

## Service Description

---

### IBM Study Advance

This Service Description describes the Cloud Service. The applicable order documents provide pricing and additional details about Client's order.

#### 1. Cloud Service

The IBM Study Advance Cloud Services are a collection of integrated cloud-based, data-driven, authoring tools designed for clinical trial protocol optimization. The Cloud Services merge both real-world patient population data and standardized protocol template guidance through a collaborative workspace designed to facilitate efficiency.

##### 1.1 Offerings

The Client may select from the following available offerings.

###### 1.1.1 IBM Study Advance

The IBM Study Advance Cloud Service combines real-world patient population data insights and standardized template guidance in a collaborative workspace. Up to one hundred (100) unique authorized users may access one Instance of the Cloud Service during a 12-month subscription period.

The real-world patient data insights are provided via the Participant Insights feature of the Cloud Service. Participant Insights allows authorized users to experiment with inclusion and exclusion criteria within a protocol by reviewing counts of potentially eligible clinical trial participants meeting the criteria. Counts are derived from the Commercial and Medicare Supplemental claims dataset of the IBM MarketScan® Research Databases ("MarketScan Data"), which is included as part of this Cloud Service.

Standardized template guidance in a collaborative workspace is included in the Cloud Service on a per protocol basis. Each protocol includes:

- Standardized template for authorized users to enter content for one (1) synopsis;
- Standardized template for authorized users to enter content for one (1) protocol that is auto-populated with relevant content, if any, from the associated synopsis;
- Project management capability to assign authorized users to synopsis or protocol sections;
- Functionality for authorized users assigned to sections to build, edit, review, and approve synopsis and protocol elements;
- Notifications for authorized user review and action; and
- Option to export the synopsis and protocol content to an open document compliant format.

###### 1.1.2 IBM Study Advance MarketScan User

The IBM Study Advance MarketScan User Cloud Service includes all the functionality of the Cloud Service described in Section 1.1.1 above except it does not include access to the subsets of the MarketScan Data. Client must already have sufficient rights and access to the MarketScan Data prior to ordering this Cloud Service.

###### 1.1.3 IBM Study Advance Participant Insights

The IBM Study Advance Participant Insights Cloud Service is comprised of solely of the real-world patient population data insights component of the IBM Study Advance Cloud Service. This Cloud Service provides insights that can support protocol authoring which Clients may perform outside of the Cloud Service. Participant Insights allows authorized users to experiment with inclusion and exclusion criteria within a protocol by reviewing counts of potentially eligible clinical trial participants meeting the criteria. Counts are derived from the MarketScan Data, which is included as part of this Cloud Service. Authoring features, such as standardized template guidance in a collaborative workspace, are not included in this Cloud Service.

This Cloud Service allows up to ten (10) unique authorized users access to one Instance of the Cloud Service during a 12-month subscription period.

#### 1.1.4 IBM Study Advance Participant Insights MarketScan User

The IBM Study Advance Participant Insights MarketScan User Cloud Service includes all of the functionality of the Cloud Service described in Section 1.1.3 above except it does not include access to the subsets of the MarketScan Data. Client must already have sufficient rights and access to the MarketScan Data prior to ordering this Cloud Service.

### 1.2 Acceleration Services

#### 1.2.1 IBM Study Advance Set Up

Client must acquire this set up service in order to provision each protocol used by the IBM Study Advance Cloud Service. Set up of protocols are acquired on an Item basis, with a minimum requirement of one (1) Item per Instance of the Cloud Service. Clients may request additional protocols to be set up at any time during Client's subscription period by acquiring additional Item entitlements. Each protocol established in the Cloud Service remains available for use as long as Client has a valid Cloud Service subscription.

#### 1.2.2 IBM Study Advance MarketScan User Set Up

Client must acquire this set up service in order to provision each protocol used by the IBM Study Advance MarketScan User Cloud Service. Set up of protocols are acquired on an Item basis, with a minimum requirement of one (1) Item per Instance of the Cloud Service. Clients may request additional protocols to be set up at any time during the Client's subscription period by acquiring additional Item entitlements. Each protocol established in the Cloud Service remains available for use as long as Client has a valid Cloud Service subscription.

