

PVAI SUBSCRIPTION AGREEMENT

This PVAI Subscription Agreement ("Agreement") is entered into and effective as of September 7, 2020 ("Effective Date") by and between Genpact (UK) Limited, a UK private limited company, having its principal place of business at 6 Lloyds Avenue, Suite 4CL, London, EC3N 3AX, England ("Supplier") and (1) The Medicines and Healthcare products Regulatory Agency, having its principal place of business at 10 South Colonnade, Canary Wharf, London, E14 4PU ("The Authority"), each a "Party" and collectively, the "Parties".

[REDACTED]

WHEREAS, Supplier is a financially stable publicly traded organization (NYSE: G) and a global professional services firm capable of providing the Services.

1. SERVICES

1.1 Service.

[REDACTED]

1.2 Literature Review.

[REDACTED]

1.3 Restrictions. To the maximum extent permitted by applicable law, The Authority shall not (directly or indirectly), and shall not authorize any person (including Authorized Users) to:

[REDACTED]

[REDACTED]

1.4 Professional Services. Subject to The Authority's timely payment of applicable Professional Service Fees, Supplier will use commercially reasonable efforts to provide to The Authority the professional services on a mutually executed statement of work ("SOW") based on the form set forth in Exhibit C ("Professional Services"). Supplier shall provide the Professional Services in accordance with the rate card attached hereto as Exhibit B ("Rate Card").

1.5 Affiliates. The Authority and any Affiliate of The Authority may enter into Orders or SOWs with Supplier under this Agreement. For purposes of this Agreement, "Affiliate" means any entity which directly or indirectly controls, is controlled by, or is under common control with the subject entity. 'Control,' for purposes of this definition, means: (i) the direct or indirect ownership or control of more than fifty percent (50%) of the voting interests of the subject entity or (ii) the contractual power and right to control the day to day management of such entity.

1.6 Supplier Personnel. Supplier shall provide personnel with the necessary experience and expertise necessary for performing the Services ("Supplier Personnel"). Supplier Personnel shall be properly educated, trained and qualified for the Services they are to perform. Unless otherwise provided in this Agreement or otherwise expressly agreed by the Parties in writing, Supplier shall provide all office equipment (including PCs), consumables, services and the like required to support Supplier Personnel's provision of Services. Supplier agrees that all such Supplier Personnel shall be advised (i) of the standards imposed upon them with respect to the Services they render and (ii) that they are not employees or agents of The Authority for any purpose. Supplier shall advise all Supplier Personnel of all standards, policies and procedures of The Authority applicable to the Services to the extent Supplier has knowledge of such standard, policies and procedures. Supplier is responsible for the breach of any Supplier Personnel of any such standards, policies or procedures or non-compliance with the terms of this Agreement (including the confidentiality and ownership provisions herein).

2. FEES; PAYMENT

2.1 Fees. The Authority will pay Supplier the non-refundable and non-recoupable fees ("Fees") of the type, amount and payment schedule set forth in Exhibit F, each Order and/or SOW, as applicable, which may include subscription and other fees for the Service ("Subscription Fee") and fees for Professional Services ("Professional Service Fee"). [REDACTED]

2.2 Payment Terms. [REDACTED]

2.3 Taxes. [REDACTED]

3. TERM AND TERMINATION

3.1 Term. This Agreement will start on the Effective Date and, unless terminated earlier in accordance with this Agreement, will continue for a period of twelve (12) months. Thereafter, this Agreement will automatically renew for one year renewal term(s) (each, a "Renewal Term," and together with the Initial Term, collectively, the "Term"), unless either Party provides written notice of non-renewal at least thirty (30) days before the expiration of the then applicable term. Each Order will start on the effective date thereof ("Order Effective Date") and, unless terminated earlier in accordance with the terms hereof, will continue until the expiration of the initial term specified in such Order ("Initial Order Term"). Thereafter, each such Order will automatically renew for one year renewal term(s) (each, a "Order Renewal Term," and together with the Initial Order Term, collectively, the "Subscription Term"), unless either Party provides written notice of non-renewal at least thirty (30) days before the expiration of the then applicable term.

