



# Final report

---

## Review of data utilisation in other industries

Project code: V.ISC.2019

Prepared by: Richard Heath, Komal Patel, Teresa Fox, Sarah Nolet  
Australian Farm Institute & AgThentic

Date published: 12 November 2020

PUBLISHED BY  
Meat and Livestock Australia Limited  
PO Box 1961  
NORTH SYDNEY NSW 2059

Meat & Livestock Australia acknowledges the matching funds provided by the Australian Government to support the research and development detailed in this publication.

*This publication is published by Meat & Livestock Australia Limited ABN 39 081 678 364 (MLA). Care is taken to ensure the accuracy of the information contained in this publication. However MLA cannot accept responsibility for the accuracy or completeness of the information or opinions contained in the publication. You should make your own enquiries before making decisions concerning your interests. Reproduction in whole or in part of this publication is prohibited without prior written consent of MLA.*

## Abstract

This project analysed supply chain initiatives focused on data and technology in non-agricultural sectors for insights to help inform improvements for the Australian red meat sector. The analysis centred on the approaches to digital processes, data use, and data analytics employed across the supply chains studied. A framework was developed to identify and select three use-cases driving the adoption of technology in supply chains: provenance, compliance, and commercial efficiency. The three industry case studies selected using this framework were: *apparel (specifically Nike), pharmaceuticals, and oil and gas.*

Interviews and desktop research were conducted, and findings from the case studies were analysed through a common framework to extrapolate insights, with a particular focus on drivers for adoption and keys to successful implementation, that could be applied to the Australian red meat sector. Two critical features which were used to classify data and technology transformations were: (i) the stakeholder(s) that stand to benefit from change; and (ii) the level of coordination required to successfully implement change. The research identified three key methods in which industry bodies such as ISC and MLA can support the implementation and adoption of data and technology solutions in the red meat industry: build the case for change, facilitate coordination, and ensure interoperability.

## Executive summary

Integrity Systems Company (ISC) has responsibility for a critical component of Australia's red meat sector - delivering a system that provides trust in the quality and safety of red meat, and that is embedded in Australian livestock management. The Integrity Systems 2025 and Beyond Strategy articulates that to continue to deliver an effective and trusted integrity system, new approaches and technologies that leverage data to add value to red meat supply chains will be needed. ISC has also recognised that relevant approaches and technologies are likely to come from industries other than agriculture. This project has analysed supply chain data transformations in non-agricultural industries to determine critical success factors in technology use, organisational culture, and application, and provided insights that will help inform and improve the Australian red meat industry's approach to digital processes, data use, and analytics across the supply chain.

Technology and data use applications that could be transferred to the red meat industry were identified, along with key factors common to successful technology implementation across all the case studies. These factors - ***building the case for change, facilitating coordination, and ensuring interoperability*** - provide guidance for how industry bodies such as ISC and MLA can support the implementation and adoption of data and technology solutions for the sector.

The case studies that were selected for the project were ***apparel (specifically Nike), pharmaceuticals, and oil and gas***. These case studies were selected on the basis that they provided insights on three drivers for technology adoption that are particularly relevant to the red meat sector: *provenance, compliance, and commercial efficiency*.

Lessons from the individual case studies that feed into the guidance for industry bodies include:

- Nike's adoption of RFID technology is part of a broader organisational digital transformation strategy. While it is too early in the adoption phase for Nike to fully utilise the data collected through RFID tags, it is clear that implementation is delivering immediate benefits to the company. Nike acknowledges that further efficiencies could be realised in the future if RFID and data analytics capabilities were extended throughout the supply chain – particularly to partner organisations. For this to be achieved, clear business cases and value propositions for adoption will need to be extended to partner organisations, and standards for data interoperability aligned.
- Regulation can enforce rapid adoption of new supply chain technology and processes; however, design of regulation can also have a large impact on the complexity of technology implementation. A comparison between EU and US regulatory approaches to pharmaceutical serialisation highlights that clearly established data standards and guidance on system interoperability can help facilitate industry adoption. Although it remains unclear which regulatory approach ultimately will drive better results, the EU has been able to move more quickly towards implementation and adoption by establishing a centrally-managed system with a well-defined scope. The US's approach to serialisation and track and trace has placed an additional burden on industry stakeholders by leaving them to organically solve challenges around interoperability. However, the US's industry-led approach could have more innovation potential than the EU's government-led approach.
- The oil and gas sector is under pressure to increase efficiency to address declining profitability. Oil and gas companies recognise that better utilisation of data would lead to

more efficient resource discovery and extraction, as well as enable predictive maintenance, but had been slow to capitalise on this opportunity. Public sector provision of open-source aggregated Geoscience data and data vocabularies have helped accelerate transformational change in data utilisation to support machine learning and artificial intelligence capabilities. Oil and gas companies are now more actively participating in standards and compatibility initiatives so that the same transformational use of machine and operational data can be realised.

While the three case studies cover a range of data transformation examples - (i) a private company overhauling its internal inventory management system, (ii) regulations catalysing new systems to share data and verify products across a supply chain, and (iii) efforts to harmonise and aggregate data collected by individual actors across an industry – there are clear success factors common to all, including:

- The case for change needs to be clear and well demonstrated;
- Complexity is lowered and benefits are extended more broadly if there is facilitated coordination; and
- data interoperability is key to full value being realised.

There are, however, a variety of pathways for participation or intervention by industry bodies such as ISC in pursuing and promoting those success factors to accelerate industry change and leverage value from supply chain data. To determine the most appropriate intervention, a clear understanding of the stakeholder(s) that will benefit from change, and the coordination needed to achieve change, is required. With this knowledge, and using the framework developed in this project, we have presented several industry implementation options, including:

- develop and demonstrate business cases;
- build awareness and capability;
- create and redistribute incentives;
- align incentives amongst industry players;
- ease coordination challenges; and
- establish common and open standards.

In particular, we identified three specific opportunities for ISC and MLA to support the implementation and adoption of data and technology solutions for the sector:

- ISC should help build the evidence base and economic analyses to demonstrate value proposition to industry;
- ISC should commission the construction of a red meat industry data vocabulary, and
- ISC should facilitate a process for industry-led determination of an open data standard and open-source frameworks to enable the private sector to implement the standard.

## Table of contents

<b>Abstract .....</b>	<b>2</b>
<b>Executive summary .....</b>	<b>3</b>
<b>1. Background .....</b>	<b>7</b>
<b>2. Objectives.....</b>	<b>7</b>
<b>3. Methodology .....</b>	<b>8</b>
<b>3.1 Stage 1: Identifying case study requirements and subjects .....</b>	<b>8</b>
<b>3.2 Stage 2: Collecting data and developing case studies .....</b>	<b>9</b>
<b>3.3 Stage 3: Analysis of findings and application to ISC.....</b>	<b>9</b>
<b>4. Results.....</b>	<b>10</b>
<b>4.1 Overview of Selected Case Studies .....</b>	<b>10</b>
4.1.1 Use Cases for Supply Chain Data Transformations .....	10
4.1.2 Case Study Subjects .....	11
<b>4.2 Case Study #1: Improving Supply Chain Visibility at Nike .....</b>	<b>12</b>
4.2.1 Context and Overview .....	12
4.2.2 Challenge: Poor Inventory Data Inhibits Commercial Success .....	13
4.2.3 Solution and Approach: RFID-enabled Inventory Management .....	14
4.2.4 Results and Insights .....	18
<b>4.3 Case Study #2: Data Sharing for Drug Safety .....</b>	<b>19</b>
4.3.1 Context and Overview .....	19
4.3.2 Challenge: Compliance with Regulatory Requirements .....	19
4.3.3 Industry Response and Approach: Overhaul in IT and Packaging Infrastructure .....	20
4.3.4 Results and Insights .....	25
<b>4.4 Case Study #3: Improved Data Aggregation and Application in Oil &amp; Gas .....</b>	<b>27</b>
4.4.1 Context and Overview .....	27
4.4.2 Challenge: Collating Vast Quantities of Unstructured Data to Enable Efficiencies .....	28

---

4.4.3 Approach: Data Aggregation and Standardisation.....	30
4.4.4 Results and Insights .....	34
<b>5. Conclusion .....</b>	<b>35</b>
<b>5.1 Key findings .....</b>	<b>35</b>
<b>5.2 Benefits to industry.....</b>	<b>39</b>
<b>6. Future research and recommendations.....</b>	<b>40</b>
<b>7. References.....</b>	<b>41</b>
<b>8. Appendix .....</b>	<b>44</b>
<b>8.1 Long list of use cases for supply chain data and technology         transformations .....</b>	<b>44</b>
<b>8.2 Anonymised List of Interviewees.....</b>	<b>44</b>
<b>8.3 DSCSA Timeline.....</b>	<b>45</b>

## 1. Background

Integrity in supply chains across all industries is constantly being scrutinised. This is because supply chains around the world are increasingly under pressure from variables such as: changing consumer preferences; the need for transparency; Corporate Social Responsibility and/or sustainability commitments; regulatory requirements; and the threat of disruption. Simultaneously, emerging technologies that hold potential to strengthen supply chains and help companies proactively manage these pressures are rapidly advancing. Leading businesses across industries are taking action to futureproof the integrity of their supply chains, by improving efficiencies in the management and integration of their digital processes, as well as leveraging the effective use of data and analytics.

The purpose of Integrity Systems Company (ISC) is to deliver technologies and services to support the integrity of the Australian red meat supply chain. The current digital processes delivered by ISC successfully provide a national, industry owned framework for guaranteeing the integrity of the Australian red meat industry in the areas of food safety, quality assurance, and traceability from paddock to plate. While these digital processes are well established and adopted by industry, there is a need for continual improvement through better integration, data management, and analytics.

To ensure the future success of ISC Programs, and more broadly, to protect the Australian red meat industry's premium reputation and competitive advantage, ISC has developed the Integrity Systems 2025 and Beyond Strategy. To inform the implementation of this strategy, ISC has recognised the importance of understanding how industries outside of agriculture have successfully leveraged data across their supply chains in response to external challenges.

This report presents case studies of supply chain data transformations that have taken place in the apparel, pharmaceutical, and oil and gas industries and captures insights and lessons learned that can be applied to the Australian red meat industry.

## 2. Objectives

The purpose of this project is to: (1) analyse supply chain data transformations in non-agricultural industries to determine the critical success factors in technology use, organisational culture, and application; and (2) apply insights to help inform and improve the Australian red meat industry's approach to digital processes, data use, and analytics across the supply chain.

Specifically, the objectives of this research were to develop three case studies from non-agricultural industries and present:

- The key drivers of success in using data to strengthen supply chains, including the technologies and systems used, to better inform organisational decision making and drive increased profitability;
- Learnings from the implementation of improved digital processes, data use, and analytics, including the factors leading to increased adoption and behaviour change within a supply chain; and
- Opportunities to apply these learnings across all parts of the Australian red meat industry.

The objectives of this engagement have been successfully achieved. Three case studies examining the use of data and analytics to strengthen supply chains were developed for the apparel, pharmaceutical, and oil and gas industries. Each case study examines key drivers of change, learnings from implementation, and insights to driving adoption across the supply chain. The lessons from these case studies have been synthesised and applied to the Australian red meat industry through the development of an insights matrix.

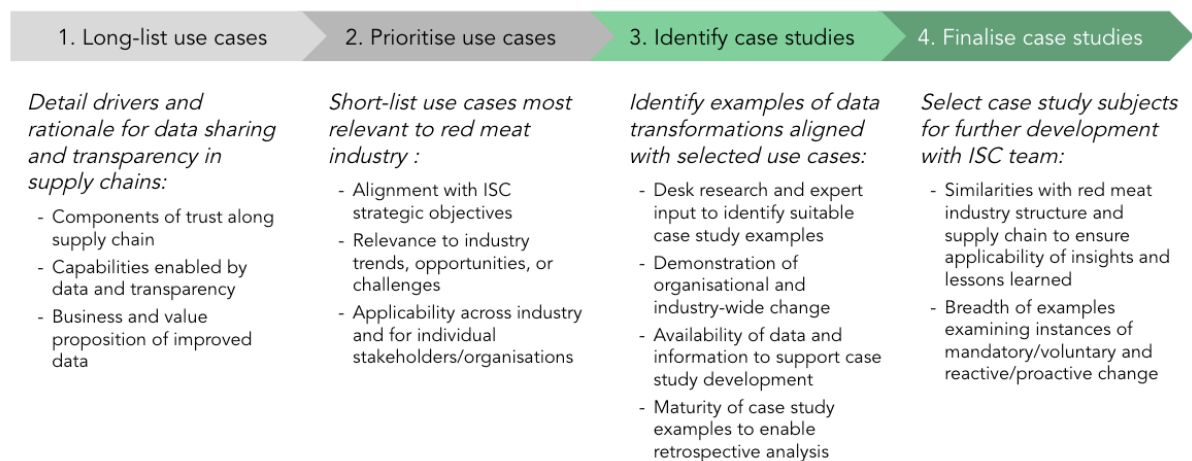
### 3. Methodology

A three-staged approach was used to develop the three case studies and insights presented in this report. In the first stage, appropriate case study requirements were defined and target industries and organisations for study were identified. In the second stage, interviews and data collection were conducted to support case study development. Finally, findings and insights from the study were synthesised and applied to ISC and the Australian red meat industry.

The sub-sections below provide additional details on each phase.

#### 3.1 Stage 1: Identifying case study requirements and subjects

The first phase of this project focused on developing and implementing a framework and process for selecting case study topics and proposing candidate industries and organisations for detailed study. The framework is summarised in Figure 1 below.



**Figure 1: Case Study Selection Framework**

Applications of data and technology capabilities are a means to an end, namely to create and capture value, whether for individual businesses, industry at large, or society more broadly. Keeping this in mind, we sought to root our case study selection process in a use-case driven model. We first developed a long list of drivers for supply chain data transformations to articulate the value proposition for businesses and industry stakeholders (see Appendix 8.1 for details). We then prioritised three unique use-cases based on their relevance and applicability to ISC's strategic objectives and the Australian red meat industry at large. For each prioritised use-case, we compiled relevant industries and organisations for further analysis and selected final case study subjects with input from ISC.

In addition to aligning case studies to use-cases relevant to the red meat industry, we established selection criteria to ensure that our work results in meaningful, applicable, and varied insights for ISC and industry stakeholders. These criteria included:

- **Data and information availability:** selected case studies must have sufficient availability of information to enable rigorous study. Sources of information can include publicly available reports, press releases, and articles, as well as access to stakeholders for interviews.
- **Maturity:** data and technology transformation initiatives must be sufficiently mature to enable a thorough retrospective analysis and evaluation of outcomes.



