IBM Watson for Oncology

This Service Description describes the Cloud Service IBM provides to Client. Client means the company 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.
- Support first-line medical oncology treatment for breast, lung, colon, and rectal cancers.
- Support second-line medical oncology treatment for lung (NSCLC), colon, and rectal cancers.

Identify potentially relevant clinical trials via a prepopulated query to clinicaltrials.gov

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

1.2 Operational Environments

The Cloud Service operational environment is comprised of one dedicated production environment ("Production Environment") and one dedicated 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

User Accounts: An end user of the Cloud Service may only be a clinician practicing and licensed to practice medicine, in the country in which Client operates and that Client is authorized to use the Cloud Service. ("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 an 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 Data Center Location
The Cloud Service is located in an IBM owned or controlled United States data center. It can only be deployed to Client’s end users that have network connectivity with minimum latency of less than 500 milliseconds from Client’s proxy server to the Cloud Service. Client is responsible for all network connectivity and quality between Client’s proxy server and the Cloud Service users.

1.5 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
IBM maintains privacy and security policies that are communicated to IBM employees. IBM requires privacy and security education training to individuals worldwide who support IBM data centers and we maintain a security team that is focused on information security. IBM security policies are revalidated annually. Security incidents are handled based on comprehensive incident response procedures.

IBM’s security description for the Cloud Service is available as a separate document entitled “Watson Advisors Security Overview.” IBM will adhere to the security description and obligations set forth in the Watson Advisors Security Overview. IBM reserves the right to modify the Watson Advisors Security Overview from time to time so long as the level of security provided does not diminish from that provided in the original Watson Advisors Security Overview.

This Cloud Service does not comply with the US-EU and US-Swiss Safe Harbor Frameworks.

3. Technical Support
Technical support for the Cloud Service is provided via an online problem reporting system. Technical support is offered with the Cloud Service and is not available as a separate offering.

Client will be the first line of support and interface to provide support to all Cloud Service end-users. Except as noted below, Client will provide Level 1 and Level 2 support to end users. If a Cloud Service problem has been identified during Client’s Level 1 support, IBM will provide the Watson-specific Level 2 support as described in this section.

3.1 Support
3.1.1 Level 1 Support
Client will take the first support call from a Client End User and fulfill the following steps:

a. Quality incoming calls:
   (1) Determine if the request is for a new or existing case.
   (2) Assign a severity to a new case (priority one through priority four as defined in the Severity Definition table below).
   (3) Obtain case information.

b. Characterize the problem and environment:
   (1) Gather information about the case and determine if the problem is associated with the Cloud Service or arises from some other source.
   (2) Completely define and describe the problem.
   (3) Identify ways to understand the problem’s behavior.
   (4) Document the characterization information.
   (5) Analyze problem symptom(s); attempt to find root cause when appropriate; and describe the result of such attempts.
   (6) Determine if the problem is a known Cloud Service problem or problem arising from another source by accessing IBM online support resources.

c. If it is determined to not be a Cloud Service problem, contact Client’s Level 2 technical support for issues unrelated to IBM Watson or the Cloud Service.

d. If it is determined to be a Cloud Service problem, contact IBM Watson Level 2 technical support:
(1) For new cases, open a case and assign a severity number as defined per severity classifications in the Severity Definition table below.
(2) For existing cases, state the case number. Provide the case information Client has gathered to the Level 2 support engineer.

3.1.2 Level 2 Support
a. Level 2 Support is the activity performed to analyze or repeat the error, or to determine the error is not repeatable. This activity also includes in-depth technical analysis. IBM's Watson Level 2 Support specialists from IBM's team and Client's Level 1 and Level 2 Support teams will work together to resolve issues.
b. IBM Level 2 technical support is included with the Cloud Service offering and is not available as a separate offering.
c. Technical support will be provided to Client via electronic communications. Technical support contact information will be provided when Client is on-boarded to the Cloud Service. IBM reserves the right to change any URL, or email address related to technical support and will promptly notify Client of any change.

