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TECHNICAL REPORT **DIGI2.0: THE GLOBAL** PHARMA TRACKER PROTOTYPE **NOVEMBER 2019**

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TECHNICAL REPORT DIGI2.0: THE GLOBAL PHARMA TRACKER PROTOTYPE NOVEMBER 2019

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1. Executive summary

The objective of Pharma. Aero is to achieve excellence in reliable end-to-end air transportation for pharma shippers, by fostering collaboration between CEIV certified airport communities dedicated in developing and pioneering when it comes to handling, storage and air transportation of pharmaceuticals.

Pharma. Aero's goal is to create more transparency and to improve performance of the supply chain for temperature-controlled pharma shipments. The ability to collect, unify and leverage data across the multiple participants in a pharma supply chain is instrumental in achieving the Pharma. Aero mission. To this end, the development of a logistics data sharing platform is an essential tool. The sharing and analysis of data through such a platform can yield deeper insights on the air transportation performance of pharma cargo, thereby enabling preventive, predictive and prescriptive capabilities.

The above gave birth to the **Digi1.0: Certification** of Pharmaceuticals Air Trade Lanes through **Digitisation in 2018.** Digi1.0 concluded that building a common digital data sharing platform that integrates data from different and multiple sources is critical to achieve greater transparency to the pharma supply chain stakeholders¹.

Subsequent to Digi1.0, the **Digi2.0: The Global Pharma Tracker Prototype** aims to develop the Proof of Concept into a Prototype – the Global Pharma Tracker (GPT) by incorporating data from real shipments for a selected trade lane and expanding the platform capabilities.

The GPT prototype was built on a Nallian's data sharing platform. Together with the Pharma. Aero project members², real data from 2 batches of 22 pharma shipments on the Brussels-Singapore-Sydney prototype trade lane were integrated into the GPT platform. The platform allows a user to visualize the door-to-door performance of the entire pharma supply chain and at the same time, control visibility of data based on the agreed data sharing and governance framework. The Digi 2.0 project was divided into 4 major work packages, executed more or less in parallel. More information on the work package details can be found in section 3.5 of this report:

The GPT was also presented and demonstrated to the Pharma.Aero User Board and key departments in major pharma shippers such as Pfizer, MSD and Johnson & Johnson, which acknowledged that the GPT is a value-adding tool to their supply chain management and expressed the interest to discuss participation in the Early Adopter Program.

Pilot Group members have also had positive evaluation on GPT and are considering participation in the Early Adopter Program, in collaboration with the shipper.

This report also summarizes the challenges faced and lessons learnt from each work package. The Digi 2.0 project concluded that the technology necessary to develop GPT is available today. Key areas to address for a successful rollout of GPT will include:

- Support for pharma supply chain participants to illustrate the importance of data sharing to their subcontractors and articulate the business value drivers to participate in GPT;
- Collaboratively define a clear data sharing and governance framework for GPT; and
- Position GPT as the single logistics window that is integrated with existing operational data sources and quality systems.

If these challenges are effectively addressed, the GPT network can gradually grow to offer unparalleled end-to-end logistics visibility for temperature-controlled pharma shipments.

2. Project charter and participation note

In July 2018, Pharma.Aero launched the project charter of Digi 2.0: The Global Pharma Tracker Prototype, supported by the results and findings from Digi 1.0: Certification of Pharmaceuticals Air Trade Lanes through Digitisation.

2.1 Project scope & goal

The **Digi 1.0** project concluded that a common digital data sharing platform that integrates data from different and multiple sources is critical to provide greater transparency to the pharma supply chain stakeholders. The platform must be able to meet key functional requirements including flexibility, interoperability, data accessibility, timeliness and immutability. The previous project group has established a validated demo model to prove that the relevant data collected from various stakeholders could be aggregated to provide greater

visibility and to enhance the reliability of end-toend air transportation, and ultimately to enable the establishment of certified trade lanes. The platform's adoption will require a collaborative mindset for the industry to reap great benefits.

Subsequent to Digi 1.0, the project group recommended for the development and implementation of a prototype of the digital data sharing platform, identified as **Digi 2.0: The Global Pharma Tracker Prototype Project**. The target of Digi 2.0 is to implement the Global Pharma Tracker Prototype on a small number of pharma lanes with Pharma. Aero members using real data. This implementation focuses on live data sources and aims to validate the value of integration and visualization with various stakeholders of the air cargo supply chain. Through each pilot, lessons learned were translated into enhancements to ensure stability, reliability and viability before GPT was being rolled out on a bigger scale to other air trade lanes.