## 2. Data Processing and Protection Data Sheets

IBM's Data Processing Addendum at <http://ibm.com/dpa> (DPA) and the Data Processing and Protection Data Sheet(s) (referred to as data sheet(s) or DPA Exhibit(s)) in the links below provide additional data protection information for the Cloud Services and its options regarding the types of Content that may be processed, the processing activities involved, the data protection features, and specifics on retention and return of Content. The DPA applies to personal data contained in Content, if and to the extent i) the European General Data Protection Regulation (EU/2016/679) (GDPR); or ii) other data protection laws identified at <http://ibm.com/dpa/dpl> apply.

<https://www.ibm.com/software/reports/compatibility/clarity-reports/report/html/softwareReqsForProduct?deliverableId=D8B41900879111E9BFD5252BC35BF06E>

## 3. Service Levels and Technical Support

### 3.1 Service Level Agreement

IBM provides Client with the following availability service level agreement (SLA). IBM will apply the highest applicable compensation based on the cumulative availability of the Cloud Service as shown in the table below. The availability percentage is calculated as the total number of minutes in a contracted month, minus the total number of minutes of Service Down in the contracted month, divided by the total number of minutes in the contracted month. The Service Down definition, the claim process and how to contact IBM regarding service availability issues are in IBM's Cloud Service support handbook at [https://www.ibm.com/software/support/saas\\_support\\_overview.html](https://www.ibm.com/software/support/saas_support_overview.html).

Availability	Credit (% of monthly subscription fee*)
Less than 99.9%	2%
Less than 99.0%	5%
Less than 95.0%	10%

\* The subscription fee is the contracted price for the month which is subject to the claim.

### 3.2 Technical Support

Technical support for the Cloud Service, including support contact details, severity levels, support hours of availability, response times, and other support information and processes, is found by selecting the Cloud Service in the IBM support guide available at <https://www.ibm.com/support/home/pages/support-guide/>.

## 4. Charges

### 4.1 Charge Metrics

The charge metric(s) for the Cloud Service are specified in the Transaction Document.

The following charge metrics apply to this Cloud Service:

- Instance is each access to specific configuration of the Cloud Services.
- Item is an occurrence of a specific item that is managed by, processed by, or related to the use of the Cloud Service.

For IBM Study Advance and IBM Study Advance MarketScan User, an Item is defined as a protocol that Client creates in the Cloud Service.

## 5. Additional Terms

For Cloud Service Agreements (or equivalent base cloud agreements) executed prior to January 1, 2019, the terms available at <https://www.ibm.com/acs> apply.

### 5.1 Client Acknowledgements

#### 5.1.1 Third Party Copyright Notices

Client shall comply with and be bound by all provisions and agreements required by other third party licensors as are contained herein in Exhibit A ("Third Party Notices"). Client's rights to use the third party licensor products terminate if Client fails to comply with any such obligations.

#### 5.1.2 Use of MarketScan Data

Client's use of the MarketScan Data accessed through the Cloud Services is limited to the following:

##### a. MarketScan Data Use Restrictions

Authorized users use of MarketScan Data is a limited, non-exclusive, non-transferable licenses for the term set forth in the Transaction Document to use with the Cloud Service for internal use only within the Territory (as described in Exhibit A).

End User is prohibited from publishing, distributing via the Internet or other public computer based information system, creating derivative works (including translating), transferring, selling, leasing, licensing or otherwise making available to any unauthorized party the MarketScan Data, or a copy or portion of MarketScan Data.

Further, Client must not remove, alter or destroy any other form of copyright notice, proprietary marking or confidential legend of IBM or any third-party licensor placed upon or contained within the MarketScan Data. Client may display and print formats, results and text to support its internal use of the MarketScan Data. Client may not copy, reproduce or duplicate the MarketScan Data, in whole or in part, except to make a back-up copy.