- **Industry relevance:** case studies selected must have similarities in the supply chain and industry structure such that learnings and insights are applicable to ISC and the red meat industry in Australia.
- **Scale:** case studies will be evaluated at both the industry-wide and organisational level to demonstrate collaborative and individual stories of change
- **Impetus for change:** propose to consider case studies in which supply chain transformations were catalysed reactively (in response to an imminent challenge) or proactively (in response to an opportunity) to assess implications on adoption, application, and outcomes.
- **Regulatory environment:** consideration of case studies in which supply chain transformations are underpinned by regulatory requirements or voluntary commitments to understand impact on coordination, adoption, and governance structures.

### **3.2 Stage 2: Collecting data and developing case studies**

In the second stage of the engagement, we gathered evidence and developed case studies for each selected industry or organisation. Data and evidence for case studies were collected through mixed methods including interviews and secondary research. In-person and phone interviews were conducted with individuals working in the selected industries or organisations, service providers supporting implementation of data solutions, and technology and subject matter experts. It is important to note that interviewees were not representing or speaking on behalf of their organisations, but rather sharing their perspectives as individuals. Interviewee insights presented in this report, therefore, should not be interpreted as endorsed statements by organisations. An anonymised list of interviewees can be found in Appendix 8.2. Secondary research included analysis of publicly available news articles, research reports, financial and investor reports, and policy documents. Research findings were then processed and developed into the case studies which are presented in Section 4 of the report below.

### **3.3 Stage 3: Analysis of findings and application to ISC**

In the final stage of work, we synthesised findings from each of the three individual case studies and developed a framework to apply insights to ISC and the Australian red meat industry. An insights matrix was developed based on two key factors: (i) the stakeholder(s) that stand to benefit from change; and (ii) the level of coordination required to successfully implement change. The framework was then used to capture lessons learned across the three case studies and inform how stakeholders across the red meat sector can help facilitate data success in the industry.

## 4. Results

### 4.1 Overview of Selected Case Studies

#### 4.1.1 Use Cases for Supply Chain Data Transformations

As outlined in the Methodology section above, the selection of case studies was driven by a prioritisation of use-cases for supply chain data capabilities. The three use-cases ultimately prioritised for this project were (i) provenance, (ii) compliance, and (iii) commercial efficiency. These use-cases were selected based on alignment with Integrity Systems 2025 and Beyond, as well as trends, opportunities, and challenges in the red meat industry at large. Below, we detail each of the three use-cases and their relevance to the Australian red meat industry.

##### 4.1.1.1 Provenance

Provenance relates to using data and technology to prove the origin and authenticity of products and to safeguard against fraud. Provenance is of particular importance to industries where there are concerns for human health and safety, counterfeiting is prevalent, and/or product quality is associated with origin. This is of particular relevance to the Australian red meat export industry, where for example, it is estimated that every second kilogram of beef sold in China under the label of Australian beef is counterfeit (Adams, 2019). China is the largest export market for Australian beef and Chinese consumers are willing to pay premium prices for Australian products which are associated with higher quality and levels of trust. However, counterfeit products can both undermine this trust and therefore the value captured by Australian producers. Provenance is also strongly aligned to Integrity Systems 2025 and Beyond, a key outcome of which is ensuring that consumers in both domestic and foreign markets have absolute trust in Australian red meat products (Integrity Systems Company, 2018).

##### 4.1.1.2 Compliance

Data-enabled capabilities for demonstrating compliance are of increasing importance in industries where production practices must adhere to strict legal requirements, industry standards, and/or voluntary certification schemes in response to consumer demand for sustainable and ethical products. Compliance is central to ISC's mandate of equipping industry with tools to ensure food safety, animal welfare and biosecurity in the Australian red meat industry (Integrity Systems Company, 2018). Furthermore, capabilities to demonstrate compliance with carbon neutrality, biodiversity, and sustainability strategies could be important to not only meet consumer demand, but also to establish competitive differentiation based on higher standards and quality for Australian producers.

##### 4.1.1.3 Commercial Efficiency

Data and technology have played a significant role in unlocking supply chain improvements, improving coordination, and optimising operations to both create value and mitigate risks for stakeholders across the value chain. A key priority of the Integrity System is to create cost and operational efficiencies for stakeholders in the red meat industry (Integrity Systems Company, 2018). There has been an explosion on technology solutions to help optimise everything from on-farm management practices to transport and logistics. Track and trace capabilities are also particularly valuable in industries involving cold-chains and which are sensitive to safety and recall risks because they can enable early detection of breaches and isolated, rather than mass, redressal.

Data sharing and visibility along the supply chain can also help with standard operational improvements such as demand forecasting, inventory management, and flexibility for crisis management as well.

#### 4.1.2 Case Study Subjects

Three case study subjects were then selected in line with the prioritised use cases and with input from ISC. The proposed case studies also reflected the selection criteria outlined in section 3.1 above, namely: data availability; maturity; relevance; and variety in scale and the impetus for change. In order to capture variety in scale, we opted to conduct the apparel case study at an organisational, rather than industry, level. The apparel case study is therefore centred on data transformation led by an individual company: Nike. Table 1 provides a summary of each case subject and its relevance to the red meat industry in relation to the prioritised use cases detailed above.

**Table 1: Relevance of Selected Case Study Subjects**

Case Study Subject	Relevant Use Case(s)	Description
Nike (apparel)	Commercial efficiency	The apparel sector, and the overall retail market, have needed to increase their digital capabilities as consumers are shifting to online channels. Nike, in particular, has invested greatly in data and digital capabilities to better sense and meet consumer demand in an increasingly direct, online marketplace.
Pharmaceuticals	Provenance; Compliance	Similar to the red meat industry, counterfeit products in the pharmaceutical industry pose a significant threat to the value captured by genuine producers and erode trust in consumer markets. Governments have increasingly been requiring stakeholders in pharmaceutical supply chains to implement product serialisation and track and trace capabilities to improve drug safety.
Oil and Gas	Compliance; commercial efficiency	Like agriculture, the oil and gas industry is a heavily export focused industry, working in global markets where supply chain efficiencies are key to competitiveness. Efficiency of production is also critical for profitable operation, leading to resource extraction companies working with agencies such as Geoscience Australia to identify and harness available resources through geo-spatial data infrastructure and platforms.

## 4.2 Case Study #1: Improving Supply Chain Visibility at Nike

### 4.2.1 Context and Overview

NIKE, Inc., founded in 1967 in the United States, has grown to be the largest seller of athletic footwear and apparel in the world, bringing in revenue of USD 39 billion in FY 2019 (Nike, Inc., 2019). Nike has long considered innovation to be a critical path to commercial success. Historically, innovation at Nike has focused on product design and manufacturing to deliver enhanced performance to athletes and consumers. While product innovation no doubt remains at the core of Nike's strategy, since the early 2000s, Nike has increasingly viewed advancements in two additional areas as key drivers of growth: sustainability and digital.

Although Nike's sustainability transformation offers lessons on effective change management (summarised below in Figure 2), it was not underpinned by technology and data capabilities, and is therefore not the focus of this case study. Instead, this case study focuses on how Nike is leveraging supply chain data and analytics to accelerate its digital transformation and drive commercial value.

#### Figure 2: Lessons from Nike's Sustainability Journey

In the late 1990s, Nike was the target of public protests over problems within its supply chain including unsafe working conditions, wage rates, excessive overtime, and environmental impacts (Schifrin, Carroll and Brady, 2013). Today, though not immune to labour and environmental challenges, Nike is recognised as an industry leader in sustainability. How did Nike achieve this transformation?

The public pressure Nike was facing in the 1990s was no doubt a catalyst for a decades-long effort to improve sustainability within its supply chain. Nike's success, however, stems from its approach to change management, which sought to reframe sustainability as an opportunity for innovation rather than a 'problem'. Three critical elements to Nike's approach were (1) embedding sustainability at the highest levels of the organisation, (2) transitioning from sustainability policing to capacity building, and (3) establishing systems to measure and incentivise desired outcomes.

##### *Integrating sustainability into the core business*

In 2009, Nike underwent a company-wide reorganisation during which it moved its Corporate Responsibility division upstream (Schifrin, Carroll and Brady, 2013). Prior to the reorganisation, the Corporate Responsibility division was reporting to the CEO and the Communications division, and was seen as "an outside police force that was not aligned with creating business value" (Kaul et. al., 2017). Nike's leadership recognised that if sustainability were to be seen as a priority and a driver of growth and innovation, the Corporate Responsibility function would need to be reimagined (Kaul et. al., 2017). As a result, the 130-person Corporate Responsibility team was reformed as the Sustainable Business and Innovation team which reported to the CEO and had direct or reporting links to the Product, Category and Marketing, Supply Chain, and Innovation divisions (Schifrin, Carroll and Brady, 2013). The Sustainable Business and Innovation team was responsible for collaborating with other business functions to address the root causes of sustainability issues through new business models and innovation practices (Schifrin, Carroll and Brady, 2013). The restructuring was critical in recasting Nike's sustainability approach from one that was based on retroactive assessments to one that was proactively feeding into strategy and design choices.

##### *Shifting from policing to capacity building*

Nike also recognised that improving its track record on labour and environmental impacts would

also require changes at its contracted manufacturing factories. Rather than merely policing contract manufacturers for compliance, Nike turned its attention to capacity building to improve management practices, working conditions, and ultimately productivity. As explained by Steve Castellanos, Nike's lean enterprise director, a supply chain policed by auditors was seen as a "losing proposition" and the company believed that it was to their "advantage to grow capability with [their] factory partners" (Schifrin, Carroll and Brady, 2013). To that end, Nike offered human resource management and lean manufacturing training to its contract factories. For example, in 2009, Nike launched its Apparel Innovation and Training Center in Sri Lanka where managers from its contracted facilities could attend an eight-week training on lean manufacturing and management (Distelhorst, Hainmueller and Locke, 2017). Because lean manufacturing requires high-engagement and workforce empowerment, these trainings could provide a pathway to improve working conditions and social standards in Nike's supply chain even though they did not focus specifically on sustainability. Indeed, factories that adopted lean practices were found to have a 15% reduction in noncompliance with labour standards (Distelhorst, Hainmueller and Locke, 2017).

#### *Developing systems to measure and incentivise outcomes*

In order to measure the sustainability impacts of the design and production of its products and identify opportunities for improvement, Nike developed a series of tools for its designers and manufacturing partners (Schifrin, Carroll and Brady, 2013). The Considered Index was developed to evaluate and rate product designs on environmental sustainability, including waste, water, energy and chemistry impacts (Schifrin, 2013). The Considered Index was used to give proposed products a bronze (baseline sustainability), silver (minor improvement), or gold (major improvement) rating (Kaul et. al., 2017). The Considered Index allowed designers to see the footprint of their proposed choices and pathways to reducing the impact of their final design proposals (Kaul et. al., 2017). Nike also added a sustainability component to its Manufacturing Index, which was a balanced scorecard to evaluate factory performance and historically consisted of cost, delivery, and quality metrics (Schifrin, Carroll and Brady, 2013). Sustainability metrics were introduced as an equally weighted component (25%) of the overall score, and performance against the Manufacturing Index was used to determine whether sanctions (e.g., order reductions or removal from supplier base) or incentives (e.g., priority consideration for orders) would be applied (Schifrin, Carroll and Brady, 2013). Both the Considered Index and Manufacturing Index allowed Nike to establish clear priorities and measure progress against them.

#### **4.2.2 Challenge: Poor Inventory Data Inhibits Commercial Success**

In 2017, Nike announced its 'Consumer Direct Offense', a call to action aligning the company around a focus on better serving the consumer personally, at scale (Nike News, 2017). In other words, the strategic priority is to engage directly with consumers and deliver what they want, where and when they want it. In order to deliver this vision, Nike has invested in building digital capabilities to both connect directly with consumers as well as improve supply chain speed and efficiency to better serve consumers.

In order to effectively serve consumers on-demand, it is important for Nike to have real-time information about its inventory. In physical retail settings, for example, consumers want to know if the products they are searching for are available and where they are physically located in store. To optimise delivery times for online sales, Nike also needs to know where inventory is being held and how it can most quickly and efficiently get the product into consumer hands. Knowing what products are selling and where, both in terms of sales channels and geographic markets, is also crucial for planning production and future product designs.

Poor supply chain visibility, however, has been a significant barrier to effectively serving consumer demand in real-time. Conventionally, inventory tracking has been an expensive, cumbersome, and manual process. In retail settings, inventory stock-taking generally requires storefronts to close and for staff to individually scan barcodes on items. Because this process results in businesses losing a revenue opportunity while continuing to incur labour costs, physical inventory counts may only occur a few times a year, resulting in static, point-in-time data. Furthermore, poor visibility in retail supply chains also contributes to billions of dollars in both claims and chargebacks between supply chain players and in inventory shrinkage (Auburn University RFID Lab, 2019). Claims and chargebacks arise when there are discrepancies in inventory counts for shipments between a sender (e.g., Nike distribution center) and a receiver (e.g., a retail outlet) and parties need to settle financial responsibility. Inventory shrinkage occurs when physical inventory does not align with inventory listed in accounting records, possibly due to theft, damage, or counting errors.

### **4.2.3 Solution and Approach: RFID-enabled Inventory Management**

To improve its supply chain visibility and address the challenges described above, in 2019 Nike announced that it would integrate radio-frequency identification (RFID) technology into all of its footwear and non-licensed apparel. Embedding products with RFID would provide Nike with real-time inventory data, enabling it to efficiently match available supply and existing demand and to predict and respond to future demand. As former CEO, Mark Parker, explained during Nike's Q4 2019 earnings call, RFID is "becoming the most precise tool in [Nike's] arsenal to meet an individual consumer specific need at the exact right moment" (Cosgrove, 2019).

#### **4.2.3.1 Why RFID?**

Nike's announcement to integrate RFID into its non-licensed footwear and apparel represents a significant shift, impacting "hundreds of millions of items" the company produces (Cosgrove, 2019). Given the scale of the initiative, the decision to pursue and invest in RFID capabilities is not one that Nike would have taken lightly. Key factors that contributed to Nike's decision to implement RFID include alignment with the company's strategic objectives, augmentation of capabilities, and economic feasibility.

##### *Strategic Alignment*

The adoption of RFID at Nike has been directly in service of its Consumer Direct Offense. As one Nike supply chain employee noted, Nike's journey with RFID started with a problem-led rather than solution-led framing. The organisation understood that to achieve its objective of directly serving consumer demand, it would need to improve the accuracy and precision of inventory management. An RFID-enabled inventory system emerged as a solution to this high-priority and well-defined problem, and as a result, has been prioritised as an organisation-wide initiative.

