



Disruptive technologies in Pharmaceutical Operations

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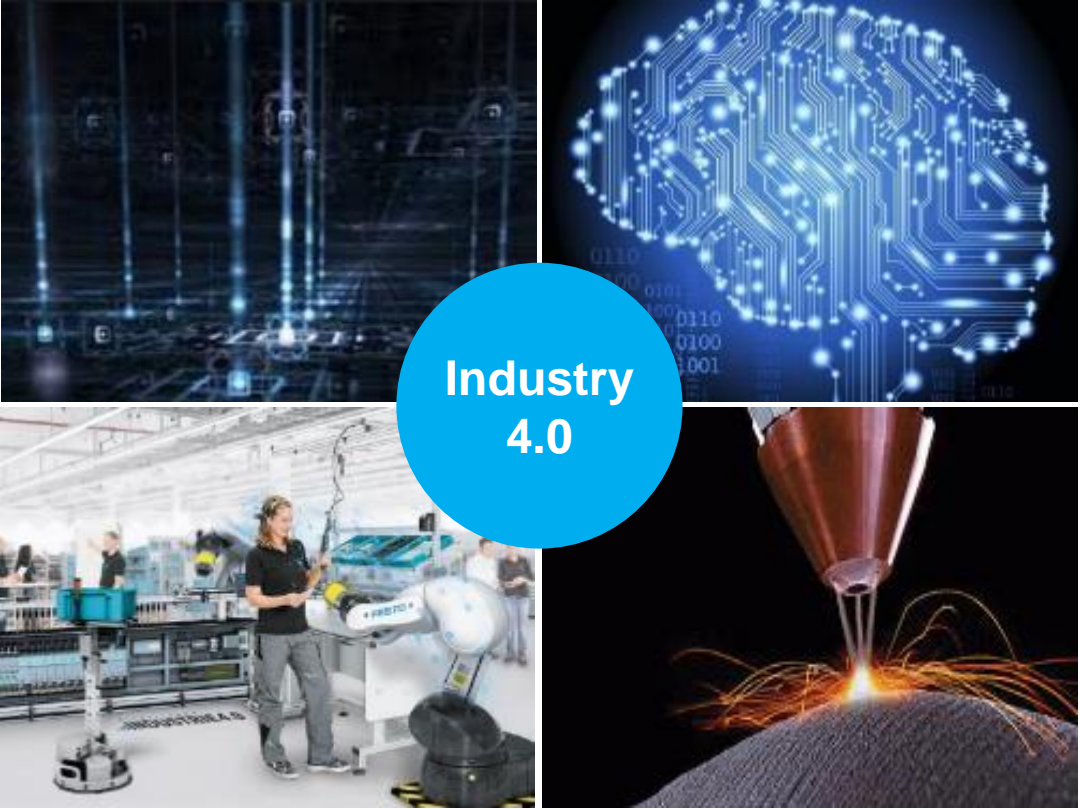
However, Industry 4.0 is revolutionizing the pharma ops landscape along four dimensions

Data, computational power, connectivity

- Sensors
- Internet of Things
- Cloud technology
- Blockchain

Human machine interaction

- Virtual and augmented reality
- Robotics and automation (collaborative robots, AGVs)
- RPA, chatbots

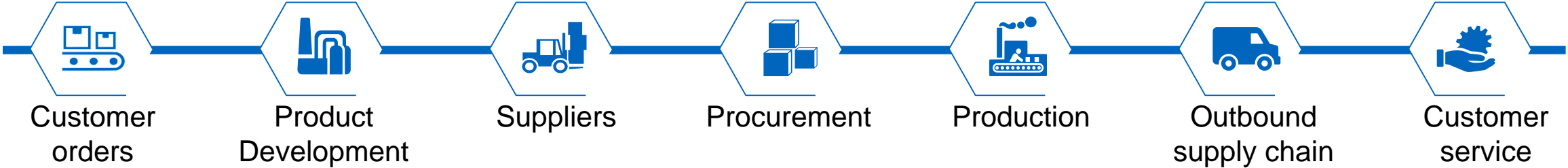


Analytics and intelligence

- Automation of knowledge work
- Advanced analytics and Artificial intelligence

Advanced production methods

- Additive manufacturing (i.e., 3D printing)
- Renewable energy



End-to-end Digital thread – seamless data flow along the value chain / product life cycle



WHY now?

– Digital trends



WHAT can be done? -
Examples of what is already happening today



HOW to make it happen? -
Approach

WHY



Is it time to now switch gears
for Industry 4.0 in Pharma
industry?

Digitization changes our world and generates a data explosion...



























