Final Technical Report
On Certification of Pharmaceuticals Air Trade Lanes through Digitisation

17/06/2018

Contents

1. Introduction

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. 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. Developing a temperature controlled logistics data platform is a tool to achieve this goal. The gathering and analysis of data can yield deep insights on the transportation performance of pharmaceutical cargo and strengthen the position of Pharma.Aero and its members.

This technical report summarizes the requirements identified in the project group for start-to-end monitoring and tracking of temperature controlled pharma shipments. A vision was developed to collect and combine standardized cargo documents, shipment status data, sensor data and quality control data into a coherent and uniform data stream on shipment level using a data sharing platform.

With the help of an IT service provider, our vision was translated into a demo model, which demonstrates the existing technologies and capabilities to the Pharma.Aero members. The model was presented to key departments in major pharmaceuticals shippers such as Pfizer, MSD and Johnson & Johnson, and received acceptance from these organisations.

2. Project charter

In September 2017, Pharma.Aero launched the project charter "Certification of Pharmaceuticals Air Trade Lanes through Digitisation" with the aim of developing a data sharing platform where relevant information across shareholders in the supply chain can be shared and translated into valuable insights without jeopardizing the data integrity.

2.1 Project scope & goal

- To establish transparent and certified pharma trade lanes involving various stakeholders who embrace the IATA CEIV certification.
- Identify common KPIs amongst stakeholders during the airport to airport transportation process.
- Explore technologies to integrate and share data in the form of a dashboard.

2.2 Project leads

As the project co-leads, Changi Airport Group (CAG) and Pfizer coordinated the identification of common KPI's and requirements for the common data sharing platform. Together with Brussels Airport Company (BAC), the parties identified existing technologies and potential partners in the market. Eventually, BAC co-ordinated with the IT provider Nallian to create a demo version. The external consultant Mr. Geert Leroy from Eureachi was appointed as project manager.

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2.4 Project participants

Company	**Category**
Pfizer	Project Co-sponsor, Shipper
Changi Airport Group	Project Co-sponsor, Airport
Johnson & Johnson	Shipper
MSD	Shipper
Brussels Airport	Airport
Mumbai Airport	Airport
EuroAirport Basel	Airport
MVD Free Airport	Airport
DHL Global Forwarding	Forwarder
Brussels Airlines	Airline
Singapore Airlines	Airline
Envirotainer	Service Provider

2.5 Summary of project milestones and project meetings

- Define and confirm scope of project
- Launch project group and connect with local community workgroups
- Collect inputs on information that are currently captured under respective milestones in IATA Cargo IQ Master Operating Plan (MOP)
- Identifying technologies that can monitor and publish the data
- Finalise the list of data points being captured, as well as identify a list of other potential data sets
- Presenting demonstration of data sharing platform and publishing a technical report

3. Opportunity finding and GAP analysis

According to IATA, the annual losses of pharmaceutical products due to temperature excursions range between USD 2.5 to USD 12.5 billion.

Today, Shippers are not fully aware on how their pharmaceuticals cargo are handled in the airport environment (i.e. duration in ground handlers' warehouse, duration on tarmac, etc.). While different stakeholders hold different data, they are not necessarily being shared across the supply chain.

While the use of data loggers with GPS capabilities can give insights to shippers on how their cargo are being handled, these devices also have their own limitations. Majority of these data loggers rely on cellular signals (e.g. 3G data) or WIFI signals to transmit its location. In this regard, tracking the exact location of a product would be challenging if (a) there are no cellular towers in the vicinity or (b) the data loggers are in a compound that is surrounded with several buildings.

In addition, pharmaceutical shippers typically use passive data loggers that accompany the shipments, allowing shippers to record temperature data of their products and identify excursions. However, such data is only available upon delivery of the shipment and it is usually too late to take any corrective measures, should a temperature excursion occur. While active data loggers can record and transmit real-time information on temperature, the devices are costly and the use of such devices only makes economic sense if the pharmaceutical product is of high value. Moreover, data loggers that transmit real-time data, be it location or temperature, would require airlines' approval to be carried onboard during take-off and landing as these devices transmit signals and could interfere with aircraft communications.

Given the above, pharma shippers today are unable to monitor the location and temperature of their shipments on a real-time basis and take corrective measures when temperature excursions occur. Very often when an excursion takes place, the investigation would undergo a lengthy process across different stakeholders.

3.1 Project steps

In today's context, different data is already being collected, stored and monitored in silos by various stakeholders in the supply chain. However, such data might not necessarily be shared

across the supply chain, leading to KPIs not being cascaded across the supply chain and the lack of awareness how pharmaceutical cargo are being handled.
From the early beginning the IATA Cargo IQ's Master Operating Plan (MOP) was used to map out the respective milestones of transport.

An initial value mapping for all involved stakeholders (shippers, airlines, forwarders, handlers, airports), revealed the potential of data sharing, potentially allowing them to:

- Provide a single-version-of-truth visibility to all concerned stakeholders, while keeping data which is shared with them under control of the data owner
- Detect temperature excursions and send notifications
- Enable statistical and KPI analysis for benchmarking and process optimization purposes.

