

IBM Watson for Oncology

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

1.1 IBM Watson for Oncology

IBM Watson for Oncology, trained by Memorial Sloan Kettering, is designed to assist oncology clinicians making treatment decisions for individual patients.

The Cloud Service offering is a cognitive computing decision support system that includes the ability to:

- Analyze patient data against thousands of historical cases and insights gleaned from thousands of Memorial Sloan Kettering Cancer Center physician and analyst hours.
- Provide treatment options to help oncologists make informed decisions. These treatment options are based on literature curated by Memorial Sloan Kettering, and over 300 medical journals and 200 textbooks, resulting in almost 15 million pages of text.
- Evolve with the fast-changing field of oncology through periodic training provided by Memorial Sloan Kettering.
- Focus on a variety of cancers types as outlined in the latest product release announcements or notes.
- Identify potentially relevant clinical trials via a prepopulated query to <https://clinicaltrials.gov/>.

The Cloud Service offering includes support for iPad and desktop browsers.

For every Patient entitlement acquired, 1 Authorized User is included. If Client requires additional Authorized User entitlements beyond what is included with the Patient entitlement, Client may order such Authorized User entitlements.

1.2 Operational Environments

The Cloud Service operational environment is comprised of one production environment ("Production Environment") and one non-production environment ("Test Environment"). The Production Environment of the Cloud Service is accessible to all of Client- authorized end users. It provides responses to clinical trial match requests based solely on the Cloud Service code and content that has been promoted to the Production Environment. When required, IBM will perform all code publishing to the Production Environment.

The Test Environment will be used for any necessary testing of the Cloud Service and is not in a production mode where the Cloud Service programs are run and relied on by Client and sites for daily operations and intended uses by end users.

1.3 Account Types

1.3.1 User Accounts

An end user of the Cloud Service may only be an oncologist with a current license to practice medicine under the laws of the Client's country location ("Licensed Oncologist") who is the current treating clinician for a patient, or someone authorized to utilize the system under the direct supervision of the Licensed Oncologist. Client may input information into the Solution only if Client is a Licensed Oncologist or Client is a licensed health care professional being directly supervised by a Licensed Oncologist ("Client End User"). A patient may not be a Client End User.

Client controls the Client End Users who may access a user account or use the Cloud Service. This control is exercised through a proxy server deployed by Client and/or an SAML (Security Assertion Markup Language) identity provider on Client's site, which must be deployed before Client allows any Client End User access to the Cloud Service.

Client will route all user traffic for the Cloud Service through the proxy server. Client will set the proxy server to perform a SSL TLS (Transport Layer Security) confirmation of the proxy server in the Cloud Service, which does the same in reverse. If Client elects to implement a SAML identity manager

authentication for user access, it is Client's responsibility to ensure and control the accuracy and authenticity of the list of Client End Users that are provided access to the Cloud Service as well as the authentication information provided through Client's proxy.

Client understands and agrees that Client is solely responsible for (i) controlling all end user accounts, including without limitation, verification of the identity of any Client End User; and (ii) ensuring that only authorized Client End Users access an end user account or use the Cloud Service. All Client End users are provided a copy of an end user terms of use upon access to the Cloud Service to which they must agree.

1.4 Language Limitations

Client will provide content, test patient data and production patient data in English-language textual data. The Cloud Service is not configured to process languages other than English. Grammatical errors and similar improper English language conventions in the content may reduce the effectiveness of the Cloud Service.

2. Security Description

The Watson Health offerings including this Cloud Service follows the Watson Health Security Policy which is built upon the principles of IBM's Cloud Security policy for 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.

In addition to normal account and user data IBM collects to support the use of the Cloud Service, IBM may also collect the following types of information set forth below ("Client Data"). The specific data collected shall be determined in accordance with the applicable laws of the country where the Cloud Services are being utilized.

- Anonymized Health Data – information, such as current health status and current and past medical treatments, in a de-identified or anonymized format.
- Personal Data – information relating to an identified or identifiable natural person
- Sensitive Personal Data – Personal Data concerning health, which shall include Protected Health Information ("PHI") as defined by the Health Insurance Portability and Accountability Act of 1996, as amended, including by the Health Information Technology for Economic & Clinical Health Act of the American Recovery and Reinvestment Act of 2009 ("HITECH Act"), certain regulations promulgated under HIPAA by the United States Department of Health and Human Services at 45 C.F.R. Parts 160 and 164 and certain regulations promulgated pursuant to the HITECH Act (collectively, "HIPAA").

2.1 Security Features and Responsibilities

The Cloud Service implements the following security features: Sensitive data stored in the cloud service is encrypted.

The Cloud Service does encrypt content during data transmission between the IBM network and a Datapower network access point and firewall. The Cloud Service does encrypt content when at rest awaiting data transmission.

