

**STATEMENT OF WORK 2020-1
FOR PVAI RELEASE 1 IMPLEMENTATION PROJECT**

Date: September 7, 2020

SOW Number: 1

This Statement of Work Number: 1 (“SOW”) forms part of and shall be governed by that certain PVAI Subscription Agreement by and between Genpact (UK) Limited (“Supplier”) and Medicines and Healthcare products Regulatory Agency (the “Authority”) dated September 7, 2020 (“Agreement”). Any proposed changes to the terms of the Professional Services set forth in this SOW shall be negotiated in good faith and shall become effective only upon mutually agreed written amendment hereto. All capitalized terms used, but not defined, in this SOW will have the meanings ascribed to them in the Agreement. This SOW covers the implementation and configuration of the Supplier Technology. The Authority’s licensure and use of the Supplier Technology in a production environment is addressed in a separate Order 2020-1 between the Parties.

I. DESCRIPTION OF SERVICES

This SOW describes the activities and deliverables (“Services”) to be delivered by Supplier to implement a solution for the automated extraction of COVID-19 related Yellow cards for Authority (“Release 1”). The timing of the services to be provided hereunder is as follows:

Release 1 will comprise of two key components to be delivered by Supplier:

- **Extraction Framework** – This component will acquire COVID-19 related Yellow card files from the Authority’s COVID Yellow Card system and forward them to the PVAI core extraction engine (“XCE”). The Extraction Models deployed within the XCE will extract structured ADR data from the COVID-19 related Yellow cards and the extracted values for selected data fields will be updated in each file and returned to the Authority’s Yellow Card system for further processing by the Authority. This is detailed further in section 1 below.
- **Extraction Models** – The extraction models deployed within the XCE will be utilized to extract specific field level structured ADR data from COVID-19 related Yellow cards. This is detailed further in section 2 below.

The above will utilize a combination of custom developed components and existing PVAI product components.

1. Specifications: Extraction Framework

1.1 Solution Scope

The scope and solution outline of the Extraction Framework is as follows:

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- [REDACTED]
- The format of the COVID Yellow Card files will be E2B R2.
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

- The solution will code Extracted values against the following Authority supplied reference data:
 - Authority's Product Dictionary – for pharmaceutical products
 - Authority's MedDRA Dictionary – for medical terminology

A diagram of the proposed release 1 solution is given below in Figure 1.

