BT for Life Sciences Value Added Services

1 Definitions

The following definitions apply, in addition to those in the General Terms and Conditions.

- "Accelrys Enterprise Platform" means a software platform by Dassault Systèmes S.A..
- "Apache License 2.0" means the free software licence written by the Apache Software Foundation (ASF), version 2.0 January 2004.
- "API" means an Application Programming Interface which enables the Customer to manage the service without the use of the Portal.
- "Applications Library" means a collection of third party business and research applications to run In Silico research or simulation.
- "Availability Zone" means the configuration of hardware and software to create a platform where the Virtual Machines are deployed.
- **"BT for Life Sciences Value Added Services"** means each of Workbench R&D Informatics, Workbench R&D Life Sciences Data Sources and Compute Conform.
- "BT Cloud Compute" means a Cloud based service providing the Customer with a self-service capability to browse, select, provision, and deploy virtual infrastructure including Virtual Machines, network, Storage and security.
- "Business Hour" means an hour between 0900 and 1700 on a Business Day (in the country or locality in which the Service is being provided).
- "Channel Bundle" means a service bundle for the Workbench R&D Informatics that may be ordered by a Channel Partner.
- "Channel Partner" means a Customer that has entered into a separate agreement with BT, titled 'BT for Life Sciences Alliance Agreement', to give the Customer specific reseller rights.
- "Chef" means software that allows the configuring and maintaining of servers/applications. It originated from the company Opscode, Inc. and is released as open source under the Apache License 2.0.
- "Chef Recipes" means a script that describes how Chef manages server applications and how they are to be configured.
- "Cloud Components" means is a collection of components that allows an existing Pipeline Pilot customer to interact with the BT Cloud Compute environment from a Pipeline Pilot Service hosted on BT Cloud Compute.
- "Cloud Connect" means the physical and logical connection point between the Service and an external IP based network.
- "Cloud Management System (CMS)" means the portal and the automation / orchestration system that manages and drives the Service.
- "Cluster Management Tool" means a type of HPC Tool that can manage the operation of clusters.
- "Compute Conform" means the service described in Clause 5 "Bronze", "Silver" "Gold" or "Platinum" Service options are described in Clause 5.
- "COBIT" means Control Objectives for Information and Related Technology, the framework created by ISACA for information technology management and information technology governance.
- "Conform Availability Zone" means an Availability Zone that has been Qualified according to the principles of GxP compliance.

"Control Framework" means controls encompassed in established frameworks such as (but not limited to) COBIT and ISO.

"Customer Information" means data, information, video, graphics, sound, music, photographs, software and any other materials published or otherwise made available by or on behalf of the Customer.

"**DCF**" means Data Capture Form, the form provided to the Customer after an Online Order is submitted, which sets out the further information required by BT to provide Workbench R&D Informatics and/or Workbench R&D Life Sciences Data Sources, as applicable.

"CPU" means central processing unit.

"EQMS" means Electronic Quality Management System, the document management system used by BT that can be configured and shared with the Customer.

"Grid Middleware Tool" means a type of HPC Tool that shares the processing in a distributed computing environment.

"GxP" means Good Clinical, Laboratory or Manufacturing Practices.

"Hardware" means, the physical elements that comprise the data centres.

"HPC Tools" means High Performance Computing Tools, a collection of third party tools that distribute workload across BT Cloud Compute Virtual Machines, consisting of Cluster Management Tools and Grid Middleware Tools.

"Hypervisor" means the software that provides the capability to deliver Virtual Machines.

"Identity Federation Service" means the process of sharing electronic identities between the Workbench R&D Informatics Environment and the Customers' specified identity management system compliant with SAML 2.0.

"In Silico" means performed on computer or via computer simulation.

"**Incident**" means an incident which is not part of the standard operation of a Service and which causes, or may cause, an interruption to, or a reduction in the quality of that Service.

"Informatics Applications" means the applications that are provided by BT as part of the delivered Workbench R&D Informatics Environment.

"IQ/OQ" means Installation Qualification / Operational Qualification, the documented validation act demonstrating that a procedure, process, and activity will consistently lead to the expected results.

"Internet" means the global data network comprising interconnected networks using the TCP/IP protocol suite.

"IP" means Internet protocol, a protocol that was designed to interconnect networks and is part of a suite of protocols known as TCP/IP, where "TCP" means transmission control protocol, a reliable connection-based protocol.

"ISO" means the International Organization for Standardization.

"**Key Controls**" means those activities documented in the QMS Manual that delineate how the Life Cycle of the Qualified Hardware is managed.

"Life Cycle" means the time from the point of installation to the point of decommissioning of Hardware and/or Software that has been Qualified according to the QMS Manual.

"Month" means a calendar month.

"Online Order" means a Customer request for the Service. The Online Order is only available online via the Portal or API.

"Pipeline Pilot" means an authoring tool for the Accelrys Enterprise Platform.

"Portal" means the online system that allows the Customer to place Online Orders, change Online Orders, see the status of the Service and access certain systems (depending on the Service option chosen by the Customer).

"Puppet" means an open source configuration management tool from Puppet Labs, Inc..

"Puppet Manifests" means a script that describes how Puppet manages server applications and how they are to be configured.