By 2020, there will be **21 billion** connected devices in a global Internet of Things, producing an ever-increasing amount of data

90% of the world's data today has been created in the last 2 years only






Each day we create **2,500,000,000,000,000,000** (2.5 quintillion) bytes of data. This would fill 10 million Blu-ray discs, the height of which, stacked, would equal the height of 4 Eiffel towers

... triggering new business models that are disrupting traditional ones

<p> World's largest Taxi company</p> <p></p> <p>Owns NO</p> <p> Taxis</p>	<p> World's largest Accommodation provider</p> <p></p> <p> Real estate</p>	<p> World's largest Phone companies</p> <p></p> <p> Telco infra</p>	<p> World's most Valuable retailer</p> <p></p> <p> Inventory</p>
<p> Most popular Media owner</p> <p></p> <p>Owns NO</p> <p> Content</p>	<p> World's fastest Growing bank</p> <p></p> <p> Actual money</p>	<p> World's largest Movie house</p> <p></p> <p> Cinemas</p>	<p> World's largest Software vendors</p> <p></p> <p> Apps</p>

This disruption is also now happening in healthcare with technology companies heavily investing and leading Pharma companies also embracing digital




Atypical disrupters in pharma & healthcare

-  Amazon invested \$1 billion to buy mail order pharmacy company PillPack
-  Google (Alphabet) invested in Oscar Health, joining GV, Verily Life Sciences, and CapitalG
-  GE invested in Evidation Health (generates real world evidence) & Verana Health (focused on ophthalmology data)
-  Apple acquired Beddit (sleep monitor company) & Glimpse (personal health data platform)
-  Intel invested in Lumiata (uses predictive analytics to improve care in hospitals) & EchoPixel (develops tools to enable non-invasive colon cancer screening)

Other tech investors in recent past



Bold pharma investments in digital

- 
 - 2012: Moved supply chain to cloud
 - 2015: Complete visibility into the status of products at all times; identify demand and quickly alert the best production facility to manufacture
 - Pfizer is also looking to move into the e-commerce space for prescription medications in the near future
-  **MERCK**
 - Merck uses Hadoop to crunch huge amounts of data so it can develop vaccines faster
 - 15 billion calculations and more than 5.5 million batch-to-batch comparisons to link characteristics in fermentation phase to yield in final purification
-  **AMGEN**
 - Use of machine learning & deep learning to better diagnose osteoporotic fractures

As we think about Industry 4.0 in Pharma, it is the “new lean” of a decade ago

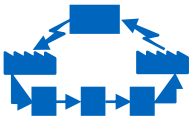
Lean method examples



- Visual management



- Pareto (e.g., OEE)



- MIFA



- Ishikawa



- Gemba/Process Confirmation



- Zero waste mindset



Industry 4.0 method examples



- Digital Performance management
- Data lake (1 million times more data)



- Machine learning



- Digital twin
- “Waze”



- App store



- Google glasses
- Enhanced reality
- Video analysis



- Digital mindset

Five major paradigm shifts are driving the way data is used in pharmaceutical operations

A Data

- Data lake
- Analytics platform



True product masters

Quality-by-design by using insights from CMC, manufacturing, Quality and customers. Parametric release.

B People

- New roles and capabilities
- Digital performance culture



Real-time Digital Twin

Complex analytics models accurately mirror assets, people, and supply chains. Simulations, optimizations, e-validations, master date update



Predictive Analytics

Live prediction of deviations, quality outcomes and demand. Proactive interventions to ensure reliability and agility.

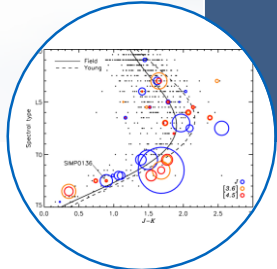
C Regulations

- Proactive regulatory strategy



Digital operations assistance

Augmented reality elevating operators reliability (human error reduction/digital SOPs) and efficiency (real-time task allocation)



Knowledge work automation

Digital robots execute (e.g., supply planning/scheduling, change mgt) or support decision making (e.g., CAPA, portfolio) based on self-learning algorithms

Vertical and horizontal digital integration – From supplier to patient

The question is NOT: is this relevant for us as well ...



... BUT RATHER: How can we shape the future using it?