The Pharma.Aero working group identified three types of data are required to create more transparency and to improve performance of the supply chain:

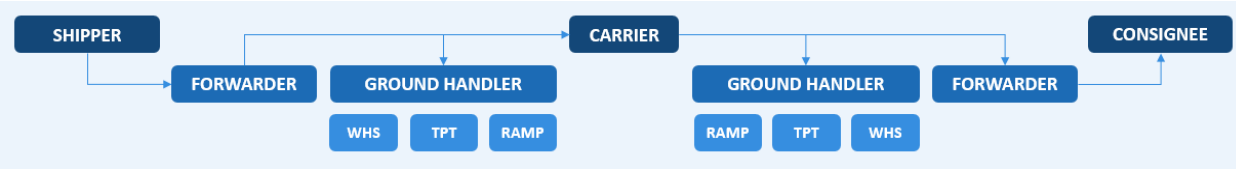
- Status and location data
- Temperature data
- Quality data

Per type of data the requirements were mapped to be included in a data sharing concept.
Pfizer and Changi Airport Group took the lead in this phase. For the mapping of the respective milestones for these three types of data, the IATA Cargo IQ's Master Operating Plan (MOP) was used.

3.2. Status and location data

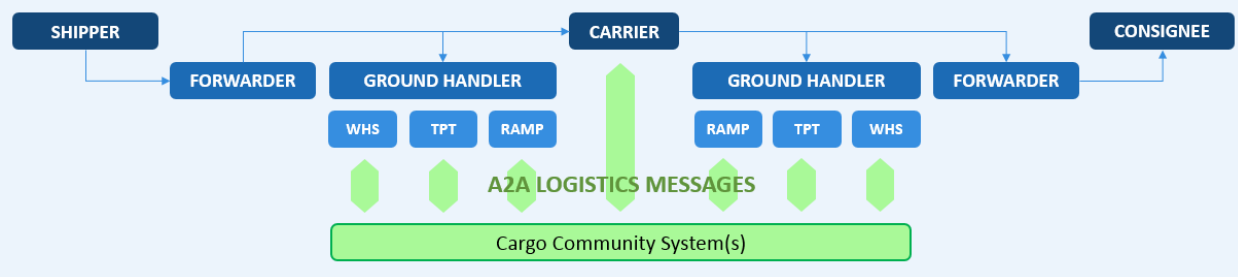
The typical air cargo supply chain for a direct flight shows that there are a lot of shareholders involved.

Fig 1: Illustration of stakeholders involved in an air cargo supply chain



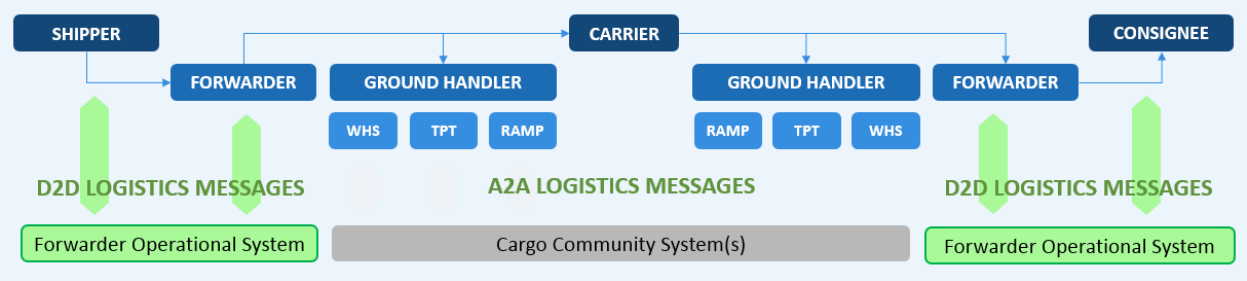
In the airport to airport process, forwarders and airlines' operational systems are already connected using standardized Cargo IMP/XML messages. However, shippers do not have ready access to this information.

Fig 2: Communication between carrier and ground handler via Cargo Community Systems



During the transit process from an origin to a destination airport, airlines provide tracking information (e.g. flight status, shipment handover milestones) to forwarders via the cargo community system. However, shippers might not have direct access to this information.

Fig 3: Communication systems that are not connected throughout supply chain



Through co-ordination with Brussels Airlines and Singapore Airlines Cargo, common key milestones represented by flight status update (FSU) messages were identified. These milestones are currently being time-stamped by the airlines and allows a viewer to interpret the location of a pharma shipment (see Table 1 below).

