



Service Description

IBM Watson for Genomics for Illumina TruSight Tumor 170

This Service Description describes the Watson for Genomics Light Cloud Service (“Cloud Service(s)”). Client means and includes the company, its authorized users or recipients of the Cloud Service.

1. Cloud Service

The IBM Cloud Service is intended to assist licensed healthcare professionals by providing (i) access to an analysis of a cancer patient’s sequenced genomic data contained in an anonymized mutation file (“Sample”), and (ii) a list of existing potential therapeutic options identified in medical literature, supported by evidence in the form of medical literature.

The Cloud Service utilizes the Samples and other associated attributes of the patient (e.g. Cancer type) provided by Client to the Cloud Service to identify information regarding variations specific to the patient tumor and potential therapeutic options by searching medical literature and retrieving evidence. The Client authorized user submitting the patient data will receive a PDF report containing a summary with information regarding genetic alterations and a list of drugs by levels of evidence with hot links to literature and clinical trials associated with the biomarkers.

The report does not assist in the diagnosis of patients, nor does it provide treatment plans for patients; it provides information on genetic variations specific to a patient’s tumors. The Cloud Service or any resulting report, does not replace a clinician’s expert professional judgment and training. Client expressly acknowledges that the Cloud Service is utilized pursuant to terms and conditions prescribed in Section 4.

The Cloud Service currently does not support the input and management of content containing information that may be considered as personal information (“PI”) or sensitive personal information (“SPI”), including protected health information (“PHI”). Accordingly, Client shall not input any information into the Cloud Service that is PI, SPI or PHI.

Overview of the Cloud Service

Actor	Actions
Authorized user of the Cloud Service	Logs into the Cloud Service and: <ul style="list-style-type: none"> Uploads a sequenced tumor Sample <ul style="list-style-type: none"> Selects a Cancer Type (and subtype, if applicable) Uploads anonymized alterations file(s) in the formats supported by the system (“Client File”)
Cloud Service program	Parses the uploaded files and information. Identifies variations specific to the patient tumor by searching medical literature and retrieving evidence. <ul style="list-style-type: none"> Filters out benign and likely benign alterations Identifies the potential driver alterations: pathogenic, likely pathogenic and variants of unknown significance (VUS) For each potential driver alteration, the Cloud Service identifies potential therapeutic options that are likely to be relevant and presents the findings in a PDF report. The report includes evidence-based insights on driver alterations and potential drugs and clinical trials that may be relevant to the patient’s unique DNA profile.

IBM Responsibilities

The following is a high level summary of IBM’s responsibilities:

- Provide a web site for Client authorized users to submit Client Files;
- Provide a web site for Client authorized users to access to the PDF report; and
- Provide to Client the formats that the Client may use for specific Client Files.

Client Responsibilities

The following is a high level summary of the Client’s responsibilities:

- Ensure that only anonymized Client Files are uploaded to the Service or otherwise emailed or transmitted to IBM;
- Ensure that you will not otherwise transmit to IBM any Client Files or other data or information that contains personal health information or personally identifiable information;

- Ensure only authorized Client users have access to the Service;
- Ensure proper safeguards for any user access credentials used with the Service;
- Ensure you use the file formats as determined by IBM for Client Files;

1.1 Operational Environments

The Cloud Service is delivered via a “Software as a Service” model, running on a multi-tenant production environment. The production environment will be accessible to all Client authorized users.

The Cloud Service is located in an IBM owned or controlled data centers in the United States. It can only be accessed by Client authorized users who have network connectivity with minimum latency of less than 500 milliseconds from your proxy server to the Cloud Service. Client is responsible for all network connectivity and quality between the Client’s proxy server and the Cloud Service users.

IBM will notify Client when the Cloud Service is available for use by providing Client’s designated administrator access to the Cloud Service.

1.2 Availability Objectives

The service level objective for this Cloud Service is 99% uptime outside of any Deployment of Updates or Scheduled Maintenance Windows.

Service level objectives are a goal and do not constitute a warranty to you. There is no refund, credit, or other remedy available to you in the event IBM does not meet the service level objectives.

2. Security Description

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

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

2.1 Health Information

Client represents and warrants it shall not provide or disclose to IBM any information or data subject to the requirements of the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”), the Health Information Technology for Economic & Clinical Health Act of the American Recovery and Reinvestment Act of 2009 or any regulations thereto, or any other world-wide laws pertaining the health information or world-wide privacy laws. Client Files will be de-identified and anonymized data in accordance with applicable law prior to uploading to the Cloud Service to an extent sufficient to ensure that a person without prior knowledge of the original data and its collection cannot, from the de-identified data and any other available information (such as postal-code charts or a list of the people recruited for the study), deduce the personal identity of the data-subjects.

Client understands and agrees, and will ensure all Client authorized 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 authorized users, with all applicable privacy laws or regulations under the laws of the Client and its Client authorized users’ country. If applicable, Client represents and warrants it shall obtain all required patient permissions 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.

3. Technical Support

3.1 Scheduled and Emergency Maintenance

- a. **Scheduled Maintenance Windows.** IBM may perform regularly scheduled maintenance during maintenance windows as defined by IBM at its discretion. The maintenance window at the date of this Service Description is:

- 12:01 AM Tuesday – 7 AM Tuesday, 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. The Cloud Service support will post a notification of scheduled down times to the Cloud Service web site at least one (1) day in advance.

- b. **Emergency Maintenance** Other non-scheduled down times may occur due. IBM will 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, Cloud Services support will manage the situation as severity 1 incident.

3.2 Updates to the Cloud Service and Deployment of Updates

IBM may periodically provide or make available Updates to the Cloud Service platform, which may include enhancements, modifications, variations, revisions, supplements, or add-on components and replacements (collectively “Updates”). IBM is under no obligation to create, provide, or install Updates.

