The intelligent pharmaceutical supply chain

Enable a superior patient-and-caregiver experience with a leading-edge digital supply chain

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Arthur D Little

Content

Authors:

Marc Herlant,
Partner, Healthcare & Life Science,
Brussels
herlant.marc@adlittle.com

Simon Bauwens,
Consultant, Strategy & Organization,
Brussels
bauwens.simon@adlittle.com

Hugues Bocquet,
Consultant, Strategy & Organization,
Brussels
bocquet.hugues@adlittle.com

Executive summary

The combination of new drugs, new treatments and advanced data analytics solutions creates superior opportunities for patients, making treatment more effective, more affordable and less intrusive, with a positive impact on their quality of life.

This evolution will bring fundamental changes in the way companies interact with patients and caregivers, which, in turn, will impact the capabilities required for operations and supply chain.

The challenge for companies is to develop these new capabilities by identifying useful and necessary initiatives, without putting the ongoing operations at risk by building service models on the basis of correlations that will not be sustainable in the future.

To navigate through this data analytics environment, Arthur D. Little has developed a maturity model to evaluate the current situation and development priorities in the supply chain.

This model allows understanding of the functional areas in which a company has developed the most advanced analytical capabilities, with potential to leverage these.

To develop these new capabilities, we propose a scientifically validated methodology to evaluate the data analytics pilot projects. This model allows companies to gain confidence in the models, and use them as foundations for new service models supported by new capabilities and sets of analytical competences.

Combining the maturity model with the analytical methodology provides a concrete starting point for leaders who want to develop new capabilities in the supply chain.

1. Build advantage through digital supply chain

Pharmaceutical companies are looking into the next paradigm to deliver the promise of new treatments and build superior competitive advantage. With the emergence of data analytics solutions, the transformation from reactive to predictive supply chain brings the potential for a superior patient-and-caregiver experience. However, gaining confidence and know-how in the new predictive models is a prerequisite to the major capability-building effort required. To enable such models, companies need to develop advanced analytical models along with the ability to understand the causes and effects that will make their predictions successful. There are important opportunities in transforming operations and industrializing those solutions that address new supply chain needs, which will ultimately allow deployment of new models of care.

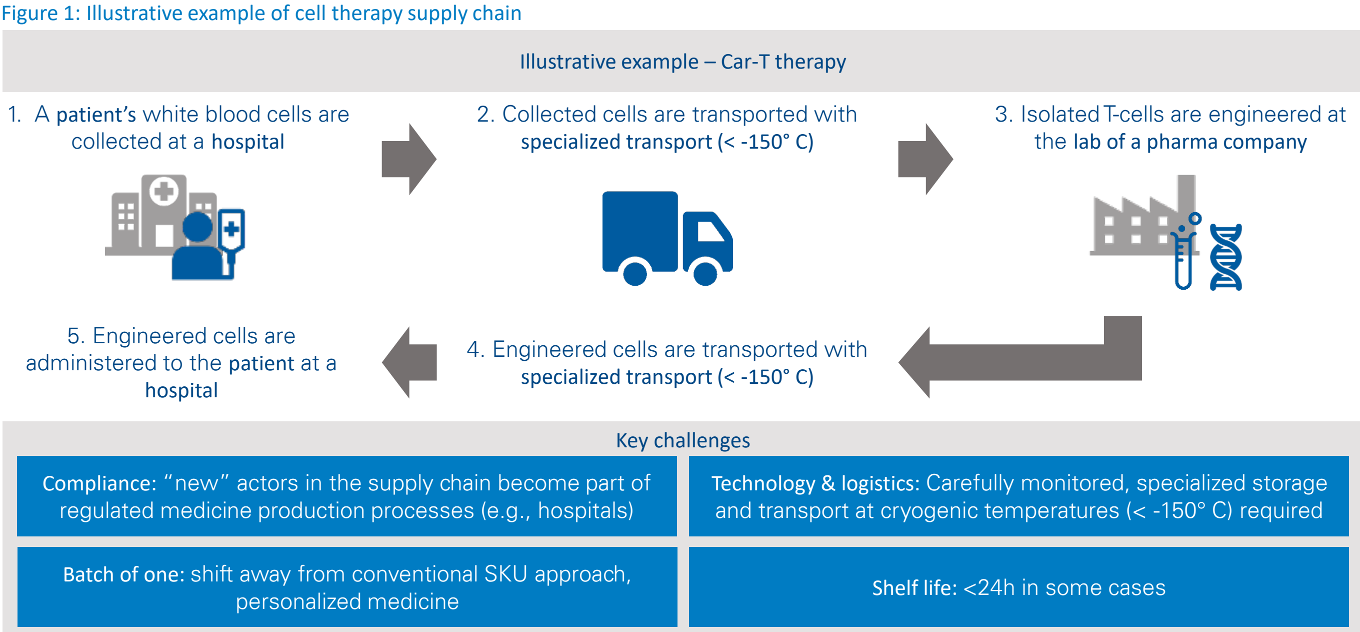
The distribution and drug consumption models are rapidly changing with the emergence of new business avenues around individualized medicine, combination therapies, device/drug convergence, etc. These new models create a superior patient-and-caregiver experience, but have major consequences for the supply chain in that they strongly increase its complexity.