Table 1: FSU messages and its corresponding milestones

Type of movement	Status Codes	Milestones
Exports	RCS	Cargo ready for carriage
Transit	RCT	Cargo received from another airline
Transit	TFD	Move cargo to another airline
Exports	DEP/MVT	Departure of aircraft
Imports	ARR	Arrival of aircraft
Imports	RCF	Shipment received at warehouse from a given flight
Imports	NFD	Forwarders Notified
Imports	AWD	Handover Documents
Imports	DLV	Documents and Cargo Delivered

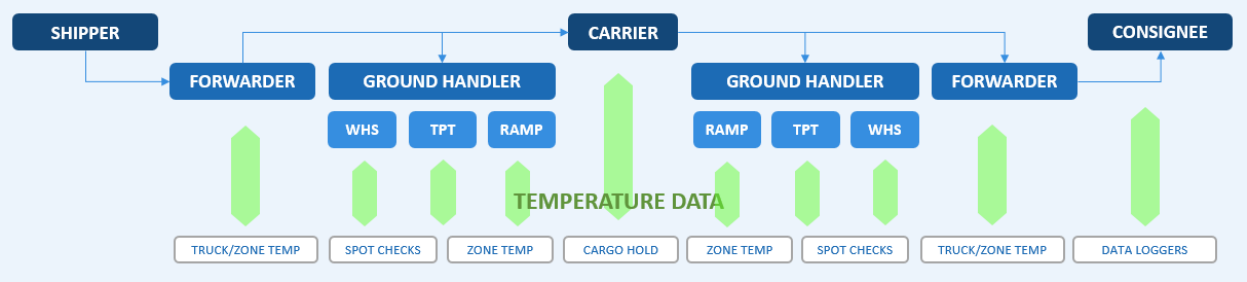
In the above regard, an opportunity presents integrate the existing data points across the players in the supply chain to provide a 'single-version-of-truth' visibility to all concerned stakeholders, greater visibility on the status and location of the cargo. These data could then be overlaid onto temperature data from data loggers to gain useful insights on temperature excursions and when combined with live temperature monitoring, the system will be able to send immediate notifications to the appropriate stakeholders.

3.3. Temperature data

With regards to temperature data for door-to door logistics and road feeder services, it is well covered. Shippers use data loggers that travel with the shipments, offering transparency in product temperature. However, this info is only available after arrival, which is (usually) too late in case of a temperature excursion.

CEIV certified operators each have temperature monitoring of transport or storage activities. However, this data is only shared in case of a CAPA investigation.

Fig 4: Temperature data that can be recorded at specific points in supply chain



Requirements for the data platform specific to temperature related data:

1. Temperature data can be registered at relevant points during the cargo movement
2. Possibly conflicting information coming from multiple sensors for the same data point can be recorded, managed and resolved
3. Temperature shipment data which is provided after the product has been delivered at a destination, can be overlaid with (near) real-time data such as weather temperature
4. Reliability of provided temperature data can be ensured.

3.4. Quality data

Typical examples of quality data are CEIV Pharma Acceptance Checklists and other QA checks (example: ACT containers). Shippers only get access after an excursion/QA issue and during a CAPA investigation.

Fig 5: Information of shipment quality that can be shared at specific points in supply chain

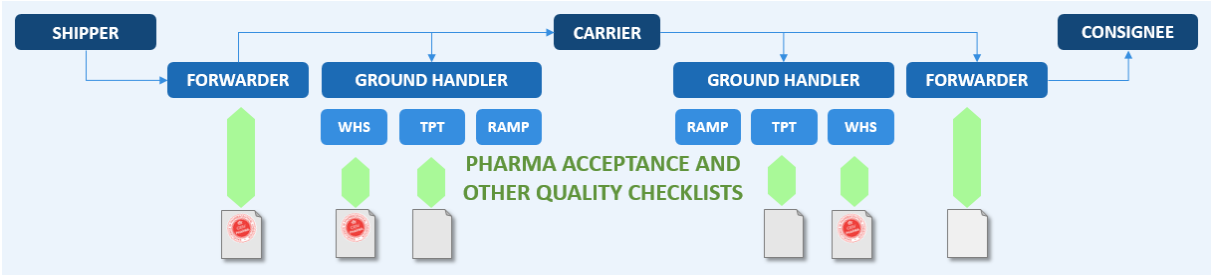
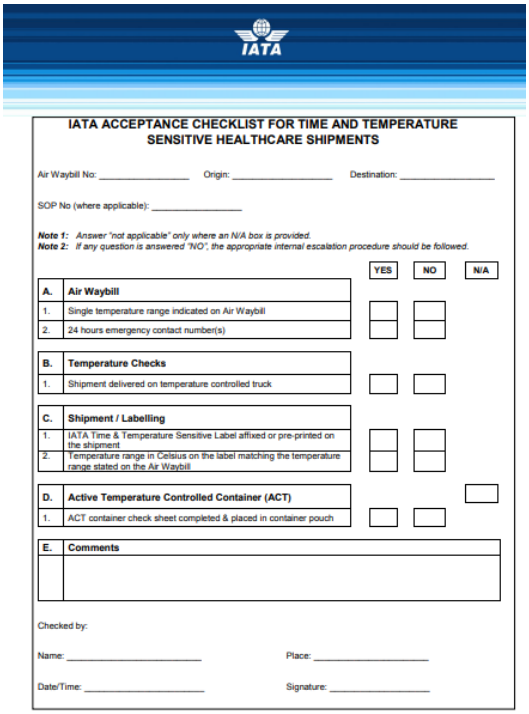


Fig 6: Sample of Quality Information (IATA Acceptance Checklist)