##### b. Prohibition on Data Linking and Re-Identification

Client and its authorized users will not:

- (1) re-identify, attempt to re-identify, or allow re-identification of any individual (whether a patient, beneficiary, provider or other person) contained within the MarketScan Data; or
- (2) re-identify, attempt to re-identify, or allow the re-identification of, any relative(s), family or household member(s) of such individual(s), unless required by law; or
- (3) re-identify, attempt to re-identify, or allow any re-identification of the entities that are the sources of information that is included within the MarketScan Data.

If the identity of any person, establishment or organization is discovered inadvertently, then (a) no use will be made of this knowledge; (b) the information that would identify any person, establishment or organization will be safeguarded or destroyed; and (c) no one else will be informed of the discovered identity.

##### c. Authorized Users

Client agrees that it is solely responsible for ensuring its authorized users' use of the MarketScan Data is in accordance with this Service Description, and paying all applicable charges arising from its authorized users' access and use of the MarketScan Data. Client agrees to use appropriate

safeguards and take all reasonable steps to protect the MarketScan Data from any use, reproduction, publication, or disclosure that is not specifically authorized under the Service Description and will report to IBM any known misuse of the MarketScan Data within ten (10) calendar days of discovery.

For the purposes of this Service Description, "authorized user" means an individual who: (a) accesses, uses, or manipulates MarketScan Data; or (b) accesses, uses, or manipulates the MarketScan Data to produce or enable an output (data, reports, or the like) that could not have been created without the CPT embedded in the MarketScan Data even though CPT Editorial Content may not be visible or directly accessible; or (c) makes use of an output of the MarketScan Data that relies on or could not have been created without the CPT Editorial Content embedded in the MarketScan Data even though CPT Editorial Content may not be visible or directly accessible.

d. **No Use for Litigation**

Client may not use the MarketScan Data or any data resulting from analysis of the MarketScan Data for the purpose of use in any pending or anticipated litigation.

**5.1.3 Medical Device and Drug Regulatory Disclaimer**

IBM is acting as an information technology provider only. IBM does not purport to be engaged in the practice of medicine or any other professional clinical or licensed activity, and the Cloud Service, all components thereof and future updates thereto, and all deliverables of related IBM professional services are not designed or intended to constitute protocols for delivering medical care, a substitute for professional medical advice, diagnosis or treatment or judgment, a drug, drug-adjunct technology, or drug development tool subject to quality system requirements or medical device as defined under the laws of any jurisdiction. As between IBM and Client, Client is solely responsible for complying with all such laws and regulations relative to Client's use of the Cloud Service and IBM's professional services.

**5.1.4 Publicity**

Client agrees not to use any name, trade name, trademark, or other designation of IBM, including any contraction, abbreviation, or simulation of any of the foregoing in advertising, promotion, publication, publicity, or any marketing activity without IBM's prior written consent.

**5.1.5 Consent Management**

Client is responsible for having and maintaining the consents, authorizations and/or other legal permissions required by federal, state or other applicable law to provide Content to IBM and to permit IBM to process and use Content and other personal data as specified in the Agreement, including with respect to all data provided by its participants and authorized users. The consent management tools and systems associated with Content are maintained by Client outside the Cloud Service ("Client Consent Tools") and it is the responsibility of the Client to ensure that Content in the Cloud Service is used, stored, and processed in accordance with such Client Consent Tools.

**5.2 United States Additional Terms**

The following terms apply for Cloud Services delivered in the United States.

**5.2.1 Debarment**

To the extent applicable to the services being provided to Client, IBM will not use any individual to perform services for Client who is currently on the exclusion list issued by the Office of the Inspector General of the U.S. Department of Health and Human Services pursuant to the provisions of U.S.C. §1320a(7) or the excluded parties list system maintained by the U.S. General Services Administration, or is otherwise debarred, disqualified, excluded or subject to sanctions by any U.S. federal or state government or regulatory authority. If IBM becomes aware that an individual used by IBM to perform services for Client has been debarred, disqualified, excluded or sanctioned, IBM will promptly notify Client and cease utilizing such individual to perform services for Client. Client may terminate Client's subscription to the Cloud Service without penalty, if IBM is debarred, disqualified, excluded or subject to sanctions by any U.S. federal or state government or regulatory authority.