The table below compares the project scope of the Digi1.0 and the Digi2.0:

	DIGI 1.0	DIGI 2.0	
	PROOF OF CONCEPT	PROTOTYPE	
Data used	Dummy shipments based on realistic data samples.	Live data from 2 batches of in total 22 real shipments . Data was provided by multiple live systems from each stakeholder , integrated by using a set of adapters. ³	
Scope	Airport-to-airport	End-to-end: Shipper to Consignee	
Business logic	Limited : focused on reproducing the Cargo iQ milestones in a linear timeline and ingesting quality data	Extended : focused on building the enhanced data stream of the entire cold chain process and cargo flow processes. Tying together the MAWB to HAWB to shipment batch number and even down to the specific Purchase Order (PO) number to provide interpretation context.	
Data exploitation	Basic visualization	Additional functionality to enhance platform capabilities enabling preventive and prescriptive actions by actors of the supply chain.	

Table 1: Digi 1.0 and Digi 2.0 project scope



2.2 Project leads and participants

Project leads

Brussels Airport Company (BAC) and Changi Airport Group (CAG) are the project co-leads. BAC, CAG, together with DHL Global Forwarding, Singapore Airlines and Pfizer, played a key role in the selection of the prototype lane and identification of the key players on the lane. Nallian, which supported the Digi 1.0 project with the proof of concept and is ready to take the GPT further, was selected by Pharma. Aero as IT service provider. External consultants were hired by Pharma.Aero as project managers.

The authors of the technical report are

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Participants

The scope of the Digi 2.0 project required the sharing of live data and integration effort by the participating organizations. Participants were categorised in 2 groups, the Digi 2.0 Pilot Group members and the Digi 2.0 User Board members.

The Digi 2.0 Pilot Group comprised of members that actively participated in the project and delivered data on the specifically identified lanes. They also engaged their partners who are non-Pharma. Aero stakeholders in order to fulfil the data sharing obligations of the project.

The Digi 2.0 User Board comprised of full and strategic members of Pharma.Aero that supported the project and were invited on regular updates, calls and evaluations of the project in order to broaden the overall interest of the project

Digi 2.0 Pilot Group members		
Company	Category	
Brussels Airport Company	Project lead, Airport	
Changi Airport Group	Project lead, Airport	
Pfizer	Project lead, Shipper	
Mumbai Airport⁴	Airport	
Singapore Airlines	Airline	
DHL Global Forwarding	Forwarder	
Nallian	Digital Platform Developer	

Table 2: Pilot Group members

Digi 2.0 User Board members		
Company	Category	
Amerijet	Airline	
Brussels Airlines	Airline	
AirBridgeCargo Airlines	Airline	
EuroAirport Basel	Airport	
Hong Kong International Airport	Airport	
Kansai International Airport	Airport	
MVD Free Airport	Airport	
Sharjah Airport	Airport	
Johnson & Johnson	Shipper	
MSD Merck⁵	Shipper	

Table 3: User Board members



2.3 Lane identification and commitment of participants

Pre-requisites for the pilot project

In the scope of the project, sharing and integration of live data sources into the GPT platform was foreseen. This required the participating organizations to:

- be ready and be prepared to share data based on the data sharing and governance framework; and
- make resources available for data sharing and integration.

Lane identification

The first step in the project was to identify the prototype air trade lanes for Digi 2.0. The prototype air trade lane would need to feature members of Pharma.Aero at each node of the supply chain. After alignment between all potential participants in the project, the **BRU – SIN – SYD** air trade lane was identified as the prototype lane.

The Pharma. Aero members active on the lane formed the Project Pilot Group members. All Pilot Group members actively contributed to the project by providing access to data. They involved their IT departments for integration with existing transport management systems or other data sources. Their operational staff also supported through the identification of relevant pilot shipments.

Data sharing and data ownership

Data ownership, protection and security are key concerns for all organizations involved in the supply chain: data is an important (and often commercially sensitive) asset for each company, so it is important to be able to control and share relevant data with only those specific organizations who are involved in a particular shipment.