3.2 Termination. Each Party may terminate this Agreement by written notice if the other Party (i) is in material breach of this Agreement, which is not cured within 30 days (10 days if breach is nonpayment of amounts owed by The Authority that are not being disputed or following the Dispute Resolution Time) after written notice of such breach; (ii) files for bankruptcy that is not dismissed within 90 days, is adjudicated bankrupt, or suffers any other analogous event; (iii) or by Supplier by providing 30 days advance written notice of termination, in whole in in part, including terminating certain Services under an applicable SOW or Order or in an applicable geographic area if Supplier reasonably determines there is a change in applicable law or regulation that impacts Supplier's ability to provide the Services or impacts the Supplier Technology. Additionally, the Parties will have a key management checkpoint approximately following the start of the implementation project ("Key Checkpoint"). Within following the Key Checkpoint, The Authority may elect not to proceed with implementation of Services hereunder and may terminate this Agreement and any related SOWs without penalty by providing Supplier with no less than written notice of termination. In the event of any termination of this Agreement, Supplier shall be entitled to payment for all work completed and any costs expended prior to the effective date of such termination.

3.3 Effect of Termination. Upon the effective date of expiration or termination of this Agreement for any reason: (i) all outstanding Orders, SOWs, and access to Supplier Technology will automatically terminate; and (ii) all outstanding payment obligations of The Authority become due and payable immediately. Following termination or expiration of this Agreement, upon The Authority's request and at mutually agreed upon fees and duration set forth in an applicable termination assistance SOW, Supplier will provide The Authority reasonable transition assistance to migrate The Authority Data in Supplier's possession to a replacement cloud-based service or software solution of The Authority's choice. The following provisions will survive the expiration or termination of this Agreement for any reason: Sections 1.3 (Restrictions), 3.3 (Effect of Termination), 4 (Confidentiality; Ownership; Data), 5 (Indemnification), 6 (Limitation of Liability), and 7 (General).

4. CONFIDENTIALITY; OWNERSHIP; DATA

4.1 Definition. "Confidential Information" means any information disclosed directly or indirectly by one Party ("Disclosing Party") to the other Party ("Receiving Party") pursuant to this Agreement that is either designated as

“confidential” or under the circumstances of disclosure or by the nature of the information itself is reasonably understood by the Receiving Party to be the confidential information of the Disclosing Party. Confidential Information does not include any information which (a) is or becomes generally known and available to the public through no act or omission of the Receiving Party; (b) was already in the Receiving Party’s possession at the time of disclosure by the Disclosing Party, as shown by the Receiving Party’s contemporaneous records; (c) is lawfully obtained by the Receiving Party from a third party who has the express right to make such disclosure; or (d) is independently developed by the Receiving Party without use of the Disclosing Party’s Confidential Information. As between Supplier and The Authority, the Supplier Technology is the Confidential Information of Supplier, and the Authority Data is the Confidential Information of The Authority. The terms (but not the existence) of this Agreement is each Party’s Confidential Information.

4.2 Use; Maintenance. Neither Party shall use the Confidential Information of the other Party for any purpose except to exercise its rights and perform its obligations under this Agreement. Neither Party shall disclose, or permit to be disclosed, either directly or indirectly, any Confidential Information of the other Party, except to employees

[REDACTED] of the Receiving Party with a need to know, [REDACTED] each subject to a written obligation of confidentiality. Each Party will take reasonable measures to protect the secrecy of, and avoid disclosure and unauthorized use of, the Confidential Information of the other Party, and will take at least those measures that it takes to protect its own confidential information of a similar nature. The Receiving Party will use reasonable efforts to provide timely notice of compelled disclosure to facilitate confidential treatment of the Disclosing Party’s Confidential Information and will furnish only that portion of Confidential Information that it is legally required to disclose, after exercising reasonable efforts to obtain assurance that such information will receive confidential treatment. Supplier shall not make any press announcements or publicise the execution of this Agreement or specific contents or otherwise use the Authority’s name or band in any promotional or marketing announcements made publicly without the prior written consent of the Authority, which shall not be unreasonably withheld conditioned or delayed. .

