

FDA DSCSA Pilot

Product Identifier Verifications by a Contract Manufacturer on behalf of a Marketing
Authorization Holder



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SANOFI



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Pilot project

This Pilot project tested the ability of a Contract Manufacturer (CMO) to provide Product Identifier (PI) verifications on behalf of a Market Authorization Holder (MAH). CMO's encode GTIN, Serial Number, Lot #, and Expiry on the Unit-of-Sale and Case/Shippers in accordance with the DSCSA requirements. The serialized batches are shipped to the MAH, but that does not mean the PI data was sent to the MAH. Because some of the serialization activity may have been completed prior to the implementation of automated data exchange platforms, the PI information for electronic verifications is stored within the CMO's level 4 serialization solution provider. In other words, the original PI data is stored in the CMO's system, not in the MAH's system. This Pilot project was structured to examine whether a MAH can delegate an electronic verification request to the system that has the original PI data for the verification response. This project leveraged the Verification Router Service (VRS) network currently being built for verifications of saleable returns.

Goals

The goal of this project is to ensure interoperability between systems to allow PI verifications to be electronically verified by the CMO PI repository system.

Objectives

The objective of the project is to ensure feasibility of passing electronic verification requests to a CMO PI repository by engaging a MAH. The project participants included a CMO (Sanofi acting as a CMO), a MAH (Advanz Pharma), VRS Solution Providers, and a wholesaler/distributor (McKesson) to scan 2D Data Matrix Bar Codes to initiate verification requests.



Table of Participants

Company	Type	Contact	Size: Number of employees
Sanofi	Manufacturer	Arthi Nagaraj Arthi.Nagaraj@sanofi.com Reid Graves Reid.Graves@sanofi.com	110,000
McKesson	Wholesale Distributor	Scott Mooney Scott.Mooney@McKesson.com Vinod Vedire Vinod.Vedire@McKesson.com	80,000
Advanz Pharma	Virtual Manufacturer	Chris Humphrey Chris.Humphrey@advanzpharma.com	400
Adents	Service Provider	Saad Achouri sachouri@adents.com	100

Terms / Abbreviations used

Abbreviation	Terms
MAH	Marketing Authorization Holder
CMO	Contract Manufacturer
PI	Product Identifier. This consists of the GTIN, Serial number, Lot and Expiry
GTIN	Global Trade Identification Number. This is part of the GS1 standards that can be used by companies to identify their Trade items
DSCSA	Drug Supply Chain Security Act
VRS	Verification Router Service. This is interoperable solution used to primarily address DSCSA verification requirements for the Saleable returns' regulation
HDA	Healthcare Distribution Alliance. HDA is a national organization representing primary pharmaceutical distributors
LD	Lookup Directory. This is akin to a phonebook where manufacturers store their products' GTINs so that the VRS knows to route the verification request to the correct manufacturer's repository of product identifiers
GLN	Global Location Number. This is part of the GS1 standards that can be used by companies to identify their locations
Pilot	A small-scale study to evaluate feasibility of a concept



Executive Summary

Analysis of saleable returns by the Healthcare Distribution Alliance (HDA) shows that approximately 60 million units of drug product are returned annually for resale. The industry today has 800+ manufacturers and 100+ wholesale distributors. There are about 15+ solution providers providing Verification Router Service (VRS) solution to service this industry. In the current landscape, 96% of the requests for verification will be triggered through a single sub network in the VRS architecture leading to a “one to many” pattern.

The Pilot group consisted of a manufacturer (CMO), a virtual manufacturer (MAH), a major wholesale distributor and 4 solution providers. The challenges and delays encountered with a small network will be multifold when the system goes live, if not addressed.

The Pilot demonstrated that interoperability and delegation of verification was possible between the Contract Manufacturer (CMO) and the Marketing Authorization Holder (MAH) using the VRS network. In general, we concluded that it would be easier if the party responsible for the verification loads the Lookup Directory and points the Global Trade Identification Number (GTIN) to their solution provider for verification. There needs to be an agreement and coordination between partners so that the Lookup directory (LD) is not updated with conflicting information for the same GTIN. When the GTIN is initially pointing one entity (MAH) and is then delegated to the CMO, we found that just updating the Look up directory with the GTIN pointing to the CMO did not automatically update the network. There were multiple steps that needed to be performed, as elaborated in the [Lessons Learnt](#) in Phase 2.

We also found that while the solution providers typically provide a report to show the responses sent as a result of a verification, they may not display all the data elements of Response (e.g. GLN) that are often mandatory as part of the HDA specifications. This leads to a heavy dependence on solution providers to investigate potential errors that occur. In addition to this, different solution providers having different terminologies for features, further complicates the issue on hand.