"Qualification" or "Qualified" means that BT has determined that Hardware and/or Software used with the Service requires the activities involved in the IQ/OQ and Life Cycle management related to that Hardware and/or Software.

"QMS Manual" means the document that details the QMS.

"Quality Management System" or "QMS" means the quality management system that identifies the specific tasks, roles and responsibilities regarding the management of the Life Cycle of the Qualified Hardware and or Qualified Software used to provide the Service.

"Quickstart Process" means the process of consultation that occurs between the Customer and BT for scoping and sizing a Customer Online Order for Workbench R&D Informatics and/or Workbench R&D Life Sciences Data Sources that results in a final Online Order setting out the options selected by the Customer, and which follows the steps set out in Clause 2.2.1.

"SAML 2.0" means Security Assertion Markup Language 2.0, is a version of the standard for exchanging authentication and authorization data between security domains.

"Service" means Workbench R&D Informatics and each, or any, of, as applicable, Workbench R&D Life Sciences Data Sources and/or Compute Conform, as ordered by the Customer in accordance with this Schedule.

"Service Desk" means the facility provided by BT to handle enquiries and administration for the Service.

"**SDK**" means Software Development Kit, a set of software development tools that allows for the creation of applications for a certain software package, software framework, Hardware platform, computer system, operating system, or similar development platform.

"Storage" means the recording and storing of information and data.

"tranSMART Platform" means an open-source, community-driven knowledge management platform made available by the tranSMART Foundation that enables integrated analytics and data-sharing for clinical and translational research.

"**User Guide**" means the guidance document that contains further information on Workbench R&D Informatics and which does not form part of the Agreement.

"Virtual Desktop" means the pre-configured virtual desktop environment through which the Customer and its Users can access Workbench R&D Informatics.

"Virtual Machines" or "VM" means a self-contained operating system that functions as a separate server.

"VM History SDK" means a SDK that enables access to a Virtual Machine's history.

"VM Template" is a pre-defined operating system to be used within a specific Hypervisor.

"Workbench R&D Informatics" means the Workbench R&D Informatics Environment along with associated service provided by BT.

"Workbench R&D Informatics Environment" means a pre-configured virtual desktop environment created for a Customer that consists of a Workbench R&D Informatics Virtual Desktop and a Workbench R&D Informatics Platform.

"Workbench R&D Life Sciences Data Sources" or "Data Sources" means a research repository of healthcare and clinical trials data that allows a pharmaceutical or healthcare company to examine how healthcare is delivered and the results that are achieved in the real world setting, largely from open data published by the UK National Health Service 'Health and Social Care Information Centre', with additional data derived from that published by the Office of National Statistics, Department of Health, US Food and Drug Administration and other sources.

"Workbench R&D Informatics Platform" means a software platform based on BT Cloud Compute.

2 Workbench R&D Informatics

2.1. The Workbench R&D Informatics Environment

If selected by the Customer in an Online Order, BT will, within seven (7) days of the date the Online Order is accepted, provide Workbench R&D Informatics to the Customer, which will comprise the following, as further specified in the Online Order:

- 2.1.1. Workbench R&D Informatics Virtual Desktop, which is comprised of:
 - (a) the Virtual Desktop; and
 - (b) the Identity Federation Service; and
- 2.1.2. the Workbench R&D Informatics Platform, that is based on BT Cloud Compute and is comprised of:
 - (a) the Informatics Application servers which are created at the time of set-up and hosted on BT Cloud Compute;
 - (b) the HPC Tools;
 - (c) the Applications Library; and
 - (d) if selected by the Customer in the Order, Workbench R&D Life Sciences Data Sources.

2.2. Quickstart and Ordering Process

- 2.2.1. If agreed by the Parties, BT will undertake the Quickstart Process with the Customer during which:
 - (a) the Customer and BT will work together to define the requirements for the Customer to obtain Workbench R&D Informatics; and
 - (b) BT will provide the Customer with the DCF that defines the components and services needed to be ordered by the Customer;
- 2.2.2. BT may require the Customer to pay Charges for the Quickstart Process as set out in the Order.
- 2.2.3. After the Quickstart Process, the Customer will:
 - (a) place the Online Order via the BT Cloud Compute portal for Workbench R&D Informatics (including any other services available from BT and required by the Customer);
 - (b) place the Online Order for the dedicated Identity Federation Service (if required);and
 - (c) provide BT with the username and password details used to create the Online Order.

2.3. Amendment

Amendments and upgrades are not in scope of Workbench R&D Informatics. To amend Workbench R&D Informatics another Quickstart Process is required to be initiated and depending on the output the Customer may be required to place a new Online Order to replace the existing service.

2.4. Termination

In addition to its other rights under the Agreement, the Customer may terminate Workbench R&D Informatics by providing ten (10) days' prior notice to BT, and subsequently de-selecting Workbench R&D Informatics on the Portal.