According to a Nike employee, RFID has also emerged as a priority because it supports Nike's broader push to establish a "single source of truth" to inform decision-making across the organisation. As could be expected with an organisation as large as Nike, different business units and teams have developed their own data tools, repositories, and management practices over the years. This in turn has led to a disconnect between the parts of the business where data might be collected and where that data could meaningfully feed into decisions. Nike's vision for a "single source of truth" instead reimagines a future where one database is used to guide decisions in all areas of the organisation from manufacturing through to retail. RFID, which can provide valuable information to many parts of the organisation in real time, is strongly aligned with this effort as well.

##### *Value-adding Capabilities*

There are two important ways in which RFID technology solves Nike's existing challenges around supply chain visibility: (1) it encodes more product-specific information, and (2) it enables more streamlined scanning than traditional barcodes.

Unlike traditional barcodes, RFID tags provide information about unique products and have read-write capabilities (GS1 Australia). Barcodes provide information at the category level—for example, that a product might be a pair of white Nike Air Force 1 shoes in size 7. RFID tags meanwhile, can go a step further and be used to differentiate individual pairs of white Nike Air Force 1 shoes in size 7 from one another. Because RFID tags enable serialisation, they can be used to record product-specific information ranging from production date and time to lot numbers. Additionally, the read-write capability of RFID tags means that data can be added as an item moves through the supply chain. For example, location data can be recorded to an RFID tag as a product moves throughout the supply chain. This location data, in turn, could help resolve inventory claims, optimise distribution pathways, or map geographic demand, among other uses. RFID tags therefore allow a wider range of data to be captured at a more granular level compared to barcodes.

RFID tags can also be scanned at greater volumes and speeds than barcodes. Barcodes require a direct line of sight between the barcode and the scanner. Further, only one item can be scanned at a time. RFID tags on the other hand can be processed by spatial scans in which multiple tags can be read at once without direct visibility. Practically, this means that individual products can be scanned even if they are aggregated (e.g., in pallets) and that less labour is required to take stock of inventory. The increased efficiency of scanning RFID tags means that inventory tracking can happen on a more frequent basis, even in real-time.

These capabilities unlocked by RFID are why former CEO Mark Parker has touted the technology as enabling “almost 100% visibility into what [Nike has] by style, colour, and size across our marketplace” and as “an incredible opportunity in terms of meeting consumer demand real time, in the moment” (Cosgrove, 2019).

#### *Feasibility*

While the technology has been around for decades, the miniaturisation and declining costs of RFID tags in the past 10-15 years have led to increased implementation. RFID tags are now small enough that Nike can integrate them into labelling for its footwear and apparel, and with costs as low as a few cents per tag, it is also economically viable for Nike to pursue as well.

The financial viability of the decision to adopt RFID also stems from the fact that Nike is able to independently derive value from the technology. Nike has calculated that the use of RFID within in-house distribution and retail channels will drive significant value to the company, even if external supply chain partners do not invest in capabilities to leverage the technology. As a Nike employee bluntly shared, “it does not matter if any of our retailers decide to adopt RFID capabilities or not, we'll still see substantial benefits internally.”

#### **4.2.3.2 Leadership: A top-down priority**

As previously noted, Nike's decision to pursue RFID technology has been fuelled by a broader strategic initiative led by the executive team. Internally, support from the organisation's top leadership has been viewed as a critical success factor for the RFID initiative. One employee noted that compared to other fashion and apparel companies, Nike's leadership team, including the CEO and several board members, may be more willing to use technology solutions for intractable business problems because they come from tech backgrounds. Nike's leadership has not only

supported the initiative internally, but also established it as a priority to key external stakeholders as well. Notably, Nike's executives have openly discussed efforts to implement RFID in investor and earnings calls. These discussions have boosted the visibility of Nike's internal transformation and also created an accountability mechanism for the organisation to follow through on its plans.

In addition to establishing RFID product tagging as a key organisational objective, Nike's leadership also introduced a new central team, the Connected Product Team, within the company to lead the effort. In addition to overseeing implementation of RFID capabilities, the Connected Product Team is also responsible for related efforts, including integration of QR codes on products. Dedicating a central team to oversee the initiative creates accountability and responsibility for implementation. The central team works with individual business units through a collaborative, consultative process to understand the pain points, challenges, and opportunities related to RFID implementation. This helps build internal buy-in and support for changes that need to take place within individual business units, and also ensures that the organisation progresses towards its goal. As a Nike employee explained, if RFID implementation hadn't been assigned to a dedicated team, progress would have been much slower because RFID would have been just one item on a longlist of existing priorities and 'business as usual' tasks. Having a dedicated team overseeing RFID implementation has also enabled efficiencies in implementation because procurement and vendor management for RFID tags and scanners is centrally managed, and learnings from implementing the technology in different parts of the organisation can be integrated into future work.

#### **4.2.3.3 Implementation: Start small and close to home, then scale**

Nike has focused its initial implementation of RFID where it has the most control and where it is most practical. While RFID can be used for a number of applications, Nike began with implementing the technology in areas where the value proposition was the clearest: shipping and inventory management. Additionally, Nike began the integration of RFID in a manner that reduced complexity and provided an opportunity to demonstrate success prior to scaling. For example, Nike initially began introducing RFID into its North America operations. Rather than integrating RFID into products at manufacturing, where there would be little control of an individual product's final destination, Nike only started tagging products in the middle of the supply chain when they were already in North America. This ensured that RFID enabled products were ending up in the right channels where the technology could be leveraged.

Nike also began implementing RFID within its own organisational boundaries, rather than with external partners, to reduce risk and maintain autonomy. For example, even when Nike participated in the Auburn University RFID Lab's Chain Integration Project (CHIP) proof of concept, which was designed to test item-level data sharing between supply chain stakeholders in the retail industry, it did so as a vertically integrated entity (Auburn University RFID Lab, 2019). While other brands in the CHIP proof of concept were tracking and sharing data as items exchanged hands from their own distribution centers to external retail partners, Nike tracked product data entirely within its own organisational boundaries.

By first implementing RFID within its own borders, Nike's approach mitigates potential risks associated with data and technology failures. As explained by a Nike employee, RFID technology is not yet fool-proof in either transmission or scanning, and these failures would increase the costs of sharing data externally and perhaps create more problems than are being solved. By first implementing the solutions in-house, Nike can work through technology hardware and process challenges in a lower-risk setting prior to scaling to external partners.



Furthermore, by focusing on internal implementation first, Nike has been able to test the technology and gain experience while bypassing the challenges of data standardisation and permissions that come with external engagement. When only transmitting data within the company, Nike can use its internal data formats and standards, without significant changes to documentation processes and requirements. However, to share with external stakeholders, Nike would need to translate its data into a common format so that the company and its partners are 'speaking the same language' and can make use of shared data streams. For example, as part of the CHIP proof of concept, all participating organisations had their internal data translated into the Electronic Product Code Information Services (EPCIS)<sup>1</sup> standard, which has been developed by GS1 to facilitate the sharing of transactional information regarding the movement and status of items at various stages of the supply chain (Auburn University RFID Lab, 2019). In the CHIP proof of concept, Nike shared data in its internal format with the research team at Auburn University, which then processed and translated it into the EPCIS format for the purpose of the study. However, for Nike to externally share data as part of normal business operations, it would either need to assume responsibility for translating its data into formats that are interoperable with external supply chain partners or persuade partners to adapt to Nike's existing formats.

Similarly, Nike would also need to navigate data security and governance challenges when sharing its data externally. As part of the CHIP proof of concept study, the Auburn research team was again responsible for centrally managing permissions on the blockchain used to share data between participating organisations. The research team established unique channels between trading partners on the blockchain to maintain privacy and ensure that only relevant data elements on the blockchain were visible to each organisation (Auburn University RFID Lab, 2019). However, having an intermediary organisation control data access for a network of organisations is unlikely to be a viable solution at scale. A centrally managed data exchange system that is owned by a third-party would no doubt raise concerns over data privacy, security, and ownership; and industry independence more broadly. How organisations solve for data privacy and governance when implementing cross-organisation data sharing solutions is yet to be seen.

Although Nike has started with implementing RFID within its own organisation, it also recognises that additional value could be realised if external retail partners developed capabilities to read, capture, and share data from its RFID tagged products. Adoption from retail partners, for example, could help efficiently and fairly resolve inventory claims and allow Nike to better understand product demand in external retail channels. According to an employee, Nike is currently focusing on helping retail partners "imagine the benefits of RFID capabilities for themselves" to encourage adoption, and has also made documentation and specifications from its own efforts available to share insights and make implementation easier for its trading partners. At present, the focus from Nike has been on building a sound business case for its supply chain partners and easing any potential barriers to adoption. It's also worth noting that Nike is actively reducing its reliance on external retail partners as part of its direct consumer strategy. As Heidi O'Neill, Nike's President of Consumer and Marketplace explained, Nike will "continue to shift away from undifferentiated retail" and focus instead on a few key partners who also share a commitment to delivering a more digital, direct, and differentiated service to consumers (Nike, Inc., 2020). Having fewer wholesale and retail partners increases the feasibility of integrating RFID capabilities through Nike's end-to-end supply chain.

---

<sup>1</sup> More details on EPCIS can be found in Section 4.3.3.2 below.

## 4.2.4 Results and Insights

### 4.2.4.1 Organisational impact

Nike's push to integrate RFID technology into its products was launched in 2019, and to-date there has been little publicly available information regarding the specific financial and operational outcomes of this initiative. However, the organisation has acknowledged its overall digital strategy and transformation as the reason it was able to withstand the shock of initial COVID-19 impacts and even thrive in the post-COVID era. As current CEO John Donahoe explained at Nike's 2020 Annual Shareholders Meeting:

*"The consumer-direct offense coming into this pandemic was working. The results prove that out and there's no doubt that's the case. But what's been interesting during the pandemic, in many ways you could say it stress-tested the strategy and reaffirmed how correct the direction is"* (Nike, Inc., 2020).

Donahoe and Nike's executive team are confident that the COVID-19 pandemic has helped accelerate a permanent shift to digital channels for consumers, and believe the company's investment in capabilities to support a seamless digital experience, including RFID-enabled supply chain visibility, will support success in this new marketplace.

### 4.2.4.2 Lessons from the Nike journey

*Technology for data-sharing embedded in a larger organisational strategy*

Nike's efforts to introduce RFID technology in its supply chain have been grounded in a broader strategic shift towards digital capabilities, which is seen as critical for the company's future success. A clear link between the individual technology solution for data sharing and the strategic objectives of the firm have helped to align stakeholders across the organisation and build momentum for implementation as the business case for change has been clear from the outset. Additionally, the establishment of a centralised team to oversee the initiative has helped ensure visibility, accountability, and authority for implementation.

*Benefits from investment can be independently achieved*

The fact that Nike has been able to realise benefits of the technology without participation of other supply chain players has been critical for its quick deployment within the organisation. Because cooperation from external stakeholders and coordinated data standards are not a necessary condition for success, Nike has been able to quickly move to implementation and gain experience with the technology. Data sharing across organisational boundaries can deliver additional benefits to Nike, and is on the radar for the company, but the complexities and challenges of external coordination have not stifled technology adoption so far. In order to enable external data exchange in the future, however, Nike and its partners will need to align on common or interoperable data standards.

*External engagement predicated on building a clear business case and reducing barriers to participation*

Nike recognises that it needs to build a clear business case and value proposition for its external partners to invest in capabilities that could amplify the value of its efforts to tag products with RFID. It understands that it needs to make implementation as easy as possible for its partners, and is looking to provide documentation and support where possible. Furthermore, participation in

research projects such as CHIP offer Nike a learning opportunity regarding protocols and mechanisms that can make it easier to communicate and coordinate with external stakeholders.

### **4.3 Case Study #2: Data Sharing for Drug Safety**

#### **4.3.1 Context and Overview**

Counterfeit and falsified drugs pose a significant threat to the USD 1.25 trillion global pharmaceutical industry and to public health more broadly (IQVIA, 2020). The OECD estimated that in 2016, trade in counterfeit pharmaceuticals was nearly USD 4.4 billion, close to 3% of the total global pharmaceutical market that year (OECD / EUIPO, 2020). In addition to lost sales and reputational risk for pharmaceutical companies, counterfeit drugs result in negative health impacts for patients and are costly for governments, which are responsible for oversight and management of healthcare systems (OECD / EUIPO, 2020).

In response to the challenge of counterfeit medicines, governments around the world have started to put in place regulations to help prove the provenance of drugs that are dispensed to patients. This case study examines how government regulations, particularly in the US and EU markets, have catalysed data sharing and technology adoption in the pharmaceutical industry.

#### **4.3.2 Challenge: Compliance with Regulatory Requirements**

To help demonstrate the authenticity of drugs that are marketed to consumers, governments have established regulations which require product serialisation and supply chain track and trace capabilities. Serialisation means that each saleable unit carries a unique identifier, typically a serial number encoded in barcode or data matrix. Product tracking is the ability to follow a product's downstream journey from start to finish, while tracing is the ability to retrospectively map the upstream journey of a product through to the beginning of the supply chain. While many governments have put in place regulations, the specific compliance requirements that the pharmaceutical industry needs to navigate differ from country to country. Regulations in the EU and US, which are the two largest pharmaceutical markets in the world, are the focus of this case study.

##### **4.3.2.1 EU Falsified Medicines Directive**

The European Union's Falsified Medicines Directive (FMD) was passed in 2011 and took effect in January 2013. A key measure of the FMD is that two safety features had to be integrated into the outer packaging of medicines by February 2019: (1) a unique identifier encoded in a 2-D barcode; and (2) an anti-tampering device (European Medicines Agency). The unique identifiers assigned to medicines must comprise of the following elements:

- a product code allowing the identification of the name of the medicine, the common drug name, the pharmaceutical form, the strength, the pack size, and pack type;
- a serial number which is a numeric or alphanumeric sequence of a maximum of 20 randomly generated characters;
- a batch number;
- an expiry date;
- and a national reimbursement number, if the country in which the medicine is being supplied requires it (UK Medicines & Healthcare products Regulatory Agency, 2018).