Updates will be deployed during a scheduled maintenance window.

IBM may at any time update the underlying Cloud Service infrastructure environment to improve availability, stability, security, or throughput and will be applied simultaneously to all aspects of the Cloud Service operating environment (also referred to as “Updates”). Client will not be able to defer such infrastructure Updates. IBM will use commercially reasonable efforts to deploy such infrastructure environment Updates in such a manner as to not inhibit Client’s use of the Cloud Service.

3.3 Severity Classification

Cloud Service support will designate severity for each service request. Cloud Service support will validate such severity and reserves the right to re-prioritize based upon the definitions below.

Severity Classifications and Definitions:

Severity	Description	Example
1	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.	User interface is down and Cloud Service is not available for all users
2	Significant business impact: A service business feature or function of the service is severely restricted in its use or you are in jeopardy of missing business deadlines.	Users can login but the system is so slow to respond
3	Minor business impact: Indicates the service or functionality is usable and it is not a critical impact on operations.	Results returned appear to be incomplete or out of date
4	Minimal business impact: An inquiry or non-technical request. A request to add a feature or function.	How to add a new user to the Cloud Service? Can you change access rights for a user? Suggesting a new feature to be added to the Cloud Service.

3.4 Customer Support Contacts

For questions about product orders or the Illumina BaseSpace Sequence Hub, contact TechSupport@illumina.com.

For questions about Watson for Genomics and reports, contact WfG@us.ibm.com.

For information about available options once all allocated samples have been used, contact CustomerService@illumina.com.

4. Additional Terms

4.1 Regulatory Considerations

THE CLOUD SERVICE AND ANY UPDATES ARE NOT INTENDED TO CONSTITUTE A MEDICAL DEVICE AS DEFINED IN SECTION 201(h) OF THE UNITED STATES FOOD, DRUG AND COSMETIC ACT AS AMENDED AND SECTION 2 OF THE CANADIAN FOOD AND DRUGS ACT (OR A SIMILAR DEFINITION UNDER APPLICABLE LAWS AND/OR REGULATIONS OF OTHER JURISDICTIONS).

The Cloud Service is not intended for use or shall be used as a medical device subject to regulation by the U.S. Food and Drug Administration ("FDA") or any other similar authority in any jurisdiction. In the event that the FDA or such similar authority seeks to enforce any requirement of such agency with respect to the Cloud Service, IBM has sole responsibility for communicating with any or all regulators regarding the Cloud Service. For purpose of clarity, Client agrees that it shall not communicate with any or all regulators regarding the Cloud Service. If IBM is required to submit the Cloud Service to medical device regulation, Client shall provide, if applicable, reasonable requested support and cooperation with IBM to facilitate regulatory filings and post market regulatory compliance.

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 any such regulation of the Cloud Service offering (or any portion of it) occurs during the subscription period, and IBM is not willing or able to comply, IBM shall at its sole discretion suspend the Cloud Service or terminate this Order Document, the Service Description, or any other related agreement immediately upon written notice to Client. Such suspension or termination shall be at no penalty to IBM and shall not entitle Client to any refunds, credits or offsets under the IBM Cloud Services Agreement, the Order Document, this Services Description or any other agreement with IBM.

4.2 No Guaranty 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 all relevant laws, regulations and licensing requirements to the use of the Cloud Service offering and the delivery of healthcare services. Client is solely responsible to ensuring Client and Client authorized users' activities comply with all applicable laws, regulations, standards and practices. Any directions, suggested usage, or guidance provided by the Cloud Service does not constitute legal, accounting, or other professional advice, and you are cautioned to obtain your own legal or other expert counsel. .

Client is solely responsible for ensuring that its Client authorized users, , if applicable, obtain all necessary permissions of patients relating to the use, transfer and storage of EMRs, any 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 ethics boards of Client's institution. Notwithstanding the foregoing, Client shall not provide or disclose to IBM any information or data that is subject to the requirements of United States privacy laws.

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.

The out of the box TruSight Tumor 170 plus Watson for Genomics offering is a research solution. Client is responsible for performing/obtaining the necessary laboratory compliance certifications prior to use in a clinical capacity. Notwithstanding the foregoing, 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 authorized users of the Cloud Service will not diminish Client's or its Client authorized 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 assumes 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.

4.3 General

Client agrees to allow IBM to cite your agency name and the general nature of the Services IBM performed for you to IBM's other clients and prospective clients as an indication of IBM's experience.

Client may provide feedback to IBM regarding the Cloud Service ("Feedback"). Client grants to IBM an irrevocable, nonexclusive, royalty free, worldwide right to use Feedback for any purpose.

Client agrees that IBM may use the Client Files and Feedback to enhance or otherwise modify the Cloud Service. Client represents and warrants it has all necessary consents to upload the Client Files to the Cloud Service, to enable IBM to use Client Files and Feedback to enhance or otherwise improve or modify the Cloud Service, or otherwise provide any other data or information to IBM.

Client is responsible for backup and recovery of the Client Files you upload to the Cloud Service and of all reports.

IBM owns the Cloud Service and any Updates. Client agrees that title to, ownership of and all rights in and to patents, copyrights, trademarks, and all other intellectual property rights in the Cloud Service and any Updates and any copy or part of the Cloud Service and any Updates will remain with IBM.

SUBJECT TO ANY STATUTORY WARRANTIES THAT CANNOT BE EXCLUDED, IBM MAKES NO WARRANTIES OR CONDITIONS, EXPRESS OR IMPLIED, REGARDING THE SERVICE, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OR CONDITIONS OF MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE, AND TITLE, AND ANY WARRANTY OR CONDITION OF NON-INFRINGEMENT.