Supply chain imperatives are evolving, moving from drug production and delivery that are limited in scope towards a versatile supply chain addressing the needs of multiple stakeholders (caregivers, patients, insurance companies, etc.). To face these new challenges and deliver the promised service levels, pharmaceutical supply chain managers need to develop new competencies.

The traditional supply chain approach based on materials requirement planning (MRP2) has progressed to its limits:

- From the **patient perspective**: the current supply chain creates frustration and complications in individualized treatments, or even fails to offer satisfactory performance with new treatment types (companion diagnostic, individualized dosage, combination therapies, etc.).
- From an **industrial perspective:** as new treatments become available, new types of supply chains need to be established, with new actors, as well as new technological and logistical systems. Managing these new treatments with traditional supply chain methods is costly and complex, with high

Figure 1: Illustrative example of cell therapy supply chain



Source: Arthur D. Little

risk of non compliance, e.g. cellular and genetic therapies indeed require modification of cells collected from individual patients to create personalized medicines, and so extend the supply chain to include "new" players such as the individual patients themselves, or hospitals and other health-care providers (e.g., Car-T therapy – see figure 1). Yet, while creating new challenges in terms of regulatory compliance and scaling, the incorporation of these players also provides significant opportunities in terms of data collection for predictive analytics.

Illustration: cryogenic supply chain

Additional technological and logistical challenges are related to the need to store and transport harvested or modified cells at cryogenic temperatures (below -150°C) across a cold chain that extends from the place where cells are collected from an individual – e.g., a hospital – to the lab for processing, and back to the individual via the health-care provider. The conventional vessels (refrigerators, containers) to do this are bulky, and liquid nitrogen used for cryogenic storage is not allowed on planes, so other technological solutions are required, e.g., in the form of special developed containers. Temperature and storage conditions need to be monitored carefully to ensure the medicine's quality at all times. Even under optimal conditions the medicine's shelf life is very limited – in some cases less than 24 hours. These factors make scaling cell therapy treatments difficult, expensive, challenging to manage and, simultaneously, an interesting playing field to gain competitive edge through operations.

Furthermore, current forecasting approaches based on correlations encompass multiple statistical biases:

- Correlations are backward-looking and describe what has happened in the past. However, this has, as such, no predictive value as it does not in itself establish any causality: one cannot be sure that because an event occurred in the past, it will happen again in the future (and with neither the same amplitude nor recurrence). Today, AI-generated predictions are based on probability, not causality : this works well in a number of situations, much less so in others.
- More specifically, correlations between variables do not mean that one of the results is caused by the other (causality), as illustrated by the example of Google Flu Trends below. Practically, pilots demonstrate the occurrence of thousands of incidental correlations ("noise"), which would result in catastrophically wrong forecasts if used for predictions.
- With the multiplication of consumption and distribution patterns having small volumes and high variations, forecasting tools based on extrapolation of past demand are malfunctioning. This causes problems for on-time product delivery, despite being critical for new treatments.
- The challenge, when applying predictive analytics to supply chain, is to distinguish the random correlations from the ones that result from causal determinism

Learnings from past initiatives – Google Flu Trends

The failure of Google Flu Trends in 2013 illustrates the logical fallacy between correlation and causality: Google aimed to predict the number of people with flu symptoms based on the number of Google search queries for flu-related topics.