In addition to assigning unique identifiers to individual products, manufacturers are required to upload this information to a central EU repository that is part of an end-to-end medicines

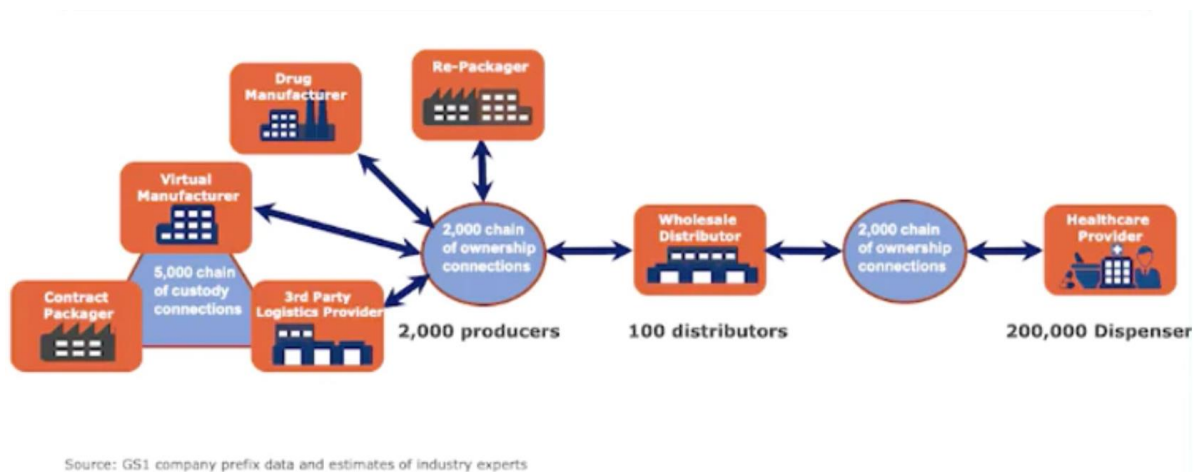
verification system introduced by the regulations (European Medicines Agency). Wholesalers must also scan medicines at various points along the supply chain to verify authenticity. Additionally, hospitals and pharmacies must scan medicines to verify authenticity, as well as decommission associated serial numbers from the repository when medicines are administered to patients (European Medicines Agency).

#### 4.3.2.2 US Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA), which was passed by Congress in 2013, outlines steps to build an electronic, interoperable system to identify and trace prescription drugs that are distributed in the United States (Center for Drug Evaluation and Research, 2019a). Initial requirements of the DSCSA started to take effect in 2015, and are slated to be fully phased in by 2023, when individual units should be digitally trackable and traceable throughout the entire supply chain. The DSCSA requires drug manufacturers, repackagers, wholesalers, distributors, and dispensers to participate in serialising packages with unique product identifiers; sharing and verifying transaction information, transaction history, and transaction statements with direct trading partners; and identifying and investigating suspect products.

A notable difference between the DSCSA and the EU's FMD is that supply chain players in the US are responsible for sharing data directly with their immediate trading partners rather than through a centralised repository. As Figure 3 below demonstrates, the US pharmaceutical supply chain contains thousands of connection points between supply chain stakeholders. Appendix 8.3 provides a timeline and summary of key provisions of the DSCSA for each sector of the pharmaceutical supply chain.

**Figure 3: Illustration of US Pharmaceutical Supply Chain and Connection Points for Data Exchange**



Source: (Lerner, 2020)

#### 4.3.3 Industry Response and Approach: Overhaul in IT and Packaging Infrastructure

With the DSCSA and FMD, the world's two largest pharmaceutical markets introduced major regulatory overhauls in the span of just a few years. The scale of change was unprecedented, impacting operations across all areas of pharmaceutical businesses. Dan Walles, a senior executive at TraceLink, a pharmaceutical track and trace solution provider, assessed that the impact of these regulations would be "profound" and that it would be "safe to say that all pharmaceutical companies will have to operate differently in a serialised world" (2017).

Despite their differences, the US and EU regulations both required the pharmaceutical industry to adopt significant changes related to product packaging and IT systems in particular. Packaging technologies and processes needed to change to be able to encode serialised product data on items, namely in 2D data matrices. IT systems, on the other hand, needed to evolve to accommodate requirements for data documentation and exchange with external entities.

#### **4.3.3.1 Buying, rather than building, solutions**

Pharmaceutical companies have largely turned to external service providers and consultants to implement the changes required to comply with regulations. One reason that industry has sought to buy, rather than build, solutions is because the software and hardware capabilities needed to support the necessary changes to packaging and IT systems is squarely outside of their expertise. Additionally, timelines for change were established by the regulations and would require industry to quickly move to implementation. The decision to outsource these services may also, however, point to the fact that pharmaceutical companies didn't see these capabilities as critical drivers of growth or commercial success that would warrant in-house specialisation.

The pharmaceutical industry's demand for these software and hardware solutions, in turn, has helped create new market opportunities and fueled the growth of new businesses as well. For example, SAP and TraceLink are two of the leading providers of serialisation and track and trace software solutions. SAP developed its Advanced Track and Trace for Pharmaceuticals (ATTP) application, which provides a corporate serialisation repository, serial number management, and reporting capabilities, in response to the growing demand for pharmaceutical companies to comply with global regulations (SAP). While SAP saw the opportunity to augment its enterprise resource management offering for its customers, TraceLink was able to establish a business focused entirely on serving the pharmaceutical industry with track and trace solution support. In fact, TraceLink had previously attempted to launch its business in 2009, before regulations in the US or EU existed, and did not succeed. The introduction of the regulatory measures, however, established a clear market need for their services and TraceLink successfully raised US\$5.5 million in 2012 and has since grown to employ more than 500 people and serve over 1,000 customers.

On the other hand, the regulatory changes have also contributed to increasing cost pressures for certain parts of the pharmaceutical supply chain, including packaging companies. Industry has expected packaging companies to provide services that meet serialisation requirements. Even though the technology, infrastructure, and process changes needed to support serialised packaging have been significant and expensive, there has been little opportunity for cost recovery. For example, According to Craig Rogers, former CEO of PCI Pharmaceutical Services, a pharmaceutical packaging company, the changes required to enable serialisation encoding, which included not just modification to packing lines (printing and packaging equipment) but also infrastructure adjustments to accommodate the 20-30 metre-long equipment, could cost up to US\$50 million. Process costs also increased as additional labour was required for quality assurance checks.

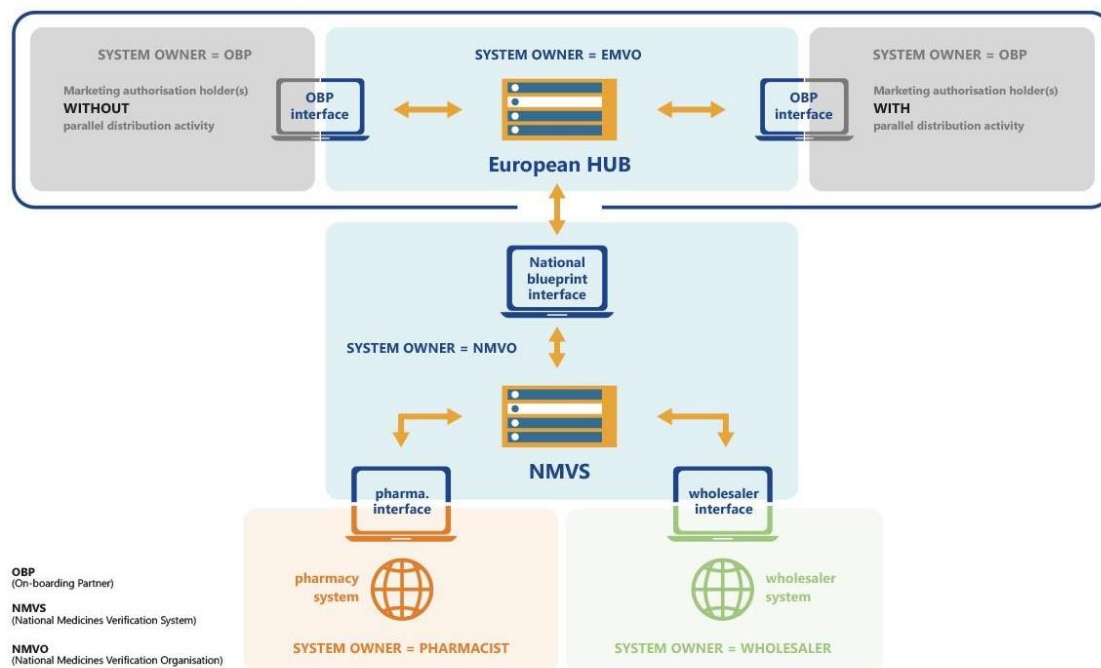
#### **Establishing Interoperability**

In order to fully track and trace products throughout a supply chain, data systems used by different stakeholders have to be interoperable. There are two ways to achieve interoperability--one is to align all stakeholders around common standards; the other is to build data translation solutions that enable individual organisations to ingest each other's data.

In the EU, common data standards and formats have been established as part of the European Medicines Verification System (EMVS). As indicated in Figure 4 below, the EMVS consists of an EU

Hub, which stores and transmits data to relevant national systems, and National Medicines Verification Systems (NMVS), which are repositories for each EU member state (emvo-medicines.eu). Pharmaceutical companies are required to pay annual fees for each NMVS they participate in, and these levies provide the financing to operate and maintain the overall EMVS. The technical and quality standards of the EMVS, including system interoperability, data ownership, and access, have been agreed by stakeholders representing manufacturers, wholesalers, and community pharmacists in accordance with requirements of the FMD.

**Figure 4: EMVS System Landscape**



Source: (emvo-medicines.eu, n.d.)

While the EU's approach to ensuring interoperability has been relatively straightforward, it has relied on government-led technology development and management. The EMVS has been designed with the sole purpose of ensuring compliance with FMD. Although the private sector has financed the development of the EMVS, there is little scope to use the resulting capabilities and data for other purposes or additional innovation because the system is not industry held. Further, the system depends on government capabilities and knowledge of technology trends and best practices.

In contrast to the EU, the US government has not established a centralised system to facilitate data exchange between industry stakeholders. Instead, the Food and Drug Administration (FDA) is leaving it up to industry to develop the necessary solutions. For example, the FDA is hosting the DSCSA Pilot Project Program to help drug supply chain stakeholders develop electronic, interoperable systems that will allow for compliance with the regulation. The DSCSA Pilot Project Program is intended to explore and evaluate potential industry solutions for interoperability, and includes 20 initiatives that are funded fully by participants (Center for Drug Evaluation and Research, 2019b). As explained by one participating project, "without a centralised host of systems for trading partners to use in support of verification and serialised interoperability, the industry must take an active part and collectively come together to evaluate solutions that fit their needs while complying with the law" (Blockchain Interoperability Pilot Project Report, 2020). The FDA intends to release a final report

with results from each pilot to share learnings and insights with supply chain stakeholders, but it will not mandate use of a specific system or technology to comply with regulations.

In the absence of a centrally mandated system in the US, a number of proprietary solutions are being developed in the market and adopted by various stakeholders. As indicated by the projects participating in the FDA Pilot Program, these solutions range from blockchain-based to point-to-point systems for data exchange between supply chain players. Blockchain solutions enable supply chain players to share information with each other through a distributed and shared ledger that all participating stakeholders have access to. Point-to-point systems, on the other hand, facilitate data exchange directly between trading partners who are involved in a transaction. The adoption of multiple solutions within industry could easily cause complications as the DSCSA requires direct data exchange between trading partners. For example, if a wholesaler is supplying medicines to hundreds, or even thousands, of hospitals and pharmacies, it would need to send and receive data from each one individually. If each of these hospitals and pharmacies are using different systems which have unique data formats or requirements, it would become extremely costly and burdensome, if not impossible, for the wholesaler to navigate.

In an environment where multiple solutions or systems are being used to share data between stakeholders, common standards can help reduce this friction. For example, with common data standards, a wholesaler can send data to all its pharmacy and hospital endpoints in the same format, irrespective of the individual systems used by each client. Although exchanging data through multiple systems may still have its challenges, use of standard formats reduces the complexity and costs of processing and handling data along the supply chain.

In 2014, the FDA issued draft guidance on data standards to support interoperable exchange of product tracing information among supply chain stakeholders. The draft guidance indicated that acceptable methods of data exchange could include, but are not limited to, the use of:

- paper or electronic versions of invoices;
- paper versions of packing slips;
- Electronic Data Interchange (EDI) standards, such as 856 Advance Ship Notice (ASN), which is currently used to provide the receiving entity with advance data on shipments; and
- Electronic Product Code Information Services (EPCIS), which defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain (FDA, 2014).

The FDA has not issued further guidance on data standards to date, and the preliminary advice still allows multiple formats to be utilised by industry. Industry stakeholders, however, have recognised the importance of aligning on a common data standard and there has been increasing momentum for EPCIS as the de facto standard for serialised data exchange, which will be required starting in 2023.

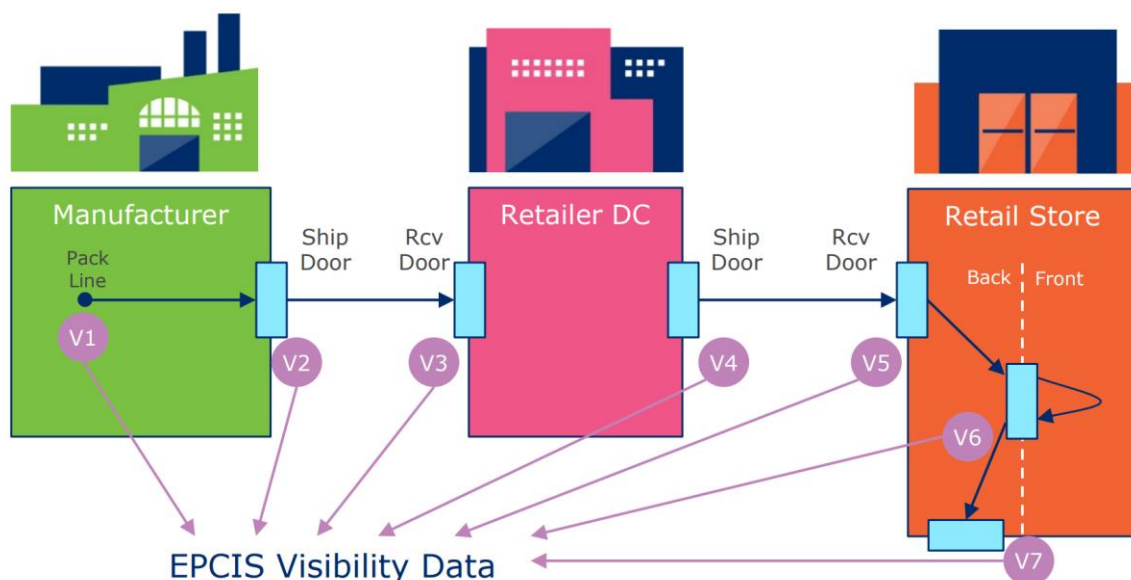
#### *What is EPCIS?*

EPCIS is a data standard developed by GS1, a non-profit that develops and maintains global supply chain standards for business communication. EPCIS defines a common data model for supply chain visibility data and interfaces for capturing and sharing the visibility data within an organisation or across a supply chain (GS1, 2017). The goal of EPCIS is to enable disparate applications used by businesses to create and share data that provides visibility as an object moves throughout the supply chain. EPCIS is a general standard that has applications across industries and business settings, including healthcare, retail, transportation and logistics, and more.