IATA

IATA ACCEPTANCE CHECKLIST FOR TIME AND TEMPERATURE SENSITIVE HEALTHCARE SHIPMENTS

Air Waybill No: _____ Origin: _____ Destination: _____

SOP No (where applicable): _____

Note 1: *Answer "not applicable" only where an N/A box is provided.*
Note 2: *If any question is answered "NO", the appropriate internal escalation procedure should be followed.*

		YES	NO	N/A
A.	**Air Waybill**			
1.	Single temperature range indicated on Air Waybill	☐	☐	
2.	24 hours emergency contact number(s)	☐	☐	
B.	**Temperature Checks**			
1.	Shipment delivered on temperature controlled truck	☐	☐	
C.	**Shipment / Labelling**			
1.	IATA Time & Temperature Sensitive Label affixed or pre-printed on the shipment	☐	☐	
2.	Temperature range in Celsius on the label matching the temperature range stated on the Air Waybill	☐	☐	
D.	**Active Temperature Controlled Container (ACT)**			☐
1.	ACT container check sheet completed & placed in container pouch	☐	☐	
E.	**Comments**			

Checked by:

Name: _____ Place: _____

Date/Time: _____ Signature: _____

Requirements for the data platform:

1. Information from quality control actions can be ingested at relevant points during cargo movement (e.g. IATA Acceptance Checklist)
2. Reliability of provided quality data can be ensured.

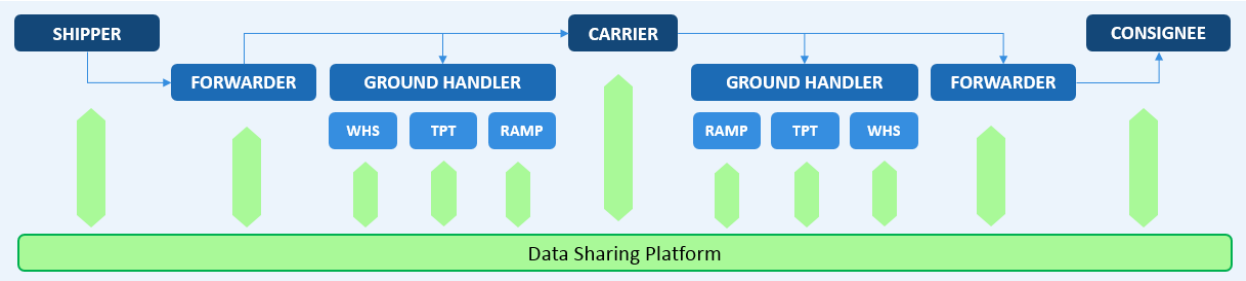
3.5 Evaluation of data analysis

The Pharma.Aero project group concluded that there is already a lot of data available but in a scattered and stand-alone way. There is a greater collaboration need for data sharing, which will lead to better transparency and a better control of the supply chain.

High level requirements for this data sharing concept:

1. Offer flexible integration with current and future operational systems.
2. Bring together all relevant information from all relevant systems, sources and formats.
3. Giving each data owner control over who sees their data and in which situation.
4. Provide an augmented tracking data stream for application developers.

Fig 7: Coverage of the data platform



4. Project outcome

4.1 Creation of demo version

The user requirements were translated in high level functional requirements for a data sharing platform by Brussels Airport, based on its experience in setting up its own local data sharing cloud and ecosystem of applications using these data.

The intention was to create a demo version (not be a complete functional solution). In this way, we could demonstrate in a more visual way the key functionalities and capabilities of a data sharing platform using actual data provided by a group of participating pilot companies.

The demo was intended to:

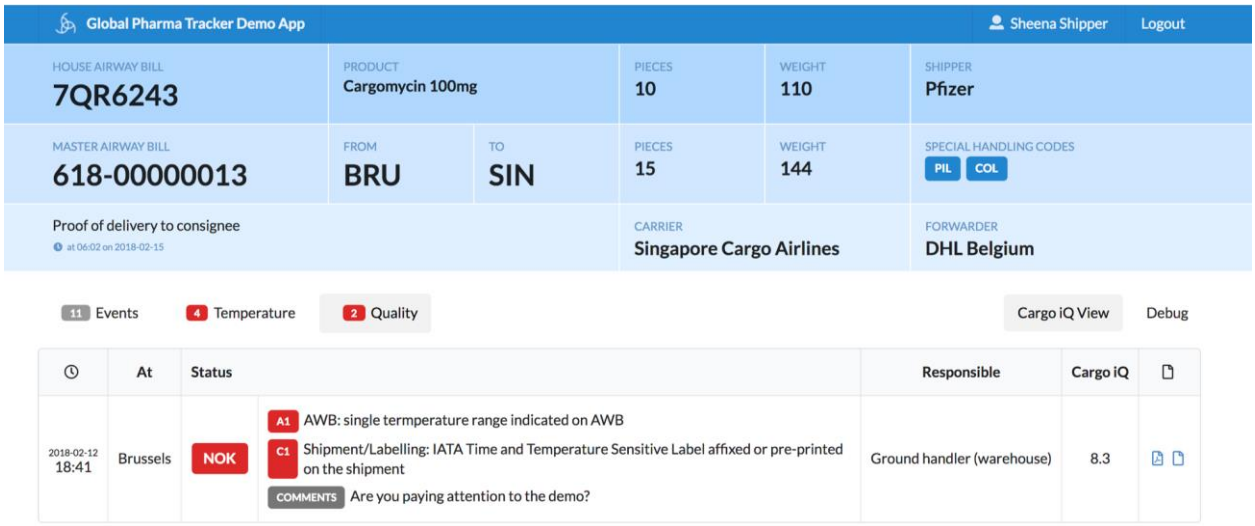
- Outline a proposed high-level solution architecture
- Demonstrate capability to satisfy the project requirements
- Develop and demonstrate limited, prototype versions of key functionalities

After a selection phase of IT solution providers, the Pharma.Aero project group initiated a collaboration with Nallian to create a technical demo.