However, its results have been largely wrong; it estimated that 11 percent of the US population had had influenza in winter 2012–2013, which was approximately 2 times more than shown in official statistics (6 percent).

The bias of Google Flu Trends lies in the search for statistical patterns in the data, not for causality. Hence, when in December 2012 the news was full of stories on flu, many healthy people carried out internet searches on flu, which influenced Google's prediction.

2. Understand the "Why"

The intelligent supply chain (based on predictive analytics and machine learning) is better at demand anticipation (SKU, quantity) and characterization (localization, service levels) by identifying and understanding the patterns influencing it, rather than projecting past demand. However, seeing patterns is not sufficient; understanding the "why" behind them is key.

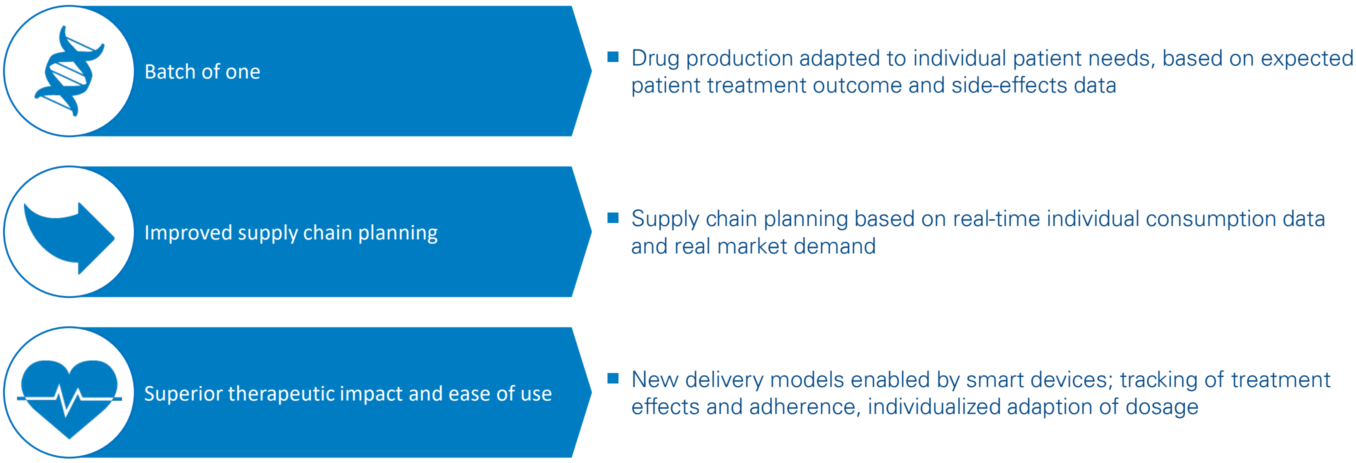
Anticipation tools allow pharmaceutical companies to ensure fluid and fast access to their treatments to clinicians. For new types of treatments, e.g., individualized therapies with "batch of one" drugs, operations should be transformed and new capabilities are required (recruitment of data scientists, sociologists and AI specialists, among others). Furthermore, companies need to build the skills to adapt their factory and personnel planning to demand in real time, and industrialize their approaches.

Joint development with experienced partners is required, of course, but not sufficient: injecting own business and process expertise into the system is required to understand causal relations influencing demand-and-supply patterns sustainably.

The most advanced pharma companies have started to experiment with new forms of analytics to change the way operations are planned and service is delivered, but solutions are not yet at an "industrialized" level. (See figure 2)

To move forward in this development, many executives face the challenge of navigating through a vast data analytics environment that encompasses multiple concepts. To clarify those notions, Arthur D. Little has developed a data analytics maturity model.

Figure 2: Forward-looking: can your supply chain keep up with digitally enabled therapies?



...All while managing the right network of partners, being regulatory compliant, and managing data safety and privacy.

Source: Arthur D. Little

3. Navigate through data analytics

Moving beyond the world of descriptive statistics, which relies mainly on the extrapolation and (often poor) observation of recurring patterns, companies are entering the domain of predictive analytics, which requires deep data analysis to understand causal links. Leveraging those links, predictive analytics will be able to predict potential future states. The complexity of such models is to identify and select the links with predictive value.