2.5. Workbench Service Bundles

BT will provide Workbench R&D Informatics to the Customer in one of the following service bundles, whichever is selected by the Customer as set out in the Online Order:

- 2.5.1. small bundle, which will accommodate up to 50 Users and will use a 'shared' Identity Federation Service that is used by many Workbench R&D Informatics customers;
- 2.5.2. medium bundle, which will accommodate between 50 and 250 Users and will use a 'shared' Identity Federation Service that is used by many Workbench R&D Informatics customers:
- 2.5.3. large bundle, which will accommodate between 250 and 1000 Users and which may use a dedicated Identity Federation Service which is exclusive to the Customer's use, subject to additional Charges as set out in the Online Order;
- 2.5.4. channel bundle, which will enable the Channel Partner to resell Workbench R&D Informatics and provide up to 200 simultaneous Users as further set out in Clause 2.11. Identity Federation service is not included in the Charges for the Channel bundle.

2.6. Customer Dependencies

- 2.6.1. The Customer will be responsible for all preparatory work required for the Customer to use Workbench R&D Informatics, including but not limited to procuring and maintaining:
 - (a) all consents and licences required for use of any third party applications or to set up any Chef or Puppet service required for the HPC Tools; and
 - (b) any server required for set-up of a Chef, Puppet or Pipeline Pilot service for use of the HPC Tools or the Applications Library.

2.7. BT Service Management Boundary

- 2.7.1. For small bundle, medium bundle and large bundle, BT is responsible for:
 - (a) Conducting the Quickstart Process along with the Customer;
 - (b) Creating the DCF along with the Customer;
 - (c) Delivering the Workbench R&D Informatics Environment;
 - (d) Providing the Customer with access to a Customer administrator account that will enable the Customer to perform their administration activities;
 - (e) Delivering the Data Sources bundle (where applicable);
 - (f) Configuring, and maintaining the configuration, of the Identity Federation Service;
 - (g) Creating and restoration of the back-up of the Workbench R&D Informatics Environment;
 - (h) Provision and upgrade of new applications to the Workbench R&D Informatics Environment, subject to validation by Quickstart Process;

- (i) Creating and managing VM Templates and make them available to the Workbench R&D Informatics Environment;
- (j) Patches and providing antivirus for VM Templates and make available to the Workbench R&D Informatics Environment;
- (k) Support issues related to templates and scripts (such as back-up scripts) created as part of the delivered Workbench R&D Informatics Environment; and
- (I) Monitoring the status of the Virtual Desktop servers and bring them up proactively. If new application servers are created by the customer for existing Informatics Applications then these will not be monitored or supported by BT except as part of the standard BT Cloud Compute support for the underlying platform;
- (m) Monitoring the status of the federation servers and bring them up proactively; and
- (n) Providing support for issues caused by the underlying platform supporting the applications.

2.7.2. The Customer is responsible for:

- (a) Ordering BT Cloud Compute bundles, Compute Conform, Informatics bundles, Data Sources bundle based on the DCF;
- (b) Ordering dedicated Identity Federation Service (if required);
- (c) Creation and maintenance of their Users;
- (d) Associating specific Informatics Applications and data sets to their User;
- (e) Creation and management of shared folders;
- (f) Approving the addition of new applications, provided as part of the Workbench R&D Informatics Environment, to their User groups and Users;
- (g) Loading new datasets to the Workbench R&D Informatics Environment from external sources:
- (h) Transferring of data to/from the Workbench R&D Informatics Environment to the external world;
- (i) Managing access to personal folders for their Users;
- (j) For small bundle and medium bundle, obtaining licenses for third party products other than Virtual Desktop service and Identity Federation Service; and
- (k) For large bundle, obtaining licenses for third party products other than Virtual Desktop service.

2.8. Firewall Management

In order for the Virtual Machines to be accessible by the Customer over the Internet, the Customer is responsible for ensuring they set up Firewall access list and port forwarding rules.

2.9. Applications Library

- 2.9.1. BT will provide to the Customer access to a collection of supported versions of Chef Recipes, Puppet Manifests and Cloud Components for the Pipeline Pilot, which will work with supported versions of featured Virtual Machine Templates.
- 2.9.2. The Customer may import:
 - (a) the Chef Recipes and Puppet Manifests into their Chef or Puppet service for use in deploying applications on BT Cloud Compute only; and

- (b) Cloud Components for Pipeline Pilot, into servers hosted on BT Cloud Compute.
- 2.9.3. This provides capability for:
 - (a) creating, starting, stopping or destroying of a Virtual Machine;
 - (b) listing the Virtual Machines within the Users BT Cloud Compute account;
 - (c) listing the characteristics of a specific Virtual Machine;
 - (d) listing storage volumes within the Users BT Cloud Compute account; and
 - (e) checking on the progress of specific asynchronous jobs running within the user's BT Cloud Compute account including the creation or destruction of a Virtual Machine
- 2.9.4. BT reserves the right to decide whether to package an application using Chef or Puppet technology.
- 2.9.5. BT does not provide support for usage and configuration of the business application itself, only the successful deployment/orchestration of the information technology aspects of application installation and excludes business configuration.
- 2.9.6. BT reserves the right to add or remove applications from the Applications Library without notice to the Customer.

2.10. HPC Tools

2.10.1. BT will not support use of HPC Tools Cluster Management Tool to deploy clusters into any other cloud provider estate and will only support usage with BT Cloud Compute.