This Cloud Service is included in IBM's Privacy Shield certification and applies when Client chooses to have the Cloud Service hosted in a data center located in the United States, and is subject to IBM's Privacy Shield Privacy Policy, available at http://www.ibm.com/privacy/details/us/en/privacy_shield.html.

3. Technical Support

Watson Support will provide a web-based support portal for submission and management of incidents requiring IBM Watson Health support to assist or resolve. IBM will make available the IBM Software as a Service Support Handbook which provides technical support contact information and other information and processes. Technical support is offered with the Cloud Service and is not available as a separate offering. IBM reserves the right to change any Uniform Resource Identifier ("URL") or web address, or email address related to technical support and will promptly notify Client of any change.

Client will identify a team to provide first line of support to all Cloud Service authorized-users.

4. Entitlement and Billing Information

4.1 Charge Metrics

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

- a. **Patient** – is a unit of measure by which the Cloud Service can be obtained. A Patient is a person receiving or registered to receive medical treatment. Sufficient entitlements must be obtained to cover all Patients managed or tracked within the Cloud Service during the measurement period specified in Client's PoE or Transaction Document.

For purposes of this Cloud Service, Patient entitlements are sold in groups of 100 per each entitlement.

- b. **Authorized User** – is a unit of measure by which the Cloud Service can be obtained. Client must obtain separate, dedicated entitlements for each unique Authorized User given access to the Cloud Service in any manner directly or indirectly (for example, through a multiplexing program, device or application server) through any means. Sufficient entitlements must be obtained to cover the number of Authorized Users given access to the Cloud Service 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 Verification

Client will i) maintain, and provide upon request, records, and system tools output, as reasonably necessary for IBM and its independent auditor to verify Client's compliance with the Agreement, and ii) promptly order and pay for required entitlements at IBM's then current rates and for other charges and liabilities determined as a result of such verification, as IBM specifies in an invoice. These compliance verification obligations remain in effect during the term of the Cloud Service and for two years thereafter.

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.

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.

6.2 Publicity

This Service Description does not confer any rights to Client to use in advertising, publicity or other marketing activities any name, trade name, trademark, or other designation of IBM, including any contraction, abbreviation, or simulation of any of the foregoing, without prior written agreement, and Client agrees not to use or refer the Cloud Services, this Service Description or its terms in any such activities without the express written approval of the other party.

6.3 Links to Third Party Websites or Other Services

If Client or an end 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 the end users provide IBM with the consent to enable any such transmission of content, but such interaction is solely between Client,

the end 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.

6.4 Transactions

IBM is not responsible for any matters related to the offer and sale of products or services by and among Client and Client's end users ("Transactions") regardless of whether these Transactions are communicated by or among such entities as a result of the Cloud Service.

6.5 No Guarantee of Compliance

Use of the Cloud Service does not guarantee compliance with any law, regulation, standard or practice. Client is responsible for determining the applicability of and complying with all relevant laws, regulations and licensing requirements that apply to the use of the Cloud Service offering and the delivery of healthcare services. Any directions, suggested usage, or guidance provided by the Cloud Service does not constitute legal, accounting, or other professional advice, and Client is cautioned to obtain its own legal or other expert counsel. Client is solely responsible to ensuring Client and user activities comply with all applicable laws, regulations, standards and practices.

Client is solely responsible for ensuring that Client and its Client End User activities comply with all applicable laws, regulations, standards and practices. Client is solely responsible for ensuring that its Client End Users comply with the end user terms of use associated with the Cloud Service offering and obtain all necessary consents of patients relating to the use, transfer and storage of EMRs, individually identifiable health information and any other patient information. Client is solely responsible for ensuring that Client complies with all applicable policies of Client's institution and for obtaining any necessary approvals of research ethics boards of Client's institution. Use of the Cloud Service does not guarantee compliance with any law, regulation, standard or practice. Any directions, suggested usage, or guidance provided by the Cloud Service does not constitute legal, accounting, medical or other professional advice, and Client is cautioned to obtain Client's own legal or other expert counsel.

Client understands the Cloud Service was developed and contains information which was solely based on and originally generated for use in the United States; there is no specific information in the Cloud Service based on any other jurisdiction.

Client understands and agrees the Cloud Service is intended to assist clinicians in making decisions but that IBM has no responsibility whatsoever for the conduct of Client's business or patient care. Client agrees that any use by Client or its Client End Users of the Cloud Service will not diminish Client's or its Client End Users responsibility for patient care. In undertaking and providing the Cloud Service under this Service Description, IBM is acting solely as a services provider and does not purport to be engaged in the practice of medicine or any other professional clinical or licensed activity, and the Cloud Service consists solely of support to facilitate providing information to Client and Client's medical or other health care professionals who must evaluate the safety and security of the Cloud Service, and exercise Client's/Client independent professional judgment regarding any care decisions resulting from the use of the Cloud Service, and not in reliance thereon. IBM and its development and content providers, including without limitation, Memorial Sloan Kettering Cancer Center, assume no responsibility or liability for the accuracy, completeness, propriety, necessity, security or advisability of the Cloud Service and any medical information which is accessed through the use of the Cloud Service, other than the responsibilities and liabilities stated in this document and in the Cloud Services Agreement.