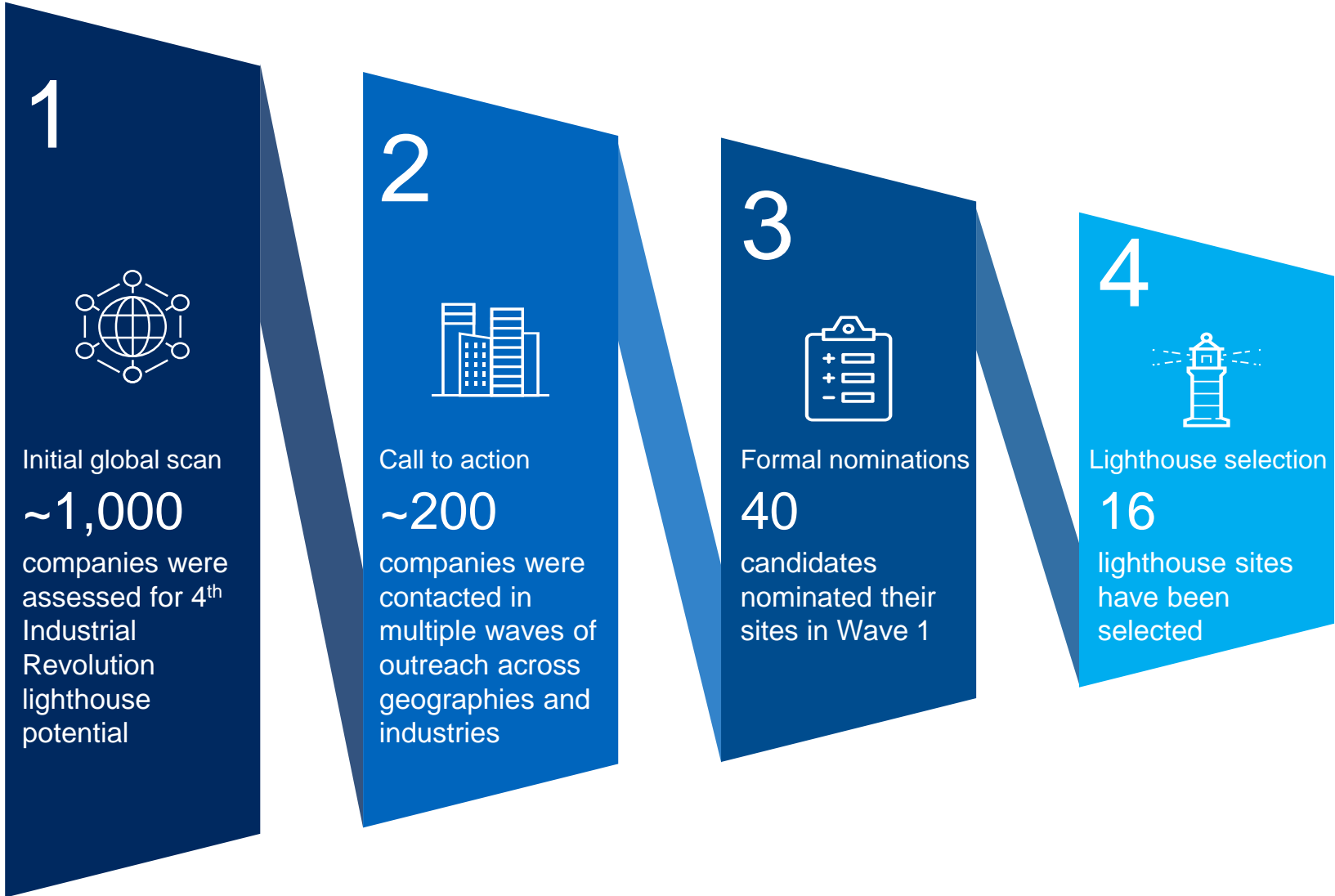
WHAT



can be done?
Examples of what
is already
happening today

In 2018, we set out to identify the factories at the forefront of the Fourth Industrial Revolution – the “lighthouses”

