

Service Description

IBM Clinical Trial Management System for Sites

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 Trial Management System for Sites ("Cloud Service") is a cloud-based application designed to centralize and manage research related activities at clinical research sites as well as hospitals and academic medical centers conducting clinical research. Using the Cloud Service, personnel at all levels of the research organization can have role, Clinical Trial, and site specific access to the following capabilities:

- Configure specific fields and pick-lists for use in the Cloud Service
- Perform budget analysis to determine Clinical Trial profitability based on proposed budget, fees, and potential Clinical Trial Visits
- Build Clinical Trial protocol and budget
- Budget outgoing provider payments and Clinical Trial Participant stipends
- Build Clinical Trial Visit calendar timeline to represent protocol intervals and windows for use in scheduling and revenue backlog projection
- Document coverage analysis
- Configure system medical history data capture form
- Populate patient database manually or import demographics from a spreadsheet template
- Search the Client's patient database in the Cloud Service to locate potential Clinical Trial Participants
- Upload Clinical Trial documents
- Track Clinical Trial Visits with a configured checklist to assist with protocol compliance and to generate revenue and billable items
- Use recruitment workflow to register Clinical Trial Participants, answer predefined recruitment questionnaires, and enroll Clinical Trial Participants into Clinical Trials
- Schedule appointments for Clinical Trial Participants or Clinical Trial staff
- Generate sponsor invoices and apply payments to invoices, Clinical Trial Visits, individual items, or receivable balances
- Build and generate reports combining available data fields, detail levels and filters

1.1 Optional Features

1.1.1 IBM CTMS for Sites Non-Production Environment

This Cloud Service provides Client with a separate Non-Production Environment. Non-Production means the Cloud Service can only be used as part of the Client's internal development and test environment for internal non-production activities, including but not limited to testing, performance tuning, fault diagnosis, internal benchmarking, staging, quality assurance activity, and training.

1.1.2 IBM CTMS for Sites Patient Demographics Interface

With the Patient Demographics Interface, organizations can feed the Cloud Service with patient demographics records in a supported format from an Electronic Medical Records (EMR) or other system.

1.1.3 IBM CTMS for Sites Extended Electronic Medical Records Interface

With the Extended Electronic Medical Records Interface, organizations can push specific Clinical Trial data from the Cloud Service to certain leading EMR systems via an Application Program Interface (API) such as the Clinical Trial definition, billing grid, calendar, and status. Clinical Trial Participant enrollments and status changes in the Cloud Service are also propagated to the EMR automatically to flag patients

who are Clinical Trial Participants. The Extended EMR Interface is available only to Clients that also subscribe to the Patient Demographics Interface.

1.1.4 IBM CTMS for Sites Active Directory Interface

The Active Directory Interface allows organization users to login to the Cloud Service using their local Active Directory credentials.

1.2 Set-Up Services

The following optional features require a setup service with a corresponding setup fee:

- IBM CTMS for Sites Patient Demographics Interface
- IBM CTMS for Sites Extended Electronic Medical Records Interface
- IBM CTMS for Sites Active Directory Interface

1.3 Pay Per Use Services

1.3.1 IBM CTMS for Sites Consulting

IBM will provide hourly consulting and training 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, deep knowledge of the Cloud Service application, customer specific Cloud Service instance configuration, or falls outside of standard Technical and Customer Support for the Cloud Service. 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 normally requires a larger understanding of the industry, the Cloud Service, common practices, and experience with the situation. Consulting will be provided remotely using online web conference tools, as needed for the situation.

Consulting may also be used for scheduled training for up to six individuals. Training may include instruction related to the following Cloud Service functionality: System configuration and planning, study setup, budget setup, Clinical Trial Participants and Clinical Trial Visit tracking, financial features such as accruals, receivables, and payments, patient search and recruitment, scheduling, document tracking, reports, and questionnaire building. The agenda can be tailored to cover the topics the Client would like to learn.

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.

1.3.2 IBM CTMS for Sites Study Entry

IBM will provide study data entry services as requested by Client and agreed to by IBM ("Study Data Entry"). Study Data Entry involves IBM engagement to input Client data directly into the Cloud Service as part of the initial Cloud Service set-up.

Study Data Entry services may only commence upon receipt of customer's study protocol title page, annotated protocol schedule of events, clinical trial agreement (CTA), and sponsor research budget. This information is used to enter data into the following Cloud Service screens: Study Definition, Visits and Procedures, and Budget. Study Data Entry services may require telephone, email, and/or web conference correspondence.

Client may request Study Data Entry by contacting IBM. Upon receipt of a request, IBM will confirm that the request is within the scope of Study Data Entry, provide an estimated number of Hour entitlements required to complete the requested Study Data Entry 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 principles 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/eClinicalctms_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. Application Instance is a unit of measure by which the Cloud Service can be obtained. An Application is a uniquely named software program. An Application Instance is a copy of the Application. An Application in multiple environments such as test, development, staging or production is considered a separate Application Instance. Multiple instances of an Application in a single environment are considered separate Application Instance. Sufficient Entitlements must be obtained to cover the number of Application Instances connected to or managed by the Cloud Service during the measurement period specified in Client's Proof of Entitlement (PoE) or Transaction Document.
- b. Clinical Trial Visit 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 Participant is an individual who is participating, or is being recruited to participate, in a Clinical Trial. A Clinical Trial Visit is an encounter between a Clinical Trial Participant and Clinical Trial staff. Sufficient entitlements must be obtained to cover all Clinical Trial Visits managed or tracked by the Cloud Service during the measurement period specified in Client's PoE or Transaction Document.
- c. Engagement is a unit of measure by which the services can be obtained. An Engagement consists of professional and/or training services related to the Cloud Service. Sufficient entitlements must be obtained to cover each Engagement.
- 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 Set-Up Charges

A one-time setup fee will be billed at the rate specified in the Transaction Document for each setup service ordered.

4.3 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.

4.4 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 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.

6.8 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.