3.1.3 Support Hours:
Client provided Level 1 and Level 2 support hours are determined by Client. Level 2 support and above is provided by IBM from 9:00 AM – 5:00 PM in the time zone as selected by Client from the list below, Monday through Friday (excluding IBM-recognized local holidays in the time-zone selected).
- 9:00 AM – 5:00 PM Eastern US time
- 9:00 AM – 5:00 PM Dublin, Ireland time
- 9:00 AM – 5:00 PM Sydney, Australia time
After hours Support by IBM is not available in any time zone.

3.1.4 Scheduled and Emergency Maintenance
IBM may perform regularly scheduled maintenance during maintenance windows as defined by IBM at its discretion. The maintenance window is 9 PM Saturday – 9 AM Sunday, U.S. Eastern Time, weekly.
Though generally kept brief, down time may occur during portions of these maintenance windows. Other scheduled down times may occur. IBM will provide Client at least thirty (30) days’ notice for other scheduled down times.
b. Emergency Maintenance.
Other non-scheduled down times may occur. IBM shall use all reasonable endeavors to notify Client when these down times occur. The Cloud Service will not be available during these times. If the Cloud Service is unavailable during an emergency maintenance situation, IBM will handle the situation as Severity 1.

3.2 Updates and Deployment of Updates
3.2.1 Updates
This Service Description applies to all enhancements, modifications, variations, revisions, updates, supplements, add-on components, and replacements for the Cloud Service (collectively, "Updates") that IBM may provide or make available for the Cloud Service. IBM has no obligation to, and nothing in this Service Description may be construed to require IBM to, create, provide, or install Updates.

3.2.2 Deployment of Updates
Any Updates that IBM releases will be deployed during a Scheduled Maintenance Window. While all released Updates must be deployed, IBM will work with Client to determine a mutually agreeable schedule for the deployment of an Update in the production zone, which will occur no later than three (3) months after IBM releases the Update. Client may test Updates in the test zone prior to publishing the Updates in the production zone.
3.2.3 Updates to Overall Cloud Service Environment
An overall service environment update improves quality of service attributes of availability, stability, security, or throughput. IBM will apply service environment updates simultaneously to all aspects of the service environment and Client will not be able to defer these updates. Cloud Service environment updates may occur at any time as part of IBM’s efforts to continuously improve the Cloud Service. IBM shall use reasonable efforts to deploy service environment updates in such a manner as to not inhibit IBM’s obligations under this Services Description.

3.3 Back up of Content
Client is responsible for backing up and maintaining all master copies of Client’s content. Client’s content includes information, software, and data, including, without limitation, hypertext mark-up language files, scripts, programs, recordings, sound, music, graphics, images, applets, or servlets that are created, provided, uploaded, by Client and any Client End User authorized by Client for processing by the Cloud Service.

3.4 Incident Management
IBM will:
- Manage, track and report on incidents detected within the Cloud Service
- Direct incidents to the appropriate IBM administrator or technical specialists;
- Provide a web-based support portal and forum for submitting and working incidents.

3.5 Severity Classification and Target Incident Response Time
For the Cloud Services Production Environment, the incident response time is the elapsed time measured from the time in which the incident is reported to IBM by website to an active acknowledgement by IBM support staff of the problem. No PHI data can be included in reporting an incident IBM will use commercially reasonable efforts to meet the incident response time objectives described below.

Severity Classifications and Definitions:

<table>
<thead>
<tr>
<th>Severity</th>
<th>Severity Definition</th>
<th>Example</th>
<th>Response Time Objectives During Support Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Critical business impact/service down: Business critical functionality is inoperable or critical interface has failed. This usually applies to a production environment and indicates an inability to access services resulting in a critical impact on operations. This condition requires an immediate solution.</td>
<td>Oncology user interface is down/not responding for all users.</td>
<td>Reasonable efforts within support hours</td>
</tr>
<tr>
<td>2</td>
<td>Significant business impact: A service feature or function is severely restricted in its use or Client is in jeopardy of missing business deadlines.</td>
<td>Users can login but the system is slow to respond</td>
<td>Reasonable efforts within support hours</td>
</tr>
<tr>
<td>3</td>
<td>Minor business impact: Indicates the service or functionality is usable and it is not presenting a critical impact on operations.</td>
<td>Screen logistics that do not prevent functionality</td>
<td>Reasonable efforts within support hours</td>
</tr>
<tr>
<td>4</td>
<td>Minimal business impact: An inquiry or non-technical request. A request to add a feature or function.</td>
<td>Can you change access rights for a user? Suggesting a new feature to be added</td>
<td>Reasonable efforts within support hours</td>
</tr>
</tbody>
</table>
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 unique individual for whom a set of attributes is input in the Cloud Service. Sufficient entitlements must be obtained to cover all Patients managed or tracked within the Cloud Service during the measurement period specified in Customer's Proof of Entitlement (PoE) or Transaction Document.