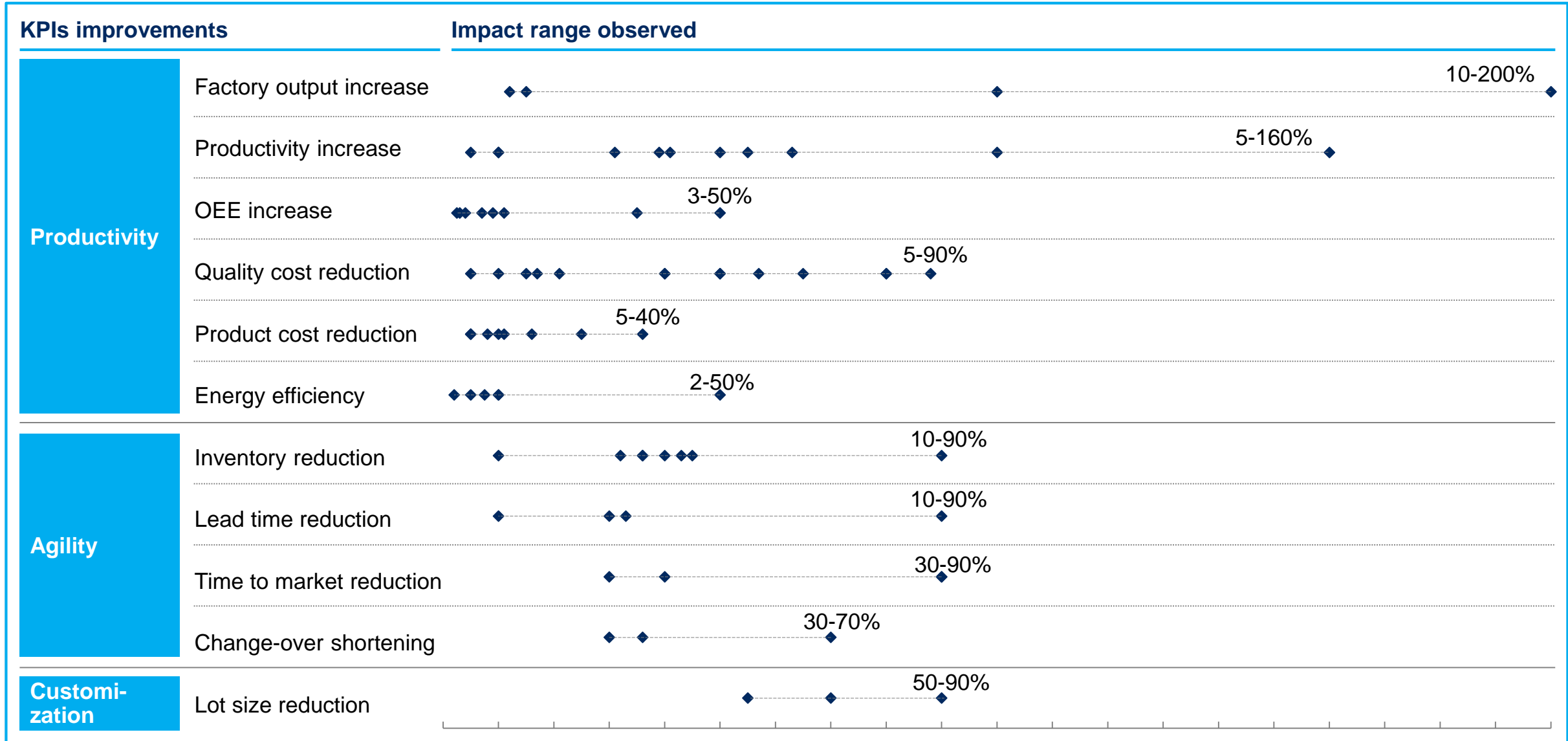
- Collaboration between McKinsey & Company and the World Economic Forum aims at accelerating an inclusive diffusion of Fourth Industrial Revolution technologies across the manufacturing sector
- First-of-its-kind global network of lighthouse production sites has been created, containing of 16 leading factories which overcame the prevalent “pilot purgatory” and achieved significant financial and operational benefits from at-scale Fourth Industrial Revolution (4IR) technology deployments



The sixteen recognized lighthouses cover a broad range of geographies and industries



The reported KPI improvements show that the lighthouse factories achieve significant impact from the at-scale technology deployments