In preparation of data sharing on live shipments during the project, the expected contribution by each stakeholder and the data sharing rules for each data element were communicated to each participant. This allowed every Pilot Group Member to validate these data sharing rules internally and to obtain approval for the disclosure of the prototype data.

The abovementioned expectations and data requirements were summarized in an NDA between each of the Pilot Group members and Nallian, the data sharing platform provider. The NDA assures each party take steps to prevent unauthorised disclosure of the data collected and outlines the consequences of a data breach. In addition, a data-sharing matrix which outlined the condition for each data element i.e. who to provide the data (the data owner) and who having access to this data, was established.

Lessons Learnt

A clear onboarding process covering the legal, business and functional aspects of the data exchange would reduce the time required to get alignment with data providers on the practical aspects of sharing data. We believe that the approach used during this project can be further enhanced with a practical playbook, outlining all relevant steps and the responsibilities of all parties.



2.4 Project structure

Digi 2.0 was divided into 4 work packages, each focused on a specific working area. The work packages were executed more or less in parallel.

- Work Package 1 Technical implementation: Configuration of Nallian's data sharing platform to integrate various types of data sources, defining the output required of the GPT platform and configuring processing logic of the GPT.
- Work Package 2 Pilot onboarding: This phase was split into 2 parts: first the business onboarding part, which focused on securing the buy-in from individual pilot group members to provide the necessary data, and second the technical onboarding portion, which involved in establishing the ability to automatically retrieve real-time data from the participants' IT systems and integrate it into the GPT prototype.
- Work Package 3 Business Value drivers: Mapping the business value of the GPT for various stakeholders – pharma shippers, freight forwarders, airlines, ground handlers, airports, etc.
- Work Package 4 System Validation: Complying with the data collection and governance requirements as stipulated by the Good Distribution Practice and Computerized System Validation guidelines.

Phase / Other	Lead	Support
Work Package 1 Technical Implementation	Nallian	Pharma.Aero project group
Work Package 2a Pilot Onboarding – Business	Pharma.Aero	Pharma.Aero project group
Work Package Pilot 2b Onboarding – Technical	Nallian	Pharma.Aero project group
Work Package 3 Business Value	Nallian	Pharma.Aero User Board
Work Package 4 System Validation	Nallian	Pharma.Aero User Board

Table 4: Project structure and related responsibilities



3. Project Outcomes

The individual project work packages each focused on distinct aspects of Digi 2.0, and were not performed sequentially. The project was mainly steered by the business value drivers and finding a solution to specific business needs for improved visibility and transparency on pharma shipments.

3.1 Business value drivers

Information collection

This phase focused on understanding how various stakeholders perceived the business values of the enhanced data stream provided by GPT. A set of questionnaires was established and sent to each participant (shippers, forwarders, airlines, ground handlers, airports, etc). In addition to the questionnaires, additional inputs were also sought from the User Board members during the presentation of the GPT platform and from interviews with the Pilot Group members.

Key Outcome - Shippers

As the primary stakeholder, the **pharma shipper's inputs towards** the project's business value drivers were key.

Getting the high-quality pharma products to the patient on time can help preserve lives. So, the shippers' principal value driver is the **ability to prevent excursions or respond in a timely manner**. Increased **reliability and performance** of temperature-controlled pharma logistics will lead to fewer damaged or lost shipments and will increase availability of pharma products in the market at the right time in the right place.

The **lack of visibility** and **risk of excursions** erode the confidence of pharma shippers, so it is logical that any solution in these two areas is perceived as very valuable.

Reduction of financial impact is seen as a secondary business value driver for the pharma shippers. The financial impact includes the value of lost shipments, resources spent in root cause analysis, replacement cost and abortive logistics cost. Overall, the feedback from shippers confirmed three main value buckets:

- Simplifying excursion analysis and reducing the cost associated with it;
- Increasing the ability to intervene by providing (near-) real-time information on shipments; and
- Providing the ability to use historical performance as a predictive tool in avoiding excursions.

Key outcome - Airports

Airports are interested to attract niche cargo segments to diversify and grow their cargo base and to sustain flights in the airport. Pharma cargo is a specific cargo segment of interest to airports as it is a high-yielding cargo. Handling of pharma cargo is generally considered to be more complex; the ability to efficiently handle pharma shipments has become an implicit quality label for airports.