4.3 Ownership: [REDACTED]

[REDACTED]

4.4 Consents. The Authority will obtain, maintain and comply with all licenses, consents, authorizations and approvals (the “Consents”) necessary to allow Supplier to (i) use any The Authority materials or systems, including The Authority Provided Data and (ii) use or access any third party materials, systems, or software provided by The Authority or otherwise reasonably necessary to interface with the Supplier Technology to enable Supplier to perform the Services hereunder. The Authority will pay all costs and expenses with respect to obtaining, maintaining and complying with all such Consents.

4.5 Transparency and Freedom of Information

4.5.1. The Parties acknowledge that:

- a. the reports described in Exhibit G (“Transparency Reports”);
- b. the content of this Agreement, including any changes to this Agreement agreed from time to time, except for –
 - i. any information which is exempt from disclosure in accordance with the provisions of the FOIA, which shall be determined by the Authority; and
 - ii. Commercially Sensitive Information; and
- c. the publishable performance information included in Transparency Reports

(together the “Transparency Information”) are not Confidential Information.

- 4.5.2. Notwithstanding any other provision of this Agreement, the Supplier hereby gives its consent for the Authority to publish to the general public the Transparency Information in its entirety (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA redacted). The Authority shall, prior to publication, consult with the Supplier on the manner and format of publication and to inform its decision regarding any redactions but shall have the final decision in its absolute discretion.
- 4.5.3. The Supplier shall assist and co-operate with the Authority to enable the Authority to publish the Transparency Information, including the preparation of the Transparency Reports in accordance with this Section.
- 4.5.4. If the Authority believes that publication of any element of the Transparency Information would be contrary to the public interest, the Authority shall be entitled to exclude such information from publication. The Authority acknowledges that it would expect the public interest by default to be best served by publication of the Transparency Information in its entirety. Accordingly, the Authority acknowledges that it will only exclude Transparency Information from publication in exceptional circumstances and agrees that where it decides to exclude information from publication it will provide a clear explanation to the Supplier.
- 4.5.5. The Authority shall publish the Transparency Information in a format that assists the general public in understanding the relevance and completeness of the information being published to ensure the public obtain a fair view on how the Agreement is being performed, having regard to the context of the wider commercial relationship with the Supplier.
- 4.5.6. The Supplier agrees that any Transparency Information it holds that is not included in the Transparency Reports but is reasonably relevant to or that arises from the provision of the Services shall be provided to the Authority on request unless the cost of doing so would exceed the appropriate limit prescribed under section 12 of the FOIA. The Authority may disclose such information under the FOIA and the Environmental Information Regulations 2004 (“EIRs”) and may (except for Commercially Sensitive Information, Confidential Information (subject to Section 4, Confidentiality) publish such Transparency Information. The Supplier shall provide to the Authority within five (5) business days (or such other longer period as the Authority may reasonably specify) any such Transparency Information requested by the Authority.
- 4.5.7. The Supplier acknowledges that the Authority is subject to the requirements of the FOIA and the EIRs. The Supplier shall:
 - a. provide all necessary assistance and cooperation as reasonably requested by the Authority to enable the Authority to comply with its obligations under the FOIA and EIRs;
 - b. transfer to the Authority all Requests for Information relating to this Agreement that it receives as soon as practicable and in any event within 2 business days of receipt;

- c. provide the Authority with a copy of all Information held on behalf of the Authority which is requested in a Request For Information and which is in its possession or control in the form that the Authority requires within 5 business days (or such other period as the Authority may reasonably specify) of the Authority's request for such Information; and
- d. not respond directly to a Request for Information addressed to the Authority unless authorised in writing to do so by the Authority.