Finally, we also saw cases where there could be conflicting verification responses as seen by a Manufacturer and a Distributor when viewing a verification response. This scenario is elaborated in the [Lessons Learnt](#) in Phase 2. We recommend this be addressed as part of the VRS solution to make the network more robust.

The VRS is the first step in working towards an interoperable network in the industry. The HDA has done a great job in bringing together the industry to make this happen. It is important that manufacturers and wholesale distributors understand the Business Requirements document published by the HDA, and not just leave it to their solution providers. It is important the business understands the two different positions in the industry today on

responding to a verification request for example, when a product is recalled and chose the one which aligns with their business rules. Should their business requirement call for a delegation of verification, it is important to understand which party will update the LD, to minimize the challenges that may arise with both parties' doing an update.

Pilot Methodology

The project was divided into two Phases. Phase 1 sets a baseline with the verification being done by the MAH while in Phase 2, the verification is delegated to the CMO.

It is important to note that there are two parts to the response provided for a verification. One part returns the verification as True or False. The other part provides additional information on the verification such as Recalled, Expired, etc.

Phase 1 (Traditional VRS Architecture)

The purpose of Phase I was to establish a baseline of testing with the Lookup Directory (LD) pointing to the MAH. This phase is to ensure interoperability is established between the different VRS Solution providers and to prove the MAH can provide accurate responses.

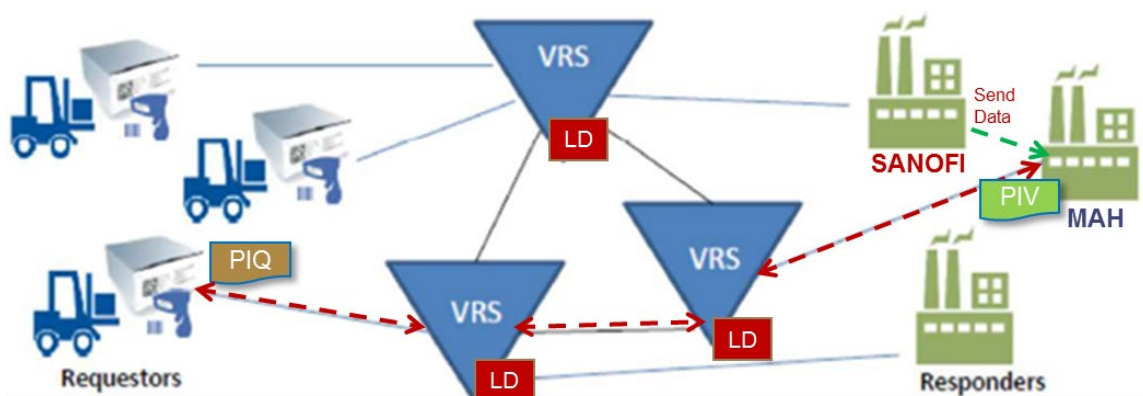


Figure 1 Traditional VRS Architecture

Phase I Data

1. PI data sets using product Global Trade Identification Number (GTINs) were prepared for testing purposes



2. PI's were loaded into the MAH Verification Router Service (VRS) Solution Provider repository
3. The LD was populated with the appropriate URL pointing to the MAH VRS Solution Providers repository (Phase 1)
4. We interjected 'false' PI's to test the conformance of providing accurate verification responses to the Wholesaler/Distributor
5. PI data sets including Human Readable and corresponding 2D Bar Codes were sent to the participating wholesaler(s) for testing purposes

Challenges/Lessons Learned

1. There were significant delays and challenges with interoperability. An upgrade to a different environment by a service provider in the network caused significant delays
1. Bar code scans using an app on the phone showed incorrect results as "Not Verified" for all responses in an initial scan for verification. This was due to a configuration issue that was later fixed.
2. Also, Initial verification results did not show additional information on the Product Identifier such as "Recalled" etc. This reiterated the need for master data to be set up correctly in Manufacturer systems.
3. Once master data was fixed and the test was repeated, the response now came back from the MAH as Verified – True with additional information "Recalled" (Fig 2 below). But, for the Product Identifier's where serial number was set as destroyed, sampled, stolen etc., the response came back as Verified (no other information was sent back to the wholesaler). We learnt that the current solution and standards support status of Recalled, Expired and Suspect and not that of destroyed, sampled etc.
4. However, the manufacturer report shows the additional information of "Destroyed", "Sampled" etc.