In addition, for an airport, not only the surrounding airports can be seen as competitors, but also other alternative transport modes such as sea freight and road freight. Hence, it is in the interest of airports to improve the cargo handling capability within their airport community in order to maintain their competitiveness compared to the other modes of transport.

To attract pharma shipments, airports need to motivate all participants in the air supply chain to deliver an outstanding service, and this not only within their own airport community but also in collaboration with other airports along the trade lane. More and more initiatives are set up between airports to develop air pharma corridors on high-volume lanes. Increased transparency on the supply chain along these air pharma corridors will support airports in steering investments and taking the correct measures to improve quality. It will support them to make the implicit quality labels measurable.

Key outcome – forwarders, airlines and ground handlers

Forwarders are the party tasked by the shipper with handling of pharma shipments. As such, lack of visibility and the dependency on the logistics partners in the airport-to-airport segments result in forwarders sharing similar business value drivers with shippers.

Both **forwarders** and **airlines** interested in pharma shipments want to be the best in class and want to comply with the requirements of the pharma shippers to be the provider of choice for their pharma shipments. 09

Their business drivers are focused around meeting or exceeding the requirements or expectations of a pharma shipper. Being able to efficiently handle temperaturecontrolled shipments is also seen as a business differentiator.

Similarly, **ground handlers** are key stakeholders in providing visibility to shipment transport and storage conditions under their care. The ground handlers share the objective of forwarders and airlines and see the ability to correctly handle temperature-controlled shipments as a business differentiator to meet the expectations and requirements of their customer.

Conclusions

We found strong alignment among all supply chain partners on the relevant business value drivers. Individual participants of the supply chain realise that the entire supply chain is only as strong as the weakest element, and that visibility is key: shippers are interested in what will happen with their shipment along the entire logistics journey, forwarders are interested in what will happen with their shipment as soon as it arrives at the GHA and airline, and other participants also see benefits from enhanced transparency, which is not available today. The consensus was that GPT's augmented⁶ data stream can support these business value drivers, and that the benefits are likely to be achieved progressively:

- The prototype demonstrated that better visibility can be achieved, resulting in a short-term return.
- Although participants are actively running proof-ofconcepts and pilots, real-time data is not yet generally available, and leveraging real-time insights will require stronger process and SOP alignment between logistics partners;
- The availability of large historical datasets will gradually permit a predictive model for pharma logistics, allowing for optimal packaging and lane selection for a given shipment.

Figure 1: Progressive Business Benefits shows how GPT can be divided into 3 releases, going from a first step where simplified excursion analysis is facilitated through increased visibility when an excursion has occurred. Based on this information, further process alignment and SOP alignment can be steered between individual participants in the process. This will lead to the availability of real-time information, linking the required actions in a second release. As soon as large sets of historical data will be available, historical performance analysis can support predictive capabilities.

ſ	Simplified Excursion Analysis Complete and reliable	 Less effort required to collect information on excursions Faster product release by qualified person Commercial value in faster delivery to customer / market 	E
	information is available when it is needed	Additional visibility allows stakeholders to synchronize operational processes	
Global Pharma Tracker's Augmented Data Stream	Real-time Information	Ability to <i>prevent</i> issues from happening by preventive action Avoid logistics cost for compromised	Æ
	Key events and non- conformances are signaled automatically	shipments	
		Ability to leverage machine learning to predict risk	
L,	Historical Performance Analysis	 Avoid under/overpackaging and associated cost Lane validation can be done based on data from all lane traffic, across multiple 3 	ε
	Database of parameterized historical performance	 forwarders and shippers Simplified performance evaluation of the logistics chain 	

3.2 Pilot onboarding

Business onboarding

The business onboarding process is described in section 3.3. A data sharing matrix (this matrix can be obtained upon request at administration@pharma.aero) was established to detail the data ownership and data governance structure, outlining who provides the data (the data owner) and who would have access to this data under specified conditions. The disclosure of specific data for live shipments is a sensitive matter as companies need the assurance that data is made available only to the intended parties. A clear and comprehensive definition of which data is collected, who the data provider is and who (in terms or roles related to a shipment) will have access to this data was instrumental in obtaining approval. The preliminary data sharing matrix established during Digi 2.0 can be used as a basis for this, and can be extended to cover additional data elements.