4.5.8. Supplier acknowledges that the Authority may be required under the FOIA and EIRs to disclose Information (including Commercially Sensitive Information) without consulting or obtaining consent from the Supplier. The Authority shall take reasonable steps to notify the Supplier of a Request For Information (in accordance with the Secretary of State's section 45 Code of Practice on the Discharge of the Functions of Public Authorities under Part 1 of the FOIA) to the extent that it is permissible and reasonably practical for it to do so but (notwithstanding any other provision in this Agreement) the Authority shall be responsible for determining in its absolute discretion whether any Commercially Sensitive Information and/or any other information is exempt from disclosure in accordance with the FOIA and EIRs.

5. INDEMNIFICATION

5.1 By Supplier.


5.2 By The Authority.

6. DISCLAIMER; LIMITATION OF LIABILITY

6.1 Supplier Warranties. Supplier represents and warrants that: (i) the Services will be performed by workers generally experienced in performing the type of services specified in the applicable Order / SOW; and (ii) the Services will be performed in a diligent, workmanlike and professional manner.

6.2 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN SECTION 6.1, SUPPLIER HEREBY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, LOSS OF DATA, ACCURACY OF RESULTS OR REPORTS (INCLUDING WITH RESPECT TO ANY DATA EXTRACTION OR PROCESSING OR SUBMISSIONS OR NOTIFICATIONS), OR ARISING FROM THE COURSE OF DEALING OR RELIANCE. SUPPLIER DOES NOT WARRANT ANY THIRD-PARTY WEBSITE CONTENT OR FUNCTIONALITY OR THAT THE SERVICE WILL BE ERROR-FREE OR UNINTERRUPTED. Notwithstanding anything to the contrary herein, Supplier has no obligation hereunder to obtain, collect, store or use any data or information from any source, except if in the public domain or if The Authority has sufficient rights to such data as may be necessary for Supplier to exercise its rights under this Agreement without infringing or violating rights of others or the applicable law.

6.3 Limitation of Liability.



7. GENERAL PROVISIONS

7.1 Compliance with Laws. Supplier will comply with all Laws applicable to Supplier in its operation of its business and its provision of the Services (“Supplier Laws”), and The Authority will comply with all Laws applicable to The Authority in the operation of its business and its receipt of the Services (the “The Authority Laws”). For purposes of this Agreement, the term “Laws” shall mean any treaty, directive, statute, legislation or other law enacted by a federal, state or local government in the applicable jurisdiction. Each Party shall also comply with (i) any law with respect to the regulation of payments or accommodations to government officials or others, including without limitation to the extent applicable, the Foreign Corrupt Practices Act as is, or will be from time to time, applicable in the United States of America and the 2010 Bribery Act, as is, or will be from time to time, applicable in the United Kingdom

7.2 Changes in Law. If Supplier becomes aware of a change in law that occurs or will occur during the Term that is reasonably likely to (or does) impact the Services provided hereunder (a “Specific Change in Law”), Supplier shall: (a) notify the Authority as soon as reasonably practicable of the likely effects of that change, including: (i) whether any Change is required to the Services, the Fees or this Agreement; and (ii) whether any relief from compliance with the Supplier's obligations is required, including any obligation to Achieve a Milestone and/or to meet the SLAs; and (b) provide the Authority with evidence: (i) that the Supplier has minimised any increase in costs or maximised any reduction in costs, including in respect of the costs of its Sub-contractors; and (ii) as to how the Specific Change in

Law has affected the cost of providing the Services; and (c) any variation in the Fees or relief from the Supplier's obligations resulting from a Specific Change in Law shall be implemented in accordance with the Change Control Procedure.

7.3 Assignment. Neither Party may assign this Agreement nor any of its rights or obligations under this Agreement without the prior written consent of the other Party, except that either Party may assign this Agreement without the written consent of the other Party to an Affiliate or as part of a corporate reorganization, upon a change of control, consolidation, merger, reincorporation, sale of all or substantially all of its assets related to this Agreement or a similar transaction or series of transactions. Subject to the foregoing, this Agreement will be binding upon and inure to the benefit of the Parties and their respective permitted successors and assigns.