The last levels of complexity are machine learning, in which a machine can accomplish certain tasks without prior programming, and prescriptive analytics, wherein systems identify the recommended choices through a complex web of options.

Figure 3: Illustrative examples of predictive analytics and machine learning use cases in pharma

Demand Solutions	■ **Enables** the use of **predictive analytics** in **pharma supply chain management** by making use of relevant (causal) data and supporting forecast management, requirements planning, retail, and sales & operations planning	■ Demand Solutions' DSX allows companies to use relevant sales-forecast data to **predict real expected demand** (not based on historic data) ■ Customizable **dashboards** allow for easy decision-making, and presentation of sales-forecasting information in a **variety of formats** ■ Demand Solutions' DSX Offers a **"Lead Time module"** which tracks every line item of every transaction and runs the data through a forecasting engine to inform purchasing decisions
splice MACHINE	■ Offers **machine-learning solutions** that, while working with numerous suppliers, **improve inventory management**	■ Working with a major pharma company in the US to help **predict delays in inbound shipment orders** ■ The client pharma company has complex formulations and works with hundreds of global suppliers; using **machine learning** enables it to better assess ATP* dates from suppliers and make sure to **balance inventory** appropriately
MERCK Aera	■ Merck KGaA intends to **deploy sensors**, coupled with a **machine-learning** program, to **improve demand forecasts** and **agility** in its inventory and distribution processes	■ The objective is to have computers make more decisions and create an **autonomous supply chain operation** (implementation 2017) ■ The technology allows users to **change forecasts immediately** based on far-off events, such as hospital fires or natural disasters, that impact demand ■ The company considers an Aera (formerly FusionOps) software-based system able **to react quickly and effectively** to market changes ■ Pilot runs show the **technology is 80% more effective than humans** in demand-planning processes

*Available to promise
Source: Company websites, supplychaindive.com, Arthur D. Little research

4. Learn from initiatives in other functions

Leading pharmaceutical companies are piloting data analytics solutions in different functional domains, essentially starting with R&D. They then investigate how those foundations can be exploited in other domains.

For example, GlaxoSmithKline is using a machine learning-based platform to improve pre-clinical candidates' discovery, in partnership with Exscientia. This technology designs new molecules; assesses them for their potency, selectivity and ability to bind to specific targets; and uses a rapid "design-make-test" cycle to modify drug candidates according to the desired criteria.

Similarly, Pfizer and IBM have partnered to accelerate drug discovery in immuno-oncology thanks to Watson technology. Their collaboration aims to quickly analyze and test hypotheses extracted from large and broad data sources (laboratory and data reports, medical literature).

In a different context, we have seen the use of predictive analytics in production quality management: predicting from the external factors of the production chain which batches will be likely to deviate from the quality requirements and, consequently, significantly improving planning in the downstream part of production.

Some illustrative use cases of these new technologies to gain an operational edge in supply chain can be found in figure 4.

Figure 4: Data analytics maturity model developed by Arthur D. Little

	Descriptive statistics	Statistic Forecasting	Pattern Matching	Predictive Analytics	Machine Learning	Prescriptive Analytics
Key question	What **has happened** (why, where, how many times, …) ?	What **will happen if past demand** equals the future demand while considering market insights ?	What are the **additional parameters/** simulation patterns that impacted the demand in the past by **identifying correlations?**	**What is likely to happen**, considering probabilities?	How to improve probability-based prediction by constantly integrating additional relevant patterns	What **should we do** to anticipate properly what will happen?
What it is	**Analyze data** so as to describe the situation as it is	**Extrapolate historic demand** and include human sensing factor to define a forecast	Identification of **recurring patterns** and behaviors in internal and external datasets	Predict potential **future states**, based on the probabilities	Makes a computer perform a task **without explicitly programming** it. Can compute decisions	Prescription of the **recommended choice** of action among a complex web of options, and showing likely outcome
How it works	Gather **data on past activities** in a purely descriptive mindset (standard & ad hoc reporting, alerts…)	Using **statistics technique**, extrapolation of historic data	Primarily driven by **broad data** sets more than longitudinal data sets	Deep analysis of data sets to identify recurring relationships between data points	Prescriptive data combined with learning models to create new algorithms	Define **supply chain management rules** that leverages machine learning
Comments	Crucial step in data analytics to collect large amount of data & develop a data-friendly mindset	Backward looking strategy, that can include insights, leveraging correlations but without clear identification	**Correlations** are clearly identified as datasets are further looked into	If possible identification of causal factors drives success, next to data quality, interpretation capabilities, statistical analysis	Still mainly experimental	Still in early development phase for complex decision making situations