EPCIS breaks down supply chain business processes into individual steps or events, such as commissioning, packing, shipping, receiving, and so forth, and provides a standard language for businesses to communicate essential information regarding these processes with each other. Figure 5 below illustrates the points across a simple supply chain where EPCIS visibility data would be captured: as the product is manufactured and shipped to a distribution centre, where it is subsequently received and later shipped to a retail store, where it is received and later moved into the sales area and finally sold. For each EPCIS event, four dimensions of data are recorded:

1. **What:** information about the product(s) involved
2. **When:** the time and date the event occurred
3. **Where:** the location of the product(s) at the time of the event, and the anticipated location of the next event
4. **Why:** the reason why and context in which the event is occurring, including relevant business processes and transactions.

**Figure 5: Generation of EPCIS Data for Simple Business Process**



Source: (GS1, 2017)

#### *Why industry has broadly aligned on EPCIS*

The DSCSA requires the pharmaceutical industry to be able to digitally trace individual, serialised products throughout the supply chain by 2023. To achieve this, supply chain stakeholders will need to share large volumes of data amongst themselves. Industry stakeholders recognised that common data standards could help reduce costs and improve efficiencies in meeting these requirements, and that alignment would be prudent, even if not mandated by regulation. As explained by Jeffery Denton, the senior director of Global Secure Supply Chain at AmeriSourceBergen, one of the largest pharmaceutical wholesalers and distributors in the US, “using EPCIS message standards provides for a more streamlined process, in that systems are established with similar data file expectations across the supply chain” (GS1 US, 2016b).

A key reason that industry stakeholders have rallied around EPCIS as the preferred data standard is that the benefits of EPCIS adoption could extend beyond compliance, ultimately driving additional business value to industry. For example, EPCIS can provide supply chain data to support tracking and



tracing of recalled products, new product introductions, optimisation of supply chain routes, and more (GS1 US, 2016a). As explained by Chris Reed, former Product Serialisation and Traceability lead at Johnson and Johnson, a large pharmaceutical manufacturer, adoption of EPCIS was “more than just a regulatory compliance effort,” as it was also a means to “improve internal and external supply chain integrity” (GS1, 2016b). Industry stakeholders would have to invest in data capabilities to comply with DSCA, and EPCIS offered a clear opportunity to derive additional benefits and maximise returns from this investment.

Adoption of EPCIS has also been facilitated by support from key supply chain stakeholders and industry associations. As previously illustrated in Figure 3, the most concentrated segment of the US pharmaceutical supply chain is the wholesale-distribution segment, where there are a hundred or so companies, as compared to thousands of producers and hundreds of thousands of dispensers. Furthermore, just three distributors, AmeriSourceBergen, McKesson, and Cardinal Health control nearly 90% of all drug distribution in the US (Deloitte, 2019). Each of these ‘big three’ distributors were part of the Secure Supply Chain Workgroup that defined EPCIS implementation guidelines for DSCSA. Furthermore, each of the ‘big three’ have indicated that they will only support serialised data exchange in EPCIS formats. Given the market control these players wield, their trading partners will either need to comply with EPCIS requirements or forgo doing business with what are likely some of their largest accounts. As more and more industry players adopt EPCIS, the costs of not aligning to EPCIS increase for any given organisation. Thus, the stakeholders with significant supply chain power are able to catalyse industry-wide adoption and alignment.

#### *Implementation of EPCIS for DSCSA*

The EPCIS is a general and flexible standard that can be used for a wide variety of business needs across a number of different industries, and there are numerous options for how the standard could be implemented to accommodate different applications and environments (GS1 US, 2016). To ensure that the standard aligned with the data requirements of the DSCSA and to support consistent application between trading partners, GS1 brought together more than 50 organisations across the industry, including manufacturers, wholesalers, retail pharmacies, healthcare providers, and industry associations to form the Secure Supply Chain Workgroup. The Secure Supply Chain Workgroup developed and published the *Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability* after two years of collaboration. The Implementation Guideline defines the EPCIS events which are required to support both lot-level and item-level data required by DSCSA, and provides guidance on the accompanying XML data formats which are to be used by trading partners.

### **4.3.4 Results and Insights**

#### **4.3.4.1 Compliance Outcomes**

In the EU, the EMVS was launched in 2019, and in its first year, more than 2,000 pharmaceutical companies, 6,000 wholesale distributors, 140,000 independent pharmacies, and 5,000 hospital pharmacies have been connected (European Medicines Verification Organisation, 2020). In the US, while the DSCSA does not come into full effect until 2023, the FDA has delayed enforcement deadlines for several provisions due to industry implementation challenges. For example, the deadline for manufacturers and repackagers to print unique identifiers on individual products was extended after the FDA acknowledged that limited availability of vendors who had expertise in IT systems for data management and specific equipment for packaging and manufacturing lines was contributing to implementation delays (US Food and Drug Administration, 2018). Although stakeholders in the pharmaceutical supply chain were preparing to implement changes, the sudden

increase in demand for support services and equipment led to supply shortages that ultimately hampered adoption efforts. The FDA also extended the deadline for wholesalers to verify saleable returned drug products due in part to “the complexities of building an interoperable, electronic system with the capabilities to timely and efficiently verify the large volume of saleable returned products amid immature technologies” (US Food and Drug Administration, 2019).

Although the US appears to have faced initial delays in implementation, there is no clear evidence to suggest whether the FMD’s centralised approach in the EU, or the DSCSA’s distributed approach in the US, yields better results in terms of drug safety and compliance outcomes. However, as the DSCA comes into full effect in 2023, and the systems to support implementation mature, data will likely become available and enable a robust comparative analysis of the two approaches.

#### **4.3.4.2 Industry Impacts**

In both the EU and US markets, pharmaceutical supply chains have moved quickly to adopt new data sharing practices because it has been mandated by law and is therefore necessary to maintain market access. While regulations have provided a non-negotiable driver for change, businesses have had to navigate trade-offs between minimising complexity and costs, and retaining the right to operate in different markets. For example, according to an employee, TraceLink has seen some of its clients pull out of certain markets because the costs of navigating and complying with regulations in each jurisdiction are simply too high. In other cases, businesses are deciding to scale back the product variety offered for individual medicines (e.g., 10-count pack vs. 25-count pack) because the implications for re-fitting various packaging lines to print unique identifiers on each product are too great. Industry stakeholders have incurred significant costs in adapting to the changes required by these regulations.

#### **4.3.4.3 Results and Insights**

##### *Regulatory design drives complexity*

While regulations will move industry to action, the design of the legislation can have a significant impact on the complexity of the solutions that are implemented, and industry’s ability to comply with required timelines. As the comparison between the EU’s FMD and the US’s DSCSA highlights, clearly established data standards and guidance on system interoperability can help facilitate industry adoption. Although it remains unclear which system ultimately will drive better results, the EU has been able to move more quickly towards implementation and adoption by establishing a centrally-managed system with a well-defined scope. The US’s approach to serialisation and track and trace has placed an additional burden on industry stakeholders by leaving them to organically solve challenges around interoperability. However, as discussed in greater detail below, the US’s industry-led approach could have more innovation potential than the EU’s government-led approach.

##### *Regulation can create opportunities for coordinated industry innovation*

Although the US’s approach of deferring to industry to develop solutions to meet serialisation and traceability requirements has perhaps resulted in more complexity, it has also created an opportunity for private sector innovation. As seen with the GS1-hosted Secure Supply Chain Workgroup and projects participating in the FDA DSCSA Pilot Project Program, organisations across industry have come together to develop and test solutions that can not only meet regulatory requirements but also drive additional business value. The regulatory mandate has created an environment in which the benefits of pre-competitive collaboration are clear and has brought

stakeholders together in a manner that has not been achievable in the past. For example, although EPCIS standards have been available since 2007, there was no significant momentum towards adoption across the pharmaceutical industry until the DSCSA was passed. As industry adopts EPCIS for compliance reasons, businesses will also be able to derive other commercial benefits, including optimisation of supply chain routes and improved product launch planning, from their new data capabilities and accompanying supply chain visibility. However, in the absence of a regulatory mandate, it is unlikely that trading partners and competitors would have had the incentive to come together to define a solution, share in the costs of developing it, or subsequently implement it.

In contrast to the US, the establishment of the EMVS in the EU has to a large extent circumvented the need for pre-competitive, industry-led collaboration. Although regulators solicited industry input in the development of the EMVS, the system was designed with the express purpose of enabling compliance with the FMD and is government owned and managed. The system enables regulators to trace and verify medicines, but does not necessarily unlock private sector supply chain visibility and data capabilities that can deliver additional commercial benefits.

#### *Availability of support services is critical for compliance*

Regulation-driven change can cause a simultaneous spike in demand for support services and infrastructure that enable compliance. This surge in demand can give rise to new businesses opportunities and industries, but can also contribute to shortages, as all supply chain players are seeking the same support and solutions at the same time. Regulators should keep the availability of ancillary support services in mind when establishing compliance deadlines to ensure feasibility. Additionally, regulators and industry bodies could help develop and disseminate guidance related to documentation, implementation, and best practices to help facilitate industry adoption.

## **4.4 Case Study #3: Improved Data Aggregation and Application in Oil & Gas**

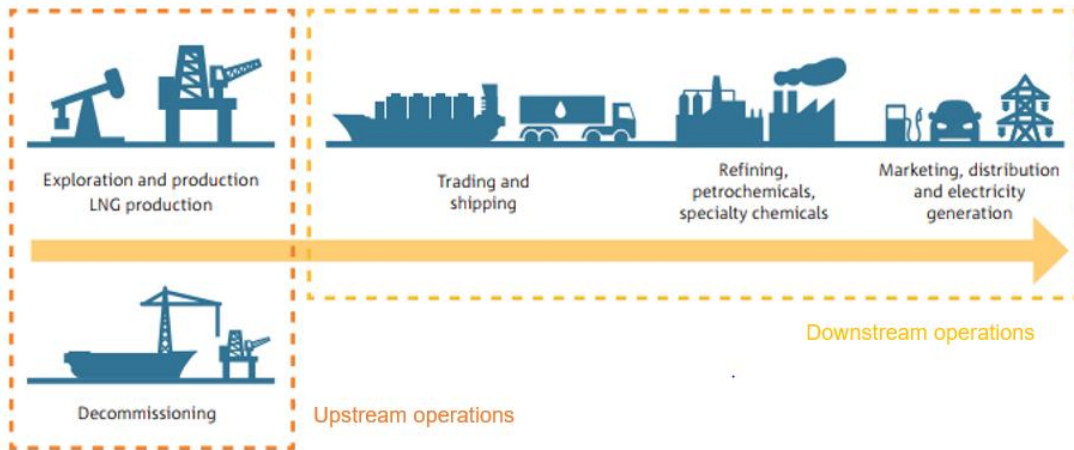
### **4.4.1 Context and Overview**

The oil and gas sector has played a crucial role in the development of Australia's economy. In 2016-17, the domestic oil and gas supply chain contributed \$31 billion to the Australian economy, which equated to approximately 2% of GDP. Total energy exports amounted to around \$59.8 billion in 2015-16, with oil and gas equating to roughly 40% of this total figure (CSIRO, 2017). The exploration and extraction of petroleum is predominately based in Western Australia, particularly the Perth and Carnarvon Basins, while the extraction of natural gas occurs across the entire country (Granwal, 2020). It is estimated 29,000 people are employed in the extraction oil and gas industry in Australia. Although this is significantly less than the agricultural sector, it is on par with the sector's GDP impact (CSIRO, 2017).

Australia exports the majority of its liquified natural gas (LNG) production, with most destined for Asian markets such as Japan, South Korea and China. Since 2009-10, Australian exports of LNG have more than doubled. However, Australia is a net importer of oil which poses an energy security risk for the country (CSIRO, 2017).

Domestic oil and gas supply chains can be segregated into upstream and downstream segments. Upstream operations include exploration, production and decommissioning; and downstream operations include trading, shipping, refining, marketing, distribution and electricity generation (Figure 6). This case study will focus on upstream operations in the domestic supply chain.

#### **Figure 6: Oil and gas supply chain example**



Source: Adapted from (CSIRO, 2017)

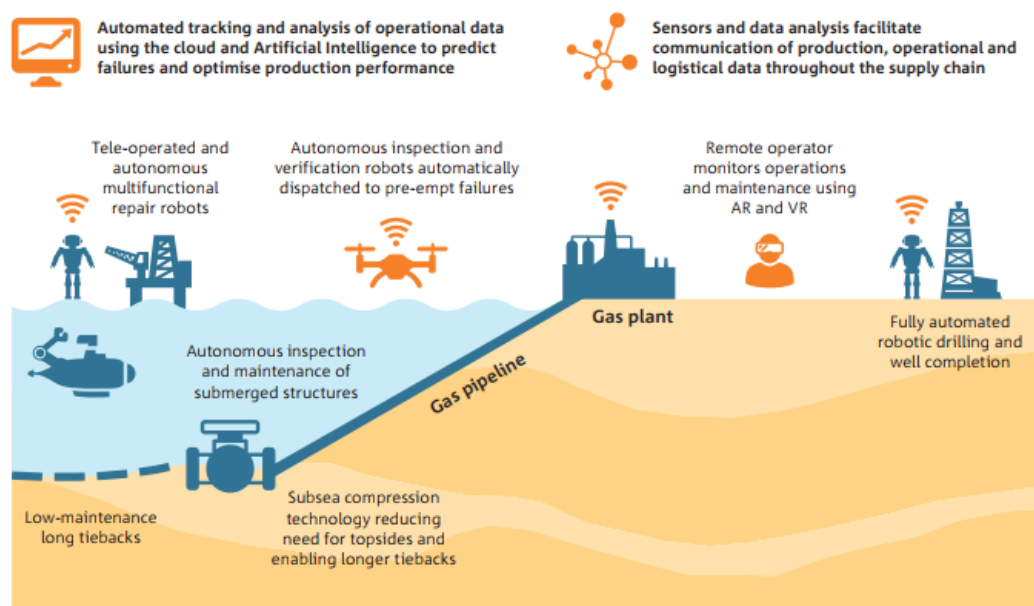
#### 4.4.2 Challenge: Collating Vast Quantities of Unstructured Data to Enable Efficiencies

Despite high growth over the last 15 years, the oil and gas sector is facing significant headwinds for continuing profitability. Regulatory pressures for decarbonising the economy, a sustained decrease in oil prices, and the commodification of the LNG industry are all combining to create an environment of uncertainty and economic pressure. It is estimated that by 2040, global demand for energy will increase by 30% while resources will become increasingly harder to discover and extract. Maximising efficiencies in resource exploration, operation and maintenance, and supply chain management are therefore crucial determinants in remaining competitive.