7.4 Force Majeure. Except for the obligation to pay money, neither Party will be liable for any failure or delay in its performance under this Agreement due to any cause beyond its reasonable control, including an act of war, terrorism, act of God, earthquake, flood, embargo, riot, sabotage, labor shortage or dispute, governmental act or failure of the Internet. The delayed Party shall give the other Party notice of such cause and shall use its reasonable commercial efforts to correct such failure or delay in performance.

7.5 Governing Law. This Agreement shall be governed by and construed under the laws of England and Wales without reference to conflict of laws principles. The application of the United Nations Convention of Contracts for the International Sale of Goods is expressly excluded. All disputes arising out of or related to this Agreement will be subject to the jurisdiction of London, England, and the Parties hereby agree and consent to the exclusive jurisdiction and venue of these courts.

7.6 Miscellaneous. This Agreement (including the Exhibits), together with the Orders and SOWs, is the sole agreement of the Parties concerning the subject matter hereof, and it supersedes all prior agreements and understandings with respect to said subject matter. The following order of precedence shall apply: the main body of this Agreement, Exhibits, Order, SOW. No terms of any purchase order, acknowledgement or other form provided by The Authority will modify this Agreement, regardless of any failure of Supplier to object to such terms. Any ambiguity in this Agreement shall be interpreted equitably without regard to which Party drafted hereof. This Agreement may only be amended by a writing signed by both Parties. This Agreement may be executed in counterparts. The headings in this Agreement are inserted for convenience and are not intended to affect the interpretation of this Agreement. Any required notice shall be given in writing by customary means with receipt confirmed at the [REDACTED]

[REDACTED] or to such other address as either Party may substitute by written notice to the other and with regards to The Authority. Notices will be deemed to have been given at the time of actual delivery in person, 1 day after delivery to an overnight courier service, or 3 days after deposit in the mail. The relationship between the Parties shall be that of independent contractors. Supplier may use subcontractors. The Authority's Affiliates may enter into separate Orders under this Agreement; provided that The Authority remains primarily liable under this Agreement. Waiver of any term of this Agreement or forbearance to enforce any term by either Party shall not constitute a waiver as to any subsequent breach or failure of the same term or a waiver of any other term of this Agreement. Any provision found to be unlawful, unenforceable or void shall be severed from the remainder of this Agreement, and the Agreement will continue in full force and effect without said provision. Unless expressly set forth in a SOW or Order, the Parties do not intend to create any obligations of or any rights, causes of action or benefits in favor of any third party or entity other than The Authority or Supplier

7.7 Audit. During and following the term of the Agreement, The Authority retains the right to audit or have audited Supplier's systems, records and any other documentation relating to the Service once annually during normal business hours. For such audit purpose Supplier will grant The Authority or a third party accepted by Supplier in writing and contracted by The Authority access to such systems, records and documents at Supplier's sites and facilities. Subject to Supplier confidentiality and information security provisions and to the extent necessary to conduct a required audit, The Authority will be granted access to the systems audit trail. If a third Party is contracted by The Authority to perform all or part of the audit they may not be a competitor of Supplier in the fields of the Service. Supplier agrees to maintain accurate and detailed records of information and data pertaining to the Service.

If any aspect of the Service is subcontracted to a third Party by Supplier then Supplier shall ensure that the subcontractor [REDACTED] grants The Authority access to the systems, records and facilities of the subcontractor for the purpose of the audit equivalent to the access rights agreed upon herein. Such audit will require reasonable prior written notice by The Authority. Each Party is responsible for bearing their own costs resulting from the conduct or support of any audit activity. The Authority and its audit representatives will abide by Supplier's work place rules and policies and may be required to sign confidentiality undertakings towards Supplier. Supplier shall provide a written response to findings. If Supplier performs any internal audits relating to or associated with the Service as part of an internal program, Supplier shall provide a summary of any findings and proposed corrective actions to The Authority following completion of the audit. Should the European Medicine Agency ("EMA") or any other government authority conduct any inspection at The Authority's offices related to PVAI, or take any other action with respect to PVAI, then Supplier will provide adequate support.

7.8 Change Management. Any material change made to the Services will be subject to a mutually agreed change management process.