In addition, a clear legal basis for the confidentiality and protection of shared data must be in place to support the rights of each participant under the proposed governance and sharing model. This must be covered in the agreements between each participant and the platform service provider.

The entire discussion is a complex process which also needs to be approved by senior management in all participating organizations. Hence, the business onboarding process took more time than expected.

Technical Onboarding

Subsequent to the lane identification, a technical protocol was established. This protocol included mapping of the process flows, identification of all the supply chain actors involved, registration of flight schedules, and setting out data to be captured by the different actors. *Figure 2* identified the required data elements.

The next step was to involve the relevant operational personnel within the Pilot Group members and to develop a concrete plan on data exchange. Each stakeholder dedicated internal resources to enable the process.

The preferred approach was an automated exchange of data through an available interface:

- For some cases, data exchange was straight-forward as companies used standardized data exchange formats such as Cargo-IMP messages and Cargo-XML;
- During the prototype, a dedicated API integration was developed with the forwarder's IT systems to allow easy integration of the data on the door-todoor segment as well as external data sensors placed by the forwarder;
- In some cases, data was available but could only be provided by manual internal retrieval. The retrieved information was then provided through email or shared file location.

Other data is known to exist but could not be made available to the project due to technical, organizational or operational issues.

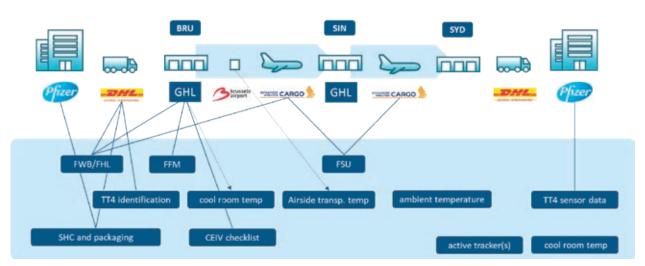


Figure 2: Identified data elements linked to potential data source



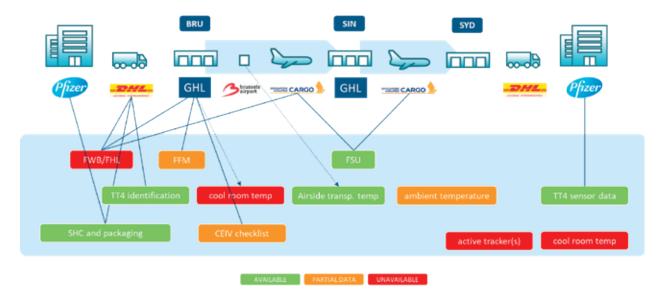


Figure 3: Data elements integrated for the pilot

The first batch of trial shipments proceeded with the data sources that were available at that time, in order to kick-off the prototyping phase. The findings quickly revealed additional information that could be useful, and operational gaps were uncovered and resolved. A second batch of shipments was conducted soon upon pivoting from the first shipment trial.

Figure 3 illustrates the availability of data sources for the GPT prototype.

Green indicates data was available in an automated and integrated fashion.

 An integration with the cool dollies of BAC is available and temperature logging is already integrated in the Nallian data sharing platform.
 However, the airline involved in the specific lane did not use the cool dollies⁷ for the prototype shipments and therefore, the data could not be included for the 2 batches of shipments.

Orange indicates data was partially available or required manual intervention:

 The sensor placement sheet is currently a paper document, made available in scanned (PDF) format.
 A future digitized record of sensor placement would be possible;

- Sensor data was provided as a series of data files after retrieval of the loggers upon arrival, and needed to be uploaded and processed by the prototype team;
- While CEIV acceptance checklists were electronically available for only one of the shipment batches due to the switch in service provider during the prototype phase, electronic CEIV acceptance checklists were already being successfully processed on the BRUcloud platform.

Red items were unavailable during the prototype:

- Integration of the cool room temperature at the GHA facility was a technical timing issue as the GHA, not being member of Pharma. Aero, needed to be involved through the airline and the internal approval process was initiated much later.

Lessons Learnt

A clear and advance onboarding process covering the legal, business and functional aspects of the data exchange would reduce the time required to get alignment with data providers on the practical aspects of data sharing. We believe that the approach used during this project can be further enhanced with a practical playbook, outlining all relevant steps and the responsibilities of all parties.