Low — Degree of complexity — *Very High*

Source: Arthur D. Little: Gartner

5. Scale-up your pilots

In spite of being a nascent technology, predictive analytics is a top priority of healthcare supply chain executives. Failing to prepare to leverage this technology is therefore not an option, and companies need to reflect on how to minimize risks linked to initiatives in this field. Similarly, experiments around the business model of new cell therapies are ongoing, but will require further investment in innovative supply chain solutions to be sustainable in the long run when scaled

A prerequisite to mobilizing investments and competences around predictive analytics is to develop confidence in the systems. It implies assessment and understanding of the scalability and reproductive value of predictive analytics models, preferably by identifying causal links that tend to make pilots successful. Building on this idea, Arthur D. Little, has developed a methodology to understand causal links and their resilience in predictive analytics pilots.

Our methodology allows thorough testing and leveraging of existing analytics pilots to outline key causal factors to integrate into the predictive supply chain (figure 5).

1. List and understand pilots

The first step is to better understand methodologies applied to various pilots, confirm their underlying hypotheses, and identify whether other options are available.

2. Quantitative retrospective validity

Secondly, pilot methodologies need to be tested on historical company data and their results compared to actual history, in order to exclude most of the "false positive" methodologies and identify repeated correlations. Those methodologies should be tested in an exhaustive, systematic and automated manner.

3. Qualitative scenario validation

At this step, the correlations have proved to be resilient over time; hence, causality can be assumed, but is not yet proven. A large number of "false positives" have already been excluded, and a qualitative assessment of the repeated correlations is the best way to identify meaningful (with explainable links – no random coincidences) and useful causality links (where the variables can be measured).

4. Future-proof validation

Ultimately, the stability of the methodology is pressure-tested, applying "derived laws" in step 3 against all possible future scenarios to evaluate maximum variability and their implications (Monte Carlo simulation).

Figure 5: Methodology to outline key causal factors to integrate into predictive supply chain

Source: Arthur D. Little

Contacts

If you would like more information or to arrange an informal discussion on the issues raised here and how they affect your business, please contact:

Austria
Karim Taga
taga.karim@adlittle.com

Belgium
Marc Herlant
herlant.marc@adlittle.com

China
Russell Pell
pell.russell@adlittle.com

Czech Republic
Marcel Hominda
hominda.marcel@adlittle.com

France
Marc Herlant
herlant.marc@adlittle.com

Germany
Wilhelm Lerner
lerner.wilhelm@adlittle.com

India
Vikas Kharbanda
kharbanda.vikas@adlittle.com

Italy
Fabrizio Arena
arena.fabrizio@adlittle.com

Japan
Satoshi Ohara
ohara.satoshi@adlittle.com

Korea
Kevin Lee
lee.kevin@adlittle.com

Latin America
Guillem Casahuga
casahuga.guillem@adlittle.com

Middle East
Vikas Kharbanda
kharbana.vikas@adlittle.com

The Netherlands
Martijn Eikelenboom
eikelenboom.martijn@adlittle.com

Norway
Diego MacKee
mackee.diego@adlittle.com

Nordic
Ulrica Sehlstedt
sehlstedt.ulrica@adlittle.com

Singapore
Satoshi Ohara
ohara.satoshi@adlittle.com

Spain
David Borras
borras.david@adlittle.com

Switzerland
Wilhelm Lerner
lerner.wilhelm@adlittle.com

Turkey
Coskun Baban
baban.coskun@adlittle.com

UK
Richard Eagar
eagar.richard@adlittle.com

USA
Craig Wylie
wylie.craig@adlittle.com

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Arthur D. Little

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