7.9 System Changes and Assistance. The Authority will be informed of all material system changes before they are implemented by Supplier. Changes must be first validated by The Authority prior to implementation in the production environment. The Authority will install any Supplier provided components required for integration of PVAI with The Authority systems.

7.10 Insurance. At its own expense, Supplier shall maintain insurance during the term and if any policy is written on a 'claims made' basis without interruption during the Term of the Agreement and for a period of one (1) year thereafter with the insurance coverages described below, each of which must be issued by an insurance company having an AM Best rating of A- or better. Supplier shall maintain deductibles that are appropriate in relation to the risks associated with its business and its financial strength and is responsible for all such deductibles and self-insured retentions. Supplier minimally shall maintain the insurance coverage types and amounts specified below. The Authority shall be named as additional insureds on Supplier's commercial general liability and umbrella liability policies.

- Commercial general liability insurance covering claims for bodily injury (including death), personal injury and broad form property damage arising out of operations in connection with the Agreement, including liability assumed under the Agreement, with a single limit in USD currency equivalent of not less than [REDACTED], and these insurance limits may be achieved by a combination of primary and/or umbrella/excess liability policies.
- Workers compensation insurance as required by the statutes of the jurisdiction in which the Services are being performed covering all employees employed by Supplier in the performance of their duties who are required to be covered by the statutes of the jurisdiction where the Services are being performed with a single limit of the amount required by such statutes.
- Employers liability insurance with limits of not less than the greater of: (a) the amount required by the statutes of the jurisdiction where the Services are being performed; [REDACTED] for UK for all personnel engaged in operations covered by the Agreement.
- Errors and omissions insurance with limits of not less than [REDACTED] providing coverage for negligent acts in the rendering of, or failure to render, professional services under the Agreement, which shall include, electronic data losses, damage or breaches of electronic data security, destruction of data (other than casualty exclusions) or failure to design an adequate system arising out of Supplier's negligent acts in the rendering of, or failure to render, professional services under the Agreement.
- Umbrella (excess) coverage in USD currency equivalent in the amount of [REDACTED], written on a non-contributory basis for commercial general liability, automobile liability, and employers' liability coverage.

Upon The Authority's request, Supplier shall furnish The Authority with certificates of insurance evidencing the insurance required herein. Supplier shall provide written notice to The Authority at least thirty (30) days in advance of the cancellation, lapse, reduction, or other adverse change, in respect of any insurance coverage maintained by Supplier as required hereunder.

7.10 Disputes. Any dispute or claim arising out of or in connection with this Agreement, any Service Order or their subject matter or formation, including any non-contractual dispute or claim (each, a “Dispute”) shall be addressed and resolved in accordance with the following process. First, the parties’ designated personnel shall work to resolve the Dispute within a reasonable period of time, after which either party may escalate the Dispute for resolution to executives with the authority to resolve it by good faith negotiation. Any Dispute not resolved within thirty (30) days after such an executive escalation shall be finally resolved by arbitration pursuant to the commercial arbitration rules of the London Court of International Arbitration, provided that the following provisions shall prevail over any conflicting provisions within such rules:

- The arbitration shall be conducted by a sole arbitrator. If the parties cannot agree on an arbitrator within fourteen (14) days of the arbitration demand, then the appointment of the sole arbitrator shall be made by the London Court of International Arbitration;
- The seat of the arbitration shall be in London, United Kingdom and the arbitration shall be conducted in the English language;
- The arbitrator has discretion to award costs and shall issue a written decision that is final and binding on both parties and states the reasons for the decision.
- All arbitration documents, hearings and proceedings shall be confidential, save to the extent necessary to enforce any award or to comply with any requirement of any lawful authorities or as otherwise agreed between the parties.
- Judgment upon the arbitrator’s decision shall be final and binding and judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant party and its assets.

7.11 Non-Solicitation. Neither Party shall, without the express consent of the other Party in each instance, during the Term and for a period of [REDACTED] thereafter, directly or indirectly solicit, employ, offer to employ, nor engage as a consultant, any employee or independent consultant of the other Party with whom such Party had contact pursuant to this Agreement or SOW hereunder.