Nallian, Brussels Airport, Changi Airport and Eureachi coordinated the development of the demo, allowing Pharma.Aero to show how relevant information can be collected and shared with various logistics stakeholders, using existing data sharing technology.

This demo proved to be an effective tool to show the project members what type of functionalities can be implemented with existing technology. The following sub paragraphs in detail the functional requirements formulated by the Pharma.Aero project group.

Fig 8: Sample of demo interface



4.2 Guiding principles

In summary, the following guiding principles were formulated:

Provide a **data platform** which is open both towards the **data providers** (offering a wide range of data entry points) as well as to **data consumers** (enabling a rich ecosystem of application providers who can tap into the data and offer value-added services and applications).

A large amount of existing data related to cargo movements may already be available in other systems and/or platforms, so the solution needs to ensure the **interoperability** with them. Similarly, we do not want the solution to restrict data providers for new data points in terms of technical connection, and we require the platform to offer a wide range of integration options.

4.3. An integrated pharma audit trail

An integrated audit trail must be provided compared to the required handling conditions. This will **reduce the effort** currently spent by shippers and forwarders identifying who was responsible for which part of a route and **chasing data** to verify performance, even if this data is not available in real-time.

The data platform should allow:

1. All relevant information for a temperature-controlled cargo movement to be represented in a single, coherent and end-to-end manner.
2. To collect, store and share this information with all relevant parties in a secure way, both at a per-movement level and at an aggregated/analytics level
3. Parties to benefit from such an information exchange to improve process performance and quality
4. Provide an integrated view of a cargo movement with the following parameters to be considered:
    a. Use a standardized representation of a route (related to the milestones in the Cargo iQ Master Operating Plan)
    b. Report on transport parameters (temperature and quality)
    c. Provide information at a detailed level (house waybill, lot number, etc.)

Fig 8: Data platform demo representing milestones in Cargo iQ Master Operating Plan

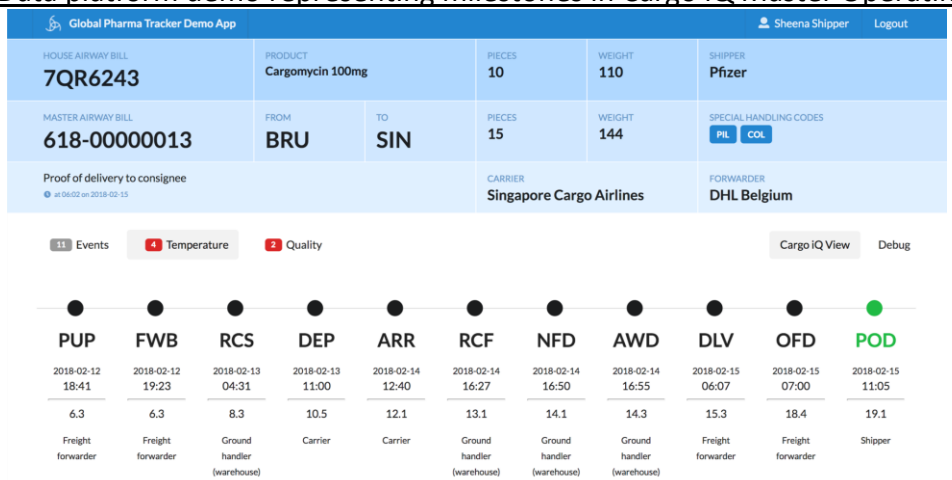
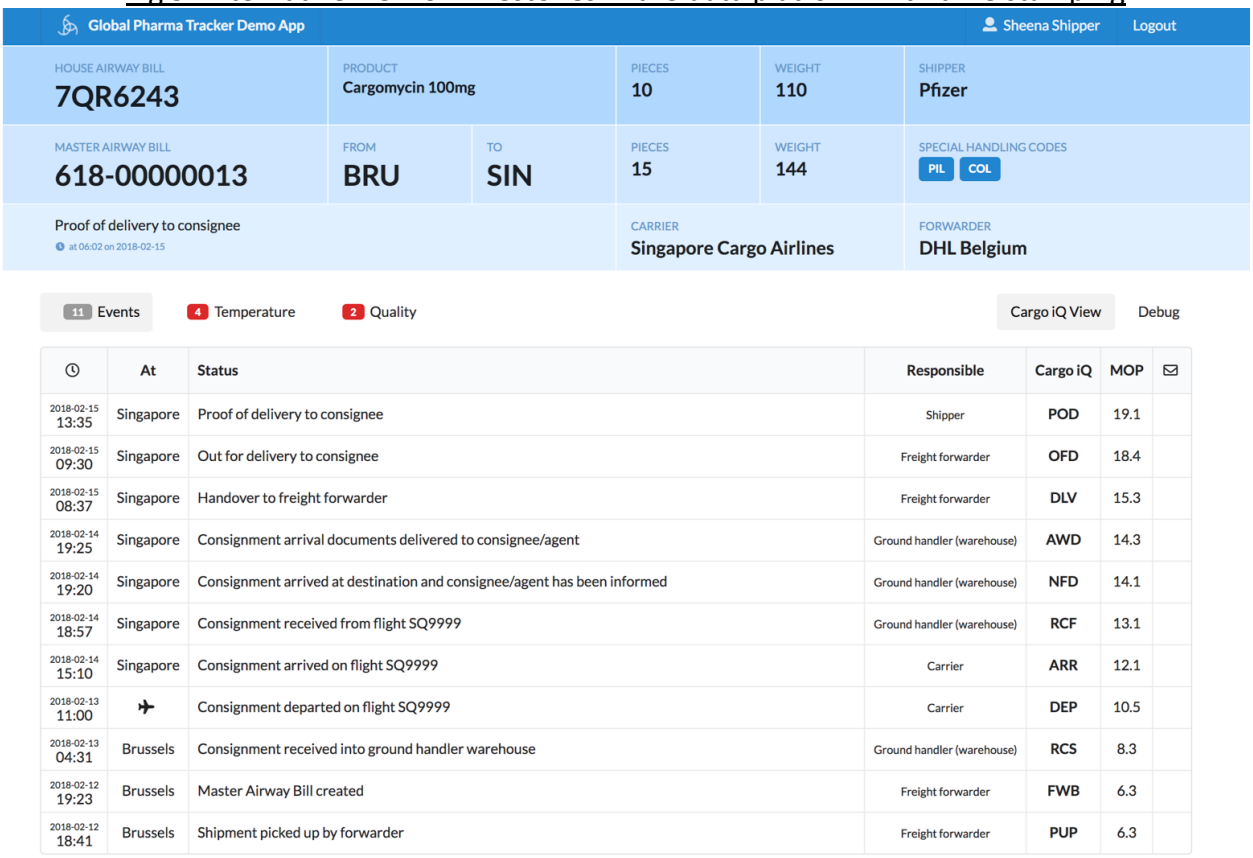


