overage charge will be billed at the rate specified in the Transaction Document in the month following such overage.

4.3 Pay per Use Charges

A pay per use charge will be billed at the rate specified in the Transaction Document in the month following such use.

5. Term and Renewal Options

The term of the Cloud Service begins on the date IBM notifies Client of their access to the Cloud Service, as documented in the PoE. The PoE will specify whether the Cloud Service renews automatically, proceeds on a continuous use basis, or terminates at the end of the term.

For automatic renewal, unless Client provides written notice not to renew at least 90 days prior to the term expiration date, the Cloud Service will automatically renew for the term specified in the PoE. Renewals are subject to an annual price increase.

For continuous use, the Cloud Service will continue to be available on a month to month basis until Client provides 90 days written notice of termination. The Cloud Service will remain available to the end of the calendar month after such 90 day period.

6. Additional Terms

6.1 General

Client agrees IBM may publicly refer to Client as a subscriber to the Cloud Services in a publicity or marketing communication.

The Cloud Service is not a substitute for independent medical research and judgment.

Client agrees that IBM may use, without restriction whatsoever, any feedback about the Cloud Service that Client provides to IBM.

6.2 Client Data Rights and Use

Client is responsible for obtaining all necessary permissions to use, provide, store and process content in the Cloud Service, including without limitation informed consents from individuals participating in a Clinical Trial that allow data to be disclosed to and used by entities such as IBM that are providing vendor support services in connection with the Clinical Trial.

In providing the Cloud Service to Client, IBM generally is providing vendor support services to Client in connection with research as defined in Section 164.501 of the U.S. Health Insurance Portability and Accountability Act, as amended, including its implementing regulations ("HIPAA") and is therefore not acting as a business associate under HIPAA. In the event that the circumstances surrounding Client's particular use of the Cloud Service renders IBM a business associate or downstream business associate under HIPAA, IBM and Client will enter into a business associate agreement to the extent appropriate and required by HIPAA.

6.3 Federal Healthcare Programs

IBM represents and warrants that it (a) is not excluded, debarred, or otherwise ineligible to participate in any U.S. federal health care program as defined in 42 U.S.C. § 1320a-7b(f) (the "Federal Healthcare Programs"); (b) has not been convicted of a criminal offense related to the provision of health care items or services and has not been excluded, debarred, or otherwise declared ineligible to participate in the Federal Healthcare Programs, and (c) is not under investigation or otherwise aware of any circumstances which may result in IBM being excluded from participation in the Federal Healthcare Programs.

6.4 Request for Access

IBM will promptly notify Client upon receipt of request by any properly authorized officer or employee of any Regulatory Authority to have access to or verify any record, report, documentation or data belonging to Client or related to a Client project that is in IBM's possession, custody or control.

"Regulatory Authority" is used in this Service Description to mean the United States Food and Drug Administration ("FDA") or any other applicable country specific authority or regulatory body having jurisdiction over approval of therapeutic or pharmaceutical drugs or medical devices.

6.5 Notice of Inspection

IBM will promptly notify Client upon receipt of notification of an impending inspection by any Regulatory Authority at IBM's premises if such inspection relates to the Cloud Service under this Service Description, and provide Client the right to be present at and observe any such inspection. Client will promptly notify IBM following receipt of notification of an impending inspection by any Regulatory Authority at Client's premises if such inspection relates to the Cloud Service provided to Client under this Service Description (including, any applicable Order(s)).

6.6 Links to Third Party Websites or Other Services

If Client or an authorized user transmits content to a third party website or receives information from it or other services that are linked to or made accessible by the Cloud Service, Client and its authorized users are providing IBM with consent to enable any such transmission of content, but such interaction is solely between Client, the authorized user and the third party website or service. IBM makes no warranties or representations about such third party sites or services, and shall have no liability for such third party sites or services.

6.7 Enabling Software

The Cloud Service requires the use of enabling software to be downloaded to facilitate use of the Cloud Service, as applicable. Client may use enabling software only in connection with use of the Cloud Service. Enabling software is provided "AS-IS" without warranties of any kind.

The Enabling Software provided with the Cloud Service is:

- IBM My Clinical Diary Mobile
- IBM Clinical Development DICOM Uploader

6.8 Backup

Backups are performed daily for production instances and weekly for customer facing non-production instances. IBM will retain a backup copy of Client's data for a maximum period of 90 days for production instances and up to 7 days for non-production instances. Client is responsible for configuring the Cloud Service security to prohibit individual users from deleting data, and once the data is deleted Client acknowledges and agrees IBM is not obligated to recover the deleted data and, if available, may charge for such effort.

6.9 Cloud Service Expiration

Before expiration or termination of the Cloud Service, Client can use any of the provided reporting or export features of the Cloud Service to extract data. Custom data extraction services are available under a separate agreement.

IBM will retain Client data in accordance with IBM's records management and retention policy. In the event this Service Description is terminated due to IBM's business cessation, IBM will use its commercially reasonable efforts to ensure that Client's data will be retrievable from IBM servers, free and apart from any asset claims brought forth by IBM creditors.