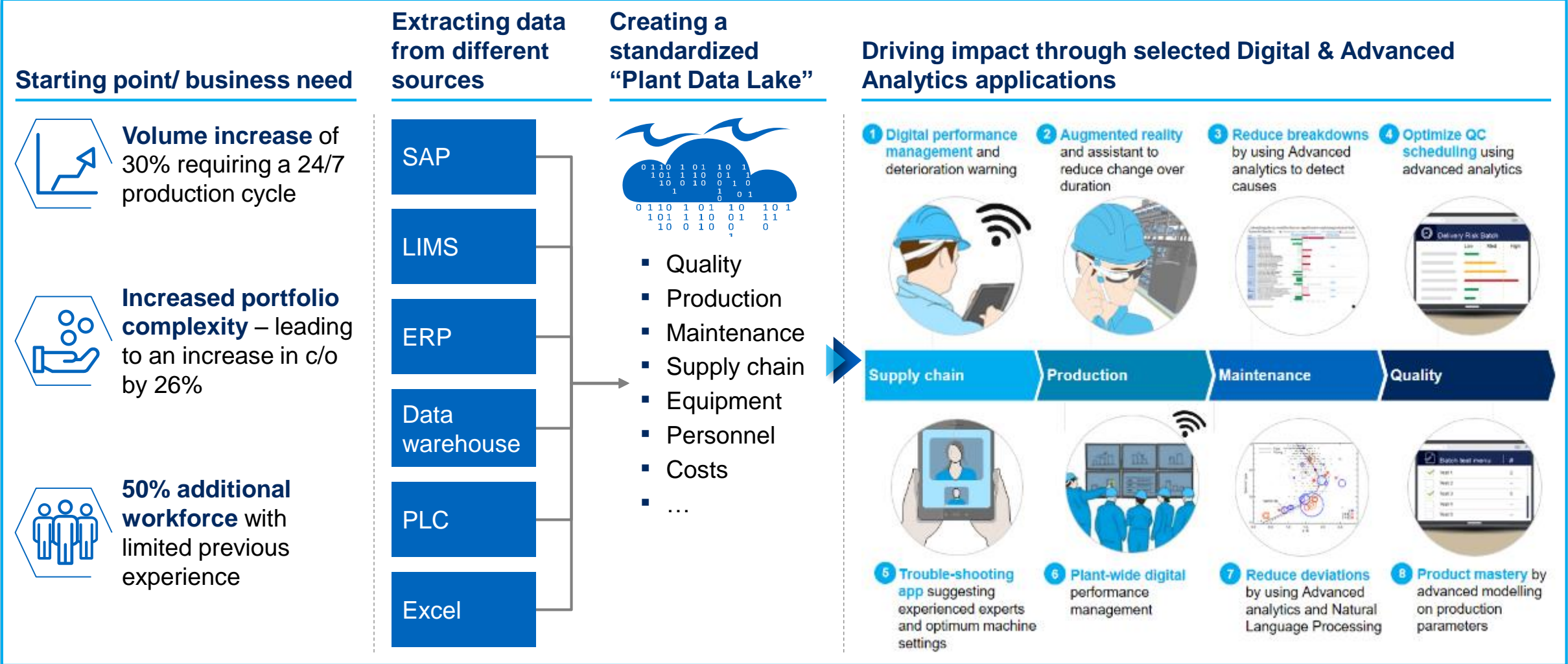


Bayer's Garbagnate (Italy) site was the only pharmaceutical site to be nominated by the World Economic Forum



Bayer
Pharmaceuticals






Case example#1: Transformation of the site into a digital plant to support growth



Change management & capability building

Scalability management (global roll-out, eco-system of vendors, validation, etc.)

The resulting impact across areas exceeded expectations

	QC lab productivity	+50% increase of lab productivity by applying advanced schedule optimization
	Changeover	-30% reduction in time on tablet press using smart glasses
	OEE	+40-50% OEE increase on packaging line supported by AA insights and Digital performance management
	Deviations	-80% reduction in deviations since applying advanced analytics (0% recurring)
	Deviation handling/ closure time	-90% reduction of deviation closure time by AA based deviation advisor tool

VIDEO

Indian pharmacos have also successfully implemented several use cases- Some examples

1

Yield improvement in API: Advanced analytics helped identify *critical parameters* that impact yield. *Yield improvement of 5-7%*

2

Invalidated OOS reduction: Identified ~10% of tests likely to contribute to ~60% of future invalid OOS. *35% reduction in OOS within 1 month of implementation*

3

Cost reduction in indirect spend: *Use of NLP and fuzzy logic* to categorize spend into actionable categories & identify ideas to *reduce spend by 3-5%*

4

People analytics to reduce attrition: Identified granular reasons and recommendations to *address 65+% of QC analyst attrition*