Fig 9: Alternative view of milestones in the data platform with time stamping



	At	Status	Responsible	Cargo iQ	MOP	
2018-02-15 13:35	Singapore	Proof of delivery to consignee	Shipper	POD	19.1	
2018-02-15 09:30	Singapore	Out for delivery to consignee	Freight forwarder	OFD	18.4	
2018-02-15 08:37	Singapore	Handover to freight forwarder	Freight forwarder	DLV	15.3	
2018-02-14 19:25	Singapore	Consignment arrival documents delivered to consignee/agent	Ground handler (warehouse)	AWD	14.3	
2018-02-14 19:20	Singapore	Consignment arrived at destination and consignee/agent has been informed	Ground handler (warehouse)	NFD	14.1	
2018-02-14 18:57	Singapore	Consignment received from flight SQ9999	Ground handler (warehouse)	RCF	13.1	
2018-02-14 15:10	Singapore	Consignment arrived on flight SQ9999	Carrier	ARR	12.1	
2018-02-13 11:00	✈	Consignment departed on flight SQ9999	Carrier	DEP	10.5	
2018-02-13 04:31	Brussels	Consignment received into ground handler warehouse	Ground handler (warehouse)	RCS	8.3	
2018-02-12 19:23	Brussels	Master Airway Bill created	Freight forwarder	FWB	6.3	
2018-02-12 18:41	Brussels	Shipment picked up by forwarder	Freight forwarder	PUP	6.3	

4.4 Detection of non-conformances

The tool must allow for automatic detection of deviations from the planned route – both in time, location and quality (CEIV and temperature). This can be achieved by comparing the cargo documents/messaging describing the intended route with the actual handover checks and temperature measurements.

The data platform should demonstrate how

1. Non-conformances can be detected automatically and service quality metrics can be derived from the data stream
2. notifications of Non-conformances can be provided to Parties
3. such notifications could be provided to Parties in real-time (provided such information is provided in a timely manner)

Examples of non-conformance checks:

- Compare actual data to expected/required parameters (temperature ranges and CEIV verifications)
- Detect anomalies such as temperature excursions, quality issued or delays
- Identify interested parties based on cargo documents
- Offer the ability to alert such interested parties when a non-conformance occurs
- Offer real-time notifications, provided data is provided timely