4.2 Set-Up Charges
An initial one-time setup fee applies at the rate and billing term specified in the Transaction Document.

4.3 Partial Month Charges
A partial month charge as specified in the Transaction Document may be assessed on a pro-rated basis.

4.4 Overage Charges
If actual usage of the Cloud Service during the measurement period exceeds the entitlement specified in the PoE, Client will be charged for the overage as specified in the Transaction Document.

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. General

6.1 Data Collection
Client is aware and agrees that IBM may, as part of the normal operation and support of the Cloud Service, collect personal information from Client (Client’s employees and contractors) related to the use of the Cloud Service, through tracking and other technologies. IBM does so to gather usage statistics and information about effectiveness of our Cloud Service for the purpose of improving user experience and/or tailoring interactions with Client. Client confirms that it will obtain or have obtained consent to allow IBM to process the collected personal information for the above purpose within IBM, other IBM companies and their subcontractors, wherever we and our subcontractors do business, in compliance with applicable law. IBM will comply with requests from Client’s employees and contractors to access, update, correct or delete their collected personal information.

6.2 Audit Rights
Client shall retain records to substantiate (i) that each Patient corresponds to a unique individual for purposes of calculating charges; (ii) the correct and true identity of all end users; (iii) that only authorized Client End Users use the Cloud Service.

Upon IBM's request, but no more frequently than annually (unless in response to a good-faith dispute), Customer will permit an independent accounting firm chosen by IBM to have access during normal business hours to such Customer records and information as may be necessary to determine the correctness of Charges incurred under this Agreement. Customer will provide its full cooperation in such an audit, which must be communicated in advance by IBM with a two business days written notice.

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 Guaranty of Compliance

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, any protected 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/Clien’t 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 Protected Health Information.

Client and its Client End Users will be able to upload onto the Cloud Service offering a patient’s health information. Client understands and agrees, and will ensure all Client End Users understand and agree that the Cloud Service is provided from a data center located in the United States. Client is solely responsible for compliance, with respect to itself and any Client End User, with all applicable privacy laws or regulations under the laws of the Client and its Client End Users’ country. Client represents and warrants it shall obtain all required patient consents to enable the transmission, storage and use of such patient’s health information to a data center located in the United States. Client is solely responsible and will indemnify IBM for any claims, damages, penalties, fines or any other losses for failing to obtain such consent.

6.7 Regulatory Considerations

a. The Cloud Service offering is not intended for use as a medical device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FDC Act), as amended, Section 2 of Canada’s Food and Drugs Act, as amended, or similar definition by global or local regulatory authorities (“Device”).

b. 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.

c. 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.

d. 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 post market 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.

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

6.8 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.

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

b. 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;

a. Client ensures that only Client End Users are authorized to access the Cloud Service;

b. 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;

c. Any information Client submits or inputs into the Cloud Service offering will be accurate and complete to the best of Client’s knowledge;

d. Client does not:
   (1) use the Cloud Service offering as a substitute for independent medical research and judgment;
   (2) use, copy, modify, or make the Cloud Service offering or any component thereof or information contained therein available, in whole or part, to third parties, except as expressly permitted in this Service Description;
   (3) reverse assemble, reverse compile, and otherwise translate, or reverse engineer the Cloud Service, unless expressly permitted by applicable law without the possibility of contractual waiver;
   (4) use any of the Cloud Service offering’s components, files, modules, audio-visual content, or related offering materials separately from that of the Cloud Service offering;
   (5) rent, sublicense, or lease the Cloud Service offering;
   (6) create Internet “links” to or from the Cloud Service offering; or
   (7) “frame” or “mirror” any content forming part of the Cloud Service offering, other than on Client’s own intranets in connection with Client’s authorized use of the Cloud Service offering.

e. Use of the IBM SaaS by Client’s End Users is subject to the end user terms of use.
f. 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.