3.3 Technical implementation

GPT platform

The Nallian data sharing engine and the Nallian CargoFlow model form the basis for GPT.

By integrating all relevant data sources into a single data model, GPT offers an **enhanced data stream** which can be leveraged in different ways:

- By integrating the data stream in participant's own operational monitoring / control tower solutions
- By sharing this data with partners who can benefit from the increased visibility to provide a better quality of service
- By offering real-time insight into shipment properties, status and conditions using GPT Explorer.

The combination of shipment properties, logistics milestones and sensor data provided a rich context which facilitates decision making by both the shipper and its logistics partners.

Integrating all relevant data

GPT covers all data which is considered relevant for optimal handling of the shipment, in order to provide a comprehensive single-version-of-the-truth for all parties.

GPT integrates all kinds of shipment data:

- Definition of shipments at the lowest level of detail and their aggregation into logistics units of transport (such as house/air waybill, consignment, container etc.), including packaging and temperature / protection ranges
- Logistics events and activities across the end-to-end supply chain, identifying at each moment who is currently in control of the shipment
- Temperature (product, transport/storage and ambient)
- Other relevant sensor data (e.g. humidity, location)
- Quality data such as CEIV checklists, pictures, damage reports etc.
- Other documents related to the shipment (e.g. invoice, packing list, certificate of analysis etc.)

While the data samples and visualization in Digi 1.0 represented common logistics messages on shipment level (airway bill) and some contextual data sources, the Digi 2.0 project collected and represented data on the next level of the sub-shipment (house waybill, purchase order) and included detailed contextual data sources on each of these detail levels. Consolidation of all these available data sources provides the possibility to create context around the data collected for the shipment.

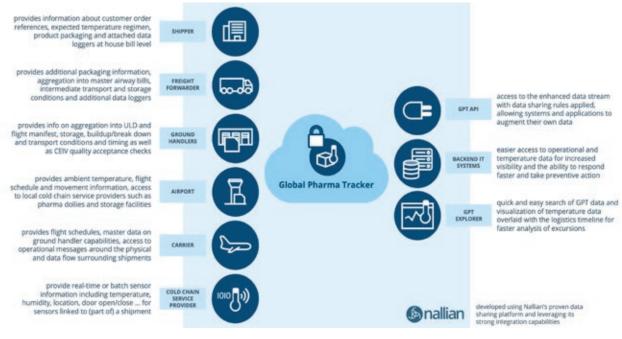


Figure 4: Overview of GPT data sources and data consumption

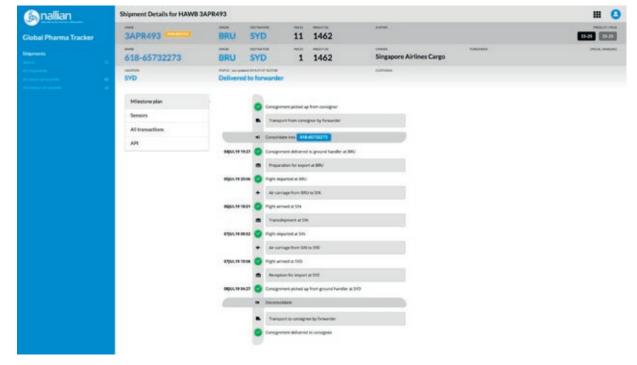




Figure 5: Visualisation of shipment and sub-shipment data

Building a dynamic milestone plan

GPT uses Nallian's **CargoFlow Engine**⁸ to model the journey of a shipment as a sequence of logistics activities connected by milestones. Each activity clearly identifies the responsible partner, who will provide details of the activity itself and signals its starting or ending milestone. Each shipment's **milestone plan** is selected from the CargoFlow Engine based on its properties, including the selected SOP and service levels and the route selected, to form a digital representation of its logistics journey. Milestone plans can be dynamically adapted to reflect delays, route changes, offloads and other events, which will trigger additional business logic, facilitating decision-making on the best course of action. For instance, a delayed flight departure can propagate the delay through the milestone plan and can highlight the fact a connecting flight will be missed, and additional cold chain services are needed at the destination airport. In such an event, the GPT platform can identify the responsible participant and will issue a **notification**. This allows participants to prioritise incidents based on their actual impact and triggers **operational response**







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scripts that decide on a corrective or preventive course of action. Any change in the milestone plan which would result from such a decision would also be reflected in the platform, providing visibility to all partners.