Fig 10: Illustration of auto detection of non-conformance check on data platform

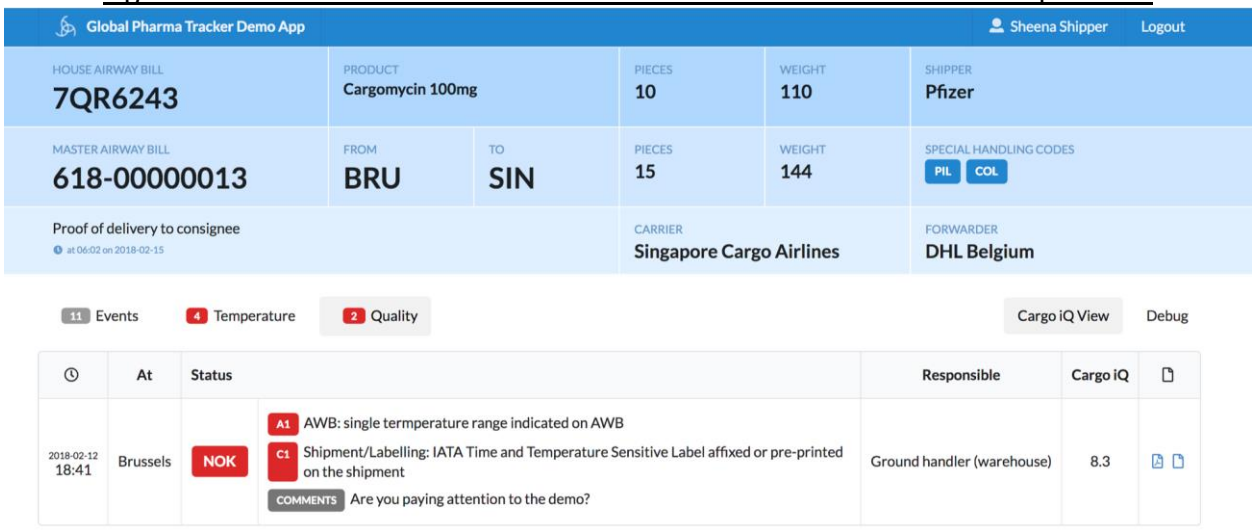
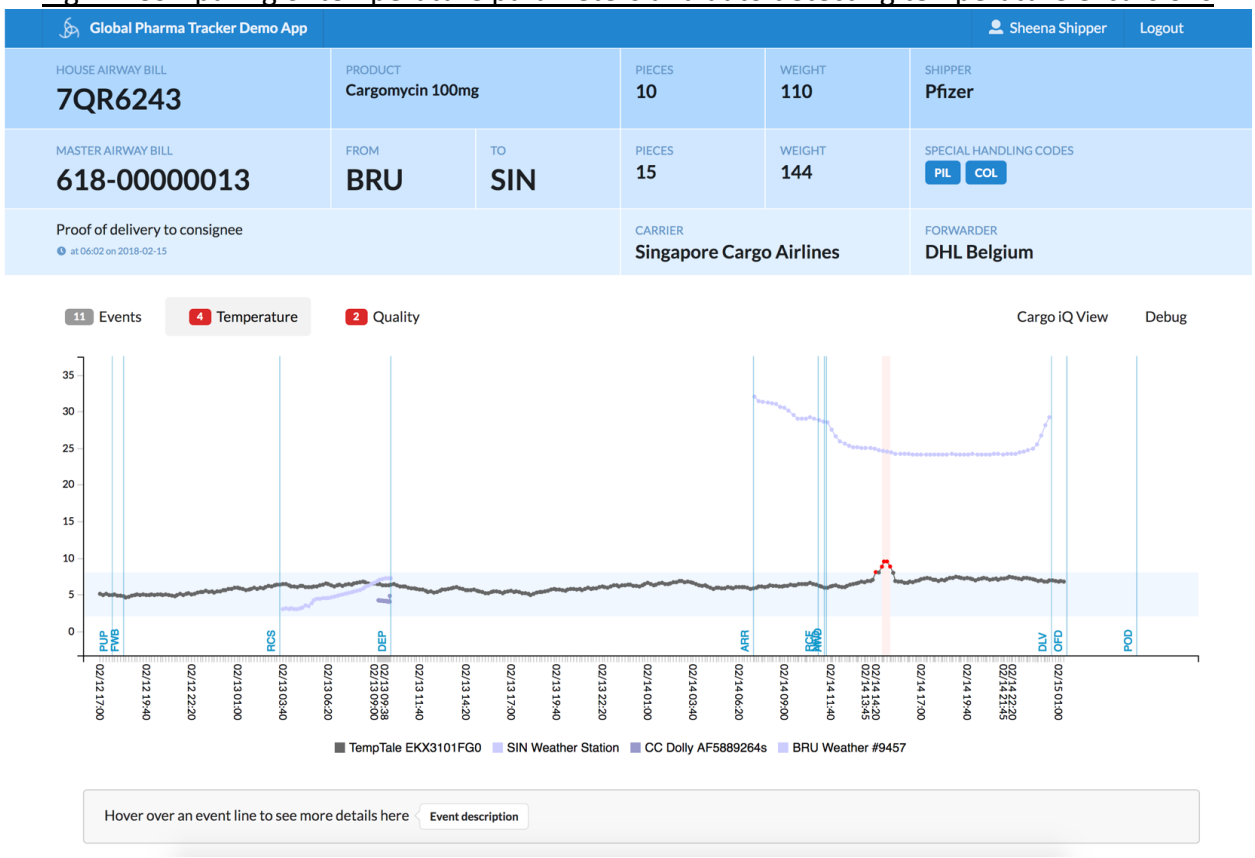


Fig 11: Comparing of temperature parameters and auto detecting temperature excursions



4.5. Process improvement: visualization and analytics

The data can be used to review performance and to facilitate pharma lane risk assessment and validation. For this purpose, the following functional requirements were identified by the Pharma.Aero project group.