2.11. Channel Bundle

- 2.11.1. Only a Customer that is a Channel Partner may submit an Online Order for the Channel Bundle.
- 2.11.2. A Channel Partner may resell the Workbench R&D Informatics Environment to its customers.
- 2.11.3. Every new customer of a Channel Partner requires a new Workbench R&D Informatics Environment.
- 2.11.4. Every new Workbench R&D Informatics Environment requires the Channel Partner to acquire another Channel Bundle.
- 2.11.5. Every Channel Partner agrees to disclose to BT any of its new customers that will be added to the Informatics Platform with at least two (2) weeks' notice prior to being added.
- 2.11.6. Under a Channel Bundle, BT is responsible for:
 - (a) Provisioning / Upgrading new applications to the Workbench R&D Informatics Environment, subject to validation by the Quickstart Process;
 - (b) Creation VM Templates and make them available to the Workbench R&D Informatics Environment:
 - (c) Manage VM Templates on the Workbench R&D Informatics Environment, where they have been created by BT;
 - (d) Patching and providing antivirus for, VM Templates and make available to the Workbench R&D Informatics Environment;
 - (e) Support issues related to the templates and scripts (such as back-up scripts) that have been provided by BT;

- (f) Support issues caused by the underlying platform for Informatics Applications; and
- (g) Monitoring the status of the Virtual Desktop servers and bring them up proactively. If new application servers are created by the Channel Partner's customer for existing Informatics applications then these will not be monitored or supported by BT except as part of the standard BT Compute support for the underlying platform; and
- (h) Monitoring the status of the federation servers and bring them up proactively.
- 2.11.7. Under a Channel Bundle, the Channel Partner is responsible for:
 - (a) Conducting the QuickStart Process with its customers;
 - (b) Creating the DCF as output from the customer's Quickstart Process;
 - (c) Delivery of the Workbench R&D Informatics Environment to its customers;
 - (d) Creation, back-up, and restoration of back-up of the Workbench R&D Informatics Environment: and
 - (e) Configuring, and maintaining configuration of the customer's Identity Federation Service.

3 tranSMART Platform

- 3.1. If selected by the Customer as set out in an Online Order, BT will host the tranSMART Platform for the Customer on BT Cloud Compute.
- 3.2. The tranSMART Platform is made available by the tranSMART Foundation, not BT, and BT's only obligation will be to host the tranSMART Platform on BT Cloud Compute.
- 3.3. The tranSMART Platform is licenced under separate terms available at http://transmartfoundation.org/legallicensing, not this Agreement, and the Customer acknowledges and agrees that it will use the tranSMART Platform only in accordance with those terms.
- 3.4. Hosting of the tranSMART Platform is provided on an "as is" and "as available" basis.
- 3.5. BT does not guarantee that:
 - (a) the tranSMART Platform will be error-free or uninterrupted, or that we'll correct all errors in the tranSMART Platform;
 - (b) the tranSMART Platform will operate in combination with your content or applications, or with any other software, hardware, systems, or data; or
 - (c) the tranSMART Platform, including any products, information or other material you obtain under or in connection with this Agreement, will meet the your requirements or expectations, and

will have no liability in relation to any of the above.

- 3.6. BT makes no warranty, representation, guarantee or undertaking regarding, and will have no lability for, network security, the encryption employed by the tranSMART Platform, the integrity of any data that is sent, backed up or stored; or that our security procedures will prevent the loss or alteration of or improper access to, loss, destruction, alteration or disclosure of the Customer Data.
- 3.7. BT will not indemnify the Customer against any claims for third-party IPR infringement arising out of Customer's use of the tranSMART Platform.
- 3.8. The Customer will not use any other equipment or services provided by BT in combination with the tranSMART Platform in any way that would create a derivative work subject to GPL 3 or any other open-source license.

4 Workbench R&D Life Sciences Data Sources

4.1. The Service

If selected by the Customer in an Online Order BT will provide, within seven (7) days of the date the Online Order is accepted, the Workbench R&D Life Sciences Data Sources to the Customer either:

- 4.1.1. as part of the Workbench R&D Informatics in accordance with clause 2.1.2(d); or
- 4.1.2. without Workbench R&D Informatics.

4.2. Quickstart and Ordering Process

- 4.2.1. The Customer will:
 - (a) indicate on the Online Order which data source shall be required from a list of existing data sources;
 - (b) grant BT access to the Customer's virtual computing environment for a maximum of seven (7) Business Days from the date of the Online Order to enable delivery of Workbench R&D Life Sciences Data Sources; and
 - (c) provide its public IP address(es), its database username and API keys for the User.
- 4.2.2. The Customer may at any time make an Online Order for the Workbench R&D Life Sciences Data Sources to be automatically refreshed periodically with new data based on any new updates made by the original publisher of the data source. BT reserves the right to determine the specific scope of the data to be updated as well as the process and periodicity of any such updates.
- 4.2.3. In the event the Customer alters a database prefixed with 'btfls' the Customer agrees that they will no longer be supported for the Workbench R&D Life Sciences Data Sources to be automatically refreshed periodically with new data as set out in clause 4.2.2.