HOW

To make it happen?
– Approach towards
industry 4.0

732
respondents

14%

N America

28%

Europe

13%

LatAm

45%

Asia

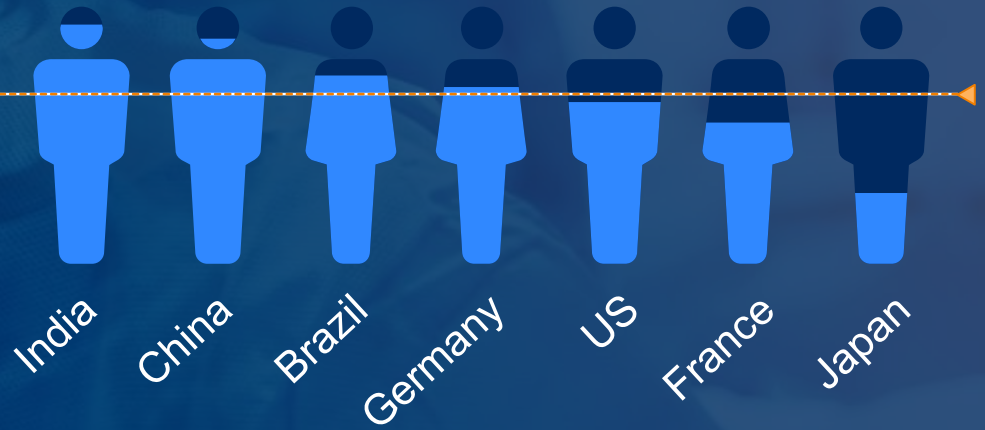
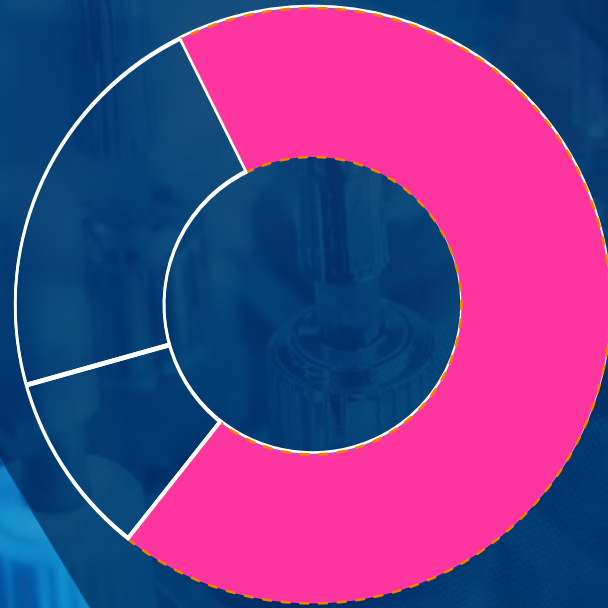


Industry 4.0 is a top
priority for
manufacturers

Top priority
68%



Top priority
68%



Variation exists
across countries

However, ASEAN companies are still struggling to make Industry 4.0 a reality

Aware of I4.0



**Respondents on the implementation of Industry 4.0,
Percent¹**



I4.0 strategy defined



Clear I4.0 roadmap defined

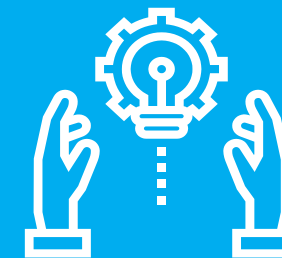


Owners for use cases defined



Implementation launched

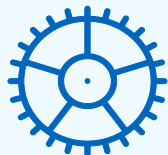
Digital company



Reasons holding back implementation



Problems defining clear business plan



Siloed data not integrated across BUs



Limited talent to execute roadmap



Concerns of Cybersecurity risks



Limited coordination across BUs

Additionally, companies face change management challenges

A digital transformation is challenging because ...



...involves **many stakeholders from different units**, with potentially diverging agendas (e.g., Business units, Risk Management, IT, Operations, ...)



...requires a **radical change of mindset** in many aspects



...creates completely **new jobs** and **competences** (e.g., data scientists, data owners, data translator, ...) and the evolution of traditional jobs (e.g., CRM)



...requires the **capability to react fast and frequently revise plans** to adapt to a very changeable and unpredictable market environment (e.g., new data technologies)