Standard ▼ Hide Filter Bar Filters

Request Time: GTIN: Lot/Batch Number: Verified: ▼

Serial Number: Additional Information: Requestor GLN: Responder GLN:

Verification Log (11) ↓ ↻

Request Time	GTIN	Lot/Batch Number	Expiration Date	Serial Number	Verified	Requestor GLN	Responder GLN	Additional Information
Feb 7, 2020, 10:00:39 AM	00366993057026	DT04317	21-09-04	13511RPX018HY P	true	0010939000002	5021691000006	
Feb 7, 2020, 10:00:31 AM	00366993057026	DT04317	21-09-04	13511RPX01E3H A	true	0010939000002	5021691000006	
Feb 7, 2020, 10:00:18 AM	00366993057026	DT04317	21-09-04	13511RPX01G06 P	true	0010939000002	5021691000006	
Feb 7, 2020, 9:58:47 AM	00366993057026	DT04317	21-09-04	13511RPX0162X C	true	0010939000002	5021691000006	
Feb 7, 2020, 9:58:27 AM	00366993057026	DT04317	21-09-04	13511RPX00WNA3	true	0010939000002	5021691000006	
Feb 7, 2020, 9:58:13 AM	00366993057026	DT04317	21-09-04	13511RPX00VKV G	true	0010939000002	5021691000006	Recalled

Figure 2 – Sample Phase 1 results as seen by the Wholesale Distributor

verificationRequestSerialNum	verificationRequestL	verificationResponseResu	pimPVSerialNum	pimPVL	pimPVExpirationDa	pimPVSerialNumberStat	pimPVItemStatus	pimPVAttribu
13511RPX00WNA3	DT04317	VALID	13511RPX00WNA3	DT04317	210904	DECOMMISSIONED	AVAILABLE	SAMPLED
13511RPX00VKVG	DT04317	VALID	13511RPX00VKVG	DT04317	210904	DECOMMISSIONED	AVAILABLE	RECALLED
13511RPX018HYP	DT04317	VALID	13511RPX018HYP	DT04317	210904	DECOMMISSIONED	AVAILABLE	SAMPLED
13511RPX0162XC	DT04317	VALID	13511RPX0162XC	DT04317	210904	DECOMMISSIONED	AVAILABLE	DISPOSED
13511RPX01E3HA	DT04317	VALID	13511RPX01E3HA	DT04317	210904	DECOMMISSIONED	AVAILABLE	SAMPLED
13511RPX01G06P	DT04317	VALID	13511RPX01G06P	DT04317	210904	DECOMMISSIONED	AVAILABLE	STOLEN

Figure 3 – Sample Phase 1 results as seen by the MAH

Phase 2 (PI Verifications are delegated to the CMO)

Once the baseline was established for the Traditional VRS Architecture, testing with the Lookup Directory pointing to the CMO for verification responses was conducted.

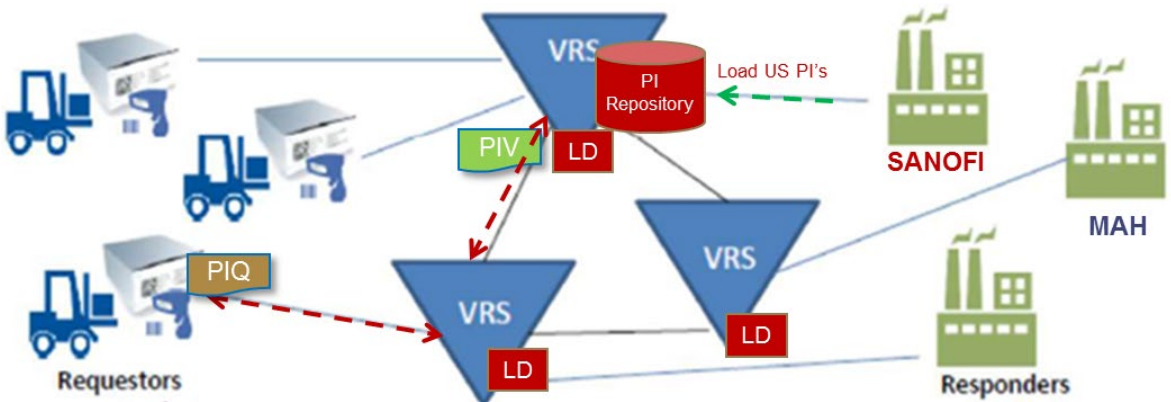


Figure 4 - Delegation to the CMO

Phase II Data

1. A subset of the PI data sets used in Phase 1 were used in Phase 2 and some additional data sets were also added.
2. We interjected 'false' PI's to test the conformance of providing accurate verification responses to the wholesaler/distributor
3. PI data sets including Human Readable and corresponding 2D Bar Codes was prepared as a PDF file and sent to the participating wholesaler
4. The LD was populated with the appropriate URL pointing to the CMO VRS Solution Providers repository