4.3. Set-up and Delivery

- 4.3.1. BT may connect to the Customer's database from BT addresses.
- 4.3.2. The Customer will retain the 'btsupport' user account, permissions and rules for seven (7) Business Days after BT provides the Customer with access to Workbench R&D Life Sciences Data Sources. Thereafter the Customer will disable but not delete the "btsupport" user account and re-instate it prior to logging a fault.
- 4.3.3. BT will provide a one-off build of Workbench R&D Life Sciences Data Sources on a single Virtual Machine hosted in the Customer's BT Cloud Compute environment ("Data Sources Virtual Machine"). The Data Sources Virtual Machine will be commissioned, tested and handed over to the Customer in good working order.
- 4.3.4. BT will configure Workbench R&D Life Sciences Data Sources. Any support provided by BT to recover the Data Sources Virtual Machine, from changes made by the Customer is on a reasonable endeavours basis and BT will be entitled to charge the Customer for any resolution or redeployment.
- 4.3.5. An overview of the 'as built' security configuration of the Data Sources Virtual Machine will be provided to the Customer and documented in a handover document. After handover of the Data Sources Virtual Machine to the Customer, security will be entirely the Customer's responsibility.

4.4. Provision and Use

4.4.1. Data available on all drug products will be collected from certain regulatory agencies' websites and BT provides the data on an "as is" basis. BT does not report the labelling

information of a given drug product and the Customer will have sole responsibility to ensure that it refers to the appropriate regulatory agency that has granted the marketing authorisation to obtain any labelling information the Customer requires.

- 4.4.2. BT may add or remove data sources from Workbench R&D Life Sciences Data Sources, including but not limited to the right to change database, table, column and field structures without notice to the Customer. BT shall not be responsible for resolving any issues with database gueries as a result of such amendments..
- 4.4.3. BT does not provide database backup or recovery service and is not liable for recovery from snapshots taken from data volume.
- 4.4.4. The Customer may not copy the Workbench R&D Life Sciences Data Sources to locations or systems outside BT Cloud Compute.
- 4.4.5. The Customer acknowledges that it may not distribute, publish, transmit, sell or license all or any part of the content, products or services obtained from any data or documentation extracted from the Workbench R&D Life Sciences Data Sources in any medium to any third parties to this Agreement (except to the Customer's Affiliates) without BT's prior written consent.
- 4.4.6. The Customer assumes all risks related to the use of any information obtained via Workbench R&D Life Sciences Data Sources. BT will not be liable nor have any obligation to restore a Customer's Workbench R&D Life Sciences Data Sources system to working order in the event the Customer has made changes to the data that have resulted in loss of or degraded service or faults caused by automated security updates.
- 4.4.7. The Workbench R&D Life Sciences Data Sources may include hyperlinks to external sites or resources and such hyperlinks are provided solely for the Customer's convenience. BT is not responsible for the availability of these external sites or resources and does not endorse and is not responsible or liable for any content, advertising, products or other materials on or available from such sites or resources. The Customer will be responsible for its own review of any terms and conditions and privacy policies of these linked sites, as terms and conditions and policies may differ from those agreed with BT under this Agreement.
- 4.4.8. The Customer acknowledges and agrees that the use of:
 - (a) the Workbench R&D Life Sciences Data Sources;
 - (b) any BT information (including, without limitation, information provided in User Guides, manuals and BT hosted forums); and
 - (c) APIs,

is entirely at the Customer's risk and BT is not responsible for the quality of such information and/or APIs.

5 Compute Conform (where available)

- 5.1. The Compute Conform service enables the principles of GxP compliance to be met in the Conform Availability Zones chosen by the Customer. Where Compute Conform is available, BT will provide the services in accordance with this Clause 4.
- 5.2. Evidence of the Key Controls required to meet most GxP compliance requirements for the cloud environment will be provided by BT as part of the Compute Conform service. The Customer acknowledges and agrees that it is responsible for determining whether such Key Controls meet its own regulatory compliance requirements.
- 5.3. IQ and/or OQ documentation is managed in EQMS. Self-service access is provided by BT depending on the service option selected by the Customer as specified below:
- 5.3.1. Complete IQ and OQ documentation for Hardware for the Conform Availability Zones including Cloud Connect

- (a) Only the following Cloud Connect Hardware will be Qualified:
 - a. the Cloud Compute core switch;
 - b. Cloud Connect ethernet switches: and
 - c. connections to BT Provider Edge ("PE") device, Customer local premises equipment and Customer or third party Telco WAN / LAN / VPN equipment.
- (b) The aforementioned BT PE equipment and Customer or third party equipment will not themselves be Qualified as part of Cloud Connect Hardware qualification.

5.3.2. Cloud Management System

- (a) CMS includes OQ documentation for all components of the CMS, including Cloud Connect, but otherwise strictly limited to:
 - (i) Access Control
 - (ii) Addition of a new sub account
 - (iii) Creation of a Virtual Machine
 - (iv) Acquisition of an external IP address
 - (v) Creation of a firewall rule
 - (vi) The forwarding of a port to a specific Virtual Machine
 - (vii) Stopping of a Virtual Machine
 - (viii) Starting of a Virtual Machine
 - (ix) Destruction of a Virtual Machine
- (b) IQ/OQ documentation for the Hypervisor

5.3.3. Qualified VM Templates

- (a) Qualification documents include full IQ documentation for the VM Templates and OQ templates for VM Templates
- (b) Not all VM Templates are Qualified. All Qualified VM Templates are managed in a download server. Every user of the Customer will need to download and import the Qualified VM Template as a Customer generated template in order to avail of the benefits
- (c) BT retains the right to update the Qualified VM Templates that are made available via BT's download server. Qualified VM Templates may be removed and/or replace by new VM Templates. BT will not be responsible for notifying the Customer of these updates
- (d) The Customer will retain the downloaded version of the Qualified VM Templates
- 5.3.4. IQ documentation and associated OQ templates for VM History SDK Qualification
- 5.4. The Compute Conform service options available are:
- 5.4.1. The Bronze Compute Conform service provides:
 - (a) IQ/OQ documentation for the Hardware and Cloud Management System in the Conform Availability Zone selected by the Customer as described in Clause 4.3.1 above.
 - (b) Monitoring and maintenance of Life Cycle evidence for the Qualified environment.