The system must enable statistical analysis on cargo movements:

- provide cargo movement in a format suitable for business intelligence analysis
- provide summaries from the point of view of each process stakeholder (airline, airport, handler, consignee, auditor, etc.)

The data platform should demonstrate how:

1. Parties can visualize an individual cargo movement as a timeline of the collected data stream, including Non-conformances
2. Parties can visualize a selection of cargo movements (over a time period, involving a particular party), including service quality metrics
3. Parties can extract a dataset allowing them to perform additional analytics/BI reporting in their own environment

Note that 'visualization' can have many forms, from 'available through an API' to 'downloadable' or 'presented on a screen'. The systems should not focus on providing the ultimate user interface, but rather demonstrate an openness to many ways of consuming the data provided.

4.6. Data sharing and security / data integrity

Data contributors need to be able to trust that the information they provide will only be used for the intended purpose and shared only with those who have been allowed to see it by the data owner. For this purpose, the following functional requirements were identified by the Pharma.Aero project group.

4.6.1. Provide data security:

The data collected will be sensitive in nature, and the solution needs to offer all the required flexibility for a data provider to

- ensure that their data can only be seen by specific Parties (possibly defined by the context of the cargo movement, e.g. only by the ground handler at the destination airport)
- exert fine-grain control over data can be seen under specific circumstances (e.g. visible to an airport, not to a ground handler)
- categorize data elements over the entire range from 'public/community visibility' to 'restricted to a single Party'
- have a complete audit trail over who has seen certain data elements.

4.6.2 Guarantee data authenticity:

In addition, information needs to be reliable and tamper-free. Provide proof of compliance for interested parties and auditors.

In this respect it can be useful to explore the use of block chain technology for:

- Provision of temperature measurements without risk of tempering
- Record cargo custodianship
- secure cold chain status publishing

5. Conclusion

In today's context, different data is already being collected, stored and monitored in silos by various stakeholders in the supply chain. However, such data might not necessarily be shared across the supply chain, leading to KPIs not being cascaded across the supply chain and the lack of awareness how pharmaceutical cargo are being handled. There is hence a strong call for collaboration among all parties to share data and provide complete supply chain visibility.

Inputs from the project members revealed that there is an acute need when it comes to obtaining specific location and real-time temperature data at the airport compound. These specific needs can be addressed by sharing information such as Flight Status Update (FSU) messages and integrating different data across multiple parties to form a single source of truth. Outside the airport environment, most forwarders are already sharing these data with shippers.

Members of the project group have deliberated and concluded that a common data sharing platform that integrates data (both at the airport and outside of airport environment) from different sources would be essential. The platform must be able to meet key functional requirements including flexibility, interoperability, data accessibility, timeliness and immutability.

To this end, the project group has established a validated demo model to proof that the relevant data can be collected from various stakeholders to provide greater visibility and ultimately to certify trade lanes and enhance the reliability of end-to-end air transportation. The platform's adoption will require a collaborative mindset for the industry to reap great benefits.

6. Recommendations for further development

As a result of the demo version of the dashboard, the Pharma.Aero project group hereby prepared recommendations for a development and implementation plan which will be used in a next project to create a live prototype of the data sharing platform, known as Digi 2.0: The Global Pharma Tracker Pilot Project. The Digi 2.0 will be implemented on a small number of pharma lanes will serve as a proof of concept. If the proof of concept can be successfully implemented and tested, a broader rollout to other lanes can commence.

During the Digi 2.0 project, further enhancements to the data sharing platform could be explored, which include but not restricted to:

- **Door-to-door data mapping –** to include data that are captured from the point a pharmaceutical shipment leaves a manufacturer's compound, till it arrives at distributor.
- **Integrating with active containers –** incorporating temperature data that are transmitted by active containers when it is on-route.
- **Integration with temperature of storage facility/reefer truck -** temperature recording of transportation assets or storage facilities are being done by CEIV certified companies
- **Integrating ambient temperature of meterological station -** Allowing stakeholders to aggregate historical data to understand the average temperature during specific winter and summer seasons.
- **Temperature of on-tarmac solutions -** solutions such as cool dollies that record temperature during the transportation between warehouses and aircraft.
- **Integrating aircraft temperature –** To include the temperature of the cargo hull compartment when the aircraft is in flight.
- **Air trade lane validation through data aggregation –** To aggregate historical data and determine if stakeholders involved in a specific trade lane have the necessary infrastructure and processes to minimize temperature deviations of a pharmaceutical product.
- **Predictive analytics –**To compute probability of excursions of a selected trade lane, based on aggregation of historical data, as well as live events (e.g. traffic congestion on the road, natural disasters, etc.)