The notifications to be issued and their related responses can be integrated in the SOP between all parties involved.

Open GPT platform

GPT is based on an **open platform** which facilitates integration and remains **agnostic and neutral** towards all logistics partners: every trucking company, carrier, forwarder, terminal operator etc. can connect to the platform. For each partner, a single integration point is sufficient, therefore reducing the integration cost.

GPT provides standardized integration APIs for all types of logistics partners and is capable of ingesting data in various formats (B2B messaging, bulk uploads, direct API integrations etc.). If a customised integration is desired or necessary, this can be provided by Nallian itself, the data provider or a third party. Nallian does not restrict data feeds to any particular vendor of sensors or backend systems.

Similarly, GPT's enhanced data stream can be consumed from a standard API. Pre-defined data sharing rules provide the necessary governance allowing logistics partners to access the data they are entitled to see. This allows all concerned partners to have access to the single version of truth, which they can also integrate into their own backend solutions. The GPT platform will also provide a standard user interface for users that do not wish to use such backend integration.

3.4 System Validation

Certification requirements

During the project, the need for GdP certification was examined. GdP stands for Good distribution Practices and is part of Good Practice (GxP), which is a certification for controlling quality in all aspects of the pharmaceutical production and distribution chain.

A consensus was reached that GdP certification of a GPT system is limited to the part called of 'Computerized System Validation' of GdP⁹. The Computerized System Validation validates automated systems and provides producers of pharmaceutical products the security that their computer-operated processes and systems function in a consistent manner and in accordance with the valid regulations. This includes computerized systems involved in the production process of pharmaceuticals as well as computerized systems used in the quality management process.

The GPT is a computerized system that is involved in the quality assurance of the supply chain of pharmaceutical products. When implementing the GPT system for operational use, it will be required to conduct a Computerized System Validation together with the organization that implemented the system. During this validation, the way in which GPT is implemented in the operational processes, as well as the way the GPT is interacting with other systems, needs to be documented.

During this validation process, a detailed description of the system and the way the system is implemented in an organization must be available. The detailed description needs to contain:

- System scope and main features
- Principles and objectives
- Security measures
- How the computerized system is used
- The way the system interacts with other systems

Based on the above, the computerized system can be classified according to its level of concern. Table 5 indicates the documentation requirements for the software according to the identified level of concern.

No	Title	Software classification			
	R= Required D= Desirable	Hi	gh	Medium	Low
1.	Operation & Maintenance Manual	R	R		R
2.	Software Requirements Specification	R	R		R
3.	Architectural Design	R	R		D
4.	Detailed Design	R	D		
5.	Source Code Review and Report	D			
6.	Unit Test Report	R			
7.	Integration Test Specification	R	R		
8.	Integration Test Results	R	R		
9.	Software Test Specification	R	R		R
10.	Software Test Results	R	R		R

Table 5: Software Documentation requirements according to level of concern

Nallian's best practices applicable in software development and SaaS operations that are followed in their existing data sharing platform assured that the GPT is prepared to facilitate the company-specific system compliance guidelines and validation.



4. Conclusion and next steps

4.1 Lessons learnt

Technology is not the bottleneck

A fundamental lesson is that the technology to implement GPT is available and capable of supporting all requirements. During the Digi 2.0 project, we were able to quickly integrate data from carriers, forwarders, shippers and sensor data providers once an agreement was reached to perform the technical onboarding.

Business onboarding takes time

While there is general consensus among logistics partners about the need for increased logistics visibility, the process of obtaining alignment within a participant's organization takes considerable effort. Many innovative and improvement projects compete for time and resources, often involving people with extensive operational roles.

Making the case for a collaborative, data-sharing approach requires a strong internal sponsor who can promote the solution and will inform and convince several organisational stakeholders, and we need to provide support for their effort. This will include assistance to build a strong business case, explain the data governance framework and facilitate the technical onboarding and integration process. In addition, the advocacy from Pharma. Aero to provide industry-wide visibility of GPT will ensure management-level support for this initiative.