- (c) Access to Virtual Machine history through the use of VM History SDK. BT will not be responsible for the support for installation, management, maintenance and in life support for this SDK. BT will provide the relevant User Guides.
- (d) Access to Life Cycle documentation regarding change management for the Qualified Hardware provided in electronic format.
- (e) Access to documentation via the BT electronic document management system.
- (f) Virtual Machine Usage limit of 36,000 CPU hours per quarter.
- (g) Audit support is not included within the Bronze option.

5.4.2. The Silver Compute Conform service provides:

- (a) The Bronze Compute Conform service, plus;
- (b) Access to procedural documentation in support of Qualification activities to satisfy computer system validation requirements
- (c) Access to documentation in support of Qualified VM Templates
- (d) Virtual Machine Usage limit of 108,000 CPU hours* per quarter
- (e) One (1) Standard audit per year (see description below)

5.4.3. The Gold Compute Conform service provides:

- (a) The Silver Compute Conform service, plus;
- (b) Access to IQ/OQ templates to guide the Customer's Qualification activities
- (c) Virtual Machine usage limit of 216,000 CPU hours* per quarter
- (d) Two (2) Standard audits per year (see description below)

5.4.4. The Platinum Compute Conform service provides:

- (a) The Gold Compute Conform service, plus;
- (b) Access to evidence demonstrating infrastructure compliance with industry standard Control Framework
- (c) No Virtual Machine or CPU usage limit
- (d) Three (3) Standard audits per year (see description below).

For the avoidance of doubt, the Virtual Machine usage limits are total hours of usage, not incremental usage above the respective lower categories.

- 5.4.5. The above four (4) options have a Minimum Period of Service of three (3) Months, which will automatically renew for further three (3) Month periods unless the Customer terminates within any three (3) Month period. Additional audits are available and are subject to additional Charges in accordance with the General Terms and Conditions.
- 5.4.6. The following CPU hour limits apply to the above options:

Option Virtual Machines (VM) CPU Hours per quarter

Bronze 4 VM 36,000

Silver 12 VM 108.000

Gold 24 VM 216,000

Platinum Unlimited

5.4.7. If the Customer exceeds the CPU hours set out above for any of the options for a rolling period of three (3) Months, the Customer agrees that it will be upgraded to the next option.

- 5.4.8. If the Customer upgrades, by choice or because it has exceeded the CPU hours for the quarter, the Customer will pay the difference between the set-up charge for the option it is moving from and the set-up charge for the option it is moving to (e.g. from Bronze to Silver, the difference between the set-up charge for the two options is payable).
- 5.4.9. If the Customer has not used the audit(s) included with the option before the upgrade occurs then the audit(s) for that option will not be available. The Customer will only be able to select the audit(s) available in the upgrade option.
- 5.4.10. Audit activities will be undertaken within a year of the date of Online Order. Audit activities cannot be carried forward.
- 5.4.11. If the Customer wishes to upgrade from one of the options set out above, the Customer will deselect the then current option and subscribe to the newly chosen upgrade option. If the period from de-selection to subscription is seven (7) Business Days or less, then no reactivation Charges will apply. If the period exceeds seven (7) Business Days then reactivation Charges will apply.
- 5.4.12. All stored documentation for EQMS regarding IQ/OQ will be frozen for retention and available to the Customer on request prior to termination of the Compute Conform service. If the Customer does not request such stored documentation, the Customer acknowledges and agrees that it will not be available from BT after termination of the Compute Conform service.

6 Audits

- 5.1 The Customer will, prior to ordering an audit, familiarise itself with the Compute Conform service description and User Guide. BT will facilitate the audits below, which do not include the provision of any written reports by BT.
- 5.2 The available audits are:

(a) Questionnaire

BT will provide answers to a single questionnaire, designed to provide assurance over the provision of the Service. BT will coordinate answers from the appropriate BT subject matter experts and will provide a completed response within 15 Business Days of receiving the questionnaire. BT will provide limited support for follow up questions or clarification based on initial responses.

(b) Standard

BT will provide access to appropriate BT subject matter experts to provide assurance about the Compute Conform methodology and the provision of the Service.

The audit will consist of a maximum of two (2) consecutive Business Days of BT support, either onsite at an appropriate BT facility or by via tele/web conferencing services hosted by BT.