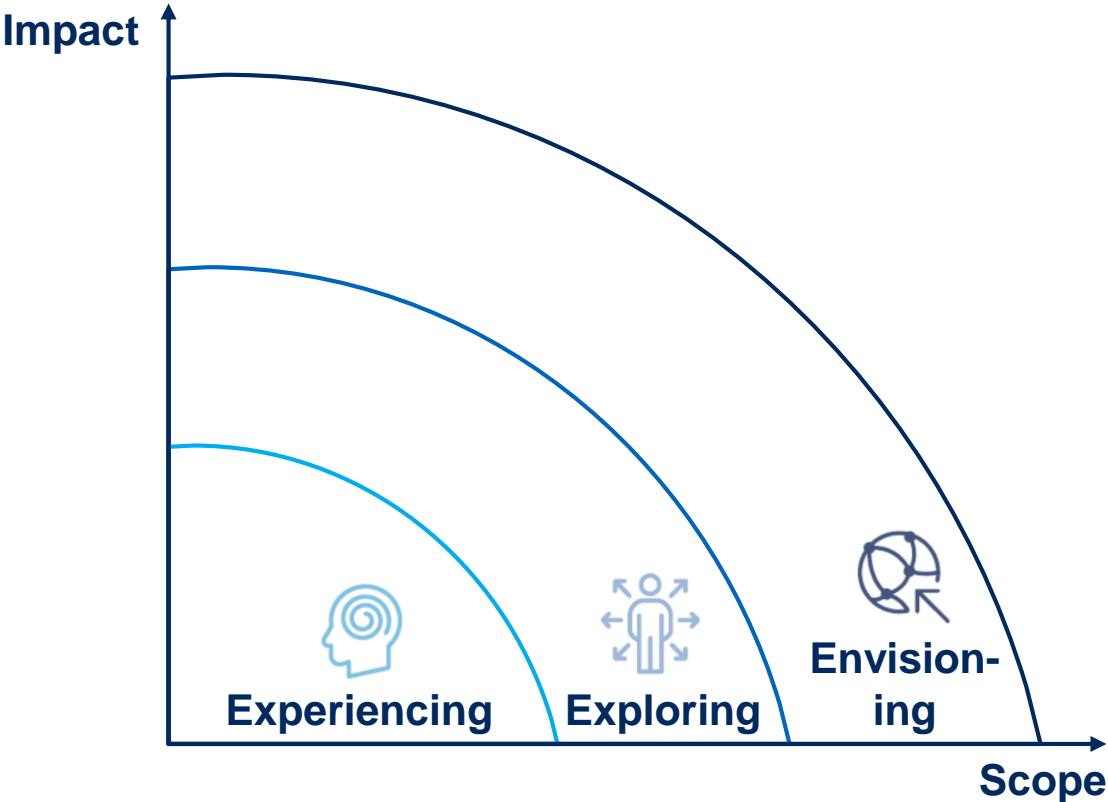


It is essential to outline cornerstones of a **robust change management program** to ensure effective execution

Companies typically look to capitalize on I4.0 opportunity in one of three horizons of impact / scope

Experiencing Horizon

- Launch use cases that are high impact but limited in scope – typically aimed at one specific unit or process
- The objective is to build up experience and generate momentum

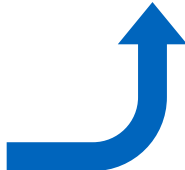


Envisioning Horizon

- Roll out digital across value chain
- Fully utilize machine learning models that can actively suggest optimization measures

Exploring Horizon

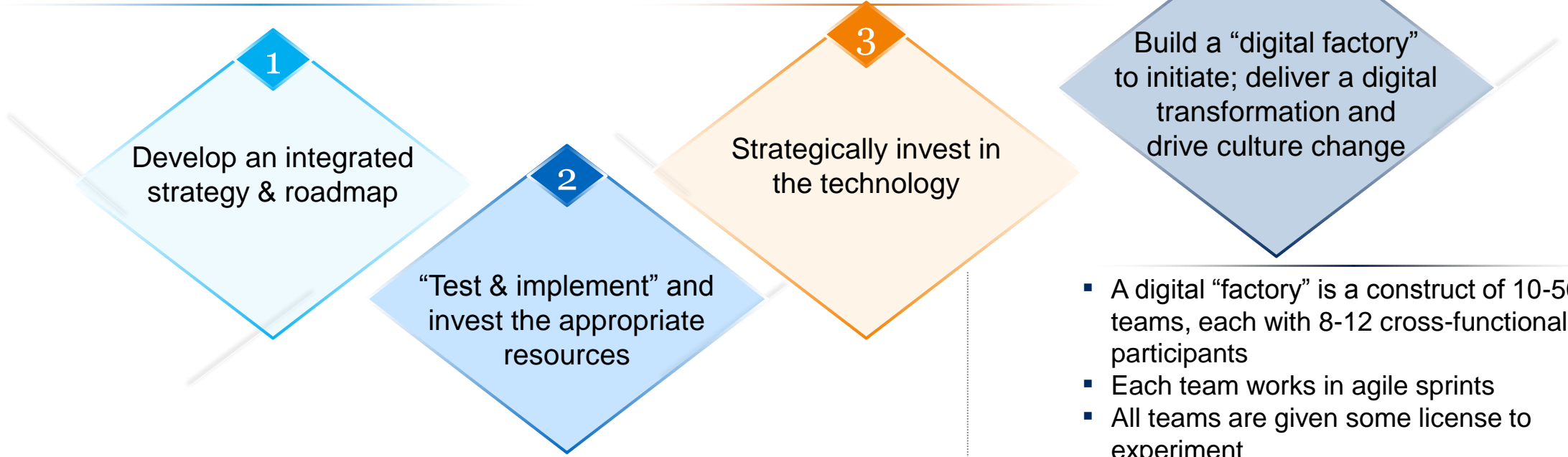
- Launch "Lighthouse" projects – typically aimed at a site
- The objective is to demonstrate full potential of a given technology and serve as inspiration for the company as a whole



There are four common themes that we have seen translate to success regardless of the scope / impact horizon pursued