A solid data sharing and governance framework

The advance availability of a clear contractual structure which includes the data sharing and governance framework will facilitate faster completion of the necessary legal process every pharmaceutical company and logistics partner will require in order to participate to GPT. Providing clarity on this aspect in the early stages of discussions with potential participants will likely result in faster onboarding.

The (perceived) conflict between transparency and liability

Many parties still express concern over the potential increase in exposure to claims, where more transparency could lead to additional claims.

It is likely that significant steps towards full transparency will need to be matched by a review of contractual liability standards. This requires an industry-wide open debate, which should better articulate the business benefits of logistics visibility as well as investigate solutions to handle excursions, claims and Corrective Actions/Preventive Actions (CAPA) in the future. In addition, a change in the mindset of all logistics service providers is needed to support a stronger and more open collaboration.

Data is key

Once business onboarding is covered, technical integration of data sources is the next challenge. This is more a practical aspect, but nonetheless important, as a logistics partner's required IT resources are often scarce. GPT will define onboarding playbooks, which will be made available early in the process, to outline the steps and techniques that are available to quickly integrate data sources. In addition, GPT will investigate low-cost solutions for secure provisioning of the required input data.

Moving beyond the airport-to-airport segment, shippers and forwarders who require visibility at the purchase order or house waybill level will also need to provide shipment aggregation details. This needs to be combined with packaging details, temperature control requirements and sensor placement details. GPT can facilitate this by providing an integration playbook for shippers and forwarders, and allowing master data to be set up for the packaging standards, SOPs, lane definitions and so on.



Building the GPT Network

A final lesson is that building a global visibility network will require a gradual approach. The initial backbone of the GPT network will be defined by shippers who will identify their most important lanes, and the forwarders, carriers, ground handlers and airports that participate in implementing visibility along those lanes. Every onboarded partner will have the opportunity to leverage GPT to offer an increased quality of service for all of their customers.

The GPT Early Adopter Program will provide these pioneers with a framework to quickly generate the business value they seek.

4.2 Recommendations

Operational use of the platform will make relevant shipment data like e.g. milestones and activity duration, temperature events etc. available to shippers in a data warehouse format, enabling analysis with business intelligence tools and machine learning. These can lead to a more fine-grained predictive and prescriptive decision-making on a particular trade lane. GPT could collect anonymised and aggregate information from all partners to increase the overall volume of data available for predictive modeling.

Through the successful prototype and lessons learned from Digi 1.0 and Digi 2.0, we have demonstrated that our original project objectives were met. Based on the project results, an Early Adopter Program (EAP) for operational use is defined as a next step. It is recommended that Pharma. Aero and Nallian continue their partnership, and define a collaborative framework on the deployment of GPT globally.



- 1 The Digi1.0 technical report and whitepaper can be requested at administration@pharma.aero
- 2 Pharma. Aero Pilot Group members and User Board members are defined in 2.2 Project leads and participants
- With adapters we mean all interface capabilities, including API and ingestion of standard Cargo iQ messages. For detailed information on the adapters see 4.3
 Mumbai Airport was among the initial Pilot Group members as the airport was involved on the pilot lane BRU BOM. Due to changes in organizations and flight schedules, the lane was no longer operated by Pharma. Aero members at a later stage of the project.
 MSD Merck was among the initial Pilot Group members. Due to organizational reasons MSD Merck was moved to the User Group members in a later stage.

- 6 By combining the data stream from various participants to the supply chain and by adding additional data beyond the pure logistics events, additional interpretation of what has happened or is happening will be possible.
- A Airport Pharma Transporter (APT) cool dollies have been designed for the most common lower deck pharma shipments. However, it happened that the 22 selected pilot shipments have been transported via main deck and therefore the data could not be included for the pilot shipments.
 Nallian's CargoFlow Engine is part of Nallian's product portfolio and contains a rich air cargo data model, that maps out air cargo processes with their individual milestones, milestone sequences and facilitates collection of data for each milestone and taking specific actions based on conditions derived from the data.
 Classification according to Eudralex the rules governing medicinal products in the European Union; Volume 4 Good Manufacturing Practice (Medicinal Products for Volume 4 Good Manufacturing Practice (Medicinal Product
- Human and Veterinary Use Annex 11; and Guideline of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)



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