Challenges/Lessons Learned

1. Challenges and delays continued during the setup of the LD to test phase 2
2. The Record Owner in the LD was set up incorrectly and not according to the HDA specifications which resulted in an intermediate solution provider in the network rejecting the record during an LD synchronization process
3. The initial assumption was that updating the CMO's LD with the GTIN's (that initially pointed to the MAH), now pointing to the CMO's service provider, would automatically update all the LD's in the network.
4. However, the start and end date fields in the LD entry by the CMO overlapped with the dates in the LD entry by the MAH. Due to this, the LD update by the CMO was rejected. This is consistent with the guidance provided by the HDA technical specification document for the VRS
5. Following this, for delegation to occur, there were multiple steps to be performed:
 - a. The initial record owner needed to "Delete" or "Inactivate" the GTIN so the LD would synch the delegation to the CMO. We found different terminologies and system functionalities used to achieve this action between service providers, which also led to confusion.



- b. The CMO would then need to update their LD to have the GTIN point to their service provider
6. Once the delegation in the LD was done, we did a test for one PI. We found that while the response was from the CMO VRS system, the GLN was pointing to the MAH. The reason for pointing this out is that the GLN may be used as part of analytics to track the responder and this could be misleading. In this case, we found the GLN pointing to the MAH as part of the settings in the CMO's master data. We changed this to reflect the GLN of the CMO for consistency
 7. In another test performed, the manufacturer report showed that the verification was responded to (Figure 5) while the Distributor received an error on the verification (Figure 6). This was because when the service provider for the manufacturer responded to the request, their report marked it successful. However, since they did not pass a GLN in the response an intermediate service provider rejected the response and passed on an error which is what the Distributor received.

Date (UTC)	Lot	Exp. Date	GTIN	Serial	Requestor GLN	Verified	Response Date	Response Reason
03/10/2020 18:06:34 +00:00	DT04317	210904	00366993057026	13511RPX000KCN	0010939000002	FALSE	03/10/2020 18:06:35 +00:00	No_match_GTIN_Serial
03/10/2020 14:27:09 +00:00	DT04317	210904	00366993057026	13511RPX000KCN	0010939000002	FALSE	03/10/2020 14:27:09 +00:00	No_match_GTIN_Serial
03/10/2020 13:42:42 +00:00	DT04317	210904	00366993057026	13511RPX009A7E	0010939000002	FALSE	03/10/2020 13:42:42 +00:00	No_match_GTIN_Serial
03/10/2020 13:42:38 +00:00	DT04317	210904	00366993057026	13511RPX008F6D	0010939000002	FALSE	03/10/2020 13:42:38 +00:00	No_match_GTIN_Serial
03/10/2020 13:42:24 +00:00	DT04317	210904	00366993057026	13511RPX0070MA	0010939000002	FALSE	03/10/2020 13:42:24 +00:00	No_match_GTIN_Serial
03/10/2020 13:42:18 +00:00	DT04317	210904	00366993057026	13511RPX00604N	0010939000002	FALSE	03/10/2020 13:42:18 +00:00	No_match_GTIN_Serial
03/10/2020 13:42:11 +00:00	DT04317	210904	00366993057026	13511RPX005DTA	0010939000002	FALSE	03/10/2020 13:42:11 +00:00	No_match_GTIN_Serial
03/10/2020 13:42:03 +00:00	DT04317	210904	00366993057026	13511RPX004ERP	0010939000002	FALSE	03/10/2020 13:42:03 +00:00	No_match_GTIN_Serial
03/10/2020 13:41:55 +00:00	DT04317	210904	00366993057026	13511RPX003RKH	0010939000002	FALSE	03/10/2020 13:41:55 +00:00	No_match_GTIN_Serial
03/10/2020 13:41:49 +00:00	DT04317	210904	00366993057026	13511RPX0025VA	0010939000002	FALSE	03/10/2020 13:41:50 +00:00	No_match_GTIN_Serial
03/10/2020 13:41:44 +00:00	DT04317	210904	00366993057026	13511RPX001E2W	0010939000002	FALSE	03/10/2020 13:41:44 +00:00	No_match_GTIN_Serial
03/10/2020 13:41:33 +00:00	DT04317	210904	00366993057026	13511RPX000KCN	0010939000002	FALSE	03/10/2020 13:41:33 +00:00	No_match_GTIN_Serial
03/10/2020 13:41:14 +00:00	DT04317	210904	00366993057026	13511RPX14XX3M	0010939000002	FALSE	03/10/2020 13:41:16 +00:00	No_match_GTIN_Serial