7.12 Injunctive Relief; Remedies. The Parties agree that in the event of any breach or threatened breach of any provision of this Agreement or an applicable Order or SOW concerning (i) Confidential Information, (ii) intellectual property rights or (iii) other matters for which equitable rights are expressly provided in this Agreement, money damages would be an inadequate remedy. Accordingly, those provisions may be enforced by the preliminary or permanent, mandatory or prohibitory injunction or other order of the arbitrator(s) or a court of competent jurisdiction. Any remedies shall be considered cumulative unless otherwise expressly stated in this Agreement.

7.13 Further Assurances. Each Party hereto shall do or shall cause to be done all such acts, and shall deliver any such other agreements, Consents, access, and documents as expressly required hereunder or as reasonably necessary for each Party to carry out the respective obligations or requirements of this Agreement or any applicable SOW or Order.

7.14 Contract Management. Both Parties shall proactively manage risks attributed to them under the terms of this Agreement. Supplier shall develop, operate, maintain and amend, as agreed with the Authority, processes for: (a) the identification and management of risks; (b) the identification and management of issues; and (c) monitoring and controlling project plans. Ongoing contract management shall be a part of the agreed Governance procedures mutually agreed in an applicable Order.

7.15 Income Tax and National Insurance Contributions. Where the Supplier or any Supplier Personnel are liable to be taxed in the UK or to pay national insurance contributions in respect of consideration received under this Agreement, the Supplier shall at all times comply with the Income Tax (Earnings and Pensions) Act 2003 and all other statutes and regulations, as applicable, relating to income tax, and the Social Security Contributions and Benefits Act 1992 and all other statutes and regulations applicable to Supplier relating to national insurance contributions, in respect of that consideration.

AGREED:

The Medicines and Healthcare products Regulatory Agency

[Redacted signature block for The Medicines and Healthcare products Regulatory Agency]

Genpact (UK) Limited

[Redacted signature block for Genpact (UK) Limited]

Exhibit A: Form of Order Form

Sample Order Form

[Redacted Form Content]

Exhibit B: Rate Card

Additional services provided by Supplier as part of change requests or additional projects will be delivered by roles that are mapped to the rate card below.

[illegible]

[illegible]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Exhibit D: Information Security Policy

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Exhibit E: Data Protection Terms

Data Protection Legislation means all applicable laws that relate to data protection, including any laws applicable from time to time implementing the Data Protection Directive 1995/46/EC ("Directive") on the protection of individuals with regards to the processing of Personal Data and on the free movement of such data in any relevant jurisdiction, General Data Protection Regulation ((EU) 2016/679)) ("Regulation") once it applies.

- 1.1 For the purposes of this Exhibit E, the terms "data controller", "Personal Data", "processing", "data processor", and "data subject" shall have (until 24 May 2018) the meanings given under the Directive and (from 25 May 2018) the meaning given under the Regulation.

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

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- [REDACTED]

- [REDACTED]

- [REDACTED]

2.0 Subprocessors

[illegible]

Supplier may utilize non-Supplier employees (freelancer) as contractors for the purposes of resource augmentation from time to time as well as the following subcontractors:



Exhibit F
PVAI Pricing and Invoicing

This Exhibit includes details of the Genpact Professional Service Fees and Subscription Fees for the PVAI Release 1 Solution as set forth in the Implementation SOW 2020-1 and the SaaS Order 2020-1. The Payment Schedule shall be as set forth in the Implementation SOW 2020-1 and the SaaS Order 2020-1, and invoices shall be due for payment within [REDACTED] days of receipt.

- 1) **Professional Service Fees:** A one-time fee of [REDACTED] will be paid by Authority to Genpact for implementation of Release 1 in accordance with the terms and payment schedule set forth in Implementation SOW 2020-1.
- 2) **Annual Subscription Fees:** Genpact will charge [REDACTED] per year for Release 1 as set forth in SaaS Order 2020-1, invoiced quarterly in advance, commencing from the time of deployment to the production environment.

Exhibit G
Sample [REDACTED] Reports