- Set the aspiration – Define the future organization
- Identify opportunities for improved operation; Identify use cases that will drive impact
- Prioritize and sequence use cases; Define approach to scale across network

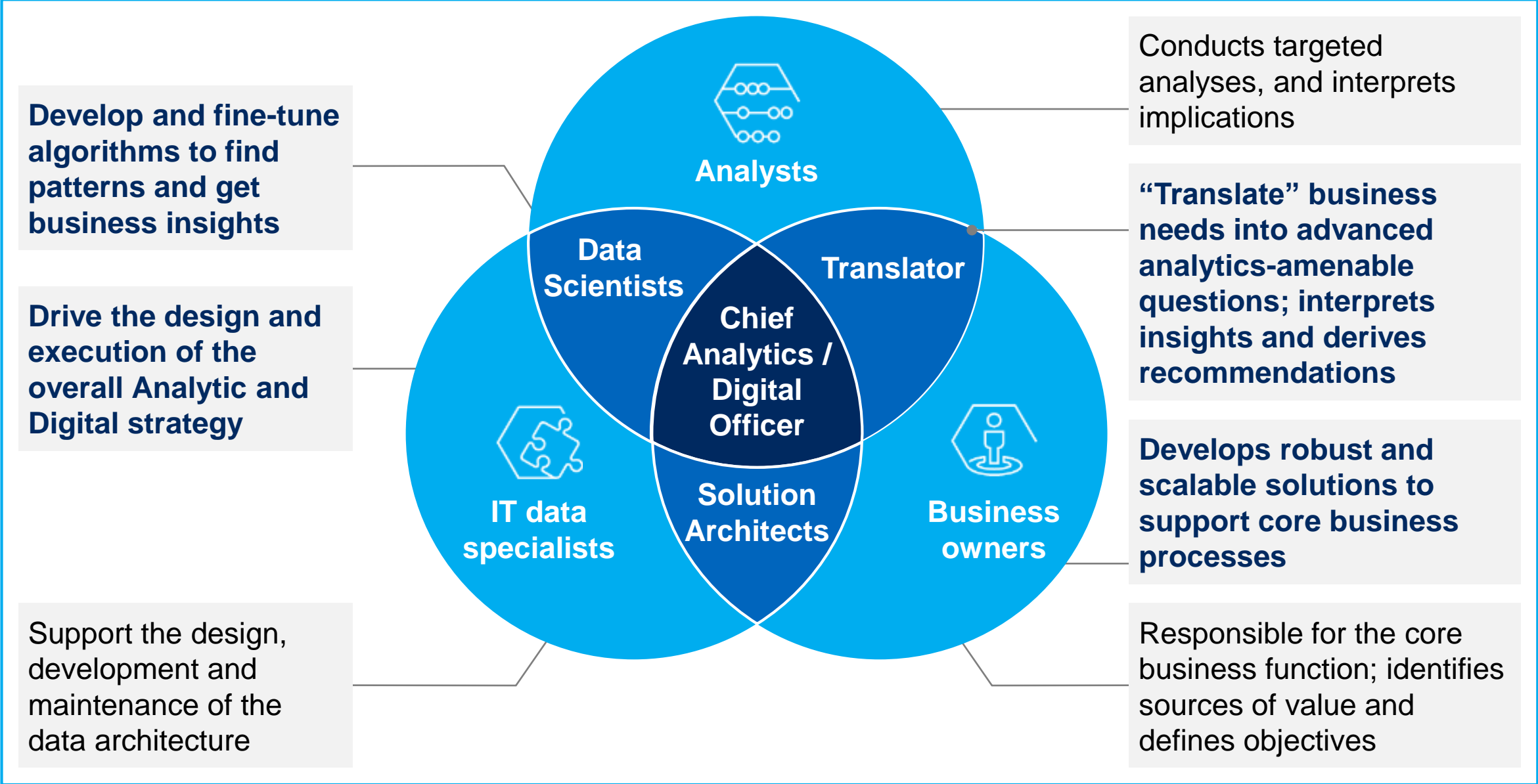
- Invest in strong Internet of Things (IoT) infrastructure for data capture
- Create an advanced analytics platform and build in house capabilities
- Fit or retrofit physical technology to robotic or automated processes



- Avoid getting stuck in pilot purgatory
- Invest in right number & type of resources
- Focus disproportionately on culture & mindset shift

- A digital “factory” is a construct of 10-50 teams, each with 8-12 cross-functional participants
- Each team works in agile sprints
- All teams are given some license to experiment
- Senior leaders in the organization sponsor 1-2 elements each of the digital factory

Finally, successful companies focus on talent needs and organizational shifts to enable success



THANK YOU



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