In addition, the content and information provided through the Cloud Service offering was current when published but such information, including any relevant guidelines, may no longer be current or reliable. IBM may include updated Cloud Service offering content during scheduled updates, provided that its content providers, including Memorial Sloan Kettering Cancer Center furnish more current information. IBM currently plans 3-4 updates annually.

6.6 Regulatory Considerations

For countries: Australia, Bangladesh, Bhutan, Brazil, Canada, Chile, India, Mexico, Nepal, New Zealand, Peru, Philippines, Russian Federation, South Korea, Thailand, and the United States:

- Client agrees that the Cloud Service IS NOT INTENDED to constitute a medical device for use in clinical decision support in the investigational treatment of subjects or in the commercial treatment of patients, as defined in Section 201(h) of the United States Food, Drug and Cosmetic Act as amended and as per the Laws and Regulations of the Client's country where implemented.

For countries: Finland, Ireland, Netherlands, Sweden, Switzerland, and the United Kingdom:

- Client agrees that the Cloud Service IS NOT INTENDED to constitute a medical device for use in clinical decision support in the investigational treatment of subjects or in the commercial treatment of patients, as defined in Section 201(h) of the United States Food, Drug and Cosmetic Act. The Client further agrees that the Cloud Service IS INTENDED to constitute a medical device per the Laws and Regulations in the Client's country where implemented.

Despite the foregoing intent, Client understands and agrees that the Cloud Service offering may be deemed subject to regulation by one or more applicable regulatory authorities. If this contingency occurs during the subscription period, and IBM is not able or willing to comply, IBM may decide to continue to make the Cloud Service available to Client; otherwise, IBM shall terminate the agreement. Such termination shall be at no penalty to IBM and shall not entitle Client to any refunds, credits or offsets under this Service Description or any other agreement with IBM.

At no time shall Client initiate contact with regulatory authorities regarding the Cloud Service. If Client has any questions or concerns about regulatory requirements associated with the Cloud Service, Client should raise them with IBM. As between Client and IBM, IBM has sole responsibility for communicating with any or all regulators regarding the Cloud Service, unless such regulators contact Client directly, in which case Client shall notify IBM immediately while cooperating with such regulators to the extent required by law.

If IBM submits a future iteration of the Cloud Service offering to medical device regulation, Client shall provide reasonable requested support and cooperation with IBM to facilitate applicable regulatory filings and postmarket regulatory compliance. In this regard, IBM may request the pertinent materials, data and information, including without limitation, descriptions of Client health data, Client content, Client electronic health records systems, Client documents regarding standards of care, and information about adverse events and similar information needed for postmarket reporting and all other regulatory requirements. IBM acknowledges that Client might be limited to disclose some information in order to comply with the applicable laws.

Client shall conduct appropriate training of the Cloud Service to Client's End Users.

6.7 Use of the Cloud Service

Client may use the Cloud Service offering as authorized by IBM on condition that:

- a. Client complies with the terms of this Service Description, all relevant laws, regulations and licensing requirements that apply to the access and use of the Cloud Service offering and the delivery of healthcare services.
- b. Client ensures that only Client End Users are authorized to access the Cloud Service.
- c. Client will obtain the required trainings regarding the authorized permissions and intended uses of the Cloud Service prior to using the Cloud Service offering for any purpose. A self-paced online course and on-site in person training are available as additional lab services. Any information Client submits or inputs into the Cloud Service offering will be accurate and complete to the best of Client's knowledge. Client does not use the Cloud Service offering as a substitute for independent medical research and judgment.
- d. Use of the Cloud Service by Client's End Users is subject to the end user terms of use.
- e. Limitations: The limitations of liability and disclaimers contained in the Agreement also apply to Memorial Sloan Kettering Cancer Center and any of Cloud Service offering's solution developers, content providers and suppliers and any of their affiliates, licensors, and their respective directors, officers employees or agents and is the maximum for which those parties are collectively responsible. End users are not third party beneficiaries under the Agreement, and Client shall hold IBM harmless of any end user claim.

6.8 Data Rights

For US based contracts, in addition to the permitted uses and disclosures granted in the business associate agreement, Client also hereby provides IBM the right, as well as the necessary permission as a business associate, to create de-identified data sets from Client Data, as well as perform data aggregation services. Additionally, IBM has the right to use, modify, disclose and distribute those data sets for any purpose during and after the term of the Agreement.

Where allowable, and in accordance with applicable law, IBM may use Client Data, as well as insights and other information that result from Client's Client Data in the course of providing the Cloud Service with personal direct and indirect identifiers removed and/or replaced with pseudonyms, for the purposes

of product research, testing, and product development. Clients may opt-out of this use by contacting Client's assigned representative from the Offering Management team.