## **6. Overriding Terms**

### **6.1 Data Use**

The following prevails over anything to the contrary in the Content and Data Protection section of the base Cloud Service terms between the parties: IBM will not use or disclose the results arising from Client's use of the Cloud Service that are unique to Client's Content (Insights) or that otherwise identify Client. IBM will however use Content and other information that result from Content as part of the Cloud Service for the purpose of improving the Cloud Service and other Cloud Services that utilize the same underlying technology.

## Third-Party Notices

Pursuant to IBM's CPT License Agreement for Domestic Distribution with The American Medical Association ("AMA"), as it may now or hereafter be amended, IBM is authorized to distribute and sublicense to Client Physicians' Current Procedural Terminology, Fourth Edition, a coding system of nomenclature and five-digit codes for reporting of physician services, and/or ICD-10-CM/PCS (collectively, "CPT"), as part of the MarketScan Data, provided that Client is bound by certain terms and conditions. Client's rights to use the CPT terminate if Client fails to comply with any of the material terms and conditions thereof.

The terms and conditions set forth in the Service Description that apply to the MarketScan Data generally also apply to the CPT.

The following are the additional terms and conditions that apply to the CPT:

- a. CPT is copyrighted by the AMA and all notices of proprietary rights, including trademark and copyright in CPT must appear on all permitted back-up or archival copies made by the user; any printout or other output from the electronic media that contains any portion of CPT (other than that which would constitute fair use, internal reports and claim forms for specific patients and external reports distributed outside of Client's entity containing less than twenty (20) CPT codes and/or descriptions) will display the following:  
*CPT only © 2018 American Medical Association. All Rights Reserved.*  
The year specified in the copyright notices must conform to future CPT updates.
- b. Except as otherwise expressly provided in the Agreement, the MarketScan Data is provided "as is" without any warranty from or liability to IBM or the AMA, including, without limitation, liability for consequential or special damages or lost profits for sequence, accuracy or completeness of MarketScan Data, or that it will meet Client's requirements; IBM's and AMA's sole responsibility is to use reasonable efforts to provide corrections to or a replacement of the MarketScan Data; AMA disclaims any liability for any consequences due to use, misuse or interpretation of information contained or not contained in CPT.
- c. The MarketScan Data includes CPT which is commercial technical data developed exclusively at private expense by the American Medical Association, 330 North Wabash Avenue, Chicago, Illinois 60611. Except as permitted under the applicable license grant, the American Medical Association does not agree to license CPT to the Federal Government based on the license in FAR 52.227-14 (Data Rights – General) and DFARS 252.227-015 (Technical Data – Commercial Items) or any other license provision. The American Medical Association reserves all rights to approve any license with any federal agency.
- d. The responsibility for any content of any "National Correct Coding Policy" included in the MarketScan Data is with the Centers for Medicare and Medicaid Services, formerly known as the Health Care Financing Administration, and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable to or related to any use, non-use or interpretation of information contained in the MarketScan Data.
- e. Territory ("Territory")
  - (1) Print Licensed Products:  
Worldwide.
  - (2) Electronic Licensed Products:  
Algeria, Argentina, Australia, Bahamas, Belgium, Bermuda, Brazil, British Virgin Islands, Canada, Cayman Islands, Chile, China, Colombia, Costa Rica, Denmark, Dominican Republic, Ecuador, El Salvador, Finland, France, Germany, Guatemala, Hong Kong, India, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Republic of Korea (South Korea), Lebanon, Mexico, New Zealand, Norway, Panama, Philippines, Portugal, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, United Arab Emirates, United Kingdom, United States and its territories, and Venezuela.

Countries may be added to the Territory upon written notice from the AMA. The AMA reserves the right to delete countries from the Territory where trade is prohibited by U.S. law or where the AMA, in its reasonable judgment, determines that it cannot protect its copyright.