Figure 5 - Response seen in the CMO system

PI	Reason for failure
(01)00366993057026(21)13511RPX000KCN(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX001E2W(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX0025VA(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX003RKH(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX004ERP(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX005DTA(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX00604N(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX0070MA(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX008F6D(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway
(01)00366993057026(21)13511RPX009A7E(17)210904(10)DT04317	Received Error code: 502 ; Reason-502/{"error":"10022","message":"Bad Gateway","detail":"Bad Gateway

Figure 6 - Error received by the distributor but not reflected in the CMO system

8. The phase 2 test to delegate the verification to the CMO was successful. However, we found results from the CMO's service provider different from that of the MAH for the same PI. The MAH returned a Recalled



product as Verified – True with additional information as Recalled (Figure 2) while the CMO returned that same PI as Verified – False with additional information as Recalled (Figure 7)

Request Time	Correlation Id	GTIN	Lot/Batch Number	Expiration Date	Serial Number	Verified	Requestor GLN	Responder GLN	Additional Information
2020-03-10T13:40:33.000Z	00505685-42aa-4eea-98da-96b	00366993057026	DT04317	210904	13511RPX00VKVG	false	0010939000002	3700991200010	Recalled

Figure 7 - verification response from the CMO as seen by the Wholesale Distributor

Key Findings

1. In case of a delegation, there is no current standard or guidance on which party is responsible to update the LD. This could also apply when there is a transfer of GTIN’s due to merger and acquisitions.
2. For a Pilot test involving 1 wholesale distributor 2 manufacturers and 3 different solution providers, we had significant delays due to communication and investigations to be done at each step. For an industry wide test, involving 800+ manufacturers and 100+ distributors, having a well-tested and robust system is key. Please note that along with this Pilot, VRS testing was also occurring in parallel. Some of our challenges were due to a premature VRS system.
3. Each solution provider has different terminologies and functionalities to perform similar tasks which is unique to their system. This caused significant challenges during troubleshooting.
4. The VRS solution systems store and send additional information such as “Recalled”, “Expired” etc. to be used in addition to the Verified/Not verified response. However, this is not standardized across different solution providers. For the same PI, there were different responses by the MAH and the CMO. Not all the “additional information” is returned back to the WD as seen in Phase 1, leading to risks especially if the response is verified but additional information if say “Destroyed” was not returned.
5. The granularity of the response could be impacted by the granularity of the data in the data warehouse of the responder. For example, there is no guideline stating if only commissioned/valid data is stored in the responder’s data warehouse or if all data with statuses including sampled, destroyed etc. is stored. If a result of Verified is returned for a PI match, the system may inadvertently return a result of Verified if the Manufacturer stores statuses like ‘Destroyed’ which is not currently supported as a status.
6. The current design is highly dependent on solution providers response time when issues arise that require investigation. Often this is also tied to escalating costs.
7. The interrogation of the data is different for each solution provider so that one while solution sees the file as OK, another considers the file defective in its structure. This caused inconsistent responses to verifications by different solution providers. This was driven messaging standards being loosely followed.

Recommendations

1. It is important to have a clear understanding on the partner responsible to update the LD if delegation is necessary.
2. There are currently two ways of responding to a PI whose status may have changed (Recalled, Expired, etc.) since originally manufactured. A manufacturer could return either a True or a False based on their internal policy when the PI matches but the product is Recalled. However, in both cases the response would also include additional information returned by the system as Recalled. Business users must understand the different solutions available and make an informed decision based on the granularity of the data/status in their systems as well as their legal/regulatory preferences
3. Business users need to have a good understanding of the system and make sure their system displays all data elements passed in a request/response, in case of trouble shooting. It is important for the user to understand where to look in the system when something goes wrong and who they need to reach out to resolve errors.
4. All solution providers need to conform to the shared messaging standards. It is important to capture and pass on any errors caught by intermediary systems to the requestor and responder, so all systems are aligned on the request and the response provided.
5. Finally, it is recommended that a complete industry network test is done prior to go-live. The suggestion is to do this in a production environment with all (or most) of the GTIN's loaded. A period of 2-3 months should be used to thoroughly test the system for errors or false positives that the system shows without having to trigger a suspect product process unless proven otherwise during investigation.