The assessment will consist of:

- A. The BT Compute Conform Approach & Methodology
- B. The BT Compute Conform Quality Management System
 - (i) Infrastructure Qualification
 - (ii) Document & Records Management
 - (iii) Training
- C. Logical Security
- D. Data Centre Security
- E. Operational Processes
- F. Roles and Responsibilities

In addition to the above two (2) consecutive Business days of BT support, BT will provide a single point of contact to work with the Customer to perform up to four (4) Business Hours of planning, scoping and scheduling in advance of the assessment and to coordinate all assessment communications.

(c) Advanced

An advanced audit will follow the standard audit content but will accommodate topics selected by the Customer about the provision of the Cloud Compute Conform service, comprising a maximum of five (5) consecutive Business Days of BT support.

In addition to the above five (5) consecutive Business days of BT support, BT will provide a maximum of one (1) Business Day's support in advance of the audit for planning, scoping and scheduling purposes. BT will also facilitate required follow up activities after the conclusion of the audit, up to a maximum of two (2) Business Days in total.

(d) Bespoke

Bespoke Audits may be requested by the Customer, subject to additional Charges and conditions to be agreed in writing or in an Order.

BT will categorise audit findings within either of the following categories:

- A. Non-conformity with terms and conditions of the Service or the BT Compute Conform Quality Management System. BT will ensure that appropriate remediation actions are developed and implemented.
- B. Applicability of the Compute Conform Service to the Customer control environment. BT will consider these findings for future Service improvements but is not obligated to implement the findings.
- C. Compliance documents are available via self-service directly from the EQMS. The Customer will be provided with one (1) user account to access EQMS for the duration of the Service.

7 Service Management

7.1. Service Desk Support

7.1.1. BT will provide a Service Desk operating twenty four hours per day, seven days per week, including national, public or bank holidays, which will receive and record Service incident reports from the Customer.

7.2. Incident Repair Service

- 7.2.1. If BT detects, or if the Customer reports an Incident to the Service Desk, BT will respond to the Incident without undue delay. BT will perform tests to determine the cause of the Incident, and will notify the System Administrator by telephone or e-mail.
- 7.2.2. The Service Desk will keep the Customer updated at regular intervals until the Incident is resolved.
- 7.2.3. BT will raise additional Charges for work performed and money spent to address incidents resulting from Service failures caused by the Customer on a time and material basis at the prevailing Charges.
- 7.2.4. If the Customer asks BT to perform any additional work this will be subject to prior written agreement between the Parties and additional Charges will apply.

8 Planned Maintenance

8.1. The Customer acknowledges and accepts that occasionally BT may have to carry out routine or emergency maintenance, updates and other procedures for reasons of health, safety, security or otherwise to protect the Service, and which may cause a

disruption to the Service, ("Planned Maintenance"). BT will provide the Customer with as much prior notice as practicable with respect to Planned Maintenance.

9 Service Updates

9.1. BT may make updates to the Service from time to time provided that such updates do not materially decrease or impair performance of the Service.

10 Security

- 10.1. The Customer is responsible for the security and proper use of all User IDs, Checkwords and passwords. BT reserves the right to suspend access to the Service at any time if BT has reason to believe that there is, or is likely to be, a breach of security or misuse of the Service. BT will notify the Customer as soon as possible after it has done so.
- 10.2. The Customer must immediately inform BT if there is any reason to believe that a User ID, password, or Checkword allocated by BT has, or is likely to, become known to someone not authorised to use it or is being, or is likely to be, used in an unauthorised way.
- 10.3. BT reserves the right to require the Customer to change any or all of the Checkwords or passwords associated with the Service and used by the Customer in connection with the Service.
- 10.4. The Service is delivered within a secure BT data centre with a security policy for the protection of Site, infrastructure and network. Although BT will use reasonable care and skill in carrying out its obligations under this Agreement in accordance with BT's security policy, it is not possible to guarantee that all instances of fraud, misuse, unwanted or unauthorised activity or access to the Customer's Information will be prevented or detected. Whenever BT becomes aware that security has been compromised, BT will take actions in order to limit any further occurrences of fraud, misuse, unwanted or unauthorised activity or access to the Customer's Information. Nevertheless, BT accepts no liability for any such incidents, or for any loss or damage suffered by the Customer. The Customer shall therefore take responsibility for the security of the Customer Information, Content and application of security policies designed to prevent unwanted or unauthorised activity or access to the Customer's Information.

11 Intellectual Property

- 11.1. All trademarks and copies of original documents appearing on the BT for Life Science cloud platform are the property of their respective owners as stipulated by the related trademark and copyright notices and are protected by copyright and other intellectual property laws. Any documents published or produced by the US Food and Drug Administration are in the public domain.
- 11.2. All other content in the Services, including BT for Life Science cloud platform layout, design, images, programs, text and other information (collectively, the "Content") is the property of BT and its affiliated companies or licensors and is protected by copyright and other intellectual property laws.
- 11.3. The Customer may not engage in systematic retrieval of Content from the Service to create or compile, directly or indirectly, a collection, compilation, database or directory without prior written permission from BT
- 11.4. Notwithstanding the intellectual property right provisions set out in the General Terms and Conditions, any ideas, concepts or materials submitted to BT by the Customer regarding the Service become BT's property to exploit or to not exploit as BT deems appropriate in its sole discretion without necessity for remuneration or attribution to the Customer during and after termination of the Agreement.