In 2017, CSIRO released a roadmap for the oil and gas industry to unlock future growth opportunities in Australia. The report identified several opportunities for the sector, and noted that technology and data systems will be pivotal in capitalising on these identified opportunities. They include:

- enhanced basin productivity;
- digital operations and maintenance;
- advanced environmental solutions and processes; and
- high-value diversification.

The value and potential for digital technologies and data analytics to transform the sector appears to be well-understood. It is estimated that digital transformation could create up to \$1 trillion in value for oil and gas businesses globally, partly through allowing a more collaborative ecosystem for innovation. Through the use of increased automation and technology such as robotics, there are opportunities for oil and gas companies to reduce maintenance by 20% and reduce CO<sub>2</sub> emissions by 20 million tonnes (between 2016-26) as well as improve the safety of operations (Figure 7) (CSIRO, 2017).

**Figure 7: A sample future vision for digital operations and maintenance**

Source: (CSIRO, 2017)

While the oil and gas sector is continuously collecting significant amounts of data, it faces critical challenges in making better use of that data for efficiency improvements. The significant volume and vast array of data formats from both public and private sources make it challenging for industry to collate, standardise, and use this information. Before technology such as machine learning and artificial intelligence can be utilised in the oil and gas sector, significant improvement in data aggregation will be required.

*“The challenge for this sector is the integration of multiple technologies to capitalise on the next wave of the digital-enabled future.” – CSIRO, 2017*

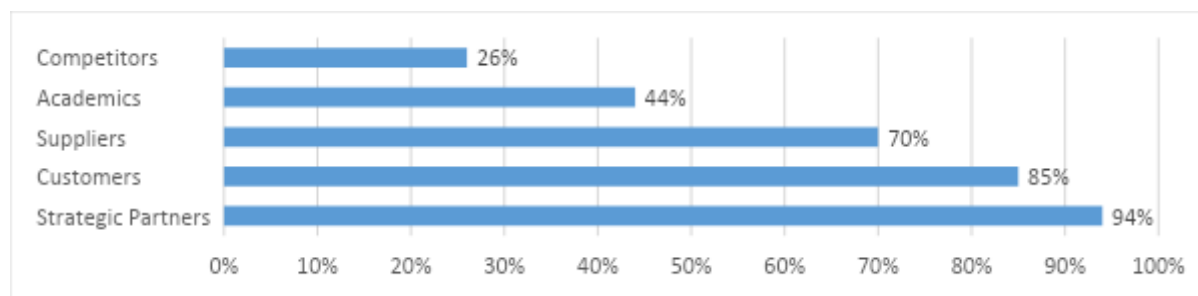
#### 4.4.2.1 Barriers to change

Several interviewees noted that a barrier to change in some cases has been the perception that technological innovations would replace humans in the workforce, thereby displacing jobs. This fear extends from the possible displacement of humans in manual processes by technologies such as autonomous vehicles, through to the potential for data analytics to make knowledge and experience redundant. Interviewees also noted that large companies in the oil and gas sector often struggled with organisational-scale digital transformation. This barrier was described as an inertia which limited rapid change and was driven by factors such as costs of technology implementation. Sensitivity to social license challenges also contributed to this inertia, as technology changes, which could be perceived by the workforce as threats, were treated cautiously by oil and gas companies.

Barriers to collaboration between companies in direct competition with one another also inhibited change. A PwC study surveyed oil and gas executives on their strategic plans for digitisation, innovation and collaboration. Figure 8 shows results regarding collaboration plans: 94% of respondents were planning collaborations with strategic partners in the next 3 years, while only 26% were planning to do so with competitors. Although this 2013 study is now quite dated, it provides relevant considerations regarding the likelihood of pre-competitive collaborations.

Commercial examples mirror these findings. Organisations such as Woodside Energy have their own initiatives for collaboration and innovation with strategic partners such as NASA, rather than competitors. Although this is to be expected given commercial firms wish to maintain a competitive advantage and differentiate from one another, it highlights the importance of public sector work.

**Figure 8: Percentage of oil & gas executives who are planning collaborations to deliver innovation in the next 3 years**



Source: (PwC, 2013)

A more recent and widespread survey of 350 oil and gas executives in 25 countries by the IBM Institute found 39% of respondents ranked 'collaboration across partners outside the organisation' as very important, but only 25% noted it as a high capability strength of their organisation (IBM Institute for Business Value, 2020). The IBM study also noted that less than 50% of respondents said that data and analytics informed their innovation strategies. So while the benefits derived from better use of data are recognised, the collaborative structures and strategic investment required to realise the benefit still lags required effort.

#### 4.4.3 Approach: Data Aggregation and Standardisation

The approach and associated implementation strategy taken by organisations to better utilise data is dependent on the type of data in focus. For example, public datasets describing geo-physical resources will have different challenges and applications than commercially sensitive data relating to machine maintenance and organisational operating systems. While oil and gas companies benefit from more efficient data use in both cases, there is an additional public good aspect to using data for better resource identification and extraction, as public assets are used more efficiently and with minimal environmental impact.

Data held by organisations such as Geoscience Australia and Government departments is available to the oil and gas industry at large, meaning initiatives to improve its utilisation benefit the entire sector. Whereas insights delivered from company operational data through machine learning and artificial intelligence provides competitive advantage for the benefit of the company. Examples of both approaches are explored below in further detail.

##### 4.4.3.1 Data for industry benefit: resources efficiencies and environmental drivers

The **Geoscience Data Modernisation Project** managed by the Geological Survey of Queensland aims to enable data-driven exploration and future success for the sector. The major outcome of the Geoscience Data Modernisation Project has been the creation of an online data portal<sup>2</sup> to allow easy and fast access to open file geoscience data and company reports. A soon to be released outcome of the project is access to data from tapes and disks which were not previously available online. This

<sup>2</sup> <https://vocabs.gsq.digital/>

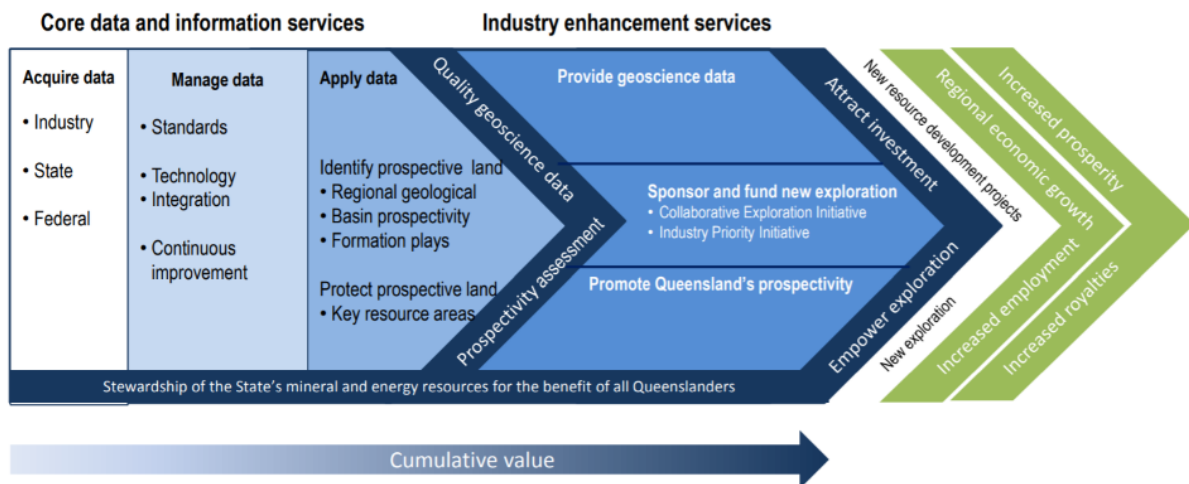
platform allows for enhanced efficiency and capabilities for searching data, including linked data functionality and the ability to draw inferences and discoveries from different geoscience data types.

Data analytic capabilities have been enhanced ‘through a standards-based metadata catalogue’ to provide data which is more meaningful and can support AI and machine learning (Knight, 2019). There are numerous forms of data which are available on the platform, some examples include:

- 3D data sets
- GIS packaging
- electrical surveys;
- geological mapping data;
- map collections; and
- radiometric surveys.

Figure 9 highlights the public good aspect driving Government involvement in enhancing data information services. This also demonstrates the value proposition for transformative changes involving data. Attributes of this cumulative value stream could potentially be applicable or replicated in other industries.

**Figure 9: Value Stream of Queensland Government involvement in Geoscience data**



Source: (Knight, 2016)

### Leadership & Consensus Building

Interviewees noted that the need for the outputs from the Geoscience Data Modernisation Project had been apparent for decades. Although the project was not politically driven, it has had political support from the Government, which has been beneficial in its progression. Strong internal senior management and external stakeholder support were also mentioned as important factors in building consensus and contributing to the overall success of the project.

A lengthy stakeholder consultation period of 12-18 months was undertaken as part of the project, which included influential stakeholders such as the Queensland Resources Council as well as commercial stakeholders. Project members were advised on their sentiment when speaking and engaging with stakeholders to ensure relationships were carefully managed. This strong stakeholder engagement period allowed cultural barriers and aversions to change to be overcome, such as the

perception that short-term costs and efforts would not be worth the long-term, transformational benefits to the sector.

The project first focused on delivering the highest value proposition to help showcase the benefits of the project to stakeholders. This involved a pilot release of data in July 2019 which provided 400% more geoscience data than was previously available to industry online. Essentially, the pilot provided an example of the output of the project prior to the final completion date. Since the project was operated by a Government organisation, the project team was able to promote regulation which directed that compliance data be provided in more structured formats. However, the lengthy consultation period with relevant stakeholders aided in ensuring that the mandated changes considered industry opinions and perspectives.

### Technical Design and Capability

Three key principles were embraced in the design of the data platform - scalability, broad compatibility, and data structures enabling machine learning and artificial intelligence.

To achieve scalability and economies of scale, the platform was built using cloud rather than in-house storage (i.e., Amazon Web Services). The project team estimated that the cloud-based approach resulted in 90% savings on data storage costs. Broad compatibility was achieved by focusing on universal common components in digital supply chains, rather than industry-specific processes or technologies. For example, sensors and sensing technology were identified as the common component regardless of the industry specificity of the application. This led to the adoption of an international standard on sensor data - the Sensor Open Systems Architecture (SOSA)<sup>3</sup> - as the underpinning data architecture for the platform.

#### ***SOSA Technical Standard***

**Sensor Open Systems Architecture (SOSA)** are a set of technical standards created through a 'unified modular open reference architecture'. They are applicable to commercial sensor systems with the aim of increasing interoperability and accelerate the adoption of affordable sensor systems (SOSA, 2020).

The Geoscience Data Modernisation Project team chose to use these standards over others, which were more specific to the oil and gas sector, to adopt international best practices and increase the longevity of the output of the project. This approach of using technology specific rather than sector specific standards suited the project and its desired outcomes.

Data linked through a common vocabulary is critical to facilitating machine learning and artificial intelligence approaches. A major part of the project has therefore been creating the vocabulary needed,<sup>4</sup> as none existed for oil and gas sector applications. The vocabulary was developed in-house and is already being adopted as a national and international standard in some cases and extended into other sectors (e.g. in many instances there is overlap with the natural resources sector in terms of geological descriptions, etc). It defines both terminology within the oil and gas sector, and the

<sup>3</sup> <https://www.opengroup.org/sosa>

<sup>4</sup> <https://vocabs.gsq.digital/>



relationships between terms, which is integral to machine learning and artificial intelligence capabilities.

While the initial design of the platform has been focused on the aggregation of existing datasets, it is very much intended to be constantly updated with new industry and public data as it becomes available. Lodgement portals<sup>5</sup> and Microsoft Excel-based templates have been developed to help ensure standardisation and provide quality assurance as private companies upload their own data into the system.

The project also included a strong focus on data governance. Several forums were set up at different levels to govern data standards and usage. The *data governance group*, for example, had a strategic focus at a management level, while a *data integrity team* worked at an operational level to govern data mechanics, and a group of *data managers* were established to focus on the day-to-day quality assurance of the data across sectors including oil, gas, petroleum and minerals.

As the data modernisation project is yet to be completed, full insights into the value and uptake by industry are unknown. However, engagement with industry to this point indicates likely success, and metrics on data retrievals and contributions will enable an assessment of effectiveness in the future.

#### **4.4.3.2 Data for company benefits: commercial application of machine learning technology**

Woodside Energy is a natural gas producer in Australia and is one of the largest leading LNG producers globally (UNSW, 2018). After using the IBM Watson interface to aid their analytics capacity, they have gone on to develop an in-house cognitive computing and advanced analytics application. This capacity has allowed Woodside to make better use of data being collected to improve commercial efficiency and make new process discoveries.

##### **Leadership & Consensus Building**

Senior management at Woodside noted the importance of maximising the value of decades worth of operational data. Senior engineers' knowledge of data capture and usage practices was also identified as a key asset that needed to be built into data analysis processes and passed on to junior engineers (IBM, 2019). Once Woodside identified opportunities for generating better and more valuable insights from its data and knowledge, IBM was engaged to develop and implement the Watson Assistant solution.

##### **Technical Design and Capability**

Although implementation of a solution was outsourced, Woodside developers were involved in the process, particularly regarding the application program interfaces (APIs). Advanced text analysis and algorithms were used to aggregate the unstructured data into a format which enabled the creation of relationships among elements of data, enabling more sophisticated machine learning capabilities (IBM, 2019).

Several versions of the IBM Watson platform have been implemented throughout different sections of the company, including drilling and workplace health and safety. This was done to accommodate the different languages, sublanguages and terminology used in various disciplines and departments within the organisation. Using the IBM Watson interface, Woodside Energy has reportedly saved A\$10 million in employee costs from increased efficiencies when accessing and analysing data and

---

<sup>5</sup> <https://geolodgemnet.dnrme.qld.gov.au>

reduced the amount of time geoscientists spend on searching and reading sources by 75% (IBM, 2019).

Building upon the IBM Watson interface, Woodside Energy has created its own virtual assistant, Willow. The goal of this technology is to create a central workstation for the entire organisation to communicate, access information and complete tasks to increase business productivity and efficiencies (Woodside, 2018).