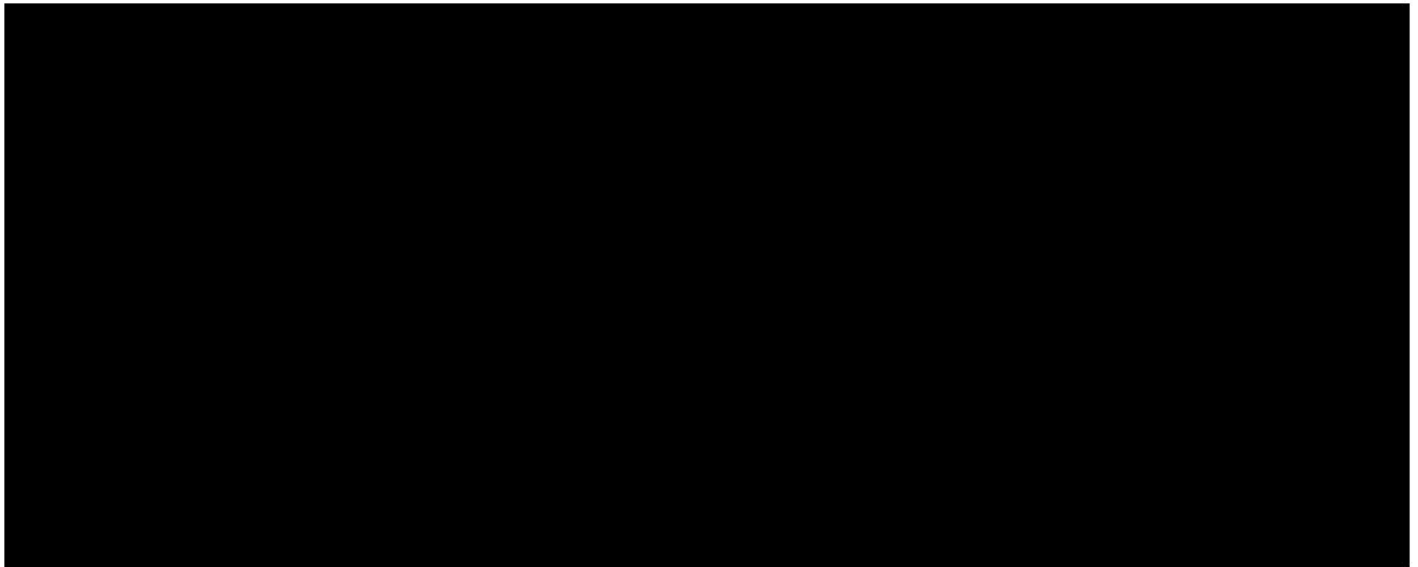


Figure 1 – Solution Outline

1.2 Out of Scope

- Coding of extracted data against the WHO Dictionary
- Transmission of COVID Yellow Card files to and from the File Drop location
- Integrations or interfaces not expressly stated as in scope in this SOW
- Any Authority system changes
- Changes or customizations of the core PVAI product unless mutually agreed upon in writing via a change request

2. Specifications: Extraction Models

2.1 Solution Scope

The scope and solution outline of the Extraction Models is as follows:

- I [REDACTED]
- I [REDACTED]
- I [REDACTED]

2.2 Out of Scope

- I [REDACTED]

3. Implementation Project Scope

The implementation of Release 1 will follow Supplier's System Implementation Lifecycle ("SILC") through the following phases:

- Design: [REDACTED]
- Configuration & Solution Build: [REDACTED]
- Solution Test Phase: [REDACTED]
- Service Introduction: [REDACTED]
- Deployment: [REDACTED]

3.1 Out of Scope

[REDACTED]

4. Implementation Environments Scope

[REDACTED]

Environment	Intended Purpose	Availability Hrs. (all times in GMT).
DEV	To support development of the solution.	[REDACTED]
TEST	To support the Solution Test of the solution	[REDACTED]
PROD	To support the live solution	[REDACTED]

[REDACTED]

4.1 Out of scope

[REDACTED]

II. PROJECT SCHEDULE

1. Project Timelines



Figure 2 – Project Schedule



The change control process will be initiated when a change to the project scope or plan is identified by either Supplier or Authority. Supplier and Authority will assess if the change is valid. If valid the change will be assessed and put forward for approval via the mutually agreed governance process for appropriate decision and action.

1.3 Assumptions

General Assumptions and Identification of Risks

[illegible]

Solution Test Phase Assumptions

Deployment Phase Assumptions

Additional Authority Responsibilities:

Project Management

2. SOW Managers

The following SOW managers will be responsible for all communication and management under this SOW.

Authority

Genpact

3. Delivery Schedule

The high-level project plan and illustrative SOW schedule are as depicted in Section I – Project Schedule. [REDACTED]

The table below illustrates indicative deliverables by phase and work stream. It illustrates which deliverables Supplier will create and which deliverables Authority will create. This list is not exhaustive.

Phase	Work stream	Authority SDLC Deliverables created by Authority	Authority SDLC Deliverables created by Supplier	PVAI SILC Deliverables created by Supplier	Date Completed
[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
	[REDACTED]	[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
	[REDACTED]	[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	
		[REDACTED]		[REDACTED]	

Phase	Work stream	Authority SDLC Deliverables created by Authority	Authority SDLC Deliverables created by Supplier	PVAI SILC Deliverables created by Supplier	Date Completed

5. Other

Authority shall provide Supplier with the materials, data, personnel and access (including, if applicable, remote access) to Authority systems, premises, equipment and resources as reasonably requested by Supplier to enable provision of the Professional Services. The Authority may incur additional fees and expenses if it requests Supplier to perform services that are materially different than, or in addition to, those described in this SOW (the “Additional Work”). Prior to commencing any such Additional Work or incurring any expenses in connection with the Additional Work, Supplier will notify the Authority that the requested services are outside of the scope of this SOW, will provide a fee estimate using the Rate Card in Exhibit B of the Agreement and will obtain the Authority’s written approval to proceed.

AGREED:

The Medicines and Healthcare products Regulatory Agency

Genpact (UK) Limited