12 BT's use of Customer Information and Personal Data

- 12.1. In order for BT to provide and support the Service, BT may use personal data, (typically name, email address, telephone number and business and/or Site(s) address), of Users within the Customer's organisation or control in order to:
 - (a) process, track and fulfil Online Orders for the Service;
 - (b) deliver and commission the Service,
 - (c) process, track and resolve Incidents with the Service,
 - (d) administer access to the online portals relating to the Service;
 - (e) compile, dispatch and manage the payment of invoices relating to the Service;
 - (f) manage the contract and resolve any disputes relating to it;
 - (g) respond to general queries relating to the Service or;
 - (h) provide security and technical support.
- 12.2. BT may also send the Customer additional information concerning the Service, or related services. This information will typically be sent to the Customer Contact, involved in the procurement or management of the Service.
- 12.3. Any personal data that may be collected and processed by BT (including payment data) is subject to, and will be handled in accordance with, applicable data protection laws.
- 12.4. BT will have no access to the Customer Information stored by the Customer.
- 12.5. The location and access points of the Customer Information are defined by the Customer and as such the Customer needs to ensure compliance with relevant laws and regulations.
- 12.6. BT will not change the country where the Customer Information resides without providing notice to the Customer, unless required to do so in order to comply with applicable laws and regulations.

13 Customer's Responsibilities

- 13.1. If the Customer has selected a Service in accordance with Clauses 2, 3 or 4 above it is the Customer's responsibility to ensure that:
- 13.1.1. it has in place the BT Cloud Compute service, which is required in order for the Service to be provided by BT under a separate agreement;
- 13.1.2. the correct data centre has been selected, as not all data centres support the Service;
- 13.1.3. the IQ/OQ and related Life Cycle documentation provided by BT are sufficient to meet the GxP or similar requirements of the Customer;
- 13.1.4. it adheres to the processes in the QMS Manual for access to and request of information;
- 13.1.5. requests for information are appropriate to their chosen Compute Conform Service Option as BT reserves the right to charge the Customer for requests for information beyond that described in the Compute Conform Service Options described in Clause 4.4 (Bronze, Silver, Gold or Platinum options) and Compute Conform audits defined in Clause 5.2 (questionnaire, standard, advanced, bespoke);
- 13.1.6. the correct security classification and encrypted its data apply;
- 13.1.7. all applicable agreements in relation to accessing data sources are in place; and
- 13.1.8. any data from Virtual Machines and associated Storage prior to termination of the Compute -Conform Service is securely deleted; and
- 13.1.9. VM History SDK is installed and managed.

14 BT's Acceptable Use Policy

14.1. The Customer is solely responsible for all aspects of Customer Information which are not specifically set out in this Service Schedule as being BT's responsibility. The Customer acknowledges that it has read and agrees to be bound by and to ensure that any Users will comply with this BT Acceptable Use Policy ("AUP") and generally accepted Internet standards.

- 14.2. The Service must not be used:
 - (a) fraudulently or in connection with a criminal offence under the laws of any country where the Service is provided;
 - (b) to send, receive, upload, download, use or re-use any information or material which is offensive, abusive, indecent, defamatory, obscene or menacing, or in breach of confidence, copyright, privacy or any other rights;
 - (c) in contravention of any instructions that BT has given under the Agreement;
 - (d) to cause annoyance, inconvenience or needless anxiety; or
 - (e) to send or provide or receive unsolicited advertising or promotional material.
- 14.3. The Customer must not use a Domain Name which infringes the rights of any person in a corresponding trade mark or name.
- 14.4. If the Customer, or anyone else (with or without the Customer's knowledge or approval), uses the Service in contravention of the AUP; or uses the Service in any way which, is, or is likely to be, detrimental to the provision of the Service to the Customer or any other customer and fails to take corrective action within a reasonable period of receiving notice from BT, then BT can treat the contravention as a material breach and as such BT may either suspend the Service or terminate the Service pursuant to the General Terms and Conditions. If Service is suspended it will not be restored until the Customer provides an acceptable assurance that there will be no further contravention.

15 Termination of Service

- 15.1. The following Clause will replace and supersede Clause 12.1 of the General Terms and Conditions.
- 15.2. The Customer may terminate any or all of the Services via the Portal at any time, provided that the Customer agrees:
 - (a) to pay any outstanding Charges or interest properly due and payable for the applicable Service up to the date of termination; and
 - (b) that there will be no refund of Charges which have been paid in advance.
- 15.3. BT may terminate this Agreement or the Service at any time by giving at least 90 days' notice to the Customer.

16 Exclusion of liability

BT will have no liability for the quality or security of the VM History SDK and accepts no responsibility that the use of the tools and VM History SDK under this Schedule will meet the functionality required by the Customer.

17 Service Desk Support

17.1. In the event of a Service Incident the Customer will report such Incident to the following Service Desk:

Email: ah.support@bt.com

Telephone: +44 (0)800 731 / +44 (0)29 2022 9474

- 17.2. The Service Desk will update the Customer at regular intervals on the Incident until the Incident is resolved. BT will not resolve any Incident which BT determines to have been caused by the Customer.
- 17.3. Any work undertaken by BT will be subject to prior agreement between the Parties and additional Charges.

18 Service Levels

No Service Level applies to BT for Life Sciences Value Added Services.