The technology solutions Woodside Energy is implementing are focused on increasing commercial efficiency and producing a competitive advantage. There is little incentive and a lack of value proposition for commercial organisations like Woodside to ensure the standards used to implement data-driven technologies within their organisations are compatible with their competitors' standards.

For example, academics at the University of South Australia noted a lack of an open standards-based framework to enable condition-based predictive maintenance (CBPdM) (Kaur, et al., 2018). Predictive maintenance models would require data inputs from various sources and organisations. However, companies do not appear to have a coordinated approach for collecting data on maintenance logs and operating systems to enable collaboration and improved efficiencies and productivity.

Therefore, data utilisation and aggregation initiatives within the oil and gas sector vary depending on whether the data is a public good or owned by an organisation and commercially sensitive. The application of digital technologies which enhance the use of data in commercial organisations, such as Woodside Energy, are underpinned by the work of Government initiatives such as the Queensland Data Modernisation Project. Without the strong foundations of data access, standardisation and machine learning capabilities, the value proposition for the commercial application of these technologies is not maximised.

#### **4.4.4 Results and Insights**

There is great pressure to deliver increased commercial efficiency in oil and gas supply chains to counter declining profitability. The sector has focused on delivering increased efficiency through better analysis of data, enabling a range of outcomes including more targeted resource identification and extraction, and predictive maintenance. However, a significant barrier to this process has been finding and connecting to appropriate data: estimates indicate that companies were spending 80% of their time in this activity, and only 20% of their time performing analysis on the data collected.

*Collaboration between competitors can be difficult to foster, even if could benefit wider industry*

Commercial organisations have little incentive to ensure standards for internal data collation are compatible with competitors. Although this is to be expected given commercial firms wish to maintain a competitive advantage and differentiate from one another, it highlights the importance of public sector work. Transformational change to benefit the entire industry, such as the work done by the Queensland Data Modernisation project, can be successful when fostered by Government organisations who are able to mandate changes through regulation.

*Regulation resulted in a rapid value demonstration which overcame industry inertia*

While industry recognised the need to improve data aggregation to enable better analysis, the scale of transformational change required had slowed progress. The Queensland Government, having a

progressive attitude towards open data, was able to accelerate change through a regulated approach. By requiring oil and gas companies to submit compliance data in more structured formats, a process of change was enabled.

The result of this initiative has been the rapid development of an open data hub specifically designed to facilitate machine learning and artificial intelligence analysis of multiple historical and ongoing datasets provided from both public and industry sources. Industry buy-in has been achieved as the commercial value enabled by access to this data has been realised. It is likely that without the Queensland Government initiative and regulatory approach, industry reluctance to change would have prevented the development of such an initiative, even though the need was identified and understood by industry. A drive to deliver the highest value in initial versions of the final product also ensured that industry could see the value of participating in the initiative.

#### *Look beyond industry standards for solution longevity*

In addition to new requirements for data submission, a significant amount of development was required to create the data infrastructure, governance and standards that would enable the creation of an open data hub that was genuinely useful to the sector. The underpinning data architecture for the Queensland Government data platform - Sensor Open Systems Architecture (SOSA) – is focused on sensors and sensing technology rather than technology specific to the oil and gas sector. This provides broad compatibility and longevity in the solution, as well as opportunities to utilise the created vocabulary in other areas.

#### *Importance of data governance and ecosystem support in fostering success*

Data governance is an important foundational element of improved data utilisation and aggregation. The Queensland Data Modernisation project focused significantly on establishing robust governance structures to ensure the longevity and success of the project. Ecosystem support is also integral to success of data-driven technology solutions. In both Government initiatives and commercial examples of technology change, ensuring senior management and the wider organisation are on board has been a critical factor determining the success of the change.

## **5. Conclusion**

While insights from individual case studies are presented in Section 4 above, this section provides a synthesis of learnings across the three case studies and considers the application of these insights in Australia's red meat industry.

### **5.1 Key findings**

#### **5.1.1 Insights framework**

The three case studies examined in this report provide three very different examples of data and technology transformation: (i) a private company overhauling its internal inventory management system, (ii) regulations catalysing new systems to share data and verify products across a supply chain, and (iii) efforts to harmonise and aggregate data collected by individual actors across industry. As varied as these examples are, they can be analysed through a common framework to extrapolate general insights that can be applied across industries and business contexts. This analysis framework, detailed below, was developed to help classify different archetypes of data and technology transformation efforts and subsequently identify options for industry engagement to ensure successful implementation.

Two critical features that can be used to classify data and technology transformations are (i) the stakeholder(s) that stand to benefit from change, and (ii) the level of coordination required to successfully implement change. The stakeholders who might benefit from change can range from an individual organisation to the whole of industry. Similarly, successful implementation could be achieved by an individual organisation on one end of the spectrum, or require coordination across the value chain on the other end of the spectrum. The combination of these features gives rise to four possible outcomes, illustrated in Figure 10 below. In the sub-sections below, we demonstrate each of these outcomes in the context of the case studies presented in this report and explore how the red meat industry can apply insights to its own efforts for data and technology transformation.

**Figure 10: Classification framework for data and technology transformation archetypes**

		Level of coordination required	
		<i>Company</i>	<i>Cross-value chain</i>
Who accrues the benefit of change	<i>Company</i>	<b>I.</b> Individual, internal change	<b>II.</b> Industry impasse
	<i>Industry</i>	<b>IV.</b> Uncoordinated change	<b>III.</b> Possible, but improbable, change

**5.1.1.1 I. Individual, internal change**

*Overview*

The first outcome represents initiatives in which an individual organisation can benefit from implementing a change and it has the ability to independently execute the necessary change. In such situations, the organisation would be expected to implement the transformation on its own, provided that the benefits outweigh the costs of change. Nike’s decision to implement an RFID-enabled inventory management system within its own supply chain is a prime example of this category of change. The company had strong convictions about the benefits that RFID technology would deliver to its business, and it also had the independent ability to implement the technology in its own distribution and retail network. With full control over the transformation agenda and a clear business case to adopt change, Nike has not hesitated to invest in its RFID capabilities.

Nike, however, remains an outlier in the apparel industry, and is only one of very few organisations who are implementing RFID technology to improve their supply chain visibility. Most of the apparel industry has not moved towards adoption, despite seemingly having similar incentives and ability to drive change. Why is this the case?

One reason other apparel companies have not moved towards RFID adoption is that they lack a clear understanding of the business case to do so. While Nike views RFID capabilities as a crucial driver of growth and customer success, other companies may not have a strong quantifiable basis on which to evaluate the merits of RFID capabilities. Additionally, they may face inertia as large investments in the short-term are required to enable future benefits. Strong leadership is required to catalyse organisational change in these circumstances. In the future, if Nike and other key brands are able to demonstrate success in their RFID initiatives, we might expect more of the industry to follow their lead.

#### *Insights for industry implementation*

- **Develop and demonstrate the business case:** Organisations need to be equipped with a strong business case and clear evidence of value in order to adopt change. In Australian red meat, industry groups such as ISC and MLA could play a key role in demonstrating the value of data and technology transformations that organisations can implement on their own to help catalyse change. Technology solution providers (e.g., RFID vendors in the Nike example) or research groups (e.g., Auburn University RFID Lab) could also help gather evidence and articulate the value proposition for industry organisations to adopt change.
- **Build awareness and capabilities, not solutions:** In situations where there is a strong business case for organisations to adopt change and they can independently implement change, the private sector will organically build and deploy solutions. In these circumstances, ecosystem supporters should seek to build awareness and capabilities where gaps may exist, but they should be careful not to crowd-out private sector innovation and investment by building or proposing solutions of their own.

#### **5.1.1.2 II. Industry impasse**

##### *Overview*

When an individual organisation stands to benefit from the implementation of a data or technology solution, but requires cooperation from its supply chain partners to succeed, change is unlikely to occur. A misalignment of incentives, control, and required effort along the supply chain makes collaboration difficult and is likely to result in an impasse. For example, Nike could realise additional benefits if its retail partners developed capabilities to read and write data to the RFID tags embedded in Nike products. Cooperation from retail partners would give Nike full visibility of product movement across all of its sales channels, not just brand-owned channels. However, Nike's retail partners are unlikely to benefit from the investment in RFID scanners and processes unless all of the inventory they carry is RFID-enabled. So long as traditional barcodes are used on other products held by these retail partners, they will incur the costs of building RFID-compatible capabilities and still face the costs and challenges of traditional inventory management.

One way in which Nike is addressing this misalignment of incentives with its retailers is reducing the number of retail partners they work with. Nike is not only reducing its dependence on external retail partners but also increasing the value of its limited partnerships. Nike's powerful brand and selective partnership model may provide sufficient incentives for some retailers to invest in the capabilities that Nike may demand of them in the future in order to retain the account. Nike is also reportedly working to develop business cases to demonstrate the value of RFID capabilities to its retail partners to help motivate cooperation and adoption.

*Insights for industry implementation*

- **Create and redistribute incentives:** Organisations who would benefit from change need to create or share incentives with their supply chain partners in order to break gridlock. Incentives could take the form of either positive rewards, such as premiums or preferred trading status, or penalties, such as loss of market access. In order to successfully implement penalty-based incentives, however, organisations must command sufficient market power or risk losing trading relationships.

**5.1.1.3 III. Possible, but improbable, change**

When multiple stakeholders in an industry could benefit from the implementation of a coordinated data or technology transformation, change is theoretically possible, but practically difficult to achieve. In theory, distributed incentives should enable industry stakeholders to coordinate and problem solve in a win-win manner. However, the practical challenges of collaborating across organisational boundaries in a competitive environment, often make successful implementation difficult. The coordination challenge is particularly difficult to overcome if there are significant imbalances in the potential reward and required effort across the supply chain--for example, if there are some stakeholders who would benefit greatly with little investment required, while other stakeholders who would benefit moderately with large investment required.

Serialisation and track and trace in pharmaceutical supply chains provides an example of a situation in which industry players were unable to overcome coordination challenges on their own in order to implement changes that could benefit all of industry. Protection against counterfeit and falsified medicines and improved supply chain visibility could benefit all value chain stakeholders from manufacturers through to health care providers. However, in the absence of regulation, the pharmaceutical industry was not able to align on and implement a coordinated approach to serialisation and track and trace. Regulations have now brought the pharmaceutical industry together to implement capabilities for serialisation and track and trace under non-negotiable terms. In the EU, regulators further side-stepped industry coordination challenges by building a centralised data system that industry is now required to adopt. Meanwhile, in the US, regulations have created an environment in which industry has had to pre-competitively collaborate to develop and implement solutions.

*Insights for industry implementation*

- **Align incentives amongst industry players:** When supply chain stakeholders have common objectives and equal skin in the game, the probability of successful collaboration is likely to be higher. Regulation can be a viable pathway to align incentives and achieve coordination, in circumstances where a public benefit may also accrue from industry collaboration (e.g., consumer safety, biosecurity, etc.). In situations where there are no public benefits, private organisations could seek to redistribute value capture along the supply chain in order to incentivise cooperation from other industry players.
- **Ease coordination challenges:** Industry organisations, government agencies, and other ecosystem support organisations can also help the private sector overcome coordination challenges to successfully implement shared solutions. Approaches to easing coordination challenges could include building or defining potential solutions, developing open standards that enable cooperation, or creating mechanisms (e.g., working groups, pilot programs, etc.) that bring industry players together to collaborate in pre-competitive settings.

#### 5.1.1.4 IV. Uncoordinated change

##### *Overview*

Finally, in situations where multiple industry stakeholders could benefit from data and technology transformations, and individual organisations have the ability to implement the necessary changes, change is expected to occur in a fragmented nature. Individual organisations for whom the costs of implementing change are outweighed by the potential benefits would be expected to drive change on their own, developing solutions and approaches that are best suited to their own business needs and operations. As a result, the industry could see development and use of many different solutions to the same fundamental problems. This is not necessarily an issue, and could be a healthy outcome as it could help drive innovation and competition in the solution market. However, if there is additional value (including public good outcomes) that can be extracted from a coordinated industry effort, then having fragmented approaches could be a challenge.

For example, in the oil and gas industry, stakeholders across the value chain have developed independent solutions for collecting and analysing maintenance and operational data that can enable commercial efficiencies. However, the aggregation of this data for application in machine learning and artificial intelligence models could deliver additional value to industry by reducing environmental and safety risks and increasing efficiencies related to resources exploration and extraction. The fragmented nature of existing data collection, storage, and management approaches has inhibited aggregation and advanced application efforts; a challenge that industry and government stakeholders are now attempting to address.

##### *Insights for industry implementation*

- **Establish common standards:** Common and open data standards and formats can help ensure interoperability between proprietary solutions that are developed by the private sector. Large industry players or stakeholders who command significant market power can play a key role in establishing common standards and setting precedents or expectations within industry. Industry associations, regulators, and standards developers (e.g. GS1) can also help promote and implement standards across a supply chain.
- **Regulated change can lead to wider impact:** Demonstrated benefit from well-designed regulatory changes applied to compliance processes can overcome inertia to adopting similar processes in un-regulated areas. Accelerated industry and internal change may be achieved by industry organisation and government led processes which may be driven by public good outcomes but are implemented in a way which improves commercial efficiency.

## 5.2 Benefits to industry

Our research and analysis points to three key ways in which industry bodies such as ISC and MLA can support the implementation and adoption of data and technology solutions in the Australian red meat industry:

1. **Build the case for change:** help jumpstart industry-led efforts by building and demonstrating robust business cases for change when value-propositions are poorly understood or unproven for industry;
2. **Facilitate coordination:** help align motives and incentives for collaboration amongst industry players and host mechanisms that promote pre-competitive collaboration;

3. **Ensure interoperability:** help develop and promote open standards that allow industry to innovate in an additive and cohesive manner; ensuring interoperability of systems and solutions used by industry not only makes coordination more achievable, it can also increase the value and possible applications of those solutions in the long-run.

The insights framework can help guide ISC, MLA, and other industry stakeholders in designing interventions and support activities that will be most effective and efficient in facilitating data and technology transformations in the red meat supply chain. The insights framework also helps to distinguish between situations in which regulators and industry bodies are best placed to drive change, and those in which the private sector is best suited to independently lead efforts. The application of the lessons and insights from this study can help ISC deliver on the Integrity Systems 2025 Strategy and support industry in using data and technology to improve supply chain integrity and unlock new value.

## 6. Future research and recommendations

Technology and data use applications that could be transferred to the red meat industry were identified in the case studies detailed above. However, it was also evident that there were key factors common to successful technology implementation across all the case studies. These factors - ***building the case for change, facilitating coordination, and ensuring interoperability*** - provide guidance for how industry bodies such as ISC and MLA can support the implementation and adoption of data and technology solutions for the sector.

### *Building the case for change*

ISC should continue to highlight the value proposition of better data use throughout the supply chain through the continual development of an evidence base, backed by engaging and specific case studies targeted at key stakeholders. In particular, ISC can support industry to quantify the economic benefits of proposed data sharing initiatives to help spur adoption. Economic and cost-benefit analyses can help establish a clear value proposition and help industry overcome inertia.

### *Facilitating coordination and ensuring interoperability*

Development of the Australian AgriFood Data Exchange by ISC and others provides a pathway through which coordination and interoperability of data can be enabled. However, additional and parallel work to the development of the data exchange will be required to ensure that the full value of the data collection is realised, for both private and public benefit. To complement the development of the Australian AgriFood Data Exchange, and to incorporate the learnings from the case studies compiled in this report, we recommend that:

- ISC should commission the construction of a red meat industry data vocabulary, and
- ISC should facilitate a process for industry-led determination of an open data standard and open-source frameworks to enable private sector to implement the standard.

These initiatives, if adopted as part of a data aggregation process, would reduce complexity in analysis and lead to more rapid adoption of tools and processes to realise the full value of digital transformation in the red meat supply chain.



## 7. References

Adams, P. (2019). China is hungry for Australian beef, but every second kilo shoppers buy could be fake. *ABC News*, [online]. Available at: <https://www.abc.net.au/news/2019-11-03/blockchain-detecting-beef-fraud-in-australian-exports-to-china/11662950>

Auburn University RFID Lab (2019). Chain Integration Project: Proof of Concept Whitepaper.  
Distelhorst, G., Hainmueller, J. and Locke, R.M. (2017). Does Lean Improve Labor Standards? Management and Social Performance in the Nike Supply Chain. *Management Science*, 63(3), pp.707–728.

Blockchain Interoperability Pilot Project Report. (2020). [online] Available at: [https://www.merck.com/wp-content/uploads/sites/5/2020/07/FDA\\_DSCSA\\_Interoperability\\_Pilot\\_Project-Final\\_Report\\_Feb2020.pdf](https://www.merck.com/wp-content/uploads/sites/5/2020/07/FDA_DSCSA_Interoperability_Pilot_Project-Final_Report_Feb2020.pdf).

Center for Drug Evaluation and Research (2019a). Drug Supply Chain Security Act (DSCSA). [online] U.S. Food and Drug Administration. Available at: <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>.

Center for Drug Evaluation and Research (2019b). DSCSA Pilot Project Program. [online] U.S. Food and Drug Administration. Available at: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/dscsa-pilot-project-program#:~:text=FDA's%20DSCSA%20Pilot%20Project%20Program,distributed%20within%20the%20United%20States>.

Cosgrove, E. (2019). When it comes to speed, Nike says RFID is key. [online] Supply Chain Dive. Available at: <https://www.supplychaindive.com/news/Nike-RFID-speed-inventory/557875/>.

CSIRO. (2017). Oil and Gas: A Roadmap for unlocking future growth opportunities for Australia. CSIRO.

Deloitte, (2019). The role of distributors in the US health care industry. [online] Available at: <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf>

emvo-medicines.eu. (n.d.). The EMVS and NMVOs : EMVO. [online] Available at: <https://emvo-medicines.eu/mission/emvs/#countries>

European Medicines Agency (n.d.). Falsified medicines: overview. [online] Available at: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/falsified-medicines-overview>

European Medicines Verification Organisation (2020). The European Medicines Verification System (EMVS) celebrates its first anniversary!. [online] Available at: [https://emvo-medicines.eu/new/wp-content/uploads/EMVS\\_1\\_year\\_anniversary.pdf](https://emvo-medicines.eu/new/wp-content/uploads/EMVS_1_year_anniversary.pdf).

Granwal, L. (2020). *Oil and gas industry in Australia*. Statista. <https://www.statista.com/topics/5608/oil-and-gas-industry-in-australia/>

GS1 Australia (n.d.). RFID in Retail - GS1 Australia. [online] Available at: <https://www.gs1au.org/for-your-industry/general-merchandise/rfid-in-retail/>

GS1 US, (2016a). Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2. [online] Available at: [https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core\\_Download&EntryId=749&language=en-US&PortalId=0&TabId=134](https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=749&language=en-US&PortalId=0&TabId=134)

GS1 US, (2016b). Case Study: Piloting Traceability with GS1 Standards, AmerisourceBergen teams with Johnson & Johnson Supply Chain for significant learnings. [online] Available at: [https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core\\_Download&EntryId=718](https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=718)

GS1, (2017). EPCIS and CBV Implementation Guideline: Using EPCIS and CBV standards to gain visibility of business processes, Release 1.2. [online] Available at: [https://www.gs1.org/docs/epc/EPCIS\\_Guideline.pdf](https://www.gs1.org/docs/epc/EPCIS_Guideline.pdf)

IBM. (2019, August 13). *Woodside Energy*. <https://www.ibm.com/case-studies/woodside-energy-watson-cognitive>

IBM Institute for Business Value. (2020). *Essential tactics to foster innovation in oil and gas*. IBM Corporation.

IQVIA Institute for Human Data Science (2020). Global Medicine Spending and Usage Trends: Outlook to 2024. [online] Available at: <https://heatinformatics.com/sites/default/files/images-videos/FileContent/global-medicine-spending-and-usage-trends.pdf>

Integrity Systems Company, (2018). *Strategic Plan: Integrity System 2025 and beyond*. [online] New South Wales: Integrity Systems Company. Available at: <https://www.integritysystems.com.au/globalassets/isc/pdf-files/integrity-system-2025-strategic-plan.pdf>

Kaul, A., Kellogg, K., Kelly, E., Jay, J., Patten, B. and Truelove, E. (2017). Hannah Jones and Sustainability at Nike (B). MIT Sloan School of Management.

Knight, T. (2016). *Geological Survey of Queensland*.

Knight, T. (2019). Approaches to data-driven exploration in Queensland. *The APPEA Journal*, 59(2), 896–898. <https://doi.org/10.1071/AJ18077>

Lerner, Gary (2020). Visibility Requires Connectivity and Interoperability. Presented at GS1 Connect: Digital Edition.

Nike News. (2017). NIKE, Inc. Announces New Consumer Direct Offense: A Faster Pipeline to Serve Consumers Personally, At Scale. [online] Available at: <https://news.nike.com/news/nike-consumer-direct-offense>.

Nike, Inc. (2019). 2019 Annual Report and Notice of Annual Meeting. [online] Nike, Inc. Available at: [https://s1.g4cdn.com/806093406/files/doc\\_financials/2019/ar/354352\(1\)\\_76\\_Nike-Inc\\_COMBO\\_WR\\_R1.pdf](https://s1.g4cdn.com/806093406/files/doc_financials/2019/ar/354352(1)_76_Nike-Inc_COMBO_WR_R1.pdf).

Nike, Inc. (2020). Nike, Inc. Annual Shareholder Meeting Transcript September 17, 2020. [online] Nike, Inc. Available at:

[https://s1.q4cdn.com/806093406/files/doc\\_downloads/2020/09/NIKE-Inc-2020-Annual-Shareholders-Meeting-Transcript-FINAL.pdf](https://s1.q4cdn.com/806093406/files/doc_downloads/2020/09/NIKE-Inc-2020-Annual-Shareholders-Meeting-Transcript-FINAL.pdf)

OECD/EUIPO (2020). Trade in Counterfeit Pharmaceutical Products. *Illicit Trade*, OECD Publishing, Paris. Available at: <https://doi.org/10.1787/a7c7e054-en>.

Pew Charitable Trusts (2014). Timeline for the Drug Supply Chain and Security Act (Title II, Drug Quality and Security Act, 2013). [online] Available at: <https://www.pewtrusts.org/-/media/assets/2017/05/timelineforthedrugsupplychainandsecurityact.pdf>

PwC. (2013). Gateway to growth: Innovation in the oil and gas industry. <https://www.pwc.com/gx/en/oil-gas-energy/publications/pdfs/pwc-gateway-to-growth-innovation-in-the-oil-and-gas-industry.pdf>

SAP. (n.d.). SAP Advanced Track and Trace for Pharmaceuticals | Serialisation Software. [online] Available at: <https://www.sap.com/australia/products/track-trace-pharmaceuticals.html>

Schifrin, D., Carroll, G. and Brady, D. (2013). Nike: Sustainability and Labor Practices 1998-2013. Stanford Graduate School of Business.

SOSA. (2020). *About the SOSA Consortium*. SOSA. <https://www.opengroup.org/sosa>

UK Medicines and Healthcare products Regulatory Agency (2018). Implementing the Falsified Medicines Directive: Safety Features. [online]. Available at: <https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features>

US Food and Drug Administration, (2014). DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information Guidance for Industry DRAFT GUIDANCE. [online] Available at: <https://www.fda.gov/media/90548/download>

US Food and Drug Administration, (2018). Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy: Guidance for Industry. [online] Available at: <https://www.fda.gov/media/106198/download>

US Food and Drug Administration, (2019). Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy: Guidance for Industry. [online] Available at: <https://www.fda.gov/media/131005/download>

Woodside. (2018). You asked for it. *Truckline*. [https://files.woodside/docs/default-source/news-and-media-documents/publications/2018q1.pdf?sfvrsn=5925eedc\\_10](https://files.woodside/docs/default-source/news-and-media-documents/publications/2018q1.pdf?sfvrsn=5925eedc_10)

## 8. Appendix

### 8.1 Long list of use cases for supply chain data and technology transformations

Drivers of Data & Technology Transformation	Application to Red Meat Industry
Provenance (Marketing, Risk)	Proving origin and authenticity of products to protect against fraud and counterfeit products
Compliance (Regulatory, Risk)	Demonstrating compliance with industry standards and regulatory requirements
Safety (Regulatory, Risk)	Capabilities to identify and contain contaminants or other safety risks in a manner that limits waste and losses across the supply chain
Efficiency (Commercial)	Enable supply chain improvements, coordination, and optimisation to maximise value capture in low-margin setting (e.g., demand planning and forecasting)
Storytelling (Marketing)	Meeting consumer demand and achieving premium positioning for goods that are sustainably and ethically produced
Responsibility (Marketing, CSR, Risk)	Enable individual organisations and collective industry to uphold and improve upon CSR and sustainability commitments

### 8.2 Anonymised List of Interviewees

Title & Organisation	Category
Researcher, Auburn University RFID Lab	Apparel (Nike)
Supply Chain and Operations Manager North America, Nike	Apparel (Nike)
Consulting Manager, GS1 Australia	Apparel (Nike); Pharmaceutical
Previous CEO, PCI Pharma Services	Pharmaceutical
Director, TraceLink	Pharmaceutical
General Manager, National Energy Resources Australia	Oil and Gas

Project Manager, Queensland Data Modernisation Project	Oil and Gas
Research Fellows, University of South Australia Industrial AI Lab	Oil and Gas
Professor, NC State University Poole College of Management	General (Supply Chain and Operations)
Professor, MIT Sloan School of Management	General (Supply Chain and Operations)
Research Scientist, MIT Center for Transportation and Logistics	General (Supply Chain)
Associate Partner, EY	General (Technology and Supply Chain)

### 8.3 DSCSA Timeline

Measure	Implementation Date	Description	Relevant Parties
Trading with authorised trading partners	January 2015	Sales transactions must only take place between appropriately licensed or registered trading partners	Manufacturers Repackagers Wholesale distributors Dispensers
Provide transaction information to trading partners	January 2015 July 2015 (dispensers)	Transaction information (what drugs were shipped, when, and to whom), transaction history, and transaction statement must be shared with trading partners, and product ownership should not be accepted unless this information is received. Transaction information, history, and statements should be made available to regulators upon request.	Manufacturers Repackagers Wholesale distributors Dispensers
Quarantine and investigate suspect products	January 2015	Establish systems to investigate product suspected of being potentially counterfeit, diverted, or otherwise unsafe. If a suspect product is identified, it must be quarantined, and the applicable transaction history or transaction information must be validated. Records of	Manufacturers Repackagers Wholesale distributors Dispensers

		an investigation must be kept for six years.	
Identify and remove illegitimate products, and notify FDA and trading partners	January 2015	Have systems in place to remove products identified as potentially counterfeit, diverted, or otherwise unsafe from distribution, and to notify trading partners of the same. If an illegitimate product is identified, or if there is high risk of illegitimacy, the FDA and all immediate trading partners must be notified within 24 hours.	Manufacturers Repackagers Wholesale distributors Dispensers
Serialisation with unique product identifier	November 2017	Manufacturers must put a unique product identifier on each drug package and sealed homogeneous case.	Manufacturers
	November 2018	Repackagers must put a unique product identifier on each drug package and sealed homogeneous case, and it must be associated with the original manufacturer's product identifier.	Repackagers
	November 2019	Wholesalers may engage only in transactions of products encoded with unique product identifiers.	Wholesale distributors
	November 2020	Dispensers may engage in transactions only of a product encoded with a unique product identifier.	Dispensers
Provide transaction information to trading partners in electronic format	November 2017	Manufacturers must provide transaction information, transaction history, and transaction statement (confirming that the manufacturer is licensed and did not knowingly supply false information) in an electronic document to trading partners for all sales.	Manufacturers
Respond to verification	November 2017 (Manufacturers)	Respond to requests from trading partners to verify a	Manufacturers Repackagers

requests from trading partners	November 2018 (Repackagers)	product identifier within 24 hours of receipt or another reasonable time to be determined by FDA	
Verify unique product identifier of suspect products at package level	November 2017 (Manufacturers) November 2018 (Repackagers) November 2019 (Wholesalers) November 2020 (Dispensers)	Verify the product identifier, which includes the standardised numerical identifier, or SNI, for product they suspect is counterfeit, diverted, or otherwise unsafe	Manufacturers Repackagers Wholesale distributors Dispensers
Verify the unique product identifier of returned products intended for resale	November 2017 (Manufacturers) November 2018 (Repackagers) November 2019 (Wholesalers)	Verify the product identifier, including the SNI, of the returned product intended for resale.	Manufacturers Repackagers Wholesale distributors
Participate in electronic package-level traceability system	November 2023	All supply chain actors must exchange transaction information and statements in an interoperable electronic manner, and transaction information must include product identifiers. Systems and processes must be in place for electronic package level verification and traceability information must be provided to regulators to enable access to a drug's full distribution history during a recall or when investigating suspect products.	Manufacturers Repackagers Wholesale distributors Dispensers

Source: (Pew Charitable Trusts, 2014)